
7 Special exemptions

Key points

- The following goods were given a 'special exemption' from the TTMRA at its inception because governments needed more time to decide whether mutual recognition, harmonisation or a permanent exemption would apply in the longer term:
 - hazardous substances, industrial chemicals and dangerous goods
 - therapeutic goods
 - road vehicles
 - gas appliances
 - radiocommunications devices.
- With ten years having passed since the TTMRA came into force, governments should consider reducing the extent of special exemptions by adopting:
 - a permanent exemption for hazardous substances, industrial chemicals and dangerous goods, given that fundamental differences are likely to remain in how Australia and New Zealand control the risks posed by those products
 - mutual recognition for natural gas appliances, given the progress towards harmonising regulations
 - a permanent exemption for 'nonuniversal' LPG appliances, since differences in LPG composition between the two countries make it difficult to achieve mutual recognition or harmonisation without compromising public safety
 - after opportunities for harmonisation have been exhausted, a permanent exemption for remaining short-range and spread-spectrum radiocommunications devices.
- Special exemptions should continue for:
 - therapeutic products and road vehicles, given the prospects for harmonisation (although therapeutic products should have a permanent exemption if legislation for a harmonised trans-Tasman regime cannot be passed in the next 12 months)
 - radiocommunications devices that are expected to soon become obsolete, or where future harmonisation is considered likely.
- Governments should improve the cost effectiveness of administering any remaining special exemptions by increasing the maximum allowable period between rollovers (and associated reporting requirements) to three years.

As noted in chapter 2, some goods were given a ‘special exemption’ from the Trans-Tasman Mutual Recognition Arrangement (TTMRA) when it was established. This category was used for cases where Australia and New Zealand were hopeful that greater integration could be achieved, but recognised that further work was required. Each special exemption has a multi-year work program (termed a ‘cooperation program’) that aims ultimately to resolve the outstanding issues by mutual recognition, harmonisation or a permanent exemption.

Five areas remain subject to special exemptions:

1. hazardous substances, industrial chemicals and dangerous goods
2. therapeutic goods
3. road vehicles
4. gas appliances
5. radiocommunications devices.

The issues associated with each of these special exemptions are examined in this chapter. The chapter concludes by considering the overarching administrative issue of annual rollovers for special exemptions.

7.1 Hazardous substances, industrial chemicals and dangerous goods

Background

The issues underpinning the special exemption for hazardous substances, industrial chemicals and dangerous goods — collectively termed ‘industrial chemicals’¹ in this chapter — primarily concern requirements for:

- notification and assessment of industrial chemicals²

¹ Industrial chemicals include: dyes; solvents; adhesives; laboratory chemicals; chemicals used in mineral and petroleum processing, refrigeration, printing and photocopying; paints and coatings, as well as chemicals used in the home, such as weed killers, cleaning products, cosmetics and toiletries.

² This includes notification and assessment requirements for domestic poisons. It does not include agricultural and veterinary products, which are permanently exempted from the TTMRA (chapter 8), and therapeutic goods, which are subject to a separate special exemption (section 7.2). Strictly speaking, New Zealand applies assessment and approval requirements for industrial chemicals, rather than notification and assessment.

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- industrial chemical classification, labelling, packaging and safety data sheets.³

Efforts to resolve the issues underpinning the industrial chemicals special exemption are managed through a cooperation program. Australia's lead agency for the industrial chemicals cooperation program is the Office of the Australian Safety and Compensation Council (OASCC).⁴ In New Zealand, this responsibility lies with the Environmental Risk Management Authority (ERMA).⁵ Both the OASCC and ERMA are assisted by various other agencies — such as government departments for agriculture and health — due to the diversity of issues associated with chemicals regulation.

The Productivity Commission's 2003 review of the mutual recognition schemes found that various deficiencies in Australia's chemical regulations — particularly duplication and inconsistency between different agencies and jurisdictions — were a major obstacle to achieving mutual recognition with New Zealand (PC 2003). The Commission recently reviewed Australia's chemicals regulations and recommended a national approach to overcome the problems with existing arrangements (PC 2008b). A key aspect of the recommended reforms was a new governance framework that clearly divides responsibilities between numerous agencies and jurisdictions according to task (such as standard setting) and area (such as workplace safety). In contrast, New Zealand has a single agency (ERMA) to deal with most assessment and standard-setting functions, no states to which tasks are delegated, and fewer regulators to administer and enforce the regulations.

In response to the Commission's recommendations, Australian heads of government agreed in early October 2008 that 'improved and better coordinated governance structures are required' for Australian chemicals regulation (COAG 2008d, p. 7). They directed the Ministerial Taskforce on Chemicals and Plastics Regulatory Reform to develop a governance structure for their consideration at the next COAG meeting in November 2008. The heads of government also directed relevant Ministerial Councils to report in November 2008, through the COAG Business Regulation and Competition Working Group, on responses to specific

³ These standards vary in Australia according to whether a chemical is to be used in a workplace or home. Safety data sheets specify the properties of a chemical and the measures that should be taken to reduce the risk of injury.

⁴ The OASCC is located in the Australian Department of Education, Employment and Workplace Relations. It supports the Australian Safety and Compensation Council which is a group of representatives from national, state and territory governments; industry; and unions tasked with leading and coordinating national efforts to develop policy for occupational health and safety.

⁵ ERMA is an autonomous Crown entity created under the *Hazardous Substances and New Organisms Act 1996* (NZ). Its main role is to make decisions on applications to import, develop, or field test new organisms, or to import or manufacture hazardous substances.

recommendations made by the Commission. It was subsequently announced at the November 2008 COAG meeting that:

Recognising the need for greater coordination and oversight in chemicals and plastics regulation, COAG agreed to a new governance structure for chemicals and plastics reform. COAG also responded to the recommendations of the Productivity Commission Research Report on Chemicals and Plastics Regulation, with further reforms to be considered in 2009. (COAG 2008f, p. 9)

Consistent with the Commission's recommendations, the new governance structure announced by COAG included the establishment of the Standing Committee on Chemicals to coordinate policy formulation, oversee regulatory arrangements, and make recommendations to Ministerial Councils (COAG 2008g). An interim response to other specific recommendations made by the Commission was also released following the November 2008 COAG meeting, indicating the governments' commitment to pursuing the reform of Australian chemicals regulation (COAG 2008b).

The Commission's recommended reforms to chemical regulations did not extend to New Zealand, and so that country would retain its distinctive regulatory regime, unless it chose to align itself closely with Australia's reformed arrangements.

Developments in the special exemption since the 2003 review

This section outlines key developments with the industrial chemicals special exemption since the last mutual recognition review in 2003, and considers the implications for how the exemption should be resolved.

Notification and assessment of industrial chemicals

In 2004, a five year work plan was established under the auspices of the industrial chemicals cooperation program to resolve issues underpinning the TTMRA special exemption for industrial chemicals. The work plan largely focuses on notification and assessment arrangements, and is primarily undertaken by ERMA and Australia's NICNAS (National Industrial Chemicals Notification and Assessment Scheme).⁶ A key element of the work plan has been a comparison of arrangements in both countries. The Australian Government Department of Health and Ageing (DOHA) noted that this exercise revealed fundamental differences in the regulatory regimes:

⁶ NICNAS is responsible for administering Australia's national notification and assessment requirements for industrial chemicals. It is located in the portfolio of the Australian Government Department of Health and Ageing.

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- Australia assesses all new chemicals and priority existing chemicals, both hazardous and nonhazardous ...
 - New Zealand assesses only hazardous chemical substances as identified by the manufacturer or importer
 - the definition of ‘hazardous’ is not the same for Australia and New Zealand, with New Zealand adopting the GHS [Globally Harmonised System for Classification and Labelling of Chemicals] definition which currently is more conservative than the Australian workplace classification (currently aligned with European Union definitions)
 - NICNAS, like [regulators in] all other OECD countries, but unlike New Zealand, is a chemical-entity based scheme (that is, not product registration). New Zealand assess products as well as chemical entities
 - New Zealand must have regard in their assessment for the principles of the Treaty of Waitangi with the legislation requiring an assessment to provide any known and possible adverse effects throughout the life cycle of the hazardous substance (or new organism) on the relationship of Maori and their culture and traditions
 - differences between the New Zealand and Australian ecosystems may result in different risk assessment outcomes. (sub. 38, p. 1)

DOHA also expressed a concern that New Zealand does not require the notification and/or assessment of some chemicals that, while technically classified as nonhazardous, are not necessarily safe:

Furthermore, notwithstanding the difference in definition of ‘hazardous’, some nonhazardous chemicals (substances) are not subject to notification and/or assessed in New Zealand but do require notification and/or assessment in Australia. Mutual recognition would allow these chemicals (substances) to be sold in Australia without the need for the risk assessment deemed necessary. Even if a chemical is classified as nonhazardous in Australia, it may still be recommended that certain safety and risk information be required — ‘nonhazardous’ does not necessarily mean safe for all purposes. Australia’s regulatory system covers the broad spectrum of chemicals where nonhazardous substances still require labelling for consumers. (sub. 38, p. 1)

This illustrates the difficulties that would be likely to arise if mutual recognition was applied while there are still fundamental differences in what Australia and New Zealand consider to be appropriate ways to control chemical-related risks. Community expectations about those risks are such that achieving wholesale mutual recognition seems unlikely, unless it is accompanied by a high degree of regulatory harmonisation, if not uniformity.

DOHA claimed another barrier to mutual recognition is that it could jeopardise Australian trade with third countries:

... the differences between countries as noted in the analysis of both NICNAS and ERMA ... are such that to move towards mutual recognition could, in some

circumstances, jeopardise Australia's trading position, particularly noting Australia's trade in chemicals with South-East Asia, the EU and North America. (sub. 38, p. 2)

Accord Australasia claimed that there would be significant benefits from removing cosmetics from the industrial chemicals special exemption, and that this is feasible because the relevant regulations are now closely harmonised between Australia and New Zealand:

Since the Australian Government finalised its reforms to cosmetic products at the therapeutic interface in September 2007 and New Zealand introduced the Cosmetic Products Group Standard on 1 July 2006, the regulatory controls for cosmetic products are now closely harmonised and there is a strong case for TTMRA to apply to this class of consumer goods. The application of TTMRA for this class of low-risk, fast-moving consumer products will have significant benefits in facilitating trade and reducing unnecessary barriers. (sub. 39, p. 2)

However, cosmetics are subject to Australia's notification and assessment regime for industrial chemicals, and so the abovementioned differences identified by NICNAS and ERMA are relevant. Nevertheless, Accord Australasia argued that:

Both Australia and New Zealand have the same regulatory objective for industrial chemicals in the protection of public health, OHS and the environment. The different approaches to achieving these regulatory outcomes should not be used as an excuse not to mutually recognise ...

Cosmetic products provide an ideal opportunity for both governments to demonstrate their commitment to TTMRA ...

We therefore question the dismissal of this proposal ... on the basis that cosmetics are subject to Australia's notification and assessment regime ... can the regulator and the PC not see the current benefit and real opportunity for the free trade of goods such as soap across the Tasman, since soap, as a cosmetic product is regulated as part of the industrial chemicals regime? (sub. DR92, pp. 1-2)

The Commission considers that the best way of resolving this matter is through a cost-benefit analysis of whether the industrial chemicals special exemption should continue beyond the end of the five year work plan in 2009 (discussed further at the conclusion of this section of the chapter and reflected in the resulting recommendation).

The new regulatory regime that the Commission recently recommended for Australia would largely maintain the abovementioned regulatory differences between Australia and New Zealand, assuming New Zealand retained its approach. Nevertheless, the industrial chemicals work plan has identified some potential for the two countries to at least partially harmonise their notification and assessment processes regarding:

- chemical inventories

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- ‘low regulatory concern’ chemicals
 - scenarios for ‘controlled-use’ approvals (NICNAS 2008).

Furthermore, NICNAS and ERMA have a memorandum of understanding that facilitates cooperation in their industrial chemical notification and assessment activities.

Chemical classification, labelling, packaging and safety data sheets

The Australian Government Department of Education, Employment and Workplace Relations (DEEWR, sub. 57) and the New Zealand Government (sub. 53) noted that a key step towards resolving the industrial chemicals special exemption will be for Australia to implement the Globally Harmonised System for Classification and Labelling of Chemicals (GHS).⁷ The GHS was developed under the auspices of the United Nations, and provides an internationally-agreed system for the classification of chemicals and the communication of hazards through labels and safety data sheets.

No country has fully implemented the GHS, although New Zealand has made the most progress, and the European Union began phasing in the GHS in December 2008 over a period of about seven years:

The new European regulation on classification, labelling and packaging which is based on the GHS came into effect on 1 December 2008; the deadline for substance classification according to the new criteria is 1 December 2010 whereas for mixtures the deadline is 1 June 2015. (DEEWR, sub. DR90, p. 2)

New Zealand has applied the hazard-classification aspects of the original version of the GHS to all sectors, and is now updating its arrangements to the latest revised edition (New Zealand Government, sub. 53). In Australia, the Australian Safety and Compensation Council (ASCC) has proposed that the GHS (first revised edition) be adopted as part of a new national framework for regulating chemicals in workplaces.⁸ Progress in finalising this proposal has been slow, and its implementation would involve a long phase-in period:

Work on the new workplace chemicals framework has been ongoing for several years, and while significant progress is being made, this has occurred slowly ... Once a new GHS-based national standard for workplace chemicals has been declared ... GHS implementation in Australia would not actually occur until the new standard has been

⁷ This was also identified as a major prerequisite in the 2003 review of the MRA and TTMRA.

⁸ The OASCC’s proposal does not apply to domestic poisons, or agricultural and veterinary chemicals used solely in homes.

adopted into, or given effect by, the relevant state and territory legislation and regulations. This process can take a number of years to occur. (DEEWR, sub. 57, p. 3)

In 2006, a draft regulation impact statement (RIS) supporting the ASCC's proposal was released for public comment (ASCC 2006). The Commission examined the RIS as part of its recent review of Australia's chemical regulations, and concluded that the benefits of adopting the GHS in the immediate future were overstated. Implementing the GHS now would impose significant costs on industry without offsetting trade benefits, due to the limited adoption of the GHS by other countries. The Commission recommended that a further RIS should be prepared when some of Australia's key trading partners, such as China and the United States, have commenced implementing GHS-based regulatory regimes for workplace chemicals (PC 2008b).

There has been even less progress in applying the GHS to domestic poisons and agricultural and veterinary (agvet) chemicals in Australia. New Zealand has a GHS-based code of practice for labelling agvet chemicals, but the use of GHS label elements (such as pictograms) is not mandatory, and the code allows for alternative approaches to labelling. A major issue for Australia is that domestic poisons and agvet chemicals are currently classified and labelled according to the risk they pose (taking into account the probability of harm and the magnitude of the consequences), whereas the GHS only identifies hazards (potential for harm).

Application of the GHS to domestic poisons is currently being considered as part of the abovementioned five year work plan for industrial chemicals under the TTMRA. In Australia, this is being managed by DOHA in cooperation with state and territory governments, and with New Zealand as a participant in discussions. December 2009 is the target date for a decision on how the GHS would be applied to domestic poisons and agvet products (NICNAS 2008). DOHA observed that this work has already led it to conclude that there is little prospect of mutual recognition being achieved with New Zealand in relation to the GHS for domestic poisons:

... work in regard to the implementation of the ... GHS has demonstrated that [its] adoption ... in Australia is likely to require different approaches [compared to New Zealand] to classification and labelling for consumer chemicals that reflect different legislative arrangements (eg state/territory framework for poisons scheduling), differences in risk-management approaches and the need to align with trading partners. Consequently, the Department of Health and Ageing also sees little likelihood of mutual recognition being achieved in relation to the GHS in the consumer-chemical sector. (sub. 38, p. 2)

The New Zealand Government (sub. 53, p. 9) claimed that Australia's current consideration of how to apply GHS classification criteria 'creates an opportunity to harmonise the assessments relating to the intrinsic hazardous properties of ...

[domestic and agvet] chemicals'. However, DOHA cautioned that the GHS itself is not intended to harmonise regulations between countries:

While the GHS will help to bring about international harmonisation in regard to chemicals classification and some elements of labelling, it is not an objective of the GHS to bring about harmonisation in the overall approach to chemical regulation. The GHS is specifically not intended to harmonise risk assessment procedures or risk management decisions and therefore regulatory approaches between countries, given the varying national priorities and chemical use situations that may exist, will continue to differ. (sub. DR64, p. 2)

Conclusion

The industrial chemicals cooperation program has made progress in a range of areas, particularly in establishing greater cooperation between regulators on process issues. However, the cooperation program has also revealed fundamental differences in how Australia and New Zealand control chemical-related risks. Wholesale mutual recognition seems unlikely unless it is accompanied by a high degree of regulatory harmonisation, if not uniformity.

Some areas — particularly the GHS classification and labelling of workplace chemicals — are already in the process of being harmonised, but this is expected to take several years (which is desirable from Australia's perspective, given the limited adoption of the GHS by its major trading partners). Harmonisation of many other important areas appears unlikely in the foreseeable future, unless New Zealand is prepared to align itself closely with the reformed regulatory regime Australia adopts following the Commission's recent review of chemical regulations.

The five year industrial chemicals work plan is due to be completed in 2009. Given that there is no prospect of significant mutual recognition or harmonisation being achieved by that time, the Australian and New Zealand Governments should then critically examine the case for moving to a permanent exemption (but possibly with mutual recognition for selected products) rather than continuing the special exemption. This should involve a cost-benefit analysis comparing a permanent exemption with a continuation of the special exemption, and possibly combining these options with the application of mutual recognition to selected products such as cosmetics. The Commission does not favour a further extension of the special exemption unless it is supported by such an analysis, since the history of the cooperation program, and fundamental differences between the countries' regulations, suggests that wholesale mutual recognition or harmonisation is unlikely in the foreseeable future.

DEEWR questioned the need for a cost-benefit analysis of a permanent exemption:

Such a change would be purely administrative in nature, and would result in no change to the existing regulatory arrangements nor have an additional compliance burden on Australian business. A cost–benefit analysis is unlikely to yield any useful information to inform such a decision. Further, it is unclear who would be responsible for undertaking the analysis, and how such a cost–benefit analysis would be funded. (DEEWR, sub. DR90, p. 2)

However, the abovementioned reservations that Accord Australasia expressed about the treatment of cosmetics suggest that there would be costs as well benefits in either maintaining the special exemption or moving to a permanent exemption. Such issues need to be assessed in a systematic way, rather than continuing the special exemption by default on the implicit assumption that the as yet ill-defined benefits outweigh the similarly unknown costs. A cost–benefit analysis may also enable governments to make an informed decision that some elements of the regulation of hazardous substances, industrial chemicals and dangerous goods are best retained in the special exemption category, while others are recategorised as a permanent exemption or subjected to mutual recognition. Accord Australia’s suggestion that mutual recognition apply for cosmetics is one possible outcome. Responsibility for undertaking and funding the cost–benefit analysis should lie with the Ministerial Council overseeing the industrial chemicals special exemption.

Moving to a permanent exemption is unlikely to change significantly the timing of Australia’s adoption of the GHS, as the TTMRA does not seem to have been a major consideration. A more important determinant of when Australia adopts the GHS should be its implementation by major trading partners.

A permanent exemption need not have adverse consequences for the cooperative arrangements Australian and New Zealand regulators have established on process issues. DOHA noted that such arrangements exist between Australia and New Zealand for agvet products, despite there being a permanent exemption for those products:

... it would seem timely and appropriate to consider a permanent exemption being applied thereby placing notification and assessment of industrial chemicals on the same footing as agricultural and veterinary [agvet] chemicals, where, despite this permanent exemption, the level of cooperation between Australia and New Zealand on issues relating to agvet chemicals has not diminished. A similar position in regard to industrial chemicals would be anticipated under a ‘permanent exemption’ status. (sub. 38, p. 2)

Shifting to a permanent exemption would also eliminate the administrative costs associated with rolling over the special exemption annually. As detailed below in section 7.6, the administrative process for obtaining rollovers is onerous and time consuming.

Following completion of the five year work plan for industrial chemicals in 2009, Australian and New Zealand Governments should consider converting the TTMRA special exemption for hazardous substances, industrial chemicals and dangerous goods into a permanent exemption, and/or applying mutual recognition to some areas. This should involve a cost–benefit analysis, based on a realistic assessment of the likelihood of achieving mutual recognition or harmonisation in the foreseeable future, given the slow progress to date.

7.2 Therapeutic goods

Background

Therapeutic goods comprise medicines and therapeutic devices (for example, hearing aids, prosthetics and walking frames). They are of benefit to the community, but they also pose risks for the health and safety of consumers and for suppliers, institutions and health professionals advising on their use. This, combined with information failures that make it difficult for individuals to make fully-informed decisions about their use, provides a case for regulating therapeutic goods.

Differences in the classification and regulation of medicines, and an underdeveloped regulatory regime for therapeutic devices in New Zealand, contributed to the decision to create a special exemption for this category of products in the TTMRA. Australia's concerns about New Zealand's limited regulatory regime for therapeutic goods have been central to the creation and continuation of the special exemption. Particular areas of concern were:

- complementary medicines and medical devices, for which the former New Zealand Government admitted it had 'minimal regulation' compared with Australia (King 2006)
- dietary supplements, which Australia regulates as either medicines or foods, but which New Zealand regulates as a distinct category.

In 2001, the Australian and New Zealand Governments agreed in-principle to harmonise the vast majority of therapeutic product regulations, and to establish a joint therapeutics agency as a means of achieving such harmonisation (ANZTPA 2003). The joint therapeutics agency was expected to regulate therapeutic products manufactured in Australia and New Zealand and/or traded

between the two countries to ensure they met appropriate standards of quality, safety and effectiveness (PC 2003). This agency was intended to replace both the Therapeutic Goods Administration in Australia (TGA) and Medsafe (New Zealand's therapeutics regulatory agency).

The New Zealand Institute of Economic Research (NZIER) was commissioned by the two governments to undertake a cost–benefit analysis of a joint regulatory scheme and agency (box 7.1). NZIER found that, while the proposed scheme would yield only modest net economic benefits, it would offer medium to long-term nonquantifiable benefits from combining the regulatory capacity of the two countries (NZIER 2000).

At the time of the Commission's 2003 review, it was expected that a treaty to establish the joint agency would be signed by 2004 and that the joint agency would begin operating in 2005. In light of this, the Commission recommended extending the special exemption for therapeutic goods without requiring annual rollovers until the middle of 2006. It was expected that, by this time, it would be possible to identify a realistic timeframe for removing or reducing the exemption (PC 2003).

Developments since the 2003 review

Some progress was made towards the creation of a joint therapeutics agency in the years since the Commission's 2003 review. As anticipated, Australia and New Zealand signed a treaty in December 2003 to establish a joint regulatory scheme for therapeutic products and a joint therapeutics agency to oversee the scheme (King and Worth 2003).

The joint regulatory scheme would require all therapeutic products to undergo safety approval and licensing before they were allowed to be sold. Therapeutic products were defined broadly to include over-the-counter and prescription medicines, complementary medicines (including dietary supplements and herbal medicines) and medical devices, as well as blood, blood products and cellular and tissue therapies (King 2006).

While the treaty established the high-level framework for the joint regulatory scheme and joint agency, it required both countries to pass legislation in order to give effect to the new arrangements (King 2006). In preparation for this, a Therapeutic Products Interim Ministerial Council — consisting of the Australian Parliamentary Secretary for Health and the New Zealand Minister for Health — was established to facilitate the creation of the joint regulatory scheme and joint agency (TGA 2004).

Box 7.1 **Cost–benefit analysis of a joint therapeutics agency**

In July 2000, the New Zealand Institute of Economic Research (NZIER) was commissioned by the Australian and New Zealand Governments to undertake the regulation impact analysis for a joint Australia–New Zealand therapeutics agency. NZIER’s task was to assess the likely costs and benefits for Australia and New Zealand of establishing the joint agency.

For Australia, NZIER was required to assess costs and benefits relative to the status quo, namely Australia’s current therapeutics regulatory regime, which the Institute assessed as ‘much stronger’ than that of New Zealand (NZIER 2000, p. iii).

For New Zealand, however, NZIER was directed to assess costs and benefits not relative to the current regulatory regime — which NZIER described as ‘unsustainable’, with only ‘limited regulatory oversight’ of complementary medicines and medical devices (NZIER 2000, p. iii) — but relative to each of two counterfactual scenarios:

- a more comprehensive regulatory regime in New Zealand for medicines, medical devices and complementary medicines
- the above option, but in a way that permits New Zealand to unilaterally recognise some other countries’ certification of therapeutic goods.

In its analysis, published in October 2000, NZIER found that the proposed joint agency would yield only modest net economic gains for both countries. One reason for this was that the proposed joint agency would mainly affect therapeutic goods approved and supplied for the New Zealand market only, and these goods would not represent a large proportion of the total market for therapeutic goods in both countries. Another factor affecting the result was that the costs and benefits for New Zealand were assessed relative to a more stringent New Zealand regulatory regime, rather than to the existing regime.

NZIER estimated transitional costs for both countries from a joint agency at about A\$3 million per year and about A\$10 million in total, which it noted could be met mainly by government, although with possible partial cost recovery from industry.

However, NZIER anticipated additional benefits in the medium to longer term from combining the regulatory capacity of the two countries. This is achieved by pooling the ‘high-level’ knowledge and expertise required for approval and registration of therapeutic goods — expertise that it argued is ‘in short supply globally’ (NZIER 2000, p. ix). NZIER (2000, p. iv) concluded that these ‘nonquantifiable medium-term public benefits’ from a joint agency would ‘dominate the quantifiable economic gains’.

NZIER acknowledged that its analysis was largely qualitative, seeking to identify the direction and relative scale of costs and benefits rather than quantifying them. It attributed this to data constraints and difficulties in measuring or valuing some of the costs and benefits.

Source: NZIER (2000).

Some key decisions of the Interim Ministerial Council in 2004 and 2005 were to:

- include blood and blood products under the joint regulatory scheme (TGA 2004)
- create a new joint expert committee to coordinate reviews of medicine labelling, with the aim of working towards common standards (TGA 2004)
- include medical devices within the scope of the joint regulatory scheme, with independent conformity assessment of these devices (King and Worth 2004)
- appoint a joint expert advisory committee on therapeutic goods standards in preparation for the new regulatory scheme, with the committee given the task of creating harmonised standards for therapeutic products (King and Pyne 2005a)
- confirm that the new trans-Tasman agency would be known as the Australia New Zealand Therapeutic Products Authority (ANZTPA) and defer the agency's start-up date — previously set for 1 July 2006 — to enable extensive public consultation (King and Pyne 2005b).

The consultation process took place in three phases over 2006 and 2007, and was designed to gather public and industry views on the draft rules for the joint regulatory scheme (ANZTPA 2006).

Following these extensive preparations, the Therapeutics Products and Medicines Bill was tabled for introduction into the New Zealand Parliament in December 2006 (King 2006). Its Australian equivalent, the Therapeutic Products Bill, was released as an exposure draft for public comment in April 2007 (Mason 2007).

Progress came to a halt in July 2007, however, when the New Zealand Government announced that it would not be proceeding with the Therapeutics Products and Medicines Bill. The Government cited insufficient parliamentary support for the legislation (King 2007). Opposition to the bill came from minor party members of Parliament, including the Greens, the National Party and ACT New Zealand (Health Freedom New Zealand 2007a).

Opposition to the legislation reflected a public campaign in New Zealand against the proposed joint regulatory scheme. The main issue of contention was the inclusion of complementary medicines in the new regulatory scheme, which would have introduced more stringent regulatory controls on herbal and traditional medicines, medical devices and dietary supplements produced in New Zealand. Health Freedom New Zealand, which led the campaign, dubbed the legislation the 'Anti-Vitamin Bill' and warned New Zealanders that the proposed scheme would lead to price increases of between 30 and 100 per cent for vitamins and herbal supplements, as the more stringent regulations would increase costs to suppliers (Health Freedom New Zealand 2007b). Health Freedom New Zealand (2007b) also

expressed concerns that up to 60 per cent of supplements would disappear from the New Zealand market due to excessive compliance costs.

The former New Zealand Government stated that it remained committed to establishing the joint scheme and therapeutics agency, with the Therapeutics Products and Medicines Bill remaining on its Parliamentary Order Paper (New Zealand Government, sub. 53). A new government was formed in New Zealand following the November 2008 election, but it is unclear at this stage whether it will retain the approach of its predecessor. Its Ministry of Economic Development (sub. DR89) simply noted that the Commission's draft report had made a recommendation regarding the special exemption for therapeutic goods.

Interim arrangements

Both Australia and New Zealand decided to unilaterally reform their domestic regulatory regimes while implementation of a joint therapeutics regulatory regime remains postponed.

Prior to the recent change of government, New Zealand prepared reforms to its dietary supplements regulations that involved the regulatory separation of products New Zealand classifies as food-type and therapeutic-type dietary supplements (NZFSA 2008a). Under the proposed arrangements, food-type dietary supplements — such as sports drinks — would be taken out of New Zealand's dietary supplements regulations and, instead, regulated under a new Supplemented Food Standard. Therapeutic-type dietary supplements — such as vitamin tablets — would continue to be regulated as dietary supplements, but suppliers would be required to register their products on a database to be operated by Medsafe (NZFSA 2008b).

This appeared to represent a move towards the registration and administration of therapeutic-type dietary supplements as therapeutic products by Medsafe, even though they would still be regulated as dietary supplements. The former New Zealand Government (sub. 53, p. 26) referred to the changes as 'interim arrangements' intended to 'facilitate, or at the least not compromise' the resumption of negotiations towards a joint therapeutics scheme with Australia.

According to the Complementary Healthcare Council of Australia (CHC) (sub. 33), some industry representatives have taken these developments to suggest that therapeutic-type dietary supplements would eventually become regulated as complementary medicines in New Zealand under therapeutic product legislation, as in Australia. The CHC expressed concern that, under the new arrangements for food-type dietary supplements, many of these supplements currently imported into Australia from New Zealand would no longer be able to be marketed as 'foods'.

Barring an amendment to the joint Australia–New Zealand food standards code, such supplements would be regarded as therapeutic goods and would therefore become exempt from the TTMRA, raising compliance costs to Australian businesses importing these New Zealand products for supply to the Australian market (CHC, sub. 33).

Australia is also initiating domestic regulatory reforms to its therapeutic products regime. While the joint regime was being negotiated with New Zealand, Australia postponed a series of regulatory reforms, with the intention of implementing them as part of the new regime (CHC, sub. 33). With the postponement of negotiations on the joint scheme, Australia has decided to progress those reforms on its own. Public consultations have commenced on reforming regulations for prescription and complementary medicines, over-the-counter medicines, and medical devices in Australia.

The Commission supports Australia and New Zealand’s efforts to progress regulatory reforms unilaterally while negotiations for a joint therapeutics scheme are postponed. The unilateral reforms are likely to strengthen each country’s regulatory regime. In the case of Australia, delaying reforms imposes costs on local producers — who face regulatory uncertainty — as well as on consumers, who may be exposed to the risk of unsafe therapeutic products. Progressing the reforms, seen as long overdue, would offer local manufacturers and suppliers to the Australian market greater certainty about the regulatory environment, as well as improving protection for local consumers.

Options for dealing with the special exemption

The Commission maintains that a joint scheme and therapeutics agency would be the preferred means of resolving the special exemption in the long term. The available evidence on costs and benefits would support this view (box 7.1). However, there are various possible options for dealing with the special exemption in the interim. These are set out below.

Continue to roll over regardless of the fate of the joint regime

Under this ‘business-as-usual’ scenario, the special exemption for therapeutic goods would continue to be rolled over even in the event that there was negligible progress towards either harmonisation or mutual recognition. This would involve the continued preparation of cooperation reports outlining any progress made and the case for another rollover of the special exemption.

Retain special exemption, without cooperation reports, until negotiations are resumed

The recent election of a new parliament and government in New Zealand may provide a basis for the Australian and New Zealand Governments to reopen negotiations on the foreshadowed joint regime for therapeutic goods.

Until negotiations resumed, there would be little point in continuing to produce regular cooperation reports on the progress made in resolving the special exemption. Waiving the requirement to produce cooperation reports until negotiations resumed would also significantly reduce the administrative cost of continuing to roll over the special exemption. Such a change would not require legislative amendment because cooperation reports are only required under the administrative arrangements for rollovers (detailed in section 7.6).

It could be argued that the requirement to roll over the special exemption should also be waived until negotiations resume. However, in section 7.6 below the Commission recommends a general change to the rollover arrangements so that rollovers are only required every three years. It would be highly undesirable for a period of more than three years to pass without the Australian and New Zealand Governments having reached agreement on whether or not to resume negotiations on the joint regulatory regime (and indeed to complete the negotiations).

Industry groups stressed that the postponement of negotiations had created considerable uncertainty, and it was important that a time limit be placed on governments to remove that uncertainty, even if it forced governments to abandon the concept of a trans-Tasman regulatory regime:

The CHC considers industry is continuing to bear the cost of meeting two different regulatory systems and supports the reinstatement of a joint regulatory scheme between Australia and New Zealand. However, the CHC strongly suggests that this occur within an appropriate time period for the best interest of the complementary medicines industry ...

If the joint regulatory agency is agreed to by both governments, an appropriate deadline for implementation must be established. The CHC suggests that if the deadline is not met by either party, the concept of the joint regulatory scheme be abandoned and plans for therapeutic goods to fall under permanent exemption be initiated. (CHC, sub. DR69, pp. 1–2)

The Australian and New Zealand Governments should resume negotiations to establish a joint regulatory scheme for therapeutic products, with a joint agency to administer the scheme, as a matter of urgent priority ... The two governments should agree on a time limit within which agreement must be reached; within that period, the special exemption for therapeutic goods should continue ... Beyond that period, however, a

permanent exemption should be put into effect. (Australian Self-Medication Industry Inc, sub. DR60, pp. 1–3)

DOHA (sub. DR64) noted that the Australian Government is unwilling to resume negotiations unless the New Zealand Government can provide it with some certainty that the legislation for a joint regulatory regime would be passed by the New Zealand Parliament. DOHA also cautioned that a resumption of negotiations might delay reforms that Australia has recently decided to implement independently, which by implication would prolong industry uncertainty. This concern was reflected in views expressed by industry:

ASMI [Australian Self-Medication Industry Inc] believes that Australia should not delay further adopting the best of the ANZTPA proposed reforms on an Australia-only basis. Further, we do not believe the Australian Government should delay these reforms until the New Zealand position is clear. We should press ahead now. (ASMI, sub. DR60, p. 2)

During the consultation period under Trans-Tasman harmonisation, the introduction in Australia of a number of policy and legislative changes to improve the current therapeutic goods regulatory system was delayed as they were to be addressed under the new regulatory scheme — the CHC considers there is now an urgency to address these issues. The CHC considers it essential this work be progressed in an Australia only environment if a supported commitment cannot be made by the New Zealand Government. (CHC, sub. DR69, pp. 1–2)

However, a resumption of negotiations might not necessarily require a significant delay in reforms already underway. DOHA (sub. DR64) noted that Australia’s recently initiated reforms are essentially ones that were agreed as part of the trans-Tasman regulatory regime. Furthermore, both countries have committed to implementing their recently initiated reforms in a way that is consistent with the intent of the joint regime:

Since the postponement of negotiations Australia and New Zealand have proceeded with domestic regulatory reforms. Health Ministers of the two countries have agreed that this work should proceed in a manner that would be consistent with minimising trade barriers as envisaged for the joint regulatory scheme.

In Australia, these reforms have essentially implemented the initiatives agreed during the ANZTPA negotiations. (DOHA, sub. DR64, p. 2)

On this basis, it seems that each country’s reforms could largely continue as planned at a domestic level without significantly hindering the prospect of achieving agreement on a trans-Tasman regime at a later date. This view does, however, depend on how New Zealand proceeds with its proposed regulatory separation of food and therapeutic-type dietary supplements.

Narrow the scope of the special exemption

Rather than try to achieve regulatory harmonisation for the whole range of therapeutic products, it might be simpler to work towards mutual recognition or harmonisation for the less contentious products, while retaining the special exemption — or seeking a permanent exemption — for the remaining areas.

Complementary medicines and dietary supplements (and probably also medical devices) have been sticking points. Australia will not accept products in these categories that do not meet its more stringent requirements, while New Zealand has faced domestic opposition to the prospect of stricter regulations on these products.

As a result, it might be appropriate to accept that progress is not possible for these product areas, at least at the present time, and to move towards a limited permanent exemption for these products. Efforts could instead be directed towards achieving mutual recognition or harmonisation for the other categories of therapeutic products, including over-the-counter and prescription medicines, blood and blood products, and tissue and cellular therapies.

Study participants did not favour such a piecemeal approach to achieving harmonisation:

ASMI is firmly of the view that the ANZTPA regulatory scheme must cover all products which make a therapeutic claim, as that term is currently defined in Australian legislation. We will not support any scheme to ‘exempt’ or ‘exclude’ dietary supplements, or any other class or group of therapeutic products. (ASMI, sub. DR60, p. 2)

Complementary medicines are fully integrated into the Australian system and their removal would put at risk the integrity of a joint therapeutic products regulatory scheme ...

If either party to the [Australia New Zealand Therapeutic Products Authority] Treaty sought to exclude complementary medicines, then renegotiation of the Treaty may be required.

This option would also increase the complexity of the joint scheme as the agency would be required to enforce different rules in each country and medicines would need to be carefully categorised for trade purposes. (DOHA, sub. DR64, p. 3)

Seek a permanent exemption for all therapeutic products

Alternatively, Australia and New Zealand might decide that therapeutic products is an area in which they have such different views that it would be easier to make the whole range of products a permanent exemption from the TTMRA. A permanent exemption could be implemented administratively through regulation, rather than

requiring legislative change, and would only require the support of two-thirds of the jurisdictions.⁹

The advantage of this approach is that it might be simpler than determining which products to harmonise and which to exempt. It would also remove the requirement for annual rollovers, reducing administrative costs. However, this approach would lessen the pressure for governments to achieve progress, and would result in the two countries forgoing potential benefits of mutual recognition in product areas where mutual recognition or harmonisation might have been achieved.

DOHA (sub. DR64) favoured a permanent exemption for all therapeutic goods, noting that this would reduce industry uncertainty and government administration costs without necessarily ruling out the possibility of a trans-Tasman regime in the future. It also considered that, by simplifying the bilateral relationship, a permanent exemption may encourage narrower forms of harmonisation in the interim:

A permanent exemption:

- would not require repeal of the ANZTPA Treaty, and negotiations to establish a joint agency could recommence at any time
- may simplify the bilateral therapeutic goods regulatory relationship and may encourage cooperation efforts short of full harmonisation
- would present the least administrative burden of the options identified, and does not require an alteration to the current operation of the TTMRA
- would provide certainty for industry and allow domestic reforms to go ahead immediately in each country.

A permanent exemption does not imply that the Australian and New Zealand Governments have abandoned the goal of harmonised therapeutic products regulation. The TTMRA provides a framework for either country to seek removal of the exemption once current concerns have been addressed. (DOHA, sub. DR64, p. 3)

For instance, the Australian and New Zealand Governments could explore harmonisation in the areas of therapeutic-product labelling, prescription regulations, and the scheduling of medicines.

Conclusion

Of the possible approaches canvassed above, the Commission considers that it would be in the interest of both Australia and New Zealand to attempt to resolve the special exemption through harmonisation under a joint regulatory scheme, rather

⁹ *Trans Tasman Mutual Recognition Act 1997* (Cwlth), s. 45; and *Trans Tasman Mutual Recognition Act 1997* (NZ), s. 83.

than immediately move to a permanent exemption for some or all therapeutic products. The recent election of a new parliament and government in New Zealand provides an opportunity to resume negotiations on a joint regulatory regime. As a result, the Commission supports the approach of retaining the special exemption in the short term to allow for the possibility that agreement can be reached.

There should, however, be a strict time limit placed on the New Zealand Government to indicate that passage of the required legislation is likely, and for both countries' parliaments to enact the legislation. If these time limits cannot be met, a permanent exemption should be adopted as soon as possible in order to remove the uncertainty industry currently faces. Given the advanced stage that negotiations reached before they were postponed, the New Zealand Government should be able to indicate within three months of receiving this report whether it is likely to secure passage of the necessary legislation within the following nine months. If it advises that enactment is likely, the Australian and New Zealand Parliaments should enact the resulting agreed legislation within twelve months of governments receiving this report. Implementation of the joint regime should then occur as soon as possible.

RECOMMENDATION 7.2

The New Zealand Government should advise the Australian Government within three months of receiving this report whether the foreshadowed trans-Tasman regulatory regime for therapeutic goods is likely to be enacted by the New Zealand Parliament within the following nine months. If it advises that enactment is unlikely within this period, therapeutic products should be granted a permanent exemption from the TTMRA as soon as possible. If it advises that enactment is likely, but the parliaments fail to enact the legislation within twelve months of governments receiving this report, a permanent exemption should also be adopted as soon as possible.

7.3 Road vehicles

Road vehicles sold in Australia and New Zealand are subject to a range of standards. The rationale for road vehicle standards is twofold:

- consumers find it difficult to obtain and interpret technical information about models being considered for purchase
- the costs borne by vehicle owners do not always fully reflect the burden they impose on others (such as from pollution and accidents).

However, the development and application of vehicle standards also has costs, and so governments need to be mindful that these do not outweigh the benefits to the community as a whole.

One way in which governments can limit the costs of vehicle standards is to harmonise their requirements with those of other countries. A high proportion of road vehicles are sold in a different country from that in which they are manufactured. As a result, countries that maintain unique vehicle standards to achieve the same outcomes as their trading partners are likely to create unnecessary regulatory duplication and inconsistency. Uniqueness makes it more costly for governments to develop and administer standards, and add to the costs incurred by vehicle suppliers, which will in turn be passed on to consumers.

Governments around the world, including those of Australia and New Zealand, have recognised the potential benefits of harmonising vehicle standards across countries. At a multilateral level, the United Nations Economic Commission for Europe (UNECE) has been the primary forum through which harmonisation of vehicle standards has been pursued (box 7.2). Australia and New Zealand participate in the UNECE but have also been pursuing bilateral harmonisation through a TTMRA cooperation program for road vehicles.

Because of the potential for economic benefit resulting from common road vehicle requirements, Australian and New Zealand governments have sought either mutual recognition or harmonisation. The special exemption was accorded under TTMRA due to the desire to overcome significant differences in road vehicle regulation. While Australian exports to New Zealand are not affected by these differences — because of New Zealand acceptance of Australian regulations — it is not clear how trade in components from New Zealand to Australia have been impeded by the lack of mutual recognition (box 7.3).

Given that around 80 per cent of all light vehicles sold in Australia in 2007 were imported (FCAI 2008), harmonisation with other countries' standards could result in substantial economic benefit, by avoiding the need for costly adjustments to the standards of imported vehicles. New Zealand, which recognises a number of standards and imports virtually all of its cars, already realises this benefit to a large extent. New Zealand consumers can access cars produced to a range of acceptable standards and, hence, reap the benefits of larger production runs and innovations of international manufacturers.

The rest of this section outlines Australia and New Zealand's current approach to vehicle standards, their progress in harmonising standards through UNECE and TTMRA processes, and the Commission's assessment of should happen in relation to the road vehicle special exemption.

**Box 7.2 United Nations Economic Commission for Europe (UNECE)
World Forum for Harmonisation of Vehicle Regulations**

Both New Zealand and Australia are active participants in the United Nations Economic Commission for Europe (UNECE) World Forum for Harmonisation of Vehicle Regulations, the pre-eminent forum for the development of vehicle standards. This forum aims to initiate and pursue actions aimed at the worldwide harmonisation, or development, of technical regulations for vehicles, with the specific aim of reducing duplication of conformance procedures.

The UNECE began as a forum to harmonise European regulations, resulting in the UNECE Agreement 1958. The 1958 Agreement currently has 38 signatories including Australia, New Zealand, the European Union and Japan. APEC has also agreed that the UNECE should be the forum for the region to debate the alignment of road vehicle standards.

The principal objective of the 1958 UNECE Agreement is to eliminate the need for duplicate conformance assessment. This is achieved by a country 'applying' all or any of the UNECE standards. In applying a UNECE standard, a country agrees to accept products that have been assessed by a conformance assessment body accredited by the country manufacturing and/or supplying the product. A country that has applied a particular standard, also has the right to issue approvals or accredit third-party conformity assessment to that UNECE standard. The United States and Canada have not applied standards under the 1958 Agreement as they have a policy of not accepting certification done in other countries.

UNECE members made another agreement in 1998, which runs parallel to the 1958 Agreement, providing for the development of Global Technical Regulations (GTRs). The GTRs Agreement does not provide for the mutual recognition of certification of automotive products, allowing the United States and Canada to play an active role in development of global vehicular standards. The GTR forum establishes a global process for the joint development of GTRs for vehicles and components.

New Zealand acceded to the GTRs Agreement in 2001, and Australia in 2008. As noted in the Road Vehicles 2007 Joint Annual Cooperation Report, the GTRs Agreement has become the global centre of discussions about vehicle regulations, such that 'in time there will no longer be a need for bilateral or regional mutual agreements on vehicle standards' (DITRDLG and MED 2007, p. 3).

Source: DITRDLG and MED (2007); UNECE (2005).

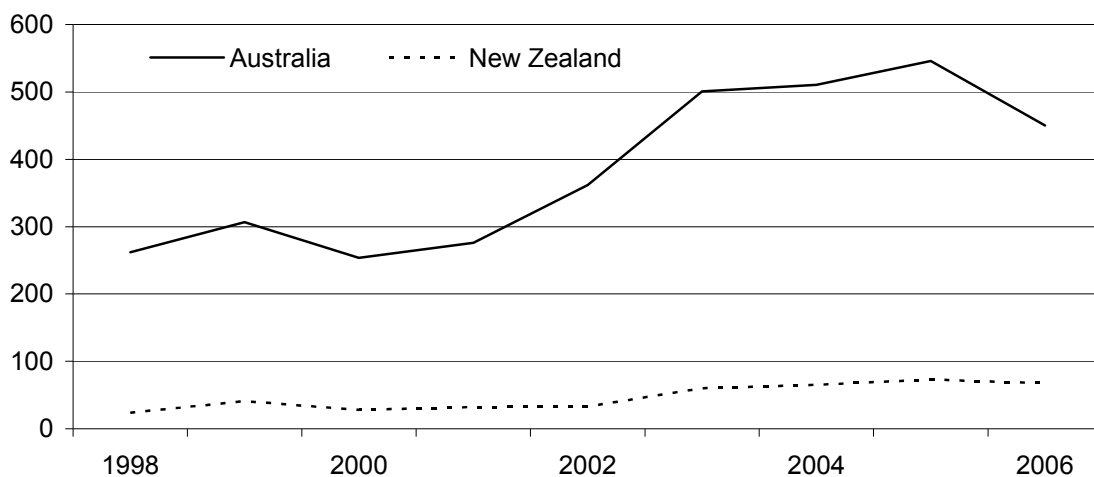
Box 7.3 Trans-Tasman automotive trade

The degree to which trans-Tasman trade in vehicles may have been hampered by the lack of mutual recognition is unclear. In particular, as New Zealand unilaterally recognises Australian standards, Australian exports to New Zealand are unaffected by the exemption. As the figure below shows, the period since the introduction of the TTMRA has seen an increase in the value of trade in vehicles between the two countries, with gross exports from Australia increasing by over 70 per cent. Exports to New Zealand currently comprise around 16 per cent of all automotive exports from Australia (Bracks 2008).

The 2003 review of the mutual recognition schemes noted that New Zealand manufacturers commonly experience problems in accessing the Australian market (PC 2003). While exports of automotive components from New Zealand to Australia have increased over the period of the TTMRA, they still amount to less than \$US 70 million per annum.

Trans-Tasman exports of road vehicles and vehicle parts

Gross exports (\$US million)



Source: World Integrated Trade Solution (WITS) database (accessed 25 July 2008).

Road vehicle standards in New Zealand

New Zealand currently accepts all road vehicles and components that comply with Australian, Japanese, United States or UNECE standards. That is:

... the overall policy is to provide a range of standards covering vehicles from the main four safety-conscious standards-setting regimes from which New Zealand's vehicles are sourced. (Land Transport New Zealand 2008a, p. 2)

This policy facilitates the supply of vehicles to New Zealand consumers at a lower cost than otherwise, while providing a level of vehicle standards acceptable to the community. It also benefits Australian motor vehicle exporters because they are not required to comply with standards unique to New Zealand.

The range of road vehicle standards currently accepted in New Zealand are expected to converge with UNECE standards over the long term, allowing for effective harmonisation between the New Zealand and Australian approaches to motor vehicle standards. However, the New Zealand Government (sub. 53, p. 23) pointed out that the international convergence of standards is ‘at a very early phase and it would be very difficult to estimate when it may be completed’.

New Zealand also accepts compliance certification by other countries where it has confidence in that country’s certification procedures. This includes conformity assessments carried out in Australia. The New Zealand approval process is based on a whole-vehicle approach, whereby a new model of motor vehicle must be certified as complying with one of the accepted suites of standards.

Road vehicle standards in Australia

All vehicles manufactured in or imported into Australia need to conform to a set of national standards — referred to as Australian Design Rules (ADRs) — that provide a comprehensive range of performance and design requirements for motor vehicle safety. ADRs are developed by the Department of Infrastructure, Transport, Regional Development and Local Government (DITRD LG) in consultation with a range of stakeholders.

Australian Design Rules and the UNECE standards

Australia became a signatory to the 1958 UNECE Agreement in 2000, and has sought to harmonise ADRs with UNECE standards. In 2008, Australia also acceded to the 1998 UNECE Agreement on Global Technical Regulations. Currently, over 70 per cent of the ADRs are consistent with UNECE standards. This understates the extent of harmonisation because some of the remaining 30 per cent of ADRs have been superseded by ADRs that are consistent with UNECE standards. However, there are a number of significant ADRs that continue to impose unique Australian requirements on manufacturers, such as for child restraints (ADR 34) and frontal impact (ADR 69). The Commission understands that the Australian Government

has no plans to harmonise some of these requirements, such as child restraints, with UNECE standards.¹⁰

It is unclear what environmental or public health benefits Australia gains from having unique ADRs that differ from UNECE, Japanese or US standards. Discrepancies between ADRs and other standards accepted internationally can result in additional requirements being imposed upon automotive products beyond what is necessary to improve safety. While it is not possible in the context of this study for the Commission to make judgements about the need for unique Australian standards, any differences between Australian and widely accepted international standards for road vehicles need to be rigorously justified on either safety or environmental grounds because of their potential to create barriers to trade.

Such barriers to trade potentially disadvantage automotive producers and consumers alike, in both Australia and New Zealand. The Federal Chamber of Automotive Industries noted that compliance with unique local standards can impose a ‘cost penalty’ on Australian automotive manufacturers, leading to a ‘significant disadvantage in an export market’ (FCAI 2006, p. 2). In its submission to the Commission’s 2002 review of automotive assistance, Ford Australia (2002) noted that compliance with unique ADRs costs those supplying vehicles to the Australian market around \$1–2 million for each model, without adding any safety benefits.

Car buyers are also disadvantaged by what amounts to a barrier to trade. As unique ADR requirements are imposed on all vehicles being sold in Australia, the cost penalties associated with the differences in standards are to some extent passed on to the consumer. These ADR requirements apply to both second-hand and new vehicles imported into Australia. Increased car prices reduce the level of income available to be spent on other goods and services, in turn discouraging investment and employment in industries that supply those goods and services.

Compliance and certification in Australia

Each model of a particular vehicle design to be either imported into, or manufactured in, Australia has to be certified as complying with the relevant ADRs.

The certification process in Australia is administered by Vehicle Safety Standards (VSS) in DITRDLG. Manufacturers demonstrate compliance with ADRs by submitting details of vehicle design and results of various tests specified under the

¹⁰ The special exemption for motor vehicle child restraints is currently listed under the hazardous substances special exemption in schedule 3 of the TTMRA legislation. In the context of other changes being made to the TTMRA, child restraints should be transferred to the road vehicles special exemption.

ADRs. These tests can be carried out within Australia or overseas in certified testing facilities. Audits of both the testing facility and the manufacturing process are also conducted by VSS, to ensure that vehicles are constructed to the production design and that tests are carried out correctly. A physical inspection of a new model before it goes on sale is also conducted to ensure registration requirements are met.

Certification is contingent on a new model meeting the entire suite of ADRs. For ADRs harmonised with UNECE standards, Australia accepts test reports and certifications approved to those UNECE standards from other countries signatory to the 1958 Agreement. However, as certification in Australia is based on whole-vehicle approvals, audits of the manufacturing process and the test facilities are still required to ensure compliance with Australian regulations (PC 2003).

Imports of second-hand vehicles

Australia and New Zealand approach the regulation of imported second-hand vehicles differently.

Australian imports

Australian imports of second-hand vehicles are restricted by a mix of industry and transport policy. As the 2008 Bracks Review noted:

All used vehicles built on or after 1 January 1989 need to qualify under the Specialist and Enthusiast Vehicle Scheme [SEVS] or the Registered Automotive Workshop Scheme [RAWS] and be certified as complying with the Australian Design Rules applicable at the time of the imported vehicle's manufacture ... Used vehicles attract a tariff of 10 per cent for passenger vehicles and 5 per cent for light vehicles and 4WDs, in addition to a non-*ad valorem* tariff of \$12,000. Vehicles imported under the two schemes do not attract the non-*ad valorem* tariff. (Bracks 2008, p. 33)

Special interest second-hand vehicles aimed for niche markets and imported under the low-volume SEVS or RAWS schemes are assessed as conforming to the relevant ADRs on a vehicle-by-vehicle basis. The Australian Government's rationale for vehicle-by-vehicle assessment is that the condition of second-hand vehicles is difficult to determine, and there may be quarantine risks associated with bringing vehicles in from certain areas.

In addition to conformance assessment, imported second-hand vehicles that are not on the special interest list are subject to a \$12 000 tariff. The 1999 Review of the Motor Vehicles Standards Act described the tariff as being:

... expressly provided for the purpose of limiting the numbers of used vehicles imported into Australia in full volume to give effect to industry policy. (Review Task Force 1999, p. 106)

As the Commission has noted previously, this tariff essentially prohibits the importation of second-hand cars that do not qualify for either scheme (PC 2002, 2008).¹¹

The cost to consumers of effectively prohibiting large-scale importation of second-hand vehicles through the combination of vehicle-by-vehicle inspections, ADR requirements and the \$12 000 tariff is likely to be significant, and any benefits from such a policy need to be clearly demonstrated.

New Zealand imports

Second-hand cars can be imported into New Zealand from a number of countries, with around 95 per cent of these originating in Japan.

Importing used vehicles involves a number of compliance steps including: quarantine and border control, certification of ownership and legal entitlement, verification that the vehicle met required standards at the date of manufacture, compliance with safety and emissions requirements, and verification of the condition of the vehicle (Land Transport New Zealand 2008b). After completing these steps, the vehicle is then issued with a warrant of fitness, which has to be renewed on a six-monthly or yearly basis, depending on the age of the car.

Restrictions on importing second-hand vehicles to New Zealand are relatively relaxed compared to Australia, with consumers benefiting from an increased range of vehicles and lower prices. This is evidenced by the fact that imports of used vehicles comprised around 61 per cent of new car registrations in New Zealand during 2007 (Land Transport New Zealand 2007). However, increased access to second-hand cars from other countries is accompanied by a diminished autonomy regarding vehicle standards, and an increase in the number of vehicles that may be less suited to local conditions. As international standards converge and the UNECE becomes more widely accepted, these problems are likely to become less significant.

¹¹ The 2002 Review of Automotive Assistance found that there was merit in retaining the \$12 000 tariff, but only because its removal would destabilise other adjustment measures (PC 2002).

Cooperation program

The Australian and New Zealand Governments established a TTMRA cooperation program covering all road vehicle standards, with the clear intention of promoting mutually acceptable standards and common conformance and certification requirements. Annex 4 of the TTMRA specifies the goals of the cooperation program for road vehicles as being to establish a harmonised set of trans-Tasman vehicle standards based, at least in part, on UNECE standards:

Australia and New Zealand will embark on a program aimed, where appropriate, at harmonising Australian and New Zealand standards with the internationally recognised UNECE standards, or those national or regional standards that are agreed by the Parties, and at developing consistent conformance assessment and certification requirements in both countries. This body of internationally harmonised standards is intended to form the basis of a set of trans-Tasman road vehicle standards. It is intended that, as far as possible, all vehicles would be certified against these trans-Tasman standards. All road vehicles certified as meeting these standards will be able to be freely traded between Australia and New Zealand. (TTMRA 1998, Annex 4, p. 40)

It is important to recognise that this commitment to removing impediments to trans-Tasman trade in road vehicles and their components was, in 1998, agreed upon in the context of New Zealand's acceptance of multiple standards and imports of used vehicles, with imports of second-hand vehicles increasing rapidly in New Zealand:

The program of importing used vehicles into New Zealand (mainly from Japan) which began to have effect in 1987 when the percentage of used imports in new registrations in New Zealand rose from about 5 per cent to about 13 per cent. The levels of used imports rose again to about 50 per cent over the next three years and at present about two-thirds of the newly registered light vehicles are used imports. (Newstead and Watson 2005, p. 2)

That is, both parties agreed to seek mutually acceptable road vehicle standards in the full knowledge that New Zealand already accepted the importation of second-hand vehicles from Japan.

However, there has been little progress in developing a set of mutually acceptable trans-Tasman standards. The justification for this lack of progress appears to be the expectation that future prospects for mutual recognition or harmonisation rest on the convergence of the ADRs and other international standards. As the New Zealand Government noted:

... the full or partial removal of road vehicles, their components and systems from the scope of the [TTMRA special] exemption would be difficult, and its success and impact may depend on the progress of the work carried out at the WP.29 [UNECE World Forum for Harmonisation of Vehicle Regulations, Working Party 29] on global harmonisation. (sub. 53, p. 23)

Similarly, the 2007 Joint Annual Cooperation Report stated that:

... the objectives of TTMRA could be best served by both parties pursuing a program with the regulations adopted by [UNECE]'. (DITRDLG and MED 2007, p. 1)

With the focus on international convergence, currently there seems to be little occurring in the way of active cooperation between Australia and New Zealand. This lack of bilateral cooperation pending international convergence creates potential for divergence in trans-Tasman automotive standards resulting from country-specific regulatory and technological developments. Two recent examples are:

- the development of New Zealand fuel economy standards for all new and used light vehicles entering the fleet (Bracks 2008). This is likely to have implications for the Australian automotive industry, given that the New Zealand market absorbs a significant proportion of Australian automotive exports
- the introduction of vehicle security measures such as microdots — aimed at minimising vehicle theft — which are proposed for all vehicles imported into New Zealand.

An effective cooperation program with a well-defined strategy for facilitating trans-Tasman automotive trade and promoting consistency in Australian and New Zealand motor vehicle standards and conformance procedures can:

- provide a mechanism to ensure coordination of policy developments and a means of preventing further differences in standards from emerging
- remove barriers to trans-Tasman trade in vehicles by Australia considering the range of standards already accepted in New Zealand.

Further, as was noted in the 2003 review of the mutual recognition schemes, there remains potential for mutual recognition of conformance assessment. This would involve New Zealand manufacturers obtaining approval in New Zealand for components they produce, via administrative processes run by the New Zealand Government, and having that approval recognised in Australia without further testing or evaluation.

Future directions

There are three broad policy options for achieving harmonisation and hence resolving the special exemption:

- New Zealand only accepts vehicles that meet Australian standards.
- Australia accepts third-country standards recognised by New Zealand.

-
- Australia and New Zealand use the TTMRA cooperation program to negotiate harmonised requirements.

The exclusive adoption of Australian standards by New Zealand would adversely affect New Zealand consumers and exporters by raising the cost of trade with third countries.

Australian acceptance of third-country standards recognised by New Zealand would be a major policy shift for Australia. In the 2003 review of the MRA and TTMRA, the Commission concluded that the associated benefit would be of limited duration because the requirements of many of Australia and New Zealand's trading partners were converging on UNECE standards in any case. As a result, it was thought that the interests of both countries would be best served by focusing on international harmonisation through the UNECE. In hindsight, it is apparent that the goal of multilateral harmonisation is a long-term one that will take some time to achieve. The New Zealand Government (sub. 53) observed that the convergence of international standards is still at an early stage, and it is unclear when the major international automotive standards will converge. Indeed, Australia may never fully converge with international standards because, as noted previously, it is committed to retaining some unique ADRs, such as for child restraints.

The Commission has, therefore, concluded that there is merit in Australia and New Zealand continuing to explore opportunities to harmonise their vehicle standards and associated procedures through the TTMRA cooperation program, rather than relying solely on the UNECE process. As suggested by the New Zealand Government (sub. 53), the respective differences in regulations applying to child restraints could be an area where the cooperation program could progress beyond the expected UNECE convergence.

Continuing the special exemption also emphasises harmonisation as a common policy goal, and reinforces the commitment to harmonisation of standards that New Zealand and Australia have under both UNECE and TTMRA. There are still impediments to trans-Tasman trade in vehicles and their components, and without a formal, structured, and effective dialogue between the two regulators, there remains the possibility of unilateral measures leading to a divergence of standards.

The need for an effective program of cooperation is demonstrated by the tendency for divergence in the absence of a structured dialogue between Australian and New Zealand regulators. This is evidenced by New Zealand pursuing unilateral changes such as fuel economy standards and security measures, which are not mentioned in either the 2007 or 2008 cooperation reports. Indeed, the two most recent cooperation reports show little evidence of progress and are remarkably similar in content, suggesting an absence of communication and cooperation.

To avoid the development of different vehicular standards, a reinvigorated cooperation program needs to be implemented, featuring clear objectives and deadlines by which they can be met, and supported by a clear intention to reduce impediments to trans-Tasman trade in vehicles.

It is important to remember that the cooperation program was initiated with the purpose of facilitating either mutual recognition or harmonisation, and that the underlying premise of mutual recognition is that the existing regulatory arrangements for each party are acceptable to the other. Persistence with standards and conformance procedures that are not mutually acceptable contradicts this premise, and requires strong justification on public health or environmental grounds.

RECOMMENDATION 7.3

The TTMRA special exemption for road vehicles should remain because there are opportunities for Australia and New Zealand to harmonise their vehicle standards and associated procedures in advance of, and in some cases to a greater extent than, the harmonisation expected to eventually be achieved at a global level. To ensure that the special exemption delivers results, the Australian and New Zealand Governments should develop a reinvigorated cooperation program for road vehicles that has clear objectives and deadlines, and is supported by a clear intent to reduce impediments to trans-Tasman trade in vehicles.

7.4 Gas appliances

Gas appliances improperly designed or produced can lead to gas poisoning, fire, burns and asphyxiation, sometimes with fatal consequences. Combined with information failures that make it difficult for consumers to identify unsafe appliances, these dangers provide a case for regulation.

This area was originally made a special exemption under the TTMRA due to differences between Australian and New Zealand compliance regimes for gas appliances, and to accommodate Australia's concerns about the safety and effectiveness of New Zealand's less stringent regulatory regime. Another reason for the special exemption was the difference in liquefied petroleum gas (LPG) composition between the two countries, which led to safety concerns about mutual recognition of some LPG appliances.

The cooperation program covering gas appliances was expected to identify and implement the changes that would enable mutual recognition to be extended to

these products. In recent years, satisfactory progress has been made towards bridging the regulatory gap between the two countries.

Background

Australia's regulatory regime for gas appliances includes mandatory requirements to protect health, safety and the environment, and for energy efficiency, fitness for purpose and labelling. Australian regulations require laboratory testing against appliance specifications and standards, and independent third-party certification and labelling prior to sale (DTEI 2005).

In contrast, at the time of the TTMRA's inception, New Zealand had a system of voluntary compliance and post-market surveillance only (PC 2003). In 2002, New Zealand introduced a new compliance system for gas appliances, involving mandatory supplier declarations. Under this system, suppliers of gas appliances are required to post declarations of compliance on the Energy Safety New Zealand website and produce supporting documentation upon request. However, pre-sale certification by a third party was not made mandatory and so the new regime was not harmonised with Australia's requirements (PC 2003).

Without mutual recognition or harmonisation, New Zealand manufacturers and suppliers seeking to export gas appliances to Australia are required to obtain third-party conformity assessments by accredited conformity assessment bodies. In their submissions to the previous review, the Gas Appliance Suppliers Association of New Zealand and Fisher & Paykel claimed that conformity assessments are a significant barrier to trans-Tasman trade in gas appliances (GASA 2003; Fisher & Paykel 2003). New Zealand exporters incur the cost of sending each appliance model to Australia for testing and approval before it can legally be sold there. Appliances imported by New Zealand from third countries must also be tested and certified again before they can be sold in Australia (PC 2003).

There are safety concerns about mutual recognition for some LPG appliances due to differences in LPG composition between Australia and New Zealand. Australia uses LPG that is predominantly propane, while New Zealand uses LPG that is a mixture of propane and butane. According to the 2007 cooperation program report for gas appliances (GTRC 2007a), the problem arises because some LPG appliances built to burn propane-based LPG become hazardous when used with propane-butane LPG, and vice versa. It is impractical for either country to change its LPG supply (New Zealand Government, sub. 53) and, as a result, this is an area of the special exemption that has remained unresolved.

In the early years of the TTMRA, this difference was recognised by the Gas Technical Regulators Committee (GTRC) — a forum for gas regulators from all Australian jurisdictions and New Zealand) — as a safety issue mainly for LPG cabinet heaters, which are portable heaters containing an LPG cylinder. In contrast, GTRC (2007a) expressed concern that the incompatibility would affect all LPG appliances. However, recent work on a regulation impact statement (RIS) for a permanent exemption for LPG appliances — discussed in the next section — suggests that the safety risk will not affect ‘universal’ LPG appliances, which are able to be used with both types of LPG supply.

In its 2003 review of the MRA and TTMRA, the Commission found that only modest progress had been made towards enabling gas appliances to become subject to mutual recognition. It suggested extending the special exemption for gas appliances for a maximum of three years, without the need for annual rollovers, but with a project plan to be submitted to COAG in the interim. That plan — accompanied by annual progress reports — would focus on key issues such as unflued heaters, and the effectiveness of New Zealand’s new compliance regime (PC 2003).

In its response to the Commission’s review, the CJRF (2004) rejected the idea of extending special exemptions without annual rollover requirements, because it would require all jurisdictions to coordinate legislative changes, which would be administratively cumbersome.

Developments since the 2003 review

By 2005, Australian gas regulators — comprising a majority of GTRC members — were expressing support for the special exemption for gas appliances to be made permanent (DTEI 2007). They considered that New Zealand’s new scheme of mandatory declarations of compliance with general safety standards, without pre-sale third-party certification and labelling as in the Australian system, did not offer sufficient safety assurance to be compatible with mutual recognition or harmonisation. Australia maintained the view that mutual recognition for gas appliances would not be appropriate unless New Zealand made major changes to its regulatory regime (DTEI 2005).

New Zealand undertook an extensive review of its gas appliance regulatory regime during 2006 and 2007, including consultation with industry and with Australian regulators. The review culminated in the release of a proposed new set of gas regulations for New Zealand in December 2007 (Energy Safety 2007).

The draft regulations signal New Zealand's move towards a more rigorous safety compliance regime for gas appliances, including a system of third-party pre-sale certification. Under the proposed third-party certification system, a manufacturer or supplier of a gas appliance must obtain a safety certificate from a recognised conformity assessment body (Energy Safety 2007). Conformity assessment bodies would need to be recognised under the Joint Accreditation System of Australia and New Zealand, the accreditation body appointed by the Australian and New Zealand Governments and responsible for providing accreditation of conformity assessment bodies. The draft regulations also include a system of common labelling across Australia and New Zealand.

The proposed changes to the New Zealand gas appliances safety regulations are expected to become law on 1 July 2009. It is anticipated that the changes will be fully implemented by the end of a transition period of 18 to 24 months (the exact period to be determined by a forthcoming ministerial decision). The special exemption for gas appliances is likely to be extended until the changes are fully implemented.

In the case of LPG appliances, the GTRC considered that mutual recognition or harmonisation would not be possible due to the difference in LPG composition between Australia and New Zealand. Consequently, in the 2007 cooperation program report for gas appliances, the GTRC (2007a) agreed to seek a permanent exemption from the TTMRA for LPG gas appliances.

However, permanently exempting LPG appliances from the TTMRA would impose costs on trans-Tasman exporters. Under the current special exemption, for example, Stainless Tanks and Pressure Vessels (sub. 27) reported that it has to arrange for every model of its Australian-manufactured LPG cylinders to be extensively tested and inspected in New Zealand prior to sale. A permanent exemption would limit the prospects of those duplicated costs ever being reduced. Nevertheless, these costs must be considered against the potential safety hazards associated with mutual recognition of some LPG appliances, or the costs of harmonising LPG composition between Australia and New Zealand.

The New Zealand Ministry of Economic Development (sub. DR89) noted that New Zealand regulates LPG cylinders under its hazardous substances regulations, rather than its gas-appliance regulations. As a result, it argued that LPG cylinders should be included in the special exemption for hazardous substances, industrial chemicals and dangerous goods, rather than the special exemption for gas appliances. It appears that LPG cylinders are not currently being considered by the cooperation program for either special exemption, and so its classification is unclear. The governments should work to resolve this matter.

The Department of Resources, Energy and Tourism has prepared a RIS for the proposed permanent exemption of LPG appliances. The RIS was released for public comment by the Ministerial Council on Energy in September 2008, following consideration by the GTRC. The RIS considered the costs and benefits of mutual recognition, harmonisation and permanent exemption of LPG appliances, and noted that the GTRC had concluded that a permanent exemption would be the only feasible solution. The Commission understands that public comments on the RIS have since led to a narrowing of the range of LPG appliances to be permanently exempted, so that universal LPG appliances that can safely receive either form of LPG supply will be mutually recognised. Thus, the permanent exemption would apply only to ‘nonuniversal’ LPG appliances for which the different types of LPG composition pose a safety risk.

It is expected that the implementation of both the proposed New Zealand regulations for natural gas appliances and a permanent exemption for nonuniversal LPG appliances would lead to the removal of the special exemption for gas appliances (New Zealand Government, sub. 53).

FINDING 7.1

The Commission notes the progress made by the Australian and New Zealand Governments towards harmonised regulations for natural gas appliances. It supports the move towards a permanent exemption for ‘nonuniversal’ LPG appliances, subject to a cost–benefit analysis of the change.

7.5 Radiocommunications devices

Background

Radiocommunications devices such as wireless computer networks, mobile and cordless phones, radios, electronic paging devices and some therapeutic devices serve an increasing range of useful purposes in modern life. These devices operate via radio waves within the radiofrequency spectrum — the range of different frequencies of electromagnetic radiation capable of supporting radiocommunications.

Regulation of the use of the radio spectrum is necessary to ensure that different sections of the spectrum are allocated for specific purposes, and that the likelihood of signals from different devices interfering with one another is minimised. Interference between radiocommunications devices can reduce the performance of

these devices, but also has the potential for severe consequences, particularly when the health and safety of people are dependent on the functioning of these devices.

In developing the TTMRA, it was recognised that there were historical differences between Australia and New Zealand in the technical standards and regulatory requirements for electromagnetic compatibility (EMC) and radiocommunications. In particular, there were differences in the parts of the radio frequency spectrum allocated to different devices.¹² These differences could result in interference problems if devices compliant with regulations in one country were used in the other.

A special exemption from the TTMRA for radiocommunications devices was therefore granted, to allow the two countries to address their differences and to develop harmonised regulatory arrangements where possible. This allows the economic benefits from harmonisation and mutual recognition of standards to be realised, while protecting public health and safety.

Cooperation program

The Australian Communications and Media Authority (ACMA) and the New Zealand Ministry of Economic Development (MED) are responsible for implementing the joint cooperation program in their respective countries. This cooperation program has been particularly successful in achieving harmonisation of standards where possible, exhibiting ‘a high degree of proactive regulatory cooperation and coordination supported by a clear appreciation of the objectives of the TTMRA’ (CJRF 2004, p. 36).

The high level of cooperation between trans-Tasman spectrum regulators has led to a number of achievements, including:

- the development and use of common compliance marking (box 7.4)
- the narrowing of the scope of the special exemption through the harmonisation of electromagnetic compatibility requirements
- the partial harmonisation of radiocommunications standards and regulatory arrangements.

¹² The frequency within the radiofrequency spectrum at which radiocommunications devices operate is often hardwired into the devices themselves, meaning that they cannot operate at different frequencies. Changing the allocated frequency would render these devices obsolete and would require that they no longer be used, so as to avoid potential interference problems. The cost of changing the allocated spectrum for some devices is likely to outweigh the benefits of harmonisation.

Box 7.4 Common compliance marking — the ‘C-tick’

In managing their respective radiofrequency spectrums, the Australian Communications and Media Authority (ACMA) and the Radio Spectrum Management Group of the New Zealand Ministry of Economic Development have implemented a scheme to ensure that radiocommunications products meet appropriate mandatory standards before such products are placed on both the Australian and New Zealand markets.

Suppliers of radiocommunications products to the Australian or New Zealand market, for which mandatory standards apply, must affix a label to their product indicating electromagnetic compatibility. The label comprises a ‘C-Tick’ logo and a unique supplier identification number, as shown below.

The compliance marking is intended to indicate that the product complies with the applicable standard and establishes a traceable link between a product and the supplier responsible for placing it on the Australian or New Zealand markets. ACMA (sub. DR75) noted that the C-tick is widely recognised and understood within the electrical and communications industry.

Example of ‘C-tick’ logo with unique supplier identification



Source: ACMA (2006, sub. DR75).

Electromagnetic compatibility (EMC)

A key outcome of the cooperation program has been the harmonisation of electromagnetic compatibility regulatory schemes, to the extent that ‘products which comply with specific regulatory requirements in one country can be supplied into the other country without additional regulatory intervention’ (ACMA and MED 2005, p. 3). The 2004-05 joint annual cooperation report noted that the special exemption for the labelling of radiocommunications devices was no longer required for this aspect of the cooperation program. As a result, requirements for the labelling of electromagnetic goods were removed from the special exemption.

Despite the fact that EMC labelling requirements are no longer subject to the special exemption, the cooperation program is important in ensuring ongoing harmonisation in this area. Both Australian and New Zealand regulators have agreed to continually review the EMC arrangements to ensure that regulations remain both harmonised and up to date with industry requirements. The close

cooperation between the regulators allows relevant standards to be updated in both countries simultaneously (ACMA and MED 2005).

However, ACMA (sub. DR75) expressed concern that removing the special exemption for EMC labelling had the unintended consequence of allowing EMC goods subject to labelling schemes of a third country to be sold within Australia, without allowing ACMA to first consider the appropriateness of these schemes. In particular, New Zealand has recognised the China Compulsory Certification (CCC) mark, as part of the New Zealand–China Free Trade Agreement. The combination of the NZ–China FTA and the TTMRA means that the CCC mark can effectively be used as a substitute for the C-tick label within Australia. This issue is considered further in chapter 10.

Differences in radiocommunications standards

The special exemption for radiocommunications devices covers a large range of different devices, which can be broadly grouped into 34 categories. Requirements applying to the majority of these categories have now been harmonised on the basis of a set of common standards and labelling requirements (New Zealand Government, sub. 53).

Historical differences in the allocation and use of the radio spectrum between Australia and New Zealand have precluded harmonisation of radiocommunications standards in seven categories of devices:

- digital electrical cordless telephones (DECT)
- personal handyphone services
- short-range devices
- digital modulation transmitters (spread spectrum devices)
- high frequency citizen band (HF CB)
- in-shore boating radio services
- cordless telephones using the medium and high frequency bands.

ACMA considered that there are good prospects for the harmonisation of standards for the HF CB, in-shore boating radio services and DECT. In relation to the other nonharmonised categories, it noted that:

[Personal Handyphone Services] and cordless telephones (other than DECT) are regarded by both Australia and New Zealand as technologies which are likely to become obsolete in the near term and not considered to be a valuable focus of harmonisation activity. (ACMA, sub. 13, p. 3)

There is little prospect for harmonisation in the broad areas of short-range and spread spectrum devices, and there was agreement that these exempted categories ‘potentially could be transferred to a permanent exemption in the longer term’ (New Zealand Government, sub. 53, p. 25). ACMA (sub. DR75) agreed, stating that historical differences in spectrum allocation meant that harmonisation is unlikely, and that 2013 would be an appropriate time to consider whether all prospects for harmonisation have been exhausted.

Future directions

The radiocommunications devices under the special exemption fall into three broad categories:

- Devices for which historical differences in the spectrum allocation mean future prospects for harmonisation are limited, such as short-range and spread spectrum devices. However, regulators are still developing options for resolving some of these differences, and permanently exempting these devices would be premature. Once opportunities for harmonisation of standards are exhausted, a permanent exemption should be sought for the remaining nonharmonised devices. This option should be considered in the next review of the TTMRA in 2013.
- Devices for which complete harmonisation is a possibility and the special exemption should be continued. This applies to HF CB, in-shore boating radio services and DECT devices.
- Devices subject to the special exemption and are likely to become obsolete in the near future. The special exemption for these devices should continue until obsolescence occurs, after which the special exemption should be removed.

RECOMMENDATION 7.4

Because of the different historical paths of Australian and New Zealand spectrum allocation and use, a permanent exemption should be considered for short-range and spread-spectrum devices, once opportunities for harmonisation of standards are exhausted. A special exemption should remain where there is a possibility of harmonisation of spectrum allocation, including for the high frequency citizen band, in-shore boating devices and digital electrical cordless telephones. Devices likely to become obsolete in the near future should also remain as a special exemption until the exemption is no longer needed.

7.6 Annual rollovers

The legislation underpinning the TTMRA requires special exemptions to be ‘rolled over’ every 12 months if they are to remain in force, and each rollover has to be approved by at least two-thirds of the Heads of Government.¹³ In addition, the governments have agreed that a rollover will only be granted after Heads of Government have received a report from the relevant regulators outlining progress made with the cooperation program and why a 12-month extension is needed (box 7.5).

The terms of reference for this study mention annual rollovers as an area where administrative provisions might be amended and/or enhanced to support more efficient operation of the TTMRA.

The Commission understands that the current rollover process can last up to eight months, starting around August each year with the drafting of cooperation reports for each of the special exemptions, and ending in April the following year with rollovers being implemented through regulation. Thus, there can be as little as four months between implementation of the current rollover and the start of procedures to obtain the next. The lengthy process can be attributed in large part to a requirement to consult all relevant regulators, government departments, ministers and Heads of Government before granting a rollover. Another factor is the legislative requirement that at least two-thirds of jurisdictions endorse any rollover. In practice, this has meant that a draft regulation to roll over the special exemptions is first circulated to Australian states and territories to endorse in their gazettes before that regulation can be implemented by the national governments of Australia and New Zealand.

In 2003, the Commission found that the annual rollover process had been cumbersome and resource intensive, and that there was agreement among government officials that it had not served a useful purpose (PC 2003). As a result, the Commission favoured extending the prevailing special exemptions for more than 12 months without requiring annual rollovers. This was subsequently rejected by the jurisdictions on the grounds that they would all have to amend their legislation and pass the amendments around the same time:

The [CJRF] ... considered this approach and found that extending cooperation

¹³ Under s. 48(2) of the *Trans-Tasman Mutual Recognition Act 1997* (Cwlth), the duration of a special exemption is limited to 12 months, but can be extended in whole or part by one or more further periods each not exceeding 12 months. Under ss. 48(4)-(5), such an extension is implemented as a regulation made by Australia’s Governor-General, and has to be endorsed by at least two-thirds of the jurisdictions. Equivalent requirements are prescribed in s. 82 of the *Trans-Tasman Mutual Recognition Act 1997* (NZ).

programs without the need for annual rollovers, would in fact create further administrative burden, as each jurisdiction would need to amend its legislation and ensure passage of the amendments through the respective legislatures around the same time. The [CJRF] concluded that because of the legislative difficulty involved, the current special exemption system of annual rollovers and progress reports should remain in place. (CJRF 2004, p. 34)

Box 7.5 Process required for annual rollovers

The legislation underpinning the TTMRA does not prescribe a process for how governments should consider whether a special exemption is rolled over for an additional 12 months. Such a process is, however, mentioned in the intergovernmental agreement that led to enactment of the TTMRA:

Regulatory authorities will, through the relevant [COAG] Ministerial Council(s), provide to heads of government an annual cooperation report outlining progress made and the program and timelines for further work. The reports will also nominate the sections of the relevant laws ... for which special exemption is no longer required. If a special exemption is to be maintained in order to undertake further work, the report will provide heads of government with supporting evidence for such a continuation. A cooperation report will be due three months before the first anniversary of the date of commencement of the [TTMRA] and subsequently at 12-month intervals until the cooperation program has been completed. (Trans-Tasman Mutual Recognition Arrangement, s. 9.3.1)

The official users' guide to the mutual recognition schemes provides additional detail on the process used to consider annual rollovers:

Three months before each 12-month special exemption period expires, the regulatory authorities responsible for pursuing the various cooperation programs must submit to heads of government a jointly-agreed annual cooperation report through the relevant ministerial council. The chair of the relevant Ministerial Council should write to the Prime Minister of Australia enclosing the cooperation report which will then be passed on to the heads of government of the other participating parties. The report should set out the progress that has been achieved over the previous year in progressing the cooperation program and, if relevant, provide a justification as to why a further 12-month extension to the special exemption period is needed. In addition, the report should:

- list any laws or parts of laws currently on the special exemption schedule which can be removed
- set out a timetable for the completion of the cooperation program.

On the basis of the progress achieved and the timetable for completion, heads of government decide whether a further 12-month special exemption period should be granted. Cooperation reports will need to be submitted annually until the cooperation program is completed. (COAG and New Zealand Government 2006, pp. 29–30)

However, the jurisdictions did agree that cooperation reports would only be required every three years for the radiocommunications special exemption (although rollovers still have to be approved annually):

Acknowledging the constraints facing the early resolution of the cooperation program

[for radiocommunications] and the desire to reduce the administrative burden of annual reporting, it is recommended that the special exemption be continued with annual rollovers, and that detailed reporting under the cooperation program be extended to a three-year cycle rather than the current one-year cycle. (CJRF 2004, p. 37)

It appears that this was possible because the legislation underpinning the TTMRA does not require the production of cooperation reports. As noted in box 7.5, governments agreed to have cooperation reports as part of the process for considering rollovers, but did not prescribe this in legislation.

The Commission acknowledges that governments have a legitimate concern about the cost of changing the maximum allowable time between special exemption rollovers. Legislative amendments would have to be coordinated in ten jurisdictions at the same time (Australian Commonwealth, Australia's six states and two territories, and New Zealand). This is because the Australian states implemented the TTMRA in a way that does not authorise the Commonwealth to make amendments to the TTMRA's design unless the changes have been enacted by state parliaments.¹⁴ Similarly, the territories made a request in their TTMRA legislation that the Commonwealth obtain their approval for any changes to the TTMRA's design. Sturgess (1993) noted that Australia implemented mutual recognition in this way because the states were concerned about the Commonwealth gaining the power to pass further legislation in the area and establish a bureaucracy to regulate the states.

Participants in this study indicated that the cost effectiveness of the annual rollover process remains doubtful, and that this problem is becoming more acute because the remaining special exemptions involve difficult issues that require more than 12 months to achieve notable progress. As a result, there was some support for extending the period between rollovers from one year to three years (Department of Education, Employment and Workplace Relations, sub. 57; New Zealand Government, sub. 53; Queensland Government, sub. 52).

While it may be costly to amend the TTMRA legislation, this could be mitigated by enacting changes to the special exemption provisions as part of a package of other

¹⁴ The TTMRA was implemented by the states referring their power to the Commonwealth in a relatively unusual way under s. 51(xxxvii) of Australia's Constitution. The Commonwealth was only authorised by the states to apply the *Trans-Tasman Mutual Recognition Act 1997* (Cwlth) as it existed at the time of referral. The Act does allow its schedules to be changed by regulation, but the purpose of the schedules is primarily to list which goods or laws are not subject to mutual recognition, rather than to specify the TTMRA's design. Furthermore, the Act requires changes to its schedules to be endorsed by all jurisdictions (or at least two-thirds in the case of rolling over a special exemption in whole or part), rather than just the Commonwealth (unless it is a special exemption that has expired).

reforms recommended throughout this report. The large fixed cost of coordinating legislative amendments in ten jurisdictions would then be spread across a broader range of issues, and so there is more likely to be a net benefit from changing the rollover requirements (NSW Government, sub. 55).

If governments are still unwilling to amend the legislative provisions for special exemption rollovers, they should at least consider reducing the frequency of cooperation reports, as has already occurred for radiocommunications. As noted above, cooperation reports are only prepared for radiocommunications every three years. However, this option is inferior to amending the legislation because it still involves making a regulation every 12 months to roll over the radiocommunications special exemption.

It is difficult to determine the most appropriate length of time between special exemption rollovers. A balance has to be struck between providing sufficient time for progress to occur, and not providing so much time that governments resolve the issues underpinning a special exemption at an unreasonably slow pace. In practice, the time required will vary between issues, so it is hard to prescribe a one-size-fits-all rule. However, administrative simplicity favours prescribing a uniform time limit in the legislation. This should not prevent governments from developing cooperation programs with deadlines for achieving milestones, and that aim to remove a special exemption before it would have to be rolled over. The Commission has concluded, given the difficult issues associated with the remaining special exemptions and the views of officials who handle special exemptions, that three years is an appropriate period to prescribe between rollovers.

The Commission's proposal was favourably received by participants at the roundtables for this study, and in submissions commenting on the draft report (for example, ACMA, sub. DR75; DEEWR, sub. DR90; DOHA, sub. DR64; New Zealand Ministry of Economic Development, sub. DR89). However, the New Zealand Ministry of Economic Development (sub. DR89, p. 6) suggested that 'some form of annual reporting should be retained to maintain discipline and drive progress'. This could simply be implemented at an administrative level, rather than through regulation, but it has the drawback that it would reduce the administrative benefits of the Commission's proposal. Furthermore, it does not appear that annual reporting under existing arrangements has done much to 'maintain discipline and drive progress'. The most recent cooperation reports for road vehicles and therapeutic goods do not convey the impression that annual reporting has facilitated significant progress on the relevant special exemption. Conversely, notable progress has been made on the radiocommunications special exemption, despite cooperation reports only being produced every three years in that case.

The TTMRA legislation should be amended so that special exemptions can have a maximum duration of three years, and can be extended for one or more further periods, each not exceeding three years. This reform should be reflected in the administrative procedures that governments use when considering special exemption rollovers, including that cooperation reports only need to be prepared every three years.