
8 Regulation of agricultural and veterinary chemical products

Key points

- Agricultural and veterinary (agvet) chemical products are regulated under the National Registration Scheme (NRS) — a partnership between the Commonwealth and state and territory governments.
- Under the NRS, a national regulator — the Australian Pesticides and Veterinary Medicines Authority (APVMA) — undertakes the assessment and registration of agvet chemical products, while states and territories are responsible for regulating agvet chemical use after retail sale.
- The effectiveness and efficiency of APVMA assessments could be improved by introducing a formal obligation on the APVMA to ensure that the costs of chemical assessments are commensurate with the risks of the chemicals concerned and that APVMA assessment priorities are directed to the most efficient management of aggregate risks of all agvet products.
- The efficiency of APVMA assessments could be further improved by rectifying the currently dysfunctional arrangements for registering low regulatory concern products and through greater use of international assessment data.
- Interjurisdictional inconsistency in control-of-use regimes limits the effectiveness of the APVMA and the overall effectiveness and efficiency of the NRS. Vertical integration of regulations governing agvet chemical use into a single national regime delivered by the states and territories would improve effectiveness and efficiency.

The additional costs of the national control-of-use regime should be cost recovered by the APVMA.

The use of agricultural and veterinary (agvet) chemical products can pose potentially significant risks to human health and the environment. In particular, due to their function, pesticides¹ are frequently toxic and are applied directly on the environment including various food producing crops. In addition, the use of agvet chemical products on exported primary produce can affect Australia's international

¹ The terms of reference for this study exclude veterinary chemicals from its scope. The Commission's approach has been to only consider issues relating to them that are common to agricultural and veterinary chemicals regulation.

trade. In recognition of their hazardous properties, direct environmental and human exposure paths, and direct trade impacts, agvet chemical use is regulated via a dedicated regime. This regulatory treatment is similar to arrangements adopted in most OECD countries.

8.1 Regulatory arrangements for agricultural and veterinary chemicals

Scope

The National Registration Scheme (NRS) for agvet chemicals regulates the introduction and use of all agvet chemicals and products. This includes: the assessment and registration of agvet chemicals and products; development of conditions of use and product quality monitoring; and control-of-use of agvet products after retail sale. Agricultural chemicals are defined to include all pesticides including herbicides, fungicides, insecticides and plant growth regulators, but exclude fertilisers, which are defined as industrial chemicals for the purpose of assessment. Veterinary medicines are defined broadly to include all substances that can be used to prevent, cure or alleviate a disease or injury of an animal.

Institutional arrangements

The NRS is a partnership between the Commonwealth, state and territory governments underpinned by an intergovernmental agreement (IGA). Under the agreement, state and territory governments conferred their power to regulate the supply of agvet chemicals to the Commonwealth, and adopted a template Agricultural and Veterinary Chemicals Code (Agvet Code). The responsibility for regulating the use of agvet chemicals after retail sale remained with the state and territory governments.

The Australian Pesticides and Veterinary Medicines Authority (APVMA) — a statutory authority within the portfolio of the Commonwealth Minister for Agriculture, Fisheries and Forestry — derives its powers from the *Agricultural And Veterinary Chemicals (Administration) Act 1992* (Cwlth). Its functions include (among others):

- to assess the suitability for sale in Australia of chemical products, active constituents for proposed or existing chemical products, and labels for containers for chemical products
- to provide information to governments about approved active constituents,

registered products, and approved labels

- to fund a program to ensure compliance
- to evaluate the effects of the use of chemicals in states and territories
- to facilitate the introduction of uniform national standards on controlling the use of chemicals.

APVMA obtains policy direction from the Primary Industries Ministerial Council (PIMC), which is supported by the Primary Industries Standing Committee (PISC) and the Primary Industries Health Committee (PIHC). In turn, the PISC and PIHC obtain policy advice from the Product Safety and Integrity Committee (PSIC), whose members include representatives from the:

- Commonwealth Government Department of Agriculture, Fisheries and Forestry (DAFF)
- Australian state and territory departments responsible for agriculture
- New Zealand Food Safety Authority
- CSIRO
- APVMA
- Environment Protection and Heritage Council
- Workplace Relations Ministerial Council
- Australian Health Ministers' Advisory Council.

Funding

APVMA operates on cost-recovery principles and is principally funded via a levy imposed on sales of registered agvet products² and via application and annual registration fees. APVMA also collects licensing fees from manufacturers of veterinary medicines. In 2006-07, total revenue amounted to \$25.3 million, of which \$17.7 million, or around 70 per cent, came through the sales levy. APVMA has recorded operating surpluses in 2005-06 and 2006-07 of around \$3.1 million and \$2.1 million respectively (APVMA 2007a).

Assessment and registration of new products

APVMA assesses a chemical or product on its potential impact on human health, the environment, and trade as well as on its efficacy (box 8.1). Some aspects of

² The levy applies to individual products and is tiered on the basis of value of the sales.

assessment are performed within APVMA after consultation with other agencies. A number of subject matters are assessed entirely by other government agencies. For example, the Office of Chemical Safety (OCS) assesses the toxicology of the product or chemical and looks at worker safety issues, while the Department of the Environment, Water, Heritage and the Arts (DEWHA) assesses the risks to the environment. Some of the risk-management decision making is also done externally — for example, dietary and occupational exposure standards are set by the OCS, while DEWHA can recommend risk-management strategies to mitigate environmental impacts (APVMA, sub. DR105).

Box 8.1 Criteria for approving applications

The Agricultural and Veterinary Chemicals Code (s. 14(3)(e)) states that the Australian Pesticides and Veterinary Medicines Authority must approve an application where (among other things) it is satisfied that the product or constituent would:

- not lead to an undue hazard to the safety of people exposed to it during its handling, or people using anything containing its residues
- not be likely to have an effect that is harmful to human beings
- not be likely to have an unintended effect that is harmful to animals, plants or things, or to the environment
- not unduly prejudice trade or commerce between Australia and places outside Australia
- be effective if done according to instructions.

Where the application is for approval of a label, the label must contain adequate instructions covering a range of issues prescribed by the Code.

On completion of the evaluation, if APVMA is satisfied that the product is safe and effective and that the label contains adequate instructions, it will grant the application. APVMA may refuse an application if it is not satisfied that the above conditions have been met.

APVMA may put conditions on the manufacture and supply of the product. For example, it can require the product to be supplied in a container of a particular kind. The product label also has to be approved by APVMA. Product labels are predominantly based on managing the *risks* of the product, although some *hazard* information may also be included. Matters that are required to be included on labels include:

- circumstances in which the product should be used and how it should be used
- approved times and frequency of product use

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- withholding period after use of the product
 - re-entry period after use of the product
 - disposal of the product and its container when they are no longer required
 - safe handling of the product and first aid in the event of an accident caused by the handling of the product.

Permits

In addition to registering agvet products, APVMA can, in some circumstances, issue permits for using an unregistered agvet product, or for using a registered product in a manner that contradicts the registration conditions. Permits can be issued in response to an application for a minor use, emergency use, or for research purposes.

Assessment of existing chemicals and products

When the NRS was introduced in 1995, APVMA assumed responsibility for over 5000 agvet products that were registered under prior state and territory arrangements (APVMA 2007a). APVMA runs a Chemical Review Program for assessing previously approved chemicals and products. Reviews decide whether the product is safe, requires reformulating, requires restrictions on conditions of use, or whether it should be suspended, cancelled or withdrawn from the market.

Interface with other national schemes

Some of the outcomes of APVMA assessments serve as inputs into other national schemes:

- When APVMA sets a maximum residue limit in food, it also makes a recommendation to Food Standards Australia New Zealand (FSANZ) to incorporate this maximum residue limit into the Food Standards Code (chapter 5).
- As part of the APVMA assessment, the product may also be classified as a poison. The product is then referred to the National Drugs and Poisons Schedule Committee.

Interface with state regulators

APVMA cooperates with state and territory governments in monitoring and enforcing compliance with the Agvet Code provisions. Also, while the scope of the NRS does not extend to controlling product use, the conditions of use specified by APVMA during product registration form part of the state and territory control-of-use regimes.

8.2 Effectiveness and efficiency of agricultural and veterinary chemicals assessment

Clarifying the objectives — recognition of effectiveness and efficiency principles

The assessment and registration provisions of the Agvet Code generate benefits and impose costs on the community. As noted previously (chapter 4), the Commission considers that an effective and efficient chemical assessment scheme should have provisions for prioritising its assessment effort and calibrating assessment requirements in a way that maximises net community benefit.

There is some acknowledgment in the legislation underpinning the NRS of the potential tradeoffs involved in the operation of the scheme. For example, the long title of the *Agricultural and Veterinary Chemicals Act 1994* (Cwlth) recognises among other things:

- a) that the protection of the health and safety of human beings, animals and the environment is essential to the well-being of society and can be enhanced by putting in place a system to regulate agricultural chemical products and veterinary chemical products ...
- c) that the furthering of trade and commerce between Australia and places outside Australia, and the present and future economic viability and competitiveness of primary industry and of a domestic industry for manufacturing and formulating such products, are essential for the well-being of the economy and require a system for regulating such products that is cost-effective, efficient, predictable, adaptive and responsive ...

The Agvet Code also requires that the APVMA satisfy a public interest test or consider different risk management options for some of its regulatory decisions.³

³ Section 93 of the Agvet Code requires the APVMA to satisfy a public interest test when declaring a product to be a 'restricted product' (subject to greater post-registration control). Section 34 of the Agvet Code requires the APVMA to consider risk management alternatives

However, such provisions offer only a limited and fairly fragmented recognition of community wellbeing. There is little specific instruction in the Code on how to promote the achievement of the objectives outlined in the long title of the *Agricultural and Veterinary Chemicals Act*. The only general legislative instruction to the APVMA on the exercise of its functions pertains to the requirement to have regard to the principle of ecologically sustainable development (s. 7(4) of the *Agricultural and Veterinary Chemicals (Administration) Act 1992* (Cwlth)).

The APVMA (sub. DR105) argued that it was pursuing the objective of efficient regulation through a series of reforms to its operations that are currently in progress. Those reforms are addressed later in the chapter. However, industry comment to this study and to the Commission's study of regulatory burdens on primary sector businesses (PC 2007a), as well as some of the findings of the Australian National Audit Office review of APVMA operations (ANAO 2006), suggest that the APVMA is not as clearly focused on the objective of net community benefit as it might be. The Commission considers that, as a matter of general principle, there should be a formal obligation on the APVMA to set its assessment requirements to be commensurate with the risks and to appropriately direct its assessment and regulatory effort to managing the risks in the most effective way. The features of an efficient assessment regime specified in box 4.2 could help inform the pursuit of that objective.

RECOMMENDATION 8.1

The Australian Government, in consultation with the states and territories, should impose a statutory obligation on the Australian Pesticides and Veterinary Medicines Authority to ensure that:

- ***the costs of chemical assessments are commensurate with the risks posed by the chemicals concerned***
- ***its assessment priorities are directed to the most efficient management of the aggregate risk of all agvet chemicals.***

Governance structures

The NRS provides for extensive governance structures to address APVMA's current dual roles of chemicals and products assessment and risk-management standard setting. A ministerial council (PIMC) is responsible for policy development and scheme oversight, and is supported by a hierarchy of committees including PSIC, which provides expert advice to the Council. APVMA can provide

when reconsidering the conditions of registration of an existing product due to new information about its risk.

advice on emerging issues via its membership on PSIC. In addition, APVMA has a number of consultative committees including the Registration Liaison Committee — consisting of representatives from APVMA, Commonwealth, state and territory agencies, which operates as a forum for consulting on the operational management issues of the NRS.

In line with the Commonwealth Government's response to the Uhrig review of corporate governance (chapter 3), APVMA's Governing Board was recently abolished and replaced with a statutory advisory board appointed by the Minister. The board comprises representatives of a range of stakeholder interests from:

- regulation of chemical products at state and territory level
- agricultural chemical industry
- veterinary chemical industry
- primary production
- environmental toxicology
- protection of consumer interests
- public health and occupational health and safety (OHS) (APVMA 2007a).

The board provides expert advice to the Chief Executive Officer and is an internal governance mechanism aimed at improving the performance of APVMA in achieving its policy objectives.

Scope of APVMA — separation of risk-assessment and risk-management functions

APVMA's functions include both agvet chemicals assessment and subsequent setting of controls on those chemicals. As stated earlier, the Commission's preferred approach involves effective separation of the chemicals assessment and standard-setting functions. While this option should be kept open, it is not a high priority at the moment. First, most of the scientific assessment of agvet chemicals is already outsourced to other agencies. Second, the hybrid nature of APVMA as an assessment and regulatory body is an integral feature of a nationally agreed regime for agvet chemicals. The NRS has delivered significant effectiveness and efficiency benefits over past arrangements through national uniformity. Any moves to substantially alter the scheme would need to proceed with great caution so that those gains are not jeopardised. Nevertheless, the Commission considers that the devolution of the current technical assessment responsibilities of APVMA to a specialist assessment agency may be warranted as a longer-term objective.

Quality and rigour of APVMA assessments

The APVMA Principal Scientist Program is an internal program that has operated since 2002 with the aims of managing the science-related issues and projects within APVMA, and improving the quality of scientific assessments and the domestic and international credibility of APVMA's scientific work. APVMA is also currently implementing a quality-assurance framework for its external service providers by requiring a performance assessment before sign-off on all work orders (APVMA 2008). In 2007, the Principal Scientists audited APVMA evaluation reports and found them to be 'in the range good to excellent' (APVMA 2007a, p. 36).

APVMA assessments also appear to be accepted internationally — for example, APVMA participates in the OECD pesticide work-share program.

Animal health industry surveys undertaken by Business Decisions Limited (2007) for Animal Health Alliance suggest that APVMA assessments were seen as being of high scientific quality. However, a common concern pertained to the quality of product efficacy testing. Efficacy testing is undertaken by state governments for APVMA. Survey participants have argued that the selection processes for engaging efficacy reviewers were opaque, that reviewers were frequently less competent than APVMA reviewers, and that there was inadequate oversight by APVMA of those external reviewers.

The Australian Academy of Technological Sciences and Engineering (AATSE) reviewed APVMA risk-assessment processes for pesticides and concluded:

The assessment of pesticides by the National Registration Authority for agricultural and veterinary chemicals appears to be generally a rigorous process that uses internationally accepted principles of risk assessment. In particular, assessments reported in the full texts of recent reviews of products under the Existing Chemicals Review Program are indicative of a careful scientific approach and use of all available information and literature in the assessment. (AATSE 2002, p. 246)

Nevertheless, AATSE identified some gaps and limitations in APVMA assessments. The most significant limitation is that APVMA hazard and risk assessments are product specific and do not consider the cumulative and synergistic environmental and health effects of multiple chemicals. There is no routine assessment of multiple exposures or of all likely workplace mix combinations of pesticides. Further, there is no assessment of the cumulative or synergistic effects of multiple pesticide residues on human health, or on the environment. Australian Chemical Trauma Alliance argued:

... with so many chemical products being used in our every-day environment (not just in pesticides) there has not been any meaningful attempt to assess synergism: assessing each chemical on its own is not in the real world. (sub. 9, p. 1)

Internationally, the issue of assessing the cumulative risks of multiple chemicals is beginning to generate considerable attention. For example, the US Environment Protection Agency (US EPA 2007a), as part of its program of review of existing pesticides, is required to assess the cumulative risks of pesticides that ‘share a common mechanism of toxicity, or act the same way in the body’. A number of pesticides have been placed into four groups that share common toxicity characteristics. The cumulative risks of pesticides in each group will be assessed to determine whether the current risk-management standards are appropriate. The World Health Organization, under its International Programme on Chemical Safety, is currently developing a framework for ‘assessing the combined risk from exposure to one or more agents (with or without a common mechanism-of-action) via all relevant routes and pathways’ (WHO 2007). The Commission encourages APVMA to monitor the international developments on cumulative risk assessment methodology and policy and to investigate the feasibility of their implementation in Australia.

Feedback mechanisms supporting assessment activity

Strong feedback mechanisms supporting assessment activity can improve the accuracy of assessments and relieve the pressure for overly conservative data requirements and conclusions. Such mechanisms could include post-market monitoring of adverse experiences and a well-functioning existing chemicals review program that is responsive to public and industry feedback.

The NRS has an Adverse Experience Reporting Program consisting of voluntary reporting by the general public, health workers and state agencies and mandatory reporting by registrants of pesticides of any adverse experiences with their products that are drawn to their attention. The operation of the program has been criticised by some participants. Croplife Australia (sub. 35) argued that the program was not comprehensive due to its largely voluntary nature,⁴ and poorly coordinated, with no national database to collate the information.

Thus, a strengthening of the feedback mechanisms may be warranted. However, as in the case of industrial chemicals, any substantial increase in the scope of the

⁴ The Environment Protection and Heritage Council Chemicals Working Group also suggested that the program was limited by its voluntary nature, and has sought a commitment from state and territory government agencies with a role in agvet chemicals to report adverse events through this program (chapter 9).

existing Adverse Experience Reporting Program would need to be preceded by a comprehensive consolidation and evaluation of existing post-market monitoring information on agvet chemicals.

Grandfathered agricultural and veterinary chemicals

The NRS was introduced in 1995, replacing the previous state and territory-based systems. Over 5000 of the 6500 agvet chemical products currently available in Australia were registered under the previous arrangements, often involving less rigorous assessments, some of which dated back to the 1950s.

Where potential safety or performance risks have been identified, APVMA, as part of its Chemical Review Program (CRP), undertakes public reviews of already registered chemicals (including those assessed under the previous jurisdictional regimes) to assess whether they still work as intended and are safe for humans and the environment.⁵ Potential reviews are prioritised and scoped, based on the level of concern about possible adverse effects determined against agreed selection criteria. There have been around 100 reviews completed or underway under this program, with over 40 existing chemicals currently nominated for future review.

As existing agvet chemical products have already received some form of assessment under previous state and territory registration schemes, the problem is not as significant as for industrial chemicals. In addition, about 75 per cent of agvet chemical products were registered pre-1995, compared to around 95 per cent of grandfathered industrial chemicals.

An Australian National Audit Office audit of APVMA's regulation of pesticides and veterinary medicines (ANAO 2006) considered that it had reasonable arrangements for identifying and prioritising existing chemicals requiring review. However, even for the relatively small subset of existing chemicals identified and prioritised for review, ANAO noted the slow rate of progress in commencing and completing reviews.⁶ It observed that this meant that the risks of using many existing chemicals remained. Hence, ANAO recommended that APVMA assess whether the time taken to complete reviews adequately incorporated the risk of delaying reviews of other products. In addition, the ANAO observed that even if the rate of formal CRP reviews was slow, communication with stakeholders about

⁵ The CRP was established in 2000 by rolling together two previous review programs which had operated since 1995.

⁶ ANAO found that the average time to review an existing product was nearly three years, and this was set to increase because many of the reviews in progress have already taken more than five years.

concerns relating to existing chemicals being reviewed or being considered for review, would assist in reducing the risks associated with using such chemicals.

APVMA accepted the above recommendations and has engaged a consultant to assess the current approaches to prioritisation, review and communication with the public under the CRP. Part of that review will involve international benchmarking of APVMA's performance against the performance of similar agencies. APVMA also argued that where areas of significant concern were identified with a particular chemical, it took rapid action to manage those risks (sub.DR105). As with industrial chemicals, the Commission considers that effectively working through the backlog of unassessed chemicals is an important priority.

Funding of the CRP is an issue. Currently, it is cost recovered by agvet product registrants. Several participants (for example, Croplife Australia, sub. DR80) suggested that aspects of the program should be budget funded. As discussed in chapter 4, a proactive screening of all grandfathered industrial chemicals is a one-off response to a legacy issue and should, therefore, not be cost recovered for equity and efficiency reasons. Subsequent steps in NICNAS's existing chemicals review program are similar to the APVMA CRP program, and would continue to be cost recovered. The Commission considers, therefore, that a cost recovery arrangement for the CRP is warranted.

Registration costs — agricultural and veterinary chemicals

APVMA registration fees range between \$320 and \$48 860 (APVMA 2004b). Examination of overseas pesticide registration schemes suggests that APVMA fees are low by international standards (table 8.1).

Table 8.1 Registration fees for new pesticide products^a

Country	Registration fee
	\$A ^b
Australia	48 860
Canada	230 000
USA	360 000
UK	405 000

^a Typical registration fees for a complete evaluation and registration of a new product with a new active constituent. ^b Exchange rate as at 18 January 2008.

Sources: Agriculture and Agri-Food Canada (2006); APVMA (2004b); DEFRA (2007); US EPA (2007b).

Part of the observed differences can be explained by differences in cost-recovery arrangements. APVMA recovers 40 per cent of the product evaluation cost through the registration fees and the remainder through the industry levy (APVMA 2005)

(implying an average cost of a full assessment to APVMA of around \$120 000), whereas other countries recover the full assessment cost through the registration fees alone.

The Commission has not received any data from participants on the costs of data collection for registering a product with APVMA. However, given that APVMA's evaluations incorporate all aspects of NICNAS assessments and also impose additional testing requirements — such as to prove product efficacy — data costs could be expected to be even greater than for industrial chemicals assessments.

Timeliness of APVMA assessments

APVMA is required to finalise all agvet product evaluations within statutory timeframes. The timeframes consist of two components — a one-month timeframe for technical screening for application completeness and timeframes for completing the evaluation itself, which vary from 3 to 15 months, depending on the nature of the application. The statutory clock runs while APVMA is conducting the application screening and evaluation but is stopped while applicants respond to APVMA requests to remedy defects in their applications.

A number of industry groups (Croplife Australia, sub. 35; Veterinary Manufacturers and Distributors Association, sub. 48) have claimed that the timeliness of APVMA assessments were a problem.

A report by Business Decisions Limited (2007) prepared for Animal Health Alliance suggests that mandatory local testing of non-controversial animal health products by APVMA typically requires less time than the testing in Canada and Japan. Nevertheless, industry survey results presented in the report indicate that assessment times have increased over the last five years. Several reasons are listed including the introduction of additional safety and efficacy testing requirements and gaps in expertise or insufficient resources within APVMA.

An audit by ANAO (2006) found that in the period between 2001-02 and 2005-06, APVMA had failed to meet its statutory obligation to assess all pesticides and veterinary medicines within the statutory timeframes. The number of evaluations finalised within statutory timeframes was between 94–98 per cent for veterinary medicines, while for agricultural chemical products it declined from 95 per cent to 87 per cent. In addition, the average APVMA processing time for pesticide applications has more than doubled over that period.

However, several initiatives introduced by APVMA in the latter part of that period — including consolidation of application categories, greater use of modular

assessment categories and reduction or elimination of application requirements for some minor applications — allowed it to reverse the trend of declining performance against timeframes. In 2006-07, 90 per cent of pesticide applications (93 per cent for applications received after 1 July 2005) and 95 per cent of veterinary medicine applications were finalised within statutory timeframes (APVMA 2007a).

The greatest contributor to the delays in the overall application process was the time taken by applicants to remedy the various defects in their applications while the statutory clock was paused. On average, the APVMA processing time was around one-third of total elapsed time from application submission to registration. ANAO (2006) found that a large number of applications were deficient (74 per cent of pesticide and 76 per cent of veterinary medicine applications had at least one error or omission). It recommended that APVMA establish a framework for systematically analysing the types and causes of errors in applications to identify initiatives to improve the quality of applications.

APVMA has accepted that recommendation and has, consequently, established mechanisms for ongoing monitoring of errors and omissions in applications, and directed resources to the analysis of those errors.

The impact of registration costs on innovation and introduction of new products

The cost of registering an agvet chemical (including delays) may discourage innovation.

Australian patent application data (IP Australia 2006) show a 103 per cent increase in applications for pesticides between 1995 (when the NRS was established) and 2005, with an increase in pesticide applications as a proportion of total patent applications from 0.4 to 0.5 per cent. However, it is difficult to draw any meaningful conclusions from these data. The number of applications may have increased despite changes in compliance costs, and, as with industrial chemicals, the number of patents is an incomplete measure of innovation.

Animal health industry surveys undertaken by Business Decisions Limited (2007) for Animal Health Alliance suggest that Australian regulations governing the registration of veterinary medicines were seen as a barrier to innovation by 58 per cent of the firms. Contributing factors cited in the survey included high registration costs and research and development resources consumed while defending existing products. Survey results also suggested that the key reason for non-introduction of new chemicals was the cost of registration compared to the

small size of the Australian market. The problem is particularly acute in the case of agvet chemicals for specialty products (discussed below).

Barriers to entry of agvet products — the minor use issue

Agvet product suppliers make commercial decisions about introducing products based on the private benefits and costs. For some low-volume uses the registration and assessment costs (in particular, the costs of conducting the requisite testing) may be enough to outweigh the commercial benefits.

The Agvet Code provides for a minor use permit system with a permit fee of \$320. There are approximately 500 minor use permit applications per annum lodged with APVMA (with over 95 per cent of the applications succeeding) (MULO 2007). Even so, industry, DAFF and APVMA agree that there is a lack of approved crop protection products for minor uses, due to the costs of registration (MULO 2007; Horticulture Australia, sub. 49).

Several reforms are currently being developed to facilitate the registration of more minor use products. These include:

- development of assessment requirements that would utilise crop grouping and extrapolation from existing registered uses
- amending data protection legislation to provide protection for data used to register additional minor uses on existing products and to obtain permits. Currently data protection only applies to registration of new products
- enhancing international collaboration including development of equivalent zones for acceptance of international efficacy and residues data.

Further, in 2006, DAFF and APVMA established a Minor Use Liaison Office (MULO) to develop a long-term strategy for managing minor uses in Australia. MULO (MULO 2007; DAFF, sub. DR120, attachment 1) has suggested that there are several costs in not addressing the issue including:

- illegal use of pesticides registered for major uses, with potential adverse environmental, health and trade effects
- animosity towards regulators.

MULO proposed that a publicly-funded research and development program be established to promote the registration of minor use products. This would involve annual funding of \$3 million to fund the research and registration activity and \$1–1.5 million to fund its administrative operation.

The Commission supports efforts to address the minor use issue, provided they lead to a net public benefit (to this end, its preferred approach would have the features specified in box 4.2). Reforms that reduce the cost of registering minor uses such as crop grouping, extrapolation from existing uses and improving utilisation of international assessments would help in this context. The Commission also supports extending data protection to registering new uses on existing products and to permit applications, because it could provide an important incentive to industry. Croplife Australia (sub. 35) argued that inadequate data protection provisions were an important contributor to the minor use problem. The Commission can see no compelling reason for inconsistent treatment of new and existing products in product registrations, nor for different treatment of permit and registration applications in this respect.

With regard to the publicly-funded registration program, MULO claimed that the program would lead to health, environmental and trade benefits by reducing the incentive to resort to illegal use of other pesticides in the absence of registered minor use products. There may also be positive externalities associated with pesticide research under the MULO proposal. And, there may be a collective action issue for some specialty crop growers as claimed by APVMA (sub. DR105). However, these must be clearly articulated, and, where possible, quantified to determine whether such a substantial subsidy is warranted. Further, it is important that the case for this program is investigated against other policy options that could address the identified problems more directly and, potentially, more efficiently.

APVMA referred the Commission to an economic impact study of the US IR-4 program (Miller 2007). The IR-4 program is generally considered the most successful minor use subsidy program in the world in terms of numbers of registered minor use products, and the study showed that it had a significant positive economic impact. However, the Commission considers that the study is severely flawed and its conclusions can not be used to justify a similar program in Australia.⁷ Some participants (for example, HAL, sub. DR81) also referred to studies that showed a large commercial return on investment in pesticide research.

⁷ The study assumed that none of the research output of the IR-4 program would be provided privately if the program had not existed. The study also misattributed the impacts of other policies to the program. For example, it attributed the entire economic benefit of the provision for expedited approval of pesticides in emergencies to the IR-4, because IR-4 data is sometimes utilised in such assessments. In estimating the benefit of that provision, the study relied on untested claims by crops producers that applied for the emergency registrations. Finally, the study assumed the program funding represented an external injection into the economy that led to a multitude of direct and indirect benefits, rather than a relocation of funds from other, potentially more valuable, uses.

A large commercial return on investment is not a ground for government intervention. A publicly-funded registration program can only be justified if: there is a market failure; the program supports activity that would not have been privately undertaken; and the program leads to the greatest net benefit of all policy options. The Commission understands that MULO is currently conducting an economic analysis of the proposed program (DAFF, sub. DR120, attachment 1), and considers that the program should only proceed if it is supported by a comprehensive analysis of the costs and benefits that also evaluates other policy options.

How can the efficiency of assessments be improved?

APVMA arrangements for low regulatory concern chemicals

In addition to the standard registration path, amendments to the Agvet Code in 2003 provided for quicker and less costly alternatives to normal registration, where the product is deemed to impose a low risk to public health and the environment. Listed registration can be granted subject to compliance with a standard previously developed by APVMA for the product or class of products. In addition, products deemed very low risk can be approved for reservation, which exempts them from the requirement to be registered, provided their use is in accordance with particular conditions determined by APVMA (sub. 59).

These registration provisions have not worked to date. ANAO (2006) found that, as of July 2006, no products were registered under those categories. A substantial barrier to the operation of these provisions appeared to be the requirement to have Ministerial approval and the drafting of subordinate legislation for every new registration under the provisions. The problem has been recognised and a new system is currently being implemented, where standards for listed registration and conditions for reservation from registration will be approved by the APVMA Chief Executive Officer. The Commission supports this change and considers that the implementation should proceed as a matter of urgency.

Other APVMA initiatives to reduce assessment costs

APVMA has been consulting with industry on other cost-saving initiatives. Several are currently being considered in a range of areas, including:

- reducing elapsed time of applications — several projects are being considered, including a review of key registration processes, reduced technical screening, process mapping, changes to some permits, improvements in label approval processes, clock audits, flow charts of processes on APVMA's website,

improvements to application guidelines, and meetings with industry to improve the quality of applications

- reducing data requirements — investigating the potential for waiving some data requirements and for reducing chemistry data requirements
- improving performance of evaluators — providing training to APVMA staff and establishing a performance-monitoring framework for external evaluators
- self-assessment — investigating the scope for self-assessment of some aspects of applications by approved registrants under a quality-assurance scheme, including allowing applicants to complete efficacy testing by approved reviewers prior to submitting the application (Croplife Australia, sub. 35; APVMA, sub. 59)
- simplifying the label approval processes — reforms have been introduced that allow specified administrative changes to the product label without the need to apply to APVMA. APVMA (sub. 65) has argued for further change that would remove the requirement for registrants to apply for APVMA approvals for changes to labels that are outside of the scope of APVMA operations (such as poisons scheduling and dangerous goods classification).

The Commission strongly supports the above initiatives. In particular, the introduction of self-assessment options for approved applicants could result in significant benefits through improvements in assessment timeliness. The Commission also agrees that requiring registrants to apply for APVMA approval for label changes that are outside the scope of APVMA operations leads to unnecessary regulatory duplication. The Commission also supports initiatives to reform the current system, whereby the registrant would only be required to apply for approval of changes that require a risk assessment by APVMA.

Moving to performance based standards on labels

The Aerial Agricultural Association of Australia (AAAA, sub. DR108) claimed that a combination of a prescriptive approach to label directions and poor expertise within APVMA concerning pesticide drift issues has led the APVMA to approve label directions that encourage outdated practices and result in environmental and human health risk. The AAAA suggested that the APVMA should be given powers to approve performance based labels. The Commission understands that the APVMA is currently implementing a new spray drift policy that should address this concern for new products by introducing performance-based standards for achieving minimum spray quality. It is intended that labels for new products will allow the use of new technology provided there is no increase in risk levels. APVMA will maintain information on new application technology that has been assessed as leading to equal or lower health and environmental risk.

With regard to old labels, the APVMA is initiating a review program to assess the relevance of prescribed application methods and equipment and intends to progressively replace those labels with new performance based labels. In addition to this initiative, applications for off-label permits can be utilised by applicators using new application technology.

The AAAA also argued for an urgent establishment of an application reference group to provide industry expertise on pesticide application issues and observed that this has been promised by the APVMA for several years. The Commission supports the establishment of a consultative mechanism that would utilise existing industry expertise on pesticide application issues as a matter of priority.

Utilisation of international linkages

Acceptance of test data generated overseas

APVMA is given the power under s. 160 of the Agvet Code to take into account information generated overseas to the extent that the information is relevant. The Manual of Requirements and Guidelines specifies the standards to which the data must conform and these standards are typically internationally accepted (APVMA, sub. DR105). Currently, APVMA decides on whether to accept international test data on a case-by-case basis. APVMA suggested that it accepted data if it supported the claims made by the applicant for the use patterns proposed in Australia. Generally, the APVMA provisions governing the acceptance of international test data appear adequate.

Acceptance of aspects of risk assessments completed overseas

APVMA engages in several international harmonisation initiatives. For example, it is an observer in the Veterinary Medicines International Cooperation on Harmonisation program, and participates in OECD pesticide work-share projects (APVMA, sub. 59).

Nevertheless, there has been very limited progress to date in developing arrangements for incorporating aspects of completed international assessments into APVMA assessment processes. APVMA observed that there were some opportunities in using international risk assessments of human and environmental toxicology (sub. 59). However, with the exception of the OECD work-share project (which involves a very limited number of assessments), APVMA has not entered

into any formal bilateral agreements nor made any unilateral undertakings to consistently accept aspects of other countries' risk assessment reports.⁸

APVMA (sub. DR105) argued that international best practice entails acceptance of hazard-assessment reports, rather than risk assessments or subsequent risk-management decisions. It suggested that the relevance of international risk assessments is often limited because of the differences in proposed uses (and exposure patterns). It also observed that risk management is country specific due to societal differences in acceptance of risk, and claimed that no OECD country applied the principle of mutual recognition of registration decisions. However, there is mutual recognition of pesticide registration decisions by EU member states, provided it can be shown that the agricultural, plant health and environmental conditions relating to the use of the product are comparable in the regions concerned (DEFRA 2008).

The Commission considers that greater effort is warranted with regard to developing arrangements where some or all of the content of assessment reports from other countries (hazard assessments in particular) are deemed to satisfy APVMA requirements without the need to fully re-evaluate the supporting data.

8.3 The case for national regulation of agricultural and veterinary chemical use

Under the NRS, the responsibility for managing the risks of using agvet chemicals is shared between the APVMA and state and territory governments that control the use of agvet chemical products after retail sale. Several participants (for example, Croplife Australia, sub. 35; Aerial Agricultural Association of Australia, sub. 17) argued that this arrangement has worked poorly to date and supported replacing the state and territory control-of-use regulations with a single national regime. DAFF (sub. 39) and APVMA (sub. DR105) observed that the current regime has been operating since 1995 and it might now be appropriate to reconsider the current structure of the NRS. This section analyses the case for vertical integration of control-of-use regulation into national regulation.

⁸ APVMA has signed a number of memoranda of understanding with the relevant authorities in the United States, Canada, United Kingdom and New Zealand. However, these appear to be primarily aimed at improving international consistency.

What are the problems with the current control-of-use regulations?

State and territory control-of-use regulations are fragmented

The controls imposed on the use of agvet chemicals at a state and territory level are varied and complex. They include: licensing and training of chemical users; notification and record-keeping requirements for chemical spraying; administration of jurisdiction-specific codes of practice, policies and guidelines; as well as the monitoring and enforcement of the conditions of use imposed by APVMA as part of the registration of the product. The controls are typically spread over several generic and chemical-specific legislative instruments. For example, in New South Wales, Queensland and Western Australia, at least six pieces of primary legislation apply to the use of pesticides.

Various coordinating mechanisms have been utilised within each state and territory to address the issue. For example, in New South Wales formal interagency memoranda of understanding exist to define the relative responsibilities of different departments and reduce inconsistencies and duplication.

In Western Australia, a Pesticides Advisory Committee with membership from various state departments — the Department of Health, the Department of Environment and Conservation, WorkSafe, the Chemistry Centre, the Department of Food and Agriculture and the Department of Water — coordinates the approach on pesticide management. In a recent review of the pesticides regulation in Western Australia, the Pesticides Advisory Committee recommended that a comprehensive code of practice on pesticide use be developed and referenced by the various relevant pieces of legislation (WA Department of Health 2006).

Nevertheless, several participants (for example, Growcom, sub. 12; Croplife Australia, sub. 35) argued that the regulatory fragmentation at state and territory level led to stakeholder confusion and duplication of regulatory burden (although little evidence on the resulting costs to industry and government was provided). DAFF (sub. 39, p. 11) also observed generally that ‘cross-portfolio overlap and duplication of regulatory requirements at state/territory level appear to be the area where greatest concern rests, particularly for users’.

State and territory regulations are inconsistent

There are significant differences in the regulatory approaches across Australia, including in those relating to enforcing APVMA requirements (table 8.2).

Some jurisdictions (for example, New South Wales and Western Australia) have adopted a prescriptive interpretation of APVMA conditions, while others (for example, Victoria) have favoured a performance-based approach that allows some diversion from product label requirements.

Table 8.2 Major differences between state and territory regulations on pesticide use

<i>Controls</i>		<i>NSW</i>	<i>Vic</i>	<i>Qld</i>	<i>WA</i>	<i>SA</i>	<i>Tas</i>	<i>NT</i>	<i>ACT</i>
Rates of application	Lower rate than on label	Yes	Yes ^a	Yes ^b	No	Yes	Yes	Yes	No
	Lower frequency than on label	Yes	Yes ^a	Yes ^b	No	Yes	Yes	Yes	No
	Higher frequency or rate than on label	No	No	No	No	No	No	No	No
Pests	Different pest than on label	No	Yes ^a	Yes ^b	No	Yes	Yes	Yes	No
Crops and situations	Different crop or situation than on label	No	Yes ^a	No	No	No	No	No	No
Application equipment	Different application equipment than on label	No	Yes ^a	Yes ^b	No	na	No	No	No
Record keeping	Records of use must be maintained	Yes	Yes ^d	Yes	Yes ^f	Yes ^h	Yes ⁱ	No	No
Training and licensing of users	General user training required	Yes	Yes ^d	No	No	Yes ^d	No	No	Yes ^h
	Commercial applicators licensing required	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Neighbour notification	Required for general pesticide use	No	No	Yes ^e	No	No	No	No	Yes ^j
	Required for vertebrate poisons	Yes ^c	No	Yes	Yes	Yes ^g	Yes ^g	No	Yes ^e

^a Subject to some conditions and restrictions. ^b Unless the label explicitly prohibits such use. ^c Only if specified in a control order. ^d Schedule 7 poisons and restricted chemical products only. ^e Only if required by label. ^f Aerial application only. ^g Only for 1080. ^h Only for commercial operators. ⁱ Only for commercial and occupational uses. ^j Only for schedule 7 poisons. **na** Not available.

Source: Croplife Australia (sub. 35).

There are also significant differences in licensing and training requirements imposed on pesticide applicators. One clear example is the aerial application of pesticides, which is currently subject to inconsistent requirements in different states and territories (box 8.2).

Box 8.2 State and territory inconsistencies in regulating aerial pesticide applicators

- All jurisdictions except Western Australia recognise Spraysafe pilot training (an industry-run training and accreditation program) for issuing a chemical distribution licence. New South Wales does not recognise the Spraysafe program for accreditation of aerial spray mixers.
- Licensing fees and the scope of licences vary between jurisdictions.
- All jurisdictions except Queensland and South Australia require aerial operators to obtain insurance for spray-drift damage.
- Record-keeping requirements differ between jurisdictions.

Sources: Aerial Agricultural Association of Australia (sub. 17); Croplife Australia (sub. 35).

In addition to the differences in the content of state and territory regulations, there is variability in compliance monitoring and enforcement effort. Croplife Australia observed:

A major concern of CropLife members is ... state and territory enforcement of state control-of-use legislation. Some jurisdictions admit to inadequate resources, particularly inspectorate/compliance staff, for enforcement of broad industry compliance. Questions of inadequate staff expertise and program priority arise in states where agricultural chemicals are regulated by a department other than agriculture/primary industries. (sub. 35, p. 9)

Similarly, DAFF acknowledged:

User and manufacturer concerns that state/territory enforcement of compliance with COU [control-of-use] regulations is inconsistent and inadequate have been made known to PSIC at stakeholder workshops in recent years. (sub. 39, p. 9)

Why move to a national control-of-use regime?

Past and current attempts to harmonise state and territory regulations have failed

Several participants (for example, NSW Government, sub. DR111; SA Government, sub. DR110) suggested that harmonisation of control-of-use regimes could be effectively pursued while retaining the current division of responsibilities under the NRS. However, past experience doesn't support this claim.

A report by AATSE (2002) analysed state and territory control-of-use regulations and detailed several unsuccessful attempts (dating from the establishment of the NRS) to harmonise them. These included: state and territory undertakings to

harmonise regulations arising out of various National Competition Policy reviews; establishment of an Agricultural and Veterinary Chemicals Policy Committee working group in 1996 to develop a common approach to off-label use; and appointment in 2000 of a control-of-use taskforce under the Agriculture and Resource Management Council of Australia and New Zealand.

More recently, an Allen Consulting Group report (2002) prepared for the Board of the APVMA proposed two reform options for harmonising control-of-use regulations. These involved either integration of all registration and control-of-use functions under a single agency, or development of National Operating Principles of the NRS, incorporating an undertaking by states and territories to achieve consistent risk management outcomes. Allen's preferred option, of the integration of all regulatory functions within a single agency, was subsequently rejected in favour of the National Operating Principles approach.

The introduction of National Operating Principles meant that, with PSIC and the Registration Liaison Committee, there are currently three mechanisms in the NRS for promoting consistent approaches to control of agvet chemical use. However, there is general agreement that these mechanisms have struggled to meet this objective.

AATSE (2002) concluded that regulatory variability was often a function of different approaches to risk management between jurisdictions. DAFF (sub. 39) identified a number of barriers to harmonising control-of-use regulations under the current regulatory arrangements:

- difficulty in achieving agreement on policy approaches, particularly when different portfolios with different approaches to risk are involved
- different jurisdictions having different priorities and political imperatives, affecting the level of resources directed towards agvet-chemical work
- periodic reviews of legislation undertaken by states and territories individually, rather than through PSIC, leading to inconsistencies.

The history of unsuccessful attempts to harmonise state and territory regulations indicates that a change in the structure of the NRS through a move to a single nationally-uniform control-of-use regime should again be considered.

Benefits from improved consistency

Establishing a national control-of-use regime would likely lead to improved overall effectiveness of the NRS in achieving consistent risk management outcomes across

Australia, particularly if all of the complementary instruments utilised by current control-of-use regimes were vertically integrated.

The greatest benefits are likely to come from having a uniform approach to off-label use of chemicals. Inconsistent implementation of the APVMA product label conditions by state and territory regimes can lead to several costs:⁹

- The effectiveness of APVMA in providing a uniform national system for registration and use of agvet chemical products is compromised.
- The relevance of APVMA's risk assessments is reduced as those assessments typically focus only on the uses permitted on the label. This could, potentially reduce the overall effectiveness of the risk management regime.
- The incentive for product registrants to undergo the full assessment and registration process for new uses is undermined (Croplife Australia, sub. 35). This might particularly affect the decision to add minor uses to an application.
- There may be anticompetitive effects. Ausveg (sub. 52) suggested that the latter issue was particularly significant for specialty crop producers, because they had limited registered pest-control options and allowing off-label use by some producers provided them with a significant competitive advantage.
- There is potential for confusion for users that operate in multiple jurisdictions and for pesticide suppliers advising customers, leading to poor compliance.

Another area where national consistency could deliver significant benefits is in licensing and training requirements. PSIC has identified user awareness and training as a key determinant of the risk of agvet products (DAFF, sub. 39). Similarly, the control-of-use component of the National Operating Principles also places a strong emphasis on user training and licensing. A nationally-consistent training and licensing regime is likely to contribute significantly to achieving consistent risk-management outcomes. It would also lead to cost-savings for product users operating in multiple jurisdictions (such as aerial applicators), and could have competition benefits. Finally, to the extent that a national training and licensing regime would overcome the problem of inconsistent state and territory implementation of industry initiatives (such as the various training and accreditation courses developed by the AAAA), it could encourage greater industry involvement and lead to greater utilisation of industry expertise.

⁹ It does not follow however, that the preferred approach is a blanket prohibition on all off-label uses, as suggested by Croplife Australia (sub. 35). Allowing some off-label uses may be a low-risk way of reducing the costs of some agvet chemical users. PSIC recognised some off-label uses as falling in this category including: use on an unspecified pest on a registered crop; use at a lower rate or frequency of application; and use on a crop and pest combination registered in another jurisdiction (WA Department of Health 2006).

In addition to improving regulatory consistency between states and territories, a single national control-of-use regime would consolidate the regulatory requirements applying to agvet chemical use. This could address some of the current intrastate fragmentation, duplication and inconsistency of regulations applying to agvet chemicals.

Cost savings in policy development

A national control-of-use regime could also improve efficiency through cost savings in policy development and implementation. Some states provided the Commission with estimates of the costs to governments of regulating agvet chemicals. For example, in Victoria these costs are around \$2.9 million per annum (Victorian Department of Premier and Cabinet, pers. comm., 15 January 2008); in South Australia — \$900 000 per annum (SA Government, sub. 56); and in Tasmania — \$750 000 per annum (Tasmanian Department of Premier and Cabinet, pers. comm., 30 January 2008). An extrapolation of these figures suggests that the aggregate Australian cost of regulating the use of agvet chemicals after retail sale is of the order of \$10 million. This estimate is an aggregate of the costs of policy development (which could be rationalised under a national regime) and administration (where the opportunities for consolidation are much smaller, because monitoring and enforcement of compliance would still need to be undertaken at the local level). Further, the establishment of a national control-of-use regime would involve some set-up costs in the short run. Thus, while a national control-of-use regime is likely to lead to cost savings in policy development and implementation in the long run, the extent and timing of accrual of those savings is unclear.

The Commission supports vertical integration of agvet chemical control-of-use regimes into a national regime. This would improve consistency in risk-management outcomes, reduce interstate competition distortions and would likely increase the net community benefit of agvet chemical regulation.

Implementation issues

While there are likely to be benefits in moving to a national regime, there are also some implementation issues.

Conferral of power on the APVMA

As discussed earlier, the APVMA derives its current powers to regulate the supply of agvet chemicals from a conferral of powers on the Commonwealth by state and territory governments under an IGA. The conferral was required to overcome the

constitutional restrictions preventing the Commonwealth from regulating the supply of chemicals. Vertical integration of control-of-use regulations would involve an increase in the scope of APVMA responsibilities and powers. Thus, a new agreement would need to be negotiated by the Commonwealth, state and territory governments conferring additional powers on the APVMA and specifying the new division of regulatory responsibilities.

Administrative arrangements for the new regime

Consistent with its preferred institutional framework, the Commission considers that the states and territories should retain involvement in the policy development for the new regime via their representation on the PIMC and PSIC. Further, the new regime may be best administered at the state and territory level under service level agreements with the APVMA. This approach would utilise existing local expertise in managing on-the-ground risks of agvet chemical use, as well as provide for greater responsiveness to emergencies.

Care would be needed to ensure that boundaries between a national control-of-use regime and state regulations are clearly defined. As discussed earlier, the legislation that currently governs the use of agvet chemicals at a state and territory level covers a broad range of areas including environmental protection, OHS and public health. Some of that regulation has generic, rather than agvet chemical-specific, objectives. Horticulture Australia argued:

To regulate control of use via the Agvet Code, presumably through the APVMA would ... potentially lead to a significant duplication of regulatory activity, e.g., State environmental controls cover a range of human activities not just pesticide use, whereas an Agvet Code based approach would focus solely on pesticides. Such a separation could conceivably result in confusion where the cause of an environmental incident is uncertain, i.e., who has jurisdictional authority. (sub. 49, p. 2)

However, most of these boundary issues appear to be existing problems. In the above example, it is likely that more than one agency would be involved already, including the environment department and the department of primary industry. Given that on-the-ground administration of a national code would be best delivered by statutory agencies under a service-level agreement, this situation would not change. Thus, the issue would need to be addressed via intrastate coordinating mechanisms.

The need to retain flexibility

One drawback of establishing a single national regime would be if this led to some loss of flexibility in addressing local issues. Several participants suggested that

some variability between states and territories would always be warranted due to the differences in geography, climate and primary industry structure. The NSW Government argued:

States and territories will always need some flexibility to vary regulatory requirements to meet local needs ... A state should not be required to remove a product use restriction or regulation provision solely for the purposes of harmonisation, where these have been judged necessary to manage the community's real or perceived view of risk in that state. (sub. 31, p. 20)

Consequently several participants (for example, Victorian Government, sub. DR112) suggested a single national regime would need to include exemption provisions to allow states and territories to respond to local circumstances.

However, much of the need for flexibility derives from differences in environments that do not correspond to state and territory borders and would, therefore, not justify retaining jurisdiction-specific regulatory approaches. Croplife Australia argued that regions with similar agricultural conditions often spread across borders and that different climatic conditions existed within jurisdictions (sub. DR80). In addition, the Agvet Code contains provisions for addressing the variability between regions. Product label instructions are already required to account for the climatic and geographic conditions associated with product use in different regions. Further, the permit provisions of the Code allow APVMA to approve off-label and emergency uses. Finally, several participants argued that incorporating significant exemptions into the new regime would compromise the purpose of establishing a single national regime.

Thus, on balance, the Commission agrees that introducing substantial additional exemption provisions into the national control-of-use regime is undesirable. The onus should be on the states and territories to justify the need for incorporating any new exemptions into the regime, taking into account the potential costs of reduced inter-jurisdictional consistency.

Funding arrangements

Currently, control-of-use regulation of agvet chemicals is funded by states and territories largely from consolidated revenue. As estimated earlier, this cost appears to be roughly of the order of \$10 million. Expenditure on a national regime may need to increase if an evaluation of the existing arrangements for monitoring and compliance enforcement finds them to be insufficient for appropriate management of the risks. On the other hand, as suggested earlier, consolidation of existing regimes could lead to some cost savings. Also, some of the regulatory costs could be expected to be recovered via licensing charges on chemical users. For example in

Victoria, over \$200 000 per annum would be recovered via chemical user licence fees.¹⁰ Nevertheless, moving the responsibility for the control-of-use regime to the APVMA (including the responsibility for funding the state and territory administration of the regime through service level agreements) is likely to require a net increase in the funding of the agency.

There are two options for funding the additional costs: cost recovery or budget funding. Several participants (for example, Croplife Australia, sub. 35, sub. DR80; PACIA, sub. DR101) argued in favour of a budget-funded control-of-use regime. The following points were raised in support of this position:

- APVMA in its current form as an assessment and registration agency does not have the legal authority to impose charges for control-of-use regulations.
- Cost recovery would lead to inefficiencies because it would increase the cost of manufacturing and supplying agvet chemicals.
- Control-of-use regimes lead to public benefits rather than private benefits that accrue to product registrants and thus should be budget funded for equity reasons.
- The links between agvet chemical manufacture or supply and adverse effects on human health and environment are often tenuous. Other factors, such as user training, condition of equipment used to apply the product, and use of the product in accordance with instructions frequently play a decisive role.

In responding to these comments, the Commission considers:

- If a national regime were established, a conferral of regulatory responsibility for control of use on APVMA would be required and this would give it the legal authority to raise the requisite funds.
- A potential increase in the costs of manufacturing agvet products does not of itself constitute an economic inefficiency as defined in chapter 2, nor as referred to in the Australian Government Cost Recovery Guidelines (DOFA 2005a). An increase in the cost may be efficient, if it creates an improved signal of the true cost to the community of using a particular product.
- The Commission does not consider that from an equity perspective the outcomes of control-of-use regimes should be perceived as a public benefit. Control-of-use regimes are in place to manage the adverse impacts of the use of pesticides and their outcomes are more appropriately described as a reduction in the negative externalities of pesticides. Further, as observed by Croplife Australia (sub. 35),

¹⁰ Estimate based on the number of licensed commercial and non-commercial ground operators and aerial applicators (DPI 2007) and the relevant annual licence fees. The estimate does not include receipts from permit fees for off-label use of restricted chemical products.

in the absence of effective control-of-use regulations, the APVMA may be required to set significantly more restrictive assessment and registration requirements and, potentially, withdraw some products from the market. Thus, it could be argued that control-of-use regulations might create some benefit to agvet product manufacturers.

- To be efficient and equitable, cost recovery arrangements should be as closely linked to the activities generating the need for regulation as is practicable to do so. In this context, a mix of user charges and sales levies differentiated according to product risk may be appropriate. The Agvet Code already provides for recognising low concern products (under listed and reserved categories) and high risk products (under the restricted category). Those categories could form the basis for this tiered approach to cost recovery.

The Australian Government Cost Recovery Guidelines (DOFA 2005a) suggest that a control-of-use regime should be subject to cost recovery, provided budget funding is not more efficient, cost effective and more consistent with policy objectives. The Commission can see no inconsistency between the policy objectives of the control-of-use regime and cost recovery of the regulatory costs. With regard to cost effectiveness, mechanisms such as the product sales levy and user licensing fees already exist to recover part of the cost of administering the NRS. Resetting those mechanisms to reflect the full cost of the regime is unlikely to have significant cost-effectiveness implications.

The Commission acknowledges that the new regime could lead to a significant change to current funding arrangements. In view of that, it would support a phased introduction of the cost-recovery arrangements.

RECOMMENDATION 8.2

The Australian Pesticides and Veterinary Medicines Authority (APVMA) should regulate the use of agricultural and veterinary chemical products after the point of retail sale through amendments to the Agvet Code:

- ***The scope of the new control-of-use regime should be negotiated through the Primary Industries Ministerial Council, and should include, at a minimum, uniform approaches to enforcing conditions of use on product labels and to the licensing and training of users.***
- ***The Commonwealth, state and territory governments should renegotiate the intergovernmental agreement to confer the necessary powers on the Commonwealth, and develop service level agreements for the regime to be delivered by the states and territories.***
- ***The APVMA should recover additional costs through a mix of charges and levies.***