



**Asia-Pacific
Economic Cooperation**

2014/SOM3/CD/002

Agenda item: 1

Principles for Best Practice Chemical Regulation

Purpose: Information

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Forum Doc. No.: 2008/SOM2/CD/002rev1 & 2008/SOM2/CTI/024att2



**13th Chemical Dialogue
Beijing, China
12 August 2014**

APEC CHEMICAL DIALOGUE

May 22, 2008

PRINCIPLES FOR BEST PRACTICE CHEMICAL REGULATION

PART 1: PREAMBLE

1.1 Why regulate chemicals?

We use chemicals every day and they are an integral part of our lives. The global production, trade, use, recycling and disposal of chemicals continues to increase with demand. When appropriately managed, chemical products contribute to the social and economic well-being of Member Economies.

It is only through the sound management of chemicals in protecting human health and our environment that economies are able to enjoy the full benefits that the use of chemicals can offer.

The sound management of chemicals may be viewed as the application of managerial best practice to chemicals throughout their life-cycle, so as to minimise risks of health and environmental impacts from the production, use and disposal of chemicals.

The role of government is to provide a policy and regulatory framework to ensure the safe and sustainable use of chemicals and to deliver a business operating environment which stimulates growth, innovation and trade. Governments regulate chemicals to protect human health, worker safety and the environment.

The challenge is to deliver efficient and effective regulation without undue burden on those being regulated.

1.2 What is Chemical Regulation?

Chemical regulation can be defined as a government endorsed measure(s) or intervention(s) that influences the way chemicals are manufactured and used across the product life cycle by industry, the community and individuals.

The challenge is to design and implement regulation which is no more trade restrictive than necessary to achieve its stated objectives.

In practice, regulation is usually a blended approach of voluntary, co-regulatory and legislative mechanisms undertaken in partnership between government, industry and community.

1.3 Why Best Practice Regulation?

The controls imposed on the chemical industry are many and often arise from cross jurisdictional responsibilities that may result in duplication of regulatory effort by Member Economies. These pressure points create an unstable business environment which detracts from other investments in research and development and innovation designed to help

increase the competitiveness, efficiency and safety of chemicals in the marketplace of our region.

Achieving good regulation involves the integration of a number of key factors including:

- o sound and credible science to identify the problem;
- o an effective risk management framework that considers costs and benefits and socio-economic factors;
- o regulations that are commensurate with the risk posed;
- o flexibility in the application and type of measures to best deliver desired outcomes;
- o the avoidance of duplication;
- o transparent and consistent approaches and open decision making processes;
- o public participation and engagement in partnership approaches; and
- o the wide availability of chemical safety information tailored to stakeholders needs.

These factors are applicable to the consideration and development of full spectrum of regulatory measures including voluntary, co-regulatory and/or legislative mechanisms.

The *Principles for Best Practice Chemical Regulation* also provide Member Economies with a mechanism for the identification of areas that would benefit most from regulatory reform, as well as assisting with market reform and openness and the application of best practices where appropriate.

PART 2: PURPOSE OF PRINCIPLES FOR BEST PRACTICE CHEMICAL REGULATION

2.1 APEC Agreed Regulatory Principles

APEC Member Economies already 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. This is reflected in the agreement for an APEC-OECD Co-operative Initiative on Regulatory Reform reached in June 2000 and endorsed at the APEC Ministerial Meeting on 12-13 November 2000 in Brunei Darussalam.

Many economies within APEC have individually embarked on ambitious programmes to reduce regulatory burdens and improve the quality and cost-effectiveness of regulations. Member Economies have collectively endorsed regulatory reform principles and policy recommendations at the highest political levels¹.

2.2 Benefits of Chemical Specific Best Practice Regulation Principles

Although there is no single model of regulatory reform, the development of a set of guiding principles for best practice chemical regulation aims to promote consistency and facilitate harmonised approaches for cooperation by Member Economies to the regulation of the chemical industry.

The value in Member Economies exploring the development of a best practice framework for chemical regulation lies in the opportunity to address the business uncertainties. This should result in greater innovation, safer technologies, enhanced trade at reduced business

¹ The 1999 APEC Economic Leader's Declaration, containing the APEC Principles to Enhance Competition and Regulatory Reform, The 1997 OECD Policy Recommendations on Regulatory Reform, and The 1995 OECD Recommendation on Improving the Quality of Government Regulation.

costs and is consistent with the objective for the safe and sustainable use of chemicals. Further, regulators in Member Economies benefit from the ability to cooperate on issues of mutual concern, exchange information, coordinate, share burdens associated with potential elements of risk assessment and facilitate risk management solutions where necessary.

2.3 Guidelines and Practical Tools

This document is aimed at providing a suitable framework for Member Economies to use when developing and implementing regulatory measures. The framework is considered broad enough to be utilised by Member Economies regardless of social, political or economic environments or stage of development.

A compendium of case studies and practical experiences may help to promote greater opportunities for learning as well as for cooperation between Member Economies. This cooperation may come from enhanced information sharing/exchange, harmonisation or mutual recognition or through a work share program.

PART 3: PRINCIPLES FOR BEST PRACTICE CHEMICAL REGULATION

According to the OECD and other experts, regulations that conform to best practice are characterised by the following nine principles and features:

PRINCIPLE 1: CHEMICAL REGULATIONS SHOULD BE THE MINIMUM REQUIRED TO ACHIEVE THEIR STATED OBJECTIVES

- Minimum necessary to achieve objectives:
 - Ensure overall benefits justify costs, and ensure that the regulatory approach chosen has higher net benefits than its feasible alternatives.
 - Keep simple to avoid unnecessary restrictions
 - Target at the problem to achieve the objectives
 - Do not impose an unnecessary burden on those affected
 - Do not restrict competition, unless demonstrated net benefit
- Not unduly prescriptive
 - Performance and outcomes focussed
 - General rather than specific
- Accessible, transparent and accountable
 - Readily accessible to the public
 - Easy to understand
 - Flexible enough to deal with special circumstances
 - Open to appeal and review
- Integrated and consistent with other laws
 - Address a specific market failure or other significant problem not addressed by other regulations
 - Recognise existing regulations so as to avoid overlap/duplication and international obligations
- Recognise industry voluntary measures
 - Voluntary industry programs such as Responsible Care and the Global Products Strategy provide effective tools to help manage the health, safety and environmental aspects of a chemical throughout its lifecycle.
- Communicated effectively
 - Written in plain language
 - Clear and concise

- Mindful of the compliance burden imposed
 - Proportionate to the problem
 - Set at levels that avoid unnecessary costs
- Enforceable
 - Provides minimum incentives needed for reasonable compliance
 - Able to be monitored and policed effectively
 - Fairly and consistently enforced

PRINCIPLE 2: CHEMICAL REGULATIONS SHOULD ADOPT A RISK MANAGEMENT APPROACH TO DEVELOPING AND ADMINISTERING REGULATION

The term 'risk' refers to the probability that a particular hazard will cause harm, or that it may lead to the occurrence of an undesirable event. The analysis of risk comprises an understanding of both hazards and exposure so that well-defined systems will enhance decision making by contributing to a greater insight into risks and their potential consequences.

It is through strategic analysis of the environment in which the regulatory body operates that those elements that may generate future risks will be identified and assessed. The objective of risk analysis is to develop efficient and effective risk management strategies through the analysis of data to assist in the identification, assessment and management of risk.

The benefits of prudent risk management are:

- a more rigorous basis for strategic planning as a result of a structured consideration of the key elements of risk;
- no costly surprises or unintended consequences to industry;
- better outcomes in terms of program effectiveness and efficiency, e.g., improved service and/or better use of resources;
- greater openness and transparency in decision-making and ongoing management processes; and
- a better preparedness for, and facilitation of, positive outcomes from subsequent internal/external review and audit processes.

PRINCIPLE 3: CHEMICAL REGULATIONS SHOULD MINIMIZE THE IMPACT ON COMPETITION

Regulation should be designed to have minimal impact on competition. Although it may be necessary, for example, to regulate some aspects of commercial practice, regulation should avoid imposing barriers to entry, exit, or innovation. Regulation should not restrict competition unless it can be demonstrated, in a fully transparent manner, that:

- the benefits to the community from a restriction on competition outweigh the costs; and
- that the objectives of regulation can only be achieved by restricting competition.

PRINCIPLE 4: CHEMICALS REGULATORS SHOULD UTILIZE RELEVANT INTERNATIONAL STANDARDS WHEREVER POSSIBLE

The WTO Agreement on Technical Barriers to Trade (TBT) recognizes the important contribution that international standards make in furthering the objectives of the General Agreement of Tariffs and Trade (GATT) 1994 by improving efficiency of production and facilitating international commerce. The Agreement obliges WTO Members to use relevant international standards (if such standards exist or their completion is imminent), or the relevant parts thereof, as a basis for their technical regulations, except when such standards or their relevant parts would be an ineffective or inappropriate means for fulfilling the legitimate objectives pursued.

Within APEC, Member Economies have committed to harmonizing their standards, for example:

- with international standards, wherever possible, by the year 2010 in the case of industrialised economies and 2020 in the case of developing economies;
- for radios and their parts, televisions, video apparatus, refrigerators, air-conditioners, industrial robots, rubber surgical and examination gloves, rubber condoms and food labelling by the year 2000 in case of industrialised economies and the year 2005 in the case of developing economies; and
- for electrical safety and electromagnetic compatibility with the IEC 60335 and CISPR series of standards, respectively, by the year 2004 in the case of industrialised economies and the year 2008 in the case of developing economies.

PRINCIPLE 5: CHEMICAL REGULATIONS SHOULD NOT RESTRICT INTERNATIONAL TRADE FLOWS

There should be no discrimination in the way technical regulations, standards, and conformity assessment procedures are applied between domestic and imported products, nor between imports from different supplying economies. Regulations should not be applied in a way that creates unnecessary obstacles to international trade.

PRINCIPLE 6: CHEMICAL REGULATIONS SHOULD BE DEVELOPED IN CONSULTATION WITH STAKEHOLDERS, SUBJECT TO PUBLIC REVIEW AND COMMENT AND PERIODIC REVIEW

Effective consultation is fundamental in ensuring that the optimal regulatory outcomes are achieved. Consultation ensures that both the regulator and the regulated understand the problems, have alternative options to address the problems, and can identify costs as well as enforcement and compliance mechanisms in administering the regulatory requirements. It also enables civil society to engage directly with government in identifying and addressing problems, leading to a more engaged and constructive dialogue with all parties involved. Consistent with APEC's Transparency Standards² as agreed by Leaders in 2002 and 2003, consultation should involve procedures that provide for advance notice of proposed rule-making; an adequate comment period; notice of final regulation, which should include a thorough response to comments received; and, adequate time for implementation.

The seven principles for best practice consultation are:

² APEC Transparency Standards available at:
http://www.apecsec.org/apec/leaders_declarations/2003_leaderssttmimplapectranspstd.html.

- Continuity - Consultation should be a continuous process that starts early in the policy development process.
- Openness - Consultation should be widely based to ensure it captures the diversity of stakeholders affected by the proposed changes. This includes the affected industry, the general public; trading partners; and relevant departments and agencies at all levels of government.
- Appropriate timeliness - Consultation should start when policy objectives and options are being identified and comments can still be taken into account. Throughout the consultation process, stakeholders and the general public should be given sufficient time to provide considered responses.
- Accessibility - Stakeholder groups and the general public should be informed of consultations through publication of proposed measures (preferably by electronic means), and be provided with information about proposals, via a range of means appropriate to those groups.
- Transparency - Policy agencies need to explain clearly the objectives of the consultation process and the regulation policy framework within which consultations will take place, and provide thorough feedback on how they have taken consultation responses into consideration, including providing a public response to the comments received.
- Consistency and flexibility - Consistent consultation procedures can make it easier for all interested stakeholders to participate.
- Evaluation and review - Policy agencies should evaluate consultation processes and continue to examine ways of making them more effective.

PRINCIPLE 7: CHEMICAL REGULATIONS SHOULD BE FLEXIBLE, NOT PRESCRIPTIVE, AND BE COMPATIBLE WITH THE BUSINESS OPERATING ENVIRONMENT

There are three main types of regulations:

- Design based – which specify the means for attaining the specified outcome.
- Performance based – which specify the desired objective in precise terms but allow the regulated entity to determine its own technique for achieving the outcome. Within the performance-based approach to regulation, market-oriented mechanisms that use economic incentives such as marketable permits and offsets should be explored. A market approach can be extremely valuable in reducing costs or achieving earlier or greater benefits, particularly when the costs of achieving compliance vary across production lines, facilities, or firms.
- Market based – which use economic incentives, such as fees, marketable, tradeable permits, or changes to liability or property rights, to achieve a regulatory goal.

In general, regulatory instruments should at least be performance-based, that is, they should focus on outcomes rather than inputs. ‘Deemed to comply’ provisions may be used in instances where certainty is needed. In such cases, regulations might refer to a standard or a number of standards deemed to comply with the regulation. In addition, market-based approaches, where feasible, often can achieve even higher efficiency by focusing on overall outcomes, while allowing an industry to trade the regulatory obligation to the lowest cost producer.

PRINCIPLE 8: CHEMICAL REGULATIONS SHOULD BE SCIENCE-BASED

Good regulation should attempt to standardise the exercise of bureaucratic discretion, so as to reduce discrepancies between government regulators, reduce uncertainty, and lower compliance costs. However, this should not preclude an appropriate degree of flexibility to permit regulators to deal quickly with exceptional or changing circumstances or recognise individual needs. Nor should it ignore the danger of administrative action effectively constituting regulation and thus avoiding disciplines of regulation review. There is a need for transparency and procedural fairness in regulation review, and administrative decisions should be science-based and subject to effective administrative review processes.

PRINCIPLE 9: CHEMICAL REGULATIONS SHOULD HAVE A CLEAR DELINEATION OF REGULATORY RESPONSIBILITIES AND EFFECTIVE AND TRANSPARENT ACCOUNTABILITY MECHANISMS

Overlapping or inconsistent regulation within the jurisdictions of Member Economies can have significant adverse consequences for economic and regulatory efficiency. High level political support is critical for implementing successful regulatory reform initiatives. An integrated policy is essential in ensuring that policies and regulations for all concerned areas are mutually supportive and not duplicative. There is also a need for institutional mechanisms to monitor and enforce the integrated policy and to oversee the cost benefit and regulatory impact assessment processes established to introduce transparency and accountability into the regulation making processes.

The overarching institutional framework for the harmonisation of regulation should:

- Encourage continuous dialogue with the regulated community and other stakeholders regarding conflicting or duplicative mandates to achieve greater regulatory efficiency within and among Member Economies;
- Encourage the timely development of consistent and preferably uniform regulations;
- Discourage regulatory agencies and standards setting bodies from adopting unduly stringent and poorly justified regulations;
- Promote compliance with decisions to rationalise and harmonise areas of regulation.

PART 5: BIBLIOGRAPHY & REFERENCES – to be further developed to include a more comprehensive list of available resources preferably with electronic links to facilitate accessibility

APEC Information Notes on Good Practice for Technical Regulation, APEC SCSC September 2000;

APEC Best Practice for Regional Free Trade and Free Trade Agreements and Other Preferential Arrangements; APEC November 2004

APEC-OECD Integrated Checklist on Regulatory Reform 2005
<http://www.oecd.org/dataoecd/41/9/34989455.pdf>

Best Practice Regulation Handbook, The Office of Best Practice Regulation, Australian Government, November 2006

OECD Guiding Principles for Regulatory Quality and Performance, OECD 2005

Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard-Setting Bodies, Council of Australian Governments, June 2004

Rethinking Regulation, Commonwealth of Australia 2006

The Business of Chemicals is Everywhere, APEC website,
http://www.apec.org/apec/apec_groups/committees/committee_on_trade/chemical_dialogue.MedialibDownload.v1.html?url=/etc/medialib/apec_media_library/downloads/committees/cti/pubs/2003.Par.0002.File.v1.1

Underpinning Australia's Industrial Growth – Government Response, Commonwealth of Australia November 2002

SUPPORTING DOCUMENTATION

The Importance of the Chemical Sector in APEC Member Economies - see Supporting Document A.