
2 Study methodology and evaluative criteria

Key points

- The supply and use of chemicals in the community can result in various market failures, including externalities, information failures and public good characteristics. There is a case for regulating to manage the risks from chemicals, if it can be demonstrated that this would materially improve community wellbeing.
- Such regulation should reduce chemical-related risks to levels where community benefits continue to exceed costs, rather than minimise risks regardless.
- The effectiveness of current regulations is assessed by considering whether they achieve their intended outcomes, and, if not explicitly stated, by also considering whether they reduce risks to levels acceptable to the community.
- Efficiency is assessed by considering the potential for alternatives — including reliance on generic regulations and self regulation — to achieve greater community wellbeing.
- National uniformity is appropriate for most of the regulatory system for chemicals and plastics, because the potential gains in effectiveness and efficiency are likely to outweigh any benefits from having local differences. An exception is administration and enforcement of (nationally-agreed) regulations, where the local knowledge of a subnational regulator may improve effectiveness.
- A high degree of harmonisation with chemical regulations in other countries, especially our major trading partners, may also be appropriate, depending on how soundly based those regulations are. The case for uniformity is strongest where technical codes and standards are concerned.

This chapter outlines how the Commission has assessed existing chemicals and plastics regulations, and formulated recommended reforms. Regulations were assessed for their effectiveness, efficiency, and impacts on productivity and competitiveness. In order to explain this methodology, this chapter starts by discussing the rationale for regulating chemicals and plastics, and how the assessment criteria in the terms of reference were interpreted.

2.1 The rationale for regulation

Chemicals and plastics play a vitally important and beneficial role in the economy, but they also have the potential to harm human health and the environment. Allowing parties to act solely in their own private interest may not lead to the best possible outcomes for the community, given that there are several potential sources of ‘market failure’:

- externalities — the costs and benefits incurred by those using chemicals and plastics do not always fully reflect the impacts their use has on others (for example, when chemicals discharged from a factory cause health problems among nearby residents)
- information failures — individuals are not always able to make fully-informed decisions about chemicals and plastics in their best interest, because they do not have access to all relevant information, or do not have the technical expertise to interpret it (box 2.1)
- public goods — measures that protect human health and the environment can be underprovided by the private sector because ‘free riders’ cannot be excluded from enjoying the benefits (for example, security controls that prevent chemical-related terrorism and other crimes).

Regulation may be appropriate to address these sources of market failure, but only if the costs of intervening are materially outweighed by the benefits, and the regulation is the most cost-effective form of intervention. There is more likely to be a net benefit if regulation is tailored to the *risk* posed by a chemical in a particular circumstance (its use), rather than the blunter approach of intervening whenever there is a *hazard* (box 2.2).

The Commonwealth, state and territory governments have agreed to take account of costs, benefits and risks when formulating national regulations they intend to implement jointly. This commitment is outlined in the Best Practice Regulation: A Guide for Ministerial Councils and National Standard Setting Bodies by the Council of Australian Governments (COAG 2007a). Ministerial councils and national standard-setting bodies are to ensure that a regulation impact statement (RIS) is prepared for regulations they propose. Each RIS has to demonstrate the need for regulation, show that it would deliver a net benefit, and explain why alternatives were not preferred. The COAG principles and guidelines also outline how risk can be considered in preparing a RIS.

Box 2.1 Information failures and the regulatory responses in the market for chemicals and plastics

There are three kinds of information failure in the market for chemicals:

- Beyond what might be required under common law, chemical producers and importers have relatively weak incentives to assess potential hazards and risks to human health, the environment and national security from the use of chemicals
- Similarly there are weak incentives to communicate these hazards and risks to chemical users.
- Even if hazard information were provided to them, many users lack the technical expertise to interpret hazard and risk information or to determine appropriate risk management strategies.

These information failures can be addressed through regulations that require information on hazards and risks to be collected, and communicated to chemical consumers (farmers, workers, households). This information can be communicated in different ways depending on their level of knowledge about chemical hazard and risk management, the intended chemical use, and the potential for harm. These regulations:

- establish specialist scientific assessment agencies that require chemical producers and importers to submit information on the chemicals they supply, and assess hazards and risks on behalf of the community. This role is undertaken by NICNAS for industrial chemicals and the APVMA for agricultural and veterinary chemicals, and other agencies that provide input to them.
- require that information on hazards be disseminated through labels and the supply of Material Safety Data Sheets for chemicals that have undefined uses. This allows chemical users to do their own risk assessment according to how they are going to use the chemical, and to develop appropriate risk management practices. This is the approach used for most industrial chemicals in Australia.
- establish processes to facilitate the correct interpretation of assessment information:
 - in cases where use is defined, labels may be risk based with specific instructions on use and how risks should be managed (for example, pesticides under the Agvet Code)
 - standard-setting bodies set standards for chemical use where hazard communication alone is unlikely to be sufficient to allow users to adequately manage risks (for example the National Code of Practice for the Storage and Handling of Workplace Dangerous Goods (ASCC Model Regulations))
 - where chemicals are very hazardous or dangerous and there is a high risk of harm, use may be confined to people who have been specifically trained or authorised (for example, schedule 7 poisons).

To varying degrees, individual jurisdictions also require the preparation of impact statements outlining the case for a proposed regulation. For national regulations implemented solely by the Commonwealth, the requirements are specified in the Best Practice Regulation Handbook and are overseen by the Office of Best Practice Regulation (Australian Government 2007). Risk analysis is a part of these requirements.

Box 2.2 Assessing hazards and risks and managing the risks

A product is said to have *hazardous* properties if it has the potential to harm human health or the environment. The *risk* such a product poses to community wellbeing depends on the probability of harm occurring and the magnitude of the consequences.

Some products with hazardous properties pose little risk to the community because adverse impacts are minor or unlikely to occur. Products that expose the community to significant risk of harm may justify costly forms of regulation to manage the risk.

To ensure regulation is commensurate with the risk a product poses, the following four-step strategy should be followed:

1. develop a policy framework — establish a clear set of objectives and governance principles including adherence to regulatory impact assessment processes and *ex post* monitoring and review
2. undertake hazard and risk assessment — identify the hazard to human health or the environment, and determine the level of risk posed to community wellbeing
3. develop a risk management approach — consider all of the regulatory options (including self-regulation) and establish standards to manage the risk in a way that delivers the greatest expected net benefit to the community
4. administer and enforce the standards — choose the most effective and efficient way to implement the standard including through existing mechanisms.

Where a government imposes regulation, a key question is how far it should reduce risk. Incremental reductions in risk may initially deliver net benefits, but as increasingly restrictive regulations are imposed, a point will be reached where the costs exceed the benefits. To avoid this, a policy intention of governments should be to reduce the risks (to human health, the environment and national security) from chemicals only to the point where the marginal costs of taking additional action materially exceed the marginal benefits.

The alternative of minimising risks regardless of costs and benefits is inappropriate, because it could make the community worse off. To illustrate, in the extreme, banning all pesticides would reduce risk from their use to zero, but the costs to consumers and industry would be very high. Rather, risk is reduced to a level

acceptable to the general community through measures such as regulated maximum residue levels.

The terms of reference for this study identify four areas where the risks associated with chemicals and plastics are of particular concern:

- public health
- occupational health and safety (including transport and on-farm safety)
- environmental protection
- national security.

The specific market failures in each of these areas are detailed in following chapters.

2.2 Interpretation of assessment criteria

The terms of reference for this study require chemicals and plastics regulations to be assessed against various criteria. The Commission's interpretation of these criteria for the purposes of this study is outlined below.

Effectiveness

The Commission has been asked to assess chemicals and plastics regulations for their effectiveness.

Effectiveness measures how well a regulatory output achieves the intended policy outcome. The relevant objective is usually taken to be that stated in the preamble to the regulation, or by the government that formulated it. Stated objectives are sometimes inconsistent with efficiency. If, for example, the objective was to minimise risk regardless of costs and benefits, the regulation could be effective but make the community worse off.

To avoid this problem, both effectiveness and efficiency have been evaluated. Thus effectiveness has been interpreted not only in terms of stated objectives but also in terms of how well a regulation reduces risks to acceptable levels (that is, levels where regulation delivers the maximum possible improvement in economic efficiency, because no further reduction in risk can be achieved without imposing a net cost on the community).

Efficiency, productivity and competitiveness

The Commission has been asked to assess the impact of chemicals and plastics regulations on the *productivity* and *competitiveness* of the chemicals and plastics industry, Australian industry, and the economy as a whole. The Commission has also been asked to report on the *efficiency* of current institutional and regulatory frameworks for chemicals and plastics regulation, and existing arrangements for security sensitive ammonium nitrate.

The concepts of efficiency, productivity and competitiveness are related. In essence, productivity is the rate at which outputs are generated from inputs.¹ This is a major determinant of competitiveness, which is the ability to compete against others in markets to sell goods and/or services. Efficiency, in its broadest sense, refers to how well resources are used to benefit the wellbeing of the whole community. This broad interpretation is known as economic efficiency and has three components, one of which — productive efficiency — also depends on productivity (box 2.3).

Box 2.3 Components of economic efficiency

Economic efficiency is about maximising the wellbeing of the members of the community. There are three components:

- *Productive efficiency* is achieved when output is produced at minimum cost. It incorporates technical efficiency, which refers to the extent to which, in the production of any good or service, it is technically feasible to reduce any input without decreasing the output, and without increasing any other input.
- *Allocative efficiency* is about ensuring that the community gets the greatest return (very broadly defined) from its scarce resources. A nation's resources can be used in many different ways. The best or 'most efficient' allocation of resources is the one that contributes most to community wellbeing.
- *Dynamic efficiency* refers to the allocation of resources over time, including allocations designed to improve economic efficiency and to generate more resources. Investments in education, research, development and innovation are involved. Dynamic efficiency can also refer to the ability to adapt efficiently to changed economic conditions.

¹ Productivity is a general term that covers a variety of measures used to quantify output(s) relative to input(s). Partial productivity measures quantify output per unit of a single input, such as labour. Multifactor productivity quantifies the use of primary inputs — labour and capital — in generating value added (the return to labour and capital). Total factor productivity uses gross output as its measure of output and, in addition to capital and labour, includes intermediate transactions in materials and services as inputs. (Gretton and Fisher 1997)

In this study, the Commission has given priority to how well regulations improve economic efficiency (that is, how much regulations improve the way resources are used to benefit the wellbeing of the whole community). This is consistent with the requirements of the *Productivity Commission Act 1998*, which obliges the Commission to take account of the wellbeing of all members of the community.

The impacts of regulations on specific groups — including on the productivity and competitiveness of the chemicals and plastics industry, and Australian industry more generally — are considered in this study as part of the broader assessment of the impact on community wellbeing. Thus, regulations that impose costs on firms may nonetheless be supported by the Commission, because they deliver a net benefit to the community as a whole. Conversely, regulations are not supported if they do not make the community better off, or due to poor regulatory design, do not deliver the greatest possible improvement in community wellbeing.

2.3 Applying the assessment criteria

In light of the above, chemicals and plastics regulations have been assessed by addressing the following three questions:

1. Are the regulations effective in achieving the stated outcomes?
2. Are they efficient?
3. Is uniformity the best approach?

Are the regulations effective?

The Commission undertook a review of all available performance data, and found only a limited number of direct assessments of the effectiveness of the chemicals regime in achieving the required health, safety, environment and security outcomes. Indirectly, inferences can be drawn from an array of available statistics on public health outcomes and reported work safety incidents. Environmental outcome measures are generally restricted to location-specific research, although ‘state-of-the-environment’ reporting is progressively developing an integrated framework. There are little publicly available data on national security outcomes, and little inference can be drawn as to the effectiveness of the regulation of security sensitive ammonium nitrate.

It can also be difficult to determine how effective current regulations are, due to uncertainty about:

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- outcomes under current regulations — impacts on human health and the environment can be hard to measure, and so there may not be sufficient data to establish outcomes with a high level of confidence
 - what would have happened in the absence of current regulations — it is not possible to observe this hence the ‘counterfactual’ benchmark is also uncertain.

Where effectiveness could not be observed directly, the Commission made a judgement based on a range of indirect measures, such as the:

- clarity of objectives in regulations (assuming these would facilitate enforcement and compliance)
- prevalence of loopholes, gaps and inconsistencies among regulations (assuming these compromise effectiveness)
- number and severity of reported adverse events, and how this compares to other jurisdictions (subject to the caveat that observed differences may not be attributable solely to differences in regulations, and some types of adverse events may be under-reported)
- extent to which regulations are enforced (using indicators such as the resources devoted to publicising and enforcing regulations, and the degree to which different regulators and jurisdictions coordinate their enforcement activities, where this could aid effectiveness).

Another useful guide is a checklist for assessing regulatory quality that the former Office of Regulation Review (now the Office of Best Practice Regulation) prepared on the basis of a range of OECD and other reports (box 2.4).

Box 2.4 Checklist for assessing regulatory quality

Regulations that conform to best-practice design standards are characterised by the following seven principles and features:

- Minimum necessary to achieve objectives
 - Overall benefits to the community justify costs
 - Kept simple to avoid unnecessary restrictions
 - Targeted at the problem to achieve the objectives
 - Not imposing an unnecessary burden on those affected
 - Does not restrict competition, unless demonstrated net benefit
- Not unduly prescriptive
 - Performance and outcomes focused
 - General rather than overly specific
- Accessible, transparent and accountable
 - Readily available to the public
 - Easy to understand
 - Fairly and consistently enforced
 - Flexible enough to deal with special circumstances
 - Open to appeal and review
- Integrated and consistent with other laws
 - Addresses a problem not addressed by other regulations
 - Recognises existing regulations and international obligations
- Communicated effectively
 - Written in 'plain language'
 - Clear and concise
- Mindful of the compliance burden imposed
 - Proportionate to the problem
 - Set at a level that avoids unnecessary costs
- Enforceable
 - Provides the minimum incentives needed for reasonable compliance
 - Able to be monitored and policed effectively

Source: Argy and Johnson (2003).

Are the regulations efficient?

Could regulation improve the way resources are used to enhance community wellbeing?

Efficiency is enhanced where regulatory intervention addresses a market failure, and intervention would produce a net benefit to the community. The Commission was more likely to assess regulation as being justified on efficiency grounds if:

- there was a clear regulatory objective to reduce risks to human health and the environment to acceptable levels, rather than to minimise risks regardless of costs and benefits
- the case for regulation had been demonstrated in a RIS (or similar process) that included a thorough cost–benefit analysis
- existing generic (not chemical-specific) regulations could not adequately address the market failure. Generic regulation is common for the four risk areas identified in this study’s terms of reference, and hence supplies a fall back option in many cases
- the regulatory response was proportionate to the problem.

Do current regulations deliver the greatest efficiency gains or are reforms required?

While there might be a case for regulating chemicals and plastics on efficiency grounds, the gains achieved in practice could be well below potential. Reasons for this include:

- loopholes and inadequate enforcement that make regulations ineffective
- overly complex requirements and administration that add to costs, change production methods or otherwise discourage innovation, impose opportunity costs (often from approval delays) and create barriers to competitive entry
- duplication and inconsistency among regulations and jurisdictions that results in an increase in the costs of administering and complying with regulations
- gaps in the regulatory framework that mean market failures are not currently being addressed and there would be a net benefit to the community from doing so.

Are administration and compliance costs higher than necessary?

The cost to government of administering regulations and to firms of complying with them should ideally be proportionate to the problem and the minimum necessary to achieve effective outcomes. Costs may be higher than necessary if best-practice approaches to regulatory design, administration and/or enforcement are not being used.

In principle, benchmarking administration and compliance costs across jurisdictions can identify the lowest cost arrangements.² The extent to which a regulation's costs are higher than necessary — termed the excess burden — can then be quantified as the difference between the regulation's costs and those under best practice. However, there are several challenges associated with quantifying a regulation's excess burden (box 2.5).

The Commission received only a limited amount of cost information that could be used to determine the relative efficiency of existing regulations. This can be partly attributed to the difficulty participants faced in isolating a regulation's incremental cost from the costs they traditionally record for accounting purposes. This was the case for government administration costs, as well as business compliance costs. Furthermore, it is unrealistic to expect participants to always know what the incremental cost would be under best-practice regulation, and hence, to calculate the excess burden of current arrangements.

In light of the limited quantitative evidence on costs, the Commission supplemented its analysis with a qualitative assessment of whether existing regulations have features likely to lead to unnecessarily high administration and compliance costs. The terms of reference suggest such features may include duplication and inconsistency within and across jurisdictions, unjustified divergences from accepted overseas standards, and overly complex data requirements and assessment processes. The evidence supplied by participants in this study is used throughout this report and summarised in appendix E. In addition, the Commission has previously published a comprehensive list of indicators that could potentially be used to assess compliance burdens (PC 2007b).

² An alternative, but more speculative, approach would be to attempt to estimate what might be the costs under a theoretical best-practice regime.

Box 2.5 **Estimating excess regulatory burden**

Although intellectually appealing and conceptually intuitive, the excess burden created by regulation is difficult to quantify. Ideally such quantification should be based on the incremental cost a regulation imposes, netting out the cost of activities that would have occurred regardless. Some of these activities may be linked to other regulations, including generic requirements onto which chemical-specific rules are grafted, thus requiring the various costs to be disentangled. Some activities required by chemical-specific regulations, such as actions to clean up accidents, may occur regardless of regulation and so also need to be factored out of the cost calculation.

Conversely, a regulation may stifle some activities by creating 'opportunity costs' through, for example, delays to project implementation, impediments to innovation, and barriers to entry. Ideally, this should also be reflected in the calculation of regulatory costs. Another challenge is how to take account of different circumstances, objectives, and effectiveness in achieving those objectives when comparing regulatory costs between jurisdictions.

There is also the question of how to obtain the necessary cost data. The Commission asked all governments to provide data on the cost of administering their chemicals and plastics regulations. It was not practical to similarly contact all firms subject to those regulations about their compliance costs. A survey of firms was not pursued because of the difficulty of ensuring a representative sample, given the wide diversity of firms and regulations involved, and of designing questions firms could readily answer. In this respect, the Commission was mindful that the accounts of firms are not primarily set up to record the incremental compliance costs of government regulations. Instead, the Commission issued a general request to industry bodies and individual interested firms to submit evidence about cases where compliance costs are claimed to be excessive.

The challenges this study faced are consistent with observations the Commission previously made in a general review of regulation benchmarking:

Many businesses would have to be surveyed in order to build up a picture of average costs so that aggregate burdens could be estimated. In addition, the relationship between indirect indicators and incremental cost would have to be quantified in order to reliably estimate actual compliance costs. Even if actual incremental compliance costs could be estimated, it would be difficult to enumerate aggregate costs. Currently, there is a paucity of information on the demographics of business, and a lack of understanding of the reach of regulations, to estimate the number of businesses affected by unnecessary regulatory burdens and the costs they incur. (PC 2007b, p. 6)

Should uniformity always be the goal?

The terms of reference for this study assume that, in general, gains could be achieved by streamlining and harmonising regulations into a national system, including by enhancing national uniformity and consistency, and by removing regulatory duplication and inconsistency within and between jurisdictions. It is also

assumed that reducing divergences from overseas standards and using alternatives to regulation would be beneficial.

Harmonisation and uniformity are key terms. Regulations are harmonised by aligning common elements, such as definitions, certification requirements, enforcement protocols, and measurement systems. National uniformity occurs when all jurisdictions across Australia have the same standards and codes of practice and, desirably, the same legislative base. Uniformity is therefore at one end of the spectrum of possibilities, with complete inconsistency at the other end, and a variety of harmonisation possibilities in between.

National uniformity

While the terms of reference assume a case in favour of converging on a uniform national system, there are often tradeoffs involved in favour of subnational jurisdictions tailoring regulations to their own circumstances and preferences. The Commission has previously noted that the ‘subsidiarity principle’ provides some guidance on how to handle this issue:

Under this [subsidiarity] principle, responsibility for a particular function should, where practicable, reside with the *lowest* level of government (see, for example, CEPR 1993; Kasper 1995, 1996). This rests on four main considerations:

- subnational governments are likely to have greater knowledge about the needs of the citizens and businesses affected by their policies
- decentralisation of responsibility and decision making makes it easier to constrain the ability of elected representatives to pursue their own agendas to the disadvantage of citizens they represent
- intranational mobility of individuals and businesses exposes subnational governments to a reasonable degree of intergovernmental competition
- initial emphasis on the lowest level of government encourages careful consideration or testing of the case for allocating a function to a higher or national government and thereby guards against excessive centralisation. (PC 2005, p. 3)

On the other hand, the Commission has also previously noted there is broad support for a national regulatory system when:

- there are significant interjurisdictional spillovers associated with the provision of a good or service at the subnational level (for example, interstate transport systems)
- there are readily identifiable areas of shared or common interest or sizeable economies of scale and scope arising from central provision or organisation (for example, defence, international or external affairs and social welfare support)

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- a diversity in rules or regulations is likely to give rise to high transaction costs with insufficient offsetting benefits (for example, regulation of companies, transport, the financial sector and trading provisions covering weights and measures)
 - there is scope for mobility of capital and people across jurisdictions to undermine the fiscal strength of the subnational level of government (for example, as arises with the income, capital gains and corporate tax bases; or with welfare entitlements). (PC 2005, pp. 3–4)

Three of the abovementioned factors — interjurisdictional spillovers, economies of scale and scope, and transaction costs — provide the grounds for cross-jurisdiction uniformity of the standards and codes of practice for chemical regulation. This is underpinned by the fact that the hazardous nature of chemicals is the same nationwide and indeed internationally.

However, it does not necessarily follow that cross-jurisdiction coordination is always best administered by a national regulator. Common codes may need to be sufficiently flexible to allow some regulatory differences between jurisdictions when the market failure being addressed depends heavily on local circumstances. For example, a national approach to regulating pesticides may need to recognise that the conditions of use should vary according to local environmental conditions. Interjurisdictional differences could also arise where chemicals legislation is grafted on to differing underlying legislative frameworks, and where there are different institutional arrangements, enforcement mechanisms, and interpretation acts.

Thus, while cross-jurisdiction coordination is generally supported in this study, the merits of taking this as far as national uniformity and a national regulator have to be judged on a case-by-case basis. This issue is dealt with in chapter 3 and subsequent chapters.

International uniformity

Given that the hazards posed by chemicals are universal in nature and many risks are also common, there can be much to be gained from aligning Australian regulatory requirements with those of similar developed countries. Having compatible regulatory requirements can facilitate trade in many ways. For example, having the same or similar assessment requirements facilitates entry of new chemicals, and having the same packaging and labelling requirements decreases costs of imports and exports. And in some circumstances, harmonisation with international standards may be required under Australia's international obligations (such as our general obligations under such agreements as the GATT Technical Barriers to Trade Agreement (Standards Code) and chemical specific obligations under such treaties as the Stockholm Convention on Persistent Organic Pollutants).

In an international context, harmonisation rather than uniformity will most often be the more realistic approach, given that different countries have different institutional frameworks, and different attitudes to risk. There can be considerable scope to adopt consistent technical standards (subordinate to the necessarily different primary legislation), especially if many countries are converging on an accepted approach. International consistency can also be promoted through deemed-to-comply and mutual recognition arrangements.

Benchmarks provided by international standards are, therefore, a key part of the assessment framework and are considered throughout this report. As a rule, closer alignment with international standards is generally supported, provided that it is consistent with the wellbeing of the Australian community.

