

Best Practice Handbook

Adopting risk assessments, standards and conformity assessment procedures in regulation

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Purpose

As part of the revitalised National Competition Policy (NCP), Commonwealth, state and territory treasurers have agreed to support work to "lower barriers to the adoption of overseas standards in regulation". The Competition Reform Guidelines, which sits under the NCP Intergovernmental Agreement (IGA) and Federation Funding Agreement (FFA), outlines the key performance requirements and milestones needed to implement this policy reform.

This Best Practice Handbook is intended to support the implementation of the Competition Reform Guidelines at the Commonwealth level. This guide will assist Commonwealth policymakers and regulators¹ to determine if, when and how existing standards, risk assessments and conformity assessment procedures should be adopted in Australia. As noted in the Competition Reform Guidelines, state and territory policymakers may wish to reference and use the Best Practice Handbook in their own jurisdictions.

If mandatory standards are deemed to be the appropriate tool to meet the regulatory objective, then policymakers should aim to use international standards, where one exists, unless they can demonstrate that the standard is not suitable for the Australian context. Similarly, policymakers should recognise regional, Australian or overseas standards, alongside the international standard, where appropriate. Adopting a new mandatory standard that recognises multiple existing standards will provide businesses with more than one pathway for compliance. This will help reduce barriers to trade, improve market access for businesses, and expand consumer choice. The regulatory design framework and accompanying policy tools aligns with Australia's obligations under the World Trade Organization and other free trade agreements, and the best practice principles in the Regulatory Policy, Practice & Performance Framework.

The policy toolkit has been designed to be adaptable, noting the diversity in risk postures, available legislative levers and scope of regulators across government. To improve the harmonisation and consistency of mandatory standards across government, this toolkit introduces several best-practice interventions that policymakers should consider when making or reviewing technical regulations. This guide should be read alongside:

- Department of Industry, Science and Resources' Best Practice Guide to Using standards and risk assessments in policy and regulation², which provides foundational knowledge on how standards and risk assessments can be used in regulation;
- Standards Australia's Standardisation Guide 009: Preparation of Standards for legislative adoption³, which outlines key considerations to assist technical committees in drafting and developing Australian Standards;
- The Department of Finance's Regulatory Policy, Practice & Performance
 Framework⁴, which provides Commonwealth regulators and policymakers with six
 principles to drive fit-for-purpose regulation in a digital era, protect against regulatory
 failures, and improve productivity;

¹ This document refers to "policymakers" as including departments, agencies, and regulators.

² Department of Industry, Science and Resources, <u>Best Practice Guide to Using Standards and Risk Assessments in Policy and Regulation</u>, 2016.

Standards Australia, Standardisation Guide 009: Preparation of Standards for Legislative Adoption, 2023.

⁴ Department of Finance, <u>Regulatory Policy</u>, <u>Practice and Performance Framework</u>, 2024.

- The Australian Government Guide to Policy Impact Analysis⁵, which ensures that advice to government is accompanied by robust analysis, data and an accurate overview of the effects of proposed policies on the community; and
- The World Trade Organisation's Agreement on Technical Barriers to Trade (WTO TBT Agreement)⁶, which aims to ensure that technical regulations, standards, conformity assessment procedures for goods do not create unnecessary obstacles to trade. All WTO Members, including Australia, are required to uphold the principles and obligations of the Agreement.

For more information on regulatory best practice and supporting resources, contact RPPPFramework@finance.gov.au.

Introduction

The Australian standards and conformance architecture involves the development of voluntary standards, primarily by Standards Australia, following extensive community, industry and government consultation. This process also includes consideration of the relevant international standards for adoption in Australia. Other members of the Australian Technical Infrastructure Alliance (ATIA) also play an important role in the architecture. The Joint Accreditation System of Australia & New Zealand (JASANZ) accredits certification and inspection bodies to conduct conformity assessments certifying that a product, service, people or management system conforms to a particular standard. The National Association of Testing Authorities (NATA) also accredits conformity assessment bodies focusing on calibration and testing laboratories, inspection bodies, reference material producers, proficiency testing scheme providers and biobanks. The National Measurement Institute (NMI) is part of the Commonwealth Government and governs the national measurement system and metrology, which conformity assessments, reference standards and other materials rely on.

ATIA Coordination

Early and ongoing consultation and coordination with ATIA members is essential to ensure regulatory objectives can be achieved and are well-supported by the appropriate standards and conformance capability. Each ATIA member has an important role to play, and there are rarely situations that would only require involvement of a singular member. Where there are issues regarding a lack of national technical capabilities, ATIA members may utilise international arrangements to establish confidence in and recognition of standards and conformance bodies and products, including international standards (e.g. those developed by the ISO and/or IEC), overseas metrology institutes recognised by the International Bureau of Weights and Measures or overseas accreditation bodies who are signatories to international accreditation cooperation mutual recognition arrangements.

⁵ Department of the Prime Minister and Cabinet, <u>Australian Government Guide to Policy Impact Analysis</u>, 2023.

⁶ World Trade Organisation, <u>Agreement on Technical Barriers to Trade</u>, 1995.

⁷ See Appendix A: Glossary for the definitions of key principles and technical terms used throughout the document.

Australia is a relatively small market, representing less than 2 per cent of the global economy. Our heavy reliance on trade makes the harmonised adoption of international, regional and/or overseas standards vital to our economic performance.

International standards enable businesses to leverage economies of scale and scope in production or supply, minimise transaction costs (e.g. avoiding suppliers having to undertake multiple tests) and improving consumer welfare. Harmonisation of mandatory standards – both internally and globally – positions Australia as one market with one set of rules within the global economy. It enhances Australia's attractiveness for trade by reducing regulatory burden and time to market for businesses, increasing local competition and product availability. Australian producers further benefit from harmonisation as they can provide goods and services using the same standards for local and international markets – potentially increasing their international competitiveness.

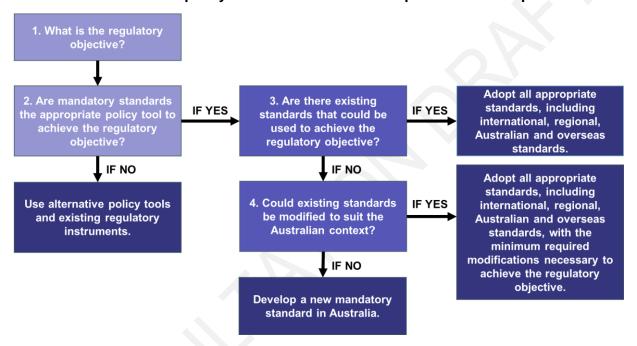
In addition, Australia has certain obligations around development, use, and adoption of standards in regulation for goods under the WTO TBT Agreement. Under this Agreement, Australia is obligated to use international standards as a base for technical regulations and conformity assessment procedures for goods wherever possible. Similarly, Australia has obligations under trade instruments like the Trans-Tasman Mutual Recognition Arrangement (TTMRA), which is an arrangement between the Commonwealth, State and Territory Governments of Australia and the Government of New Zealand. Under the TTMRA, goods produced or imported into New Zealand may be legally sold in Australia, and vice versa, subject to exceptions.

⁸ New Zealand Ministry of Business, Innovation and Employment, <u>A Users Guide to the Mutual Recognition Agreement (MRA)</u> and the Trans-Tasman Mutual Recognition Agreement (TTMRA), 2014.

Regulatory design principles and questions for standards adoption and development

This Guide outlines several regulatory design principles and questions that policymakers should consider throughout the policymaking process. These principles should support policymakers to determine whether mandatory standards should be used, and if so, how they should be implemented. A more detailed explanation of the decision tree is available in Appendix B.

Decision tree for policymakers on standards adoption and development



Question 1. What is the regulatory objective?

Principle: Policymakers should state their regulatory objective/s and explain how this contributes to the government's desired outcomes for the community.

Policymakers should clearly state their regulatory objective/s before identifying and developing policy options. ¹⁰ Policymakers should clearly identify the market failure and/or unacceptable hazard or risk that they are trying to address through government intervention and link this issue to their regulatory objective. Policymakers may have to balance multiple regulatory objectives to achieve the government's policy objectives for the community. The regulatory objective/s should be specific, measurable, accountable, realistic, and timely.

⁹ Policymakers should consider these regulatory design principles alongside the seven Impact Analysis (IA) questions whenever new polices are being developed. <u>The Australian Government Guide to Policy Impact Analysis</u> provides a useful framework that policymakers should use, regardless of whether a detailed IA is required.

¹⁰ Department of the Prime Minister and Cabinet, <u>Australian Government Guide to Policy Impact Analysis</u>, 2023.

Question 2. Are mandatory standards the appropriate policy tool to achieve the regulatory objective?

Principle: Policymakers should be empowered to use policy tools that most appropriately target the regulatory objective/s, while minimising the regulatory burden on individuals, businesses and community organisations.

Mandatory standards should be used when (a) the benefits to the community outweigh the costs and (b) other policy tools are less effective or inappropriate to achieve the regulatory objective/s.

Regulation, including mandatory standards, should not be the default solution for policymakers. In the first instance, policymakers should be empowered to consider the complete range of policy levers available, including both regulatory and non-regulatory approaches, to achieve their stated regulatory objective/s. These can involve some combination of *ex ante* regulation (e.g. voluntary self-regulation or co-regulation with industry) and/or *ex post* regulation (e.g. tort liability, fines or penalties).

The net benefits of different policy options should be explored by policymakers before commencing the standards adoption or development process. 11 After accounting for the range of costs and benefits associated with each policy option, policymakers should recommend the policy instrument offering the greatest net benefit to the community that can be implemented. Policymakers should support the policy approach that maximises the public benefit, while minimising the regulatory burden for individuals, businesses, and community organisations.

Policymakers should consider using alternative policy tools and existing regulatory instruments where appropriate.

Question 3. Are there existing standards that could be mandated to achieve the regulatory objective?

Principle: Policymakers should be empowered to recognise multiple standards – including international, regional, Australian or overseas standards – that contributes to the government's desired outcomes for the community.

Policymakers should be empowered to recognise international, regional, Australian or overseas standards where they contribute to the government's desired outcomes for the community. Where appropriate and aligned with the regulatory objective, policymakers

Public health and safety, social and community impact, environmental impact, competition and economic impact, consumer protection, and national security should be analysed in the assessment of the net benefit. This analysis may be required as part of any detailed IA process (see Appendix D and <u>The Australian Government Guide to Policy Impact Analysis</u> for more information). Regardless of whether a detailed IA is required, policymakers should develop an evidence base commensurate to the impacts of the decision.

should consider adopting a new mandatory standard that recognises multiple existing standards to provide several pathways for compliance. This will reduce barriers to trade, improve market access for businesses, and expand consumer choice (see the Bicycle Helmets case study below).

International standards should be prioritised for adoption unless policymakers can demonstrate with clear evidence that the standard is unsuitable for the Australian context and/or does not align with the regulatory objective. Australian standards should also be adopted, where appropriate, as well as relevant regional and overseas standards provided they meet the principles of consultation and consensus in development¹².

Where new standards are adopted, policymakers should undertake appropriate analysis and stakeholder consultation, set a suitable transition period, and consider whether the legislation should recognise future updates to the standard (see the Policy Toolkit for more information).

Policymakers should adopt the international standard, unless they can demonstrate that the standard is unsuitable for the Australian context and/or does not align with the regulatory objective. Similarly, regional, Australian or overseas standards should be adopted alongside the international standard, where appropriate, to provide multiple pathways to compliance.

Question 4: Could existing standards be modified to suit the Australian context?

Principle: Policymakers should be able to deviate from existing standards, including international standards, where they do not meet local community needs. However, policymakers should only deviate if the marginal benefit to the community outweighs the marginal cost of deviating from existing standards (i.e. net public benefit).¹³ The deviation should ensure suitability for the Australian context and align with the government's regulatory objective.

Existing standards should be adopted by policymakers, unless there is clear evidence that the applicable standard is not suitable for the Australian context. Policymakers should consider whether and how the Australian experience diverges from other countries and the international standard. Factors could include differences in the environment, climate or geography and issues related to national security. There may be circumstances where there is some divergence in the Australian experience, but the benefits of fully adopting international, regional, Australian or overseas standards outweigh the costs to Australian consumers.

If there are no existing standards which could be suitably mandated or modified for the Australian context, then policymakers should be empowered to develop a new mandatory standard in Australia to achieve their policy objective. Consideration should be given to

¹² World Trade Organisation, Agreement on Technical Barriers to Trade – Annex 3, 1995.

¹³ For further guidance on assessing net benefit, including the impacts of fully adopting versus deviating from the international standard, please refer to Appendix D and <u>The Australian Government Guide to Policy Impact Analysis.</u>

developing an Australian Standard to serve as a foundation for future international standardisation. Referencing existing voluntary standards in regulation should be prioritised over developing new mandatory standards, where possible.

Any deviation should involve the minimum amount of modification required to meet the regulatory objective and ensure suitability for the Australian context. The additional net benefit of diverging from the international standard should be explored and quantified by policymakers to help inform government decision-making. Where the additional cost of deviating from the international standard outweighs the marginal benefit to the community, policymakers should fully adopt the international standard without deviation.

If yes, policymakers should mandate the standard with the minimum required modifications necessary to achieve their regulatory objective.

If no, policymakers should develop a new mandatory standard in Australia. Policymakers should note that new mandatory standards should only be developed when existing standards are unsuitable for the Australian context and/or does not align with the regulatory objective.

Policy Toolkit

Once policymakers have determined that mandatory standards are necessary to achieve the policy objective (Question 2), and decided to (a) adopt or modify existing standards or (b) develop new mandatory standards (Questions 3 and 4), there are several key considerations and policy instruments that policymakers should use in designing, drafting and implementing mandatory standards. The Toolkit includes further guidance on how policymakers should approach and utilise risk assessments and conformity assessment procedures in the policymaking process.

This checklist has been included below to support policymakers in reviewing and actioning this Handbook.

Policy Toolkit			
Policy Toolkit			
Tool 1: Incorporating overseas risk assessments in decision-making			
Tool 2: Trade restrictiveness of regulation			
Tool 3: Sources of referenced standards			
Tool 4: Notifying the WTO of certain regulations			
Tool 5: Consistent referencing to standards			
Tool 6: Sunsetting clause and regular review			
Tool 7: Ambulatory referencing			
Tool 8: Performance-based criteria			
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Tool 10: Utilising the quality infrastructure for conformity assessments			
Tool 11: Recognising overseas conformity assessments procedures			

Tool 1: Incorporating overseas risk assessments in decision-making

Wł	nat	Wr	hy	
•	Where there are no Australian risk assessments to reference, overseas risk assessments should be used to inform policy decision making.	A	Public health, safety and consumer confidence can be maintained through the involvement and review of comparable risk assessments produced overseas. Although upfront costs are involved in incorporating overseas risk assessments, it could offer time and cost savings for policymakers.	
Но	w			
•	Risk assessments are used by policymakers to (a) determine the likelihood of risk and severity of consequences with allowing certain products, processes or services to be sold in Australia and (b) inform decision-makers as to whether regulatory action is required,		The other method is for regulators to set preliminary criteria to identify potentially comparable sources of risk assessments. Criteria can consist of: If the source is a multilateral agency, it has had critical engagement from many	
•	including whether mandatory standards are needed. There are several approaches for using overseas best practice risk assessments. One		If the source is a multilateral agency, it has had critical engagement from many countries, preferably including Australian regulators, during the development of the risk assessments or methodologies;	
	approach involves introducing an expedited pathway to market for applicants who can provide a recent, unredacted risk assessment from a comparable source to help inform decision-making. Another approach is establishing or expanding international worksharing arrangements with comparable overseas regulators and/or government agencies		If the source is a single country agency, it regulates for a population demographic that is broadly representative of the Australian/New Zealand population and has similar outcomes;	
>	through formal arrangements (e.g. MOUs) or informal consultation. If policymakers consider offering an expedited pathway using recent, unredacted overseas assessments from comparable sources there are a few issues to consider.		The source follows international best practice for risk assessment, for instance for food health, the Codex Alimentarius Commission and relevant joint FAO/WHO expert committees;	
	Applicants should submit all original data, plus any context specific data necessary for AU/NZ. Regulators should address and manage concerns around transparency if using overseas risk assessments. Pathways would also rely on the establishment of a list of		The source agency has a record of actively managing the quality of approvals and risk assessments (such as peer review, independent assessment, auditing of processes and outcomes);	
•	comparable sources, including international risk assessment bodies. Similarly, if establishing and/or expanding international work-sharing arrangements with		The source agency has similar regulatory objectives and conducts similar pre- and post-market regulatory activities to your agency;	
	comparable overseas regulators for risk assessment, regulators should also address any concerns around transparency and suitability for Australian conditions.		The agency routinely provides its assessment reports in English, and these are available to the applicant; and	
			A formal and robust framework for cooperation can be established with the agency.	
Мс	re			
	Similar Australian government approaches: Both the TGA and APVMA have expedited		Case study	
	pathways based upon overseas risk assessments from comparable regulators.		FSANZ, in collaboration with Finance, undertook a stocktake of food safety	
•	MA engages in Global Joint Reviews of agricultural pesticides. This is a concurrent uation undertaken through a globally coordinated system of evaluations, peer ews and report sharing. These reports are shared and used as the basis for each atry's own risk assessment and decision-making. APVMA also collaborates with their adian and New Zealand counterparts on regulatory assessments of veterinary icines.		standards. The review found changes to various food standards currently go through the same process, regardless of risk, incurring costs and time for low-risk changes. The recommended solution was to provide easier pathways for lower risk changes to be implemented, including the adoption of international standards and expedited use of risk assessments. The potential benefits were savings to business of up to 16% over five years.	

Tool 2: Trade restrictiveness of regulation

What	Why
Regulations should not be designed in a way that is more trade restrictive than necessary to achieve their legitimate objective.	Overly trade restrictive measures unnecessarily increase transaction costs, disincentivise businesses to enter the Australian market, and reduce consumer choice. In addition, regulations pertaining to goods that are more trade restrictive than necessary may contravene WTO TBT obligations.
How	
 Regulations should not be more burdensome to adhere to than is necessary and regulators should aim to identify the least burdensome pathway to achieve the objective. When assessing the potential trade restrictiveness of a regulation, factors to consider include what harm the regulation is controlling, potential consequences of no control, what alternate options might be available, and the actual effect of the regulation. Regulations should be reviewed regularly to determine if new, less trade restrictive approaches could be adopted. There may be several legitimate objectives a regulation may pursue. For example, the WTO TBT Agreement, which sets out obligations for technical regulations and conformity assessment procedures applied to goods, recognises the following as legitimate objectives: national security requirements; 	 Protection of local industry is not a legitimate reason to not use an international standard. Broadly, Australia has obligations not to introduce regulations which are discriminatory or intended to favour domestic products. For example, in Australia identical adoption of international standards may not be appropriate because of specific voltage requirements or ensuring goods can handle Australian heat. In these cases, a modified version of the international standard may be used, or a completely different standard. Standards, conformity assessment procedures and technical regulations should not simply be trade barriers in disguise. 15 Local manufacturers and industry bodies may influence the development of a national standard, overseas standard, private standard or risk assessment (through consultation) that differs significantly from the International Standard to protect themselves from competition with imported products.
 the prevention of deceptive practices; and protection of human health or safety, animal or plant life or health, or the environment.¹⁴ While the WTO TBT Agreement is focused on goods, these objectives are likely to be broadly applicable. When policymakers determine that mandatory standards are necessary, regulations should reference existing standards (including international, regional, Australian and/or overseas standards), where they exist and are deemed appropriate to meet the policy objective. Regulations which use international standards are generally (rebuttably) presumed not to create an unnecessary obstacle to international trade. However, there may be cases where there is no relevant international standard or an existing international standard 	Deviating from international standards can raise trade barriers, as using other standards (even modified international standards) may impose additional Australian testing costs for suppliers and importers, especially when businesses intend to enter multiple markets. Modified international standards should be assessed to determine whether they are more trade restrictive than necessary to achieve legitimate objectives. Where Australian-specific standards are necessary, recognising regional or overseas conformity assessments results could help the reduce transaction costs.

may be deemed not suitable.

World Trade Organisation, <u>Agreement on Technical Barriers to Trade – Article 2.2</u>, 1995.
 International Organisation for Standardisation, <u>Good Standardisation Practices</u>, 2019, p 44.

Tool 3: Sources of referenced standards

What	Why
There are many different standards in use throughout the world, however not all are appropriate for the Australian regulatory context. Policymakers and regulators should preference options in line with government policy and international obligations.	This approach best balances local conditions, trade restrictiveness and international obligations.
How	
 International standards should always be preferenced for referencing in technical regulation. When international standards are not available or suitable, the following may be considered: 	A new Australian mandatory standard should only be developed after policymakers have identified there are no suitable pre-existing standards to reference. Even after the new mandatory standard is developed, references to international and overseas standards should be considered.
 ▶ Regional standards ▶ Australian standards ▶ Overseas standards 	Consideration should be given to developing an Australian Standard to serve as a foundation for future international standardisation.
▶ Private standards More	
 Standards Australia's policy on international standards¹⁶: The policy of Standards Australia and its accredited Standards Development Organisations is to base Australian Standards on International Standards to the maximum extent feasible, with the WTO TBT principles as a benchmark. Local variations between Australian Standards and International Standards are permissible only when there is 'a demonstrable and unacceptable level of risk to human health and safety'.¹⁷ Even then, the variation is justifiable only to the extent that it brings 'the level of risk down to an acceptable level'. Technical officers should liaise with standards and conformance bodies early in the policymaking process. For support with choosing standards, technical officers should liaise with <u>Standards Australia</u> or the Department of Industry, Science and Resources Trade Facilitation Section: TradeFacilitation@industry.gov.au. 	 Standards Australia forms Technical Committees to consider proposals to develop, adopt or amend a standard. The Technical Committee will consider whether to adopt the relevant international standard as the Australian standard, modify the international standard to make the Australian standard, or make a new standard entirely (potentially informed by other pre-existing standards from other sources). Members of Technical Committees are technical experts in the relevant field, including industry representatives. Regulators are encouraged to participate in the Technical Committees relevant to their work, especially where regulators may wish to reference the resultant standard in Australian regulation. At a minimum, regulators are encouraged to engage with consultation on the draft standard. Regulators may consider directly referencing the International Standard in regulation where there have been substantial modifications in the Australian Standard adopting that International Standard.

Standards Australia, <u>Standardisation Guide 007: Adoption of International Standards</u>, 2023.
 Standards Australia, <u>Standardisation Guide 007: Adoption of International Standards</u>, 2023, p 5.

Tool 4: Notifying the WTO of certain regulations

What	Why
To fulfil Australia's international obligations, policymakers or regulators may be required to notify the WTO of certain regulations. Notifications may be required under a range of WTO provisions. In particular, notification of technical regulations or conformity assessment procedures pertaining to goods and sanitary and phytosanitary measures not based on international standards may require notification at a draft stage.	Under the WTO Agreements, Australia has a range of transparency obligations which include notifying the relevant WTO forums of certain types of regulations. For certain types of measures, the choice of standard referenced in regulation may trigger notification obligations under the WTO TBT Agreement and WTO Agreement on Sanitary and Phytosanitary (SPS) Measures.
How	
 In relation to the WTO TBT Agreement, Australia is required to notify the WTO of proposed new or amended technical regulations (e.g. technical requirements or mandatory standards) and/or conformity assessment procedures pertaining to goods that are not in accordance with international standards and will have a significant effect on trade. Not in accordance – this includes where an international standard does not exist to reference, where a measure is partly (even majority) aligned with an international standard but includes modifications or where a wholly different standard has been used. Significant effect – this includes both facilitative and restrictive effects on trade. There is no exact way to determine what is a 'significant effect' and Australia errs on the side of notify if in doubt. 	 Notifications under the WTO TBT Agreement must be made when the technical regulation and/or conformity assessment procedure is at a draft stage, and early enough that comments from other WTO Members may be considered in the finalisation of the regulation. The WTO TBT Committee recommends offering a minimum 60 day comment period. Where this is not possible, the Australian WTO TBT Enquiry Point, which manages the notification process, asks regulators to provide as much time as possible which is, at minimum, consistent with domestic consultation. In relation to the WTO SPS Agreement, notification must be made when either an international standard does not exist to the basis of a technical regulation or when a proposed SPS regulation is not substantially the same as the content of a relevant international standard and will have a significant effect on trade. Notifications are simple documents which outline the key features and objectives of the measure and provide access to the full text via a link or upload. They are published and distributed online through ePing, a free and publicly accessible database of TBT and SPS notifications (https://epingalert.org/). DFAT guides and assists regulators through the TBT notification process and DAFF is responsible for SPS.
More	
For more information on notifying the WTO of measures relevant to the WTO TBT Agreement, contact the Australian WTO TBT Enquiry Point at DFAT: tbt.enquiry@dfat.gov.au .	For more information on notifying the WTO of measures relevant to the WTO SPS Agreement, contact the Australian WTO SPS Enquiry Point at DAFF: sps.contact@aff.gov.au .

Tool 5: Consistent referencing to standards

What	Why
Acts, or primary legislation, provides for the ability to reference standards in regulations. When referencing standards in regulations, it is essential that the correct nomenclature is observed.	Incorrect or inconsistent references have many implications, from interfering with optical character recognition to referencing the wrong standard which does not meet particular policy objectives.
How	
Policymakers should ensure the enabling legislation for mandatory standards provides for international, regional or overseas standards to be referenced in regulations.	Refer to the relevant standards-issuing body like the ISO, IEC or Standards Australia for how they reference their own standard.
The general nomenclature of a standard:	Pay attention to the use of various symbols like full stops (.) colons (:) hyphens (-) en dashes (—) or em dashes (—) and the location of spacing.
AS/NZS 1698:2006 Protective helmets for vehicle users Standard issuing Standard Year of Standard name	Australian New Zealand Standards use full stops (.) to reference a section within a standard (AS/NZS 1080.1) while a colon (:) is used to identify the date version of that standard (AS/NZS 1080.1:2012). However, some old standards use hyphens (-) instead of colons (:) to delineate dates (AS 2796.1-1999).
organisation issue	When an international standard (e.g. ISO 55001) is directly adopted by Standards Australia, the AS designator is simply added to the front (e.g. AS ISO 55001:2024).
More	
For more on how Standards Australia references standards in their documents, refer to Standardisation Guide 006 on the Rules for the Structure and Drafting of Australian Standards. 18	For support with referencing standards, technical officers should liaise with Standards Australia or the Department of Industry, Science and Resources Trade Facilitation Section: TradeFacilitation@industry.gov.au .

¹⁸ Standards Australia, <u>Standardisation Guide 006: Rules for the Structure and Drafting of Australian Standards</u>, 2023.

Tool 6: Sunsetting clause and regular review

What	Why
The intent of scrutiny and review should be carried through from the Legislation Act 2003 to mandatory standards.	Regular review is particularly important to ensure a regulation continues to be the least trade-restrictive measure. ¹⁹
How	
Subsection 50(1) of the Act provides that a legislative instrument is repealed on the first 1 April or 1 October falling on or after the 10 th anniversary of registration of the	More frequent review cycles may be resource intensive. Ambulatory referencing may ameliorate this (see tool 7).
instrument ²⁰ . This is important to ensure legislative instruments are kept up to date and only remain in force as long as they are needed. ²¹ However, sunsetting provisions may not apply to mandatory standards if an exemption applies. Policymakers and regulators should review section 54 of the <i>Legislation Act 2003</i> and Part 5 of the <i>Legislation (Exemptions and Other Matters) Regulation 2015 to</i> determine if sunsetting provisions apply to a mandatory standard. The agency and the rule-maker ²² must determine whether an instrument falls within an existing exemption. It is strongly recommended agencies seek legal advice on the applicability of these provisions to an instrument.	A review of a mandatory standard may also be triggered when:
	There is a significant change to the referenced voluntary standard
	A new safety hazard has been identified which was not addressed by the existing mandatory standard
	There are technical developments or changes in the market.
Regardless of sunsetting implications, regulators should self-impose a periodic review cycle that is shorter or more rigorous than 10 years for their standards. This is because updates to voluntary standards occur on average every 5 years and will be expected to accelerate in emerging and critical technology areas. Regulations may therefore	As noted in Standards Australia's guidance ²³ , mandatory standards should be regularly reviewed to ensure they are:
	Up-to-date technically;
increasingly reference outdated voluntary standards.	Reflective of current practice;
 Existing conformity assessment procedures for standards should also be regularly reviewed to ensure that they continue to align with domestic and international best 	 Suitable for new and existing applications (products, systems or processes); and
practice.	Compatible with current views and expectations regarding quality, safety and the environment.
More	

More

For more information, contact the AGD Admin Law team: adminlaw@ag.gov.au.

¹⁹ World Trade Organisation, <u>Agreement on Technical Barriers to Trade – Article 2.3</u>, 1995.

²⁰ See s50 of the Legislation Act 2003 on sunsetting.

²¹ See s49 of the Legislation Act 2003 for the purpose of sunsetting.

See s6 of the <u>Legislation Act 2003</u> for definition of rule-maker.
 Standards Australia, <u>Standardisation Guide 001: Preparing Standards</u>, 2023.

Tool 7: Ambulatory referencing

What		Wh	hy
'undate	makers need to consider whether their selected standard will be 'dated' or ed'. 'Dated' standards refers to one specific version of the standard. In general, ed' standards refers to the latest version of the standard. ²⁴	A	Policymakers should ensure a referenced standard is reflective of current policy and effectively achieves the regulatory objective. Delays in updating references to a dated version of a standard could lead to inconsistencies between industry best practice or state and territory law with Commonwealth law.
How			

- Dated referencing may be appropriate when policy areas know exactly the technical solution or policy outcome required, or if need to reference specific clauses or tables within a standard (which may get changed if the standard is updated).²⁵
- Undated referencing allows the flexible use of subsequent revised versions of the same standard within regulation. This is appropriate in areas with continuous and rapid technical development, and subsequent frequent updates of the referenced standards. Undated referencing is often referred to as 'ambulatory referencing'.
- An ambulatory reference is a reference in regulation to an instrument as modified 'from time to time'. Sample wording:
 - 'Australian/New Zealand Standard 1 means the standard AS/NZS 2063 *Helmets for use on bicycles and wheeled recreational devices*, as in force or published on the day this instrument commences, or as updated from **time to time**'.

As opposed to:

- 'Australian/New Zealand Standard 1 means the standard AS/NZS 2063:**2020** *Helmets for use on bicycles and wheeled recreational devices*, as in force **when this instrument commences**'.
- Benefits of ambulatory referencing includes prompt adoption of the mandatory standard by regulators, simplification and clarity for compliance, improved safety for consumers, and greater international harmonisation, keeping up with technological improvements and best practice. This approach is especially critical for industries undergoing rapid technology advancement, such as those related to the net-zero transition, where standards can guickly become outdated.
- If ambulatory referencing is used, then policymakers should ensure that:
 - ▶ The referenced standard continues to be appropriate to achieve the policy objective after any amendments.
 - A suitable transition period is provided to allow businesses time to adapt to the updated requirements and remove redundant standards as they age. Businesses

- ▶ Risks of adopting ambulatory referencing include automatic adoption of revisions before the relevant review process can determine if it is still appropriate to achieve the policy objective. This is particularly important when overseas or private standards are referenced and there is no visibility of the revision process. Ambulatory referencing may not be appropriate where there are specific policy requirements to be addressed by the technical content, which may be amended in future iterations of a standard.⁵⁹
- Policymakers need to ensure the relevant primary legislation enables the legislative instrument to reference standards in force from time to time, as per section 14 of the Legislation Act 2003. An example is section 35(1)(b) of the New Vehicle Efficiency Standard Act 2024.
- The primary legislation should enable an updated version of a referenced standard to be excluded or not recognised if found unsuitable.
- The regulator should establish monitoring channels to be notified when referenced standards are being reviewed, triage the proposed updated standard to ensure it remains suitable, and move to prevent the update applying if it is not suitable to adopt.
 - Regulators should consider establishing feedback avenues, such as a webpage, to allow the public, industry and experts to be notified of updates to referenced standards and provide feedback to the relevant consultation processes for standards development and adoption.
- Policymakers must address the issues outlined in the Scrutiny of Delegated Legislation Committee Guidelines²⁶, or the Senate Scrutiny Committee of Bills Committee Guidelines²⁷ regarding absence of parliamentary scrutiny and accessibility of the law. It is important for policymakers to consider the reasons for incorporating standards 'as existing from time to time' and justify this rationale in the explanatory material. This should include:
 - Why policymakers need to override s14(2) of the Legislation Act 2003 (i.e. outlining the policy objective/s and economic rationale for adopting international, regional, Australian and/or overseas standards as modified from time to time).

²⁴ Depending on how the mandatory standard is drafted, 'undated' standards may refer to any version of said standard, including previous and outdated versions.

²⁵ Department of Industry, Science and Resources, Best Practice Guide to Using Standards and Risk Assessments in Policy and Regulation, 2016, p 18.

²⁶ The Senate, Standing Committee for the Scrutiny of Delegated Legislation – Guidelines (3rd Edition), 2024, p 5 and 19.

²⁷ The Senate, Standing Committee for the Scrutiny of Bills – Guidelines (2nd Edition), 2022, p 22.

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should be allowed to choose whether to comply with the older or updated standard during the transition period.

- How to mitigate the risk that an entity may be unable to identify what their rights and obligations are if and when adopted/incorporated standards are updated
- Whether the referenced standard is publicly available for free or at minimal cost. Where the standard is not publicly available for free, other avenues for providing access would need to be considered (such as licensing arrangements, providing the text in the instrument's explanatory material, or providing copies on request). It must describe how the standard can be accessed.²⁸

More

- Case study²⁹
 - The mandatory Australian standard for projectile toys (Consumer Goods (Projectile Toys) Safety Standard 2020) sets out mandatory requirements intended to reduce the risk of choking, eye injuries and flesh wounds during play.³⁰
 - □ In June 2020, the mandatory standard was reviewed and amended after being made in 2010. The mandatory standard was updated to keep pace with changes in industry practice and to allow compliance with the latest voluntary Australian and overseas standards including the 2019 edition of the voluntary Australian standard (AS/NZS ISO 8124.1:2019), or one of three comparable overseas standards: the ISO standard (ISO 8124 1:2018), the ASTM standard (ASTM F963 17) and the European standard (EN 71-1:2014 + A1:2018).
- However, after the mandatory standard was updated in June 2020, the voluntary Australian standard was subsequently updated in December 2020, in line with updates to the ISO standard. The amendments included updates to the tension test applied to projectiles, and amendments to the requirements for rotors and propellers on projectile toys, including renaming the relevant section to 'Flying Toys'.
- Due to the current architecture of the Australian Consumer Law (ACL), these relatively minor updates could not be automatically captured by the mandatory standard. Instead, the ACCC conducted a further consultation to assess the appropriateness of capturing the minor updates. In July 2021, legislative amendment was made to the mandatory standard, which is consistent with the current government policy and requirements under the Intergovernmental Agreement for the ACL for reviewing and updating standards.

²⁸ See s15J(2)(c) of the Legislation Act 2003 for the requirements on explanatory statements.

²⁹ The Treasury, Improving Mandatory Standards under the Australian Consumer Law – Decision Regulation Impact Statement, 2024.

³⁰ Australian Competition and Consumer Commission, Projectile Toys Mandatory Standard, 2025.

Tool 8: Performance-based criteria

What	Why
 Policymakers should preference the use of performance-based criteria in mandatory standards unless it is unable to address a policy objective or mitigate a particular harm. 	▶ Prescriptive-based standards may unnecessarily restrict how suppliers can meet the
How	
 Prescriptive-based criteria define specific steps that must be taken to meet the required outcome. They narrow the discretion that businesses can exercise in meeting requirements. This is appropriate to achieve particular policy or regulatory objectives the cannot be achieved without the prescribed requirements, or when the risk is high and there are specific safety considerations. ▶ However, overly prescriptive criteria can lock industries into specific technologies of practices. This rigidity may hinder competition and innovation, ultimately impeding long-term economic growth. ▶ The economic literature indicates prescriptive-based criteria is most appropriate an effective when (a) consumer demand for product or service variety is minimal, (b) significant economies of scale and network effects can be achieved through widespread adoption, and (c) the impact on competition is negligible. ▶ An example of a prescriptive standard is AS/NZS 3000:2018 Electrical installations (Australian/New Zealand Wiring Rules). ▶ Performance-based criteria establish desired characteristics of the final product, service or activity rather than requirements for the methodology to produce them. Performance-based criteria may identify a specific methodology but does not prevent the use of alternative methodologies if the same result, product or outcome is achieved. This optic provides a flexible compliance framework that may reduce associated costs and increat choice for the Australian market. This is the preferred type of mandatory standard³¹ because it can be the least trade restrictive. ▶ Performance-based criteria can better facilitate innovation and technology adoption by providing industry participants, especially small and medium enterprises, with greater flexibility to achieve the prescribed outcomes and meet the mandatory standard. ▶ However, performance-based criteria can impose additional burden on regulators and the cannot be achi	performance objectives are clearly defined. This will ensure duty holders can make informed choices and provide them with confidence that they are complying with the mandatory standard. An example of a performance-based regulation is National Offshore Petroleum Safety and Environmental Management Authority's (NOPSEMA) regulation of the offshore petroleum industry. The regulatory regime administered by NOPSEMA allows duty holders to use any Australian or International Standard, international industry practices or company specific standards to achieve a safety outcome. A performance-based regulation may also provide multiple compliance pathways by referencing a mix of Australian standards, international, regional, standards and/or overseas standards, which individually would be prescriptive but together are in practice performance-based. Where the regulation allows two or more alternatives for compliance, the enabling legislation should allow the regulator to require that a supplier nominate which standard has been, is or will be complied with. Non-compliance with a nominated voluntary standard should receive a proportionate penalty as non-compliance with the overall mandatory standard. Further nominations should not be accepted to minimise time for an unsafe product to remain on the market. An example of multiple compliance pathways is the Consumer Goods (Bicycle Helmets) Safety Standard 2024 ³² , which provides a list of Australian, overseas and industry standards suppliers can nominate to demonstrate their compliance.
However, performance-based criteria can impose additional burden on regulators a they would require greater expertise and resourcing to assess new and alternative compliance pathways.	as

³¹ Department of Industry, Science and Resources, <u>Best Practice Guide to Using Standards and Risk Assessments in Policy and Regulation</u>, 2016, p 5. ³² See the <u>Consumer Goods (Bicycle Helmets) Safety Standard 2024</u>.

Tool 9: Suitability for the Australian context

v	/hat	Wr	ny
	When policymakers identify potentially relevant risk assessments, standards or conformity assessment procedures for use, they need to first determine whether these tools are suitable to use in the Australian context.	•	There may be significant differences between the Australian context and international experience, such as those related to the environment, climate, geography and/or national security. The extent of these differences will determine whether policymakers should use these risk assessments, standards or conformity assessment procedures in Australia.
Н	ow		
	 When considering suitability, regulators should evaluate not just the object for adoption, but the competency and reliability of the responsible organisation, such as standards development organisations. Other important considerations include whether Australia is a world leader in a particular area of standards, or if adoption of standards or assessments would impact the international reputation of the Australian regulator. An assessment of suitability requires extensive consultation on whether the risk 		Policymakers should give consideration to National Standards developed by Standards Australia. The Australian Government has signed a Memorandum of Understanding with Standards Australia, requiring them to base Australian standards on international standards to the maximum extent feasible and to apply the requirements of the WTO TBT Agreement as a benchmark. An open and transparent process of consensus involving key stakeholder groups and the Australian community is undertaken whenever Australian standards are being developed that deviate from international standards.
	assessment, standard or conformity assessment procedure ³³ : Is or will be widely accepted amongst industry stakeholders	Engaging with international, regional or overseas standaregulators allows the Australian regulator to determine the body, quality of regulatory processes and products, organized competency and compatibility with Australian legislative criteria documents). It also facilitates the establishment cooperation and information sharing, assisting the under the cooperation and information sharing.	Engaging with international, regional or overseas standard developing organisations or
	Is or will be widely accepted amongst industry stakeholdersCan be applied		regulators allows the Australian regulator to determine the credibility of the overseas body, quality of regulatory processes and products, organisational capacity, technical
	▷ Is harmonised amongst State and Territory governments		competency and compatibility with Australian legislative and policy objectives (see
	Does not create a barrier to trade or an impediment to other international agreements or treaties that Australia is a signatory to, such as the WTO TBT Agreement.		cooperation and information sharing, assisting the understanding and adoption of risk assessments, standards and conformity assessments procedures and results.

Tool 10: Utilising the quality infrastructure for conformity assessments

What	Why
When referencing voluntary standards, policymakers and regulators should not aim to replace but leverage the expertise and international relationships each ATIA member brings. These are as important for conformity assessments as they are for standards.	Conformity assessments provide consumers with confidence that a product, service, process, management system or person will perform as expected, provides manufacturers or service providers the assurance that market requirements will be met, and gives regulators confidence that the requirements in regulations have been met.
How	
Policymakers should use the least trade restrictive approach to recognise and accept overseas conformity assessment procedures.	When using 2 nd or 3 rd party conformity assessment, regulators should consider ways to recognise the results of conformity assessment procedures conducted overseas to
When introducing mandatory standards, regulators should consider if there is a suitable means of testing compliance, such as conformity assessments, and if there are existing accredited conformity assessment bodies (CABs) to conduct testing.	reduce costs, lower trade barriers and expedite compliance processes. This may be achieved through government-to-government mutual recognition arrangements or

³³ Department of Industry, Science and Resources, <u>Best Practice Guide to Using Standards and Risk Assessments in Policy and Regulation</u>, 2016, pp 7–8.

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- Conformity assessments by NATA or JASANZ-accredited CABs should be preferred, as they are authorised through MOU or other means to represent Australia's interests at various international forums and conduct accreditation locally.
- The ISO Conformity Assessment Committee (CASCO) toolbox (based on the ISO/IEC 17000 series standards) provides a harmonised and consistent approach to conformity assessment, including definitions and various actors within a conformity assessment system.³⁴
- Regulators should consider the appropriate level of conformity assessments to achieve a policy objective, such as the consequences of product/service failure from nonconformity:
 - 1st party Self declaration of conformity. For example, this could be made by the manufacturer or the service provider themselves.
 - 2nd party Conformity assessment performed by the person or organization that requires the assurance of conformity. For the purposes of this guide, where the regulator themselves performs the assessment.
 - ▷ 3rd party Conformity assessment performed by independent organisations such as certification body, laboratory, or inspection body that has been accredited by an accreditation body. For efficiency, rather than naming individual CABs, regulations will usually specify which conformity assessment results can be accepted in Australia. These generally include results (a) produced by CABs accredited by specific accreditation bodies or (b) produced through specific accreditation pathways can be accepted in Australia.

- recognising bodies party to the mutual recognition arrangements where NATA and JASANZ represent Australia.
- For 2nd party conformity assessment, Australian regulators may recognise results from other regulators (e.g. TGA recognising Good Manufacturing Practice from US FDA or Health Canada etc.).
- For 3rd party conformity assessment, Australian regulators may recognise the competence of foreign accreditation bodies to accredit their CABs as competent to assess to Australian requirements.
- Where a referenced standard is updated, regulators should provide a transition period for the conformity assessment procedure to be updated, where there is no critical risk to be addressed.
- Policymakers should consider whether post-market surveillance is appropriate to maintain community safety and ongoing compliance with the mandatory standard. For example, this may include accepting off-the-shelf 'check testing' conducted by an accredited conformity assessment body.
- ► For major regulations, regulators may choose to work with Australia's accreditation bodies to establish a conformity assessment scheme. One example is the WaterMark certification scheme.
- The WTO TBT Committee has developed flexible, non-prescriptive guidelines to support regulators in the choice and design of conformity assessment procedures, which may be a useful resource for regulators of goods and services alike.³⁵ It includes guidance on use of risk assessments.

More

- The Australian Senate Economics References Committee into Non-Conforming Building Products published a report in 2018 recommending that where an organisation intends to import goods that have been deemed high-risk, the Australian Government require the importer to conduct sampling and testing by an accredited authority (or an equivalent testing authority in another country that is a signatory to the ILAC Mutual Recognition Arrangement).³⁶ This recommendation reflects the importance of accreditation as a quality assurance tool. More examples where accreditation has contributed to a more robust regulatory regime can be found on the Public Sector Assurance website (https://publicsectorassurance.org/).
- Contact DISR for Memorandum of Understandings that exist between the Commonwealth and ATIA members, such as Standards Australia and NATA, to understand what each party has committed to undertake.

³⁴ International Organisation for Standardisation, CASCO Educational Toolbox – 9 Modules on Conformity Assessment, 2020.

³⁵ World Trade Organisation, <u>Guidelines on Conformity Assessment Procedures</u>, 2024.

³⁶ The Senate Economics References Committee, Non-Conforming Building Products: The Need for a Coherent and Robust Regulatory Regime, 2018.

Tool 11: Recognising overseas conformity assessments procedures

What	Why
Where appropriate, policymakers and regulators should review and recognise overseas conformity assessment procedures that provide sufficient confidence in the resulting tests, inspections, or certifications.	Recognising overseas conformity assessment procedures facilitates a faster time to market for products at a reduced cost to both businesses and consumers by removing the need for repeated tests or measurements.
How	
Article 6 of the WTO TBT encourages members to mutually recognise each other's conformity assessment results in relation to goods, assuming confidence in their reliability can be established and regulators appointing their own conformity assessment bodies. ³⁷ Recognising conformity assessments conducted overseas may reduce costs for business by reducing the need to bear the costs of conformity assessment in both the exporting and importing markets.	For example, an overseas conformity assessment procedures or results could be recognised through an IAF or ILAC MRA (JASANZ is a member of both; NATA is a member of the ILAC) by writing into regulations that 'assessments must be conducted by a facility accredited by JASANZ or a JASANZ MRA partner'. This means conformity results can be accepted from (a) JASANZ accredited facilities or (b) facilities accredited by accreditation bodies party to the same MRA.
Recognition of overseas conformity assessments results can occur through government-to-government arrangements or utilising the Mutual Recognition Agreement (MRA) established under the multilateral accreditation cooperation bodies in which NATA and JASANZ represent Australia.	 Negotiated government-to-government mutual recognition arrangements may facilitate recognition of conformity assessment results conducted overseas – either by regulators or through recognition of competent accreditation bodies.
	Before mutual recognition can occur, regulators need to have developed their own conformity assessment or compliance requirements to compare against the overseas assessment (see Tool 10).
More	
For one example of how the TGA has incorporated overseas conformity assessments, refer to their reference material. ³⁹	The National Association of Testing Authorities (NATA) is an accreditation body that can provide confidence that testing, measurement and inspection data is competently produced. Its voluntary technical committee network can provide recommendations on measurement, testing and inspection requirements.
➤ The National Measurement Institute (NMI) is a trade measurement regulator and provides services to other regulators to ensure confidence in measurement activities for compliance purposes.	
	► The Joint Accreditation System of Australia and New Zealand (JASANZ) is an accreditation body for management systems, product certification, personnel certification, and the validation and verification of claims, including for greenhouse gases.

³⁷ World Trade Organisation, Agreement on Technical Barriers to Trade – Article 6, 1995.

³⁸ Finance notes the ILAC and IAF are currently merging to form the Global Accreditation Cooperation Incorporated (GLOBAC). This will create "a single international organisation for accreditation" to streamline the global accreditation framework and foster greater international cooperation. The transition to GLOBAC will commence in early 2026 and is expected to take several years to fully implement.

³⁹ Therapeutic Goods Administration, Use of Market Authorisation Evidence from Comparable Overseas Regulators and Assessment Bodies for Medical Devices (including IVDs), 2025.

Appendix A: Glossary

Accreditation – the independent third-party evaluation of conformity assessment bodies against recognised standards to formally determine that they are sufficiently competent, impartial, and consistent to perform conformity assessment activities. In Australia, this is conducted by NATA and JASANZ.

Adoption – (of an International Standard or overseas standard) publication of a technical regulation referencing a relevant International Standard, or endorsement of the International Standard as having the same status as a national normative document, with any deviations from the International Standard identified.

Australian Standard – a standard developed by Standards Australia, Australia's national standards body, developed through industry-led consensus.

Conformity assessment body – an entity that conducts conformity assessments procedures. This includes both accreditation bodies and the conformity assessment bodies they accredit, including certification, verification, testing, inspection and laboratory bodies.

Conformity assessment procedure - Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled.

Conformity assessment scheme – a set of rules and procedures that describes the objects of conformity assessment, identifies the specified requirements and provides the methodology for performing a conformity assessment procedure. ⁴⁰ A conformity assessment scheme will set out the conditions for recognising a conformity assessment body as competent to perform the conformity assessment procedure.

Harmonisation – the process of aligning and integrating various regulations and practices across different jurisdictions to eliminate or minimise barriers to trade.

International standard – voluntary standards developed by international standards organisations, with the opportunity for Australian representation and participation in the development process, and who follow the WTO TBT Principles for the Development of International Standards, Guides and Recommendations. They are developed to facilitate free and fair global trade and promote access to market. Examples include International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC) standards.

Mandatory standard – a document that specifies the design characteristics and requirements for a product, service or system supplied within a jurisdiction. This is made legally binding by State, Territory or Commonwealth legislation or regulation and requires compliance. Mandatory standards may fully or partially reference standards developed by regulatory bodies (public standard) or non-government entities (voluntary standard).

⁴⁰ International Organisation for Standardisation, <u>ISO/IEC 17000:2020 – Conformity Assessment</u>, 2020.

Overseas standard – standards developed by sovereign nations or national standards bodies that do not necessarily include Australian input into the development process. Examples include standards made by the British Standards Institution.

Performance-based criteria – criteria that sets minimum results, products or outcomes that need to be achieved, without prescribing specific processes and methods to achieve them.

Prescriptive-based criteria – criteria which prescribes both outcomes and processes to achieve the outcomes.

Private standard – a standard made by private actors like an individual company or an industry association which is usually voluntary and opt-in, but in practice become de facto mandatory where compliance with the standard increases competitiveness, such as when the majority of the market uses it, or because of consumer expectation.

Regional standard – standards that have been developed by a regional standards organisation to promote common policies and facilitate trade in a region. Examples include standards developed by the Pacific Islands Standards Committee (PISC), European CEN-CENELEC standards or ASEAN Harmonised Standards.

Risk assessments – a tool that policymakers use to assess whether regulatory action is required. They involve a systematic process of analysis to determine the extent and likelihood of occurrence of undesirable events or situations as compared against benchmarks or standards.

Standards – rules, guidelines or characteristics for products, processes, services and product methods, developed by a recognised body to demonstrate a specific function and quality and ensure products, services, and systems are safe, consistent, and reliable. Their compliance can be voluntary, mandatory, or de facto mandatory. Their appropriate use can facilitate trade, improve competitiveness, and promote innovation.

Standards and Conformance Infrastructure/national quality infrastructure – The system comprising the organisations (public and private) together with the policies, relevant legal and regulatory framework, and practices needed to support and enhance the quality, safety and environmental soundness of goods, services and processes. This infrastructure is required for the effective operation of domestic markets and to enable access to foreign markets.⁴¹ In Australia, this is represented by the Australian Technical Infrastructure Alliance, along with accredited conformity assessment bodies.

Technical deviation – (from an International Standard in a regional or national standard) any difference between the technical content of the International Standard and that of the regional or national standard. The degrees of correspondence are identical, modified and not equivalent.⁴²

Technical regulation – a document which dictates product characteristics, related processes, production methods or administrative provisions, terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method. Compliance is mandatory.⁴³ This includes mandatory standards,

⁴¹ International Network on Quality Infrastructure, Quality Infrastructure – Definition, 2025.

⁴² International Organisation for Standardisation, <u>ISO/IEC Guide 21-1:2005 – Regional or National Adoption of International Standards and Other International Deliverables</u>, 2005, pp 3–5.

⁴³ World Trade Organisation, <u>Agreement on Technical Barriers to Trade – Annex 1</u>, 1995.

and any technical requirements or specifications on any part of the lifecycle of a product, service or system.

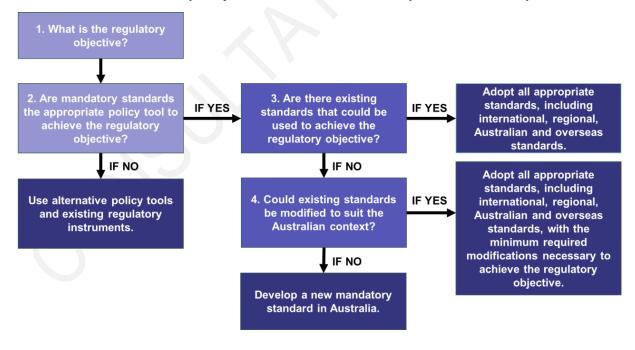
Trade restrictiveness – the degree to which a measure (such as a technical regulation) acts as a barrier to market access or discriminates against certain products and reduces its competitiveness.⁴⁴ A measure may be more obviously trade restrictive if there is a less trade restrictive option.

Voluntary standard – These are technical standards that do not require compliance but still shape business and consumer behaviour. They include industry standards and private standards and may be codified by a standards developing body such as Standards Australia.

Appendix B: Detailed guidance on the regulatory design decision tree

This Guide outlines several regulatory design principles and questions that policymakers should consider throughout the policymaking process. These principles should support policymakers to determine whether mandatory standards should be used, and if so, how they should be implemented.⁴⁵

Decision tree for policymakers on standards adoption and development



⁴⁴ Voon, Exploring the Meaning of Trade-Restrictiveness in the WTO, 2015.

⁴⁵ These principles aligns with the Government's broader regulatory reform agenda, including the <u>Regulatory Policy</u>, <u>Practice and Performance Framework</u>, which sets out six principles to ensure regulation is fit-for-purpose. The principles are: (1) targeted and risk-based; (2) integrated in existing systems; (3) user-centred; (4) evidence-based and data-driven; (5) reflective of the digital era; and (6) continuously improved and outcomes-focused.

Question 1. What is the regulatory objective?

Principle: Policymakers should state their regulatory objective/s and explain how this contributes to the government's desired outcomes for the community.

Policymakers should clearly state their regulatory objective/s before identifying and developing policy options. ⁴⁶ Policymakers should clearly identify the market failure and/or unacceptable hazard or risk that they are trying to address through government intervention and link this issue to their regulatory objective. By defining the policy problem and regulatory objective/s, policymakers can better target their regulatory intervention to improve community outcomes and support the government's policy priorities. The regulatory objective/s should be specific, measurable, accountable, realistic, and timely. This principle aligns with Clause 1.a. in the Competition Reform Guidelines, which has been developed by the Commonwealth in collaboration with State and Territory Governments and agreed under the NCP governance framework.

To achieve the government's policy objectives for the community, policymakers may have to appropriately balance multiple regulatory objectives during the policymaking process, including public health and safety; competition and innovation; and broader socio-economic and environmental impacts.⁴⁷ Policymakers should further consider the government's existing risk appetite alongside the community expectations of both safety and standards of living.

Question 2. Are mandatory standards the appropriate policy tool to achieve the regulatory objective?

Principle: Policymakers should be empowered to use policy tools that most appropriately target the regulatory objective/s, while minimising the regulatory burden on individuals, businesses and community organisations.

Mandatory standards should be used when (a) the benefits to the community outweigh the costs and (b) other policy tools are less effective or inappropriate to achieve the regulatory objective/s.

Regulation, including mandatory standards, should not be the default solution for policymakers. In the first instance, policymakers should be empowered to consider the complete range of policy levers available, including both regulatory and non-regulatory approaches, to achieve their stated regulatory objective/s. The net benefits of different policy options should be explored by policymakers before commencing the standards adoption or development process.⁴⁸ Public health and safety, social and community impact,

⁴⁶ Department of the Prime Minister and Cabinet, <u>Australian Government Guide to Policy Impact Analysis</u>, 2023.

⁴⁷ Policymakers may wish to reference Question 1 ("What is the problem you are trying to solve and what data is available?") and Question 2 ("What are the objectives, why is government intervention needed to achieve them, and how will success be measured?) in the <u>Guide to Policy Impact Analysis</u> for further guidance on identifying and balancing regulatory objectives.

⁴⁸ This net benefit analysis may be required as part of any detailed IA process (see Appendix D and <u>The Australian Government Guide to Policy Impact Analysis</u> for more information). Regardless of whether a detailed IA is required, policymakers should develop an evidence base commensurate to the impacts of the decision.

environmental impact, competition and economic impact, and national security should be analysed in the assessment of the net benefit. Consideration should also be given to incentives; interactions with the broader regulatory environment and related markets; and secondary effects, including price and international competitiveness.

After accounting for the range of costs and benefits associated with each policy option, policymakers should recommend the policy instrument offering the greatest net benefit to the community that can be implemented. Policymakers should support the policy approach that maximises the public benefit, while minimising the regulatory burden for individuals, businesses, and community organisations.⁴⁹

This principle aligns with Clause 1.b. in the Competition Reform Guidelines:

- 1.b. Determine if an alternative policy tool to the mandatory standard can achieve the same regulatory objective at a lower net cost. Comparison of the cost of regulatory options should consider relevant factors including:
 - (i) incentives;
 - (ii) interactions with other broader regulatory environment relevant to that product/service;
 - (iii) potential competition impacts, impacts in related market and unintended consequences; and
 - (iv) flow-on impacts, including price and impacts on international competitiveness.

Non-regulatory policy approaches are generally less costly to implement compared to traditional regulations, such as mandatory standards, and they can provide greater flexibility and adaptability to policymakers and industry. These approaches can involve existing self-regulation or co-regulation with industry. This can occur via voluntary or private standards through:

- Preferences and processes of business associations and large corporations, requiring their suppliers to conform to standards and non-compliance reducing the supplier's competitiveness. There is a strong culture of voluntary adherence to international, national or private standards being used for quality assurance by industry.
- Referencing of standards in non-binding documents, such as the Work, Health and Safety (WHS) Codes of Practices and Building Code of Australia (BCA), which are regularly used by inspectors. Compliance may reduce liabilities when it is reasonably practicable for the duty holder to adhere to the voluntary standard, and the court considers performance according to the standard in determining compliance with the law.
- Referencing in contracts which can be enforced if the party fails to meet them.

Alongside non-regulatory approaches, *ex post* regulation – such as tort liability or fines and penalties for non-compliance – should be considered by policymakers as an alternative

⁴⁹ This aligns with Principle 1 of the <u>Regulatory Policy</u>, <u>Practice and Performance Framework</u>, which states "regulation must be targeted, risk-based and proportionate", p 7. Regulation should "provide pragmatic solutions to minimise regulatory burden, while ensuring the regulatory intent is being met and essential safeguards are in place" and "enable regulatory intervention proportionate to the identified level of risk for an issue, drive compliance, and act as an effective deterrent", p 7.

policy tool to achieve the regulatory objective. *Ex post* regulation relies on the threat of liability – financial, legal, or criminal – to incentivise businesses to internalise the social costs of harm and adopt precautionary measures. In some cases, *ex post* approaches may be more efficient and effective than other regulatory mechanisms to achieve the regulatory objective.

Policymakers should note that regulation does not eliminate risk but shifts the burden of risk between parties. Policymakers, therefore, must provide advice to government about acceptable levels of risk. This involves balancing the likelihood and consequences of allowing the risk to continue with the costs incurred by the community in reducing or eliminating said risk. In some circumstances, this may mean the costs incurred by introducing mandatory standards outweigh the community benefits – and other policy tools should be considered to achieve the regulatory objective/s.

An evidence-based approach to determining if and how mandatory standards should be implemented is critical.⁵⁰ There may be situations where regulatory intervention is not appropriate. Where appropriate, policymakers should incorporate international, regional and overseas risk assessments to help inform their decision-making (see Tool 1 for more information).

Policymakers should consider using alternative policy tools and existing regulatory instruments where appropriate.

Question 3. Are there existing standards that could be mandated to achieve the regulatory objective?

Principle: Policymakers should be empowered to recognise multiple standards – including international, regional, Australian or overseas standards – that contributes to the government's desired outcomes for the community.

Policymakers should be empowered to recognise international, regional, Australian or overseas standards where they contribute to the government's desired outcomes for the community. The adoption of international standards is critically important for small, open economies like Australia. The economic literature indicates that bespoke national standards can hinder trade, while harmonised international standards can facilitate trade expansion and economic integration, enhance market accessibility, lower barriers to entry, and reduce country-specific adaptation costs.

The starting presumption should be international standards are safe and effective as they generally reflect the best experiences of policymakers and industry worldwide. Standards Australia actively participates in the development of international standards, representing Australia on the two major international standardising bodies, the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC). Standards Australia ensures Australia's interests are voiced in the development of

⁵⁰ See Principle 4 ("evidence-based and data-driven") of the <u>Regulatory Policy, Practice and Performance Framework</u>, pp 10–11

international standards and supports the establishment of National Mirror Committees to facilitate Australian stakeholder's participation in international standard development.

The Australian Government has committed to supporting the adoption of international standards in multiple policy documents, including the Department of Industry, Science and Resources' Best Practice Guide⁵¹, Department of Finance's Regulatory Policy, Practice and Performance Framework⁵², and Commonwealth Procurement Rules⁵³. This principle further aligns with Clause 1.d. in the Competition Reform Guidelines:

1.d. Where new or updated mandatory standards are deemed necessary to achieve the regulatory objective, identify, assess and recognise all appropriate international, regional, Australian, and overseas standards that could be fully adopted to meet the regulatory objective.

This commitment is further consistent with Australia's obligations under the WTO TBT Agreement and various free trade agreements. In relation to goods, the WTO TBT Agreement obliges that WTO Members should use international standards as a base, except where they are ineffective or inappropriate. Other trade instruments, like the TTMRA, obliges Australia to recognise goods produced or imported into New Zealand and allow them to be legally sold in Australia, and vice versa.⁵⁴ The legislation implementing the TTMRA overrides any domestic laws that regulate the manufacture or the sale of goods, such as product standards, packaging and labelling regulations, and conformance assessment requirements. There are some exemptions to the TTMRA, including but not limited to, laws relating to agricultural and veterinary chemicals; road vehicles; and therapeutical goods.⁵⁵

World Trade Organization Technical Barriers to Trade (WTO TBT) Agreement

The WTO TBT Agreement aims to ensure that technical regulations, standards, and conformity assessment procedures applied to goods are non-discriminatory and do not create unnecessary obstacles to trade. At the same time, the Agreement recognises WTO Members' right to implement measures to achieve legitimate policy objectives, such as the protection of human health and safety, or protection of the environment. The Agreement obliges members to base their measures on international standards to facilitate trade. In particular, Annex 3 of the Agreement provides guidance and "code of good practice" on the preparation, adoption, and application of voluntary standards. While the Agreement applies to goods only, the principles are relevant more widely and have been incorporated into this Handbook.

As such, in line with the government's existing commitments and policy agenda, policymakers should maximise the adoption of existing international, regional, Australian and

⁵¹ "If a system, service or product has been approved under an International Standard or risk assessment, Australian regulators should not impose any additional requirements unless it can be demonstrated that there is a good reason to do so", <u>Best Practice Guide to Using Standards and Risk Assessments in Policy and Regulation</u>, 2016, p 2.

⁵² See Principle 2 ("integrated in existing systems") of the <u>Regulatory Policy, Practice and Performance Framework</u>, pp. 8–9. ⁵³ "In prescribing specifications for goods and services, a relevant entity must, where appropriate:... b. base specifications on

international standards, when they exist and apply to the relevant procurement, except when the use of international standards would fail to meet the relevant entity's requirements", <u>Commonwealth Procurement Rules</u>, Clause 10.10.b., 2024.

⁵⁴ New Zealand Ministry of Business, Innovation and Employment, <u>A Users Guide to the Mutual Recognition Agreement (MRA) and the Trans-Tasman Mutual Recognition Agreement (TTMRA)</u>, 2014.

⁵⁵ See Section 3.2, 3.3, and 5.3 of <u>A Users Guide to the Mutual Recognition Agreement (MRA) and the Trans-Tasman Mutual Recognition Agreement (TTMRA)</u> for more information.

overseas standards over developing new standards. Where appropriate and aligned with the regulatory objective, policymakers should consider adopting a new mandatory standard that recognises multiple existing standards to provide several pathways for compliance. This will reduce barriers to trade, improve market access for businesses, and expand consumer choice (see the Bicycle Helmets case study below).

International standards should be prioritised for adoption by Australian policymakers unless there is clear evidence that the standard is not suitable for the Australian context and/or does not align with the regulatory objective. Where standards are proposed to be adopted, policymakers should undertake appropriate stakeholder consultation and provide sufficient time for businesses to transition to the new or updated standard. The length of the transition period would vary depending on the context and subject matter and businesses would be allowed to comply with the older or updated standard during this time. For goods-related measures, the WTO TBT Agreement obliges WTO Members to provide a transition period that offers 'a reasonable interval' between publication and entry into force to allow time to prepare for compliance. The WTO TBT Committee has recommended that the 'reasonable interval' is at least six months. More information about determining suitability for the Australian context is available in Question 4 and Tool 9 of the Policy Toolkit.

Adoption of international standards will enhance market efficiency, increase competition, reduce transaction costs for businesses and improve standards of living. The complexity of adopting international standards, however, will vary significantly across domains. For example, adopting international standards for bicycle helmets may be relatively more straightforward than recognising road vehicle design standards, which involves more complex trade-offs between balancing vehicle weight, safety during accidents, emissions, and Australian environmental conditions.

Alongside the adoption of international standards, Australian standards should be mandated as a pathway to compliance where appropriate. Policymakers should check whether voluntary Australian standards have already been developed by Standards Australia and mandate them if appropriate to meet the regulatory objective. Standards Australia is required to base Australian standards on international standards to the maximum extent feasible and align with the Code of Good Practice contained in the WTO TBT Agreement.

Regional and overseas standards should also be considered provided they meet the principles of consultation and consensus in development⁵⁷. Policymakers may wish to consult with ATIA members, who can help undertake cross-country comparisons and determine whether the adoption of overseas standards is appropriate. Similar to the adoption of international standards, policymakers will need to undertake appropriate stakeholder consultation and set a suitable transition period whenever regional, Australian and/or overseas standards are mandated.

The ACCC has adopted multiple Australian and overseas standards for bicycle helmets

The Consumer Goods (Bicycle Helmets) Safety Standard 2024 prescribes the design, construction, performance, testing and safety markings for bicycle helmets sold in the

⁵⁶ See Principle 3 ("user-centred") of the <u>Regulatory Policy, Practice and Performance Framework</u>, pp 9–10.

⁵⁷ World Trade Organisation, <u>Agreement on Technical Barriers to Trade – Annex 3</u>, 1995.

Australian market.⁵⁸ Approved bicycle helmets must comply with one of the following Australian or overseas standards:

- 1. Australian New Zealand standard AS/NZS 2063:2020 Helmets for use on bicycles and wheeled recreational devices:
- 2. Australian New Zealand standard AS/NZS 2063:2008 Bicycle Helmets;
- 3. European standard EN 1078:2012+A1:2012 Helmets for pedal cyclists and for users of skateboards and roller skates;
- 4. US Consumer Product Safety Commission standard US CPSC 16 C.F.R. Part 1203 Safety Standard for Bicycle Helmets;
- 5. American Society for Testing and Materials (ASTM) International standard F1447-18 Standard Specification for Helmets Used in Recreational Bicycling or Roller Skating; or
- 6. Snell standard B-95 1995 Bicycle Helmet Standard, 1998 revision, Standard for Protective Headgear for Use in Bicycling.

Allowing multiple domestic and international standards for bicycle helmets helps to reduce barriers to international trade – increasing product availability and quality for Australian consumers without reducing consumer safety.

When mandating new standards, Commonwealth policymakers should collaborate with other regulators, including with international standard bodies and state and territory agencies. By improving coordination and supporting greater harmonisation across jurisdictions, policymakers can lower international and domestic barriers to trade, improve regulatory efficiency and effectiveness, and reduce administrative burden on industry.

The National Greenhouse and Energy Reporting Scheme establishes consistent mandatory reporting requirements for Australian companies

Legislated in 2007, the National Greenhouse and Energy Reporting (NGER) Act introduces a single national reporting framework for company information on greenhouse gas emissions, and energy consumption and production. These mandatory reporting standards are guided by the Intergovernmental Panel on Climate Change (IPCC) and United Nations Framework Convention on Climate Change (UNFCCC) rules for estimation and measurement.

By establishing nationally consistent standards for reporting on greenhouse gas emissions, this Act has enabled the Commonwealth to meet Australia's international reporting obligations, supported international and interstate harmonisation, informed policy development on climate change, and avoided duplicative reporting from the states and territories.

Whenever standards are mandated, policymakers should consider whether the legislation should recognise future updates to the standard (see Tool 7). Safeguards in the legislation could be introduced to ensure that the standard remains fit-for-purpose for the Australian

⁵⁸ State and territory road use laws specify the type of bicycle helmet allowed on public roads.

market. For example, if the relevant standard is updated without Australia's active participation in the relevant standard-setting body, then policymakers will need assess the standard to ensure suitability for the Australian context. More information about ambulatory referencing and regular review is available in Tool 6 and 7 of the Policy Toolkit.

Policymakers should adopt the international standard, unless they can demonstrate that the standard is unsuitable for the Australian context and/or does not align with the regulatory objective. Similarly, regional, Australian or overseas standards should be adopted alongside the international standard, where appropriate, to provide multiple pathways to compliance.

Question 4. Could existing standards be modified to suit the Australian context?

Principle: Policymakers should be able to deviate from existing standards, including international standards, where they do not meet local community needs. However, policymakers should only deviate if the marginal benefit to the community outweighs the marginal cost of deviating from existing standards (i.e. net public benefit).⁵⁹ The deviation should ensure suitability for the Australian context and align with the government's regulatory objective.

Existing standards should be adopted by policymakers, unless there is clear evidence that the applicable standard is not suitable for the Australian context. Policymakers should consider whether and how the Australian experience diverges from other countries and the international standard. Factors could include differences in the environment, climate or geography and issues related to national security.

Although there may be differences between the Australian and international experience, this does not singularly justify the deviating from existing standards or developing new Australian standards. Policymakers should consider the likelihood of risk and severity of consequences associated with adopting the international, regional, Australian or overseas standards as compared to the transaction costs and administrative burdens related to developing new Australian standards. There may be circumstances where there is some divergence in the Australian experience, but the benefits of fully adopting international, regional, Australian or overseas standards outweigh the costs to Australian consumers.

Any deviation from existing standards, including the development of new mandatory standards, should involve the minimum amount of modification required to meet the regulatory objective and ensure suitability for the Australian context. Policymakers should retain the international standard to the largest extent possible without significantly impacting community outcomes.

⁵⁹ For further guidance on assessing net benefit, including the impacts of fully adopting versus deviating from the international standard, please refer to Appendix D and <u>The Australian Government Guide to Policy Impact Analysis.</u>

Australian Standards for sunglasses differ from the International Standard due to climatic factors

In 2016, the ACCC sought to update the mandatory standard for sunglasses by adopting the voluntary standard, AS/NZS 1067:2016 Sunglasses & fashion spectacles. The voluntary standard was divided into two parts to more closely align with content and structure of the International Standard, ISO 12312-1:2013.

Although the voluntary standard largely adopted the International Standard, there were several key differences relating to the ultraviolet radiation (UVR) protection, filtration of blue light, and labelling. Experts noted that "Australians are exposed to more UVR than northern hemisphere residents" and therefore warrant greater protection. Similarly, the International Standard for blue light filtration and labelling were assessed to be inadequate for Australian conditions.

After stakeholder consultation, the voluntary standard was adopted as mandatory in 2017. This minimised the differences between the Australian and International Standard, while maintaining appropriate safety levels for Australian consumers.

There are scenarios, however, where fully using or adopting existing risk assessments, standards, or conformity assessment procedures may be inappropriate to use in Australia. For example, there may be differences in existing risk appetites and community expectations of safety between countries. Some specific examples for each policy tool are provided below:

- Risk assessments: There may be inadequate arrangements with international, regional, or overseas regulators to provide confidence in their risk assessments.
- **Standards:** The international, regional, or overseas standard may be incompatible with other domestic legislation or standards.
- Conformity assessment procedures: There may be no 'accepted' or generally agreed means to determine conformity or compliance with the international, regional, or overseas standard (i.e. inconsistencies in conformity assessment procedures).

Furthermore, there may be situations where there is no existing international, regional, Australian, or overseas standard (e.g. standards for emerging and critical technologies).

If there are no existing standards which could be suitably mandated or modified for the Australian context, then policymakers should be empowered to develop a new mandatory Australian standard to achieve their policy objective. Consideration should be given to developing an Australian Standard to serve as a foundation for future international standardisation. Referencing existing voluntary standards in regulation should be prioritised over developing new mandatory standards, where possible.

Incompatibility with Australian conditions can prevent the adoption of international and overseas standards

There are two mandatory standards for portable fire extinguishers and these reference the Australian/New Zealand Standards AS/NZS 4353:1995 Portable fire extinguishers — Aerosol type and AS/NZS 1841:2007 Portable fire extinguishers. A range of

overseas standards were assessed for suitability to reference alongside the Australian/New Zealand Standards in the mandatory standards. It was found that the BSI standard did not align with labelling requirements in Australia or require exposed non-metallic elements to be UV stabilised. The ISO, CEN and NFPA standards also had inconsistent labelling, fire classification and rating requirements needed in Australia. In other words, these international standards were not compatible with other legislation and mandatory standards. The challenge for policymakers is appropriately balancing barriers to trade with improving community outcomes and harmonising with international standards.

Policymakers should note there are direct and indirect costs with developing new mandatory standards, such as duplicating existing work by international, regional, Australian and overseas standards-setting bodies, which is lengthy, costly and resource intensive. Fragmented standards across jurisdictions could lead to higher compliance costs, regulatory uncertainty, and reduced consumer choice. The additional net benefit of diverging from the international standard should be explored and quantified by policymakers to help inform government decision-making. Where the additional cost of deviating from the international standard outweighs the marginal benefit to the community, policymakers should fully adopt the international standard without deviation.

If yes, policymakers should mandate the standard with the minimum required modifications necessary to achieve their regulatory objective.

If no, policymakers should develop a new mandatory standard in Australia. Policymakers should note that new mandatory standards should only be developed when existing standards are unsuitable for the Australian context and/or does not align with the regulatory objective.

When deviating from international, regional, Australian and overseas standards or creating new Australian standards, policymakers should ensure these standards do not create unnecessary obstacles to international trade. Policymakers should ensure that new mandatory standards do not hinder competition, innovation, productivity or business dynamism by creating barriers to market entry and exit.

In line with Policy Tool 6, these new standards should be sunsetted and regularly reviewed to ensure they are fit-for-purpose, compatible with current views and expectations regarding quality, safety and the environment, and the least trade-restrictive policy measure. Similarly, policymakers should use ambulatory referencing and performance-based criteria, where appropriate (see Tool 7 and 8 respectively).

Australian consumers and businesses should be able to easily understand the standards enforced by policymakers. When deviating from international, regional, Australian or overseas standards, policymakers should clearly communicate their policy rationale and explain why differences are needed to improve community outcomes and better target the

⁶⁰ Policymakers may wish to reference the <u>Guide to Policy Impact Analysis</u> for further guidance on identifying and balancing regulatory objectives, particularly Question 3 ("What policy options are you considering?") and Question 4 ("What is the likely net benefit of each option?").

regulatory objective/s. Policymakers should also outline the potential risks and future opportunities related to deviating from the international standard.

Appendix C: Legislating and declaring mandatory standards

Policymakers should consider allowing mandatory standards to be determined in subordinate legislation, such as regulations and legislative instruments (see case study below). This will provide greater flexibility to policymakers and make it easier to ensure mandatory standards remain current, relevant, and safe for Australian consumers. By reducing the lag between the development of new standards and their implementation, this can streamline the standards adoption or development process in Australia, reduce compliance costs for businesses, and maintain regulatory consistency across jurisdictions. This flexibility will be particularly beneficial during the net-zero transition, as Australia will experience rapid technological change, and industry and voluntary standards will be regularly developed and updated to reflect improvements in reliability, performance, and safety.

In considering whether to allow standards to be determined in subordinate legislation, policymakers should be mindful that significant matters should be included in primary legislation. As outlined in the Standing Committee for the Scrutiny of Bills Guidelines, significant matters that are generally not appropriate for inclusion in delegated legislation include:

- the appropriation of money;
- the imposition of taxes or levies;
- key elements of new policies or fundamental changes to existing policies;
- matters which may have a significant impact on personal rights and liabilities, including the exercise of coercive or intrusive powers or the imposition of significant penalties;
- provisions which may impose obligations to undertake or desist from certain activities;
 and
- procedural matters that go to the essence of a legislative scheme.⁶¹

Where mandatory standards are determined in subordinate legislation, policymakers should include strong policy justification in the Explanatory Memorandum, including:

- Why it is appropriate to include mandatory standards in delegated legislation; and
- Whether there is sufficient guidance on the face of the primary legislation to appropriately limit the matters that are being left to delegated legislation.

The Committee has generally not accepted a desire for administrative flexibility alone to be a sufficient justification for leaving significant matters to delegated legislation.

There are multiple cases, however, where the Committee has allowed standards to be determined in subordinate legislation. Policymakers may wish to read the Explanatory

⁶¹ The Senate, Standing Committee for the Scrutiny of Bills – Guidelines (2nd Edition), 2022, pp 18–19.

Memorandum for the "Regulation of Safety Standards and Information Standards" or the "New Vehicle Efficiency Standard Bill 2024" as some examples. 62

Under Australian Consumer Law, the Commonwealth Minister can make safety standards for consumer goods and product related services

Section 104 of the Australian Consumer Law was recently amended by Parliament in November 2024 (*Treasury Laws Amendment (Fairer for Families and Farmers and Other Measures) Bill 2024*). This section allows the relevant Commonwealth Minister to make mandatory safety standards by written notice, which are given effect by legislative instrument.

The Commonwealth Minister may, by written notice, for the purposes of preventing or reducing the risk of injury to any person, make a safety standard for one or both of the following:

- (a) consumer goods of a particular kind;
- (b) product related services of a particular kind.

The legislation further allows safety standards to incorporate matters in instruments and other writings as they exist from time to time, including international standards.

These changes aimed to increase the recognition of international standards in Australia, while improving their flexibility and enforceability.

When drafting legislation to make and update mandatory standards in Australia, policymakers should ensure the legislation is proportionate and risk-based – appropriately balancing timeliness and regulatory flexibility with potential risks to the community. There may be circumstances where the benefits to the community outweigh risks. In these cases, relevant legislation could also be updated to delegate authority to regulatory agencies or sufficiently senior public servants, such as a departmental secretary, to declare new standards. They would be allowed to declare new mandatory standards where they are equivalent or higher standards than existing ones. This would allow international standards to be recognised and updated more quickly, while reducing pressure on Parliament's legislative agenda. This reform would support competition, innovation, and consumer choice in the domestic market, without significantly reducing quality or safety for the Australian public.

Victoria's *Road Safety Rules 2017* delegates responsibility for standards adoption and development to the Department of Transport

Victoria's *Road Safety Rules 2017* legislation allows the Secretary of the Department of Transport to set and amend standards for products used on Victorian roads. Section 407 states:

The Secretary, by notice published in the Government Gazette, may declare, for the purposes of these Rules

^{62 &}lt;u>Explanatory Memorandum</u> for Treasury Laws Amendment (Fairer for Families and Farmers and Other Measures) Bill 2024, pp 15–30; <u>Explanatory Memorandum</u> for New Vehicle Efficiency Standard Bill 2024, pp 28–29.

- (a) a booster seat to be an approved booster seat;
- (b) a child restraint to be an approved child restraint;
- (c) a child safety harness to be an approved child safety harness;
- (e) a horse riding helmet to be an approved horse riding helmet;
- (f) a bicycle helmet to be an approved bicycle helmet;
- (g) items to be approved as portable warning triangles; [and]
- (h) a seatbelt to be an approved seatbelt.

By delegating the responsibility for standards adoption and development to the Departmental Secretary, this ensure standards are flexible, adaptable, and contemporary – allowing policymakers to quickly respond to dynamic markets and community concerns.

Appendix D: The role of the Impact Analysis during the standards adoption and development process

Policymakers are required to notify the Office of Impact Analysis (OIA) when mandatory standards are being considered for introduction or revision. The OIA will provide advice on whether the threshold for completing a detailed Impact Analysis (IA) is met. If an IA is required, many of the tools described in the Policy Toolkit can contribute to the IA process.

The first step for policymakers is completing a Preliminary Assessment.⁶³ This is a high-level analysis which provides enough information for the OIA to determine and provide advice if the proposed change is "more than minor". In some cases, the Preliminary Assessment is the only documentation required of APS officers under the Government's Policy Impact Analysis framework, if the OIA determines that a detailed IA is not required for introduction or revision of the mandatory standard/s.

Where the proposed change is deemed to have "more than a minor change in behaviour or impact for people, businesses, or community organisations", the OIA will advise the policymaker to draft a detailed IA.⁶⁴ For example, an IA may be required when policymakers are introducing a new mandatory standard and/or deviating from existing international, regional, Australian or overseas standards.

When drafting an IA for new mandatory standard/s, policymakers need to evaluate the benefits and costs of introducing the standard against the existing status quo. A range of viable options should be examined, such as adopting the international standard (where one exists), deviating from fully adopting the international standard, and/or recognising other standards as appropriate. Factors to be considered may include the impacts on safety, health and the environment, competition, consumer protection, trade, regulatory burden and compliance, product availability, and/or national security. In examining the options, the IA

⁶³ Department of the Prime Minister and Cabinet, Australian Government Impact Analysis Preliminary Assessment Form, 2025.

⁶⁴ Department of the Prime Minister and Cabinet, Australian Government Guide to Policy Impact Analysis, 2023, p 8.

should evaluate and compare the net benefits of different approaches, such as prescriptive-based versus performance-based standards, and "dated" versus "undated" standards.

The IA should also explicitly analyse the incentives, potential unintended consequences, and secondary effects associated with new mandatory standards. Although well-intentioned, mandatory standards can create unintended consequences or secondary effects, potentially undermining their intended objectives and adversely affecting other public policy goals. This is especially prevalent in rapidly evolving sectors. For example, cryptocurrency regulations aimed at ensuring market stability often impose high compliance costs that small startups cannot afford, inadvertently favouring large, established players and reducing competition and innovation. Policymakers should also evaluate the incentives embedded within the compliance framework to ensure they align with the regulatory objective.

For more information on Policy Impact Analysis Frameworks, refer to the:

- Australian Government Guide to Policy Impact Analysis
- Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies

Please contact the Office of Impact Analysis at helpdesk-OIA@pmc.gov.au