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## 4 National hazard and risk assessment

### Key points

- Government involvement in hazard and risk assessment is warranted due to the information failures and public good nature of the information.
- The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) focuses on the assessment of hazards and risks of industrial chemicals, primarily producing recommendations to risk management standard-setting bodies.
- NICNAS has some regulatory powers to manage chemical risks, however it is recommended that these generally be transferred to other bodies to allow NICNAS to focus on chemical assessments.
- The internal governance structures of NICNAS could be strengthened with the introduction of a statutory advisory body to support its Director.
- The effectiveness of NICNAS assessments is limited given that the majority of currently used industrial chemicals have been grandfathered onto the scheme without prior assessment. Review of those chemicals has proceeded slowly to date and needs to be accelerated.
- The efficiency of NICNAS assessments could be improved through better arrangements for low regulatory concern chemicals; greater utilisation of modelling; and greater reliance on international assessment data.
- There may be gains in harmonising the assessment regimes via introducing a coordinating mechanism and consolidating common aspects of assessments.

The hazard and risk assessment of chemicals is one step in the regulation of their use in the workplace, their consumption by humans and animals, and their disposal or escape into the environment (discussed in following chapters). Only after the hazards have been identified and an assessment made of the likely risks, can appropriate risk-management decisions be taken for individual chemicals within agreed standards.

Two chemical assessment schemes — one applying to industrial chemicals and the other to agricultural and veterinary (agvet) chemicals — fall within the scope of this study. However, of these schemes, only the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is a standalone chemical assessment scheme. Agvet chemical product assessment and registration is part of a dedicated, vertically-integrated regulatory regime that manages the risks of agvet

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chemicals. The primary focus of this chapter is on issues pertaining to the operation of NICNAS. The chapter also discusses the potential for future consolidation of chemical hazard and risk assessment functions within a single agency. Issues that are specific to assessment of agvet chemicals are discussed in the broader context of agvet chemicals regulation in chapter 8.

## **4.1 The case for regulatory assessment of chemicals**

There is a number of reasons why government involvement in the hazard and risk assessment process may be appropriate.

First, there can be information failures. Much of the information needed to assess the possible risks posed by particular chemicals is held by chemical producers. These firms will have some knowledge of the hazards but will have only limited incentives to make this information available, or to more fully assess the risks to third parties of using the chemical. Hence, regulation to elicit information may be justified.

Even if full disclosure of information occurs, chemical risk assessment is also often highly technical in nature and not readily understood by many individuals or firms. Even presented with the raw data or hazards, few would be able to translate this into an appropriate risk management strategy. Hence, interpretation of the implications of this information by assessment agencies and standard-setting bodies, or other regulatory agencies, can be justified.

Second, there can be a public-good element to information provision. The appropriate level of private provision of chemical assessments would be difficult to achieve because of the cost and difficulty of charging the large number of individuals and firms who might benefit from it and of quarantining the information to those who had paid for it. Because the benefits of the assessment information are related to the extent to which it is disseminated, assessment agencies typically make this information freely available, except where there may be confidentiality concerns.

Third, independent government provision of this service or auditing of third-party assessment service providers helps ensure the integrity of the assessments, and provides a safeguard for the public interest.

While these arguments provide a basis for some form of regulatory intervention, regulatory agencies are still able to make use of market mechanisms or private sector involvement to improve the efficiency of the process — for example, parts of the assessment might be contracted out.

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There are advantages in having the chemical assessments undertaken at the national rather than jurisdictional level. There are significant resource savings in having a single national assessment available to all jurisdictions and indeed international scale economies in assessments are arising from the increased cooperation between hazard-assessment bodies in different countries. A single national body can also better use the limited supply of technical expertise needed to undertake assessments and further develop that expertise. A national approach also avoids the costs to suppliers and users of different assessments in individual jurisdictions.

## 4.2 Regulatory arrangements for industrial chemicals

### Scope

Under the *Industrial Chemicals (Notification And Assessment) Act 1989* (Cwlth) (ICNA Act), an industrial chemical is any chemical that has an industrial use. This includes specialty chemicals, dyes, solvents, adhesives, plastics, laboratory chemicals, chemicals used in mineral and petroleum processing, refrigeration, printing and photocopying, paints and coatings, as well as chemicals used in the home, such as cleaning products, cosmetics and toiletries.

Reflecting this broad scope, NICNAS defines industrial chemicals by the exclusion of other types of chemicals. Chemicals that are used solely as therapeutic agents, agricultural and/or veterinary chemicals, and/or food or food additives are subject to regulation by other bodies and are outside the scope of NICNAS. If the chemical that is being imported and/or manufactured does not fit solely into one of these categories, then notification to NICNAS may be required.

### Institutional arrangements

NICNAS is a statutory scheme within the portfolio of the Minister for Health and Ageing. The Director of NICNAS is a statutory office holder with specific functions and powers under the ICNA Act. In the exercise of these functions, the Director is responsible to the Minister for Health and Ageing through the Parliamentary Secretary.

NICNAS's legislative role and responsibilities are focused on the scientific assessment of chemical risk to public health, occupational health and safety (OHS), and the environment. NICNAS then makes recommendations for controlling these risks at each stage of the life cycle of each chemical. NICNAS also has some power to regulate the use of new industrial chemicals via its mandate to prescribe

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conditions of use for permits. In addition, the Director of NICNAS has the power to annotate particular conditions of use on the Australian Inventory of Chemical Substances (AICS), which has the effect of requiring a new assessment for uses that are outside those permitted. NICNAS also has a regulatory power in administering the Cosmetics Standard 2007 — a schedule to the ICNA Act that imposes labelling requirements on cosmetics manufacturers and importers (chapter 5). Finally, NICNAS is responsible for implementing Australia's obligations under two international treaties — the Stockholm Convention and the Rotterdam Convention.

NICNAS does not specifically register chemicals or products, in the sense that it can not prohibit their introduction after assessment. This is in contrast to the other national chemicals schemes, such as those that regulate agvet chemicals and medicines and medicinal products, all of which have a product registration function. NICNAS also does not have legislative powers to directly ban, or phase out chemicals. Instead, NICNAS can make recommendations to other regulatory authorities for such action.

## **Funding**

NICNAS operates on cost-recovery principles and is principally funded via company registration fees, and fees and administration charges for new assessments. In 2006-07, total revenue amounted to \$8.6 million. Around \$5.9 million (69 per cent of total revenue) was collected via company registration fees, with most of the remainder collected via chemical assessment fees (DOHA 2007a).

## **Assessment of new chemicals**

Chemicals currently available for use in Australia are listed on the AICS (box 4.1). The AICS is the legal device that distinguishes new from existing industrial chemicals and determines whether an industrial chemical can be used commercially in Australia.<sup>1</sup>

All new (to Australia) industrial chemicals must be notified to NICNAS for scientific risk assessment. Some aspects of the assessments (for example, OHS) are undertaken within NICNAS. NICNAS also contracts assessment work to other Australian Government agencies, such as the Department of the Environment,

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<sup>1</sup> The AICS is not the exclusive legal device that allows the introduction of chemicals — AICS listing typically only occurs five years after assessment and during that period assessment certificates are the instrument that allows the manufacturer or supplier to introduce the chemical

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Water, Heritage and the Arts (DEWHA) (for environmental assessments) and the Department of Health and Ageing (for public health assessments, where there is likely to be any public exposure to industrial chemicals).

At the end of the assessment, NICNAS produces a report containing OHS, health and environment protection recommendations, and issues an assessment certificate, which allows the chemical to be imported into or manufactured in Australia.

## Permits

NICNAS has powers to issue permits for the introduction of chemicals that have not undergone a full notification and assessment process. Permits can be issued in a number of circumstances, including: for low-volume uses; for commercial evaluation; and for early introduction while the assessment is being completed. NICNAS has powers to set conditions on permits.

## Assessment of existing chemicals

Upon the establishment of NICNAS in 1990, all chemicals in commercial use in Australia were transferred (or grandfathered) onto the AICS (box 4.1).

### Box 4.1 The Australian Inventory of Chemical Substances

The Australian Inventory of Chemical Substances (AICS) lists the industrial chemicals that are currently available for use in Australia. It is therefore used to distinguish 'new' from 'existing' industrial chemicals — that is, chemicals not on the AICS are deemed new chemicals.

Some chemicals may only be available for specific or conditional use and this is detailed in the AICS. The AICS is a list of chemical identity data and does not contain information on toxicity, manufacturers or importers. In some instances, however, the AICS does identify the classification of a chemical under another national scheme.

When the AICS was established, all industrial chemicals already in commercial use in Australia from 1 January 1977 to 28 February 1990 were included as 'grandfathered' chemicals. This included approximately 36 000 non-confidential chemicals, with 2500 in the Trade Name section and 1000 in the Confidential section. Additional (eligible) chemicals were added during a two-year amnesty from 1993 to 1995. Since 1990, there have been approximately 2000 new chemicals added to the AICS after NICNAS assessments.

*Sources:* DOHA (2004b); NICNAS (sub. 36).

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Relatively few of these chemicals have been subsequently assessed. This means that most of the chemicals in use in Australia remain unassessed, or not fully assessed, for their health and environmental risks.

A formal process has been established to identify and assess Priority Existing Chemicals (PEC). A chemical on the AICS may be nominated for inclusion on the PEC list by anyone concerned about its impacts on human health or the environment. NICNAS assesses all nominated chemicals against a set of criteria to determine whether the concerns are sufficient to declare a chemical a priority existing chemical.

### **NICNAS (company) registration**

From 1 September 2004, all importers and/or manufacturers of industrial chemicals for commercial purposes must register with NICNAS. Registration involves payment of an annual registration fee, based on the total value of industrial chemicals imported/manufactured each year.

### **Interface with other national schemes**

The NICNAS industrial chemical assessments and recommendations inform a number of national regulatory frameworks that are currently in place in Australia. These include:

- national model regulations and codes developed by the Australian Safety and Compensation Council for the control of workplace hazardous substances, and for storage and handling of dangerous goods
- the national code for land transport of dangerous goods, as developed by the National Transport Commission
- National Drugs and Poisons Scheduling Committee decisions.

### **Interface with state government regulators**

While NICNAS recommendations are advisory in nature, a memorandum of understanding (MOU) was signed in 1991 between the Commonwealth, state and territory governments, requiring each state and territory:

... to consider and wherever possible implement each recommendation in an assessment report published by the Director of NICNAS and to inform the Director of any consequential action taken in respect of any recommendations. (DOHA 2003a, p. 96)

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The States and Territories Memorandum of Understanding Group has been set up to act as a conduit for the free flow of information between the states and territories and NICNAS on OHS, environmental and health matters relating to the use of chemicals in Australia (DOHA 2006b). In all cases, states and territories have nominated OHS agencies to this group (NICNAS, sub. 36).

### **4.3 Effectiveness and efficiency of industrial chemicals assessment**

#### **Clarifying the objectives — recognition of effectiveness and efficiency principles**

As discussed earlier (chapter 2), regulatory intervention should address market failures to the extent that doing so provides a net community benefit. NICNAS operations impose costs (such as the various requirements to be met by notifiers of new chemicals) and generate benefits to the public (through contributing to the risk management of industrial chemicals). However, there is no formal obligation on NICNAS to perform its functions in a manner that maximises net community benefit.<sup>2</sup> Without such an obligation there is a risk that NICNAS might not focus its risk assessment activity appropriately, and might become unduly risk averse in the way it conducts risk assessments and the demands it places on notifiers.

NICNAS argued that it already aimed to achieve a community benefit when setting its assessment requirements:

In undertaking its risk assessment functions, NICNAS aims for the risk assessment effort to be commensurate with the hazard and/or exposure to the chemical, where this can be defined sufficiently in advance of the assessment. The reforms that have been progressively introduced into NICNAS's notification and assessment framework have sought to further this objective. (sub. DR106, p. 2)

The Commission accepts that some worthwhile improvements have been made in the design and administration of the scheme, which have had the effect of more appropriately balancing the costs of assessment with the benefits of reducing the risks posed by industrial chemicals. But in some cases, such as the administration of chemicals of low regulatory concern, elements of undue risk aversion are creeping back into the system. Further, the large backlog of unassessed existing chemicals raises questions of whether the scheme has been appropriately prioritising its

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<sup>2</sup> Currently, the legislated objectives of NICNAS are to maintain a national chemical assessment scheme to protect human health and the environment, and to perform a range of assessment, information provision and regulatory functions.

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resources and assessment effort to effectively manage aggregate chemical risk. (These issues are discussed later in the chapter.) However well the current administration might be achieving its stated aims, NICNAS lacks the explicit statutory basis to make this focus an ongoing feature of assessment.

A broad framework for an effective and efficient assessment regime should consist of the following complementary objectives:

- ensuring that the requirements of the scheme seek to reduce chemical risks to levels acceptable to the community
- ensuring that assessment effort is prioritised to most effectively manage the aggregate risk of all chemicals
- ensuring that the objectives of the scheme are achieved at the lowest cost to the community (box 4.2).

**Box 4.2      Features of an effective and efficient chemical assessment scheme**

- The requirements of the scheme should be set to reduce overall chemical risks to levels acceptable to the community, taking into account the associated costs and benefits.
  - At a minimum there should be recognition that zero risk is very costly to achieve and that there are tradeoffs (including between different risks) involved in reducing a particular risk.
  - The value imputed to accepted risk should be broadly consistent with other regulations that seek to address similar objectives. (This is because if a particular risk can be reduced at a lower cost to the community under a different scheme, resources should be shifted to that scheme.)
- Assessment effort associated with particular chemicals should be commensurate to their *relative* risk.
  - The assessment agency should have provisions for prioritising the allocation of its scarce resources on the basis of chemical risk. The administrative resources should be allocated in a way that minimises the aggregate risk of all chemicals irrespective of their status as new or grandfathered.
  - The assessment requirements should be calibrated in a way that minimises biases against the introduction of safer alternatives by manufacturers/importers.

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**Box 4.2** (continued)

- The assessment scheme should operate cost effectively.
  - The cost to the assessment agency of conducting the assessments should be minimised through choice of assessment methodology, as well as appropriate performance monitoring and review.
  - Unnecessary data requirements on introducers of chemicals should be eliminated.
  - Duplication with other national and international assessments should be minimised.
  - Licensing controls that complement or substitute the assessment should achieve their risk-management objectives at the lowest aggregate compliance and administrative cost.

The Commission considers that, as a matter of principle, there should be a formal obligation on NICNAS to ensure that the requirements of the scheme are commensurate with the chemical risks and that its assessment effort is directed to most effectively managing the aggregate risk of all chemicals. Recognition of the above objectives would be a useful starting point in improving the effectiveness and efficiency of NICNAS.

RECOMMENDATION 4.1

***The Australian Government should impose a statutory obligation on NICNAS 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 industrial chemicals.***

## **Improving governance structures**

Good governance requires that the relationships between the agency performing the hazard and risk assessments and the relevant policy and standard-setting bodies are clearly defined and underpinned by appropriate consultation and coordination mechanisms.

NICNAS's external governance arrangements are broadly consistent with its functions as an assessment agency in that its Director is accountable to the Parliamentary Secretary to the Minister for Health and Ageing for the overall legislative and financial performance of NICNAS. If it were to retain or be given

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greater powers over the control of use of chemicals it would be more appropriate to provide oversight through an interjurisdictional body. However, the Commission has concluded that NICNAS should be, for the most part, confined to assessment (discussed below), and, therefore, the current external governance arrangements are considered to be sound.

On the other hand, there are grounds to strengthen the internal governance structures. Currently, two non-statutory bodies — the Community Engagement Forum and the Industry Government Consultative Committee — provide for some consultation with stakeholders. However, there is currently no statutory requirement for an expert consultative body — similar to the advisory board of the Australian Pesticides and Veterinary Medicines Authority (APVMA) (chapter 8) and consistent with the Australian Government’s response to the implementation of the Uhrig reforms to corporate governance (chapter 3) — to advise the NICNAS Director. Even though the Commission recommends that NICNAS functions be limited to assessment, it considers that there are still sufficient grounds for introducing such a statutory requirement. Without such support there is the risk that NICNAS would be more risk averse than it should. Formalising and strengthening the current consultative mechanisms established administratively by its Director should help NICNAS operate in a more strategic manner.

#### RECOMMENDATION 4.2

***The Australian Government should establish a technical advisory committee within NICNAS, as a statutory requirement.***

## **Scope of NICNAS**

### *Separation of risk assessment and risk management functions*

As discussed earlier, NICNAS currently has a combination of chemical assessment and standard-setting functions. The Commission’s preferred institutional approach to the regulation of chemicals involves a separation of the four components of the regulatory task (chapter 3). Thus, industrial chemical hazard and risk assessments should ideally be performed by a dedicated technical expert agency, separately from the subsequent standard setting needed to manage the risks of those chemicals. The case for separation of assessment from standard setting is particularly strong for industrial chemicals because they are used in a variety of ways, and the standard setting would be more appropriately handled by bodies expert in the field.

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NICNAS has already undergone some organisational change after a decision was made to separate it from the Office of Chemical Safety (OCS) — an agency with policy-making and other functions in industrial chemicals (DOHA 2007a).

Further functional separation is warranted and may be relatively easy to achieve. NICNAS is already primarily a chemical assessment body with limited regulatory powers. Limiting NICNAS's regulatory powers to those necessary to undertake the assessment function need not have a significant effect on the management of chemical risks.

Of particular concern to the Commission is NICNAS's power to annotate the AICS to restrict or phase out the use of chemicals. While this has been rarely used since its inception, and is a rather clumsy and limited way of setting controls on the use of chemicals, it has the potential to be used more frequently in the future, particularly if a perceived need arises from a priority existing chemical review.

However, well established frameworks are already in place for setting controls on chemicals for public health (poisons) and workplace safety reasons (chapters 5 and 6). Reflecting their primary function of standard setting, the governance structures of those agencies are also better suited to the task than are the NICNAS structures.

For example, one ACCORD Australasia member argued:

This process of annotation was poorly discussed with Industry ... and now appears to be a tool without transparency for NICNAS to randomly set category restrictions, percentage use maximums restrictions and conditions of use restrictions. This seems to be setting up AICS to be an alternative to the SUSDP [Standard for the Uniform Scheduling of Drugs and Poisons] but without the ability of Industry to comment. There is no mechanism to complain without paying a fee of \$633 and further delays to the approval. (sub. 42, p. 28)

Furthermore, this regulatory device is not being systematically reviewed for its regulatory impacts. For example, the annotation of the AICS covering certain lead-based coatings for industrial applications was not subjected to a regulation impact assessment, yet the consequences of the annotation would seem to warrant such an assessment.

NICNAS argued that annotation of the AICS enables prompt action when an assessment concludes that a chemical poses unacceptable risks:

Use of the regulatory power to annotate the inventory ensures that there is no time lag between conclusion of the risk assessment and controls being legally enforceable, ensuring health and environmental protection. This is in contrast to using national standards or recommendation[s] to state/territory regulators as the risk management mechanism. (sub. DR106, p. 4)

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The Commission considers that improving linkages between NICNAS and the existing standard-setting bodies would be a more appropriate way of addressing the issue of regulatory lag. While there is currently no national standard-setting framework for managing the environmental risks of industrial chemicals, the Commission has supported addressing this gap through the establishment of a body that would examine NICNAS's recommendations and decide on the appropriate standards (chapter 9).

An additional issue concerning removal of the annotation power is the status of existing annotations. The Commission considers that, consistent with its preferred institutional approach, once the annotation power is removed, existing annotations, together with any supporting information or recommendations, should be referred to the relevant standard-setting bodies for a decision on appropriate controls. A timeframe should be prescribed for such decisions, and the existing annotations should be removed from the AICS at the expiration of that timeframe.

Two other control-of-use standard-setting functions of NICNAS should be removed. The first is maintaining the Cosmetics Standard. The Commission considers that the responsibility for regulating products should be vested in a dedicated standard-setting body such as the ACCC, rather than a chemical assessment agency (chapter 5). NICNAS should retain the responsibility for assessing new chemicals in cosmetics. It could also provide expert support to the ACCC in monitoring and enforcement of compliance and in updating the Standard under a service level agreement.

The second is the regulatory power to prohibit or restrict the introduction or export of industrial chemicals to give effect to Australia's obligations under international agreements (NICNAS, sub. 36). Currently NICNAS is responsible for implementing two international treaties — the Stockholm Convention and the Rotterdam Convention. The Stockholm Convention, among other things, requires parties to assess chemicals on their persistent organic pollutant characteristics. Its implementation is consistent with NICNAS being an assessment body.

The implementation of the Rotterdam Convention, on the other hand, could lead to restrictions or bans on the introduction or export of certain chemicals. Currently, DEWHA is the Designated National Authority responsible for international liaison and communication, with NICNAS being responsible for implementation of the Convention. The Commission considers that the responsibility for implementation could be transferred to DEWHA. This would result in an arrangement that is consistent with that applying to agvet chemicals, where the Department of Agriculture, Fisheries and Forestry is fulfilling both the Designated National Authority and implementation roles. On this issue, DEWHA observed:

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The department would be willing to exercise the implementation function and has appropriate familiarity with the Convention requirements since it leads Australia's international representation to the Convention. For the department to do so, however, may require legislative change. (sub. DR104, p. 18)

Several of NICNAS's regulatory powers that are incidental to chemical assessment should be retained. The power to issue assessment certificates at the end of an assessment is integral to the assessment process. The power to issue permits subject to prescribed conditions of use and the power to impose requirements on notifiers under low regulatory concern chemical provisions offer a way of delaying or circumventing the full assessment, provided certain conditions are met. These powers are also an important component of the assessment regime. While they provide NICNAS with some risk management responsibilities, these are subsidiary to risk assessment in the sense that they manage the risks of not subjecting a chemical to full assessment. The power to require secondary notification for significant variations to the originally notified uses is an important feature of the regime, because it ensures that the relevant new risks are assessed. To the extent that the AICS is utilised to convey the information on secondary notification, the power to annotate the AICS for *that purpose* should be retained.

In summary, the Commission considers that the current risk-management regulatory functions of NICNAS that are not integral to its primary function of administering a chemical assessment scheme should be removed.

RECOMMENDATION 4.3

***The Australian Government should generally limit the role of NICNAS to the scientific assessment of the hazards and risks of industrial chemicals. The power to annotate the Australian Inventory of Chemical Substances to ban or phase out chemicals, and the responsibilities for administering the Cosmetics Standard 2007, and for implementing the Rotterdam Convention, should be removed from NICNAS.***

*Extending the scope of NICNAS to reflect emerging technologies*

There has been limited focus both in Australia and overseas on analysing the regulatory implications for addressing the risks of emerging technologies, in particular, nanomaterials.

Nanomaterials are materials designed at the molecular (nanometre) level to take advantage of their small size and properties not in their conventional counterparts. In recent years, there has been significant growth in the research and development and subsequent commercialisation of nanomaterials in a broad range of applications

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including textiles, cosmetics, sunscreens, electronics, paints and varnishes (NICNAS nd).

Nanomaterials could present challenges to the existing chemical assessment regimes because their novel properties may give rise to currently unknown impacts on human health and the environment. Consequently, the current data requirements for ‘traditional’ chemicals and polymers may not be appropriate for adequate risk assessment of nanomaterials.

To address the emerging technological and regulatory issues, the Australian Government announced the creation of a National Nanotechnology Strategy on 1 May 2007. The Strategy is being coordinated by the Department of Innovation, Industry, Science and Research.

Two key aspects of the Strategy are:

- allocating funding to the Department of Health and Ageing, Department of Education, Employment and Workplace Relations and DEWHA, to ensure regulatory systems adequately address the health, workplace and environmental implications of nanotechnology
- establishment of a Health, Safety and Environment Working Group, consisting of policy, regulatory and research funding agencies across the Australian Government. The Working Group will coordinate the assessment of existing regulations with all relevant agencies, including non-government bodies such as Standards Australia. It will also be responsible for coordinating international engagement on policy and regulation (DITR 2007).

NICNAS is currently engaging with the Working Group to determine if and how the ICNA Act needs to be modified to accommodate nanotechnology issues. It has made a voluntary call for information to industry to determine the volumes and applications of nanomaterials in Australia. A Nanotechnology Advisory Group has also been established within NICNAS (NICNAS nd).

The Commission supports the engagement of NICNAS in the National Nanotechnology Strategy.

#### *Proposed reforms to the product scope of NICNAS — regulation of disinfectants*

Disinfectant products are substances that are applied to an inanimate object or surface to kill a range of micro-organisms. Currently, all disinfectants are regulated by the Therapeutic Goods Administration (TGA) on their safety, quality and

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efficacy under a category called ‘related therapeutic products’.<sup>3</sup> The Taskforce on Reducing the Regulatory Burden on Business (Regulation Taskforce 2006) observed that Australian regulations set a higher standard than those of New Zealand, and that this restricted competition from New Zealand and placed Australian exporters at a competitive disadvantage. The Taskforce recommended that the Australian Government progress industry reforms for the regulation of disinfectants. Consequently, a review of the current regulatory arrangements was initiated by the Department of Health and Ageing and a report proposing a new regulatory framework has been prepared (DOHA 2008).

The report advocated a risk-based regulatory approach, where the responsibility for regulating disinfectants used in different environments is divided between TGA and NICNAS depending on the associated risk. Under the proposed arrangement, TGA would continue to regulate hospital-grade disinfectants as previously, because the consequences of poor quality or ineffectiveness of products used in a clinical setting were deemed to warrant regulatory oversight. On the other hand, non-hospital grade disinfectants would now be assessed by NICNAS under its regular provisions for assessing new industrial chemicals, and would not be formally evaluated on their quality and efficacy. The quality and efficacy of non-hospital grade disinfectants would be enforced through industry self-regulation via a code of practice developed by ACCORD, and through the *Trade Practices Act 1974* (Cwlth) and state and territory fair trading legislation. The report suggested that NICNAS could annotate the AICS to reference the self-regulatory efficacy standard and that NICNAS inspectors could refer potential breaches of the Trade Practices Act to the ACCC for enforcement action.

The report also recognised the possibility of duplication in assessments by NICNAS and TGA if the same chemical is used in hospital and non-hospital grade disinfectants. It noted that NICNAS had provisions for recognising assessments of other schemes, but recommended that NICNAS and TGA further investigate options for mutual recognition of assessments.

The Commission generally agrees with the proposed regulatory approach and with the recommendations of the review. However, the proposed use of the AICS to annotate efficacy standards is not supported. The current function of the AICS is to provide a list of existing industrial chemicals and their assessment status. Extending the scope of the AICS to recording the regulatory arrangements for disinfectants

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<sup>3</sup> Under the scheme, the TGA formally evaluates the quality, health risks and efficacy, and registers ‘high grade’ products, such as disinfectants for which specific claims are made in relation to sterilants, fungicides, sporicides, tuberculocides or virucides. ‘Lower grade’ disinfectants for which no specific claims are made, are required to comply with various product standards and labelling and advertising requirements maintained by the TGA.

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would be inconsistent with the treatment of other chemicals and would confuse the purpose of the AICS. The Commission also does not agree that NICNAS should be responsible for initiating compliance monitoring and enforcement of breaches of the Trade Practices Act. This responsibility should rest entirely with the ACCC, while the role of NICNAS should be limited to provision of expert advice.

The Commission's broad agreement with the proposed reforms notwithstanding, ultimately, these reforms would need to be supported by a regulation impact statement.

### **Improving the coordination between NICNAS and the standard-setting bodies**

Good coordination between NICNAS and the standard-setting bodies is essential for effective and efficient management of industrial chemical risks. The issue of poor linkages between NICNAS chemical assessment outputs and the subsequent risk management by the relevant standard-setting bodies has been raised in a number of forums and by several participants in this study.

A NICNAS review of its priority existing chemicals program identified a number of problems relating to the uptake of NICNAS recommendations by the relevant regulatory agencies and industry (DOHA 2006b). These included:

- a narrow focus on OHS issues by the current state and territory MOU group due to its representation
- poorly framed recommendations by NICNAS, meaning that some could not be implemented
- the need for greater monitoring by NICNAS of the uptake of recommendations by relevant agencies.

The review made several recommendations including:

- a proposal to broaden the representation on the MOU group to include public health and environment representatives
- a recommendation to increase consultation with stakeholders to improve the quality of NICNAS recommendations
- a recommendation for ongoing monitoring and reporting of the uptake of NICNAS recommendations.

The recommendations were accepted by the Director of NICNAS and an implementation plan was prepared (DOHA 2007b). More generally, the review concluded that a more rigorous investigation of the barriers to the uptake of

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NICNAS recommendations was needed, and recommended that the proposal for such a review should be referred to the COAG Ministerial Taskforce on Chemicals and Plastics Regulation Reform.

One of the big issues in the plan was that of improving consultation. According to the plan, the implementation of recommendations on modifying the MOU group and improving consultation would not require significant changes to existing arrangements and could be undertaken within NICNAS in less than one year. The Commission understands that NICNAS has already taken steps to broaden its consultation to include the public health and environmental agencies of the states and territories. These steps are supported. The NChEM Working Group (sub. DR119) suggested that the requirement to consult with the relevant state and territory agencies be formalised in the ICNA Act. However, current initiatives to broaden the representation on the MOU group may be sufficient to address the problem and should only be supported by legislative change if they prove to be unsuccessful.

A potentially more important issue is to formalise the requirement that standard-setting bodies specifically address NICNAS recommendations.

NICNAS observed:

There is no legal requirement either for standard setting-bodies to consider NICNAS's recommendations nor for states/territories to adopt ... direct recommendations before NICNAS permits/certificates are issued. For both new and existing chemicals this can result in a situation where a chemical that NICNAS consider to warrant risk management measures, is on the market without controls in place and without any statutory or binding agreement on the timeframe within which such controls should be considered/adopted ... For NICNAS recommendations to be effectively linked into the Commonwealth's risk management framework, it will be necessary to strengthen and formalise the linkages between NICNAS and national coordinating bodies. (sub. DR106, p. 9)

DOHA (sub. DR116, p. 4) also argued that 'risk management agencies should be compelled to consider recommendations within statutory timeframes'.

Such an arrangement could potentially improve the utilisation of NICNAS assessments and hence, the effectiveness and efficiency of the overall regime. However, some flexibility in setting such timeframes may be needed to allow the standard-setting bodies to balance priorities (for example, differentiated timeframes may be warranted for high and low risk chemicals).

The Commission would generally support establishing a formal requirement on the relevant standard-setting bodies to consider and respond to NICNAS recommendations within a set timeframe. There would be further benefit in

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NICNAS establishing a consolidated public register of the responses of the standard-setting bodies as an information source for industrial chemical manufacturers and importers.

A similar linking mechanism (albeit in a different context) exists between NICNAS and the Office of the Gene Technology Regulator (OGTR), with NICNAS required by its legislation to seek advice from the OGTR in assessing chemicals containing a genetically modified product. There is also a legislative obligation on NICNAS to take that advice into account. The Commission considers that where the standard-setting bodies are established under statute, the requirement to respond to NICNAS recommendations should be incorporated into the legislation. Where no relevant legislation exists, the commitment to respond could form part of an agreement such as a MOU.

The Commission does not consider that the response of the standard-setting bodies should be a pre-requisite to NICNAS issuing an assessment certificate. First, general regulatory requirements already require some regard for chemical assessments. For example, a generic legislated duty for managing OHS risks applies regardless of any decisions by the standard-setting body on the specific chemical, making it prudent for employers to take into account relevant NICNAS recommendations. Similarly, generic duties not to cause an environmental hazard exist in state and territory environmental legislation. Second, provisions already exist for urgent decisions by some standard-setting bodies (for example, in poison scheduling), so the regulatory lag can be minimised when the risks are deemed sufficiently high. Third, requiring the standard-setting bodies to respond before an assessment certificate is issued could impose significant costs on introducers of chemicals through delays.

#### RECOMMENDATION 4.4

*All relevant national standard setting bodies should be required to respond to NICNAS recommendations within defined time limits. NICNAS should maintain a public schedule of all responses.*

### **Improving the efficiency of new chemical assessments**

The Commission has received significant participant comment on the efficiency of new chemical assessments by NICNAS, particularly on the costs imposed by NICNAS notification requirements and on the effect of several initiatives adopted by NICNAS in recent years to improve efficiency.

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This section focuses on:

- the appropriateness of compliance costs (including the financial costs of assessment, delays to introduction of chemicals and potential loss of commercial confidentiality following assessment) imposed by NICNAS on manufacturers and importers of new chemicals
- the impact of NICNAS on innovation and introduction of new chemicals
- the operation of NICNAS initiatives to improve the efficiency of its operations, including: initiatives for expedited assessment of low regulatory concern chemicals; efforts to integrate with overseas assessment schemes; and implementation of modern assessment methodologies that utilise data from previously assessed chemical analogues.

*Are the financial costs of assessments appropriate?*

The financial costs of obtaining an assessment certificate for an industrial chemical consist of two components — the fee for submitting an application and the cost of collecting data in support of the application. The financial fees for submitting an application to NICNAS vary between \$2534 and \$14 970, depending on the nature of the application. The Plastics and Chemicals Industries Association (PACIA, sub. 33) argued that fees were excessive compared to other OECD countries. Examination of assessment fees for non-polymer chemicals in different countries suggests that NICNAS fees are relatively high by international standards (table 4.1).

**Table 4.1 Assessment fees for non-polymer chemicals**

<i>Country</i>	<i>Assessment fee</i>
	A\$ <sup>a</sup>
Australia	14 418 <sup>b</sup>
USA	2 863
Canada	3 892
EU	8 651
Japan	-
Korea	121
China	-

<sup>a</sup> Exchange rate as at 18 January 2008; <sup>b</sup> Standard notification fee for 2006-07. – No fee is levied.

Source: ACCORD Australasia (sub. 42).

However, some of the observed differences in fees are due to differences in cost-recovery arrangements. NICNAS assessment costs are fully cost recovered from assessment fees. On the other hand, none of the other assessment schemes listed above fully recover the costs of assessment. PACIA commented:

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... there is no doubt that the NICNAS 100% cost-recovery model, coupled with the wide net of substances under the NICNAS framework, is inconsistent with most other OECD economies ... Only Canada has a scheme that captures a similar breadth and depth of chemicals, however Canadian fees are significantly lower in dollars and exchanged currency and [the scheme] is not 100% cost recovered. (sub. 33, attachment 4, p. 15)

It is, therefore, difficult to assess the appropriateness of the level of fees and charges. However, the Commission considers it appropriate that NICNAS assessment activities be fully cost recovered in accordance with the Australian Government Cost Recovery Guidelines (DOFA 2005a) including that these be periodically reviewed. The relatively modest budget of NICNAS (\$8.6 million) suggests that its fees and charges are not a huge impost on the plastics and chemicals industry. However, this is not to say that compliance costs overall (and even the financial costs of undergoing assessment) are appropriate.

The more significant contributor to financial assessment costs is the cost of complying with application data requirements. Several participants suggested that the cost of preparing a data dossier for an application to NICNAS could be significant and could exceed the cost of complying with assessment requirements in other countries such as the United States (box 4.3).

**Box 4.3 Participant examples on NICNAS application data costs**

In early 2007 the company asked its supplier to notify a fabric softening ingredient. NICNAS informed them that the toxicology data that had sufficed in the US for approval in that market wouldn't be sufficient for Australia. The testing required to generate the additional data would have cost \$418 084 ...

In a recent case there was a new chemical to add in a liquid detergent to condition fabric. After discussion with the supplier, it appeared that they did not have the data package required for Australia. Some of the data gaps relate to unique Australian requirements for human and environmental toxicity ... A standard application was required which meant €125 000 (about A\$210 000) to generate the required data ...

This company would not consider the introduction of new chemicals due to the excessive cost. They recently took on an agency for a US manufacturer who was very keen to market their many novel chemicals in Australia. Their first attempt has cost \$100 000 to date (still incomplete) and as a result they have lost interest in listing further chemicals on the Australian Inventory of Chemical Substances. (ACCORD Australasia, sub. 62, attachment 1, pp. 16–17)

The laboratory tests required by US authorities to establish the safety in use and impact on the environment cost around US\$20 000. In Australia, by contrast ... the cost of carrying out the substantially more extensive testing required to achieve listing on the AICS can easily be of the order of ten times the cost of testing required in the USA. (Albright & Wilson (Australia) Limited, sub. 5, p. 3)

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As discussed earlier, the appropriateness of the assessment requirements imposed on notifiers should be assessed in the context of whether these requirements are commensurate with the potential risk of the chemical in question. Several participants argued that this was often not the case. A survey of ACCORD Australasia members (sub. 62, attachment 1) showed that 44 per cent of respondents believed that irrelevant data was requested by NICNAS, while 64 per cent believed that the level of assessment was greater than warranted by the level of risk posed by the chemical. Implementation of recommendation 4.1 would be important in addressing this issue.

*Are the provisions for ensuring timely assessments adequate?*

Delays to the introduction of new chemicals could impose a significant cost on manufacturers and importers of chemicals, particularly if they result in the loss of first mover advantage from introducing a new product to the market.

Depending on the type of application, the statutory timeframes for NICNAS applications range between 14 and 28 days for permits, and 28 and 90 days for certificates. In contrast to the APVMA, the statutory clock does not start until the application passes all screening requirements (DOHA 2007a).

Data from ACCORD Australasia (sub. 42, attachment 2) indicate that, for standard non-polymer chemical assessments, the NICNAS statutory timeframes are similar to those in the United States and Canada, and significantly shorter than those in the European Union (10–12 months) and in Japan (up to 18 months).

Examination of NICNAS annual reports indicates that NICNAS met its statutory timeframes for 98 per cent of certificate applications in 2004-05, 100 per cent of applications in 2005-06, and 96 per cent in 2006-07. While NICNAS is not always achieving 100 per cent compliance with its statutory time frames — when arguably it should — timeliness is affected more by the quality of applications and the operation of the stop-the-clock provisions. In 2006-07, 60 per cent of non-self-assessed certificate applications were deficient and required rectification before the statutory clock could be started (DOHA 2007a). This is a slight improvement on previous years — the statutory clock did not start immediately after screening for 65 per cent of the applications in 2003-04 (DOHA 2004a); 71 per cent of the applications in 2004-05 (DOHA 2005a); and 73 per cent of the applications in 2005-06 (DOHA 2006a). Nevertheless, the high proportion of applications still failing NICNAS screening requirements is a concern.

NICNAS has introduced a number of initiatives to improve the quality of the applications. These focus primarily on providing a free consultancy service for

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notifiers and conducting seminars and workshops for industry on avoiding common problems in applications. Industry appear to be supportive of these training and consultation initiatives. For example, 3M Australia observed:

The NICNAS training seminars are an excellent forum for communicating and discussing chemical regulatory issues. NICNAS should continue to run such valuable sessions ... It would be advantageous to provide advanced sessions that could target particular areas such as physicochemical properties, when a variation of schedule data requirements may be appropriate, mutagenicity data when further data may be requested ...(sub. 34, p. 13)

In 2007 NICNAS also introduced a new application screening framework aimed at improving the timeliness of NICNAS assessments. NICNAS now aims to complete all screening prior to starting the statutory clock and commencing the assessment. To facilitate faster completion of the screening, applicants are typically given deadlines of 14–28 days for resolving outstanding matters.

The new screening framework has only been in operation since February 2007 and its effectiveness is unclear. However, several participants have criticised its operation. ACCORD Australasia (sub. 42) suggested that the absence of any statutory time limits at the application screening stage meant that NICNAS had no incentive to conduct the process in a timely manner. PACIA (sub. 33) claimed that the time taken to screen applications was significant — approximately 30 per cent of total assessment time by NICNAS. Both participants argued that the stop-the-clock provisions should be altered to include application screening within the statutory timeframe.

The Commission considers that all stages of the assessment process should be subject to timeliness requirements. To that end, a statutory timeframe for completing technical screening is warranted.

#### RECOMMENDATION 4.5

***The Australian Government should introduce a statutory timeframe for the technical screening of applications by NICNAS.***

*Are confidentiality provisions adequate?*

Manufacturers and importers of industrial chemicals may derive a commercial advantage from retaining confidentiality on the identity of the chemicals they have introduced into Australia. Accordingly, the loss of confidentiality arising from the public listing of the chemical could impose a cost on those firms.

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Currently, chemicals are typically not listed on the AICS until five years after assessment and the notifier has confidentiality protection for that period. Subsequently, the default position is no confidentiality, and the notifier has to apply for a confidential listing every five years. Industry participants (for example, PACIA, sub. 33, attachment) claimed that lack of certainty of confidential listing has imposed an unnecessary cost on firms and delayed the introduction of new chemicals in Australia.

A Technical Advisory Group operating under NICNAS considers whether to allow confidential listing of a chemical by comparing the commercial benefit of confidentiality with the public benefits of disclosure. Members of the group are selected on the basis of expertise in commercial and public interest. NICNAS has developed Guidelines on Establishing a Case for Confidentiality (DOHA 2005b). PACIA (sub. 33) have argued that chemicals that have been assessed as non-hazardous or are deemed non-hazardous (for example polymers of low concern) should have an automatic presumption of confidentiality.

The Commission considers that decisions on confidentiality should be made after an assessment of the community costs and benefits of disclosure of the information. An automatic presumption of confidentiality for non-hazardous substances is not supported because it would disregard other potential social benefits of disclosure, such as those flowing from knowledge dissemination. It could also lead to indefinite confidentiality protection for the notifier — a potentially undesirable outcome if the commercial costs and community benefits of disclosure change over time.

Analysis of NICNAS data shows that applications for confidential listing constitute a small percentage of all chemicals due for listing on the AICS. For example, in 2006-07, of the 167 chemicals due for listing on the AICS, confidential listing was only sought for 24 chemicals (DOHA 2007a). A significant majority of applications for confidential listing were successful (69 per cent in 2002-03, 100 per cent in 2003-04 and 2004-05, and 80 per cent in 2006-07) (DOHA 2007a).

Although the current arrangements within NICNAS appear generally sound, there are some shortcomings that should be addressed. In particular, the current Guidelines provide limited information on how the competing commercial and public interests are quantified and compared. Better guidance for the applicants could improve the transparency of the process and may improve its efficiency. One potential method is to supplement the guidelines with sample hypothetical applications, including successful, unsuccessful, and borderline applications.

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### *Impact on innovation and the introduction of new chemicals*

The assessment scheme could be expected to impose a cost on innovation activity by introducers of chemicals. A survey by ACCORD Australasia (sub. 62) of its member companies showed that 59 per cent of respondents cited the regulatory system as a barrier to innovation. On the other hand, analysis of Australian patent application data (table 4.2) shows an increase in applications since 1995 (when the last amnesty period for grandfathering industrial chemicals ended).

**Table 4.2 Patent applications, by industry group**

<i>Industry</i>	<i>Number of patent applications</i>		<i>Proportion of total patent applications</i>	
	<i>1995</i>	<i>2005</i>	<i>1995</i>	<i>2005</i>
	<i>no.</i>	<i>no.</i>	<i>%</i>	<i>%</i>
Basic chemicals	1 406	2 075	10.0	9.0
Soap, detergent, cosmetics and toiletries	582	1 094	4.1	4.7

*Source:* IP Australia (2006).

However, there are some problems in using these data. First, the number of patent applications that would have been made in the absence of regulation is unknowable, and second the number of patent applications is only a partial measure of innovation. It is more useful to examine the impact of NICNAS on the introduction of new chemicals.

Several participants (for example, Plastral, sub. 4; PACIA, sub. 33) argued that NICNAS requirements created a barrier to entry for new chemicals. A survey of ACCORD Australasia's member companies (sub. 62) showed that 93 per cent had some products available overseas but not in Australia; and 41 per cent reformulated their products to avoid assessment requirements. The survey also showed that, on average, 14 per cent of the companies' worldwide product portfolio was not introduced in Australia in the last two years for regulatory reasons. Some of these findings would not necessarily be attributable to the inappropriate burden of the regulations — for example, some variability in the products traded in different countries would usually be expected due to differences in market characteristics.

Introduction of new chemicals creates benefits both for producers of those chemicals (particularly if the firm is able to capture any advantages from being the first mover) and their users. These occur both immediately and over time from associated improvements in technology. However, to the extent that introduction of chemicals creates environmental and human health risks, these need to be addressed. The fact that some chemicals are not introduced due to the cost of assessment does not, *per se*, lead to inefficient outcomes. If the costs imposed on

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the community by the assessment are outweighed by the benefits of avoided environmental and human health risks, any resultant cost barriers to the introduction of new chemicals are not a market failure. However, the current regime could lead to inefficient outcomes if:

- the costs of assessment are not minimised
- there are asymmetries in the regulatory treatment of new and existing chemicals.

To the extent that assessments are not currently as cost effective as they could be, new chemicals would face a greater than optimal barrier to entry. Thus, any reductions in assessment costs (assuming the effectiveness of the regime is maintained) would be expected to lead to more efficient outcomes in the introduction of new chemicals.

The second issue arises as a consequence of grandfathering the majority of currently used chemicals while requiring a full assessment for new chemicals. The result is a bias against the introduction of new chemicals, some of which might be safer or more environmentally-friendly than existing chemicals. The European Commission also identified the absence of testing requirements on existing chemicals as ‘a barrier to innovation within the EU chemicals industry by discouraging research and invention of new substances’ (EC 2006, p. 3).

The Commission does not support discounting assessment fees for new chemicals — as some have suggested — on the grounds that they might be more benign than existing chemicals. This could only be established after an assessment was made, making it operationally difficult to implement. The better approach is to improve the efficiency with which assessments are conducted, including through not making excessive data demands on notifiers.

#### *The low regulatory concern chemicals initiative is underachieving*

The ICNA Act was amended in 2004 to introduce new assessment categories for low regulatory concern chemicals (LRCC). The reforms included:

- increasing the volume thresholds for exempting chemicals from notification requirements (in combination with new reporting requirements)
- introducing an assessment category for polymers of low concern
- introducing audited self-assessment categories for polymers of low concern and non-hazardous chemicals and polymers.

Industry has had a mixed response to these reforms. While there is general support for increased flexibility, concerns have been raised that individual reforms were not

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delivering on their cost-reduction objectives and that in some cases costs have increased.

Science Industry Australia (sub. 55) estimated the costs of the recent reporting requirements for chemicals introduced under the research and development exemption to a typical supplier of chemicals to laboratories at \$16 000 per annum. Science Industry Australia argued that the reported data was irrelevant to risk management. It suggested that the chemicals were sold into laboratory environments for use by professionally-trained personnel and that the minimal risk that remained was addressed by the requirement under OHS regulation to provide material safety data sheets for all hazardous substances.

As a rule the cost of the reporting requirements should not exceed the incremental benefit that they provide. NICNAS should investigate whether the current reporting requirements for chemicals used in research and development are warranted, given the circumstances of the use of those chemicals and the existence of other risk management measures.

PACIA (sub. 33) argued that the provisions for self-assessment of polymers of low concern did not function because the associated reporting requirements and auditing of all self-assessed reports imposes greater cost on the notifier than if the alternative notification route were taken. It suggested that initial industry enthusiasm for this option evaporated once the costs became apparent. A survey of ACCORD Australasia members (sub. 62) showed that in 50 per cent of cases, where the company had an opportunity to select the self-assessment option, it chose not to do so due to reporting and auditing requirements.

NICNAS reported that in 2006-07, there were 21 applications under the polymer of low concern self-assessment category — a sharp decline on the 45 applications in both 2004-05 and 2005-06 (DOHA 2007a). Further, since 2004-05 there have been only two applications for self-assessment of non-hazardous chemicals and polymers (none in 2006-07). NICNAS suggested that ‘industry is not fully exploiting cost savings and reduced time-to-market available following the reforms for low regulatory concern chemicals’ (DOHA 2007a, p. 36).

There are also grounds for a more general consideration of whether the current arrangements for self-assessment of low concern chemicals are unduly conservative. In the regulation impact statement (RIS) that preceded the introduction of current self-assessment provisions, NICNAS observed that while overseas regimes typically provided exemptions from assessment requirements for some classes of polymers, all polymers had to be assessed in Australia (DOHA 2003b). NICNAS concluded:

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... under the current arrangement, the costs incurred by industry in compiling a notification package, and assessment by NICNAS, do not match the level of hazard or risk of the polymers assessed. (DOHA 2003b, p. 21)

NICNAS also suggested that of the chemicals identified as polymers of low concern, about 5–10 per cent were associated with some degree of health or environmental risk, and that this risk was usually identified during their pre-screening before assessment by NICNAS. Consequently, self-assessment provisions were introduced to align the assessment requirements with the level of risk. The current poor take-up of those provisions suggests that the problem has not been resolved, and that greater effort by NICNAS to promote self-assessment (by reducing its relative cost) may be warranted.

The Commission notes that NICNAS will shortly commence a review of the LRCC reforms already introduced (sub. DR106) and considers that the above concerns should be addressed as part of that review. The Commission further considers that the review committee should include expertise relevant to the stakeholder groups and be appropriately oversighted. To this end, the arrangements adopted for the priority existing chemical program review would be appropriate.

#### *Use of analogue data and modelling in NICNAS assessments could reduce costs*

As part of its LRCC reforms, NICNAS is currently implementing a mechanism for fast tracking the assessment of chemicals considered to be analogues to previously assessed chemicals. Under the new provisions, chemicals deemed analogues would be subject to modular assessment, which would reduce the costs of notification and data preparation, and result in faster assessments.

In the RIS on LRCC reforms, NICNAS analysed several options for introducing analogue assessment. Its preferred option was a case-by-case analysis of applications relying on analogue data to determine what additional data was required (DOHA 2003b). The ultimate objective was to use the data from initial assessments to develop analogue assessment criteria for future assessments. To date, those criteria have still not been developed. Further, PACIA (sub. 33) argued that NICNAS has adopted an unduly restrictive definition of an analogue.

International experience shows that utilisation of analogue data in chemical assessments can be significantly enhanced by modelling tools. Quantitative Structure Activity Relationship (QSAR) modelling, which relies on computer simulations of risks on the basis of a chemical's physiochemical properties, has been used in the United States, Canada, Denmark, and will be used in the EU REACH scheme.

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QSAR modelling offers a number of benefits including reduced animal testing and significant cost savings over conventional assessment methods. The European Commission estimated that the use of QSAR under the EU REACH scheme could reduce assessment costs by 33–44 per cent (EC 2003).

A number of difficulties are typically associated with making QSARs a reliable predictive tool in chemical assessments:

- they require large data sets of observed relationships on which the models are built
- the data must be of high quality and generated using a consistent testing methodology
- the observed relationships that form the basis of the model must be statistically validated.

These shortcomings are being addressed in the countries that use QSAR modelling, via improving the quality of the data and the use of more sophisticated simulation tools. For example, the Danish Environmental Protection Agency (which uses an advanced QSAR system backed by a large database of test data) claimed 75–80 per cent accuracy for their QSAR modelling system (Price and Watkins 2003).

Further, there is international cooperation to improve the quality of QSAR modelling and to harmonise the different models currently in existence. QSAR Application Toolbox is an OECD project involving the United States, Canada, the European Union, Denmark and Japan, that aims to make specialised QSAR software and data from individual organisations accessible to all OECD stakeholders.

The Commission supports NICNAS investigating QSAR modelling for its assessments.

#### *Making better use of international linkages*

There are several methods for developing and utilising linkages with international chemical assessment schemes. These include both broad initiatives aimed at harmonising international methodologies of assessment (such as data requirements, reporting formats and risk-assessment methodology), and bilateral arrangements with other countries aimed at recognising aspects of their assessments (APVMA, sub. 59).

NICNAS is actively involved in various international harmonisation initiatives (box 4.4).

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**Box 4.4 Some international harmonisation initiatives by NICNAS***OECD New Chemicals Taskforce*

NICNAS participates in the OECD New Chemicals Taskforce and is involved in projects aimed at developing a common standard for data sets and report formats as well as developing a common approach to chemicals that are subject to exemptions or reduced regulatory requirements.

*International Programme on Chemical Safety*

NICNAS participates in a range of projects under the International Programme on Chemical Safety aimed at harmonising risk assessment methodology and utilises methodologies already developed under the Programme.

*Source:* NICNAS (sub. 36).

In the longer term, these can result in benefits to: regulators (through savings in scientific resources and opportunities for international collaboration on emerging issues); industry (through reducing costs and delays of assessment); and the community (through assurance that the risks of chemicals are assessed and managed consistently with international best standards). However, to date, progress in incorporating aspects of completed international assessments into NICNAS processes has been patchy.

The ICNA Act allows recognition of assessments of new chemicals completed in other countries under the approved foreign scheme provisions. So far, NICNAS has entered into a bilateral agreement with Environment Canada to recognise the Canadian New Substances Scheme as an approved scheme. Under the agreement, notifiers receive a 40 per cent reduction in assessment fees when Canadian assessment reports are provided with the notification (NICNAS, sub. 36). NICNAS also accepts assessments from EU countries and provides rebates of up to 40 per cent to notifiers (DOHA 2007a). NICNAS commenced work on entering into a bilateral agreement with the US Environmental Protection Agency in 2004 (DOHA 2004a). The agreement has not been finalised to date.

Several participants (for example, PACIA, sub. 33) argued that NICNAS did not make sufficient use of foreign assessments. NICNAS reported that in 2006-07, out of a total of 190 notification applications, it received Canadian reports for 20 notifications and EU reports for 4 notifications (implying that 13 per cent of the applications relied on foreign assessment reports) (DOHA 2007a). There are no data on how many of the applications received by NICNAS have never been assessed overseas. However, the small proportion of applications relying on Canadian and EU assessments suggests a significant scope for further integration with

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international assessment schemes. As noted earlier, the Commission supports the wider recognition of overseas assessment schemes as ‘approved foreign schemes’, provided they meet acceptable international standards.

## **Improving the assessment of existing industrial chemicals**

When the ICNA Act was introduced in 1989, around 40 000 of the chemicals in commercial use at the time were given ‘existing chemical’ status. Since then, about 180 existing chemicals (mostly priority existing chemicals), together with around 2000 chemicals new to Australia, have been assessed by NICNAS (NICNAS, sub. 36).<sup>4</sup> The very high number of unassessed existing chemicals mirrors the situation in many other developed countries where systematic approaches to chemical assessment are relatively new.

NICNAS prioritises the assessment of existing industrial chemicals based on concerns about their possible adverse impacts on people and the environment. Any person or organisation with concerns about such adverse impacts may nominate it for assessment as a PEC. Nominated chemicals are screened and ranked for declaration by the Minister for Health and Ageing. Tailored or focused preliminary assessments are also undertaken, in lieu of an immediate full hazard and risk assessment, targeting particular issues relevant to an existing chemical. In addition, NICNAS undertakes more limited data collection and distribution studies for chemicals of concern as well as sourcing and publicising international assessments.

Concern has been expressed (for example, by the Australian Chemicals Trauma Alliance, sub. 9) about the slow rate of assessment of existing chemicals and the possible adverse impacts of their continued use.<sup>5</sup> While the actual adverse impacts of unassessed chemicals are unclear, the Commission agrees that the large quantity of unassessed chemicals coupled with the slow rate of their review undermines the effectiveness of a national chemical assessment regime.

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<sup>4</sup> Professor Ian Rae (sub. 11) argued that the extent of the assessment backlog is somewhat overestimated because many of the listed existing chemicals may not be being used in Australia and are unlikely to be used in the future.

<sup>5</sup> However, even though chemicals have not been assessed by regulators, users of existing chemicals still face both common law and certain legislative duties of care. These would be expected to encourage actions to reduce the human and environmental costs of possibly dangerous existing chemicals, including their replacement by new safer chemicals.

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### *Options for reform*

Several countries have implemented or are currently implementing programs for assessing existing chemicals. Approaches range from a preliminary screening of all existing chemicals in combination with a more detailed assessment of chemicals identified as being of concern (for example, in Canada and the United States) to assessment of all existing chemicals with detailed assessment of all high volume chemicals (for example, under the new EU REACH scheme).

As observed earlier, production and use of chemicals creates benefits for both producers and users of those chemicals. However, it is important that the production and use of chemicals takes into account their potential adverse effect on human health and the environment. The net external cost to the public of an unassessed chemical is the appropriately risk-weighted cost of the possible human or environmental damage that might be avoided by assessment, less the cost of assessment. For some existing chemicals the failure to assess may generate net costs whereas for other low-risk chemicals the costs of assessment may outweigh likely benefits. In Australia, assessing the stream of around 200 new chemicals per year, has been considered affordable. However, to fully assess all existing chemicals using existing methodologies would be extremely costly and hence would only be warranted if there were reasonable prospects of the benefits materially exceeding the costs.

For example, even assuming that all of the relevant data are already available, the aggregate cost of assessing existing chemicals would be in the order of \$400 million.<sup>6</sup> On the basis of industry information on the costs of collecting data for assessments of new chemicals (discussed earlier in the chapter), aggregate assessment costs of all existing chemicals could well be over 10 times the above figure.

Aggregate assessment costs under the EU REACH scheme — which imposes significantly lower testing requirements than those applying to new chemicals in Australia, and relies on cost-reducing modelling tools currently unavailable in Australia — have been estimated at €2.3 billion (A\$3.7 billion) (EC 2003). While the benefits of the REACH scheme have not been comprehensively quantified, they can be expected to be significantly greater than for a similar scheme in Australia, due to the more than twenty-fold difference in populations.

NICNAS has recently undertaken a review of the existing chemicals program (DOHA 2006b) that made 23 recommendations for reform. These included

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<sup>6</sup> An estimate based on the current average application fee for new chemical assessments (which is set to recover the costs of reviewing the test data in the application) of \$10 000.

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improvements in engagement and communication with stakeholders, improved identification and screening of chemicals of concern together with more targeted assessments, and improvements to the efficiency of the selection and review process.

NICNAS has now prepared an implementation strategy to progress these reforms (DOHA 2007b). Timely and efficient implementation of the recommended program should produce more rapid and efficient assessment of existing chemicals and somewhat reduce public disquiet regarding unassessed chemicals.

In particular, the Commission strongly supports the following initiatives:

- Screening all chemicals would provide a low-cost way of assessing a large number of low-risk chemicals. It would also support the establishment of a scientifically prioritised list of higher risk existing chemicals that require more immediate and in-depth assessment. The Canadian Existing Substances program adopted this approach with apparent success.
- As discussed earlier, using information from overseas assessments or sharing research with overseas jurisdictions may often be cost effective, particularly with respect to hazard assessment. The Canadian and US existing chemical review programs are well advanced, while the EU REACH scheme would also likely generate a significant volume of useful information. The net benefits of extending foreign scheme recognition provisions of the ICNA Act to the *existing* chemical assessment schemes of Canada, the United States and the European Union should be assessed.
- Greater engagement with those who might have information on adverse impacts of existing chemicals and more targeted research into those impacts, together with the provision of full and easy access to information on existing chemicals to stakeholders, would improve the effectiveness of the screening and assessment process.

The Commission also considers that there is significant scope for improving the timeliness and cost-effectiveness of the screening process via the use of modelling approaches (discussed earlier). These have been utilised in the Canadian and US existing chemical schemes and will be used under REACH, and have proven to significantly accelerate the screening process. For example, the categorisation and screening of all existing chemicals was completed in Canada between 1999 and 2006.

The funding arrangements for the accelerated assessment program also need to be considered. The Commission generally considers that recovery of the costs of a chemical assessment regime from chemical manufacturers and importers is likely to

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be more efficient and equitable than sourcing the funds from general revenue. This is because it is typically more efficient and equitable to attribute the costs of regulation to the source of the negative externality that the regulation seeks to address. However, a once-off proactive screening of all grandfathered chemicals is a response to a legacy issue that would be difficult to accurately attribute to current industrial chemical suppliers. Thus, on equity and efficiency grounds, the Commission considers that the costs associated with screening grandfathered chemicals on the AICS should be met from budget funding. Subsequent detailed risk assessments of chemicals identified to be of concern should continue to be cost recovered on the grounds that the continued use of these chemicals in the community might cause various problems, the costs of which should be internalised through regulation.

RECOMMENDATION 4.6

*NICNAS should implement a program to greatly accelerate the assessment of existing chemicals that:*

- *screens all existing chemicals to develop a list of high-priority chemicals for assessment*
- *makes greater use of simulation techniques based on the hazards of chemical analogues*
- *reviews the scope for recognising the existing chemical assessment schemes of a range of other countries as ‘approved foreign schemes’. Priorities should be the schemes operated by Canada, the European Union and the United States.*

*The Australian Government should meet the cost of screening all existing chemicals from budget funding. NICNAS should continue to recover the costs of subsequent assessment of chemicals of concern.*

## **Improving the feedback mechanisms to support assessment activity**

To varying extents chemical assessments make assumptions about the risks that chemicals may impose that may or may not be borne out in practice. As DEWHA suggested:

Important assumptions made during the assessment process to estimate safety cannot be validated or revised through measurement data. Put simply, regulators make decisions based on the best available information at the time, but cannot be sure how accurately they assessed risks. (sub. 18, p. 11)

In this context, post-market feedback mechanisms can be useful for verifying risk assessment conclusions, establishing a case for further assessment, and developing new ways for undertaking future assessments. DEWHA (sub. 18) observed that

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where the feedback mechanisms are weak, chemical assessors are forced to be more conservative in their risk assessments.

NICNAS does not currently have an adverse experience reporting program and, as discussed earlier, its existing chemical review program (which includes feedback mechanisms that enable anyone to nominate a chemical for review) has operated slowly to date. A review of its existing chemicals review program recommended that NICNAS investigate the feasibility of establishing a nationally coordinated scheme of post-market monitoring and reporting of adverse experiences (DOHA 2006b). Elements of the proposed scheme would include (among others):

- clear articulation of the type, source, purpose, protection, and use of the information
- collation of information from existing monitoring programs and harmonisation of those programs
- potential incorporation of voluntary and coregulatory elements.

While the Director of NICNAS accepted the recommendation, it was seen as involving complex issues necessitating legislative change, and would, therefore, require one to several years to implement (DOHA 2007b).

Establishing an adverse experience reporting system for industrial chemicals can be a useful mechanism for fine tuning assessments. It can also provide the public with some assurance that chemical assessors are receptive to feedback. But, unlike agvet chemicals — which are used only in prescribed circumstances — industrial chemicals are used in a wide variety of circumstances, including in the household. An adverse experience reporting scheme could create an enormous number of real or perceived cases that would be costly to screen. Furthermore, a variety of existing reporting systems (such as state and territory environmental, poisons and other hotlines), consultative arrangements, and monitoring systems are already in place that would yield some information. NICNAS has noted that collation of existing information would be an integral part of any such scheme.

The adequacy of the current systems should be established before developing new systems. This would be consistent with the Commission's views on the need for additional monitoring of the environmental impacts of chemicals being considered within a well defined performance management framework (chapter 9). In the Commission's view further scoping of this proposal is required.

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## 4.4 Consolidation of chemical assessment regimes

NICNAS and the APVMA are Australia's key chemical assessment agencies, focusing on industrial and agvet chemicals respectively. The separation of these functions has long been a feature of the regulatory landscape in Australia and is not uncommon in other countries (for example, the United States). But they undertake some similar functions, and given that some other countries have combined these functions (for example, New Zealand) some consideration of amalgamation options is warranted. Such consideration need not stop with these two organisations. For example, the current proposal for developing a risk-management framework for chemicals of security concern features the establishment of a risk-assessment unit within the Australian Government Attorney-General's Department (chapter 9). Creating one integrated assessment agency at the Commonwealth level could be a longer-term option.

### What are the similarities and differences?

The similarities between NICNAS and APVMA mainly relate to their chemical hazard and risk-assessment functions (table 4.3). The hazard assessments of industrial and agvet chemicals start from a similar point because they relate to the inherent physical properties of the chemicals concerned. Both agencies also assess risks to public health, OHS and environment. Neither currently assesses chemicals for their risks to national security. Other similarities include that they maintain registers of chemicals (or products in the case of APVMA), and they both have links to other common regulatory agencies.

On the other hand, there are some substantial differences between the two schemes:

- NICNAS assesses chemicals only, whereas APVMA assesses chemicals and products (mixtures of chemicals).
- NICNAS assesses chemicals that may be used in a wide variety of ways whereas APVMA assesses products for specific purposes.
- NICNAS does not assess product efficacy, while APVMA does.
- NICNAS is a Commonwealth regulator, while APVMA is a national regulator created through a conferral of powers by the states and territories.
- NICNAS mainly relies on linkages to other national regulatory frameworks and the states and territories for the implementation of its recommendations. APVMA has much stronger powers to approve (register) or ban chemicals and set conditions of use.

The Commission’s recommendations for NICNAS and APVMA would increase those differences (vertically integrating control of use of agvet chemicals, and making NICNAS an assessment only agency are the key changes).

**Table 4.3 Key similarities and differences between NICNAS and APVMA**

	<i>NICNAS</i>	<i>APVMA</i>
Legislative base	Commonwealth Act	Conferral of powers by the states and territories
Objective	Assessment of chemicals to manage the risks to public health, OHS and environment	Evaluation and approval of chemicals and products to manage the risks to public health, OHS, environment and trade; and supporting primary industries
Scope	Industrial chemicals	Agricultural and veterinary chemicals and chemical products
Hazard and risk-assessment activities	Hazard assessment and classification; assessment of risks to public health, OHS and environment	Hazard assessment; assessment of risks to public health, OHS and environment; assessment of residues and product efficacy
Risk management activities	Primarily recommendations to standard-setting bodies and the states and territories; but also setting use conditions via annotating the AICS; administering the Cosmetics Standard; implementing international treaties	Approval of manufacture or importation of chemicals and products; approval of conditions of use on product labels and regulation up to point of sale. Enforcement of conditions of use is by the states and territories

### *What are the options for amalgamation?*

The broad options for amalgamation are: amalgamate NICNAS and APVMA as they are (or would be under the Commission’s recommendations), or amalgamate their assessment functions only. There are advantages and disadvantages with both options, some of which were discussed by participants (box 4.5).

### *Full amalgamation*

Amalgamating NICNAS and APVMA would create a one-stop-shop for many chemical producers and users and would reduce boundary issues where some chemicals may be assessed by both agencies. It would also achieve some economies of scale and scope by bringing specialist staff together under the one organisation.

However, it would create a hybrid regulator with quite disparate powers over industrial and agvet products that would confuse its purpose. In addition, some boundary issues would remain even under the Commission’s recommendations. For example, disinfectant regulation would be shared between NICNAS and TGA,

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while transferring the Cosmetics Standard to the ACCC would rationalise NICNAS regulatory responsibilities but might require ongoing technical support from NICNAS.

#### *Amalgamating assessment functions*

Under this second option a stripped-back NICNAS and the assessment functions of APVMA would be combined. This organisation could also include the national security risk-assessment functions planned for the proposed unit in the Australian Government Attorney-General's Department. The advantages of this option are that it would achieve the economies of scale and scope associated with bringing specialist staff together, and it would create an independent scientific assessor that would provide a service to all standard-setting bodies covering OHS, the environment, public health and national security. Also, APVMA outsources most of its assessment functions to other agencies such as the OCS, DEWHA and state and territory departments, so integration of APVMA's assessment functions into NICNAS would not require a significant operational change for APVMA.

#### **Box 4.5 Participant views on amalgamating NICNAS and APVMA**

DEWHA noted that there are advantages and disadvantages of amalgamating NICNAS and APVMA:

One approach could include amalgamation of NICNAS and APVMA into a single regulator with access to advice from health, environment and other departments as appropriate. Potentially, this would bring economies of scale, pooling of skilled personnel, enhanced ability to resolve overlap and gaps in responsibilities for specific chemicals and the opportunity to critically compare the approaches taken in relation to industrial and agvet chemicals. In establishing a single body, this approach could benefit industry by providing a 'one-stop-shop' when importing, manufacturing, selling or using a chemical. On the other hand, there may be disadvantages to amalgamation, if industry or users perceive a single regulator to be less aware of or responsive to their particular needs and concerns ...

Should changes at Commonwealth level be contemplated, however, the Department suggests that any new arrangement would need to take advantage of the full range of resources provided by the health and environment departments, and other agencies as appropriate. (sub. 18, p. 16)

Croplife Australia opposed amalgamation:

The APVMA is able to give priority to agricultural considerations. Croplife supports the recognition and maintenance of the APVMA's separate risk-based assessment system and sees no net benefit from amalgamation of diverse regulators at any jurisdictional level. (sub 35, p. 16)

The disadvantages are that it might create some diseconomies by separating agvet chemical product assessment from standard setting, especially given that agvet

chemical products are evaluated for specific purposes. It would also require that the National Registration Scheme for agvet chemicals be renegotiated with some risk that this could jeopardise the effectiveness and efficiency gains already achieved.

*Some of the benefits can be achieved without amalgamation*

Some of the economies of scale and scope that would come from amalgamation can be achieved by outsourcing similar assessment tasks to common organisations or competitive market providers. For example, development of guidelines for conducting assessments (such as the environmental risk assessment manuals currently being developed for industrial and agvet chemicals (EPHC 2007a, 2007b)) would facilitate competitive provision by suitably accredited private providers. There may also be grounds for consolidation of some common aspects of hazard and risk assessment undertaken within NICNAS and APVMA (and other agencies such as FSANZ) (table 4.4).

**Table 4.4 Responsibilities for aspects of hazard and risk assessment, by regime**

	<i>TGA<sup>a</sup></i>	<i>APVMA</i>	<i>NICNAS</i>	<i>FSANZ<sup>b</sup></i>
Toxicology and public health	TGA	OCS <sup>c</sup>	NICNAS	FSANZ
OHS	..	OCS	NICNAS	..
Environment	..	DEWHA <sup>d</sup>	DEWHA	..
Residues in food	..	APVMA	..	FSANZ
Product chemistry and manufacturing	TGA	APVMA	..	..
Efficacy	TGA	APVMA; states and territories	..	..

<sup>a</sup> Therapeutic Goods Administration. <sup>b</sup> Food Standards Australia New Zealand. <sup>c</sup> Office of Chemical Safety. <sup>d</sup> Department of the Environment, Water, Heritage and the Arts. .. Not applicable

Source: APVMA (sub. 59).

APVMA argued that there are some disadvantages in having different agencies undertaking similar functions:

The conduct of similar hazard and risk assessments for the same assessment component [such as toxicology or public health] by a number of groups or agencies creates opportunities for the encroachment of differing cultures or approaches to the application of policy and the potential for differing assessment methodologies. This in turn may increase the potential for inconsistencies in assessment outcomes unless managed by appropriate governance arrangements. It also disperses specialist staff, decreases flexibility and potentially increases administrative costs, particularly in terms of information sharing and national and international participation and representation. (sub. 59, pp. 39–40)

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The Commission agrees that further consolidation of common aspects of chemical assessment could deliver additional economies of scale and scope. It would also improve consistency in the assessment methodology and outcomes and could facilitate a more efficient national approach to adopting international developments in hazard and risk-assessment methodology as well as international knowledge. In this respect, moving the responsibility for performing toxicology, public health and OHS hazard and risk assessments for APVMA from the OCS to NICNAS would be warranted. This change would also be appropriate in the context of the Commission's preferred governance framework (chapter 3) as it would separate the chemical assessment function from the current and proposed regulatory and policy making functions of the OCS.

Better communication between the regulators would also help. Some participants noted that there was a lack of formal mechanisms to coordinate the operation of different chemical assessment agencies (3M Australia, sub. 34, APVMA, sub. 59). ACCORD Australasia (sub. 62) provided several case studies, where poor communication between chemical assessors imposed significant costs on industry through duplication of assessments already completed for another body and through having to apply for assessments in multiple agencies where it was unclear which agency was responsible.

In some cases formal interagency agreements may help to clarify these roles. In other cases effective communication between agencies would be difficult to formalise and will rely on good officer-to-officer connections. At a broader level, the establishment of a Standing Committee on Chemicals, as proposed by the Commission (chapter 3) would help to establish a clear delineation of roles and reduce duplication.

Given all of the above, the Commission concludes overall that there is not a sound case for amalgamating NICNAS and APVMA at the moment. However, it can see benefits in amalgamating the assessment functions at some point in the future, when doing so would not jeopardise the integrity of APVMA's risk-management functions and the inclusion of current state and territory control-of-use functions in the national regime.

