Smart regulation: Grappling with risk

Guidance note

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Preface

The Victorian Guide to Regulation (VGR) was first published in 2004 to provide guidance to policy officers and regulators about regulation design and administration. The latest version of the VGR was released in December 2014 and states that, where possible, 'regulation should be designed to facilitate a risk-based approach by regulators'. The VGR also states that all Legislative Impact Assessments and Regulatory Impact Statements should include risk-based approaches in their identification and discussion of policy options.

Risk-based regulation is not about reducing regulatory effort or diluting the Government's objectives for regulation. Rather, its focus is on prioritising regulatory effort to achieve the best outcomes for the community.

The 2014 edition of the VGR includes new guidance on the effective implementation of regulation, and how implementation issues should be considered when designing regulation. To complement the revised VGR, the Victorian Competition and Efficiency Commission (VCEC) has developed this guidance note and supporting material as practical guidance for policy officers and regulators.

This guidance note on regulation practice is based on the Commission's work — particularly its improvement studies with regulators — and has benefited from extensive consultation within Victoria's policy and regulatory community, as well as with colleagues in other jurisdictions.

The guidance note aims to provide advice to support policy officers and regulators in translating the principles of addressing risk into the practice of regulation. It also facilitates an ongoing dialogue among the policy and regulatory community on the subject. For its part, the Commission intends to refine the guidance note as lessons emerge over time. We therefore welcome feedback from policy officers and regulators to improve the quality and applicability of the guidance.

The development of this guidance note and supporting material has involved many people. Most notably, the leader and principal author was Commissioner Deborah Cope, supported by Nick Ford and Robbie Taylor. I particularly acknowledge Deb Cope's efforts and innovative approach. In addition I would like to thank the staff of many regulators whose invaluable inputs, comments and wise counsel materially improved the content. The work could not have been done without their active and enthusiastic involvement. VCEC staff and Commissioners provided the usual comment and feedback.

M W Butlin
Chair

Introduction

The Victorian Guide to Regulation (VGR) notes the role of risk-based principles in designing and implementing regulation (Government of Victoria 2014). Consistent with the VGR, this guidance note outlines how to use risk-based systems to develop policy and to design, administer and enforce any ensuing regulation.[1] It is aimed at policy officers developing policy and designing regulation, and regulators administering and enforcing regulation. It is accompanied by a supporting paper, which explores some of the conceptual issues and practical challenges associated with the steps outlined in this guidance note.

In essence, risk-based regulation improves the 'productivity' of regulating — delivering the best possible regulatory outcomes from the resources available to regulators. Risk-based regulation acknowledges that:

> ... the government cannot regulate to remove all risks and that regulatory action, when taken, should be proportionate, targeted and based on an assessment of the nature and magnitude of the risks and of the likelihood that regulation will be successful in achieving its aims. (OECD 2010, 16)

Such an approach uses tools and information to identify the risks and harms the regulation is attempting to reduce. It analyses the likelihood and consequences of those risks to design, administer and enforce regulation, and set regulatory priorities. The objective is to obtain the greatest harm reduction for the community from the regulatory resources available.

There are two necessary strands to achieving a fully risk-based regulatory system:

- regulation must be consistent with risk-based principles (*risk-based regulation*)
- regulators must apply risk-based approaches to their administration, and compliance and enforcement strategies (*risk-based regulating*).

The guidance note is based on the Commission's work, regulators' experience and feedback, and research from around Australia and internationally. Both the guidance note and supporting paper will be refined as more lessons emerge from the experiences of policy officers and regulators in applying risk-based principles. Regulators can use the documents as a framework for sharing experience and insights about applying risk-based regulation.

How to use the guidance note

The VGR states that:

> Given that legislation and regulation can potentially have significant impacts on the parties that it affects, as well as on society, the environment, and the economy as a whole, it is vital that legislative proposals are closely examined to ensure that they represent the best option available to government to meet the relevant policy objective. (Government of Victoria 2014, 2)

[1] In this paper, the term regulation refers to rules backed by government authority (legislation, statutory rules and legislative instruments) and to the activities of regulators, such as approvals processes, monitoring, and compliance and enforcement activity. It can also include other instruments, such as information and education that support the administration and encourage compliance with regulation.

This guidance note supports the VGR in prioritising regulatory effort to achieve the best possible community outcomes.

Policy officers and regulators already prioritise their efforts. Some also have policies and guidance to inform these choices. Policy offices and regulators can use this guidance note to refine these processes and ensure their choices are risk-based.

The best way of applying the guidance note will depend on context:

(1) agencies that are developing or reviewing areas of regulation could work through the guidance note systematically, follow the process described, and check and modify existing documents and processes as they go

(2) for existing areas of regulation that already focus on risk and have well-defined processes, agencies could map the steps and questions in the guidance note against their existing processes and guidance to identify and fill gaps

(3) for complex and long standing areas of regulation where harms and risks are not well defined, agencies could map existing processes, policies and guidance and use the guidance note to redesign their approach and consolidate and simplify documentation to reflect a risk-based approach.

Part 1 explains risk-based regulation and establishes a framework that is applied to the regulatory process. Subsequent parts examine the processes, tools, 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 in administering regulatory processes and undertaking compliance and enforcement (part 3).

1 A risk-based approach to regulation and regulating

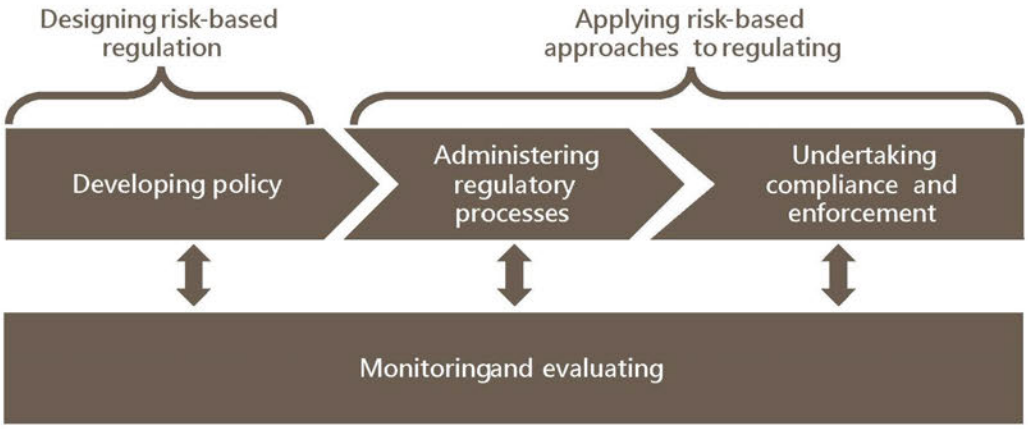
This part is for officers developing policy and designing regulation, and regulators administering and enforcing risk-based regulation. It describes a risk-based approach to regulation and regulating, building on the VGR' sprinciple that 'wherever possible, regulation should be designed to facilitate a risk-based approach by regulators' (Government of Victoria 2014, 18). For more information, see the supporting paper.

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.

Risk-based approaches are relevant at all stages of the regulatory cycle: developing policy, administering regulation, ensuring compliance and enforcement, and monitoring and evaluating regulation. Evaluation should be integrated across the preceding three stages and used to fine-tune and improve regulation (figure 1.1). (See the supporting pape r for further discussion of evaluation.)

Figure 1.1 Regulatory cycle



The approach to risk taken at each stage has implications for the scope and effectiveness of risk-based approaches at other stages in the cycle. For example, the level of prescription in regulation affects regulators' capacity to adopt a risk-based approach in administering regulation. Similarly, the choice of compliance and enforcement instruments available in the legislation affects the regulator' sability to implement proportionate approaches to compliance.

Risk-based regulation also needs to be embedded at all levels in the organisation, from strategic planning to frontline decision making, and supported by:

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

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

(3) data and information that are gathered and used

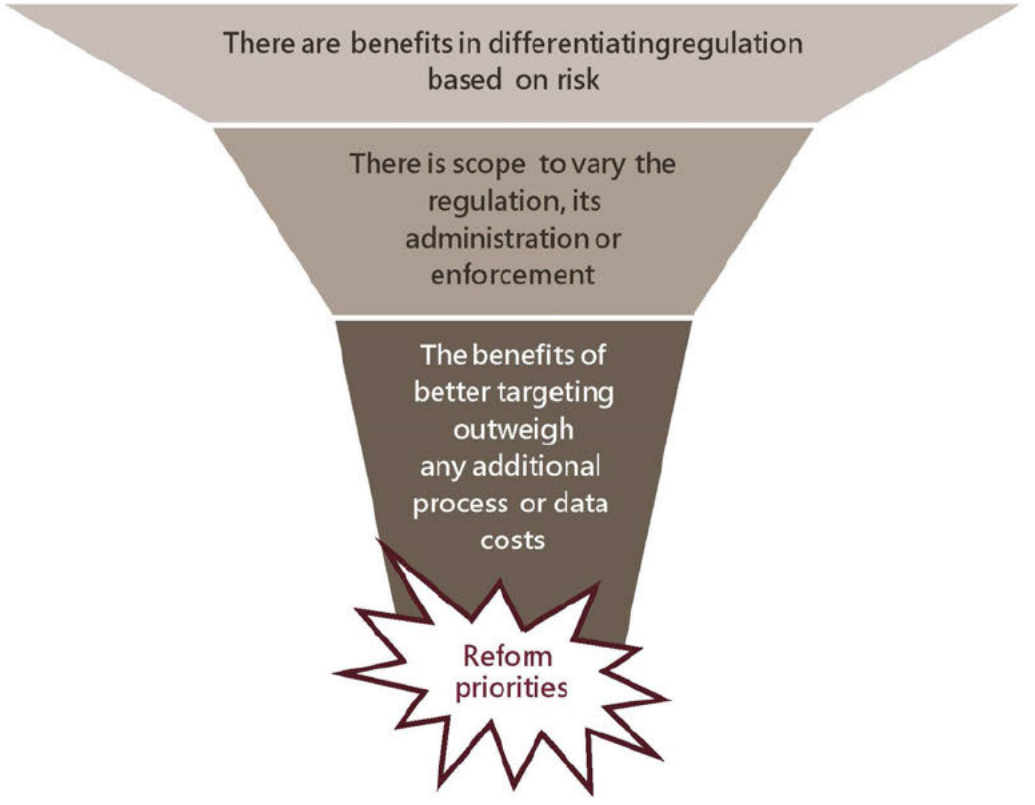
(4) regulatory documents (statements, policies, guidance and processes) that are developed with consultation, accommodate risk-based approaches, and are communicated to the regulator' staff and stakeholders.

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.

Some areas of regulation are more suited to risk-based approaches than others. There may be legislative constraints, information barriers, limits set by government policy (including in intergovernmental agreements), or a lack of community understanding and support. Policy departments and regulators can maximise the benefit of risk-based regulation by prioritising areas that pass all the filters illustrated in figure 1.2.

Figure 1.2 Prioritising areas for risk-based approaches to regulation and regulating



In many instances, agencies will transition to risk-based regulation by progressing through stages. These stages involve increasing the understanding of the risk and harms they are trying to reduce, using that understanding to inform their decision making (and to identify and address gaps or barriers to more risk-based approaches), and ultimately

embedding risk assessment in planning processes and decision making (see the supporting paper for more information).

To move through these stages, Victorian agencies usually need to better understand the harms they are trying to reduce and their characteristics, and then apply resources and policy action to reduce the risk of expected and emerging harms.

1.3 Elements of a comprehensive risk-based framework

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

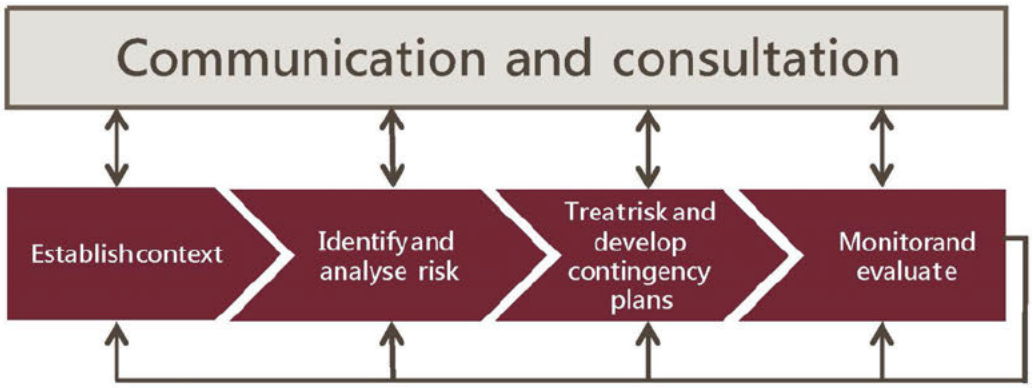
A comprehensive risk-based framework involves multiple steps (figure 1.3):

- **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 agency's risk attitude. Risks should be detailed and categorised, with clear measures to assess performance
- **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. Policy and regulatory officers should engage with a broad range of stakeholders: across government; with industry, consumer, and community groups; and with affected businesses and individuals. The right options for consultation and communication will depend on the circumstances, and may include:

- one-on-one meetings, site visits and workshops, to discuss and explain policies and regulations and to identify opportunities to improve
- industry roundtables and public forums, to obtain feedback on particular initiatives and solicit new proposals
- surveys, to gather relevant data and information
- websites, newsletters and media engagement, to disseminate news to stakeholders.

Figure 1.3 Risk management framework



These steps are applied across all stages in the regulatory cycle — policy development and regulatory design, administering regulation, and compliance and enforcement. The results inform regulatory priorities and resource allocation. The process is not linear, and analysis at all stages will be refined as regulators better understand each risk, its likelihood and consequences, and the cost and effectiveness of treatment.

2 Developing policy: for policy officers in departments and regulators

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

This part of the guidance note is for policy officers in departments and regulators. It describes how a full risk-based approach to policy development analyses all the issues listed in table 2.1 and highlights the priorities for those starting to develop risk-based policy. It complements existing policy development requirements in the VGR, including regulatory impact assessment. The supporting paper outlines the relationship between regulatory impact assessment and risk-based analysis.

Table 2.1 Developing policy: risk management framework

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	Describe the nature and scope of the problem the government is trying to address and the government's objectives in this policy area. Which harms does the government want to reduce?
	Identify relevant stakeholders and their interests	Determine who has an interest in this policy area because they would: • be affected by the regulation • administer any resulting regulation • regulate or make policy in a related area • be protected by the regulation. Describe their interest.
	Note the government's stated risk tolerance and attitude to risk	Review any statements the government has made about its attitude and tolerance to risk in this area.
Identify risk	Determine which material risks contribute to the identified harm. Assess the likelihood and consequences of these risks	Describe the activities, events, industry operations, or natural processes that create risks that potentially contribute to the identified harms and undermine the government's ability to achieve its objectives. What types of risks do they create? Assess the likelihood (probability) and consequences (effect) of these risks. If possible, measure these outcomes.
Analyse risk	Categorise risks using qualitative and quantitative indicators of likelihood and consequences	Use a matrix that ranks probability and effect to divide risks into categories of high, medium and low risk.
	Evaluate substantial risks in detail and identify their drivers	Analyse the circumstances in which the risk is likely to occur and what drives its probability and effect. With what degree of certainty can risks be predicted? What factors affect that prediction?

	Determine the level of risk acceptable to the agency	Identify the level of riskthat is acceptable in this policy area, given the government' sattitude to and tolerance for risk.
	Define how to measure success in reducing the substantial risks	Identify a small number of clear, measurable indicators that can be used to verify whether the substantial riskshave been successfully reduced.
Treat risk	Determine which risk treatments have the greatest benefits relative to their costs	Identify feasible options that involve tolerating, transferring, mitigating or avoiding the risk. Do other policies already target these risks? Are there existing incentives for businesses or individuals to manage the risksthemselves? Would regulation undermine these incentives? Which group is in the best position to manage the risk? Would government action materially affect the level of risk? Assess the strengths and weaknesses (benefits and costs) of each option against a base case of no government action. Identify the options that generate the greatest reductions in riskwith the least resources.
	Plan implementation	Develop an implementation plan agreed between the agency developing the policy and the regulator responsible for implementation. Allocate resources consistent with the prioritiesidentified in the analysis and assign responsibilityfor delivering the outco mes.
Develop contingency plans	Plan monitoring to identify and respond to emerging issues and emergencies	Develop systems to monitor expected outcomes and residual risks,and to respond if the expected outcomes are not achieved or residual risks emerge.
Monitor and evaluate	Establish data collection and feedback processes	Identify and establish processes to collect and analyse the data needed to monitor, track performance indicators and identify ways to improve the regulation. Assign responsibilityfor da ta collection and analysis.
	Evaluate the outcomes and build a culture of improvement	Determine how outcomes will be evaluated, who will be responsible for the evaluation and how they will involve stakeholders (internal and external) in the evaluation and improvement process.

2.1 Where to start

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

Existing regulatory impact assessment processes are a useful framework for considering the issues relevant for designing risk-based regulation. When a regulatory impact assessment is required, it could be augmented to identify and analyse explicitly the relevant risks and harms. Additional analysis is needed for proposals not subject to regulatory impact assessment.

Initially, policy officers should:

- clarify and understand risks, including the government's attitude to risk, and the types of risk that are acceptable and unacceptable
- build this risk understanding into designing and implementing policy options so regulation is introduced only when it is the best treatment option and the form of regulation and regulatory instruments selected accommodate risk-based administration and enforcement
- evaluate regulation and use the results to improve policy.

2.2 Establish context — clarifying objectives and the attitude to risk

Clarify the approach and attitude to risk.

Risks are ever-present, and there will always be challenges in prioritising risks. Before analysing risks, policy officers need to establish the policy context for managing risks. That is, clarify the government's objectives — particularly its attitude to risk.

In practice, the government's attitude to risk may not be explicit, so policy officers need to interpret the available information. Potential sources of information include existing legislation and regulation, second reading speeches, government policy statements, and research on government and community expectations. Later stages in the risk management process also inform the attitude to risk, as policy officers better understand the effectiveness and cost of treatment options.

Regulation is prone to error, so policy officers should consider the potential consequences of error when designing regulation. Excessive regulation imposes undue costs on those who have to comply (such as regulated businesses). But there is a greater risk of harms occurring when regulation is limited. So policy officers must clarify their priority: avoiding over-regulation or minimising adverse events.

*The **output** of this step is a risk statement that should, at a minimum, clarify:*

- *the problem that the government seeks to address*
- *that the government does not expect the regulator to eliminate risk but expects it to adopt a risk-based framework that sets and explains its priorities based on evidence*
- *whether the policy prioritises reducing harm or avoiding overregulating.*

The risk statement could be reflected in the regulator's statement of expectations (box 2.1).[2]

Box 2.1 Developing a risk statement — Housing Registrar

The statement of expectations for the Housing Registrar explicitly authorises it to direct resources away from low-risk activities:

> Regulatory engagement is tailored to the risk profile and size of community housing agencies with the level of engagement proportionate to the agency. The risk profile applied by the Housing Registrar will be transparent and available on the Housing Registrar's website. There is expected to be at least a 20 per cent reduction in engagement with low risk agencies.

Source: Rich-Phillips 2014, 2.

The stylised example attached to the supporting paper demonstrates how to apply risk-based regulation. Part 1 (below) illustrates how to establish the context. The other stages in the example are contained in the relevant sections throughout the guidance note.

Stylised example — A new fitness product (part 1)

There is a new fitness product on the market, which when used properly, is safe and valued 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.

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.

[2] In Victoria, ministers issue a statement of expectations to each regulator, which sets out the minister's expectations and priorities for performance and improvement.

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 risks over time and adjust assessments based on experience and new information.

Government and regulatory action should respond to a clearly defined problem. Misunderstandings about harms will likely lead to confusion about policy objectives and conflicting views on outcomes.

As a starting point, identify and analyse risk by thinking about the characteristics of different harms. This stage involves:

- understanding the scope and scale of risks
- testing whether the risk of harm or its consequences can and will be managed privately
- identifying the measures that will indicate whether the risk was successfully reduced.

2.3.1 Identify and analyse risk — understanding the risk

It is important to understand the nature and extent of the risk the government seeks to address. This step involves:

- identifying the risks and assessing their significance, based on their consequences and likelihood
- determining which significant risks you should consider treating
- developing a detailed understanding of the nature of the significant risks so effective treatment and contingency plans can be designed and implemented.

*The **outputs** of this step are:*

- *a risk register with high-level qualitative and quantitative assessment of the likelihood and consequences of the risks*
- *a ranking of the relative significance of the risks*
- *a list of a manageable number of significant risks (drawn from the risk matrix), with more detailed analysis of their drivers, likelihood and consequences.*

Stylised example — A new fitness product (part 2)

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 are not available, because the product is new. So, qualitative techniques may be more appropriate (such as scenario analysis). Also consider the 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

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

Stylised example — A new fitness product (part 2 cont.)

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

Risk matrix

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 characteri stics 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/o r 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?

Other factors to consider for this stage are discussed below.

Qualitative and quantitative risk assessments

Various risk assessment tools are available (attachment 1). Some tools draw on quantitative data. Other tools use qualitative sources of information, such as the views and opinions of experts. Both types have advantages and disadvantages.

- Quantitative data can be more objective and indicate risk priorities more clearly. Examples include the number of incidents reported, or the costs of different observed harms. However, data can be difficult or costly to collate and interpret. Not all data are reliable, and unreliable data may lead to erroneous perceptions of precision.
- Qualitative evidence is generally more readily available . Sources include internal corporate knowledge and surveys of stakeholder experiences. However, qualitative information is often subjective, and may not be representative of broader experiences. These can cause false trends and patterns to be inferred from the results.

In practice, policy officers should use a combined approach that draws on available data and supplements and tests the results with qualitative information. It is important to revise risk assessments over time to incorporate new data and information, particularly to reflect ongoing experience.

Types of risk and risk perspectives

Risk assessment can also be complicated by the types of risk and risk perspective. Specifically, it is important to recognise:

- emerging or increasing risks, not just experience or historical risks — for example the risk of harm from growth in internet gambling, or changes in the pattern of alcohol consumption among young people
- differences in community perceptions of risk and the views of experts — if the divergence is driven by community values, it is legitimate for regulation to reflect those values. However, community perceptions may be based on misjudging or misunderstanding the risk. In this case, it may be possible to increase community confidence and promote consensus between community and expert views by communicating and engaging with stakeholders (box 2.2). Both policy makers and regulators should be empowered to consult where appropriate
- catastrophic (low probability, high consequence) risks, which may need to be analysed using different techniques (see the supporting paper).

Box 2.2 Consultation on community attitude to risk — DEPI

In 2013 the Department of Environment and Primary Industries (DEPI) started consultation on its non-indigenous bird management policy. The summary of stakeholder views noted:

> Stakeholders agree with the need for a policy. There is broad acceptance that non-indigenous birds require management to reduce the threat that they pose to the environment. However, some stakeholders suggest that further evidence is needed to support the claim that non-indigenous birds currently kept in private collections in Victoria pose a real threat.

Such information is valuable in setting policy and consulting and communicating with stakeholders. DEPI published the consultation summary, its response to the issues raised, and the resulting non-indigenous bird management policy on its website.

Source: DEPI 2014c, 2.

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

Regulation should effect a change in outcomes, not merely respond to a perceived problem. Even when a risk has been identified, the government may not be the best party to manage that risk. There is less need for prescriptive regulation if businesses have strong commercial incentives to control risk, for example (box 2.3).

In addition, if the government assumes too much responsibility for managing risk, it could undermine people's capacity to protect themselves, reducing the community's resilience.

Box 2.3 Private accreditation schemes — Tourist accommodation rating schemes

Touristaccommodation providers must register with cou ncils under the *Public Health and Wellbeing Act 2008 (Vic)*. This legislation involves compliance inspections by council health and safety officers, among other things.

For many operators, their private accommodation rating provides transparent information on the standard of the accommodation. So some tourism operators question the need for council inspections (VCEC 2011, 175).

A risk-based approach to regulating tourism accommodation would draw on these public ratings. The regulator would minimise the effort in regulating and inspecting tourism providers with a current high rating from a reputable agency (although the regulator would need to make a judgment as to what is 'reputable')These operators are at a low riskof breaching the standards in the act.

Source: VCEC 2011.

*The **output** of this step is an analysis of the capacity and incentives for private parties to manage risks. It should inform if regulatory action is required and, if so, the appropriate form of intervention that is warranted.*

2.3.3 Identify and analyse risk — identifying measures of success

Regulation is unlikely to achieve its objectives if there is no clear view on what success looks like, or if the indicators of success are not monitored. Measurement is needed to:

- judge whether the regulation is delivered effectively
- refine and improve the regulation
- explain the approach to stakeholders and manage expectations.

*The **outputs** of this step are performance indicators and benchmarks that are measurable, inform later policy evaluation, and ideally provide an objective basis for assessing regulatory outcomes.*

Regulators are generally responsible for designing and reporting detailed performance criteria so this issue is discussed in part 3. Policy makers need to be satisfied that performance measures are in place and collect the information necessary to improve future policy design.

2.4 Treat risk and develop contingency plans

Determine how the government will respond to identified significant risks.

This stage involves:

- identifying which risks will be tolerated (which means the government takes no specific regulatory action)
- deciding what action is appropriate for the remaining significant risks (including non-regulatory options) and designing regulatory response (if necessary)
- determining what will be subject to ongoing monitoring, who will be responsible for that monitoring and who will respond if circumstances change.

2.4.1 Treat risk — ensuring regulation is the best treatment option

This step involves determining which of the following risk treatments is appropriate:

- **tolerate** — the risk is recognised but no action is taken to reduce its effect. Such risks would be considered in contingency planning
- **transfer** — risk is shared with another party, for example through outsourcing or insurance
- **mitigate** — action is taken to reduce the risk by removing its source or reducing its consequences or likelihood. Residual risks are considered in contingency planning
- **avoid** — stopping activities that might lead to a risk transpiring. (UNECE 2012, 18–9)

Government intervention is not needed or warranted when:

(1) the level of risk can be tolerated — for example, in the travel industry, existing mechanisms such as industry-run accreditation and credit card chargebacks protect consumers sufficiently, so licensing travel agents is unnecessary

(2) the government cannot easily influence the risk — for example, the conduct of internet gambling websites based overseas

(3) the costs of regulating are greater than the benefits — for example, the Victorian Environment Protection Authority (EPA) concluded the costs of requiring petrol stations to install certain types of vapour recovery technology to control fuel vapours outweighed the benefits to the environment (EPA 2013, 6).

Even if the risk is significant and amenable to being ameliorated through government action, non-regulatory responses should still be considered — including education and improved access to information — because they may satisfy policy objectives at lower cost.

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

Policy responses should be effective and proportionate. That is, the form of intervention should match the consequences and likelihood of the risk occurring. Light-handed responses (such as education) may be appropriate for low-harm risks, but more direct responses may be justified for frequent and high-harm problems.

The design of any resulting regulation is important.

(1) The objectives of the regulation should reflect the government's intended attitude to risk. Objectives that include terms such as 'as low as possible' or 'protect against' can encourage regulators to be overcautious and to try to eliminate risk, not manage it.

(2) The legislation should give regulators the flexibility to design processes to reflect risk and to adjust processes as risk changes (Government of Victoria 2014, 18). Highly prescriptive legislated processes can lock regulators into an approach and limit their ability to be risk based (box 2.4).

(3) Legislation should give the regulator access to a sufficient range of enforcement tools to adopt a risk-based approach. It is easier for the regulator to adopt a proportionate response to compliance and enforcement if it can select from a spectrum of responses — from education and instruments that encourage voluntary compliance, to enforcement tools that remediate damage or punish the offender.

Box 2.4 Legislative constraints on risk-based regulation

Environment Protection Act 1970

In Victoria, contaminated environments are identified and treated via independent environmental audits and subsequent obligations to clean-up or manage any contamination. Audits are usually triggered by a change in land use and define how the site owner must remediate contamination. The Environment Protection Act does not allow the site owner to voluntary agree with the EPA on how the site will be cleaned up, potentially discourage site owners from proactively decontaminating sites.

Similarly, the Environment Protection Act requires owners of vehicles used to transport prescribed industrial waste to hold an EPA permit. The EPA has no discretion to exempt low-risk transfer activities from this obligation.

Liquor Control Reform Act 1998

Under the Liquor Control Reform Act, all applications for a permanent liquor licence are referred to the police and local government so they have an opportunity to object to the licence. This requirement adds about one month to the licensing process. However, some licences are very low risk — such as a small café that is only open during standard shop trading hours. The process specified in the Act means the Victorian Commission for Gambling and Liquor Regulation cannot decide low-risk applications without referring them to the police and local government.

*The **output** of this step is government policy and regulation (if needed) that is proportionate in the way it targets risk, and that allows the regulator to adopt risk based approaches to administering and enforcing regulation.*

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 is likely to develop most contingency plans because it (not the department or minister) has day-to-day contact with the regulated entities. But policy officers need to allocate explicitly responsibility for contingency planning at the policy development phase, and clarify the regulator's scope to respond to emergencies or emerging issues. Policy officers should also identify the appropriate circumstances for involving the department in policy or regulatory change.

*The **output** of this step is a clear statement of responsibility for developing contingency plans and responding to adverse events. The relationship between the department and the regulator should be sufficiently defined, so all parties are clear on the department's and regulator's roles in initiating policy or regulatory changes.*

Stylised example — A new fitness product (part 3)

Treat risk and develop contingency planning

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.

2.5 Monitorand evaluate

Monitorthe 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.

Reliable data and information are needed to:

- establish a baseline for judging existing outcomes
- analyse the risksof harm to the community and design an appropriate regulatory framework
- assess regulatory performance over time (that is, evaluate policy).

The regulator is responsible for day-to-day monitoring and continuous improvement. The policy department is responsible for:

- monitoring the regulator's performance without interfering in day-to-day management, particularly for independent regulators
- assessing the appropriateness of existing policy, and changing regulation that constrains the regulator's ability to adopt risk-based approaches.

Risks and priorities can change over time, so policy officers also need to evaluate regulation 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 the regulation's underlying rationale and the regulator's performance) after a defined period (such as five years after introducing a regulatory regime).*

3 Applying regulation: for regulators administering and enforcing regulation

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

This part is for regulatory officers who manage regulators or administer regulation (including licensing and registration), and frontline staff who undertake compliance and enforcement activities.

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. Effective risk-based regulation requires a strong and sustained commitment by management in the regulator (box 3.1).

Box 3.1 Role of management in risk-based regulation

According to the Australian and New Zealand standards on risk management managers should:

- define and endorse the risk management policy
- ensure that the organisation's culture and risk management policy are aligned
- determine risk management performance indicators that align with performance indicators of the organisation
- align risk management objectives with the objectives and strategies of the organisation
- ensure legal and regulatory compliance
- assign accountabilities and responsibilities at appropriate levels within the organisation
- ensure that the necessary resources are allocated to risk management
- communicate the benefits of risk management to all stakeholders
- ensure that the framework for managing risk continues to remain appropriate

Source: AS/NZS2009, 9-10

Agency-wide analysis 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. The guidance note identifies and discusses these aspects separately.

Table 3.1 outlines the full risk-based approach to applying regulation. These steps are similar to those in table 2.1 (on developing policy), but the issues considered are generally more specific to an aspect of regulation. Policy development considers whether regulation should cover the redevelopment of contaminated land, for example, while the regulator analyses how to apply its auditing process to contaminated land that may be redeveloped:

- the regulator considers the regulatory administration context. How can it prioritise and adapt its processes for different types of land, land use and contamination?
- the regulator also considers the compliance and enforcement context. How can it address the activities of a non-compliant business where the risk of harm is significant?

Table 3.1 Applying regulation: risk management framework

Establish context	Identify the regulatory objectives and the risk government action is trying to address	Describe the objectives in this area of regulation and the specific harms it is trying to address. State how the regulator interprets these objectives. *Compliance/enforcement:* Describe risk-based objectives for the regulator's compliance and enforcement strategy and how they relate to the risks and harms the regulator is addressing.
	Identify relevant stakeholders and their interests	Determine who has an interest in this regulation (inside and outside the agency) because they are: • affected by or involved in the regulatory process • regulate or make policy in a related area • protected by the regulation. Describe their interest.
	Note the government's stated risk tolerance and attitude to risk	Review any statements the government has made about its attitude and tolerance to risk in this area, including the minister's statement of expectations to the regulator.
	Describe the current regulatory processes	Map the current regulatory powers and processes relevant to this area of regulation and summarise the current compliance and enforcement strategy. Identify the regulatory and information instruments available to the regulator.
Identify risk	Determine which material risks contribute to the potential harms. Assess the likelihood and consequences of these risks	Describe the specific activities, events, businesses' activities, or natural processes that create risks that potentially undermine the regulator's ability to achieve its objectives. What types of risks do they create and which of these risks can the regulator influence by applying its legislative powers and other tools (such as education)? Are there relevant risks the regulation (as it is currently applied) does not address? Assess the likelihood (probability) and consequences (effect) of the risks the regulator can influence. If possible, measure these effects, drawing on data and intelligence from inside and outside the regulator.
Analyse risk	Categorise risks using qualitative and quantitative indicators of likelihood and consequences	*Administration:* Develop indicators and rank probability and effect to divide the risks the regulator can influence into categories of high, medium and low risk. *Compliance/enforcement:* Develop indicators of risk that include the likelihood and consequences of the risk and the probability of compliance with the regulation. Assess the risk of individuals, businesses, types of businesses, or activities and allocate them to high, medium or low risk categories.

	Evaluate substantial risksin detail and identify their drivers	Analyse the circumstances in which the riskis likely to occur and what drives itsprobability and effect. Withwhat degree of certainty can you predict the riskwill occur? What factors affect that prediction? *Compliance/enforcement:* What are the incentives for businesses to comply or not comply with the regulation? Rank individual businesses, types of businesses, or activities according to their level of risk.
	Determine the level of risk acceptable to the regulator	Articulate the level of risk the regulator can accept, given the government's attitude to and tolerance for risk.
	Define how to measure success in reducing the substantial risks	Identify a small number of clear, measurable indicators to verify if the substantial riskshave been reduced successfully.
Treat risk	Determine which risktreatments have the greatest benefits relative to their costs	Identify feasible options that involve tolerating, transferring, mitigating or avoiding the riskand match these options to the regulatory and information instrumentsavailable to the regulator. Do other policies already target these risksor potentially conflict with the regulator's objectives? Are there existing incentives for businesses or individuals to manage the risksthemselves? Would certain approaches by the regulator undermine these incentives? Assess the strengths and weaknesses of each option and identify the options that generate the greatest reductions in riskwith the least resources.
	Implement the plan	Develop an implementation plan that those administering the regulation own and understand. Allocate resources based on the plan's prioritiesand assign responsibilityfor delivering the outcomes. Develop a plan to communicate the regulator's risk appetite and disseminate guidance on itsapproach to regulation.
Develop contingency plans	Plan monitoring to identify and respond to emerging issues and emergencies	Develop systems to monitor expected outcomes and residual risks, and respond if the expected outcomes are not achieved or residual risks emerge. Explain to stakeholders how contingency is being managed, recognising the regulation may not stop some low risks.
Evaluate	Establish data collection and feedback processes	Identify and establish processes to collect and analyse the data needed to monitor and track performance indicators, and identify ways to improve the regulation. Assign responsibilityfor collecting and analysing data.
	Evaluate the outcomes and build a culture of improvement	Determine how to evaluate outcomes, who will be responsible for the evaluation and how they will involve stakeholders (internal and external) in evaluation and improvement.

3.1 Where to start

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

While policy makers consider where regulation is needed, regulators think about how to implement and enforce regulation. Despite these different focuses, regulators applying risk-based regulation follow the same steps as those developing policy. So, their activities can be grouped in a similar way (figure 3.1).

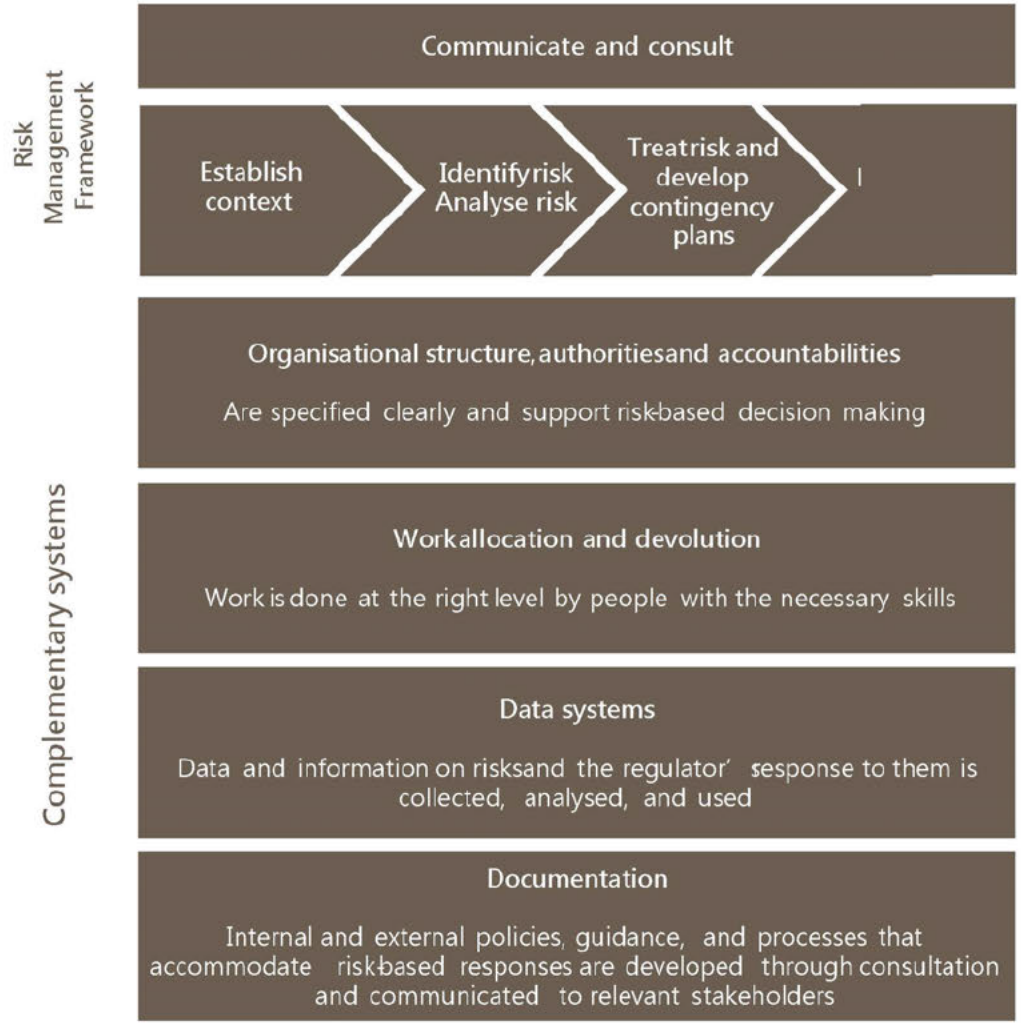
Building on policy makers' risk assessments, regulators should start by:

- 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.

Complementary systems and structures are agency-wide enablers necessary to make risk-based regulation work. These systems and structures include clear roles, responsibilities and accountabilities that support risk-based decision making, work allocated to people at the right level with the necessary skills, and supporting documentation, communication, data, and information systems.

Communication with government and stakeholders is also essential to administer risk-based regulation. The most appropriate mix of consultation tools and techniques will vary across areas of regulation.

Figure 3.1 Processes for risk-based decision making by regulators



3.2 Establish context

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

This stage involves clarifying the harms and risks the regulator is expected to manage. These expectations inform the regulators' objectives, and are derived from:

- the views of, and pressures on, the regulator's stakeholders — regulated entities and the beneficiaries of the regulation, including the community
- the government's attitude to, and tolerance for, risk and how this translates to the regulator's work.

3.2.1 Establish context — clarifying objectives and the attitude to risk

This step involves clarifying the regulation's objectives and the risks of harm it is trying to reduce. This task can be difficult when the relevant information is not available — although this information should be available where a comprehensive risk framework is adopted across the policy cycle. In practice, regulators must interpret the available information — for example, legislation, statements of expectations and government policy statements.

Sometimes, the government or the responsible department releases a formal risk statement, detailing its risk attitude. If it does, the regulator can use the statement to inform and refine its regulatory approach, and then communicate this approach to risk to stakeholders. If the government or department has not produced a formal risk statement, the regulator should document its attitude to and tolerance for risk and communicate its approach to stakeholders.

Few regulators have formal risk statements, but some have released information that could be compiled into such a statement (box 3.2).

*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*
- *the risks and harms 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 (where relevant).*

Box 3.2 Developing a risk statement

Transport Safety Victoria (TSV)

TSV provides guidance on how it prioritises risk.

> In the bus and rail sectors, our primary focus is on catastrophic risk: low-probability high-consequence events that have the potential to result in significant loss of life and damage to property. We seek to minimise the risk of these events by adopting a safety systems perspective and collaborating with industry. In the maritime sector while we retain a systems perspective, we have a stronger focus on events of higher probability and low consequences, for example vessel disablements, as these are the key drivers of risk. (TSV 2013, 10)

The Australian Skills Quality Authority (ASQA)

ASQA states that it:

> ... primarily focuses its efforts on assessing, and where necessary responding to, risks that many arise if a learner is judged competent without possessing the necessary skills and knowledge. (ASQA 2014)

ASQA's Risk Assessment Framework then explains how ASQA uses its risk analysis to rate regulated entities, and how that rating affects ASQA's priorities and processes.

> The [Vocational Education and Training (VET)] Regulator uses a risk assessment process to assess each [registered training organisation (RTO)] and all registration applications, including applications for initial registration, applications for continuing registration and applications for extensions to scope of registration, using these risk assessment processes. The risk assessment assists the VET Regulator determine how it will assess an application and informs the extent to which it will monitor an RTO to ensure its operations meet the requirements of the VET Quality Framework.
>
> A risk assessment is undertaken when an application is received, and is reviewed in the light of current evidence of performance or any other information about an RTO. (ASQA 2012, 3)

The risk assessment process assesses the potential likelihood and effect on students, industry, and the reputation of the VET sector. ASQA rates effect against a four-point scale and likelihood against a five-point scale. If the risk is low, the Risk Assessment Framework states the risk is tolerable and does not require any specific audit activity. That is, ASQA may decide not to audit the RTO.

Source: TSV 2013, ASQA 2014, ASQA 2012.

Stylised example — A new fitness product (part 4)

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 the attitude to risk to stakeholders and explain the regulatory approach.

3.3 Identify and analyse risk

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

The regulator needs to identify and assess risk at various levels, to identify and assess the risks relevant to the groups that administer regulation or conduct compliance and enforcement. Specifically, groups should understand the risk and how it affects regulated entities and their activities. Using qualitative and quantitative techniques to analyse risk and understanding community perceptions are discussed in the part of the guidance note on policy development. The same issues are relevant to regulators. Over time, regulators should strive to improve how well they collect and use qualitative and quantitative evidence, based on experience.

Some regulations are delivered using a cooperative approach. For example community-based invasive species action groups engage with private landholders to manage infestations of established invasive species. Their activities include community awareness and education, advice on control techniques and signing up landholders to voluntary land management agreements. Community based groups can be an effective, low-cost means of fostering and coordinating compliance. In such cases the regulator relies on proactive community support and action around agreed regulatory priorities.

Knowing the factors that drive each identified risk helps analyse and measure risk (box 3.3). Attachment 1 lists some of the potential information sources, tools and techniques, and outputs.

*The **outputs** of this step are:*

- *a risk register of the risks of harm the regulator is charged with reducing*
- *a ranking of the relative significance of the risks*

a list of a manageable number of significant risks (drawn from the risk ranking), with more detailed analysis of their drivers, likelihood and consequences.

Box 3.3 Measuring risk factors — Australasian Environmental Law Enforcement and Regulators Network

The Australasian Environmental Law Enforcement and Regulators Network suggests breaking down each identified environmental risk into the factors that drive it. Regulators measure the factors, and then aggregate the measure to obtain a risk score.

There are several ways to measure riskfactors, but the two common methods are:

- Many simple measures — Thismethod focuses on very simple binary or three tier outcomes (for example, Y/N/NA or Y/Partial/No) and uses a larger number of simple measures to represent the factor effectively. It is useful when the tool is automated or specific data are being used to make the assessments.
- Few complex measures — This method uses only one or a few measures, but requires more detailed definition and explanation of the differences in risk scores. It is more often used when data are not readily available or judgements are more subjective.

Source: AELERT2013, 13.

Stylised example — A new fitnessproduct (part 5)

Identifyand analyse risk

Identify and analyse specific risksand then summarise the analysis in a riskregister. Map significant risksin a riskmatrix 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' age orsocial 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 risksthey impose, and the strength of the incentives for them to comply with existing consumer standards.

3.3.1 Identify and analyse risk — identifying measures of success

In Victoria, the guidelines for developing regulators' statements of expectation emphasise performance measurement. The performance measures must be reported in annual reports, and measures for some regulators are presented in annual budget papers (specifically, *Budget Paper No. 3 — Service Delivery*). However, this task can be difficult.

First, there are no well-established best practice frameworks for identifying, measuring and reporting against performance criteria. That said, some jurisdictions, such as New South Wales, are developing guidance on establishing performance measures (NSW Department of Premier and Cabinet 2014) (see the supporting paper).

Second, significant data gaps mean regulators tend to focus on measuring outputs rather than outcomes. Some output and activity measures are important to assess process efficiency but say little about outcomes. Moreover, outcomes can be difficult to measure particularly where a low probability but high harm risk is targeted by regulation — that is, if an adverse event does not occur, is this due to the regulators' actions, or the underlying low probability?

One solution is to develop a dashboard of qualitative and quantitative indicators that illustrate the regulator's approach, assess if regulation is effective, and indicate if the regulations will lead to the outcomes expected:

- quantitative indicators could indicate if the regulator prioritises effort, and applies regulatory tools and processes consistent with risk based regulation.
- qualitative indicators could measure process maturity in applying risk-based regulation. Such indicators are a practical response to the limited availability of consistent data and information on regulator performance and practice. They can help drive regulatory improvement and help interpret quantitative indicators.

3.4 Treat risk and develop contingency plans

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

Across the agency, begin by:

- identifying the activities and regulatory tools that best reduce the risk of harm
- allocating resources based on risk priorities, identifying areas where it can:
  - initiate strategic projects to address large complex risks
  - wind back or discontinue activities because the risks are low
  - leave the response to other policies or regulation that already address the risk of harm
  - take a light-handed approach (which may involve no action) because regulated parties have incentives to voluntarily reduce the risk of harm
- planning for contingency to monitor and respond to adverse events.

3.4.1 Treat risk — prioritising harm reduction

Risk treatment at an agency-wide level focuses on allocating resources across activities to maximise harm reduction. As far as possible, move resources from areas where risk is low (tolerable), as well as areas where the capacity to reduce harm is low relative to the resources being spent, to areas where resources are more effective in reducing harms (box 3.4).

Box 3.4 Prioritising harm reduction (hypothetical examples)

Example 1

Regulator A wanted to demonstrate it was responsive to public concerns, so it followed up all complaints by sending an inspector to investigate. A risk analysis found:

- responding to these complaints took up most of its inspectors' time
- often inspections did not detect significant breaches of the regulation
- resource constraints meant inspectors did not investigate areas of potentially high risk of harm.

Regulator A developed criteria to filter complaints and only send inspectors to sites where a breach was likely, allowing it to redeploy inspectors. Regulator A explained its new approach to stakeholders and published its policy.

Example 2

Regulator B licenses businesses who want to be involved in certain activities. The risk of harm from those activities ranges from very low to very high.

In the past, Regulator B checked around 2000 applications for low-risk activities a year, to ensure applicants represented their activities truthfully and had the skills and training necessary to manage any associated risk. But the application process was costly to administer and imposed a regulatory burden on all 2000 applicants, for little gain.

A risk analysis found:

- checking low-risk applications rarely resulted in Regulator B rejecting the application
- licensee behaviour had the greatest effect on whether problems subsequently arose and this was difficult, if not impossible, to assess via the application process.

Regulator B simplified the approval process for low-risk activities and focused its effort on monitoring and complaints handling. It used information it gathered to identify and remove the few businesses that did not operate to the required standard.

Other objectives, such as maintaining confidence in the regulation and the regulator, may be relevant. For example, non-compliance is relevant, because widespread non-compliance can increase the risk of harm and undermine confidence in the regulation. But focus on the level of the harm to the community (including the extent to which low confidence in the regulation undermines its effectiveness), not non-compliance per se.

*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.

Stylised example — A new fitness product (part 6)

Treat risk

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.

3.4.2 Develop contingency plans

Risk-based regulation does not eliminate risk and problems can arise from:

- emerging or unforseen risks
- risks that remain after the regulation is implemented (residual risks)
- risks that were accepted because the risk is low, regulation would not reduce the risk, or regulation was too costly.

Regulators are often concerned that if these risks eventuate and cause harm it will raise public and political criticism and undermine confidence in the regulation. Contingency planning that monitors outcomes and responds quickly if problems occur or new issues emerge reduces the risk and impact of public criticism (see the supporting paper).

3.5 Monitor and evaluate

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

Whether administering regulatory processes or undertaking compliance and enforcement activities, regulators will face new threats and challenges to regulatory regimes. Monitoring regulatory activities and outcomes provides information to maintain (and improve) effectiveness and responsiveness. Regulators should:

- collect data to inform decision making and refine their understanding of risk

- identify trends that may affect riskprioritiesand contingency planning
- ensure the regulatory processes are efficient and working as expected
- make available information and data that explains their approaches, and builds and maintains support for the regulation.

The outputs of this stage are information and data on:

- the riskindicators used to categorise and prioritiserisk
- other aspects of risk that need more information to test their relevance and improve understanding
- the efficiency and effectiveness of the regulatory process
- the outcomes of the regulation and emerging trends that could affect risk.

Stylised example — A new fitnessproduct (part 7)

Monitoring

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 riskof harm.

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

3.6 Complementary systems

Identifyand establish appropriate complementary systems and structures.

3.6.1 Complementary systems — organisational issues

The regulator' sstructure, roles, authorities and accountabilities need to be clear and support risk-based decisions. Thisrequires:

- strong leadership from senior management. For example, governance bodies need to set the regulator' sstrategic position on risk and senior staff need to set the priorities necessary to target key risks (Sparrow 2007, 19)
- clear and well-communicated roles, authorities and accountabilities so staff know what they must do, have the tools and support to deliver, and are held to account
- training that focuses not only on the mechanics of the process but also the necessary cultural change.

Clarify roles and responsibilitieswith other agencies, including:

- who is responsible for managing particular risks and what actions and decisions they are authorised to make
- how the different agencies will interact, communicate, share information and work cooperatively when needed.

3.6.2 Complementary systems — work allocation and devolution

Risk-based regulation requires good decision making at the right level. Frontline staff need the capacity to apply risk-based judgement. Management should provide clear strategic guidance and ensure all staff are trained to understand and implement risk-based regulation. One way of managing the various roles is:

- **governing body** — sets the strategic direction
- **management** — develops internal policies, assesses risk and determines how the organisation will respond, and monitoring and improving performance
- **operational staff** — mange regulatory processes day to day, with the level of risk and complexity of individual cases matched to the skills and experience of the staff involved. (See supporting paper for more detail.)

Work allocation and devolution should be reflected in internal performance management processes and indicators.

3.6.3 Complementary systems — data systems

The objectives of collecting and analysing data and information are to:

- identify risks and analyse their consequences and likelihood
- analyse the effectiveness of treatment options relative to their cost
- set performance indicators and monitor progress.

Regulators often hold data that are not used effectively. Harness existing data and intelligence to evaluate the likelihood and consequences of the risk of harm and the effectiveness of current harm reduction strategies.

Regulators may not have all the information they need. Then, draw on available quantitative and qualitative information from a variety of sources, and build on that information to identify the knowledge gaps to be addressed as a priority (Box 3.5).

Box 3.5 Improving data collection — DEPI

The Department of Environment and Primary Industry (DEPI) collects data to support invasive species regulation and to report on how it meets its obligations.

In 2014, DEPI started to review its biosecurity information systems to develop a new performance monitoring and evaluation process. The Department intends to use this process to identify any gaps in the data being collected and then assess whether the benefits of improved evaluation with more data would outweigh additional collection costs.

Source: DEPI (pers. comm, 2014)

3.6.4 Complementary systems — documentation

Risk-based regulation requires documentation that ensures stakeholders understand the regulatory approach and it can be applied consistently. There is a hierarchy of relevant documents.

- **Regulator's response to its statement of expectations** — In a statement of expectations, the responsible minister outlines the government's expectations of the regulator, its behaviour and the outcomes it must achieve. The government could use such statements to articulate its attitude to risk and risk-based regulation for each regulator (high-level statements are already included for some regulators), and the levels and types of risks it considers are acceptable and unacceptable. Regulators must formally respond to statements by outlining the activities that will achieve the stated expectations.

- **Risk statement** — This document outlines the regulator's approach to risk and risk-based regulation. It reflects how the regulator intends to deliver the government's objectives. At a minimum, it presents:

  - the regulator's understanding of the government's objectives and attitude to risk
  - the risks and harms 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 (where relevant).

  This statement could be incorporated into other documents such as the risk policy.

- **Risk policies and processes** — These internal and public documents outline the regulator's approach to regulation and how it will apply risk-based regulation.
- **Guidelines and fact sheets** — These detailed, specific documents inform and guide stakeholders on how risk-based regulation is applied in specific areas, what stakeholders can expect in their interactions with the regulator, and the roles and responsibilities of all parties involved.

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. Attachment 1 lists some potential information sources, tools and techniques, and outputs.

3.A.1 Where to start

Identify and address barriers the regulator can control.

The issues that most often arise in administering regulation are:

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

As a first step, systematically identify and address the barriers that can be controlled to improve the way risk is considered and included in decision making. Prioritise changes that would produce the greatest savings for the regulator, regulated parties, or other stakeholders, without compromising the regulatory objectives.

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.

At this stage, analyse risk at the level of the regulated party or activity, and develop risk indicators for regulated parties. Use this information to vary the time, resources, and the requirements in regulatory processes. Use information in licence applications to stream businesses into risk categories such as high, medium, and low (box 3.A.1)

*The **outputs** of this stage are indicators that help assess and categorise regulated parties as high, medium, or low risk.*

Box 3.A.1 Streaming into risk categories

Victorian Commission for Gaming and Liquor Regulation

When applying for a liquor licence, applicants provide information on four factors relevant to their level of risk:

- **licence type** — for example, a restaurant licence is likely to be low risk compared with a late night licence (which is likely to be higher risk)
- **trading hours** — longer and later trading hours tend to indicate higher risk
- **patron numbers** — venues catering for a larger number of patrons tend to indicate higher risk, all other things being equal
- **applicant history** — an applicant who has been convicted of an offence or has a history of poor management and compliance tends to indicate higher risk.

The assessment process for each risk category is tailored, with more detailed scrutiny for high-risk applications and more streamlined, less intensive process for lower-risk applications.

Victorian Weed Risk Assessment methodology

The Victorian Weed Risk Assessment (WRA) methodology systematically compares the risk of invasive plants. The method uses qualitative and quantitative data to compare three risk factors across plant species. Each risk factor is weighted according to its importance:

(1) The plant's invasiveness (weighted at 0.12)

(2) A comparison of the plant's present and potential distribution (0.32)

(3) The plant's impact on social, economic and environmental values (0.56).

The impact score for risk factor three is weighted for the impacts on social values (0.10), the environmental impact on natural resources (0.25) and flora and fauna (0.425), and the economic impact on agriculture (0.225). The values are added to produce a single figure score used to place the plant in a risk category (from low to high).

Source: VCGLR (pers. comm., 2013); DPI 2005.

Risk ratings can and should be informed by experience and revised over time. If a regulated party's behaviour is inconsistent with the regulator's initial assessment of the party's riskiness (the regulator has been either unduly tough or weak, because of good or bad performance by the party), the party should be re-categorised and treated differently in subsequent compliance and enforcement activity or in future regulatory processes (such as, a licence renewal). This approach gives regulated parties an incentive to adopt behaviour consistent with lower risk categories.

3.A.3 Treat risk — improving processes

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

Regulatory agencies are subject to resource constraints. Usually, it is not possible to redesign the entire regulatory response in light of risk analysis. Pursuing risk-based activities requires freeing resources from other activities. In the first instance, focus 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.

The most direct and effective ways to improve regulatory processes include:

- discontinuing processes or activities that do not have a material effect on reducing risk and achieving regulatory objectives — for example, avoiding process checking that does not focus on substantive issues
- streamlining processes for low-risk activities so that they are more standardised and require less detailed analysis of individual cases
- avoiding re-examining issues that are considered by other bodies or at other stages in the process
- for low-risk areas, relying more on monitoring or compliance activities to monitor outcomes, rather than preapproval (licensing or registration) in every case.

Box 3.A.2 outlines the approach to streaming risks associated with invasive plant and animal species. Figure 3.A.1 depicts an approval process that involves triaging and streaming assessment according to risk. Figure 3.A.2 illustrates the steps in a process to improve efficiency and risk focus. (For more information see the supporting paper.)

*The **output** for this stage is an improved regulatory process that:*

- *discontinues activities that are not significantly reducing the risk of harm*
- *streamlines the remaining activities so they are as efficient as possible*
- *triages applications according to risk and tailors the process to the level of risk of each application.*

Box 3.A.2 Managing invasive plant and animal species — DEPI

In a discussion paper for the Invasive Species Control Bill 2014, DEPI outlined a new risk-based framework for managing the threats posed by invasive species. The framework streams risks into two declaration categories, each triggering different obligations and compliance responses.

- 'Category 1' threats may be triggered by an outbreak of a new invasive species and the Department expects eradication is feasible. The Department must consider the invasive species is likely to have significant adverse economic, social or environmental effects (if it can identify the likely consequences of the outbreak). For category 1 threats, the regulatory focus is on outbreak prevention and early intervention to eradicate.
- 'Category 2' threats relate to established invasive species, which the Department considers cannot be eradicated. The invasive species must impose (or potentially impose), significant adverse economic, social or environmental effects. For category 2 threats, the regulatory focus is ongoing management to prevent or contain the spread of the invasive species.

Source: DEPI 2014b.

Figure 3.A.1 Process improvement in regulators

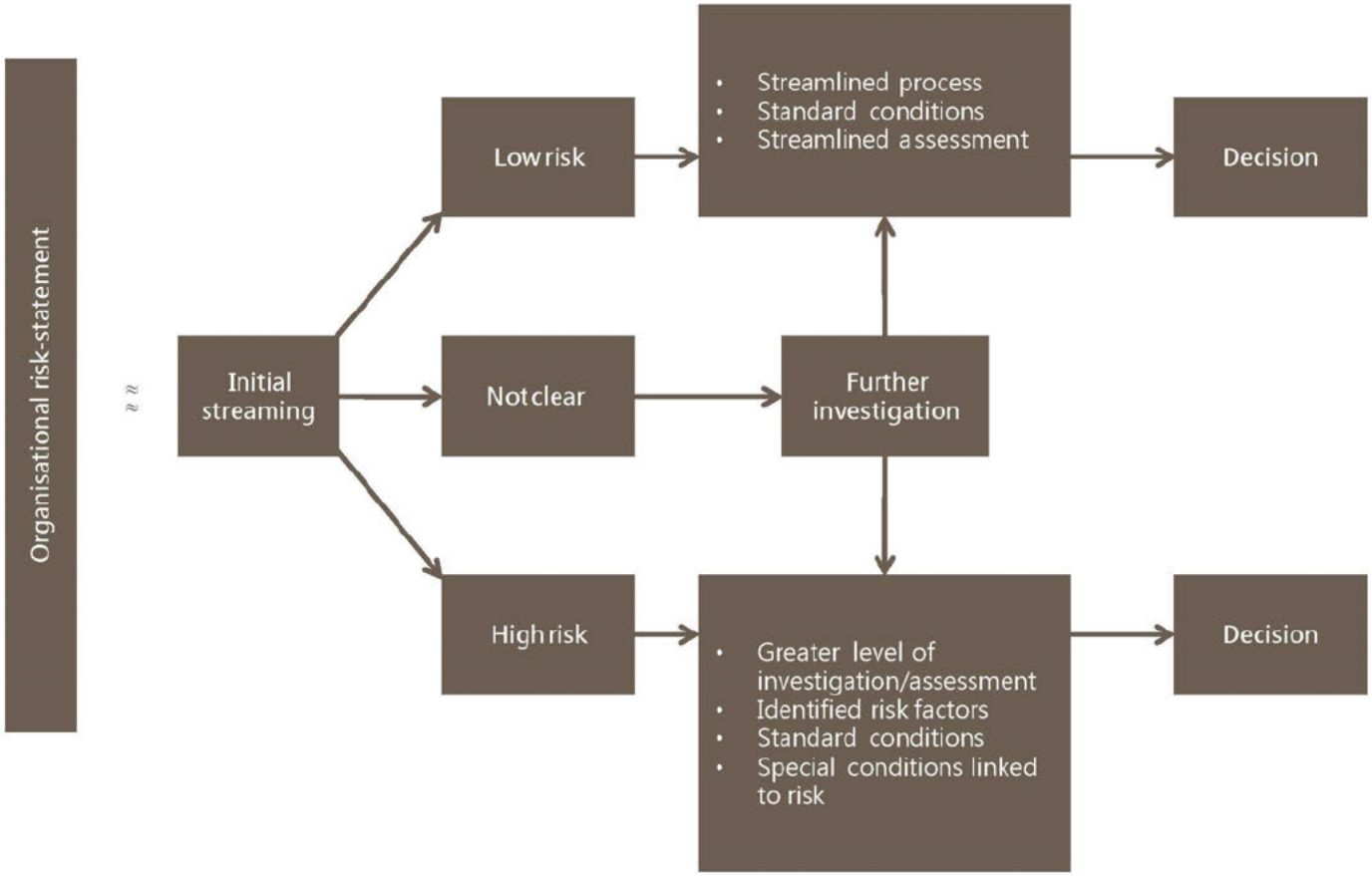


Figure 3.A.2 Process improvement in regulators

Step 1

Define the expected harm that this aspect of the regulation is intended to reduce and map current regulatory processes.

Step 2

Discontinue unnecessary or ineffective regulatory activities — that target regulated parties or activities: that do not contribute to the risk, where the level of risk is tolerable; or where the costs of intervention outweigh the benefits.

Step 3

Triage the remaining regulated parties or activities into two or more risk streams — for example, low, medium, and high risk

Step 4

Match the level of obligation/standards/scrutiny to the risk stream and match the level and skills of staff to the level of risk. For example:

For the low-risk stream:

- rely on information provided by the regulated party with less cross-checking
- audit outcomes rather than pre-check to support compliance
- allocate work to more junior staff

For the high-risk stream:

- require greater scrutiny of the regulated party or its activities
- allow for flexibility and regulatory judgement
- allocate work to more experienced staff.

Step 5

Streamline all processes to avoid unnecessary steps and rework.

Step 6

Develop and implement systems for proactive engagement with stakeholders so processes are tracked, and issues and delays are identified and dealt with in consultation with the stakeholders.

Step 7

Develop and implement complementary systems.

- Establish internal leadership, and authorities and accountabilities that support decision making.
- Train staff so they have the necessary skills and understand the risk framework being used.
- Collect and use the data and information accumulated through regulatory and related processes (such as compliance and enforcement) to refine risk assessments.
- Document policies, guidelines, and processes, and communicate them to staff and stakeholders.

3.B Undertaking compliance and enforcement

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

This part is for regulators involved in compliance and enforcement activities. It covers strategies to improve compliance and, when necessary, enforce the law — for example:

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

Risk management in compliance and enforcement draws on the agency-wide risk analysis described in part 3. In practice, regulators who develop integrated strategies across identified problems are likely to consider risk management across all of their activities — administration, and compliance and enforcement. However, many regulators consider compliance and enforcement strategies separately. Risk management issues specific to compliance and enforcement activities are discussed below.

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.

Common issues in realising risk-based compliance and enforcement activities include:

- 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

Identify risk indicators and then categorise regulated parties or activities.

Regulators use risk indicators to categorise regulated parties and activities according to their likely level of risk, and to target compliance and enforcement where it cost-effectively reduces harm.

The characteristics and activities of the regulated party and its compliance with the regulation drive the likelihood and consequences of harm. The following characteristics are potential indicators of risk in business regulation:

- **size** — The consequences of failure may be greater for larger businesses (if risks are linked to the quantity of production, the number of employees or the number of customers).
- **activities undertaken by the business** — Some business activities are inherently riskier than others (such as production that involves hazardous substances or dangerous processes).
- **location** — External factors increase the risk or effect of harm in some locations (the risk that pollutants could affect people's health is greater if the facility is in a built-up area).
- **incentives to self-manage risks** — Incentives for the business to minimise any damage can affect the likelihood of failure, and the speed with which adverse effects are contained (for example, businesses in some sectors have strong commercial incentives to maintain their safety reputation).

Businesses may be non-compliant for a range of reasons. Indicators that suggest a business is unlikely to comply with the law and more likely to contribute to harm include:

- **compliance history** — While most firms want to comply with regulation, a lack of understanding, skill, or attention to compliance issues may result in non-compliance. In addition, some businesses may deliberately flout the law.
- **awareness of the regulatory requirements** — This issue is a particular problem among small businesses, although it can also affect large businesses (particularly if regulatory requirements are complex or highly specialised).
- **internal compliance and governance processes** — Businesses with strong, well implemented, internal compliance and governance processes are more likely to comply with regulation (for example, because they are more aware of options for reducing their costs from satisfying regulatory requirements).
- **incentives and willingness to comply** — Some businesses (for example, food exporters) have strong commercial incentives to comply with the regulation because demonstrated compliance is necessary to sustain consumer demand or unlock access to international markets. In other sectors, commercial incentives may work against compliance (for example, in some areas of environmental regulation).

Non-compliance is relevant because widespread non-compliance can increase the risk of harm and undermine confidence in the regulation. But the focus should be on the level of harm caused by any breaches (including from reduced support for the regulation or the regulator), not non-compliance per se.

*The **outputs** of this stage are relevant risk and compliance indicators to focus compliance and enforcement effort on entities that provide opportunities for the greatest harm reduction.*

3.B.3 Analyse risk — allocating parties to risk categories

Once developed, indicators screen regulated parties and categorise them into high, medium, and low risk. Categorisation helps to identify where more detailed risk analysis is needed and to choose the compliance and enforcement approaches best suited to each category. Box 3.B.1 summarises the risk assessment frameworks used by the EPA, DEPI and the Australian Prudential Regulation Authority (APRA).

When there is a relatively small number of regulated parties, such as utilities or the banking sector, it is often possible to analyse each regulated entity individually. In other

areas, such as consumer or environmental regulation, the analysis needs to be based on categories of individuals, businesses or activities.

*The **output** of this step is a risk/compliance matrix or other tool for prioritising activity, which visually presents the risk analysis that rates regulated parties according to risk.*

Box 3.B.1 Examples of risk assessment frameworks

Victorian Environment Protection Authority

The EPA uses the Licenced Operator Risk Assessment (LORA) model to prioritise compliance and enforcement efforts on licensed sites such as landfills; waste treatment and storage sites; chemical, paper, food and drink manufacturing sites; and sites producing and processing metal and steel (EPA 2012a, 1).

Each site is risk rated against its likelihood of non-compliance and the risk of harm to health and the environment. The EPA uses this information to prioritise inspections and set their frequency.

The LORA rating scale comprises the following six criteria.

Box 3.B.1 Examples of risk assessment frameworks (cont.)

Department of Environment and Primary Industries

As outlined in box 3.A.2, DEPI developed a risk-based regulatory framework for managing biosecurity threats under the *Invasive Plants and Animals Compliance Strategy*. The strategy includes a risk matrix for assessing ex ante risks to determine invasive species compliance priorities. The risk matrix maps consequence and likelihood on five-point scales, which are combined to determine if a risk is 'low', 'moderate', 'high' or 'extreme'.

Consequence	Likelihood
Insignificant Event has 'little' or no detectable impact', involving a species that is already established in Victoria	**Rare**: Event occurs less than once every three to five years, on average
Minor: Potential effect limited to a 'local level' involving an already established species of concern to the community	**Unlikely**: Event occurs less than once a year, on average
Moderate: Potential effect on a 'regional level' involving an already established species of high concern to the community or a species that is not established in all areas of Victoria	**Possible**: Event occurs one to three times a year, on average
Major: Potential effect across the state, involving a species that is not established in all areas of Victoria	**Likely**: Event occurs three to ten times a year, on average
Severe: Potentially significant effects across the state, including threats to life, involving a species that has only a 'very limited distribution' in the state	**Almost certain**: Event occurs more than ten times a year, on average

Almost certain					EXTREME
Likely				HIGH	
Unlikely			MODERATE		
Possible		LOW			
Rare					
	Insignificant	Minor	Moderate	Major	Severe

Australian Prudential Regulation Authority

The Australian Prudential Regulation Authority (APRA) assesses the risk of supervised institutions (such as banks, building societies, credit unions, superannuation agencies, and insurers) using the Probability and Impact Rating Scheme (PAIRS).

APRA assesses institutions against six risk types: strategy and planning, liquidity, operation, market and investment, credit, and insurance risk. It assesses the probability of failure and combines this result with the likely effect of that failure on depositors, policy holders or fund members. APRA uses the combined scores to rate institutions for supervisory attention and to plan its supervisory task (APRA 2012, 5 and 8).

Source: EPA 2012a, 2012b; DEPI 2014a; APRA 2012.

3.B.4 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.

An effective compliance and enforcement strategy has two elements:

- matching regulatory instruments to risk categories
- setting priorities based on achieving the greatest reduction in risk given the regulator's resources.

Choose from a range of compliance and enforcement instruments to select and apply the tool that is proportionate to the level of risk and will effectively reduce that risk. Low-risk activities are not ignored. But alternative broad-based strategies, such as information and education, may be more cost effective than resource-intensive inspections or audits.

Box 3.B.2 describes how Transport Safety Victoria targets inspections to the risk profile of vessels. Figure 3.B.1 illustrates how the EPA links instruments to the level of risk, including businesses' attitude to compliance. Similarly, the Financial Services Commission of Ontario matches its compliance tools to risk (figure 3.B.2).

*The **output** of this stage is a list of the available compliance and enforcement tools, and a framework for selecting tools that respond proportionately to the risk of harm and businesses' attitude to compliance.*

Box 3.B.2 Commercial vessel safety regulation—Transport Safety Victoria

In 2013, TSV recognised its practice of inspecting all commercial vessels in Victoria each year did not match the level of regulatory activity to the industry's risk profile. It decided to align inspections with the risk profile of the vessels and the primary drivers of risk.

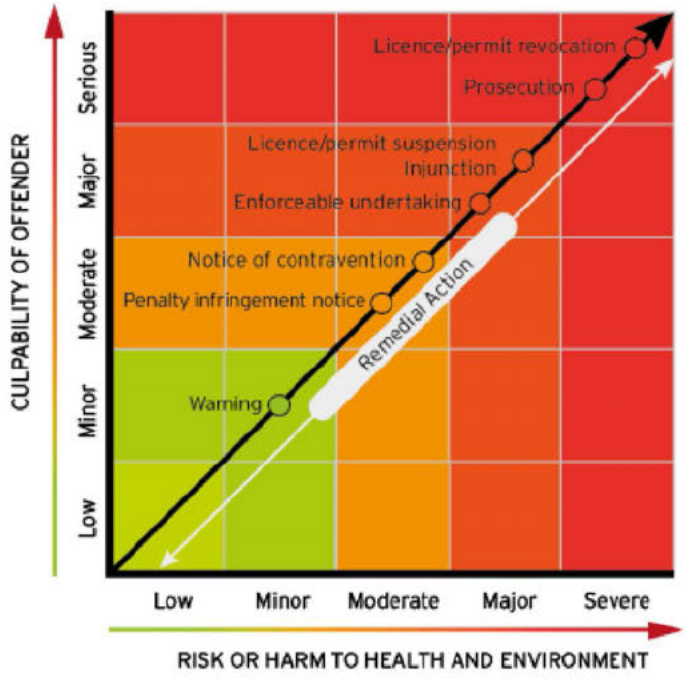
It divided vessels into three risk categories and determined the number of inspections accordingly. It inspects:

- high-risk vessels, including passenger vessels and large offshore fishing vessels, annually
- moderate-risk vessels, including medium-sized industrial vessels and large hire and drive boats, twice in five years
- low-risk vessels, including smaller industrial, fishing, and hire and drive vessels, at the initial survey only.

A year into the program, Victoria implemented the new National System for Commercial Vessel Safety. This national scheme largely adopted the structure and philosophy of TSV's risk-based commercial vessel survey program.

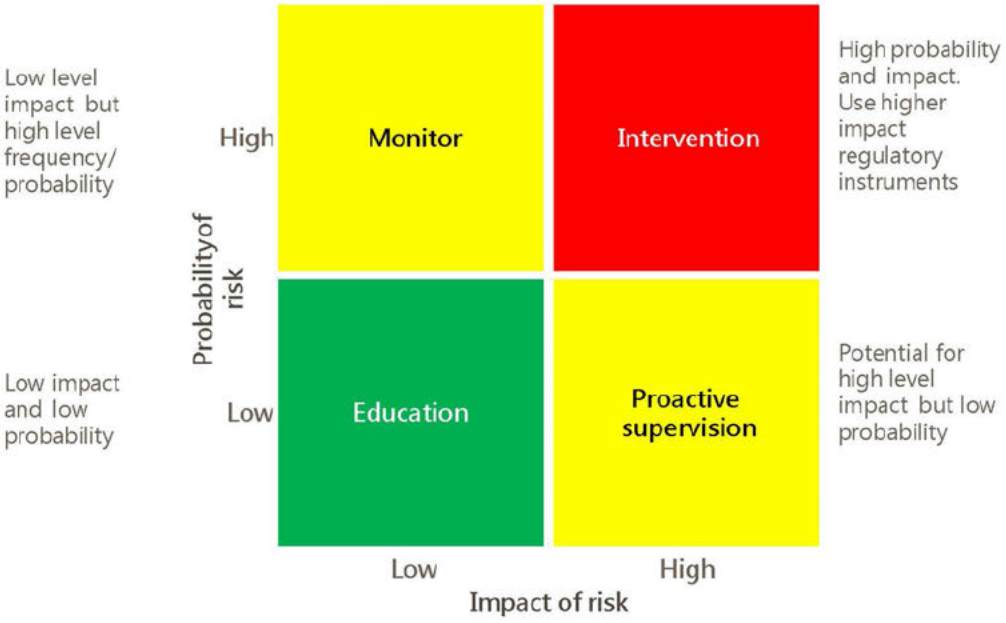
Source: TSV 2013.

Figure 3.B.1 EPA' enforcement response



Source: EPA 2011.

Figure 3.B.2 FSCO regulatory response model



Source: FSCO 2011.

Attachment 1: Analytical techniques

Businessand government have an array of risk-management tools to help them analyse and manage risks. The Better Regulation Office of New South Wales, for example, developed a guide for regulatory agencies on risk-based compliance and enforcement (BRO NSW 2008). Similarly, the Victorian Managed Insurance Authority developed a guide and toolkit to help government agencies develop and implement risk-management frameworks (VMIA 2010). International organisations are also looking at risk management in regulatory contexts (UNECE 2012 and OECD 2010).

There is no ideal technique for identifying and analysing risk. Most commentators recognise all tools are imperfect, and many advocate a combined approach that draws on available information, data and expertise to compile a set of qualitative and quantitative indicators of the types of risk, their size and their implications. Tables A.1 to A.4 summarise potential information sources, tools and techniques, and outputs. Not all of this material will be relevant to departments and regulators in all situations; the tables are simply an indicative menu of options.

Table A.1 Establish context

	Identify regulatory objectives and harms	Understand stakeholder views and experience	Understand attitude to risk and risk appetite
Information sources	• Data and intelligence on the market, industry or related environment • Previous reports and analysis • Stakeholder consultation [3] • Regulator experience	• Previous reports and stakeholder engagement • Stakeholder consultation • Regulator experience	• Existing legislation and regulation • Second reading speeches • Government policy statements • Research on government and community expectations
			Regulator • Statements of expectations
Tools and techniques	• Regulatory impact assessment • Analysis of industry data and trends • Analysis of incident data and trends • Environment scanning	• Workshops/surveys/interviews • Stakeholder mapping/persona profiling • Ethnographic research techniques(fly-on-the-wall' observation/contextual inquiry) • Participatory research techniques/ranking interests/mock purchasing	• Workshops • Review of existing reports
		Regulator • Consultation committees • Complaints mechanisms and opportunities for informal feedback	
Outputs	• Clear definition of the problem and related harms	• Identified groups of stakeholders • Documented stakeholder views • Ongoing communication plan and engagement strategy	• Risk statement clarifying – roles and accountabilities – attitudes to type 1 and type 2 errors [4] – risk thresholds
	Policy development • Clear policy objectives **Regulator** • Clear regulatory objectives		**Policy development** • Statements of expectations for regulator

[3] In the following tables 'stakeholder consultation' includes consultation with policy makers, the regulator, regulators in similar areas, those who are protected by the regulation, regulated entities and their representative groups, other parties involved in the regulatory process, experts, scientists, and wider community interests.

[4] Consider whether to prioritise harm reduction or avoiding overregulating (see supporting paper)

Table A.2 Identify and analyse risk

	Identify risk	Identify significant risks	Understand significant risks
Information sources	• Data and intelligence on the market, industry, or related environment • Data on inspection, compliance and enforcement, complaints, and incidents • Stakeholder consultation • Regulator experience, including field staff • Evaluations of past programs, initiatives, or trials • Research	• Data and intelligence on the market, industry, or related environment • Regulator experience, including field staff • Risk statement and risk criteria and categories • Experts views	• Data on complaints, inspection, compliance and enforcement, incidents and harm • Data and intelligence on the market, industry, or related environment • Stakeholder consultation • Regulator experience, including field staff and expert views
			Regulator • Data on regulated businesses or industry segments
Tools and techniques	• What-if/scenario analysis • Brainstorming/workshops • Data analysis of trends and patterns • Interviews/self-assessment/surveys • SWOT analysis • Mapping the risk landscape	• Workshops/interviews • Analysis of risks against risk indicators and risk criteria • Problem tree analysis	• What-if/scenario analysis • Brainstorming/workshops • In depth data analysis of trends and patterns • Interviews/self-assessment/surveys • SWOT analysis • Process mapping • Fault analysis/hazard analysis/cause and effect diagrams
			Regulator • Data analysis of businesses or industry segments
Outputs	• Risk register with high-level qualitative and quantitative assessment of likelihood and effect of risks • Risk criteria and categories	• Risk map or matrix • List of a manageable number of significant risks	• Analysis and reporting of significant risks, their likelihood and effect, and risk drivers • Performance indicators
	Regulator • Risk indicators for regulated entities		**Regulator** • Risk and compliance matrix • Risk ratings for regulated entities

Table A.3 Treat risk and develop contingency plans

	Identify and assess treatment options	Plan implementation		Develop contingency plans
Information sources	• Experience in other jurisdictions and with regulation in similar areas • Regulator experience, including field staff • Evaluations of programs, initiatives, or trials and other research • Stakeholder consultation • Data on the costs/benefits (monetary and non-monetary), and advantages/ disadvantages of treatment options	• Stakeholder consultation • Regulator experience, including field staff • Views of experts • Bullseye diagram		• Data on complaints, inspection, compliance and enforcement, incidents and harm • Data and intelligence on the market, industry, or related environment • Stakeholder consultation • Regulator experience, including field staff **Regulator** • Data on businesses or industry segments
Tools and techniques	• Brainstorming/workshops/interviews • Regulatory impact assessment • Techniques to compare options such as cost-effectiveness analysis/cost-benefit analysis/multi-criteria analysis/break-even analysis • Analysis of current processes	**Policy development** • Negotiation between the policy area and the regulator	**Regulator** • Internal consultation and behavioural change strategy	• What-if and scenario analysis • Brainstorming/workshops • In depth data analysis of trends and patterns • Interviews/self-assessment/surveys • SWOT analysis • Analysis of potential system failures/fault, event or hazard tree analysis **Regulator** • Data analysis of businesses or industry segments, including business characteristics and compliance history
Outputs	• Clear priorities for action that target significant risks with treatments that deliver the greatest reduction in risk to the community given the available resources **Regulator** • Process maps	• Clear roles, authorities and accountabilities • Agreed implementation plans		• Contingency and emergency plans with: – systems for collecting data, monitoring, and identifying adverse events – systems to respond if contingencies or emergencies arise

Table A.4 Monitorand evaluate

Monitorand Evaluate	
Information sources	• Data on complaints, inspection, compliance and enforcement, incidents and harm and other data available to the regulator • Data defined and collected to assess performance against performance indicators • Data and intelligence on the market, industry, or external environment , including trends and emerging issues • Stakeholder consultation • Analysis from experts (for example, scientists and researchers) • Regulator experience, including field staff
Tools and techniques	• Analysis of performance against performance criteria • Benchmarking • Sampling and random testing • Internal quality assurance frameworks • Debriefing processes • In depth data analysis on trends and patterns
Outputs	• Clear understanding of the results of the risk treatments • Improvement strategy • Internal database on shared learnings

References

AELERT (The Australasian Environmental Law Enforcement and Regulators Network), 2013, *Principles and considerations for using risk assessment in environmental regulatory agencies*.

APRA (Australian Prudential Regulation Authority), 2012, *Probability and Impact Rating System*, June.

AS/NZS (Standards Australia and Standards New Zealand), 2009, Risk management — principles and guidelines, AS/NZS ISO 31000:2009.

ASQA (Australian Skills Quality Authority), 2014, Risk-based regulation, http://www.asqa.gov.au/about/ risk-based -regulation/risk-based -regulation.html.

— 2012, *Risk Assessment Framework*, http://www.asqa.gov.au/verve/_resources/Risk_assesment_framework_2012.pdf .

BRO NSW (Better Regulation Office of New South Wales) 2008, *Risk-based compliance*, Sydney, Septemb er.

DEPI (Department of Environment and Primary Industries), 2014a, *Compliance Strategy: Invasive Plants and Animals, Biosecurity Division*, version 3.6, Melbourne, January.

— 2014b, *Discussion Paper - Invasive Species Management Bill*, http://www.depi.vic.gov .au/agriculture -and -food/pests-diseases -and -weeds/protecting -victoria -from-pest -animals -and -weeds/legislation -policy -and -permits/new -invasive -species -management -legislation/discussion-paper -invasive -species -management -bill

— 2014c, *Summary of stakeholder con sultation — Non-indigenous Bird Management Policy*, http://www.depi.vic.gov.au/agriculture -and -food/pests -diseases -and -weeds/protecting -victoria -from-pest -animals -and -weeds/legislation -policy -and -permits/policies-and -strategies/summary-of-stakeholder -consultation -non-indigenous-bird-management -policy.

DPI (Department of Primary Industry), 2005, Victorian Weed Risk Assessment Method, http://vro.depi.vic.gov.au/dpi/vro/vrosite.nsf/0d08cd6930912d1e4a2567d2002579cb/37a34a583f831df7ca2576080081cad0/$FILE/Victoria n%20Weed%20Risk%20Assessment%20method.pdf

EPA (Victorian Environment Protection Authority), 2012a, Licences and approvals: Licensed Operator Risk Assessment, http://www.epa.vic.gov.au/our -work/licences -and -approvals/lora .

— 2012b, *Annual compliance plan 2012-13: An outline of EPA's key compliance and enforcement priorities and projects in 2012-13*, Melbourne, June.

— 2011, *EPA Victoria compliance and enforcement policy*, Melbourne, June.

FSCO (Financial Services Commission of Ontario), 2011, *Risk-based Regulation Framework: consultation document*, March.

Government of Victoria, 2014, *Victorian Guide to Regulation*, Department of Treasury and Finance, Melbourne.

NSW Dep artment of Premier and Cabinet, 2014, *Guidance for regulators to implement outcomes and risk-based regulation*, July.

OECD (Organisation of Economic Cooperation and Development), 2010, *Risk and regulatory policy: improving the governance of risk*, Paris, April.

Rich-Phillips G. (Assistant Treasurer), 2014, Statement of Expectations for Housing Registrar, 13 June.

Sparrow M., 2007, 'Unravelling Risk' in *Canadian Government Executive*, pp. 16–20.

TSV (Transport Safety Victoria), 2013, *Transport Safety Victoria c orporate plan 2013-14*.

UNECE (United Nations Economic Commission for Europe), 2012, *Riskmanagement in regulatory frameworks: towards a better management of risks*, Geneva, November.

VCEC (Victorian Competition and Efficiency Commission), 2011, *Unlocking Victorian tourism An inquiry into Victoria's tourismindustry*, Final report, June, Melbourne.

VMIA (Victorian Managed Insurance Authority), 2010, *Guide—Riskmanagement: developing and implementing a riskmanagement framework*, version 2.1, April.