
5 Public health

Key points

- Chemical-related risks to public health are subject to numerous regulations — including for poisons and pesticide residues in food — on the grounds that:
 - human health protection is a ‘public good’ that is underprovided by the private sector.
 - ‘information failures’ prevent consumers from making fully informed decisions about chemical-related risks to their health.
- Existing regulations generally appear to be effective in achieving their public health goals, but some reforms are warranted to improve that effectiveness and to overcome inefficiencies.
- Distinct regulatory regimes have been established for various public health concerns. There is no case for their amalgamation, but coordination can be improved.
- Poisons scheduling requires different skills and approaches to that of drugs, and so should be undertaken by a separate body:
 - The Australian Health Ministers’ Conference should proceed with implementing the draft Australian Health Ministers’ Advisory Council reforms to poisons as soon as is feasible
 - Poisons regulatory controls and scheduling decisions should be uniformly adopted, as published in the Standard for the Uniform Scheduling of Medicines and Poisons, by all jurisdictions to remove inconsistencies and duplication.
- Risks associated with chemicals in articles would be managed more effectively and efficiently if, along with the agreed national system of regulation for consumer product safety, there was a formal system of coordination between the national agencies responsible for assessing chemicals and regulating product safety.
- All labelling requirements for cosmetics and toiletries should be administered by a single agency — the Australian Competition and Consumer Commission.
- To prevent the diversion of chemicals into illicit-drug manufacturing, every jurisdiction should adopt the same regulations (and associated risk-based schedule) since current inconsistencies raise costs and could undermine effectiveness.
- Maximum residue limits set by the Australian Pesticides and Veterinary Medicines Authority for domestically grown produce should be included in food standards automatically, to avoid unnecessary duplication and delays.

This chapter investigates the effectiveness and efficiency of regulations used to manage the chemical-related risks that products pose to domestic users and the general public. The areas of health regulation investigated are:

- poisons in formulated products (such as household cleaning chemicals and paints)
- chemicals in consumer articles (such as toys, appliances and furnishings)
- ingredient labelling of cosmetics and toiletries
- diversion of chemicals into illicit-drug manufacturing
- food safety.

All of these areas fall within the broad category of public health, but this is not a sufficient unifying force to lead to a single system of regulation. Rather, distinct regulatory regimes have been established for each area. To some extent, this can be attributed to the regulations having been grafted onto different generic regulatory regimes (detailed in following sections of this chapter).

Governments have recognised that it would be worthwhile to have some degree of coordination between the different areas of public health regulation. As a result, it is common for specific government agencies to play a supporting role across two or more of the abovementioned areas, with this often formalised in regulations or inter-agency agreements (details provided in following sections). However, the lead agency in each area tends to differ. Broadly speaking, primary responsibility for administering the different regimes is as follows:

- health departments — poisons
- consumer-protection agencies — chemicals in consumer articles, and ingredient labelling of cosmetics and toiletries
- law-enforcement bodies — diversion of chemicals into illicit-drug manufacturing
- food regulators — food safety.

The Commission has not found a case for amalgamating the different areas of public health regulation into a single regime. Implementation of the Commission's recommended Standing Committee on Chemicals (chapter 3), in addition to reforms advocated in this chapter, would facilitate an appropriate level of coordination. Opportunities are identified in this chapter to improve policy-oversight mechanisms, decision-making mechanisms and national coordination for poisons scheduling and regulation, consumer-product safety arrangements and illicit-drug precursor controls. Improvements can be achieved through changes in decision-making responsibilities and processes, and stakeholder-input mechanisms.

Finally, this chapter identifies various overlaps and inconsistencies which arise across each area of regulation in their administration and enforcement.

5.1 Poisons scheduling and regulation

The regulatory framework

The Commonwealth, state and territory governments regulate the importation, manufacture, sale and use of poisons. For products containing substances classified as poisons, the poisons have to be identified on the label, with appropriate health and safety warnings, and in many cases be sold in particular types of packaging (requiring child-proof lids for example). Some chemical products are also subject to particular storage requirements, or can be manufactured, sold and used only by licensed parties.

The aims of poisons regulation include the reduction of:

- unintentional poisoning, of which most identified cases are acute poisonings of children
- intentional poisoning, of which most cases are adult suicides or attempted suicides (Galbally 2001).

Underlying the controls is an assumption that without government intervention, firms would not have sufficient incentives to fully inform consumers of the risks of exposure to poisons contained in chemicals, and consumers would be unable to conduct their own assessments of risk without this information. Labels can provide useful information to consumers on the relevant risks, and how to manage that risk. They can also inform emergency personnel of the contents of chemical products, where poisonings have occurred. Packaging requirements act to limit exposure risks to children. Licensing requirements for some high-risk chemicals limit their use to professionals who are adequately trained to manage the risks.

National coordination for poisons scheduling and regulation is provided by the Australian Health Ministers' Conference (AHMC) through one of its subcommittees, the National Coordinating Committee on Therapeutic Goods (NCCTG). The NCCTG's terms of reference are to 'take action necessary to bring about coordination of legislative and administrative controls on therapeutic goods and poisons and to make recommendations to the Australian Health Ministers' Advisory Council [AHMAC, the committee of senior officials underneath the AHMC] as necessary' (TGA 2007c). The NCCTG is comprised of representatives from the Australian Government's Therapeutic Goods Administration (TGA) and

key health authority officials (mostly chief pharmacists). The committee is serviced by the TGA.

National scheduling and regulatory decisions are made by the National Drugs and Poisons Schedule Committee (NDPSC). The Therapeutic Goods Regulations 1990 set out the process the NDPSC must follow. This includes the process for regular scheduling and a provision for urgent scheduling decisions. The NDPSC categorises (or schedules) poisons (and drugs) according to their potential adverse effects on human health, and develops guidelines for their labelling, packaging and other regulatory requirements. In making its scheduling decisions, the NDPSC considers a number of factors, including the poison's purpose, potential for abuse, safety and the need for the substance (Galbally 2001).

Scheduling and rescheduling decisions are made in response to recommendations from the:

- National Industrial Chemical Notification and Assessment Scheme (NICNAS) (following their assessment of new or existing chemicals)
- Office of Chemical Safety (OCS) (often as part of the Australian Pesticides and Veterinary Medicines Authority's (APVMA) agricultural and veterinary (agvet) chemical product assessments)
- approaches from industry or the wider community
- other sources of evidence of a public health concern (TGA 2007b).

NDPSC scheduling decisions are published in the Standard Uniform Schedule for Drugs and Poisons (SUSDP) (also published as the 'Poisons Standard', with the most recent being the Poisons Standard 2007 (Cwlth)) (box 5.1). The Commission's terms of reference limit this study to substances in schedules 5, 6 and 7 (other schedules are essentially for pharmaceuticals).

Poisons scheduling and controls set at the national level have little legal authority in Commonwealth law, but play an important role in advising state and territory governments on how poisons should be scheduled and regulated within their jurisdictions. State and territory governments maintain full control over the manufacture, sale and use of poisons in their jurisdictions, and there is no obligation on them to adopt NDPSC recommendations. As will be discussed below, in practice this sometimes means that controls on scheduled substances differ between jurisdictions. However, jurisdictional reporting on departures from the Poisons Standard is now a standing NDPSC agenda item.

Box 5.1 The Standard for the Uniform Scheduling of Drugs and Poisons

The Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) (also published as the 'Poisons Standard', with the most recent being the Poisons Standard 2007 (Cwlth)) contains a regularly-updated list of toxic substances, including drugs/medicines, agricultural and veterinary chemicals, domestic chemicals and prohibited substances, grouped into a number of schedules. The schedules are:

- **Schedule 1** — [This schedule is intentionally left blank]
- **Schedule 2** — Pharmacy Medicine ...
- **Schedule 3** — Pharmacist Only Medicine ...
- **Schedule 4** — Prescription Only Medicine, or Prescription Animal Remedy ...
- **Schedule 5** — Caution — Substances with a low potential for causing harm, the extent of which can be reduced through the use of distinctive packaging with strong warnings and safety directions on the label.
- **Schedule 6** — Poison — Substances with a moderate potential for causing harm, the extent of which can be reduced through the use of distinctive packaging with strong warnings and safety directions on the label.
- **Schedule 7** — Dangerous Poison — Substances with a high potential for causing harm at low exposure and which require special precautions during manufacture, handling or use. These poisons should be available only to specialised or authorised users who have the skills necessary to handle them safely. Special regulations restricting their availability, possession, storage or use may apply.
- **Schedule 8** — Controlled Drug ...
- **Schedule 9** — Prohibited Substance ... (Poisons Standard 2007 (Cwlth), p. vii)

The appendixes to the SUSDP contain requirements for the packaging and labelling of drugs and poisons, which vary depending on the schedule of the substance. The SUSDP also has appendixes containing reduced labelling requirements for paints, tinters and related products that contain certain poisons and lists of chemicals for which greater regulatory controls in manufacture, storage, sale and use are suggested.

Effectiveness and efficiency

The scheduling and regulation of poisons are generally seen to be effective in dealing with the hazards and risks of toxic substances in non-industrial chemical products. The *National Competition Review of Drugs, Poisons and Controlled Substances Legislation* (Galbally 2001) concluded that most of the controls on poisons (and drugs) provided a net benefit to the community. It found that, although death and other adverse health effects continued to occur from exposure to poisons, the problems arising from poisons exposure would be much greater without the controls.

It is not possible to precisely quantify the incidence of poisonings from poisons that are within the scope of this study due to definitional issues with available data. Depending upon the source, some recorded poisonings may be due to exposure to smoke, animal and insect bites and stings, or other unspecified causes. Also, some adverse health effects from chemicals may be recorded under data for burns and corrosion injuries or other data categories. Furthermore, data on poisons-related causes of injury and death are likely to include exposure in workplace, domestic and other environments, thus incorporating adverse effects on humans of chemicals regulated by OHS or other requirements.

However, available data do suggest that death and injury rates from poisons within the scope of the scheduling and regulatory regime are relatively minor compared to those from drugs and other causes. In 2003-04, only 3 per cent of all community injury deaths were due to poisoning by 'other substances' compared to 8 per cent from drugs (Henley et al. 2007). Also, poisonings by non-pharmaceutical substances accounted for less than 1 per cent of total hospitalisations in 2003-04, compared to just over 2 per cent for pharmaceuticals (AIHW 2006).

Child-resistant packaging requirements, outlined in poisons scheduling requirements, have also been effective. The Australian Institute of Health and Welfare's National Injury Surveillance Unit argued that the introduction of child-resistant closures, in the late 1970s and early 1980s, has caused a significant decrease in deaths of young children from poisoning (Cripps and Steel 2006).

Participants in this study raised concerns about the institutional arrangements and decision-making process for poisons scheduling and regulation, inconsistencies in controls between jurisdictions and overlaps with other areas of regulation. Many of these issues were also raised by past reviews, including most recently Galbally (2001). Galbally concluded that, while most of the current controls on poisons (and drugs) provide a net benefit to the community, a number of reforms were needed to increase national uniformity, improve efficiency, reduce the level of control where possible, and improve the net benefit to the community as a whole.

Galbally (2001) made a number of recommendations, including for the:

- NDPSC to be broken into two separate committees — one for drugs (to be renamed medicines) and one for poisons
- NCCTG to develop template legislation that includes all provisions regulating the supply of medicines and poisons, which the states and territories would adopt by reference

-
- states and territories to automatically adopt all scheduling decisions in the SUSDP by reference and in accordance with timelines developed by the scheduling committees
 - APVMA to make decisions regarding the labelling and packaging, and recommend the appropriate scheduling of agvet chemicals as part of the product assessment process
 - removal of some jurisdictions' 'extra' regulatory requirements on poisons (over and above those in the SUSDP), such as a requirement for manufacturers and sellers of some poisons to be licensed.

The Commonwealth, state and territory governments released their response to Galbally (2001) in 2005, agreeing to most of the recommendations (AHMAC 2005). One important exception was that they agreed to aim for regulatory uniformity, not through the use of template legislation as recommended by Galbally, but by 'other means'.

AHMAC, through the NCCTG, is currently designing reforms to poisons scheduling and regulation in Australia. In the interests of ongoing consistency and cohesiveness, the NCCTG agreed to a single scheduling policy framework for both medicines and poisons. Key elements of the most recent proposal for changes to poisons scheduling and regulation would:

- split the scheduling committee into two (one for chemicals (poisons) and one for medicines (drugs)) and replace its current membership of representatives with nominated experts
- make the head of the Australian Government Department of Health and Ageing (DOHA) the final decision maker on poisons scheduling decisions, advised by the chemicals (poisons) scheduling committee, with the Department as secretariat
- have the states and territories adopt national scheduling decisions by reference (NCCTG 2007).

Under the AHMAC model there is no commitment to adopt regulatory controls by reference.

The NCCTG would continue to oversee regulatory policy relating to both drugs and poisons.

There are some differences between the agreed scheduling policy framework and that under current arrangements. While the guidelines for classification of substances are largely the same, the proposed framework reflects extensive work on developing scheduling criteria on a schedule by schedule basis. In addition, there

are some changes to the public consultation guidelines. It is expected that the consultation process for poisons would be broadly similar to that proposed for medicines. Under the proposed arrangements, public consultation on the scheduling of a new substance would not routinely occur, although all rescheduling proposals would be the subject of public consultation.

Under the AHMAC model, for chemicals (poisons) scheduling and rescheduling decisions, the Chemicals Scheduling Committee (CSC) would assess the evidence and send their scheduling recommendation to DOHA for a final decision. The CSC would be made up of appointed experts: one nominated expert member from each state and territory; one nominated expert member from each of OCS, NICNAS and APVMA; and OCS nominated members with professional expertise. The OCS nominated expert members would include professional expertise in areas such as toxicology, consumer and industry issues. Scheduling decisions made by DOHA would be communicated to stakeholders via an electronic register, the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), which would be administered by the TGA (NCCTG 2007).

While industry (for example, ACCORD Australasia, sub. 42; PACIA 2005; 2007b) supported Galbally's recommendations, it has expressed concern about the direction of, and processes followed, in reforms since that time. Industry concerns included that the states and territories had not made a commitment to uniformity in poisons scheduling and regulation, and proper regulation impact assessment and consultative processes had not been followed. Governments had only consulted on one reform option and no regulation impact statement (RIS) had been prepared to assess the impacts of the proposed reforms. Governments had also only started to consult late in the process after the drafting process for legislation had already begun.

The case for the reform of the administration of drugs and poisons regulation

Reviews dating as far back as 1954 have recommended that poisons and drugs be scheduled and regulated separately,¹ citing the efficiency gains in splitting up decision making responsibility between the two areas, differences in the risk profiles associated with each area and the different decision-making paradigms required (Galbally 2001; IC 1996b).

¹ The National Health and Medical Research Council first recommended that national standards for regulating drugs, poisons and foods be developed in 1954, with the intention that these areas be regulated separately (Galbally 2001). Subsequent moves to develop national standards created separate regulation for foods, but drugs and poisons continued to be regulated together.

Regulatory controls and scheduling decisions in the areas of drugs and poisons require different approaches, and having them under the same framework has the potential to lead to less effective and efficient outcomes than if they were regulated separately. As stated by ACCORD Australasia:

Scheduling decisions are based on different outcomes. Medicines scheduling decisions are made in regard to access and availability of scheduled medicines and the level of healthcare intervention while for domestic and agvet chemicals, scheduling decisions are about risk management and communication through packaging and labelling requirements. This represents two different approaches to scheduling decisions. The unified framework approach does not recognise this fundamental difference in decision making and therefore cannot be expected to represent good practice. (sub. 42, p. 23)

The membership of the current NDPSC includes individuals who have a background in either drugs *or* poisons, and consideration of therapeutic substances is seen to dominate (SA Government sub. DR110). Membership is based on representation from government (the Commonwealth, states and territories), industry and consumers. All members vote on scheduling decisions (though the vote is only passed if a majority of the committee is also a majority of jurisdictional representatives).² The NDPSC is large in membership, and where member experience and expertise is in either drugs or poisons, scheduling decisions are not always cost-effective in the use of member time and expertise. The NDPSC process has been criticised as slow and cumbersome due to the long consultation process, and the fact that it meets just three times a year means scheduling decisions are delayed (Galbally 2001). As discussed in chapter 3, best-practice arrangements for a standard-setting body are for decisions on technical standards such as scheduling decisions to be made by independent experts who are informed by public consultation processes and are required to act in the public interest. On matters of policy significance, decisions would be made ultimately by the relevant Ministerial Council.

The Commission considers that there is an overwhelming case for responsibility for the scheduling process of drugs to be separated from that of poisons. This would allow stronger focus on poisons assessments and encourage greater efficiency and more detailed consultation. The AHMAC model does not have all of the features the Commission considers appropriate, but it is an improvement over current arrangements. While the proposed CSC would retain representative membership, this would no longer be a concern given its advisory only nature.

The NCCTG should continue to have responsibility for the overall design of schedules and attached appendixes, and be overseen by the AHMAC. The CSC

² *Therapeutic Goods Act 1989*, part 6, division 3A, subdivision 4.

should make scheduling recommendations within the scheduling framework developed by the NCCTG.

The Commission considers this should be supported by a strong intergovernmental agreement (IGA) that sets out the institutional arrangements and regulatory processes. In order to ensure consistency, states and territories should adopt scheduling decisions by reference, as proposed by AHMAC. To achieve uniform regulatory outcomes nationally, jurisdictions would also need to implement consistent schedule-based poisons controls across Australia. The Commission considers the jurisdictions should adopt poisons regulatory controls by reference.

Any amendments to the overall design of the schedules, or attached appendixes, undertaken by the NCCTG in the Standard, should require the preparation of a COAG RIS where they are not minor or machinery in nature. As well, some scheduling advice by the CSC, particularly where schedule 7 substances are concerned, would meet the requirements for undertaking a RIS, and the CSC should be charged with the responsibility to determine whether a RIS should be undertaken.

Where decisions need to be made quickly in an emergency, the Secretary of DOHA should be empowered to make some decisions out of session, with limited or no consultation. Such a provision would require strict criteria to identify what constitutes an ‘emergency’ and the decision would need to be reviewed, following the normal advisory and consultation processes, as soon as practicable.

In negotiating the proposed reforms to medicines and chemicals scheduling, the NCCTG agreed to a single secretariat to support both the chemicals and medicines committees, as well as a single scheduling Standard. Coordination between the new scheduling committees would be provided by the single secretariat, and would enable appropriate handling of those substances classified as both drugs and chemicals. Where there are scheduling issues that potentially impact across the medicines and chemicals divide, meetings of the medicines and chemicals committees may be run over consecutive meeting days to facilitate consultation (NCCTG 2007).

The Commission considers that scheduling decisions could have been left to the CSC rather than with the Secretary of DOHA — however, this would only have been appropriate if the committee was not representational. On balance the Commission considers that the AHMAC model should be implemented at the earliest possible time, but that a post implementation review of its effectiveness and efficiency should be undertaken as soon as is practicable. Among other things this review should analyse any DOHA decisions that depart from recommendations by

the CSC, the reasons for these and the subsequent actions of individual jurisdictions in implementing the DOHA decisions.

Inconsistencies in the controls on poisons between jurisdictions

Inconsistencies exist in the regulations applying to poisons between jurisdictions, creating costs for firms operating across borders and, ultimately, consumers. While most jurisdictions adopt Part 4 of the SUSDP by reference, the remainder of the Poisons Standard is adopted inconsistently by the jurisdictions, if at all. The differences include retail storage requirements for schedule 5 and 6 poisons, controls on the sale and use of schedule 7 poisons, and inconsistent implementation of Appendix I of the SUSDP (the Uniform Paint Standard) (ACCORD Australasia, sub. 42; APMF, sub. 8; TGA 2007a). There are also inconsistencies between jurisdictions in the scope of their controls on schedule 7 poisons (which in some cases apply to both domestic and industrial use) (ACCORD Australasia, sub. 42). This last issue will be discussed later in this section.

One example is the inconsistency in retail storage controls on schedule 5 and 6 poisons between jurisdictions (ACCORD Australasia, sub. 42). Each jurisdiction takes a different approach in this area, with quite prescriptive requirements applying in New South Wales³ and South Australia,⁴ and either more general or no requirements applying in other jurisdictions (South Australia is currently implementing a number of initiatives including removal of licensing requirements for manufacturers and wholesalers of Schedule 5 and 6 substances (South Australian Government, sub. DR110)).

These differences may create unnecessary costs for chemicals manufacturers, distributors and retailers that operate across borders:

For example the retail storage requirements for Schedule 5 poisons differ across all jurisdictions, yet this controls the way a large number of consumer products are managed in Australia. The lack of consistency has recently encouraged retailers to attempt to impose their own conditions across Australia which is potentially more onerous than that arising out of some of the legislation. (ACCORD Australasia, sub. 42, p. 24)

Some national retailers with some degree of market power seek to simplify their supply chain management by requiring their suppliers to always meet the most stringent regulatory requirements among all jurisdictions. These costs are likely to be passed on to consumers. A more efficient outcome would be achieved if controls

³ Poisons and Therapeutic Goods Regulation 2002 (NSW), part 2, Division 2, clause 12.

⁴ Controlled Substances (Poisons) Regulations 1996 (SA), section 25.

were uniform in all jurisdictions, and set at a level commensurate with the relevant risks. One option would be to set performance-based standards that these chemicals be kept out of the reach of children, allowing firms to find the most cost-effective way in which these requirements could be met.

The Commission is of the view that the nature of the risks from poisons warrants a nationally-uniform approach. The risks of adverse health effects from exposure to poisons in the domestic, public space, or agricultural environment are unlikely to vary according to jurisdiction. Variations from the agreed national standards in this area are likely to impede interstate trade and increase costs to business and consumers, with little offsetting benefit in public health outcomes.

The Commission notes that, at COAG's meeting of 3 July 2008, there was agreement to implement the national harmonisation of poisons scheduling regulation and mutual recognition of decisions, as well as uniform implementation of scheduling of poisons by states and territories. COAG directed the Ministerial Taskforce on Chemicals and Plastics to present recommendations to the October 2008 meeting for endorsement by the December 2008 COAG meeting.

The Commission is of the view that notwithstanding the mutual recognition of decisions as agreed to by COAG, state and territory governments should continue to report any variations to nationally-agreed poisons scheduling or regulatory decisions to the Australian Health Ministers' Conference and include a statement of reasons for the variations.

RECOMMENDATION 5.1

The Australian Health Ministers' Conference should:

- ***proceed as soon as feasible with implementing its proposed reforms to separate poisons and medicines scheduling processes, including that poisons scheduling decisions be made by the Secretary of the Department of Health and Ageing, upon advice from a Chemicals Scheduling Committee***
- ***undertake a review of the Australian Health Ministers' Advisory Council model for poisons two years after commencement, including:***
 - ***an analysis of the consistency between the recommendations of the Chemicals Scheduling Committee and the decisions of the Secretary of the Department of Health and Ageing***
 - ***an analysis of the impact of the model on national uniformity of poisons regulations.***

State and territory governments should:

- *adopt poisons scheduling decisions made by the Department of Health and Ageing directly by reference, as published in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)*
- *uniformly adopt regulatory controls for poisons through either a template or model approach, as published in the SUSMP*
- *continue to report any variations to nationally-agreed poisons scheduling or regulatory decisions at the state and territory level to the Australian Health Ministers' Conference, and include a statement of reasons for the variations.*

Overlaps between poisons controls and workplace substances regulation

ACCORD Australasia (sub. 42) noted two examples where controls on Schedule 7 poisons were inadvertently applied to industrial users in some jurisdictions, despite the relevant hazards being adequately addressed by OHS regulations. One example was the scheduling of HF (Hydrofluoric Acid), and while the intention was to ensure that products containing a concentration of more than 1.0% HF were not available for domestic use, in general it had the unintended consequence of requiring bona-fide industrial users (e.g. welders) to seek certain authorities/licenses. Another example related to Methylcyclopentadienyl Manganese Tricarbonyl (MMT), where the same in-principle issues arose.

This overlap between domestic poisons controls and those on workplace substances could impose unnecessary costs on firms that have to meet additional requirements, with little benefit to public health (or occupational health and safety) outcomes. It also imposes unnecessary costs on governments administering poisons controls that apply to both industrial and domestic uses. The intent of poisons controls is to protect public health by managing the risks from chemicals in domestic use. Occupational health risks are best dealt with through the existing regulatory framework for occupational health and safety.

ACCORD Australasia (sub. 42) was concerned that despite governments having recognised this as an issue, more regulatory reform was needed to better delineate between controls on domestic poisons and workplace substances. It noted that New South Wales has dealt with this by amending its poisons regulations to exclude schedule 7 substances with an industrial purpose. However, industrial users of schedule 7 poisons in Western Australia and the Northern Territory still need to obtain approval from their jurisdiction's health department.

However, concerns were raised that exempting authorised users of poisons in the industrial environment from poisons controls could result in a regulatory gap such as in relation to atypical workplaces (SA Government, sub. DR110). For example, in WA poisons regulations pick up a gap left by workplace regulations that do not cover small workplaces. In most cases, poisons controls are not needed in the industrial environment as workplace regulations are adequate. However, there are some particularly hazardous substances, such as cyanides, where it would be appropriate to limit access to those poisons. Workplace hazardous substances regulations do not provide such controls.

RECOMMENDATION 5.3

Where a poison is adequately covered under workplace substances regulations and there is demonstrated compliance with those regulations, state and territory governments should exempt those users from poisons controls.

5.2 Controls on chemicals in consumer articles

The regulatory framework

Some chemicals contained in consumer articles (such as toys, electronic appliances, furniture or carpets) may pose health and safety risks to certain consumers if they are released from articles after purchase. These risks are sometimes immediately obvious and can be easily traced back to the use of, or close proximity to, the article. However, other risks may take a longer time to become apparent, or may arise from cumulative exposure.

Although firms face a number of incentives to supply safe articles — including market incentives, the threat of adverse media publicity, legal liability and ethical considerations — the effectiveness of these mechanisms may be reduced where:

- suppliers know more than consumers about the hazards of a product, and find it in their interest to withhold some of that information for commercial advantage
- suppliers do not have a strong or long-term commitment to particular product types and markets, and so have less need to maintain the long-term patronage of customers
- both suppliers and consumers do not have full knowledge of the hazardous characteristics of the products because the hazardous characteristics of the chemicals contained in them have not been assessed.

These issues are exacerbated where there is a lag between the initial exposure to chemicals released from articles and their effects on health and safety, or where their effects are cumulative. In these cases, causation between exposure and adverse health effects cannot easily be proven, and it may be difficult to implement appropriate market or legal remedies.

Governments may intervene to address the abovementioned concerns through public research on the health, safety and environmental hazards and risks of chemicals, and controls on how chemicals are used in articles.

NICNAS

NICNAS has the authority to assess chemicals released from articles and make recommendations to the relevant regulators:

NICNAS's assessment role in chemicals contained in articles is dependent on the method of their introduction into Australia. Articles themselves are excluded from the operation of the [Industrial Chemicals (Notification and Assessment)] Act [1989], however, chemicals released from articles can be subject to NICNAS assessment. In addition, if an article is manufactured in Australia NICNAS requirements would apply to the chemicals used in its manufacture. (NICNAS, sub. 36, p. 4)

NICNAS is informed of emerging concerns about chemicals released from articles through:

- chemical assessments and research conducted internationally (such as the European Union's work on phthalates)
- collaborative chemical assessments and research with international bodies
- approaches from other government agencies within Australia.

NICNAS also publishes information sheets for public consumption summarising its findings on the known risks and appropriate risk management methods for chemicals in consumer articles (such as for formaldehyde in blankets, furniture and mobile homes) (NICNAS 2008).

ACCC

The generic consumer product safety regulatory system allows governments to issue product warning notices, impose product bans, mandate safety and information standards and order compulsory product recalls. Product liability provisions also provide some protection to consumers from unsafe consumer products. Controls and

bans on products set by the Commonwealth are supported through customs controls.⁵

The generic consumer product safety regulatory system is overseen by the Ministerial Council on Consumer Affairs (MCCA) and administered by the ACCC under the *Trade Practices Act 1974* (TPA), and by state and territory government consumer protection agencies under each of their respective Acts.

The MCCA — which consists of Commonwealth, state, territory and New Zealand Government ministers responsible for fair trading, consumer protection and credit laws — facilitates the development of new national standards or bans. A sub-committee, the Consumer Products Advisory Committee (which also includes a representative from Standards Australia), provides advice to the MCCA on consumer safety policy matters and conducts reviews of Australian product safety standards, bans and recalls.

The Commonwealth TPA and the relevant state and territory Acts operate concurrently to regulate consumer product safety in different business sectors. The TPA applies to all corporations, interstate traders, and traders that sell goods through the post or electronic means (including e-commerce). All other suppliers of goods are regulated under the relevant Acts of the jurisdiction in which they operate.

The various governments' generic consumer product safety regulations contain only a limited number of narrowly-focused controls or bans on articles emitting hazardous chemicals. Some jurisdictions control or ban a greater number and variety of products than others.

The ACCC and its state and territory counterparts conduct regular surveys of consumer products for compliance with mandatory standards. However, most consumer protection agencies do not conduct their own product testing to check compliance with chemicals-related standards. Rather, they will either call on the appropriate firm(s) to undertake the testing of their products, or will arrange for another government or private body to undertake such testing on an as-needs basis. For example, the ACCC (2007) commissioned two recognised Australian testing authorities to test for formaldehyde in clothing and consulted with NICNAS about the issue.

⁵ Customs (Prohibited Imports) Regulations 1956, under the *Customs Act 1901*.

Poisons

Some controls affecting the use of chemicals in articles are also contained in the poisons scheduling and regulatory requirements, mainly in the area of paints and other surface coatings (section 5.1). Appendix I of the SUSDP contains a number of controls on how certain paints may be used, controlling their use on furniture and toys (as well as roofs, water tanks, fences and other places in the domestic environment). As discussed earlier (section 5.1), not all jurisdictions have implemented Appendix I, and so its effect on firms and consumers is likely to be limited.

Voluntary standards

Many product standards set limits on the substances that may be contained in or emitted from articles. Not all of these are mandatory, and many voluntary standards are administered by Standards Australia and incorporated into industry self-regulatory schemes.

Effectiveness and efficiency

Given the number and variety of consumer articles available on the market, and the lack of publicly available information on their chemical composition, it is difficult to determine the size of the overall health risks posed to consumers from chemicals in articles. Where studies have been conducted, they are often based on limited survey samples or anecdotal evidence, and while chemical compositions may be identified, the likely risks to human health from these chemicals may not.⁶

Nevertheless, there is some scope to improve the effectiveness and efficiency of regulations affecting chemicals in consumer articles, given the current lack of systematic hazard and risk assessment, and limited coordination by key regulators in this field.

The absence of a single national system of generic consumer product safety regulation is also likely to be hindering the effective and efficient management of chemicals in articles. In 2006, the Commission reviewed Australia's generic consumer product safety system and found that — in combination with other mechanisms including market forces, the product liability regime, media scrutiny

⁶ This is highlighted in research by the World Health Organisation's Intergovernmental Forum on Chemical Safety (2006) into the health risks posed to children by chemicals in toys. It highlighted that information about a toy's chemical composition, toxicological profile, and risks to human health from the chemicals contained within are often lacking.

and consumer advocacy — it was effective in maintaining a reasonable level of product safety (PC 2006b). However, the Commission also concluded there was scope for more efficient, effective and responsive regulation by establishing a single national consumer product safety law administered by the ACCC (along with other reforms).

The need for national uniformity

In its recent Review of Australia's Consumer Policy Framework, the Commission recommended a new national generic consumer law, including consumer product safety provisions. A nationally coherent consumer policy framework should be facilitated through making the Australian Government (through the ACCC) responsible for enforcing the new law nationally (PC 2008).

The Commission argued that its proposals would result in 'more effective, efficient, consistent and responsive policy and regulation, leading to better outcomes for consumers and greater certainty and lower costs for business' (PC 2008, p. 58).

The Commission further recommended that if the COAG determines that the jurisdictions should retain the power to issue interim product safety bans, these should lapse after 30 days if not extended nationally (PC 2008, Recommendation 4.3). These latter recommendations built on proposals in an earlier study looking at the issue of consumer product safety (PC 2006b).

In responding to the Commission's Report, COAG and the MCCA have endorsed the introduction of a new single national generic consumer law, and have also agreed to a set of arrangements for product safety. These include:

- The Commonwealth will assume responsibility for the making of permanent product bans and standards under the Trade Practices Act 1974 ... The States and Territories will retain their power to issue interim product bans. Interim bans will apply for 60 days. Interim bans can be extended for 30 days and then for a further 30 days in exceptional circumstances at the discretion of the Commonwealth Minister.
- The Australian Competition and Consumer Commission and the State and Territory offices of fair trading will share responsibility for enforcement of the product safety law.
- Any jurisdiction may refer a proposal for a permanent ban or standard to the ACCC and there will be requirements for the ACCC to communicate its assessment to the Commonwealth Minister and to MCCA.

It is anticipated that the revised regulatory arrangements will be fully implemented by mid 2010 and will be subject to review by MCCA two years after commencement.

Procedures will be put in place for States and Territories to have input into the policy development process as part of a comprehensive intergovernmental agreement. (MCCA 2008)

Regulatory coverage of imported articles

Some participants in this study argued that it is often unclear who has responsibility for dealing with imported articles containing hazardous chemicals, and that controls are often developed and implemented in an ad hoc, uncoordinated manner:

Identifying and managing risks from articles containing industrial chemicals is a major system gap. NICNAS is responsible for chemicals only. Responsibilities for ensuring imported articles (such as blankets) are safe are incomplete, under-resourced, scattered across agencies and portfolios and have generally been applied reactively. When combined with the lack of labelling/information requirements in Australia this results in a significant gap in our ability to ensure that consumers, the general public and the environment are safe. (Environment Protection and Heritage Standing Committee, sub. 20, p. 26)

Exposure to many lead-containing pre-painted objects imported from overseas is also inadequately regulated ... This gap in regulation raises concerns about the potential health risks resulting from imported goods and adverse effects on the competitiveness of Australian paint manufacturers and product manufacturers who would comply with future phasing out of lead-containing paints while imported goods are unregulated. (SA Government, sub. 56, pp. 12–13)

The perceived gap in the regulation of imported articles that release chemicals is not due to a lack of regulatory options. Existing frameworks appear to be underused and inconsistent, due perhaps to the lack of systematic hazard and risk assessment, and regulatory fragmentation. Of all of the product safety standards applied to consumer goods, only a small proportion relate to the issue of chemicals in articles, and even where they are used they usually apply to only a small number of narrowly-defined articles (such as specific brands and models of toys).

Both NICNAS and the ACCC have jurisdiction over chemicals released from imported products. Regardless of the origin of their manufacture, NICNAS can assess chemicals released from articles, and the ACCC can impose product standards. Recent examples relating to imported articles containing toxic chemicals include the recall and testing of formaldehyde in blankets, lead paint used on toys, and the Bindeez Beads toy.

However, it is not possible to eliminate all health and safety risks arising from articles. As Graeme Samuel, Chairman of the ACCC, wrote in a response to the Commission's consumer product safety review:

... improving protection against dangerous goods is not a simple case of beefing up regulations or calling for more tests by authorities ... It is not possible to predict or test for every potential safety issue with every imported product, but it is possible to respond quickly when a problem emerges, as the regulator did in relation to lead levels in toys. (Samuel 2007, p. 10)

European Union regulations

The Department of Environment and Water Resources (sub. 18) noted that the European Union's new regulatory regime for industrial chemicals (REACH) includes provisions for the mandatory assessment (and possible regulation) of chemicals in or released from consumer articles. These provisions are subject to threshold criteria:

REACH requires all substances that are intended to be released from articles during normal and reasonably foreseeable conditions of use to be registered according to the normal rules, including tonnage deadlines and information requirements, if those substances are present in the articles above 1 tonne per year.

In addition, all substances of very high concern (on a list of candidate substances for authorisation that will be published on the Agency-website) present in articles above a concentration limit of 0.1% weight by weight and present above 1 tonne per year must be notified to the Agency except where exposure to humans and environment can be excluded during normal conditions of use including disposal. In such cases safety instructions should be provided. Information will also be made available to consumers on request.

As a safety net, the Agency can require the registration of a substance in an article at any time when it considers that its release poses a risk to human health or the environment. (EC 2006, pp. 9–10)

Introducing similar requirements could impose significant costs on industry and the community more generally, and be difficult to implement. Thus, the Commission suggests that the European Union's experience in implementing these new requirements, including its net impacts on the European community, should be monitored before a similar approach is considered for Australia.

Information provision to business and consumers

ACCORD Australasia (sub. 42) suggested that concerns about the lack of regulatory coverage of chemicals in consumer articles were the result of a lack of information, both in the public arena and in the government sphere, about how the current generic consumer product safety system works, and a lack of communication and coordination within and between governments.

The Commission, in its 2006 review of the generic consumer product safety system, also found that there was scope for improving the provision of information about the consumer product safety regulatory regime (PC 2006b). It recommended the creation of:

... an internet-based 'one-stop shop', administered by the ACCC, to provide information about all state, territory and Australian government product safety laws and regulations, including a link to the Recalls Australia website ... (PC 2006b, p. xxxvii)

It would also include information about consumer product safety — targeted at consumers — and possibly a national consumer complaints mechanism (PC 2006b). This would address current difficulties for firms and consumers in understanding the regulatory regime and obtaining other relevant related information that arises from the current wide dispersion of information across multiple government agencies.

The need for more systematic hazard and risk assessment

The Commission's review of consumer product safety found that a more systematic approach was needed to identify the relevant hazards and risks from consumer products and determine the appropriate regulatory controls (PC 2006b). Little research had been done on the incidence, nature and severity of various consumer-product-related accidents in the community, and so it was difficult to determine the best places to target government action.

The Commission called for a national clearing house to be developed through which information, data sources and analysis of consumer product safety incidents and issues would be collated in one location, and disseminated to all jurisdictions (PC 2006b). This system would include:

- hospital emergency and admissions data
- linked consumer complaints information ...
- recalls and other information provided by business ...
- international product warnings and research
- mortality and epidemiological research. (PC 2006b, p. 208)

It was envisaged that this system would be coordinated by the ACCC, possibly through the Auzshare information sharing database, which is currently used to share information between jurisdictions on consumer complaints and scams (PC 2006b).

The Commission's proposed national clearinghouse system could be designed to incorporate information about the hazards and risks due to the chemicals contained in and released from articles.

The Commission notes that the MCCA is now developing the broadly-based hazard identification system, based on a clearinghouse approach, in line with the recommendations of the Commission's 2006 report. Following the COAG July 2008 endorsement of a harmonised national model for product safety it has been confirmed that the clearinghouse function will reside within the ACCC. Where health and safety issues are identified relating to chemicals released from consumer articles, they will be investigated and referred where appropriate⁷.

Improved assessment may also arise from accelerating NICNAS's existing chemicals review process (recommended in chapter 4). If significant health or safety issues are identified in the chemical review process, NICNAS can recommend regulatory action to the ACCC, such as legislating a product standard. NICNAS and the ACCC have cooperated on a number of recent issues.

There is scope to strengthen cooperation between NICNAS and the ACCC on chemicals-in-articles issues through more formal institutional links. This could be facilitated through the negotiation of a memorandum of understanding between the two agencies spelling out matters such as the:

- overall goals of cooperation
- roles and responsibilities of each agency
- design and operation of a systematic research program to better identify and deal with the risks of chemicals in articles
- processes for communication between agencies.

Any new regulatory action arising out of these arrangements should be developed according to best-practice principles. Identification of the problem, and the range of options available (including self-regulation and no action) should be considered.

If regulatory action were found to be required, consideration should be given to the use of hazard-specific standards, rather than standards that are confined in scope to a particular product (PC 2006b). Hazard-specific standards can be more widely applied than product-specific standards, and are therefore likely to be more cost effective than developing individual standards for every product for which a hazard is identified.

⁷ A number of submissions to the draft report argued that any hazard identification system for chemicals in consumer products should also include environmental hazards. This is addressed in chapter 9.

The ACCC and NICNAS should negotiate formal arrangements for cooperation on issues regarding chemicals in consumer articles. These arrangements should include the establishment of a more systematic research program to identify and deal with the risks of chemicals in consumer articles.

5.3 Labelling requirements for consumer products

The regulatory framework

Cosmetics and toiletries ingredient and product-claim labelling requirements are set by the ACCC and NICNAS respectively. Cosmetic and toiletry products may also need to meet state and territory labelling requirements for poisons, dangerous goods, and trade measurement. The ACCC and NICNAS regulations mandate that the full list of ingredients be shown on cosmetic and toiletry product labelling, that certain product claims only be made under specified conditions, and impose some product packaging requirements.

Some of this information may be provided through market mechanisms. Firms often label their products to promote features that consumers value. For example, some cosmetics and toiletries highlight the absence of added fragrances or other substances known to cause allergic reactions. However, without government intervention, it is likely that many firms would be unwilling to provide a full list of ingredients. This would make it difficult for consumers and medical professionals to determine which ingredients may be causing health problems when they occur.

ACCC

Mandatory information standard regulations are made under the Trade Practices Act 1974. The Information Standard administered by the ACCC — specified in the Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991 (Cwlth) — requires all cosmetics and toiletries ingredients (except incidental ingredients) to be specified on the label or associated information material. Where possible, ingredients have to be listed in descending order by volume or mass. The Information Standard is intended to inform consumers who may suffer allergic reactions from exposure to certain ingredients, or who wish to identify certain ingredients in products for their beneficial properties. Most of the

states and territories do not directly reference, or duplicate, the ACCC's Information Standard.⁸

The ACCC is responsible for enforcing the Information Standard. The ACCC conducts regular compliance checking surveys on cosmetics and toiletries to see if they meet labelling requirements. This generally involves visual checks of product packaging and displays in store to determine whether ingredient lists are displayed in the appropriate format.

The ACCC employs monitoring and enforcement resources to undertake this function.

NICNAS

The Cosmetics Standard 2007, under subsection 81(1) of the *Industrial Chemicals (Notification and Assessment) Act (ICNA) 1989*, administered by NICNAS, regulates the product claims made on labels of cosmetics and toiletries, and sets a limited number of other requirements, such as in relation to packaging, to support this. For example, skin care products with a sun protection factor (SPF) of greater than 4 and less than 15 must meet the Australian standard for the evaluation of secondary skin care products (AS/NZS 2604:1998) and not (among other requirements):

- be presented as having an SPF greater than 15 and/or being water-resistant
- have a pack size larger than 300ml or 300g
- make a therapeutic claim, including any representation about skin cancer (Cosmetics Standard 2007 (Cwlth)).

Policy direction for the Cosmetics Standard is provided by DOHA, through the Office of Chemical Safety.

The Cosmetics Standard contains controls on only a limited number of product types. NICNAS checks compliance with the Cosmetics Standard as part of its program of systematic compliance audits, and may conduct investigations in the case of potential breaches or accidents (NICNAS, pers. comm., 29 February 2008). As part of these activities, it may require firms to provide them with product test data to verify claims made on labels and packaging.

⁸ The exceptions are Queensland and South Australia, which directly reference the Information Standard. South Australia nominates its Minister rather than the Commonwealth Minister as the appropriate person for firms to apply to for confidentiality exemptions (and the appeals process related to this exemption) (Trade Standards Regulations 2000 (SA)).

NICNAS employs technical, monitoring and enforcement resources to undertake this function.

Effectiveness and efficiency

There is some evidence that the cosmetics and toiletries labelling requirements are meeting the objectives of informing consumers. As part of a 1998 RIS on changes to the Information Standard, the Australasian College of Dermatologists advised:

... that the regulations have greatly facilitated their ability to identify potential allergens without delay, and, once this has been done, consumers have been able to avoid products containing allergens, resulting in health care and pharmaceutical savings. (ACCC 1998)

ACCC annual reports also suggest that firms are generally compliant with the controls — in the three years to 2006, only a limited number of firms required administrative action or court-enforceable undertakings for non-compliance (ACCC 2004, 2005, 2006).

There are, however, opportunities to improve the efficiency of cosmetics and toiletry labelling requirements, as discussed below.

Transferring responsibility for the Cosmetics Standard from NICNAS to the ACCC

As part of the reforms to NICNAS's arrangements proposed in chapter 4 of this report, most of NICNAS's (limited) risk management responsibilities would be moved out of the agency to allow it to focus on its chemicals assessment responsibilities. As part of this process, consideration should be given to transferring the Cosmetics Standard 2007 to another government agency.

As discussed earlier, the Cosmetics Standard regulates the claims that can be made on labels for specific classes of cosmetic and toiletry products (and also sets some packaging requirements). These requirements are to assist in providing accurate information to consumers about the nature of the products concerned. Most cosmetic products were, until recently, the regulatory concern of the TGA, but a 2005 review of cosmetics regulation determined that NICNAS should have more responsibility in this area (box 5.2).

In maintaining and enforcing the Cosmetic Standard, NICNAS's role includes a technical, scientific function as well as a compliance and awareness raising function. The technical role includes, for example, determining the particular conditions and testing requirements when adding new products to the Standard. Technical expertise is also required when reviewing existing entries, for example if

new information becomes available, to ensure that the condition(s) listed in the Standard are appropriate. When undertaking enforcement activities, the skills required are mainly compliance skills. The main compliance functions include conducting audits, responding to reports of non-compliance, and conducting awareness raising programs. Compliance auditing may, in some limited circumstances, require technical skills to examine and interpret study reports to determine whether products meet required test methodology.

The Commission is concerned with the overlap and confusion that results from having more than one regulator involved in cosmetics regulations and, as noted, it is recommending NICNAS be reconstituted to focus solely on scientific assessment of the hazards and risks of industrial chemicals.

One option would be to transfer the Cosmetics Standard to the Office of Chemical Safety (OCS) in DOHA. The OCS may be suitable, because it already has portfolio responsibility for public health issues, and it has the experience and resources to design and maintain the Standard. The difficulty with this option is that there is no relevant Act or authority under its administration to which this Cosmetics Standard could be attached, and the OCS lacks the appropriate compliance monitoring and enforcement powers and mechanisms needed for the Standard.

It could also be transferred to the TGA, though this is unlikely to be a good fit due to the TGA's focus on therapeutic goods, which are distinctly different from cosmetic products, and the Cosmetic Standard focus on product claims. Besides, it has only recently been excised from the TGA for sound reasons.

The Commission considers the most effective and efficient option is to transfer the standard to the ACCC to administer. It contains the relevant compliance monitoring and enforcement powers and mechanisms. As well, it already regulates similar issues through its consumer information standards and other regulations on product claims. It does not, however, have the relevant technical expertise to be able to test products for compliance purposes.

Box 5.2 Reforms to cosmetics regulation

As part of the Chemicals and Plastics Action Agenda 2002, the Australian Government agreed to consider and develop options for the regulation of low regulatory concern chemicals (LRCC), including cosmetics (NICNAS and TGA 2005). Products that lie at the interface between cosmetic and therapeutic goods were identified as products for which there was potential to reduce regulatory requirements while maintaining public health outcomes. Products were generally identified as a cosmetic only if they did not meet the criteria for a therapeutic good, as set by the Therapeutic Goods Act.

In 2005, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) completed a review of cosmetics regulation in Australia under its wider LRCC reform program (NICNAS and TGA 2005). In its review, NICNAS found that the Australian cosmetics industry was concerned that:

- cosmetics classified as therapeutic goods in Australia were subject to more onerous data and assessment requirements than compatible cosmetics in other countries
- a paucity of assessed cosmetic ingredients in Australia compared to overseas, and slow assessment processes, was delaying or preventing the introduction into Australia of cosmetics already in use overseas.

In response to these concerns, NICNAS and the TGA developed new criteria for the definition of cosmetic products, based on that used in the Trade Practices (Consumer Product Information Standards) (Cosmetic) Regulations 1991. Under new requirements, manufacturers and importers of substances for use in products meeting the criteria of cosmetics will require registration with NICNAS, and new cosmetic substances will require NICNAS assessment and listing on the Australian Inventory of Chemical Substances. Cosmetic products will also be regulated by NICNAS (under the Cosmetics Standard 2007).

This could be overcome through cooperative arrangements with another government agency or contractual arrangements with an independent private laboratory. The ACCC's cooperation with NICNAS on testing for chemicals in consumer articles provides a precedent for such cooperative arrangements.

Following the release of the Commission's draft report, the ACCC objected to the Cosmetics Standard being transferred to it on the grounds that inefficiencies could arise as a result of, among other reasons, the division of chemical expertise between agencies (the ACCC does not currently have the chemical or scientific expertise of NICNAS). However, the Commission considers that there remain significant synergies with respect to monitoring and enforcement (compliance) resources and activities. For example, the ACCC conducts random surveys of retail outlets to check compliance with consumer product safety and information standards. When checking whether a cosmetic is compliant with the list of ingredients required under

the Information Standard it could also check to see if the product claims on that same cosmetic comply with the Cosmetics Standard.

RECOMMENDATION 5.5

The Australian Government should transfer responsibility for the administration and enforcement of the Cosmetics Standard 2007 (Cwlth) from NICNAS to the ACCC.

Recognition of foreign labels

The Commission believes that the Information Standard should be consistent with our major trading partners where a convincing counterargument does not exist. Having the same labelling requirements decreases costs of imports and exports. As a rule closer alignment with international standards is generally supported provided that the benefits exceed the costs (chapter 2 and appendix G).

ACCORD Australasia (sub. 42) proposed that a ‘deemed-to-comply’ provision be added to the Information Standard to allow fully-imported cosmetic products to be sold in Australia without the need for overlabelling, if the label satisfies the requirements of the European Union, the United States, Canada or New Zealand.⁹ It argued that:

... while there is general consistency regarding cosmetic ingredient labelling, there can be minor differences which requires a product imported into Australia to be overlabeled with no identifiable benefit regarding health and safety or improved consumer information outcomes. (ACCORD Australasia, sub 42, p. 11)

Overlabelling of cosmetics can result from inconsistencies with trading partners in a number of legislative areas, including trade measurement regulations as well as the Information Standard. Potential areas for revising the Information Standard include acceptable use of terms (such as ‘eau’) and additional ingredient listings (active ingredients). Industry estimates the cost to overlabel a product because of a unique Australian requirement is approximately \$0.50 per unit (ACCORD, pers. comm., Melbourne, 7 July 2008). No data are available on overlabelling costs specifically associated with the Information Standard.

In New Zealand, after June 2008, suppliers will have the choice to adopt the labelling requirements of the EU, US, Australia, or label hazardous substances over a certain threshold only (ACCC 2008).

⁹ ACCORD Australasia noted that New Zealand has already implemented such an exemption for cosmetics satisfying the labelling requirements of Australia, the European Union, or the United States.

Deemed-to-comply provisions in Australia would allow firms to avoid the overlabelling of imported cosmetic products due to minor differences in requirements between Australia and regimes with comparable policy outcomes. Such a provision would reduce costs to firms, and ultimately consumers. Many of Australia's trading partners have cosmetics labelling requirements that are broadly similar to those applied in Australia. The European,¹⁰ United States,¹¹ and Canadian¹² requirements, for example, all require the ingredients of cosmetics to be labelled in descending order in terms of volume, and contain other similar provisions such as the use of terms for flavours and fragrances. This provision, however, would only address one part of the issue, and some overlabelling costs to industry related to other regulations would remain.

Such a provision would not exempt the importing firm from consumer protection provisions in the TPA such as misleading conduct, false advertising, or product liability. Nor would it negate the need to update the domestic Information Standard for cosmetics as international labelling requirements change (as the ACCC has recently done), but it would add flexibility to how the Information Standard is applied and enforced.

In line with best practice regulation, and in response to industry concerns, the ACCC recently undertook the Review of the Trade Practices Cosmetic Regulations (a RIS). The ACCC considered the costs and benefits associated with a number of proposals including deemed-to-comply provisions. The RIS resulted in a minor change to the Information Standard (change to the definition of flavour). The ACCC concluded that deemed-to-comply, and other proposals, would be impractical to implement. Deemed-to-comply provisions were not supported because of the difficulty in enforcing multiple labelling requirements and the 'current state of flux of cosmetic regulation' in New Zealand¹³ and the European Union (ACCC 2008).

It is not clear that the benefits of deemed-to-comply provisions would be significant. Industry were unable to provide any examples of additional substantial costs incurred from complying with the regulations (Information Standard) (ACCC sub. DR103). Further, while ongoing efforts to harmonise labels internationally would make deemed-to-comply provisions more feasible to adopt, it would simultaneously make the need for them less.

¹⁰ Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (76/768/EEC).

¹¹ Code of Federal Regulations, Title 21: Food and Drugs, Part 701 — Cosmetic Labelling.

¹² Cosmetic Regulations (Food and Drugs Act).

¹³ New Zealand's new cosmetics requirements were introduced in July 2008. New proposed European cosmetics regulations are about to be submitted to the European Council and Parliament for consideration (ERMA NZ, Wellington, pers. comm., 15 January 2008; EC 2008).

The Commission does not regard it as appropriate to introduce such provisions at this time. However, the ACCC should review the Information Standard and scope for deemed-to-comply arrangements once EU reforms have been completed, if stakeholders identify ongoing alignment issues.

Overlaps with OHS labelling requirements

ACCORD Australasia argued that there is an overlap between OHS and cosmetics and toiletries ingredient labelling (Information Standard) requirements for industrial hand cleaners:

We are unsure as to why the ACCC requires cosmetic ingredient labelling information when industrial hand cleaners are covered under well established occupation[al] health and safety legislation under Australia's hazardous chemicals management framework. We consider that the imposition of additional labelling requirements is an unnecessary burden which should be removed by taking industrial hand cleaners from the scope of the Cosmetic Regulations as outlined in the ACCC's Guidance material. This change would not undermine the existing public health and safety arrangements in workplaces. (sub. 42, p. 11)

The ACCC advised the Commission that it had recently investigated this issue and found that there were insufficient grounds to exempt industrial hand cleaners from the Information Standard. The ACCC concluded that industrial hand cleaners would not fall within the scope of the Information Standard unless they were sold to consumers,¹⁴ in which case consumers were entitled to the protection of the standard. It also concluded that workplace substances controls made adequate provision to prevent overlap between it and the Information Standard.¹⁵

The Commission agrees with the ACCC's conclusion, and, therefore, does not recommend a specific exemption from the Information Standard for industrial hand cleaners that are sold to consumers.

¹⁴ Section 4.3 of the TPA states: 'For the purposes of this Act, unless the contrary intention appears-(a) a person who acquires goods shall be taken to be a consumer of the goods if the goods are of a kind ordinarily acquired for private use or consumption and the person does not acquire the goods or hold himself out as acquiring the goods for the purposes of re-supply'. Section 63 of the TPA, which outlines provisions for consumer product information standards, appears to use this definition.

¹⁵ The National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012 (1994)] section 3.2 lists a number of 'substances, when packed and sold as end use products, [that] should be regarded as being appropriately labelled' including 'cosmetic products'.

Is there a need for ingredient labelling on other chemical products and consumer articles?

Many consumer products containing chemicals are currently not subject to ingredient-labelling requirements. Some participants raised concerns about this issue, including the problems it causes for people with ‘multiple chemical sensitivities’:

The labelling of industrial chemicals or articles containing industrial chemicals represents another inconsistency and system gap. For example, consumers can see full ingredient listings on labels for some cosmetics such as hand creams but not for their household cleaners and they are not able to determine what chemicals may be in their furnishings, carpets and other products. (NSW Government, sub. 31, p. 17)

Much consumer concern about chemicals could be overcome by the simple provision of ingredient listings in product/merchandise labels. This would be particularly beneficial for those consumers with particular chemical sensitivities/vulnerabilities who may otherwise lobby to restrict chemicals in products. (Environment Protection and Heritage Standing Committee, sub. 20, p. 26)

... [current requirements for] labelling may not provide enough relevant information to minimise potential health risks for sensitive populations such as asthmatics or persons with ‘Multiple Chemical Sensitivities’. (South Australian Government, sub. 56, p. 13)

The Commission supports current government efforts to conduct more research on ‘multiple chemical sensitivities’ to assist in developing appropriate policy and regulatory mechanisms to deal with this issue (box 5.3).

There are two broad areas where ingredient labelling could be expanded to assist people with chemical sensitivities:

- domestic chemical products (such as household cleaners)
- articles containing chemicals of concern (such as carpets, furniture and electrical appliances).

Box 5.3 Multiple Chemical Sensitivity

A number of participants in this study raised concerns about the lack of official recognition of, and support mechanisms for, sufferers of 'multiple chemical sensitivity' (MCS). MCS has been described as a condition whereby sufferers may experience severe adverse physiological reactions to exposure to everyday chemicals at levels below that which would normally affect the general population. Characteristic symptoms can include skin and respiratory problems, 'headaches, burning eyes, nose or throat, concentration or memory lapses, nausea, muscle pain, dizziness, breathing problems and fatigue' (Parliament of South Australia 2005, p. 1).

Internationally, few governments or medical bodies officially recognise MCS as a condition, and consensus has yet to be reached on its symptoms, appropriate procedures for diagnosis, or appropriate treatment. However, the condition is officially recognised in Germany and has gained the attention of governments in the United States, Canada and Sweden (Australian Chemical Trauma Alliance, sub.9; Knott 2007). It is also listed in the International Classification of Diseases (ICD-10).

A Parliament of South Australia inquiry into MCS, conducted in 2005, made a number of recommendations calling for increased access to disability and medical support for MCS sufferers, greater controls on the use of pesticides, and the implementation of hospital protocols for MCS sufferers.

The South Australian Government agreed to many of the recommendations in principle (many of these actions were already being undertaken for other reasons), though it did not support recommendations to expand disability and medical support due to the lack of consensus on the cause, diagnosis and treatment of MCS (Hill 2005). It agreed in principle to MCS being referred to the Australian Health Minister's Advisory Council for further research, citing its support for research being conducted at the time by the Office of Chemical Safety (OCS) and the National Industrial Chemical Notification and Assessment Scheme (NICNAS).

Research by the OCS and NICNAS will act as a first step in reporting on the causation of MCS, current diagnosis and clinical management strategies, and considering practical measures to improve the management of MCS patients. It will identify priority areas for further study to inform and engage the clinical and scientific research community (OCS and NICNAS 2007). MCS interest groups are currently being advised of consultation arrangements prior to the public release of the study — planned for late August/early September. Copies of the study will be available from NICNAS.

Ingredient labelling is likely to be easier for the former than the latter. Imposing ingredient labelling requirements on manufactures or importers of consumer articles would impose significant costs on firms where they had to verify the chemical composition used in the products they sell. This would be difficult where components are derived from multiple manufacturers, as is often the case, and even more difficult for importers (who are not directly involved in the production process).

For domestic chemical products, existing regulations deal with the risk of allergic reaction or sensitisation in the following manner:

- The Information Standard requires the full disclosure of ingredients for cosmetic and toiletry products on the label.
- Poisons regulations include controls on substances that pose a sensitisation hazard (section 5.1).
- Poisons regulations require labelling on domestic chemicals to inform consumers of how to reduce the risks of exposure (such as through the use of gloves, or use in well-ventilated areas).

Furthermore, the marketing of many products emphasizes their health or environmental characteristics (such as ‘fragrance free’ or ‘soap free’ cosmetics and toiletries), giving choice to those consumers who have identified allergies.

The Commission also notes that accelerating NICNAS’s review of existing chemicals (recommended in chapter 4) should provide additional valuable information about the toxicity of chemicals. This is likely to lead to more, and better informed, regulatory action to deal with the risks of chemical sensitivities and allergic reactions.

5.4 Diversion of chemicals to illicit-drug manufacture

Industry and government have adopted measures to prevent diversion of chemicals to illicit-drug manufacture. Limiting the availability of such chemicals, some of which are readily available and have legitimate purposes, makes it more difficult for illicit-drug manufacturers to source their required inputs.

Regulatory Framework

The Ministerial Council on Drug Strategy (MCDS) functions as the peak policy and decision-making body in relation to licit and illicit drugs in Australia. The National Working Group on the Prevention of the Diversion of Precursor Chemicals (Precursor Working Group), which reports to the MCDS, endorsed the development of the National Framework for the Control of Precursor Chemicals and Equipment Project. The aim of the Framework is to promote consistency of precursor chemical regulation for the entire supply chain through the development of a Best Practice Framework and guidelines for precursor chemicals and equipment. The Precursor Working Group is made up of more than 40 members from the Australian Government, state and territory law enforcement agencies, forensic and health services, and the pharmaceutical and chemicals industry (Australian Government

Attorney-General's Department, sub. 32). PACIA is an active member of the Precursor Working Group.

The Australian Government controls the import and export of precursor substances and coordinates national efforts to monitor and control their dissemination and use. The states and territories legislate against the unauthorised possession and sale of these substances above prescribed amounts, and in some cases also specify procedures to which firms must adhere in their storage and sale.

State and territory government regulations are largely derived from the voluntary Code of Practice for Supply Diversion into Illicit Drug Manufacture (the Supply Diversion Code). The Code is sponsored by the National Precursor Strategy in association with the Australian Government Attorney-General's Department, the Australian Crime Commission, Science Industry Australia, PACIA, and law enforcement agencies. The National Precursor Strategy is funded and chaired by the Australian Government and forms part of the National Illicit Drug Strategy.

The Supply Diversion Code categorises chemicals and apparatus that could be used to manufacture illicit drugs into categories according to their risk of diversion, and sets out recommended controls on their storage and supply (PACIA and SIA 2007). Category I chemicals have the greatest level of controls, and category II and III less so:

- Category I chemicals should only be sold to account customers who have signed an End User Declaration (EUD). The EUD includes the purchaser's identification and contact details, and information about the intended use of the chemicals. Category I chemicals cannot be paid for in cash, and delivery of orders must not take place within 24 hours of the order being placed. Additionally, such chemicals must be kept under locked storage with restricted access and regular checks.
- Category II chemical purchasers must complete EUD requirements where they are not account customers.
- Category III chemicals, while not subject to specific controls, do have a requirement that suppliers report suspicious purchasing behaviour.

Law enforcers and PACIA work closely to update the Supply Diversion Code regularly (PACIA, sub. 2). Chemicals deemed to be of significant interest for diversion purposes are typically proposed for incorporation into the Code by law enforcement agencies (PACIA, sub. 33). The most recent version of the Code was released in October 2007, following a review process led by the Australian Crime Commission with input from stakeholders.

Effectiveness and efficiency of current arrangements

There are inconsistencies between each jurisdiction's regulations and the Supply Diversion Code (PACIA, sub. 33). This is despite each jurisdiction's regulations being largely derived from the Code. A notable inconsistency is that some jurisdictions do not use risk categories and risk-tailored controls for each category. Failure to tailor controls to the level of risk could lead to regulatory burdens being greater than necessary, and, therefore, greater compliance costs for firms. It could also impose a competitive disadvantage on firms operating in multiple jurisdictions compared with some single jurisdiction firms. Inconsistencies can result in unwarranted costs due to the burden of monitoring, understanding and fulfilling different controls.

Inconsistencies can also undermine the effectiveness of the regulations. This can include difficulties in complying with requirements in multiple jurisdictions, as firms attempt to understand the different controls, and regulatory gaps, that can be exploited by illegal elements (including 'jurisdiction shopping'). A uniform approach across jurisdictions would address these issues.

The Precursor Working Group has been given responsibility for the coordinated development of the framework referred to above. It aims to promote greater consistency of precursor chemical regulation through the development of best-practice frameworks and guidelines for precursor chemicals and equipment (Australian Government Attorney-General's Department, sub. 32). This project is looking at appropriate controls across the supply chain on a national basis. This includes consideration of a nationally-consistent legislated approach to the control of precursor chemicals and has made significant in-roads, including development of a risk assessment framework. The framework will provide a more systematic approach to rating chemicals and determining appropriate regulation, and is an improvement on the current more ad hoc approach. The risk assessment tool will take into account considerations such as harm, industry use, and intent. The application of the tool will advance a consistent, risk-based approach to regulation while also taking into account both industry and law enforcement needs (Australian Government Attorney-General's Department, sub. DR75). However, the focus of the framework is limited to 'promoting' consistency and falls short of ensuring nationally uniform regulation.

The Commission considers there is a strong case for nationally uniform controls to prevent chemicals from being diverted into illicit drug manufacture. While existing inconsistencies do not appear significant at present, they have the potential to undermine the effectiveness of the controls and/or lead to material regulatory

burdens over the longer term. The only relevant consideration is how best to graft the controls onto specific jurisdictional generic legislation.

The Commission's preferred approach is a single risk-based schedule of drug precursors that each jurisdiction adopts by reference. This should be maintained by an expert body drawn from Commonwealth, state and territory agencies, that currently sponsor the Supply Diversion Code and other experts as appropriate,¹⁶ and be overseen by the Ministerial Council on Drug Strategy. Industry associations and others should be consulted about proposed changes to the schedule. While the Commission recognises the important achievement so far of the Precursor Working Group in developing the framework, and the need for its ongoing involvement, it is a representational committee and hence not an appropriate body to be deciding policy on behalf of the wider community.

To ensure the associated controls are also nationally uniform, the Ministerial Council on Drug Strategy should ideally decide on supporting regulations that are adopted as a template. Alternatively, model regulations could be developed. The regulations would still be administered by state and territory agencies as they have the local knowledge to ensure effectiveness.

Adoption of the abovementioned approach would effectively make the Supply Diversion Code redundant by largely incorporating its features and associated procedures into legislation. While the Code has been useful, the jurisdictions would pursue a legislative path in order to ensure a greater level of effectiveness than is likely under a voluntary code.

PACIA has argued that drug-precursor controls should be managed jointly with those for chemicals of security concern, because they involve common issues:

Unfortunately, the developments for drug precursors and chemicals of security concern are currently proceeding in parallel with very little interaction, much to the concern of the impacted industry ... The goal and objective of both are the same — to prevent illegal diversion — and should attract the same integrated regulatory framework that works in harmony and with no overlap ... (sub. 33, attachment 3, pp. 10–14)

Subsequent to PACIA's submission, the draft framework for security sensitive chemicals has been released. It proposes that any controls on such chemicals will build on existing arrangements, including those for drug precursors:

Building, wherever possible, on appropriate existing industry and/or government arrangements will ensure that controls for chemicals of security concern do not conflict

¹⁶ The government agencies that currently sponsor the Supply Diversion Code are the Australian Government Attorney-General's Department, the Australian Crime Commission, the Australian Federal Police, and state and territory police forces.

with current arrangements for chemicals, do not unnecessarily introduce new controls and minimise the impact on stakeholders.

... most measures identified in the risk assessment process are likely to be implemented by modifying existing safety, health or environment control measures, or for the diversion into illicit drug manufacture ... (SCCRHM 2008, pp. 26–32)

Furthermore, the lead agency for drug-precursor controls — the Australian Government Attorney-General’s Department — is expected to also oversee measures for chemicals of security concern. Nevertheless, some controls aimed at preventing chemical-related terrorism may need to differ from those used to prevent drug-related crime.

RECOMMENDATION 5.6

The Ministerial Council on Drug Strategy should develop illicit drug precursor regulations for adoption by reference by all jurisdictions. The associated risk-based schedule of chemicals and apparatus, which are to be subject to the regulations, should be maintained by a committee of experts overseen by the Ministerial Council, and also be adopted by reference in each jurisdiction.

5.5 Food safety

Regulatory framework

Australia and New Zealand have a joint system for regulating food safety (summarised in figure 5.1). This system is underpinned by an intergovernmental agreement — the Food Regulation Agreement — between the Commonwealth, state and territory governments (and a treaty with New Zealand). The Australia and New Zealand Food Regulation Ministerial Council is responsible for setting policy, and amending or rejecting food standards. The standards are developed by Food Standards Australia New Zealand (FSANZ), a trans-Tasman standard-setting body. Within Australia, the states and territories administer and enforce the standards for all foods offered for sale. The Australian Quarantine and Inspection Service inspects and samples imported foods at the border to ensure they comply with the standards.

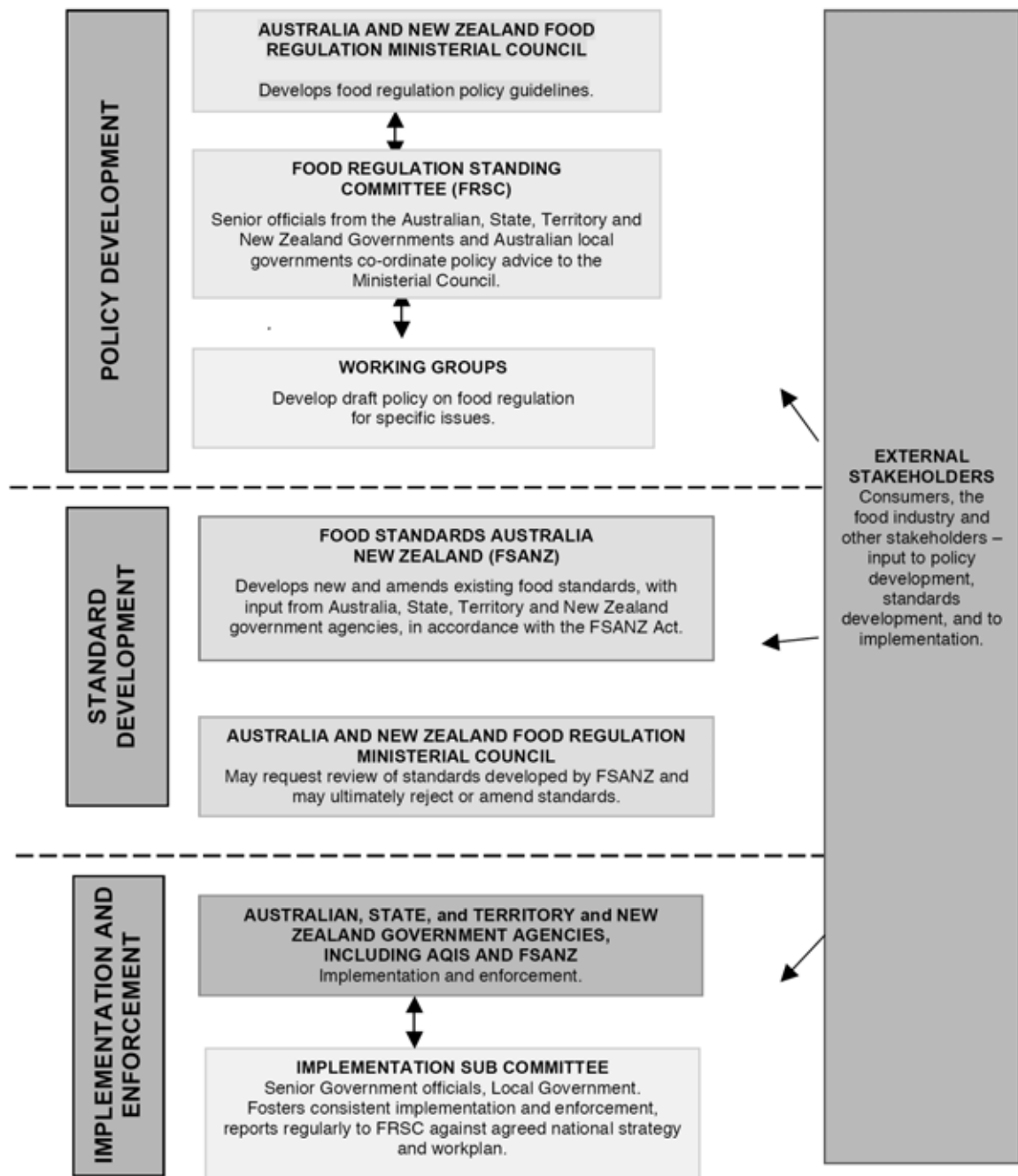
FSANZ (sub. 22) noted that chemicals and plastics are subject to three areas of food regulation. These involve limits on the extent to which foods may contain:

1. residues from agvet chemicals
2. food additives and processing aids

3. contaminants, including residues from plastics used in packaging.

The NSW Government (sub. 31) favoured more prescriptive controls on the latter two areas, which it referred to collectively as ‘food-contact chemicals’. No evidence was provided on the associated benefits and costs. This is a matter that can be raised in the Australia and New Zealand Food Regulation Ministerial Council. Any proposed regulatory changes should be subject to a RIS that includes a thorough cost–benefit analysis.

Figure 5.1 Food regulation system^a



^a In the box for FSANZ it is noted that FSANZ develops food standards with input from other government agencies. This includes input from the Australian Pesticides and Veterinary Medicines Authority regarding maximum residue limits, as detailed in the text of this chapter.

Source: FSANZ (nd).

Two agencies — APVMA and FSANZ — prescribe limits on agvet chemical residues in food — termed maximum residue limits (MRLs) — and do so in separate regulations:

-
- APVMA prescribes MRLs that reflect ‘good agricultural practice’ so breaches of agvet control-of-use requirements can be detected (chapter 8)
 - FSANZ prescribes MRLs so that crops and animals treated with chemicals can be verified as being safe for human consumption¹⁷.

APVMA consult with a wide range of groups through a number of consultative and liaison committees. In addition to these consultative structures, the APVMA routinely conducts consultations with its stakeholders, seeks their input on issues, decisions and scientific assessment outcomes relating to registration activities and the review of existing chemicals, as well as on proposals to reform requirements or procedures (APVMA sub. 59). FSANZ assessments are developed through public consultation (sub. 22), and provide an opportunity for importers to have input into the setting of residue standards (FBIA, sub. DR84).

Limits on agvet chemical residues in food is an area where there have been long-standing concerns about duplication and inconsistency. There is potential for two different MRLs to be prescribed for the same chemical in the same food by the two agencies. In such cases, primary producers in most jurisdictions would have to comply with the most stringent MRL.

In order to mitigate duplication and inconsistency, the two agencies coordinate their actions. The usual procedure has been that APVMA first prescribes an MRL as part of its conditions of approval for an agvet product, and then submits an application to FSANZ to include the MRL in the Australia New Zealand Food Standards Code¹⁸.

FSANZ has never rejected an MRL application from APVMA. This can be attributed to the fact that APVMA assesses the human-health impacts of an MRL before approving it, and does so using dietary models and reference health standards from FSANZ and DOHA¹⁹. For this reason, FSANZ does not usually undertake its

¹⁷ Food regulations in all states and territories (and Commonwealth regulations for imported foods) refer to MRLs prescribed by FSANZ in Standard 1.4.2 of the Australia New Zealand Food Standards Code.

¹⁸ This discussion applies to MRLs prescribed by APVMA for human foods (table 1 of the MRL Standard). APVMA also sets MRLs for pesticides in animal feeds (table 4 of the MRL Standard) but these are not incorporated into food standards managed by FSANZ.

¹⁹ This arrangement is formalised in a memorandum of understanding between APVMA and FSANZ, which includes an attached protocol for dietary risk assessments. DOHA’s Office of Chemical Safety assesses the toxicology of agvet chemicals and establishes the reference health standards.

own dietary exposure assessment when considering an MRL submitted by APVMA²⁰.

Inconsistencies do arise, however, because there is a time lag between when APVMA prescribes an MRL and when FSANZ mirrors it in food standards. This has led to situations where farmers complying with agvet control-of-use requirements set by APVMA cannot sell their produce because FSANZ has yet to duplicate a relevant MRL in food standards. Participants noted there can be a long delay between APVMA and FSANZ decisions, sometimes up to a year or more:

Protracted delays create situations where approval for use has been granted, making it legal to apply a pesticide to a crop but once the crop is harvested it is, in effect, illegal to have the residue in the raw agricultural commodity derived from that crop. Such delays can and have resulted in growers being found in breach of the Food Standards Code. This potentially puts them at risk of noncompliance with state regulations and any quality assurance scheme under which they may operate. (AUSVEG Ltd, sub. 52, p. 2)

This dual system involving two Commonwealth Government agencies [APVMA and FSANZ] causes unnecessary delays of up to one year in formalising MRLs. It can lead to the situation where farmers can use a registered pesticide product according to the label and follow good agricultural practice to meet the APVMA's recommended MRL, but still not meet the Food Standards Code because of delays in FSANZ assessing, approving and listing the MRL. (Croplife Australia Limited, sub. 57, p. 6)

... when a new pesticide use is gazetted by APVMA, it is not gazetted in the Food Standards Code by FSANZ simultaneously. There can be lengthy delays of up to 15 months, where some fresh produce can technically be a MRL violation despite the fact the chemical is legal. This is a national issue that has been raised by industry stakeholders for many years, however it must be recognised that this issue has still not been rectified. (Growcom, sub. 12, p. 12)

In response to such concerns, recent legislative amendments were made to reduce the time lag between APVMA and FSANZ decisions.²¹ If APVMA receives a product-registration application involving a new active constituent, and its approval is likely to require a new MRL, APVMA now has to notify FSANZ at least 30 working days before inviting public comment on the application.²² APVMA will

²⁰ FSANZ has the authority to effectively delegate dietary exposure assessments to APVMA under s.112 of the *Food Standards Australia New Zealand Act 1991* (Cwlth), which allows FSANZ to rely on the work or processes of other government agencies when this would avoid duplication.

²¹ The amendments were included in the *Food Standards Australia New Zealand Amendment Act 2007* (Cwlth) and came into effect on 1 October 2007.

²² In particular, s.13 of the *Agricultural and Veterinary Chemicals Code Act 1994* (Cwlth) requires APVMA to invite public comment on all applications to register a product with a new active constituent. Under s.13A of the Act, APVMA must notify FSANZ at least 30 days before inviting public comment on such applications, if it is likely an MRL would have to be prescribed.

follow the same procedure for any application to extend an existing product's approved uses to a major export commodity, because public consultation is also conducted for such applications.

APVMA is not required to (and generally does not) invite public comment on MRLs for minor export commodities, or for MRLs associated with permits and emergency situations (temporary MRLs). As a result, the recent reforms do not apply in such cases. Comments by AUSVEG Ltd suggest this is a cause for concern, because historically there has been an:

... apparent inability of FSANZ to accommodate temporary MRLs established by the APVMA. These MRLs are frequently the result of permit applications submitted on behalf of minor vegetable crops at the instigation of AUSVEG. The absence of these MRLs from the Food Standards Code has potentially serious implications for many growers. Many state authorities and accreditation bodies rely upon the Code to assess compliance resulting in legitimate uses prompting enforcement action. AUSVEG therefore believes that greater efforts are needed to ensure that the MRL setting process in Australia is harmonised to ensure that such anomalies no longer occur. (sub. 52, p. 2)

For cases where the recent reforms do apply, FSANZ will now be able to commence its MRL assessment procedures earlier than previously. However, FSANZ still expects a time lag of six to nine months before it adopts an MRL prescribed by APVMA:²³

In general, FSANZ [prior to the recent reforms took] ... between nine to twelve months to complete the assessment of MRLs from the APVMA. Under the new legislative requirements this should be reduced to between six to nine months. (sub. 22, p. 6)

Much of the remaining delay can be attributed to the governance arrangements for food standards. If relevant experts in FSANZ conclude that a proposed MRL would be an appropriate food standard, their decision has to be submitted to the FSANZ Board for approval. If the Board agrees, the decision then has to be submitted to the Australia and New Zealand Food Regulation Ministerial Council for its consideration. The Ministerial Council has 60 days to request a review of FSANZ's decision before it is incorporated into the Food Standards Code. A single jurisdiction can prompt such a request under the Ministerial Council's voting rules.

These governance arrangements are not consistent with the best-practice model outlined in chapter 3. The role of a ministerial council should be to provide high-level policy development and oversight of regulatory arrangements. The task of determining standards for specific chemicals and products under those

²³ The amended Food Standards Australia New Zealand Regulations 1994 (s. 10) direct FSANZ to complete its consideration of an MRL within nine months.

arrangements should be fully delegated to a national standard-setting body that has the necessary technical expertise and undertakes a public consultation process.

Another reason for delays in adding MRLs to the Food Standards Code has been that FSANZ typically waits until it has a batch of MRL applications to process. For example, in October 2007, FSANZ invited public comment on a draft assessment report for MRLs notified by APVMA in January, February and March 2007 (FSANZ 2007).

Effectiveness and efficiency

Regular surveys are used to monitor compliance with MRLs. The Australian Government Department of Agriculture, Fisheries and Forestry manages a National Residue Survey that regularly measures chemical residues in raw animal products (meat, egg, honey and fish) and plant products (grain, oilseed and horticulture). This survey is largely funded by industry levies and is used to facilitate Australia's access to export and domestic markets (DAFF 2007). FSANZ conducts the Australian Total Dietary Survey about every two years to monitor dietary exposure to residues in a range of 'table-ready' foods (FSANZ 2005). Various state government agencies and marketing bodies also monitor MRL compliance (Croplife, sub. 35; PSIC nd). For example, the Victorian Department of Primary Industries regularly tests residues in locally-grown fresh produce through its Victorian Produce Monitoring Program (DPI Victoria 2006). The abovementioned surveys typically find relatively few instances of MRLs being exceeded, and so the regulatory arrangements for MRLs appear to have been largely effective in keeping chemical residues in food to safe levels.

With respect to efficiency, recent reforms have only partially addressed long-standing concerns about duplication and inconsistency. There will still be a time lag while an MRL prescribed by APVMA is considered for incorporation into the Food Standards Code. There would be a case for retaining this dual process if APVMA did not consider food safety when determining MRLs. However, s. 14 of the *Agricultural and Veterinary Chemicals Code Act 1994* (Cwlth) specifically directs APVMA not to approve an active constituent or chemical product that would be an 'undue hazard to the safety of ... people using anything containing its residues'. And, as noted previously, APVMA assesses human-health impacts using dietary models and reference health standards developed by FSANZ and DOHA.

The case for retaining a dual process is further weakened by the fact that APVMA's approach typically leads to MRLs being set at a level that is very conservative from the perspective of food safety:

MRLs are ... normally set at levels well below those that would cause an adverse health effect. MRLs act to protect public health and safety by ensuring that residues are no higher than is necessary for effective control of pests and disease. (FSANZ 2003)

If an MRL is exceeded, it usually indicates a misuse of the chemical but does not normally indicate a public health or safety concern. (APVMA 2004a, p. 2)

MRLs are normally set well below the level that would harm health. When an MRL is exceeded, it usually indicates a chemical is being misused, rather than a public health or safety concern. (PSIC nd, p. 2)

In light of the above, it is not surprising that FSANZ has never rejected any of the MRLs submitted to it by APVMA over the years. The process managed by FSANZ has proven to be unnecessary duplication, with the added drawback that it has led to regulatory inconsistencies for as long as a year or more. A more efficient approach would be for MRLs for domestically grown produce, set by APVMA, to be automatically incorporated into the Food Standards Code.

However, the Ministerial Council (with input from FSANZ) would retain the option to amend any MRL specified in the Food Standards Code, where sufficient evidence exists to warrant it.

In its draft report the Commission recommended that MRLs, as set by the APVMA, be automatically incorporated into the Australia and New Zealand Food Standards Code, and that any decision to the contrary should be based on a cost-benefit analysis and be reported publicly. The Commission notes that COAG, at its meeting of 3 July 2008, agreed to implement recognition of MRLs set by APVMA for domestically grown produce.

FSANZ should continue to undertake its own assessments to accommodate imported foods, and public consultation arrangements for importers should remain unchanged.