Smart regulation: Grappling with risk

Supporting paper

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Victorian Competition and Efficiency Commission
GPO Box 4379
MELBOURNE VICTORIA 3001
AUSTRALIA

Telephone: (03) 9092 5800
Facsimile: (03) 9092 5845
Website: www.vcec.vic.gov.au

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Introduction

This supporting paper complements the Commission's guidance note *Smart regulation: Grappling with risk*. Whereas the guidance note acts as a 'how to' handbook for tackling risk in regulatory settings, this supporting paper discusses the underlying principles and rationale for doing so. It also examines some of the practical challenges that policy officers and regulators have raised during the Commission's consultations for this guidance. Reflecting the diversity of regulatory activities, some of these issues will not be relevant to every regulatory context — but they help illustrate the complexity of the task facing policy officers and regulators.

As with the guidance note, this paper is aimed at policy officers developing policy and designing regulation, and regulators administering and enforcing regulation. It builds on the Commission's work (including improvement studies, regulatory impact assessments and inquiries), regulators' experience and feedback, and research from around Australia and internationally.

Part 1 explains risk-based regulation and establishes a framework that is applied to the regulatory process. Subsequent parts examine the processes and challenges in implementing risk-based regulation at each stage in the regulatory cycle. It provides guidance for policy makers in departments and regulators (part 2), and to regulators administering regulatory processes and undertaking compliance and enforcement (part 3).

1 A risk-based approach to regulation and regulating

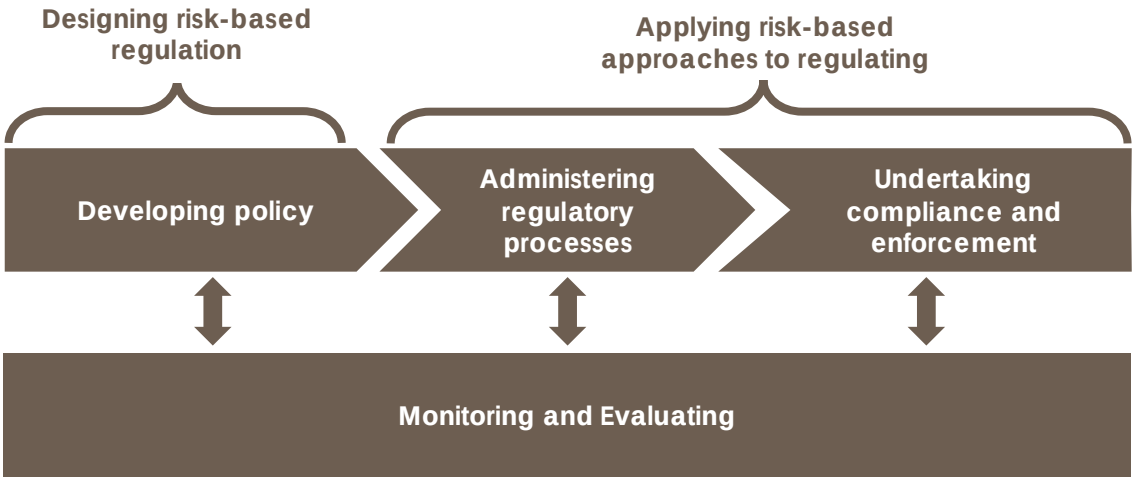
1.1 What is a systems approach to risk-based regulation?

Consider risk at all stages of the regulatory cycle and ensure the complementary systems necessary for regulators to be risk-based are considered and put in place.

The Victorian Government has an established framework for implementing risk management in the public sector, which focuses on risks that directly affect the agency and its operations. There is no similar systematic framework for implementing risk management in a regulatory context.

Risk-based approaches are relevant at all stages of the regulatory cycle: policy development, administering regulation, compliance and enforcement, and evaluation; with evaluation integrated across the preceding three stages and used to fine-tune and improve regulation (figure 1.1).

Figure 1.1 Regulatory cycle



Risk-based regulation needs to be embedded at all levels in the organisation and requires that:

(1) organisational structures, roles, authorities and accountabilities are clear and support risk-based decision making

(2) work is done at the right level by the people with the necessary skills

(3) data and information are gathered and used

(4) regulatory documents (statements, policies, guidance and processes) are developed with consultation, accommodate risk-based approaches, and are communicated to the regulator's staff and stakeholders.

Risk-based regulation is most effective when its design and implementation are consistent with the principles of good regulatory practice (box 1.1)

Box 1.1 Principles for good risk-based regulation

The Australian Environmental Law Enforcement and Regulators Network argued risk-based regulators should apply the principles of modern regulation to their decision making processes. That is, decision making should be:

- **targeted** — allocate effort to the areas of most serious harm
- **effective** — judge risk accurately and introduce regulatory responses that seek to prevent harm or improve outcomes
- **proportionate** — ensure regulatory responses are proportionate to the problem they seek to address
- **transparent** — open the processes and outcomes to the public and regulated community
- **inclusive** — develop regulation in partnership/consultation with community, business and government
- **consistent** — apply decision-making processes consistently and predictably to different parties and situations
- **authoritative** — maintain an authoritative understanding of the environment and information on the level of compliance
- **accountable** — set clear standards and prepare to be judged on the decision-making process and outcomes.

Source: ALERT 2013, 4.

1.2 Where to start

Start with reforms in areas where risk-based approaches are feasible and the potential benefits from regulatory reform are larger than the costs. Introduce processes that are more informed by risk and improve them over time.

Policy departments and regulators can maximise the benefit of risk-based regulation by prioritising areas where:

- there are benefits in differentiating regulation based on risk
- there is scope to vary the regulation or its administration or enforcement in response to different levels of risk
- the benefits of better targeting outweigh additional process or data costs.

Further, it may be worth prioritising areas where differentiating the level of regulatory burden encourages businesses or individuals to voluntarily reduce risk or improve their compliance. Similarly, policy officers may focus on areas where risk-based approaches help achieve other policy objectives such as reducing the regulatory burden on business.

Most regulators have some regulations that reflect risk, but their interpretation of what is risk-based, and the extent to which they consider risk in designing regulation and regulatory processes varies considerably. Policy officers and regulators appear to progress through three stages in using risk-based approaches to regulation (figures 1.2 and 1.3).

Nearly all regulators and those developing government policy are aware of risk and its importance in designing and delivering regulation. Some policy departments and

regulators use their current data to inform regulation and regulatory processes and explicitly consider risk in designing and delivering regulatory and enforcement activities.

Very few, however, have embedded risk-based methodologies in all stages of regulation design and delivery. For a regulator, this means considering risk in agency-wide strategic planning and then feeding those risk priorities though business planning, priority setting, and task allocation to frontline decision making. There are also gaps in the clarity of policy objectives and the appetite for risk, data availability, and the skills and resources available to the regulator.

Moving to risk-based regulation requires transition. Decision makers need time to establish the necessary processes, collect relevant data, build staff skills, and change organisational culture (Lahidji 2008, 16; OECD 2010, 220–2).

Figure 1.2 Policy officers — three stages in developing risk-based regulation

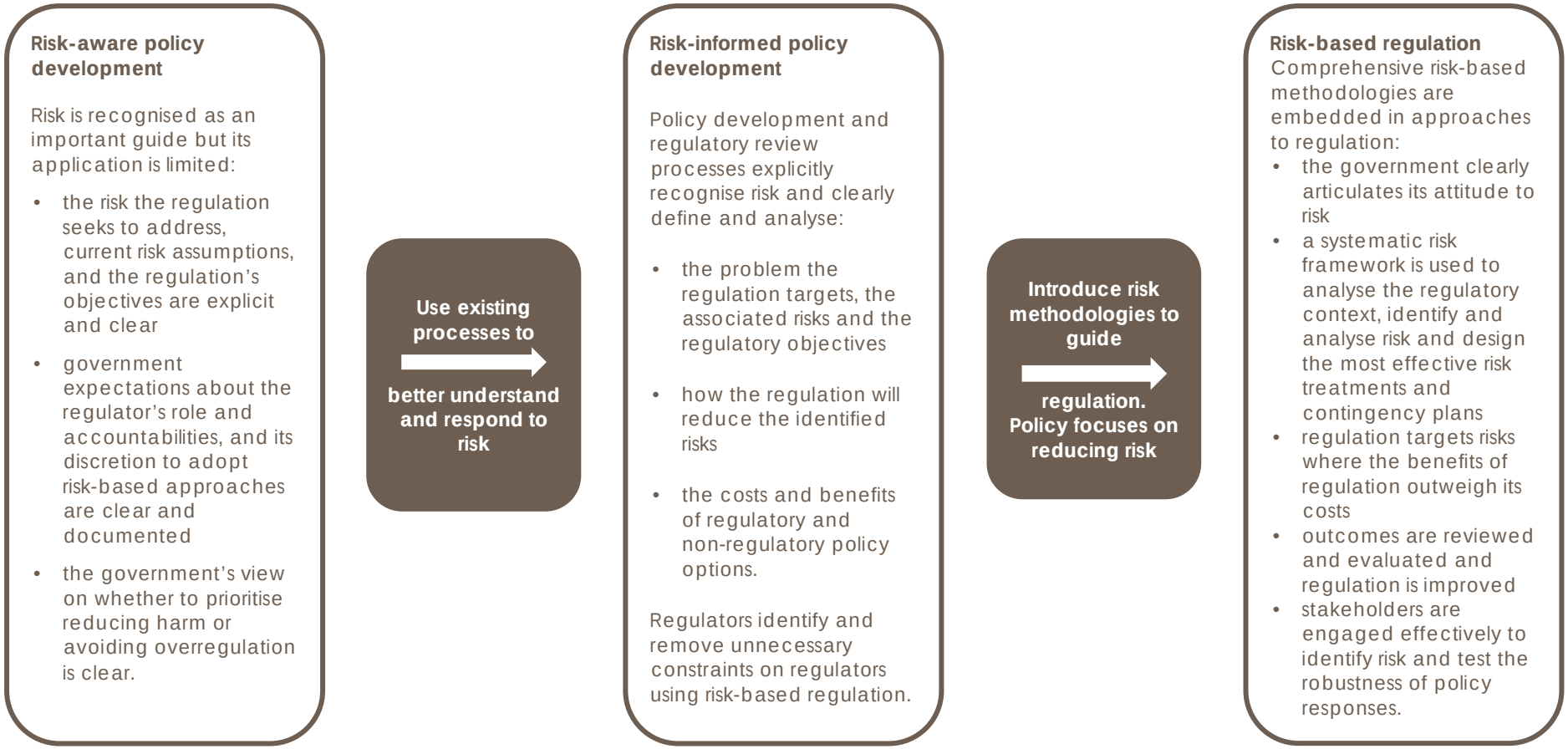
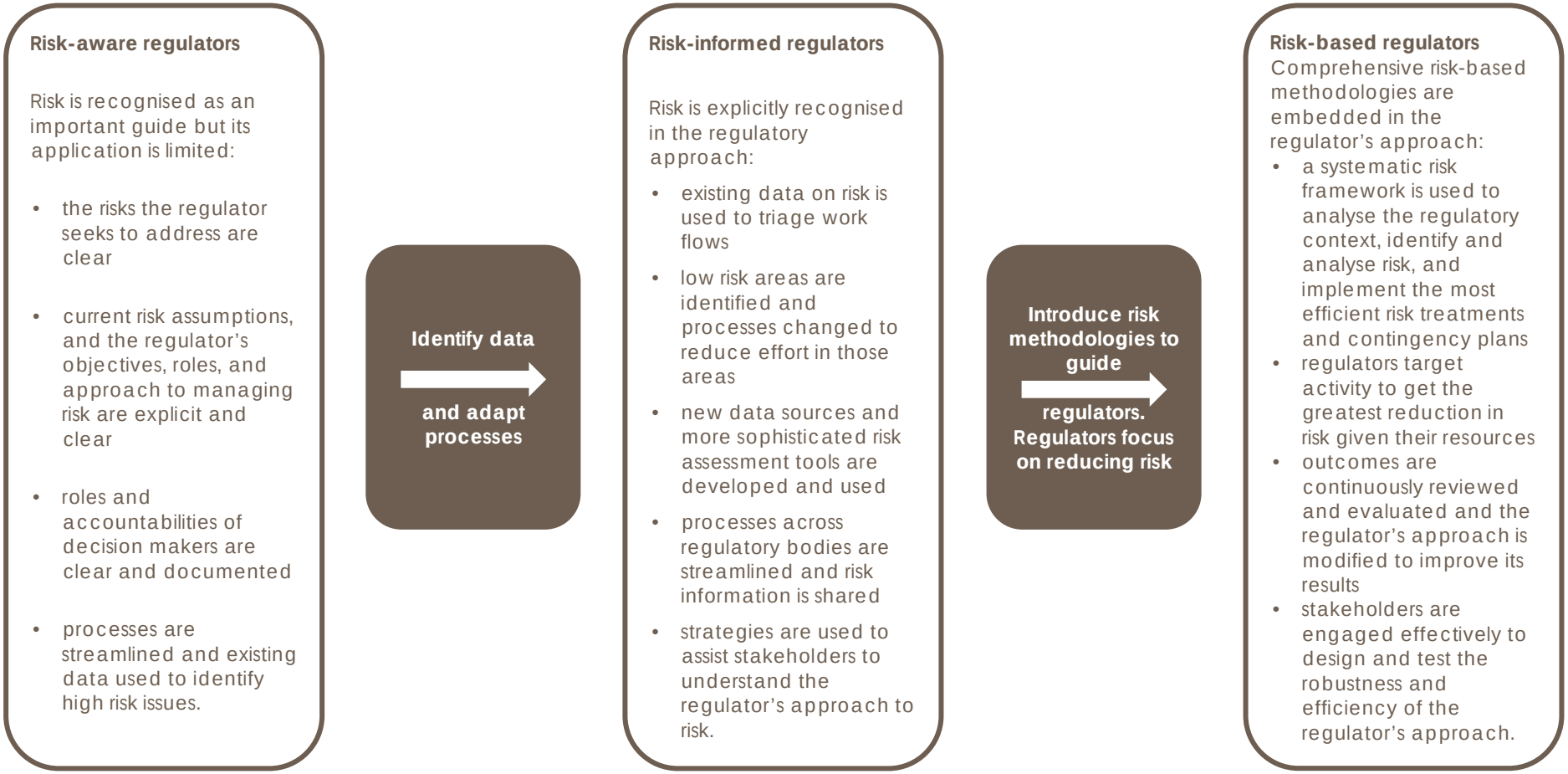


Figure 1.3 Regulators — three stages in regulators' use of risk-based frameworks



1.3 Elements of a comprehensive risk-based framework

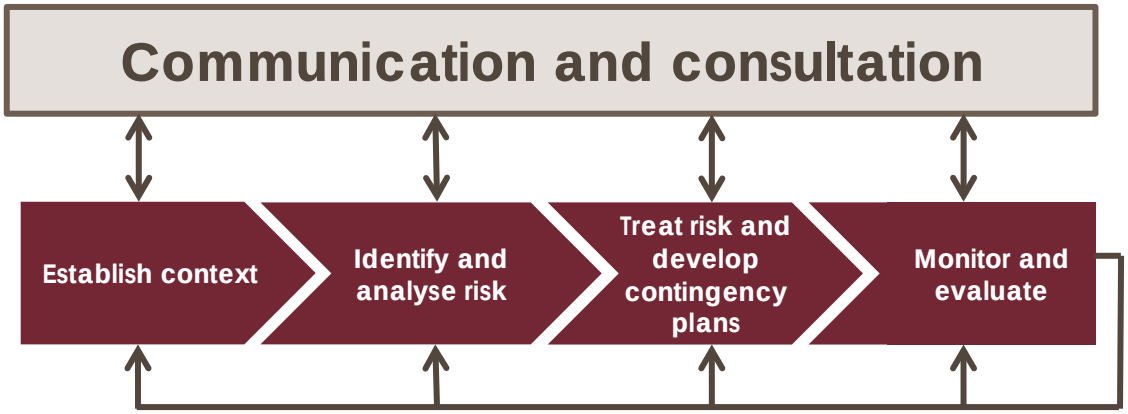
Apply a comprehensive risk-based framework to inform regulatory priorities and resource allocation.

Applying a comprehensive risk-based framework involves the following (figure 1.4):

- **Establish context** — outlining the relevant policy environment, including the interests of different stakeholders and the risk attitude of the government
- **identify relevant risks** — ensuring the policy and regulatory framework is based on a common understanding of the potential harms and the risks that contribute to those harms
- **analyse significant risks** — focusing attention on non-trivial risks, based on the government's risk attitude. Risks should be detailed and categorised, with clear measures to assess performance. An objective of zero risk (absolute safety) is neither desirable nor attainable (Majone 2010, 125). Regulators can spread their resources too thinly across many minor risks (reducing their effectiveness). It can also discourage innovation and the adoption of beneficial new technologies (Graham 2010, 239 and UNECE 2012, 30).
- **treat risks** — assessing the strengths and weaknesses of the available tools to address risks, and determining which tools are most appropriate for delivering the greatest reduction in the risk of harm to the community or the environment
- **develop contingency plans** — defining how the regulator will respond to adverse events. Such plans are critical to the regulator identifying and managing unexpected outcomes and protecting itself and the regulation from backlash if there is a crisis or a low probability incident occurs
- **monitor and evaluate outcomes** — establishing processes for collecting data and information, and reviewing the efficiency and effectiveness of the regulatory regime. This stage should be integrated throughout the process, with the results used to fine-tune and improve regulation.

Consultation and communication are important at all stages. Attachment 1 contains an indicative example of applying this framework.

Figure 1.4 Risk management framework



The guidance note and supporting paper use a risk-management framework based on conventional risk-management processes (consistent with the Australian and New Zealand standards (AS/NZS 2009)). There are some differences, however, when applying these processes in a regulatory context:

- it focuses on reducing risk that affects third parties, not risks that directly affect the regulator
- it manages risk across the regulatory cycle, often involving multiple agencies
- monitoring and contingency planning are particularly important and need to be linked closely to external communications.

The framework has two objectives: first, to analyse risks, and set regulatory priorities and allocate resources; and second, to prioritise actions that reduce risk most in areas that affect the regulator's ability to achieve its objectives. There is debate, however, about whether priorities should be set based on risk analysis alone (box 1.2). Governments may choose to adjust risk priorities on equity grounds — for example, by placing a greater emphasis on protecting disadvantaged communities. Regardless of how other factors inform priorities, rigorous risk analysis ensures decisions are informed, deliberate and explicit.

This process is not linear and analysis at all stages is refined as regulators better understand each risk, its likelihood and consequences, and the cost and effectiveness of treatment. For example, the assessment of treatment options informs the agency's assessment of the attitude to risk, including whether government action can cost-effectively reduce harm. Risks and community expectations and values are dynamic. So risk analysis must be continuously refined and improved.

Box 1.2 Debate about relying on risk-based analysis

Some commentators argued regulatory priorities should not be set based on risk alone. First, risk is difficult to measure. The tools to analyse risk may not recognise the complexity of reality (Danielsson 2003, 4; Hutter 2005, 8). Specifically, these tools may not be applied effectively, given measurement difficulties and insufficient data (Bartle 2008, 5; Lloyd-Bostock 2009, 5). Further, the results may be unreliable, reflecting bias in applying the tools or drawing conclusions from the results (Rothstein and Downer 2012, 790).

Analysing risk using both quantitative tools and qualitative information from a range of sources would help address this problem (see part 3). Decision makers should test their conclusions against information from various sources, not avoid or ignore risk analysis.

Second, other considerations may be relevant. Some commentators argued government and regulators should account for the attitudes and perceptions of society when setting regulatory priorities:

- there are times when the government needs to reassure the community (Black 2010, 212; Freiberg and Carson 2010, 158; Haines 2009, 35–6), or take action to maintain confidence in the regulation or the regulator (Bounds 2010, 29–30; Rothstein et al 2013, 221; Sparrow 2000, 250).
- precedent setting can also be important, such as when the damage caused by an incident is low but taking action would: maintain consumers' or importers' confidence in the industry (King nd, 9); or encourage compliance more broadly (Sparrow 2000, 250).

The United States Nuclear Regulatory Commission, for example, described its regulatory approach as risk-informed and performance-based, rather than risk-based (USNRC 2014). That is, risk assessments augmented, rather than replaced, the existing regulatory structure (Coburn et al 2005, 3).

1.4 Gaps in the current framework

Recognise the gaps in the tools are significant and widespread.

There are significant and widespread gaps in the tools currently available to apply the steps in a risk-management framework to regulation (table 1.1). Some comprehensive tools are available in the *Victorian Guide to Regulation*, statements of expectations, and government planning and reporting processes. Recent amendments to the regulation have increased the emphasis on implementation planning and evaluation. In table 1.1 green indicates a competent tool is available. Yellow indicates the tool can be informative but does not address all the issues required. Red indicates a gap in the available tools. Even if a tool is available it may not be used effectively to analyse and manage risk.

In some other areas, departments or regulators implement internal approaches to fill the gaps. Other research can also inform risk-based decisions — for example, Auditor General reports, public inquiries, regulatory improvement studies, or research work by academics. But there is no systematic framework for implementing risk management in regulation, so often these efforts are agency-specific and ad hoc.

Table 1.1, and much of the material in this document, focuses on the tools and processes being applied in Victoria. A number of Victorian regulators, however,

implement national regulatory frameworks. This presents additional challenges: Victoria has less control over the overarching framework and the extent to which it is risk based. Decision makers need additional processes to influence national reform.

Table 1.1 Coverage of existing policy tools

Process steps		Policy development	Administering regulatory processes	Compliance and enforcement
Establish context	Identify the policy context in which decisions are being made, including the objectives government action is trying to achieve and the intended outcomes for harm reduction	RIA[1] description of regulatory objectives and problem definition	Statements of expectations Objects of the Act Second reading speeches Policy statements	Compliance and enforcement strategies
	Identify relevant stakeholders and their interests	RIA analysis	Communication plans	Compliance and enforcement strategies
	Note the government's stated risk tolerance and attitude to risk	Government policy statements	Statements of expectations Second reading speeches	Statements of expectations
Identify risk	Determine which material risks contribute to the potential harms. Assess the likelihood and consequences of these risks	RIA problem definition		
Analyse risk	Categorise risks using qualitative and quantitative indicators of likelihood and consequences			
	Evaluate substantial risks in detail and identify their drivers			
	Determine the level of acceptable risk			
	Define how to measure success in reducing the substantial risks			

[1] Regulatory Impact Assessments (RIA) in Victoria include Legislative Impact Assessments for primary legislation and Regulatory Impact Statements for subordinate legislation.

Process steps		Policy development	Administering regulatory processes	Compliance and enforcement
Treat risk	Determine which risk treatments have the greatest benefits relative to their costs	RIA cost–benefit analysis	Corporate and business planning	Corporate and business planning
	Plan implementation	RIA implementation plan	Business planning	Business planning
Contingency planning	Plan monitoring to identify and respond to emerging issues and emergencies			
Evaluation	Establish data collection and feedback processes	RIA/high impact regulations RIA/low impact regulations	Corporate and business planning	Corporate and business planning
	Evaluate the outcomes and build a culture of improvement	RIA evaluation strategy	Annual reports Budget papers	Annual reports Budget papers

Source: VCEC analysis.

In practice, there are often gaps in:

- understanding the risks and harms the regulation is trying to reduce
- understanding the government's and agency's attitude to and tolerance of risk
- data and information on risk and using that information to analyse risk and inform decisions
- tailoring the regulatory approach to reflect risk
- contingency planning
- monitoring and evaluation and using this information to continuously improve regulation.

2 Developing policy: for policy officers in departments and regulators

Use risk-based regulation to augment existing policy development processes.

Developing policy is the first stage in the regulatory cycle. It involves:

- identifying major economic, social, and environmental problems
- considering whether government action is appropriate and cost effective (supported by regulatory impact analysis)
- drafting and passing relevant legislation and regulation.

Victoria already has requirements that influence how regulation is developed. Regulatory impact assessment is required for new and amended primary legislation (Acts); and for new, amended, and sunsetting subordinate legislation (statutory rules and legislative instruments) that impose a significant economic or social burden on a sector of the public. Specifically, this analysis:

- describes and assesses the nature and the extent of the problem(s) being addressed
- states the objectives of the proposed legislation (primary or subordinate)
- describes the expected economic, social and environmental impacts on affected groups (including small business in the case of legislative impact assessments (LIAs))
- assesses the costs and benefits of the proposal (which are quantified, where possible) and other practical means of achieving the objective
- explains why other options are not appropriate (Government of Victoria 2014, 7).

There is considerable overlap between regulatory impact assessment and the steps in a risk-management framework. They target similar issues, given most regulation is introduced to address concerns about the risk of injury or sickness, environmental damage, people being misled or exploited, or property damage or financial loss.

According to the Victorian Guide to Regulation, policy officers and regulators should use risk analysis in regulatory impact assessments to assess if the government should intervene. The guide also notes that risk analysis is an important part of cost benefit analysis (box 2.1). In addition Toolkit 1 on the purposes and types of regulation (attached to the guide) summarises how risk analysis can be applied to develop risk-based regulation.

The guidance note and supporting paper therefore complement the Victorian Guide to Regulation by describing the issues that policy officers and regulators need to consider in a risk-based approach to policy development (see table 2.1 of the guidance note).

Box 2.1 Risk analysis in regulatory impact assessment

The assessment and analysis of risk is essential to the identification of a problem. Risk analysis involves identifying the probability and extent of risks arising from a given activity or situation. It can show the relative importance of the various contributors to the overall risk profile, and help identify where work should be focused to reduce that risk. Given the limited resources of government and/or the potential costs of regulation, action should be proportionate and targeted on those risks or hazards that are significant and/or have significant consequences.

CBA should also contain an assessment of risk. Risk assessment allows regulatory options to be compared in the context of risk (noting elimination of risk is usually not possible or practicable). It is important when determining the appropriate regulation to manage the risk of harm to people, property or the environment, and to reduce it within acceptable parameters. Risk assessment should involve consideration of the wider effects of introducing a regulation, since a regulatory regime aimed at reducing one risk may lead to other unintended outcomes. (For example, the imposition of unnecessarily strict safety requirements on physical recreational activities may discourage such activities and may contribute to poorer health outcomes.) Risk management options should be informed by the government's and community's appetite for risk in relation to the problem or issue being considered.

Source: Government of Victoria 2014, 14, 22.

Analysis should be comprehensive enough to identify the target risks without omitting major risks, and focus quickly on areas where government action is a necessary, effective and efficient way to reduce risk. Attachment 1 of the guidance note lists some common techniques for analysing risk.

2.1 Where to start

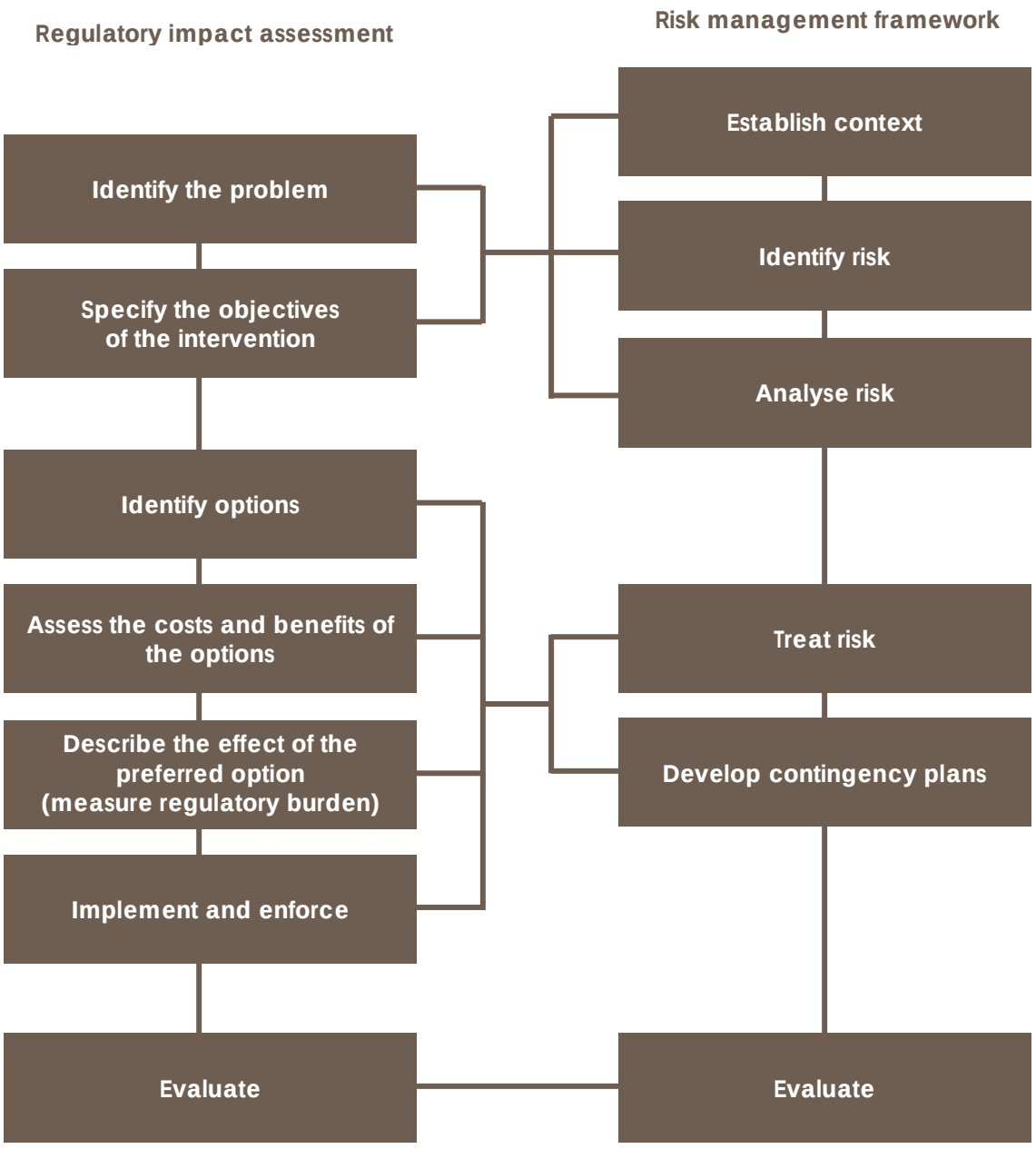
Explicitly analyse risk in the relevant legislative impact assessment or regulatory impact statement.

The regulatory impact assessment steps closely match the risk-assessment framework outlined in the guidance note (see table 2.1 of the guidance note). This relationship is illustrated in figure 2.1 below.

As outlined in the guidance note, initially policy officers in departments and regulators should:

- clarify and understand risks
- build this risk understanding into policy design so regulation is introduced only when it is the best treatment option and it is designed to accommodate risk-based administration and enforcement
- evaluate regulation.

Figure 2.2 Aligning policy development and risk assessment processes



2.2 Establish context — clarifying objectives and the attitude to risk

Clarify the approach and attitude to risk.

As noted in the guidance note, clarifying the government's objectives — particularly its attitude to risk — is important to decide which risks will be regulated. Because the government's attitude to risk may not be explicit, policy officers should prepare a risk statement that, at a minimum, clarifies:

- the problem the government is seeking to address
- that the government does not expect risk to be eliminated but the regulator is to adopt a risk-based framework that allows it to set and explain its priorities based on evidence of risk
- whether the policy should prioritise harm reduction or avoiding overregulating.

Regulation is prone to error. Overregulation imposes undue costs on those who have to comply (such as regulated businesses or individuals). But underregulation increases the risk of imposing harms on the community. These errors are known as type 1 and type 2 errors (box 2.2). Given the possibility for regulatory error, policy officers need to clarify their priority: avoiding overregulation or minimising adverse events.

Identifying government's attitude to risk is difficult. As societies mature, citizens demand greater safety and predictability, increasing regulation (McKinsey 2013, 1). These pressures can intensify during times of crisis, and in this environment, it is difficult to accept regulation cannot guarantee safety. So an explicit government statement is important, stating that the government cannot eliminate risk, and that it expects regulators to prioritise their activities based on evidence of risk, and explain how and why it sets these priorities.

Regulators may be risk averse without this authority to manage risk. In Victoria ministers issue a statement of expectations for their regulators, outlining the minister's expectations and priorities for performance and improvement by the regulator. Many of these statements say that ministers expect regulators to be risk-based, but they could be expanded to stipulate the government's attitude to and tolerance for risk, including recognising that risk cannot be eliminated.

Box 2.1 Type 1 and type 2 errors

When governments regulate, they can make two types of errors.

- ***Type 1 error —*** regulation is imposed when it should not be. That is, regulation is introduced even though it is not needed or will be ineffective, or inefficient. This error leads to overregulation and a higher regulatory burden.
- ***Type 2 error —*** regulation is not introduced when it should be. That is, a problem is not addressed by regulation when it would efficient or effective to do so. This error leads to underregulation, so the risk of harm is higher than it should be.

  Whether the government is more concerned about type 1 or type 2 errors depends on the impact of the risk and the people it affects. If the consequences are small, or the economic cost of regulation is high, then the government may err on the side of a type 2 error. For example, there may be some uncertainty about the side effects of a new drug that targets previously untreatable cancers. However, the consequences of delaying access to a potentially life-saving treatment are high and it is often worth risking that unexpected side effects may emerge.

  Conversely, if the consequences of a harm are large or the group affected is vulnerable or disadvantaged, then the government may err on the side of a type 1 error. Regulators may prefer to be conservative in vetting people who care for children in institutional settings, for example, even if the process occasionally disqualifies someone who is not a risk to the children.

Box 2.3 contains an example of explicit risk statements by the US Nuclear Regulatory Commission.

Risk statements are consistent with Dutch research that indicates the general public is realistic about risk. People asked simple questions about their attitude to risk are likely to prioritise safety above all else. But when given more information about the actual costs and benefits of safety measures, people understand safety cannot be absolute. They accept tradeoffs and even after a serious event they quickly regain their rational attitude (van Tol 2014, 3).

Further, people are more concerned about moral acceptability than they are about the size of the risk (van Tol 2014, 4). The potential for community perceptions to differ from expert views of risk is discussed below.

These observations mean how risk is explained and communicated is important. Van Tol argued:

> The research shows a tragic paradox. When the government attempts to convince citizens that a certain risk is acceptable, it often uses the argument of risk avoidance. But the emphasis on how small a risk is only enhances that implicit principle that less risk is always better. This argument is self-defeating. Technocratic argumentation only strengthens the moral need to reduce risk, as it disconnects risks from the moral reasons why we perhaps ought to take them. And only the latter contains the key to achieving risk acceptance by the public. (van Tol 2014, 4)

Box 2.2 US Nuclear Regulatory Commission safety goals

The USNRC has two qualitative safety goals:

1. Individual members of the public should be provided a level of protection from the consequences of nuclear power plant operation such that individuals bear no significant additional risk to life and health.
2. Societal risks to life and health from nuclear power plant operation should be comparable to or less than the risks of generating electricity by viable competing technologies and should not be a significant addition to other societal risks.

The USNRC uses the following quantitative health objectives to determine if it achieves these safety goals.

1. The risk to an average individual in the vicinity of a nuclear power plant of prompt fatalities that might result from reactor accidents should not exceed 1/10 of 1 per cent (0.1 per cent) of the sum of prompt fatality risks resulting from other accidents to which members of the US population are generally exposed.
2. The risk to the population in the area near a nuclear power plant of cancer fatalities that might result from nuclear power plant operation should not exceed 1/10 of 1 per cent (0.1 per cent) of the sum of cancer fatality risks resulting from all other causes.

Source: USNRC 1986.

Breakthrough requires public trust in the regulatory system (OECD 2010, 244). Regulators and governments can foster trust by showing leadership (Risk and Regulation Advisory Council 2009, 23) and consulting and communicating with stakeholders. Regulators also need good crisis management and contingency response systems, so they identify and respond to emerging risks (UNECE 2012, 43).

In practice, understanding the government's attitude to risk will be iterative. Policy officers are likely to refine their approach to risk as they better understand the feasibility, cost, and effectiveness of treatment options. They will also learn from their experience with managing contingencies.

2.3 Identify and analyse risk

Use risk analysis to understand risk better. Draw on available information to make evidence-based assessments. Continue to analyse risk over time and adjust assessments based on experience and new information.

The guidance note lists all the stages involved in identifying and analysing risk (table 2.1 of the guidance note). Generally, risk falls into two categories.

- **risk of harm** — the specific harms where the government is considering action. The size and scope of these harms should be considered from the perspective of:
  - the government
  - experts
  - the community
  - future risks and emerging trends

- **reputational risks** — given a specific harm, could how the risks are managed, or not managed, affect confidence in the regulatory system or generate community backlash that leads to overregulation.

Policy officers should also consider compliance risks, given policy design can affect how easily regulated parties can comply with regulation and whether the regulator can readily check and enforce compliance.

In practice, policy officers appear to find three areas challenging:

1. understanding risks
2. identifying the capacity and incentives for private parties to manage risks
3. identifying measures of success.

2.3.1 Identify and analyse risk — understanding the risk

Regulatory impact assessments require policy officers to identify the nature and extent of the problem and clarify regulatory objectives, but this step is not done well. Policy officers may not fully understand a specific harm or its consequences, and they can jump to policy options. Such shortcomings are not unique to Victoria. Sparrow (2000) described the difficulty and skill involved in good problem identification and analysis.

Good practice breaks down the harms to understand better the associated risks, their drivers, and their likelihood and consequences. As noted in the guidance note, policy officers can tabulate this analysis in a risk register and risk matrix to identify and prioritise risks where policy action should be considered.

Policy officers must use their judgement to select the right level of analysis and the best tools for that analysis. Data collection and research are not costless and the resources available to assess risks are limited. But the assessment must be sufficiently detailed to be useful and actionable, particularly for significant risks (IMA 2007, 11). The guidance note discusses two issues:

- How should quantitative or qualitative techniques be used to assess risk?
- What types of risk, and from whose perspective, should risks be analysed (box 2.4)?

These issues are not the only issues relevant to risk assessment, but they are important and can be controversial.

Box 2.3 Community perceptions of risk

There can be clear differences in community perceptions and the views of experts on the level of risk and need for regulation. The general public's view can be affected by:

- potential for catastrophe
- degree of control over the risk
- familiarity with the risk
- degree of equity in sharing risk
- visibility of the benefits of risk taking
- potential to impose blame on risk creators
- delay in manifestation of harm
- voluntariness with which the risk is undertaken. (Bartle 2008, 6)

Some differences in public perception arise because of community values — such as greater concern for risks that affect vulnerable and disadvantaged people (like the elderly or children). There may also be heightened community concern about risks that are rare but highly disruptive, for example extreme bushfires that can kill a large number of people.

Agencies responsible for developing regulatory policy cannot ignore community perceptions. Policy officers must consider how to manage public expectations, otherwise the public could lose confidence in the regulation (reputational risk). The best approach depends on why public and expert views diverge. If the divergence is driven by community values, it is legitimate for regulation to reflect those values. If, however, it results from misjudging the risk it may be better to consult with stakeholders and build confidence and consensus around regulatory priorities.

Assessing catastrophic risk is particularly challenging. The likelihood of some high consequence harm, such as severe bushfires, is known and can be planned for. Other harms, however, can cause devastation but are extremely rare. Such events are difficult to incorporate and rank in risk analysis, although, their drivers and indicators need to be understood so the policy and supporting regulation is designed to increase resilience without excessive restrictions or cost.

2.3.2 Identify and analyse risk — identifying capacity and incentives for private parties to manage risks

Usually three parties can potentially manage a risk:

- the people or businesses whose activities create the risk (who can reduce the consequences or likelihood of the risk occurring)
- the people or businesses who are affected by the risk (who can reduce their exposure or manage the consequences)
- the government who can use regulation or other policies to either help reduce the size or likelihood of the risk or manage its impact.

As the guidance note recognises, the government may not be the best party to manage a risk. Businesses better understand their operations and may have a greater capacity to control risk than the regulator. If they also have strong commercial incentives to control risk, prescriptive regulation may be unnecessary. A business with

private accreditation or that sells to a major buyer who requires it to meet quality standards has commercial incentives to meet those standards, for example. In such cases, government regulation can be unnecessary or even undermine the effectiveness of the private controls.

Similarly, sometimes it may be better for those affected by a risk to control their exposure or manage the impact. Often, regulation cannot account for individual circumstances. It may therefore unnecessarily constrain individuals and businesses. Such constraints can undermine people's resilience and capacity by creating an expectation that governments will protect them so they do not need to protect themselves.

2.3.3 Identify and analyse risk — identifying measures of success

As noted in the guidance note, the outputs from this step are performance indicators and benchmarks that are measurable, inform later policy evaluation, and ideally provide an objective basis for assessing regulatory outcomes.

2.4 Treat risk and develop contingency plans

Determine how the government will respond to the identified significant risks.

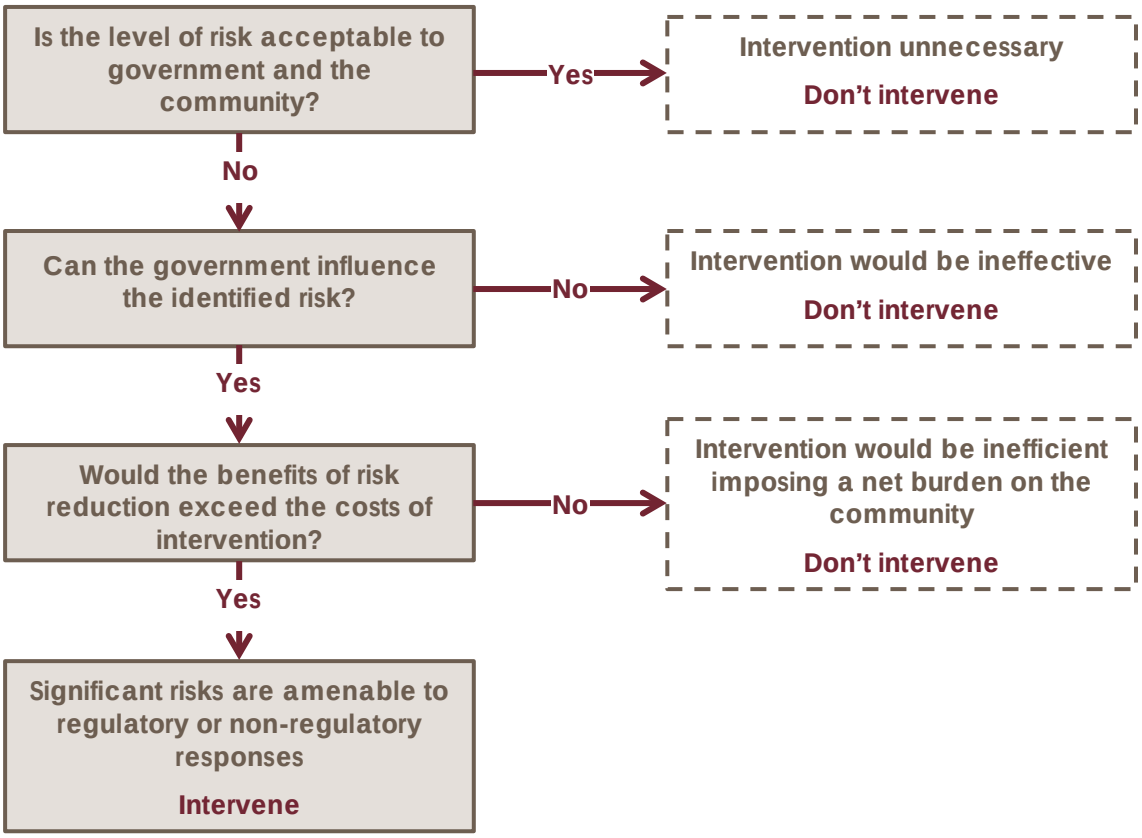
The guidance note recognises the policy development process should:

- target substantial, well-defined risks where regulation is clearly the best treatment option
- give regulators the flexibility and tools needed to be risk-based in their response.

2.4.1 Treat risk — ensuring regulation is the best treatment option

Regulatory impact assessments measure the preferred approach to regulation against alternatives, including no regulation. Government intervention is not always the best option (figure 2.2), but analysing non-regulatory options can be a weakness in regulatory impact assessments as the focus of regulatory impact assessment is often on a preferred option that involves regulation.

Figure 2.3 When should the government intervene?



2.4.2 Treat risk — selecting the right form of intervention and regulatory instruments

The form of intervention should match the risk and support risk-based administration and enforcement. At a high level, it is important to word legislative objectives carefully so they do not unduly constrain regulatory practice. Legislation should only constrain regulators' capacity to respond to risk and pursue risk-based priorities if it is necessary to meet the government's objectives. The guidance note highlights many examples in Victoria of legislation that constrains the scope for regulators to adopt risk-based regulation. Although change is occurring in many areas, there is scope to improve further (box 2.5).

Box 2.4 Reform to adopt more risk-based approaches to regulation — Consumer Affairs Victoria

The *Associations Incorporation Reform Act 2012* introduced a gradated approach to financial reporting that recognises smaller organisations generate less risk from financial irregularities. The Act divides organisations into 3 tiers.

Tier 1: Total annual revenue is less than $250 000. Organisations must have annual financial statements that give a true and fair view of the financial position.

Tier 2: Total annual revenue is greater than $250 000 but less than $1 000 000. Organisations must have financial statements that comply with the Australian Accounting Standards.

Tier 3: Total revenue is greater than $1 000 000. Organisations must prepare audited financial statements.

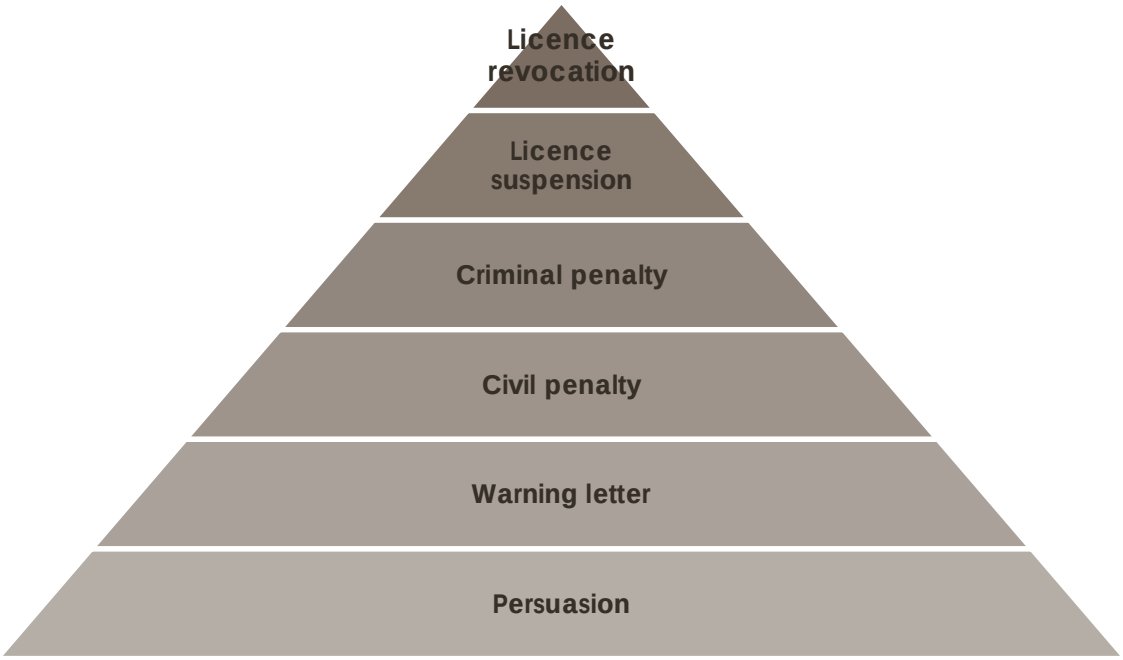
Generally, however, the Act is prescriptive. It mandates the process for deciding and applying for registration, and the registrar's processes for assessing and registering an organisation (sections 5–8). It specifies the contents and maintenance of the register of members (section 56), the criteria for categorising organisations into tiers, and the preparation, content and review of financial statements for each tier.

Such specificity locks the regulator into predetermined processes that are difficult to adapt as its understanding of risk improves or changes. It can also impose additional cost on incorporated associations. The Act specifies the information incorporated associations must provide to the registrar if they want to amalgamate, for example. However, organisations provide some of this information, such as trust deeds or other instruments (section 18), when they originally register. The regulator does not have the flexibility to adjust the requirements to reduce the burden on associations.

Source: CAV 2014.

Figure 2.3 illustrates the range of enforcement instruments the regulatory literature commonly describes. Every regulator may not need all these instruments, but it is easier to adopt a proportionate response if the regulator can draw on instruments from across this spectrum. A regulator should be able to draw on light-handed responses (such as education) for infrequent and low-impact risks; but it needs access to more direct responses for frequent and high-impact problems.

Figure 2.4 An enforcement pyramid for business regulation



Source: Ayres and Braithwaite 1992, 35.

2.4.3 Develop contingency plans

Clarify who is responsible for developing contingency plans and how regulatory change will be facilitated if needed.

The regulator will do much of the detailed contingency planning because it has day-to-day contact with regulated parties. But this step should define the relationship between the department and the regulator. The output is a clear statement of responsibility for developing contingency plans and responding to adverse events.

2.5 Monitor and evaluate

Monitor the regulatory outcomes by collecting reliable data and feedback and use that information to improve the regulatory framework and ensure it supports risk-based regulation. Evaluate the policy regularly.

The outputs of this stage are:

- a framework for collecting and interpreting data and feedback to monitor regulatory outcomes and the regulator's efficiency and effectiveness
- a plan to evaluate regulatory outcomes (including regulation's underlying rationale and the regulator's performance) after a defined period (such as five years after introducing a regulatory regime).

The Commission previously noted deficiencies in Victorian agencies' approach to evaluating regulation (VCEC 2011). Recent amendments to the *Victorian Guide to Regulation* have helped improve the focus on evaluation. Ideally, evaluation should address the following questions:

(1) Is the regulation still necessary — is there a convincing underlying problem that the regulation seeks to rectify?

(2) Is the regulation effective — does it achieve its objectives?

(3) Is the regulation efficient — does it achieve its objectives at a lower cost than feasible alternatives? (Lattimore et al. 1998, 114)

Not evaluating regulation causes problems such as:

- the absence of an evidence base for policy development, including the targeting of reform priorities
- weaker incentives to have effective and efficient regulation
- a lack of clarity about the impact of regulation (which also reinforces perceptions that regulators do not understand business realities or community values) (VCEC 2011, XLIII).

The legislation that establishes many regulatory regimes has been in place for some time. It was designed without explicitly considering risk-based approaches to regulation and regulating. As a result, the regulatory regime may not target significant risks and can constrain the regulator's capacity to target its activities and respond to changing risks. Box 2.6 presents an example of a regulatory reform that is expected to significantly improve the regulator's ability to target harms that government can reduce.

Box 2.5 Legislative constraints on risk based regulation — Department of Environment and Primary Industries

Recent changes to regulating invasive species addressed previous legislative constraints on risk-based regulation. The regulator now manages invasive species by tailoring its response. The new approach recognises:

> It is not feasible, cost effective or desirable for government to enforce the control of **all** declared invasive plants and animals or apply regulation to an increasing number of species and expect effective action against them all. (DEPI 2014, 4)

The new arrangements use risk management to identify threats, assess their relative risk, and determine the appropriate interventions. The management approach is disaggregated according to how widely established the species is and, therefore, the most cost-effective strategy for managing it going forward. That is:

- prevention/eradication — the species is absent or there is a small number of localised populations
- containment — the species is present in Victoria, with a rapid increase in its distribution and abundance or many populations
- asset based protection — the species is widespread and abundant throughout its potential range.

3 Applying regulation: for regulators administering and enforcing regulation

Apply the risk-based framework to regulatory processes and practices.

This part covers administering regulation, as well as planning and managing compliance and enforcement activities. Administering regulation is the second stage of the regulatory cycle. It includes, for example:

- licensing
- approvals and authorisation processes
- setting standards
- information campaigns
- approving codes of practice.

The third stage of the regulatory cycle, undertaking compliance and enforcement, covers strategies to improve compliance and, when necessary, enforce the law, for example:

- behavioural change strategies
- information campaigns
- inspections and audits
- undertakings
- prosecutions.

A fully risk-based regulator embeds risk-based decision making at all levels of the organisation, from agency-wide strategic planning to frontline decision making. Agency-wide analysis (discussed in this part) informs specific work by groups in the regulator. Some aspects of the analysis may affect the regulation's administration, while other aspects affect the regulator's compliance and enforcement activities (discussed separately).

Unlike policy development, there are no system-wide tools for reviewing and reforming regulation administration, and compliance and enforcement. However, regulators considering reform could share information on good practice. The guidance note and this paper could provide a framework for compiling and sharing such examples.

The Commission's improvement studies also demonstrate risk-based regulatory reform and build a body of good practice case studies. The Commission has completed a number of studies, including: a pilot with the Victorian Environment Protection Authority (EPA) on environmental auditing of contaminated environments; and studies with the Victorian Commission for Liquor and Gaming Regulation (VCGLR) on liquor licensing processes, VicRoads on medical assessment of a person's fitness to drive, and two in the primary industries sector — regulating the sea urchin fishery and controlling invasive species. These studies are joint projects led by the Commission in cooperation with the relevant regulator. Box 3.1 outlines the process for the studies.

Box 3.1 Improvement study processes

The Commission and the regulator agree on the project scope and governance arrangements at the beginning of the project. The regulator identifies areas for reform, particularly areas where a risk-based approach would deliver considerable benefits.

Understand and document current processes

The study team maps regulatory processes to identify:

- key pathways and the main decision points
- who is accountable for the decisions
- how risk is accounted for at each decision point and how regulatory requirements and guidance material affect decisions.

Consultation from inside and outside the regulator determines if the formal descriptions of the regulatory processes reflect how they work in practice.

Understand issues and problems and consider risk-based approaches

The study team identifies specific points in the processes that are unnecessarily costly, time consuming, not delivering the intended outcomes, or could be improved, based on consultation, past reports, and analysis of the regulatory processes.

For each identified problem the team:

- analyses the specific risks that aspect of the regulation is trying to reduce and the extent to which risk is considered in decision-making processes
- identifies the changes needed to make the processes more risk-based, who would action those changes, and whether the regulator has the authority to make the changes (or needs to advocate for legislative change or cooperation from other agencies).

The team identifies and tests practical specific reforms that could address the identified problems without compromising the regulation's objectives. It also estimates the size of the potential cost savings.

Source: Victorian Competition and Efficiency Commission.

3.1 Where to start

Identify and address barriers the regulator can control, and establish complementary systems necessary for good risk-based decision making.

Regulators applying risk-based regulation need to follow the steps illustrated in figure 3.1 in the guidance note and spelt out in detail in the guidance note in table 3.1. Specifically, start by:

- clarifying the attitude to, and tolerance for, risk
- analysing risk, feeding that information into decision-making processes, and deciding how to measure success
- designing regulatory processes to achieve a graduated response to risk management
- putting complementary systems and structures in place.

Regulators can be constrained by their legislative framework, but they usually have scope to improve how risk is considered and included in decision making. Well-targeted reforms can improve the regulator's productivity and produce savings for the regulator, regulated entities, or other stakeholders, without compromising the regulatory objectives.

Such reforms require good communication. Communication and consultation is needed to understand risk, regulated businesses and individuals, and how regulation affects their activities. The most appropriate mix of consultation tools and techniques will vary across areas of regulation.

The priority should be to develop and implement a plan that:

- engages effectively and is recognised as being genuine and responsive
- uses information from that engagement to improve the regulatory approach and respond to stakeholder concerns
- provides feedback to stakeholders on how their concerns were handled
- recognises the risk of regulatory capture.

Regulators do not need to accept and act on every stakeholder concern, but they should use the information obtained through consultation and communication to inform their assessments of risk and regulatory priorities.

3.2 Establish context

Clarify and document the regulator's objectives and its attitude to, and tolerance for, risk.

Regulators must understand the regulatory context, particularly the harms and associated risks they are expected to manage. In practice, there are often gaps in this analysis.

3.2.1 Establish context — clarifying objectives and attitudes to risk

The output of this step is a document that, at a minimum, outlines:

- the regulator's understanding of the government's objectives and attitude to risk (to the greatest extent possible)
- the risks and harms that are being managed
- the approach to managing those risks (whether the risks are acceptable or unacceptable)
- the regulator's area of responsibility compared with related regulators (for example, the VCGLR's liquor licensing responsibilities can overlap with Victoria Police's role in managing the law and order consequences of drinking and local government's role in local amenity).

Such a document should be endorsed by the regulator's governing body, communicated to stakeholders and staff, and supported by more detailed documentation and guidance (section 3.6).

Often the regulation's objectives and the harms and risks it is trying to reduce are not clearly articulated and communicated. This is a recurring challenge in the Commission's improvement studies. For example, in VicRoads' assessment of the fitness to drive of people with medical conditions, it was not clear how the risk of accident among drivers with certain medical conditions compared with other cohorts of drivers. Similarly, the EPA's regulation of contaminated environment was not clear about how to weigh the cost of continued monitoring and clean-up effort against the potential health or environmental impacts of residual contamination.

Clarity of objectives, roles and accountabilities is also important when multiple players are involved. For example, working together, agencies can effectively control the impact and spread of invasive species. Without coordination they risk given land holders conflicting advice, or requiring action that reduces one risk (for example slashing weeds to reduce bushfire risk) but inadvertently increases other risks (such as the spread of weeds from the seeds left behind).

Without clarity:

- it is harder to target the regulatory processes to reduce relevant risks
- stakeholders criticise the regulator for not achieving the outcomes they expect, even if their expectations differ from what the regulation can, or was intended to, achieve
- problems are harder to explain, even if they are not within the regulator's control, because the regulation's objectives are not clearly understood.

The results are conflict and confusion. Regulators may take an overly risk-averse approach and try to manage all risks with regulatory instruments that were not designed to reduce all the harms being targeted.

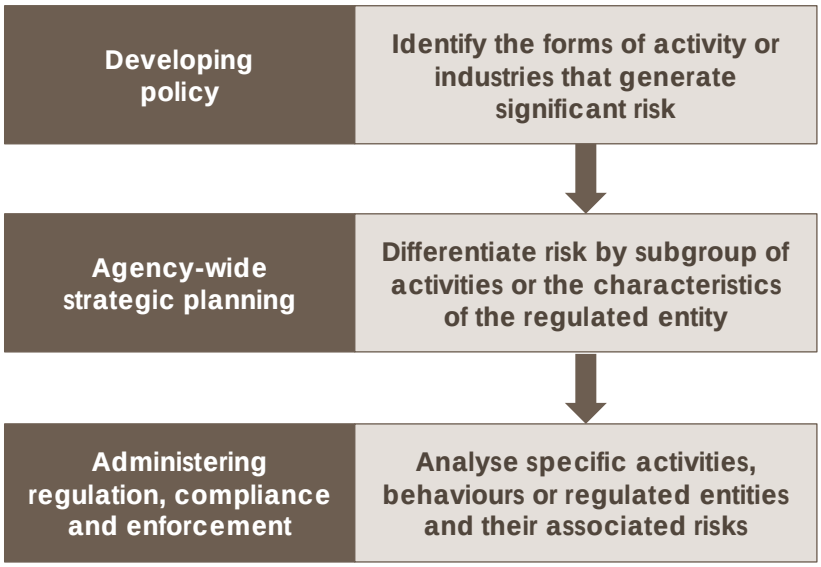
3.3 Identify and analyse risk

Identify and analyse the relevant risks and prioritise the significant risks of harm.

The guidance note states that risk identification and analysis need to occur at all levels in the regulator. An agency-wide assessment identifies and analyses the risks relevant to the regulator's scope and objectives. That assessment informs more detailed risk analysis by the groups that administer regulation or conduct compliance and enforcement.

In a well-integrated system, each subsequent stage builds on the information compiled at the previous stage. Figure 3.1 illustrates this progression in analysing the risks.

Figure 3.1 Focusing risk analysis at each stage in the regulatory cycle



3.3.1 Identify and analyse risk — identifying measures of success

Although there are no well-established best practice frameworks for measuring and reporting performance in risk-based regulation, the guidance note describes some possible approaches. Other jurisdictions, such as New South Wales, are also working on these issues (box 3.2).

More work is needed, however, to develop a consistent approach across Victorian regulators that would allow regulators to:

- assess their level of maturity in adopting risk based approaches
- track their progress over time
- compare their approach with that of other regulators.

Box 3.1 Performance measurement—NSW guidance on outcomes and risk-based regulation

New South Wales guidelines suggest how to identify performance indicators and develop a story about the regulator's contribution to short, intermediate and long-term outcomes (NSW Premier and Cabinet 2014, 27). Specifically, regulators should seek to understand their data and systems capability and use that information to develop well-defined measures with clear links to regulatory outcomes.

The NSW checklist for implementation includes the following elements:

- The regulator has worked to understand its data systems by developing a map that shows information captured, links to other systems, and key operational or legislative limitations on data use.
- The regulator uses the systems map to identify measures currently reported.
- The regulator uses the systems map to identify measures not currently reported, but that could be reported with existing data (e.g. by combining data in new ways).
- The regulator uses the systems map to identify measures not currently reported that may require additional data to be collected over time.
- The regulator examines the balance between timeliness, cost and quality for different identified measures.
- The regulator has established baselines and/or benchmarks to monitor changes in measures over time.
- Where baselines are not available, the regulator has identified appropriate interim measures (e.g. qualitative comparators).

Source: NSW Department of Premier and Cabinet 2014.

3.4 Treat risk and develop contingency plans

Prioritise regulatory activities that are most effective in reducing harm and plan for unpredictable outcomes.

Across the agency, the guidance note suggests regulators begin by:

- identifying the activities and regulatory tools that best reduce the risk of harm
- allocating the agency's resources across its activities based on risk priorities
- planning for contingency to monitor and respond to emerging issues.

Some literature proposes allocating resources to treat the largest risks, based on their combined likelihood and consequences. However, this approach fails to consider how effective government action would be in reducing risk. Regulators should use the size of the risk to identify significant risks that may warrant government action. But it may be possible to reduce the most risk by concentrating on a large number of smaller risks the government can influence, rather than by targeting a few large intractable problems.

3.4.1 Treat risk — prioritising harm reduction

All regulators are resource constrained and need to prioritise their activities regardless of whether they apply risk-based regulation. Under a risk-based approach, this priority setting focuses primarily on achieving the maximum risk reduction with the available resources. The guidance note suggests the output of this step is a plan for activities based on:

- the likelihood and consequences of different harms
- the regulator's capacity to reduce the risk of harm
- the resources available to the regulator.

Priorities should be flexible, based on evidence informed by monitoring and may need to be adjusted to reflect other objectives. However, these other objectives should not dominate in a risk-based strategy.

The regulator's impact on harm reduction may be affected by other regulations or regulators that also target a given harm. Therefore, the regulator should consider if existing tools (such as licensing, codes of practice, or general legislation) can reduce the risk.

If regulated parties do not trust the regulator, or if they think its regulatory approach is unfair they will be less likely to comply. Trust can be undermined if regulated parties think enforcement is uneven and those who fail to comply go unchallenged (Sparrow 2000, 250). The enforcement approach also affects the incentives for others to comply. If low-risk businesses do not expect to be inspected, they are less likely to be vigilant, even if they have a culture of compliance. Similarly, high-profile enforcement activity in a well-defined area, even if it only targets a few offenders, can be symbolic and encourage broader compliance (Sparrow 2000, 242).

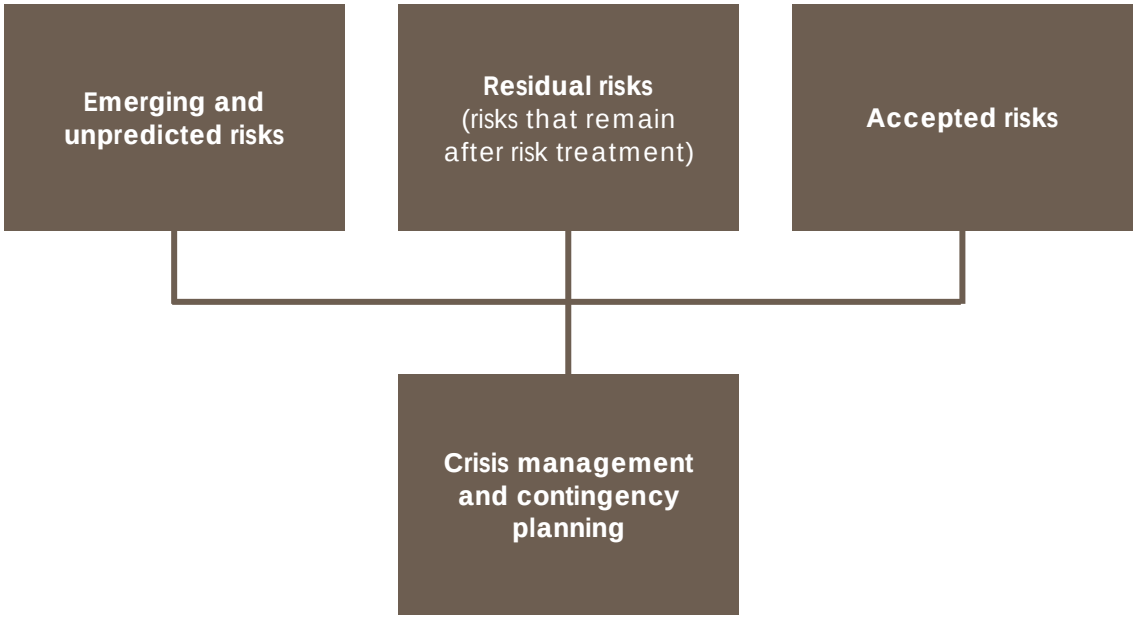
The regulator can also lose the community's confidence if it neglects issues of substantial community concern (such as disasters) or if regulated parties are uncertain about the regulation and what is needed to comply.

3.4.2 Develop contingency plans

Regulators need contingency plans to identify and control the risk of unpredictable outcomes that cause harm and raise public and political criticism. Contingency planning is, however, often neglected. Risk-based regulation, by definition, involves some continuing risk and regulators need to monitor and plan for those risks (UNECE 2012) (figure 3.2). For example, regulators need to identify early and respond to a disease outbreak that emerges despite quarantine provisions (residual risk) or a new chemical that has unexpected environmental impacts (emerging risk). Contingency plans help regulators respond effectively and proportionately, explain their response, and manage any public concern. Public concerns — and demands for action — will not be eliminated, but the more extreme reactions to adverse events may be avoided.

In addition, for many types of risk it will be more practical or effective to manage the consequences, or intervene if a risk is imminent, rather than trying to avoid the risk. Some diseases cannot be prevented, for example, so contingency planning is necessary to manage an outbreak.

Figure 3.2 Input to crisis management and contingency planning



Source: UNECE 2012, 21.

3.5 Monitor and evaluate

Improve the regulatory approach and the ability to plan for contingencies based on information gained from ongoing monitoring.

The guidance note outlines the importance of monitoring regulatory outcomes and activities over time to maintain and improve the regulation's effectiveness and responsiveness.

3.6 Complementary systems

Identify and establish appropriate complementary systems and structures.

As well as communication and consultation, risk-based regulation requires other complementary systems and structures including:

- organisational structure, authorities and accountabilities
- work allocation and devolution
- data systems
- documentation (figure 3.3).

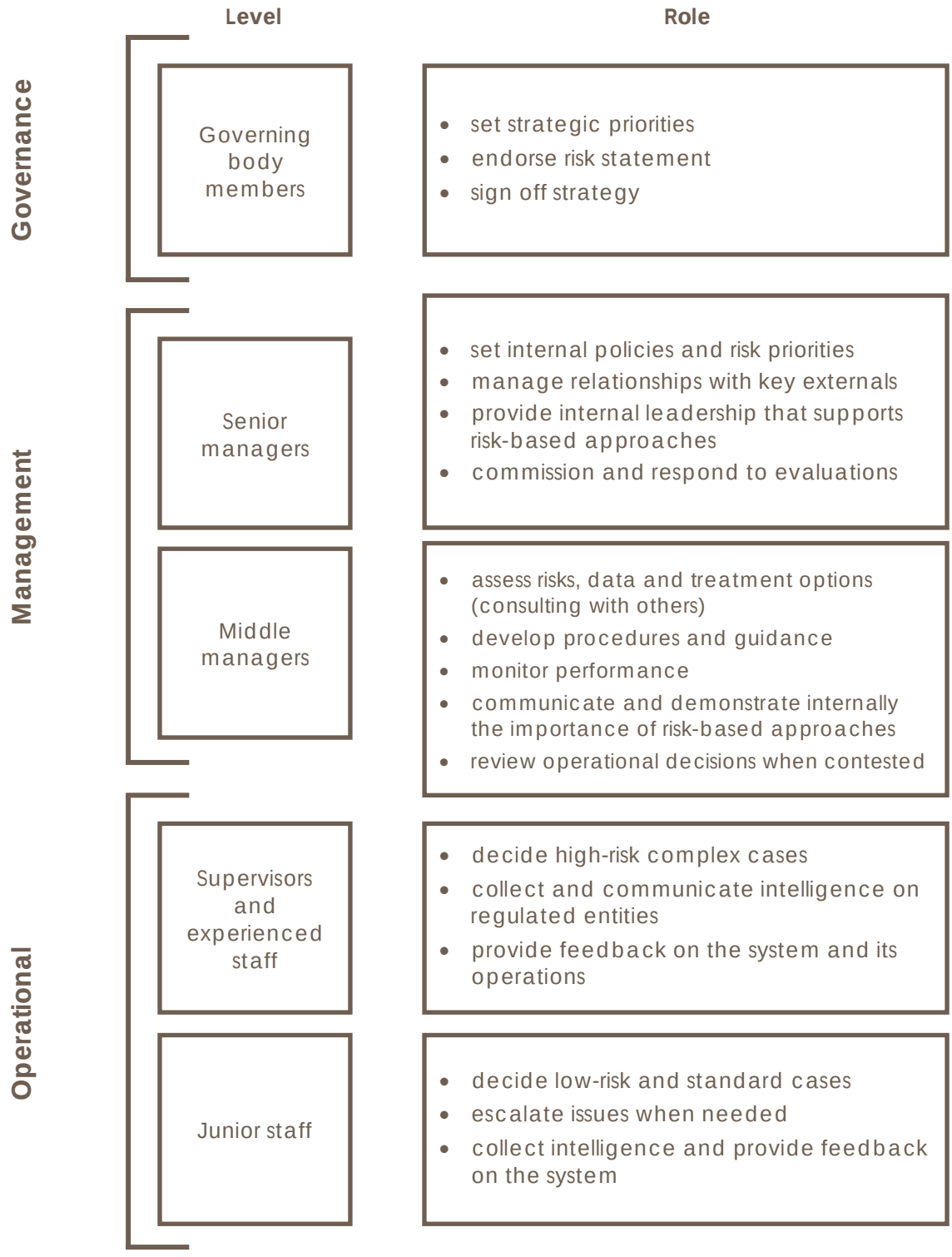
Figure 3.3 Complementary systems for risk-based decision making by regulators

Figure 3.4 illustrates one way of managing the various roles and responsibilities required to implement risk-based regulation.

Risk analysis happens at various levels in the organisation, so data collection and analysis also happens across the organisation and often draws on external expertise. Those involved include:

- frontline staff — who collect intelligence and providing feedback on the system
- scientists and subject specialists — who provide information on current and future risks of harm
- managers — who ensure the systems are in place to collect and analyse data
- data specialists — who develop the information and computer systems necessary to collect and analyse the data and assist with that analysis.

Figure 3.4 Indicative allocation of roles



3.A Administering regulatory processes

Apply the risk-based framework to design and implement regulatory processes.

This part is for regulators administering risk-based regulations. It covers activities such as licensing, approvals, and authorisation processes. These groups should draw on the agency-wide analysis described earlier in part 3 to design risk-based processes and set their priorities.

3.A.1 Where to start

Identify and address barriers the regulator can control.

The guidance note outlines the issues that most often arise in administering risk-based regulation are:

- categorising regulated parties and activities according to risk
- designing risk-based licence and approvals processes.

3.A.2 Analyse risk — establishing risk categories

Identify and analyse the relevant risks and develop risk indicators to help categorise low, medium, and high risk regulated parties or activities.

Regulators identify and analyse risk using the same process as policy developers, but the analysis is more specific. That is, regulators analyse risk at the level of the regulated party or activity, and develop risk indicators to categorise regulated parties as high, medium, or low risk.

In some areas of regulation, such as financial services, regulated parties have been risk rated for some time. In other areas it is relatively new. Sophisticated risk assessment is more commonly used to prioritise compliance and enforcement activity rather than to administer other regulatory processes. The Commission's improvement studies illustrate the potential benefits of assessing the risk of types of regulated entities or activities and using that information to vary the time, resources, and regulatory requirements applied in regulatory processes such as licensing (see the guidance note for more detail and an indicative example of a checklist).

3.A.3 Treat risk — improving processes

Initially improve processes to focus on high-risk areas and increase process efficiency.

Usually it is not possible to redesign the entire regulatory response in light of risk analysis. The guidance note suggests focusing on:

(1) improving the current processes to make them more risk-based and more efficient, to free resources for high risk areas

(2) targeting additional specific action at a few high-risk areas where the government could make a significant difference.

Sparrow (2007) advocated the second strategy, arguing regulators should focus:

> ... a little longer on the outside world, deliberately picking apart the generality to find very distinct concentrations [of harm] ... Once these specific concentrations have been identified, they are then studied carefully, understood in their own right, and picked apart using tailor-made methods that often were not in the familiar toolkit for the agency. (Sparrow 2007, 19)

The first strategy improves the regulator's core activities, by increasing:

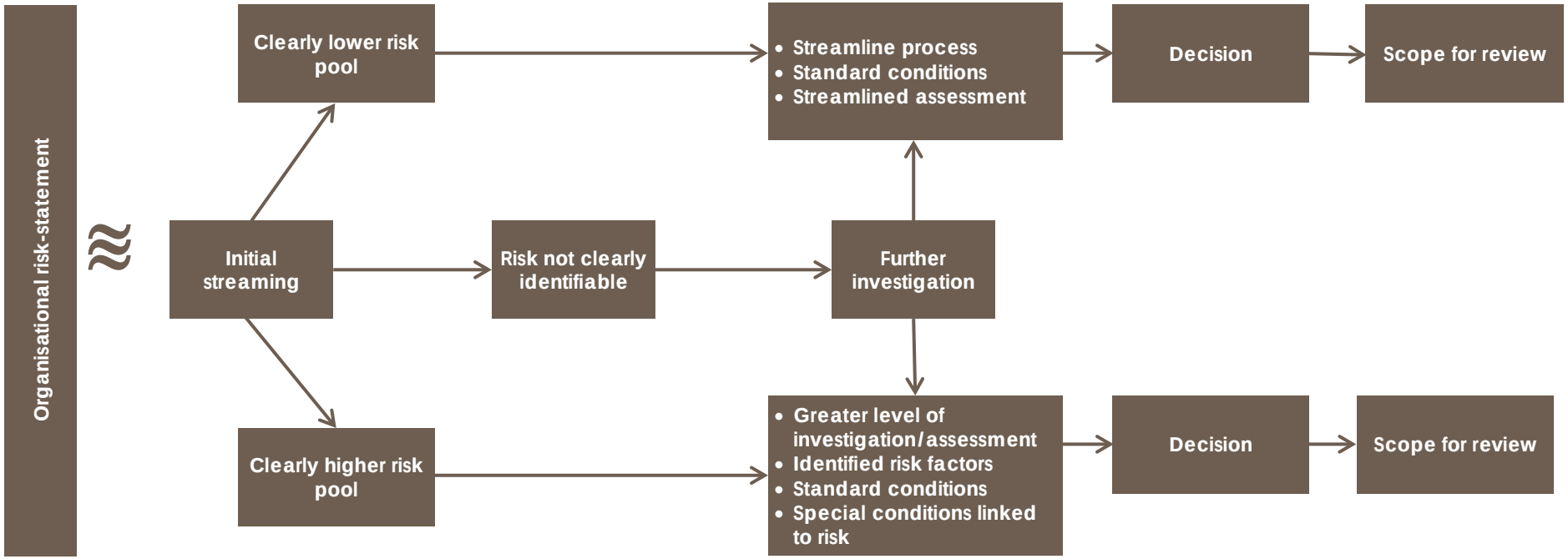
- **focus** — discontinuing activities that are not significantly reducing the risk of harm
- **efficiency** — streamlining the remaining activities so they are as efficient as possible
- **streaming** — triaging applications according to risk and tailoring the process to the level of risk of each application:
  - triaging and allocating regulated parties to process streams that reflect low, medium, and high risk
  - matching the level of obligation, conditions, standards, or process to the risk stream
  - for high-risk applications, in particular, ensuring flexibility for independent judgement rather than unnecessarily predetermining outcomes or processes (figure 3.A.1).

The EPA, for example, monitors environmental audit reports for contaminated sites. In the past it examined all reports to ensure 'administrative' compliance with the *Environmental Protection Act 1970 (Vic)*. This approach consumed a lot of EPA effort for little gain in health and environmental outcomes. The EPA is investigating more risk-based processes for managing environmental audits. These processes will have different levels of audit, with more resources allocated to high-risk audits and fewer to low-risk audits.

A common problem in many approval and standard-setting processes is a bias towards zero or very low levels of risk. The regulator checks, or sets standards, for large numbers of regulated entities or activities 'just in case something goes wrong'. As a result, many low-risk businesses or individuals go through the time and cost of detailed regulation when the risk of those parties causing significant harm is low. It also diverts the regulator's attention from activities with much greater risk.

A risk-based approach to regulation does not try to control all risk up front. Many risks can be tolerated, or dealt with through monitoring, compliance, or enforcement activities. And if harms do occur, their impact ameliorated through contingency planning.

Figure 3.A.1 Process improvement in regulators



3.B Undertaking compliance and enforcement

Improve how risk is used in compliance and enforcement activities to reduce harm.

Risk-based approaches are more common in compliance and enforcement activities. The guidance note identifies that risk could be better used to inform such activities and focus more directly on harm reduction. Risk management in compliance and enforcement would draw heavily on agency-wide risk analysis, supplemented by more specific analysis of the issues relevant to compliance and enforcement in a particular area.

Regulators need to consider five priority areas to understand risks and match compliance and enforcement tools and priorities to the levels of risk:

- set risk-based objectives for the compliance and enforcement strategy
- identify risk indicators
- allocate businesses and activities to risk categories
- match compliance and enforcement instruments to the level and type of risk
- set priorities consistent with compliance and enforcement objectives.

3.B.1 Where to start

Better understand the risks of individual, or categories of, regulated parties or activities and better match regulatory instruments and priorities to the level and type of risk.

Regulators can improve how they use risk to inform compliance and enforcement activities. The guidance note outlines two common issues specific to compliance and enforcement:

- developing and applying indicators to categorise regulated parties and activities according to risk
- matching compliance and enforcement instruments to risk categories.

3.B.2 Analyse risk — identifying indicators of risk and allocating parties to risk categories

Identify risk indicators and then categorise regulated parties or activities.

The guidance note states that the outputs of this stage are:

- relevant risk and compliance indicators that can be used to target compliance and enforcement effort on entities that provide opportunities for the greatest harm reduction

- a risk/compliance matrix or other tool for prioritising activity, which visually presents the risk analysis that rates regulated parties according to risk (see attachment 1).

Developing risk and compliance indicators is often hampered by a lack of information and data. Risk indicators can be progressively changed and refined as information improves. There are, however, ongoing problems in obtaining good information in areas such as a regulated party's ongoing effort to comply with the regulation. Without such information, regulators can spend too much time reviewing businesses with good internal processes, for example, adding to the compliance costs for those businesses and diverting resources away from scrutinising businesses that are more likely to cause harm.

Regulators could consider a range of models to help overcome information problems and refine how regulatory parties are categorised and regulated as information on their risk level improves.

Credible compliance indicators

Compliance indicators must be interpreted carefully because all regulated parties, including those who are non-compliant, have incentives to signal they are compliant. In fact, these incentives are stronger for non-compliant parties because they benefit more from avoiding the regulator's attention (van Beusekom 2011, 4–5). Regulatory systems with credible compliance indicators are likely to be more reliable. The most credible indicators of compliance are:

- directly relevant to compliance with the regulation
- verifiable and demonstrate resources are devoted to compliance
- more difficult or costly for non-compliant businesses to adopt than for compliant ones, and therefore discriminate between compliant and non-compliant businesses (van Beusekom 2011, 3–4).

Earned autonomy

Continuously monitoring all regulated parties is costly for the regulated party and the regulator. Earned autonomy tailors the level of regulatory scrutiny to the regulated entities' compliance history. The regulator spends less time monitoring parties that prove they deliver consistently high standards. For example, the EPA's statement of expectations states it will pilot an earned autonomy approach for high performing licensees in early 2015 (Smith 2014, 3).

Menu of contracts

Innovative regulatory design can also encourage businesses to reveal information on the quality of their governance and compliance effort. In some regulatory settings — such as price regulation (box 3.B.1) — a menu of regulatory contracts is suggested as one way to get businesses to reveal information. Similar approaches may also assist in other areas of regulation.

A menu of contracts could, for example, include two contract options:

(1) The regulator sets the standards and relies on the business to monitor and meet those standards with little regulatory intervention. However, if an adverse event arises, the regulated business is liable to meet the full cost of cleaning up or redressing any additional damage. They may also be required to pay additional fines, particularly where standards are breached.

(2) The regulator sets up inspections and audits to monitors the business's performance and requires ongoing redress if there appears to be an unacceptable risk of harm or if the business does not meet the required standards.

Provided there is confidence that the regulator can set and enforce both contract options, businesses that are low risk, or are confident their internal controls can manage the risk, are more likely to choose the first option. Businesses less confident in their ability to guarantee outcomes will choose the second.

Box 3.B.1 Using a menu of contracts in price regulation

A typical dilemma in setting regulated prices is choosing the pricing methodology. The following simplified example illustrates the choices available.

Prices can be linked directly to production costs. Setting a price equal to the actual cost of production avoids the risk of excluding a provider from the market (because the price is set too low) and ensures consumers pay no more than the cost of providing the product. Cost-based pricing, however, does not encourage firms to improve their efficiency and reduce cost.

Alternatively, regulators could set a fixed price. Such prices encourage firms to improve their efficiency because they can retain the additional profit. But if the price is set too low, truly high-cost producers (who may produce higher quality products) will be unprofitable. By contrast, low-cost producers can penalise consumers, because consumers pay more than the cost of the product.

Although the regulator can usually observe a firm's actual costs, it does not necessarily have information on the true efficient cost, or the scope to improve efficiency. A menu of contracts is one way of getting producers to reveal this information. The menu offers producers the choice of a cost-based or fixed-price contract. High-cost firms will tend to choose the cost-based contract, ensuring they are not excluded from the market. Because the risk of excluding some producers is removed, the regulator can set the fixed-price contract at a lower price. It will still be attractive to firms with significant potential to improve their efficiency and reduce costs, but it will also increase the benefits to consumers who pay a lower price.

Source: Rogerson 2003; Joskow 2008.

Environmental scanning

Finally, while many regulators base their risk analysis on the type and history of the regulated party, they also need to recognise risk can change as market or industry circumstances change (box 3.B.2). Therefore, the risk assessment should look forward and incorporate '"horizon" scanning and generic, industry wide risk assessment' (Black 2010, 219).

Box 3.B.2 Environmental scanning — Dairy Food Safety Victoria

Dairy Food Safety Victoria (DFSV) employs a chief scientist, whose expertise underpins DFSV's understanding, assessment, and categorisation of risks to food safety in the dairy industry. DFSV uses formal scientific risk assessments to manage food safety incidents.

The chief scientist scans the environment to understand and respond to emerging food safety issues. He/she stays abreast of the scientific literature, attends, and contributes to science-based conferences in Australia and overseas, and maintains strategic scientific relationships with government, industry, researchers, consumers, and the community.

Source: DFSV (pers. comm., 2014)

3.B.3 Treat risk — matching instruments to risk categories

Match the compliance and enforcement response to substantial risks and prioritise activities that most reduce the risk subject to available resources.

The guidance note states that reducing the risk of harm requires applying and prioritising compliance and enforcement tools appropriately. This stage has two elements:

(1) matching regulatory instruments to risk categories

(2) setting priorities based on achieving the greatest reduction in risk given the regulator's resources.

Although other priorities can inform the compliance and enforcement strategy, the regulator should focus on reducing the risk of harm.

Generally, compliance and enforcement instruments can be divided into three categories:

- **preventative instruments** focus on education or shifting the incentives to comply. Such instruments reduce harm by increasing the rate of compliance. They are particularly useful for inadvertent breaches of the regulation when the regulated party is open to change.
- **restorative instruments** remediate the adverse effects caused by a breach. Such instruments require the entity that caused the harm to compensate affected parties and/or rectify the damage, such as cleaning up a pollution spill. They can be useful for harmful or likely events, even if the breach is inadvertent. They send a clear message that compliance is important and regulated parties are responsible for rectifying the harm they cause.
- **punitive instruments** punish those who caused the harm. These instruments include fines and jail sentences, and actions such as revoking a licence. They remove offending parties from an industry or discourage bad behaviour by imposing

penalties and punishment. Such instruments send a clear message that deliberately breaching the law will not be tolerated.

A risk-based approach relies more on light-handed, broad-based, compliance tools for low-risk activities. The appropriate tool is influenced by the risk of harm and the capacity and attitude of the regulated parties complying with the regulation (figure 3.B.1). Table 3.B.1 is an example of how to analyse risk drivers across stakeholders and use that information to select regulatory tools. For each stakeholder the table breaks down the risk drivers according to the vectors for spreading invasive species (for example weeds) and the barriers and incentives to control and reduce their spread.

Some regulators, such as the EPA, also spend less time on reactive activities (responding to complaints) and maintenance activities (routine inspections) and spend more time on targeting strategic issues identified as high risk.

Figure 3.B.1 Targeting compliance and enforcement responses

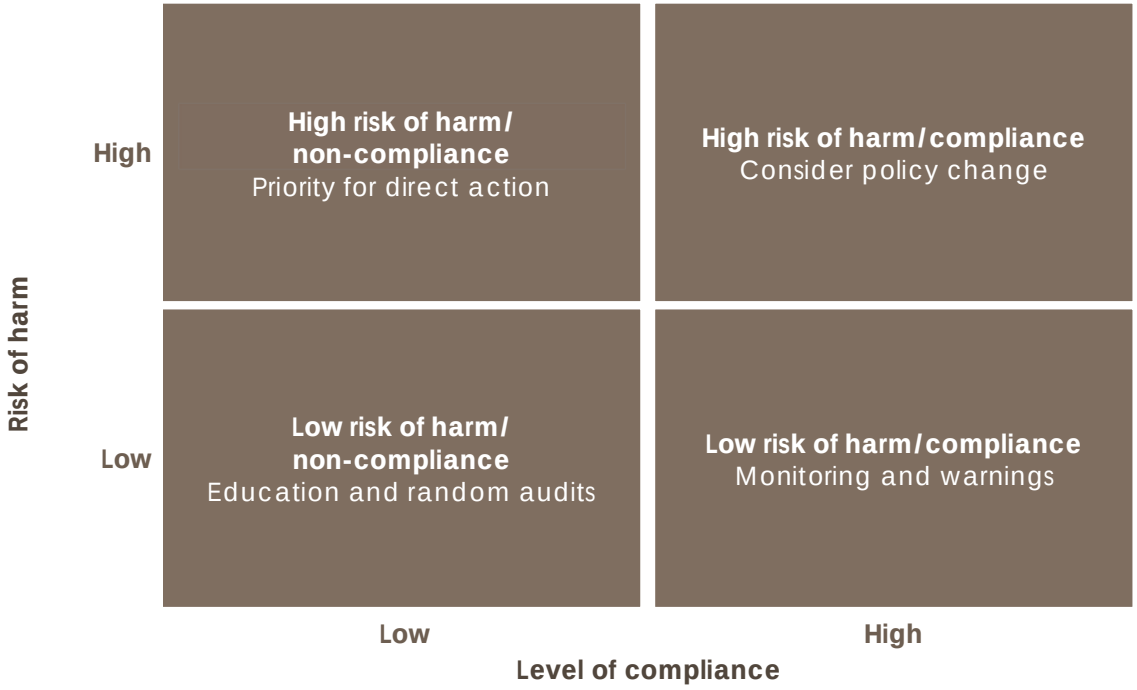


Table 3.B.1 Example of stakeholder and regulated parties analysis — Invasive species

Stakeholder	Vectors, incentives and barriers	Choice of tool
Parks Victoria	Parks can be a vector of spread to adjacent land. Strong incentives to control invasive species to protect managed park assets. Other statutory obligations interact with invasive species obligations.	Voluntary management plan

Stakeholder	Vectors, incentives and barriers	Choice of tool
Linear reserve managers	Waterways, roads and railways are significant vectors. Strong incentives to manage invasive species to protect infrastructure and the environment, for example, for bushfire mitigation. May need guidance on how to control invasive species.	Voluntary management plan
Lifestyle-based landholders	Properties can be a vector of spread to adjacent land. Generally low economic incentives to understand and manage the impact of invasive species. Absentee landholders may be difficult to contact and coordinate.	Extension (information and education) to improve awareness of obligations. Consider use of control notices and enforcement measures where extension has been unsuccessful and risks of spread are high.
Residential land developers	New developments on the urban fringe can be a significant vector of spread into regional Victoria. Economic incentive to manage invasive species may be low.	Extension (information and education) to improve awareness of obligations. Consider use of control notices and enforcement measures where extension has been unsuccessful and risks of spread are high.
Contractors*	Vehicles can be a vector of spread due to poor hygiene. Some contractors may lack incentive to perform work at required standard. Some contractors may be unaware of best-practice treatment methods.	Vehicle hygiene code of conduct for guidance on how to achieve vehicle hygiene; audits of weed and pest treatments for contractors.
Transport industry	Can be a vector of spread. May have low economic incentive to maintain adequate vehicle hygiene or to ensure transported material is free of invasive species. May be unaware of how to mitigate risk of spread.	Vehicle hygiene code of conduct. Declaration of carriers.

Stakeholder	Vectors, incentives and barriers	Choice of tool
Local government	Local roads a significant vector of spread. Strong incentive to address community priorities, but these priorities may not always align with Departmental priorities. May have limited knowledge of best-practice treatment methods, especially in regional and rural areas.	Roadside management plans. Voluntary management plans for other council-owned lands.
Primary producers and corporate landholders	Can be a vector of spread to neighbouring land. Generally have strong economic incentives to manage impact on crops, grazing and other primary industries. Incentives may be stronger for cropping than grazing, as controlling invasive species is more closely integrated with core business activity. May have an incentive to control invasive species to protect environmental values.	Voluntary management plans an option for large corporate landholders. Broaden community-based approach, supported by efficient and visible enforcement.

Notes: *Although not a regulated party under the CaLP Act, contractors accept contractual obligations to treat invasive species.

Source: Commission analysis in the Invasive Species Regulatory Improvement Study conducted with the Department of Environment and Primary Industries.

Attachment 1: Stylised example — applying risk-based regulation

The following is a stylised example of a process that could be followed to apply risk-based regulation systematically. The example is illustrative only and does not represent any particular area of regulation.

Scenario

There is a new fitness product on the market, which when used properly, is safe and value by customers. However, there is public concern about it putting customers' health at risk if used inappropriately. Some proposed banning the product, to protect people with certain medical conditions who may suffer severe health consequences from inappropriate use. The industry is new and growing, and has the potential to innovate and export.

Policy development

Establish context

Establish a consultation and research program, to understand better the context, drawing on:

- international experience
- business, consumer groups and experts in the field
- basic industry data on the size of the sector and the types of businesses involved
- information on the government's attitude to risk
- medical data on the incidence of problems and how those problems affect people.

Use this information to clarify policy objectives in this area and the government's attitude to potential risks associated with using the product.

Identify and analyse risk

Analyse the potential health risks of the new fitness product, drawing on domestic and international information and data. Specifically, consider harms and risks related to:

- the product, its market, potential consumers, and the businesses producing and distributing it
- the product's potential health risks and who they affect, and the medical data and evidence on links between the product and the potential health risks.

If necessary, supplement the desktop research with workshops involving medical experts, representatives of the affected consumers and businesses, and the regulator to:

- test the conclusions of the desktop research and fill in gaps and areas of uncertainty
- clarify which risks are significant and the likelihood and consequences of those significant risks
- obtain more detail on the drivers of the significant risks, who they affect, and how
- identify areas of public concern and the extent to which the concerns are consistent with the available evidence.

Detailed historical data is not available because the product is new. So, qualitative techniques may be more appropriate (such as scenario analysis). Also consider lessons learnt from other fitness products, to understand how consumers and businesses responded to potential health risks.

Use the information to develop a risk register and assess the potential likelihood and consequences of the identified risks.

Table A.1 Risk register

Risk	Likelihood	Effect
1. Health effects from inappropriate use by general population	Medium	Low
2. Health effects from inappropriate use by people with pre-existing medical conditions	Medium	High
3. Health effects from poor product quality used by the general population	Low	Low
4. Health effects from poor product quality used by people with pre-existing medical conditions	Low	High

Map categories of risk in a matrix to identify areas of high (red), medium (yellow) and low (green) risk.

Table A.2 Risk matrix — consequences and likelihood

Consequences				
	High	4	2	
	Medium			
	Low	3	1	
		Low	Medium	High
	Likelihood			

Analyse the most significant risks (those ranked red or yellow) in more detail to answer questions such as:

- Which medical conditions make people vulnerable and is the level of vulnerability the same for all people with such conditions?
- How do these medical conditions contribute to vulnerability?
- What characteristics of the product or its use make it more prone to causing harm?
- Do the behaviours of businesses contribute to this potential harm?
- How informed are consumers likely to be of the potential harm?
- Are there incentives or disincentives for businesses and/or consumers to self-control and limit the potential harms caused by their products?
- Is there already general regulation that could be used to address the problem?

Treat risk and develop contingency plans

Develop and analyse options to address the significant risks that can arise from using the new fitness product, in consultation with the regulator and other stakeholders. The government could, for example:

- take action to mitigate the risks among vulnerable groups via:
  - an education campaign to reduce the incidence of harm among vulnerable people
  - a compliance and enforcement strategy to reduce the incidence of people misusing the product because retailers provide misleading and deceptive information
  - publicising enforcement action to improve awareness of the risks
- tolerate the risk to the general public
- monitor developments to ensure the risks do not change significantly or increase to unacceptable levels.

Estimate and consider the costs and benefits of the options, or analyse the options if quantitative estimates are not available. Identify the preferred options and agree an implementation strategy with the regulator, with ongoing monitoring and a planned full policy review in five years.

Administration and enforcement

The regulator uses the outcome of the policy process to develop its approach to administering and enforcing the response.

Establish context

Draw on the work from the policy development stage to understand better the specific harms to be reduced, the objective you as the regulator seek to achieve, and the government's attitude to risk.

Compile, document and use the information to guide internal priority setting. Communicate to stakeholders your attitude to risk and explain the regulatory approach.

Identify and analyse risk

Identify and analyse specific risks, and then summarise the analysis in a risk register. Map significant risks in a risk matrix according to their consequences and likelihood.

The risk resister breaks down the risks faced by vulnerable people by type of conditions and other relevant factors such as severity of the condition, or the person's age or social background.

Identify what drives these risks. For example, is the information customers receive accurate or does it magnify the risk? If so:

- What claims are being made?
- Who is making the claims?
- Who are the claims made to?

Also assess businesses or business types, the risks they impose, and the strength of the incentives for them to comply with existing consumer standards. Use this information to position businesses within a risk and compliance matrix; businesses with high risk and low compliance receive the highest priority in considering subsequent risk treatment.

Table A.3 Risk matrix — risk and compliance

Risk				
	High			
	Medium			
	Low			
		High	Medium	Low
	Level of compliance			

Treat risk and develop contingency plans

Match the matrix outlining the risks of the new fitness product with treatments, selected after comparing the strengths and weaknesses of each option.

Based on this analysis, develop:

- an education campaign to reduce the incidence of harm among vulnerable groups considering using the fitness product
- a compliance and enforcement strategy that relies on existing general regulation to reduce the incidence of people misusing the product because retailers provide misleading and deceptive information. Publicise this enforcement action to improve awareness of the risks.

Monitor and evaluate

Design a program for monitoring industry development to determine whether the current understanding of the risks is consistent with experience and to identify any emerging problems. Consider how information will be collected (for example, through industry complaints). Identify strategies to respond to any unexpected increases in the risk of harm.

Publish the strategies and subsequent actions and outcomes. Decide an evaluation program, along with a plan for monitoring and data collection.

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