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Best Practice Principles Checklist for Chemical Regulations

Purpose: Consideration
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APEC CHEMICAL DIALOGUE BEST PRACTICE CHECKLIST EXECUTIVE SUMMARY

Background / Key Issues

The chemical industry is one of the largest and most globalized industrial sectors in the world and makes a considerable contribution to the economy. Chemicals are a core component in over 96 percent of manufactured goods. Regulatory divergences therefore impose substantial unintended costs on industry, including downstream industries and end-users, and affect marketing, research and development.

APEC Member Economies recognize that regulatory reform is a central element in the promotion of open and competitive markets, and a key driver of economic efficiency and consumer well-being. Regulatory cooperation has long been cited as a top priority within the Chemical Dialogue (CD). As there is no "one size fits all" approach to regulatory cooperation, in 2008 the Chemical Dialogue developed The Best Practice Principles to help guide cooperative activities within APEC towards successful, productive outcomes. The principles call for regulations to be efficient and minimum required to successfully achieve their stated objectives; that they adopt a risk management approach; that they minimize unnecessary impact on competition; that they not restrict international trade flows; that they be developed in consultation with stakeholders; that they be flexible; and that chemical regulatory decisions be science based.

With numerous APEC economies in the process of revising chemical regulations the focus of the Chemical Dialogue has turned to implementation of the Best Practice Principles. In order to help economies that are considering reforms or new legislation a checklist has been devised which provides a list of questions to consider whenpreparing to implement the Best Practice Principles.

The Dialogue can serve an important role in promoting best practices in regulation as well as in information sharing during the regulatory process to help prevent unnecessary barriers while increasing safety and environmental protection. The CD intends to continue this work through a workshop in 2017 to build the capacity of chemical regulators to implement the best practices. This ongoing work program will help to increase transparency, reduce business uncertainties and result in greater innovation and safer technologies by promoting the safe and sustainable use of chemicals.

Required Action/Decision Points

1. It is recommended that Ministers endorse the APEC Chemical Dialogue's Best Practice Principles Checklist to help economies apply those Principles during the regulatory review and rule-making process.

No	Best Practice Principle	Yes	No	Yes	No
1.	CHEMICAL REGULATIONS SHOULD BE THE MINIMUM REQUIRED TO ACHIEVE THEIR STATED OBJECTIVES			☐	☐

	• Has a problem that justifies regulation been identified?
	• Has a case for regulatory action been made?
	  o Have all relevant existing regulations at all levels of government been assessed to demonstrate that they do not adequately address the problem?
	  o Is the regulatory action under consideration focused on achieving the objective, and targeted to achieve the objective (eg specifically and significantly mitigate an identified unacceptable risk)?
		☐
		☐
			☐
			☐		

	• Have all of the alternatives to government regulation been assessed, including consideration of existing requirements, self-regulation, co-regulation and non-regulation?	☐	☐		

	• Has a cost benefit analysis been done?
	  o Has an appropriate baseline (ie how the world would look in the absence of the proposed action) been used?
	  o Have all the benefits and costs of potentially effective and reasonably feasible alternatives been assessed?
	  o Have all the impacts on consumers and business, particularly small business been assessed?
	  o Have the benefits and costs of the preferred option been quantified and to the extent possible, monetized?
	  o Have appropriate discount rates been used for benefits and costs that are expected to occur in the future?
		☐	☐		

2.	CHEMICAL REGULATIONS SHOULD ADOPT A RISK MANAGEMENT APPROACH TO DEVELOPING AND ADMINISTERING REGULATION			☐	☐
	• Has a risk assessment been undertaken? o Does the assessment adequately address exposure as well as hazard?	☐	☐		
	• If the problem involves unacceptable risks, have all the risks been properly identified?	☐	☐		
	• Is the level of intervention commensurate with the risk posed?	☐	☐		
	• Is there clear authority to take risk management actions?	☐	☐		
3.	CHEMICAL REGULATIONS SHOULD MINIMIZE THE UNNECESSARY IMPACT ON COMPETITION			☐	☐
	• Will the regulations restrict competition? o Has the impact assessment identified impact on incumbent business?	☐	☐		

	○ Will it restrict entry on new business? ○ Has an assessment of prices and production been done? ○ Will quality of goods and services be affected? ○ Will innovation be restricted? ○ Will there be impacts on market growth?				
	• If the regulations restrict competition, ○ Does the regulation maximise net benefits? ○ Can the objectives of the regulation be met any other way which does not restrict competition?	☐	☐		
4.	CHEMICAL REGULATORS SHOULD UTILIZE INTERNATIONAL STANDARDS AS APPROPRIATE			☐	☐
	• Has guidance been developed for assisting regulators in assessing whether a standard being considered was developed in an open, transparent, consensus-based process in line with the WTO TBT Committee Decision (G/TBT/1/Rev1.2, Annex 2)? • Are such existing standards relevant?	☐	☐		
	• Can international standards be adopted instead of unique domestic regulations, as the basis for regulation? • Have unique local conditions been considered when determining the extent to which an international standard can be adopted?	☐	☐		
5.	CHEMICAL REGULATIONS SHOULD NOT RESTRICT INTERNATIONAL TRADE FLOWS			☐	☐
	• Could the regulation act as a barrier to trade? ○ Has the potential impact on trade been assessed as part of the cost-benefit analysis or impact assessment? ○ Is there sufficient time provided between publication of the final regulation and its date of effect so as to allow market participants to adjust to the new requirements (including taking into account the need for translation, changes to manufacturing processes, shipping times, product already in the pipeline)?	☐	☐		
	• Does the regulation discriminate in favour of domestic products?	☐	☐		
	• Have all relevant trade agreements been considered?	☐	☐		
	• Has the WTO been notified? ○ Have comments from importers and foreign stakeholders and trading partners been assessed and reflected as appropriate?	☐	☐		
6.	CHEMICAL REGULATIONS SHOULD BE DEVELOPED IN CONSULTATION WITH STAKEHOLDERS, SUBJECT TO PUBLIC REVIEW AND COMMENT AND PERIODIC REVIEW			☐	☐
	• Were the stakeholders most likely to be impacted identified and consulted early on in the process?	☐	☐		
	• Were all stakeholders, including those outside of the economy, given an equal opportunity to access	☐	☐		

	available documents (including the text of the regulatory proposal and any risk assessment or regulatory impact assessment) and provide timely input?				
	• Have all decisions been explained and feedback provided?	☐	☐		
	• Has a timetable for monitoring and review been provided?	☐	☐		
	• Is there a mechanism to ensure that all comments on a proposal are adequately addressed before it is finalised?	☐	☐		
7.	CHEMICAL REGULATIONS SHOULD BE FLEXIBLE, NOT PRESCRIPTIVE, AND BE COMPATIBLE WITH THE BUSINESS OPERATING ENVIRONMENT			☐	☐
	• Has the regulation been tested with business to ensure ease of implementation?	☐	☐		
	• Does the regulation have clearly identifiable outcomes?	☐	☐		
	• Has the regulation been drafted in plain easy to understand language?	☐	☐		
	• Is the regulation performance based?	☐	☐		
8.	CHEMICAL REGULATORY DECISIONS SHOULD BE SCIENCE BASED			☐	☐
	• Is the regulatory action based on relevant and objective scientific and/or technological information and processes?	☐	☐		
	• Are there established data and method quality criteria?	☐	☐		
	• Does scientific information relied upon meet high standards for quality and meet any applicable data and method quality criteria?	☐	☐		
	• Has all the available scientific information been considered in a weight of evidence evaluation?				
9.	CHEMICAL REGULATORY DECISIONS SHOULD HAVE A CLEAR DELINEATION OF REGULATORY RESPONSIBILITIES AND EFFECTIVE AND TRANSPARENT ACCOUNTABILITY MECHANISMS			☐	☐
	• Is the regulatory authority clearly identified?	☐	☐		
	• Does the regulatory authority have the capacity and resources to effectively implement the requirement?	☐	☐		
	• Have all relevant authorities for chemicals management been consulted and notified of changes?	☐	☐		
	• Are the compliance requirements clear and unambiguous?	☐	☐		
	• Can the regulations be enforced?	☐	☐		