



Australian Government

Department of Health

Criteria for the adoption of international standards and risk assessments by the Health portfolio regulators

The following criteria are proposed to be used by the regulators under the Health portfolio when assessing the potential for adopting international standards and risk assessments. The criteria have been developed taking into account the factors and practicalities relevant to Australia and in turn the Health portfolio regulators.

The criteria are directed at providing a framework for adopting *new* standards and assessments from international sources. It is suggested that all criteria should be met for international standards or assessments to be adopted from a particular source, that is, all questions (A to H) should be able to be answered positively or any issues that are identified in consideration of a particular criterion should be able to be resolved.

A. *Is there credible evidence that the approach to regulation taken in Australia is leading world best practice, both in terms of effectiveness and cost/efficiency?*

If this can be demonstrated credibly for a regulator, preferably through an independent evaluation, it would seem to be counterproductive to seek to adopt international assessments and standards. It is unlikely, however, to demonstrate that there is no scope for increased regulatory efficiency and effectiveness for most regulators. Through increased adoption of international standards and assessments, if there are no increased risks involved, additional opportunities to reduce regulatory burden on businesses, particularly those that operate globally, may be realised.

B. *Do relevant standards or assessments exist internationally?*

If there are international standards or assessments available, they should be further characterised by asking:

What types of standards or assessments are available internationally?

The broad nature of the available international standards and assessments should be identified as there may be a broad range available, such as:

- *complete regulatory decisions (eg. approval of a medicine or chemical);*
- *all or part of a risk assessment underpinning regulatory decisions or standards;*
- *agreed lists (eg. prohibited substances); or*
- *assessment methodologies used in conducting regulatory risk assessments.*

The considerations around adoption of trusted international standards will be quite different from those related to adoption of regulatory decisions or risk assessments (refer to *Criterion E*).

What standards or assessments are already being adopted by the Health portfolio regulator?

It is useful for completeness and transparency purposes to identify those standards and assessments that are already being adopted by a particular regulator and these can be excluded from further assessment. Any learnings from their adoption can be used to inform assessment of new standards.

C. *Are the standards or assessments available from credible, trusted sources?*

The term 'trusted' is subjective and may need to be assessed by regulators in consultation with stakeholders. Some of the characteristics of a trusted source are: a credible and consistent track record in regulating; has publicly transparent assessment processes in place and provides full access to reports and the data its regulatory decision is based on; and a record of actively managing the quality of approvals and risk assessment (such as peer review, independent assessment, auditing of processes and outcomes).

In deciding whether to adopt assessments and standards from particular sources, the focus should primarily be on the nature of the regulatory system and the quality of the regulator within it. Those regulatory systems that do not demonstrably involve high quality, objective risk assessment or whose regulatory decisions reflect local political factors should be avoided. Adoption of international consensus approaches developed by multilateral agencies that have a long established reputation and acceptance and reflect best practice, while aligning with Australia's priorities, should be preferred to adoption of standards from individual countries. It is, therefore, suggested that there are two key questions to be posed in deciding a response to this criterion:

- *Is the source a multilateral agency that has had critical engagement from many countries (preferably including the relevant Australian regulator) involved in the development of the standards, assessments or methodologies?*
- *Is the source an internationally respected single country agency that is generally recognised for the quality, robustness and transparency of its regulatory processes?*

D. Can the Australian Health portfolio regulator establish a formal and robust framework for cooperation with the source of the assessments or standards?

This criterion requires a robust framework within which relevant information on the assessments and standards developed by international sources can be shared or adopted by our regulators. A clear and preferably public framework for information sharing is essential so that there are clear expectations about important issues such as transparency, intellectual property (e.g. copyright and data protection), confidentiality, availability of complete risk assessment reports, access to the raw data on which risk assessments are based, timeframes, etc.

For standards adopted from multilateral organisations, such a framework should at least be partly in place because of Australia's obligations as an official member/ signatory. However, it is important that a formal agreement (eg. through a Memorandum of Understanding or an exchange of letters) is established to cover bilateral relationships with regulatory agencies in other countries.

E. Is the regulatory framework (e.g. governing legislation, regulations and policies) of the potential international source of the assessment or standards compatible with the Australian Health portfolio regulator's legislative and policy obligations?

The adoption of international standards and assessments must be consistent with the legal construct of the Australian regulators. The provisions of Australian legislation – for example, the factors that must be considered in reaching regulatory decisions – must be taken into account. This will include considerations of alignment of the policy objectives of the Australian and international regulator and of any factors specific to the Australian context. It will be necessary to take account of possible differences in the respective legislative mandates e.g. differences in definitions, scope of considerations, protection goals, transparency obligations, etc. Such differences, however, will not necessarily preclude adoption of international approaches. While it may not be possible to adopt complete regulatory outcomes or even complete risk assessments, it may be possible to make use of certain significant components of the regulatory process or risk assessments, while still retaining control of the final regulatory decisions. The relevant questions under this criterion are:

- *Does the risk assessment take into account the full range of factors that are prescribed in the relevant Australian legislation and regulations?*

- *Does it take into account factors that are specifically excluded in the Australian legislation?*
- *Are there any legislative conditions and government policy objectives that need to be considered?*
- *Is it compatible with the broader Australian legislation that may need to be considered, such as Australian administrative law, privacy legislation and consumer protection law?*
- *If not fully compatible with the Australian frameworks, are there components of the regulatory process or risk assessment process that can be adopted?*

F. *Is the adoption of the international assessments and standards likely to impact positively or negatively on the international reputation of the Australian Health portfolio regulator or more broadly on areas such as Australia's trade performance?*

Health portfolio regulators are generally widely respected internationally and it is important that Australia is able to continue to leverage off this standing so that Australian interests are protected. A two-pronged question would be warranted in the assessment of this criterion:

Will acceptance of particular assessments or standards enhance or diminish international respect for Australia's regulatory outcomes, thereby adversely impacting on our:

- *ability to influence the development of consensus international standards and harmonised risk assessment methodology?; and*
- *trade performance or our ability to negotiate bilateral and multilateral agreements?*

A greater level of adoption of international assessments and standards has the potential to enhance Australia's international alignment and introduce greater efficiencies in the regulatory process. However, to help ensure that these international assessments and standards reflect Australia's interests and what we consider to be best practice, it is important that Australia is able to continue to participate with authority and respect in their development in the first place.

It is particularly important in areas of regulation that impact on trade that Australia continues to participate strongly in international standards development and harmonisation of risk assessment processes so that Australia's interests are protected.

Given Australia's significant reliance on exports, it is important that our regulatory standing continues to provide a strong underpinning for our exports. Hence, every effort should be made to ensure that the adoption of international assessments and standards does not have any adverse implications on the international standing of our regulators and confidence in our regulatory outcomes.

G. Will the adoption of the international standards or risk assessments actually reduce regulatory burden, red tape and costs?

Factors to be considered in assessing this criterion will include potential impact on costs to the businesses, Australian consumers, as well as to the government/regulators. The relevant questions in the assessment of this criterion will, therefore, be:

Will adoption of international standards and assessments:

- *reduce regulatory costs for businesses operating in Australia?*
- *These costs would include more than direct fees and charges imposed by regulators (particularly where cost recovery is involved), for example, the cost of producing data for regulatory assessments and the cost associated with delays in getting products to market.*
- *reduce the time that the Australian public must wait to have access to the new products that are subject to the regulation?*
- *reduce regulatory costs and still enable the delivery of fit-for-purpose, effective regulation?*

H. Will adoption of the international standards and assessments impact adversely on stakeholder confidence in the regulatory system?

Any loss in confidence by key stakeholder groups will have an adverse impact on the ability of the regulator to deliver on its, and the Government's, objectives, which in the Health portfolio are largely directed toward protecting public health. The likely reaction to the adoption of international assessments or standards by key stakeholders, therefore, needs to be considered, by asking:

How will their adoption of international standards and risk assessments be viewed:

- *by the broader community?*

Acceptance of international standards and risk assessments needs to be progressed in such a way that the public is convinced that the adoption of international standards and assessments does not diminish health protection or the transparency and rigour with which it is provided.

- *by industry?*

Industry's support for the adoption of international standards and risk assessments is likely to depend on whether it will reduce regulatory costs for them and facilitate access to markets, or whether it will restrict access to markets in some way.

- *by the States and Territories?*

This stakeholder group may be relevant for some regulators and is likely to be supportive in cases where there is scope for savings through reductions in costs associated with fragmentation of regulations between Commonwealth and Australian states and territory authorities.

- *by our international stakeholders?*

[\(refer to criterion 'F' above\)](#)