Australian Government

Department of the Prime Minister and Cabinet

Regulation Impact Statement

International Standards and Risk Assessments

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Introduction

The Government's Economic Action Strategy (the Strategy) is to build a stronger, more prosperous economy for a safe and secure Australia. In prosecuting this objective, the Government is pursuing opportunities that aim to raise Australia's competitiveness, productivity and growth, and will help transform Australia into a globally competitive economy.

A key step in the Government's overall strategy is the Industry Investment and Competitiveness Agenda through which the Government will target reform opportunities to give business the flexibility, certainty and confidence they need to adapt to globally competitive markets. The development of the agenda has been motivated by a decline in Australia's multi-factor productivity, and work by the Productivity Commission (PC) highlighting possible impediments to growth. In 2006 the PC found that the compliance costs of regulation by all levels of government could amount to four per cent of GDP and that national reforms had the potential to reduce regulatory compliance costs by 0.8 per cent of GDP. The same report also found that national reforms could add significantly to national output (up to around two per cent of GDP, or around $17 billion) after a period of adjustment of around 10 years.

A plan to boost productivity and reduce regulation

Before forming Government, the Coalition consulted widely with businesses, industry representatives and not-for-profit organisations across Australia. This process reinforced similar messages to those in the PC's work. In effect, Australia was struggling under a heavy burden of regulation. On coming to Government, a plan was put in place to reduce regulatory burden. At the core of this plan is the overriding objective to reduce regulatory burden for businesses, community organisations and individuals by establishing and meeting a red and green tape reduction target of at least $1 billion a year. Central to the success of this plan is the idea that regulation should only be imposed where absolutely necessary. In other words, regulation should no longer be the default position in dealing with public policy issues.

As part of the Industry Innovation and Competitiveness Agenda, a Competitiveness Taskforce has been assessing options to lower costs (through less regulation), lower taxes and build more competitive markets. This proposal, which examines options around the adoption and acceptance of international standards and risk assessments in Australia, seeks to combine the ambitions of the Taskforce with the Government's red tape objective. In particular, the preferred option set out in Section 6 proposes that ministers, portfolios and their portfolio regulators adopt the following principle:

> '*Where a trusted international standard or risk assessment already exists, and a system, service or product has been approved under that trusted standard or assessment, then regulators should not impose any additional requirements for approval in Australia, unless it can be demonstrated that there is good reason to do so.'*[1]

[1] Trusted in this context could include those international standards and risk assessments agreed multilaterally or standards or assessments from certain overseas jurisdictions that are considered to be at the forefront of international best practice.

If this in-principle option is adopted, portfolios would be required to review each of their standards and risk assessment processes as well as new policy proposals against this principle. The proposal would provide a focal point for ministers and regulators in working to identify reform opportunities that may be pursued. over the remainder of the Government's first term.

The costs and benefits from adopting or accepting trusted international standards would be evaluated at the final decision point when the scope for implementation is considered on a case-by-case basis. In recognising the further work that would follow, this Regulation Impact Statement (RIS) is an early-stage RIS to assess, at a high level, the implications of this policy. It has been developed consistent with the Australian Government Guide to Regulation.

1. What is the policy problem?

As part of the Government's ongoing discussions in the broader community, concern has continued to be raised by stakeholders that the additional burden required to comply with unique Australian standards and risk assessment processes can add unnecessary costs for businesses, community organisations and individuals. That is, when suitable international standards and risk assessments exist, and a product or service has already been approved by a trusted regulator in an overseas jurisdiction, separate Australian-specific assessment and approvals processes can impose unnecessary burden.

The implications for a small, geographically isolated country such as Australia imposing unnecessary standards or risk assessments are potentially quite large. Separate processes can create product delays, increase costs, reduce consumer choice, and can impose barriers on both export and import-competing businesses. Where suitable international standards and approvals exist, there may be opportunities for compliance and risk assessments by Australian regulators to be streamlined through the adoption of trusted international standards and the use of international risk assessments without increasing the risk of regulation failure to Australians and our environment.

How acute are these risks?

In some instances, the adoption of international standards and risk assessments already occurs in Australia. Currently, the Therapeutic Goods Administration (TGA) accepts medical device conformity assessment certification from certified European Union (EU) Notified Bodies because of the similarities between the Australian and EU regulatory systems. This process only applies to an overseas manufacturer of medical devices seeking to have their product listed in Australia. Acceptance of EU conformity assessments reduces timeframes for having medical devices marketed in Australia and as well as reducing the compliance costs on industry.

There is an exception for 'high risk' medical devices which must undergo a TGA conformity assessment even if previously approved in the EU. Further, Australian medical device manufacturers must hold conformity assessment certification from the TGA even if they have received a conformity assessment certification from the EU.

There has not been a systematic assessment of the extent to which Australian regulation frameworks differ from international standards. However, there would appear to be a range of regulatory areas where deregulation benefits could be achieved by adopting international standards

and risk assessments and therefore, there is a question as to whether the TGA example could be extended to other areas of regulation.

In the chemicals industry, it has been reported that a number of polymers which are already sold in Europe or the United States cannot be imported into Australia because they do not have regulatory approval. Testing to gain regulatory approval can cost around $50 000 (35 000 Euro) per polymer.

Further examples are the Australian Design Rules (ADRs) which are national standards for vehicle safety, anti-theft and emissions. The ADRs are generally performance based and cover issues such as occupant protection, structures, lighting, noise, engine exhaust emissions, braking and a range of other items. The standards are administered by the *Australian Government under the Motor Vehicle Standards Act 1989*. Failure to adopt overseas standards means that imported vehicles have to recertify against the ADRs which increase regulatory costs to business (particularly vehicle importers) and ultimately increase prices for consumers.

There are likely to be many more examples across portfolios where unnecessary Australian-specific regulations have resulted in delays and added financial costs to industry. However while there appear to be opportunities to reduce burden in some cases where Australia has not already adopted international standards and risk assessments, in some other cases there are good reasons why international standards and risk assessments may not be appropriate.

- Australia has many unique characteristics (e.g., environment, disease status) which, in some instances, demand Australian-specific standards and risk assessments. For example, Australia's low disease status that arises as a result of our high level of quarantine standards enables Australia to export to other countries guaranteeing that disease (such as foot and mouth disease) is not present in our products.
- Moreover, in a number of areas Australia is a world leader in setting standards, including in the transport sector. As a leader of international best-practice, efforts to accept and adopt the use of international standards and risk assessments would contradict Australia's global role and our advocacy for more appropriate vehicle safety standards.

In essence, although there is evidence of a policy problem, the scope for change is difficult to assess at this point and a decision to accept and adopt international standards and risk assessments would need to be considered on a case-by-case basis.

2. Why is Government action needed?

As part of the Government's deregulation agenda, Commonwealth portfolios are undertaking an audit of the stock of Commonwealth regulations to assess the number of and burden imposed by regulations administered by the Commonwealth at the individual portfolio level. This audit suggests that the Commonwealth administers over 81,000 regulations – comprising primary legislation, subordinate instruments and quasi regulations on businesses, community organisations and individuals. This regulatory task is overseen by approximately 151 bodies with regulatory functions in the Commonwealth (81 external portfolio agencies and 70 internal to departments).

The count of regulations arising from stage one of the audit does not provide information regarding the quality or necessity of regulations or where ineffective or inefficient regulation can be reduced

as part of the Government's deregulation objective. Rather, what it does suggest is that the Commonwealth Government is likely to be a key source of regulatory burden, and has a leading role in testing Commonwealth regulations and ensuring that an appropriate balance (in regulation) is achieved. [2] This leading role is already reflected in the Government's objective of reducing ineffective red tape and committing to an annual $1 billion red tape target.

However, while it could be expected that the Government's deregulation objective might lead portfolios and regulators to consider reforms to adopt international standards and risk assessments, there are no guarantees that this will occur as systematically and rigorously as would be desirable. This is especially relevant given the large number of regulations that are being reviewed within portfolios, and the interests of diverse stakeholder groups.

By choosing to endorse a particular reform principle, the Government can help to focus attention on an area where stakeholders can engage with portfolios and regulators to pinpoint burden, identify priorities, and maximise opportunities for reform. Moreover, recognising that the Commonwealth is not the sole source of regulatory burden, the Commonwealth Government can lead through example and encourage state and territory governments to review their own needs for unique state and territory standards and risk assessments.

3. What are the policy options being considered?

The *Australian Government Guide to Regulation* requires a non-regulatory option to be considered. In the context of this policy proposal about international standards and risk assessments, it has not been possible to identify a feasible or appropriate non-regulatory option as part of this RIS. That is, while the option of removing all regulations connected with standards and risk assessments would be non-regulatory and would reduce regulatory burden, it would also remove all the benefits of regulation such as that applying to quarantine and therapeutic goods. There are a number of potential policy options that could be undertaken, depending on where Commonwealth regulations currently sit in comparison with international standards and risk assessment processes. Three broad policy options are canvassed.

I. No Change – maintain current deregulation policy settings

Under this option, the potential for the adoption or acceptance of trusted international standards and risk assessments, or even greater alignment of Commonwealth regulations with those of overseas jurisdictions, would occur as part of ministers' or regulators' own assessment of potential red tape reform opportunities. Where scope exists for alignment, implementation would be at the discretion of individual portfolios, having consideration to the relative prospects for achieving regulatory savings *vis a vis* other reform priorities. Under this option, there would be no explicit requirement to assess against international standards and risk assessments, although portfolios would continue to be encouraged to do so.

[2] It is worth noting that this count of regulations excludes separate rules and regulations which individual states and territories, local government authorities and councils might separately apply.

II. Case-by-case reviews to augment current deregulation policy

This option proposes that where a trusted international standard or risk assessment already exists, and a system, service or product has been approved under that trusted standard or assessment, then regulators should not impose any additional requirements for approval in Australia, unless it can be demonstrated that there is good reason to do so.

As part of their efforts to develop regulatory reform priorities over the remainder of the Government's first term, ministers will be required to ensure that assessments are undertaken of the need to maintain separate Australian standards rather than adopting international standards. Adopting the principle would ensure a more systematic assessment of all regulations against international standards and risks assessments. Where scope exists for the adoption of international standards and risk assessments, or greater alignment with them, these reforms would be implemented in a manner that is consistent with the Government achieving its overall net $1 billion annual deregulation objective.

To ensure a thorough review of all regulations against international standards and risk assessments, ministers will be asked to write to regulators in their portfolio and key business and other stakeholders seeking their views on reform opportunities against this principle. The immediate opportunities identified through this process would be considered for inclusion in the reform priorities to be developed and implemented in 2015 and 2016.

Portfolios will consult with all stakeholders to develop criteria for assessing Australian regulations against this principle. These criteria will be used to justify instances where unique Australian standards are required. Moreover, these criteria will be used in assessing changes to existing regulations, as well as new policy proposals.

III. Mandating the adoption and acceptance of international standards, risk assessments and approval processes

Under this option, the Government could mandate the acceptance and adoption of trusted international standards and risk assessments without any further review. Specifically, where an international standard or risk assessment had been assessed by a trusted authority or process, and a system, service or product has been approved under that trusted standard or assessment, then that would be accepted by Australian regulators. There could be limited exceptions to this rule. Portfolios would need to justify publicly why a unique Australian standard is warranted. A full assessment would have to be done on any exceptions and agreed by all stakeholders.

4. What is the likely net benefit of each option?

As discussed in section 2, the scope for regulatory reform and alignment with trusted international standards and risk assessments remains uncertain. That is, in some cases Australian standards are the global benchmark, in other instances, the Commonwealth has already moved to adopt international standards and assessments. Where unique Australian regulations remain, the scope for further reform and the net benefit of each option will need to be individually assessed at the final

decision point. For each of the options canvassed in section 3, the broad costs and benefits of each ‘principle’ (option) are as follows.

I. No Change – maintain current deregulation policy settings

The case for reform would be considered on a case-by-case basis as part of ministers’ efforts to identify reform opportunities within their portfolios. This would allow for a considered process for accepting or adopting (or even moving towards international standards), with the case for change being assessed as part of broader consultations with affected stakeholders. Opportunities for net regulatory savings that arise from reduced duplication with international standards depend on which particular reforms are implemented within portfolios, and whether cases for accepting and adopting international standards form part of the broader suite of reform priorities. At present, one of the key shortcomings of a ‘no change’ or business-as-usual option is that opportunities to adopt international standards and risk assessments risk being crowded out as a result of ministers implementing higher reform priorities that offer larger red tape reductions. In the absence of endorsing a principle, benefits could be lost if opportunities were available, but no decisions were taken to adopt appropriate international standards and risk assessments. In essence, opportunities to maximise the benefits of deregulation could be missed. These wasted benefits are discussed further below.

II. Case-by-case reviews to augment current deregulation policy

Where Australian-specific regulations impose additional burden on stakeholders, alignment with trusted international standards would eliminate delays and regulatory approval costs arising from separate approval processes prior to a product or services use in Australia. It could also complement broader Government objectives by reducing the administrative costs for Government. In addition, there would be lower barriers to import/export competition, encouraging greater efficiency, innovation and productivity for Australian businesses. However, there are a number of drawbacks from international standards which are discussed under 4 (III) below.

As part of efforts to reduce ineffective red and green tape, ministers are already assessing the scale and scope of the regulatory burden within their portfolios. The adoption of international standards, based on a systematic, case-by-case review would add further direction to this assessment. This principle would require ministers to ensure there is specific assessment of the extent to which opportunities exist for the acceptance or adoption of, or even greater alignment with international standards and risk assessment processes as part of the Government’s deregulatory agenda. The principle would also serve as a useful criterion for assessing future Australian regulatory changes in the presence of existing international standards.

A considered approach to reform has a number of distinct advantages.

- A case-by-case assessment of reform would complement the work already underway to identify specific, concrete reform priorities for 2015 and 2016.
- A considered assessment would be consistent with international support for a case-by-case consideration of international standards.
    - Canada’s *Cabinet Directive on Regulatory Management* provides guidance to their departments and agencies around opportunities for cooperation with jurisdictions in

other countries or with the international community. In particular, agencies seek to limit the number of specific Canadian regulatory requirements or approaches to instances when they are warranted by specific Canadian circumstances and when they result over time in the greatest overall benefit to Canadians. This involves identifying the rationale for their approach, particularly when specific Canadian requirements are proposed; and minimising regulatory differences with key trading.[3]
    - Similarly past examinations by the OECD have examined the issue of standards relating to trade. In sum, the OECD finds many possibilities for how particular standard impacts on an economy, noting that some effects are positive but others are negative and the net impact depends on the context. [4]
- A considered approach would also avoid pre-empting the conclusions of reviews including the Financial System Review, Competition Review, and the Agriculture White Paper. Moreover, Inter-Governmental Agreements will require states and territories to be consulted for the regulations where they have a role (e.g. on vehicle standards), further supporting a case-by-case approach.

On balance, a case-by-case review could deliver the Government with the right balance in the acceptance, adoption or increased alignment of Australian regulations against international standards and greater use of international risk assessments. This could be achieved in a way that minimises disruption and uncertainty (particularly from significant changes that mandate reform), and supports ongoing community engagement in the reform process. The commitment that ministers would make the adopting the principle, and the mechanisms outlined in section 7 for monitoring implementation will add direction and provide additional momentum to assist ministers and regulators to deliver on the Government's red-tape target.

III. Mandating the adoption and acceptance of international standards, risk assessments and approval processes

Mandating the adoption and acceptance of international standards and risk assessments would mark a significant change in Australia's regulatory paradigm. In some instances the shift is likely to be highly contentious and contested by some stakeholders. However, for other stakeholders, mandating the use of international standards and risk assessments could arguably provide greater regulatory certainty for businesses, community organisations and individuals.

Although mandating change would prioritise the acceptance and adoption of international standards and use of risk assessments and provide some deregulatory benefit, the key shortcoming of this option is that it does not address the problem defined in section 2. It is indiscriminate and departs from the principles of good policy formulation by not requiring separate systematic assessment of the costs and benefits that would underpin an informed case-by-case decision being made.

Moreover, this approach is not without further, significant risk. A decision to accept or adopt international standards and risk assessments could be seen as undermining Australia's policy autonomy and our ability to respond to emerging local risks and crises. In some instances, Australia's

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[3] Treasury Board of Canada Secretariat, Cabinet Directive on Regulatory Management, found here.
[4] Swann, G.M.P, *International Standards and Trade, A Review of the empirical literature*, OECD Trade Policy Working Papers, No. 97, page 4.

regulators could forgo their ability to lead the setting of global standards and be subject to broader criticism that Australia is ‘free-riding’ off the work of international regulators.

Furthermore, as previously noted, there are a number of instances where international standards and risk assessments may not suit Australian conditions or circumstances.

Examples of where international standards and risk assessments may not suit Australia

Agriculture

Biosecurity import risk assessments are a technical process conducted under biosecurity regulations. They are used to identify the level of quarantine risk associated with the importation of an animal, plant or other good into Australia. These assessments allow the Australian regulator to determine what measures should be adopted to mitigate this risk, or whether the risk is too great and trade should not be allowed.

Australian regulators currently use existing international standards as a starting point when considering an import risk assessment. This is then built upon, taking into account Australia’s ‘Appropriate Level of Protection’, unique competitive agricultural advantages and in certain circumstances, disease free status. The final import risk assessment will be a hybrid of these inputs, designed to provide the best quarantine protection for domestic industry.

Australia has a unique environment that is largely free of common pests and diseases. This provides Australia with a unique competitive advantage over our trading partners. It could be detrimental to Australia to automatically adopt international standards and to do so might place our competitive advantage at risk.

For example, Australia does not import livestock despite there being an international standard for trade in this commodity. This has allowed Australia to remain free of a number of livestock diseases, protecting an export industry worth upwards of $7 billion per annum and maintain an export advantage over countries that have adopted these standards.

Fuel Quality Standards

The objectives of the *Fuel Quality Standards Act 2000* are to reduce vehicle emissions (particularly of nitrogen dioxides, carbon monoxide, volatile organic compounds, and particulate matter), ensure engine operability and facilitate new engine and emission control technology. Where possible, there is value in ensuring that Australian fuel quality standards are harmonised with international fuel quality standards, given that Australia imports a significant amount of fuel and vehicles, and fuel quality standards work in conjunction with vehicle emission standards to reduce emissions from vehicles.

There are circumstances where it may be inappropriate for Australia to adopt all international fuel quality standard parameters without consideration of Australian conditions. For example, some fuel components are subject to lower concentrations in Australian fuel compared to European standards because their higher international concentrations could risk contaminating Australia’s scarce freshwater resources, rendering them non-potable.

Australian financial sector

Historically, Australia has taken a stronger approach to financial stability than required under global standards which, in part, contributed to the robustness of the Australian financial system during the global financial crisis, and Australia's global reputation for having a sound financial system.

The global crisis was followed by a considerable international policy response through which financial supervisors around the world and the international bodies responsible for making standards on financial regulation are now seeking to coordinate their actions, develop new global standards and achieve broad consistency across countries.

An issue for Australia is the extent to which it can implement all of these new global standards. Australia adheres to a number of global prudential frameworks, in particular the Basel framework for the banking industry. Basel III, which was developed in the wake of the global crisis, seeks to significantly increase the robustness of banks globally. As a global benchmark, the Basel framework is not designed to the particular circumstances of any one country. It is designed to apply a common minimum to a broad range of countries with different financial systems. All major economies follow the Basel framework, leading to a relatively consistent global approach to bank regulation, despite some differences by countries in implementation.

Generally, Australia's approach to implementing parts of the Basel framework has been stricter than what the global standards imply. For instance, Australia has decided on a stricter approach to calculating capital ratios than the Basel III baseline. Further, in the case of capital requirements and the liquidity coverage ratio, the Australian Prudential Regulation Authority is implementing some changes faster than a number of other countries. However, Australia has been required to be more conservative in its approach to adhering to minimum 'headline' capital ratios as a result of the lack of access (by financial institutions) to high-quality, liquid, risk-free government assets. In contrast to some other more highly-indebted economies, Australia lacks the level of Commonwealth Government debt that would allow financial institutions to meet new liquidity benchmarks. As a result, Australia has been more conservative in aspects of its implementation compared to what global standards might require.

The necessary flexibility has been echoed in the Financial System Inquiry interim report which has supported efforts to drive greater financial integration with the rest of the world, provided it does not compromise appropriate standards for financial stability and conduct in Australia.

Conclusion

The above examples point to the risk of mandating the adoption and acceptance of international standards, risk assessments and approval processes. A case-by-case approach to assessing the risks and drawbacks is therefore more likely to manage Australia's transition to an environment where alignment or acceptance of international standards and risk assessments is appropriate, while at the same time managing the risk that any adoption of international standards is not appropriate for Australia (see section 6 below).

5. Who will you consult and how will you consult them?

There have been some recent statements by business stakeholder groups such as the Business Council of Australia (BCA) which indicate that there is support for moves in this direction. In its

recent publication Building Australia's Comparative Advantages, the BCA recommended that *"Australian governments should adopt as a principle that where a regulated good or service is tradeable, and subject to a regulatory approval by a European Union, a US, or Canadian national regulator, then there should be a strong presumption in favour of automatic recognition of those countries' approval"*. Similarly, representations to the Australian Government from stakeholders in the gas exploration industry and in the chemicals manufacture industry have pointed to delays and costs of Australian regulators not recognising international standards and risk assessments.

Furthermore, Commonwealth portfolios have provided broad in-principle support for adopting international standards and risk assessments. However, some have noted that a number of issues will need to be taken into account including identifying trusted international standards, who conducts assessments, the appropriateness of Australian standards, potential negative impacts on Australian business, Australia's role in developing international standards, the interaction with the states and territories regulations, and the interaction with other deregulation policy work.

If option II is chosen, consultation with key stakeholders will be required as each individual review is conducted. This would include any key stakeholders who benefit or may be disadvantaged. This consultation would then inform consideration against the relevant international standard by the Government. Any change in regulation will also need to be accompanied by an appropriate regulation impact statement, which will require an appropriate level of stakeholder consultation.

6. What is the best option from those you have considered?

In light of considerations in Section 4, and the initial feedback across Commonwealth portfolios, option II is the preferred option. It proposes that opportunities for reform can be appropriately assessed on a case-by-case basis. The adoption of the principle would ensure reviews are undertaken against international standards and risk assessments. Portfolios will be required to ensure that assessments are undertaken of the need to maintain separate Australian standards rather than adopting international standards. Where scope exists for the adoption of international standards and risk assessments, or greater alignment with them, these reforms will need to be implemented in a manner that is consistent with portfolios delivering on their 2015 and 2016 red tape targets and the Government achieving its overall net $1 billion annual deregulation objective.

7. How will you implement and evaluate your chosen option?

As part of the preferred option, a number of steps will be introduced to monitor implementation and delivery against this priority:

i. The Government will track the measures that portfolios implement to accept or adopt trusted international regulatory standards and risk assessments through the existing reporting process;
ii. the Government will report specifically on portfolio progress in achieving this proposal as part of its semi-annual repeal day updates to Parliament;
iii. use the cuttingredtape.gov.au website to invite submissions to identify examples of divergence from international standards and risk assessments. These examples will be

forwarded to relevant portfolios for examination and use the website to track progress and responses to these initiatives; and

iv. portfolios and regulators will be required to publish progress in moving to accept or adopt trusted international standards and risk assessments, and any justification for divergence in individual Australian standards as part of their annual deregulation reporting activity from 2016.