Asia-Pacific
Economic Cooperation

4th Conference on Good Regulatory Practice

(CTI 18/2006T Project)

September 4, 2006
Furama Resort, Da Nang city, Vietnam

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Contents

1	Foreword	2
2	Document list	4
3	Final program	6
4	Opening remark	8
5	Session 1: Regulation and Trade	11
5.1	Development and Implementation of the APEC Work Program on Trade Facilitation in Information Technology Products	13
5.2	Good Regulatory Practice Guidance	24
5.3	Benefits to the Wine Industry from Reducing Barriers to Trade and Improving Consumer Understanding Though the Harmonization of Labeling	33
6	Session 2: Performance Based Regulation	60
6.1	Guide on Establishing Technical Regulation Based on Application of Indonesian National Standard (SNI)	62
6.2	Relationships Between Business Sectors and Regulatory Bodies in Vietnam	74
6.3	A Case Study of Regulatory Impact Analysis (RIA)	85
6.4	Australian Performance-Based Regulatory System	94
7	Appendix	106
7.1	Information Notes on Good Regulatory Practice for Technical Regulation	108

Foreword

This booklet is a collection of all papers which were presented or submitted by SCSC members and invited speakers for the 4th Conference on Good Regulatory Practices to be held on September 4, 2006 at the Furama Resort in Da Nang city of Vietnam. The first conference of its kind was held in 2000. The importance of elements related to Good Regulatory Practice and its impact on trade flows has been addressed by the Subcommittee for Standards and Conformance during the first conference on GRP and since then SCSC decided to hold the conference on GRP in every two years. The 4th Conference was organized successfully by the host with a support fund of APEC-TILF (Trade and Investment Liberalization and Facilitation) program, CTI-18/2006T project.

Attending this conference, there were about 270 participants in total, among them more than 100 coming from public sector, 70 from the private one and other 100 from overseas including 14 SCSC member representatives. There were 7 papers to be presented. Following are some main outcomes of the conference:

- To achieve a strong conceptual framework regarding to Good Regulatory Practice and its relevance regarding to trade flows.
- To explore and continue identifying current state and challenges for these practices in the future (considering work done on SCSC).
- To highlight the interdependence of Regulatory Reform elements and their importance to decrease technical barriers to trade and to promote more goods and investment exchange within the APEC region.
- To promote the transfer of knowledge and expertise from the developed countries to developing countries.

I am really pleased to have these outcomes of the conference. Taking this opportunity and on behalf of the host – The Directorate for Standards and Quality of Vietnam, I deeply appreciate APEC Secretariat' strong support and close cooperation in organizing the event. My deep appreciation also would like to go to all SCSC members in contributing to the success of the conference.

Ha Noi, November 7, 2006

Dr. Ngo Quy Viet
Project Overseer/Director General
Directorate for Standards and Quality

Asia-Pacific
Economic Cooperation

2006/SOM3/SCSC/GRP/000

Document List

Purpose: Information
Submitted by: APEC Secretariat

4th Conference on Good Regulatory Practices
Da Nang, Viet Nam
4 September 2006

Document List

Doc. No.	Title	Submitted by
2006/SOM3/SCSC/GRP/000	Document List - 4th Conference on Good Regulatory Practices 2006	APEC Secretariat
2006/SOM3/SCSC/GRP/001	Final Program - 4th Conference on Good Regulatory Practices 2006	Viet Nam
2006/SOM3/SCSC/GRP/002	Development and Implementation of the APEC Work Program on Trade Facilitation in Information Technology Products	Ann Rollins, Vice President, Technology & Trade Information Technology Industry Council (ITI)
2006/SOM3/SCSC/GRP/003	Good Regulatory Practice Guidance	John Henry, Director-International and Standardization Policy, Standards Australia
2006/SOM3/SCSC/GRP/004	Benefits to the Wine Industry from Reducing Barriers to Trade and Improving Consumer Understanding Though the Harmonization of Labeling	Tony Battaglene, Director, International & Regulatory Affairs, Winemakers Federation of Australia, Australia
2006/SOM3/SCSC/GRP/005	Guide on Establishing Technical Regulation Based on Application of Indonesian National Standard (SNI)	National Standardization Agency of Indonesia (BSN)
2006/SOM3/SCSC/GRP/006	Relationships Between Business Sectors and Regulatory Bodies in Vietnam	Le Dang Doanh, Advisor to the Minister of Planning and Investment and Consultative Member of the Prime Minister's Research Commission for Social-Economic Issues (PMRC)
2006/SOM3/SCSC/GRP/007	A Case Study of Regulatory Impact Analysis (RIA)	Jennifer Fang-Yu Huang, Council for Economic Planning and Development, Chinese Taipei
2006/SOM3/SCSC/GRP/008	Australian Performance-Based Regulatory System	Ivan Donaldson, General Manager, Australian Building Codes Board
2006/SOM3/SCSC/GRP/009	Information Notes on Good Regulatory Practice for Technical Regulation	Australia

Asia-Pacific
Economic Cooperation

2006/SOM3/SCSC/GRP/001

Final Program

Purpose: information
Submitted by: Vietnam

Sub-committee for Standards and Conformance

Furama Resort, Da Nang, Viet Nam

4 September 2006

Final Program

08:30 - 09:30	Registration
09:30 - 09:45	Inauguration
09:45 - 10:30	Session I: Regulation and Trade
09:45 - 10:05	***Development and Implementation of the APEC Work Program on Trade Facilitation in Information Technology Products***
	Speaker: Ms. Ann Rollins, Information Technology Industry (ITI) Council, US
10:05 - 10:25	***Good Regulatory Practice Guidance***
	Speaker: Mr. John Henry, Director, International and Standardization Policy, Standards Australia
10:25 - 11:00	Coffee Break
11:00 - 12:00	Session I: Regulation and Trade (continued)
11:00 - 11:20:	***Benefits to the Wine Industry from Reducing Barriers to Trade and Improving Consumer Understanding Though the Harmonization of Labeling***
	Speaker: Mr. Tony Battaglene, Director, International & Regulatory Affairs, Winemakers Federation of Australia
11:20 - 12:00	Q & A Chaired by Dr. Du Chinjing, Deputy Director, International Cooperation, CNCA, China
12:00 - 14:00	Lunch
14:00 - 15:30	Session II: Performance-Based Regulation
14:00 - 14:20	***Guide on Establishing Technical Regulation Based on Application of Indonesian National Standard (SNI)***
	Speaker: Mr. Nyoman on behalf of Dr. Sunarya, Deputy Director General for Accreditation and Standard Application, Indonesia
14:20 - 14:40	***Relationships between business sectors and regulatory bodies in Vietnam***
	Speaker: Dr. Le Dang Doanh, Advisor to the Minister of Planning and Investment and Consultative Member of the Prime Minister's Research Commission for Social-Economic Issues (PMRC)
14:40 - 15:00	***Case Study of Regulatory Impact Analysis-RIA***

	Speaker: Ms. Jennifer Fang-Yu Huang, Section Chief, Center for Economic Deregulation and Innovation (CEDI Services), CEPD, Chinese Taipei
15:00 - 15:30	Coffee Break
15:30 - 16:30	Session II: Performance-Based Regulation (continued)
15:30 - 15:50:	***Performance-Based Building Regulations***
	Speaker: Mr Ivan Donalson, General Manager of the Australian Building Codes Office (ABCB), Australia
15:50 - 16:30	Q & A Chaired by Mr. John Henry, Director, International and Standardization Policy, Standards Australia
16:30 - 17:00	Conclusions and Closing (2007 SCSC Chair - Australia)

Opening remark

By Mr. Tran Van Hoc - SCSC Chair

Ladies and gentlemen,

On behalf of the host organization and as SCSC Chair I would like to warmly welcome all of you, representative from different agencies, institutions, local governments and business sectors to the 4th SCSC Conference on Good Regulatory Practices.

I would like to extent our special warm greetings and gratitude to the speakers and those of you who came to Viet Nam from APEC region's economies to attend this conference

As you may know, Viet Nam is the country of transition, and in this year Viet Nam is going to be accepted as member of World Trade Organization. Integration to the world economy is our high priority in the economic development strategy in achieving open trade and strong domestic markets. In this scene, Good Regulatory Practice is a very important issue for us to follow up the above strategy and policy.

Over the past 10 years, Viet Nam has an economy which is opening to foreign trade by following step by step our roadmap to access to the WTO. Our policy has aimed to improve and ensure access for Viet Nam exports to the principal world markets and, simultaneously, to stimulate domestic and foreign investment. Viet Nam has pursued its objectives by the way of Multilateral and bilateral free trade like AFTA and others and economic cooperation Agreements and also of course through an active participation in regional and multilateral forum.

Understand the importance of the role of the standards, technical regulations and conformity assessment in our accessing process to the world economy, Viet Nam National Assembly have recently approved the Law on Standards and Technical regulations which could be used I hope, as good legal framework for the development of the good regulatory practice in Viet Nam.

Ladies and Gentlemen,

During the last decades, the tariff liberalization process that has taken place throughout the world and the importance of -inter alia - achieving adequate health, safety, consumer information and environmental objectives, have made the issue of technical barriers to trade which became one of most relevant ones on the international trade agenda. These developments have resulted in a strong increase of non tariff import regulations, not yet harmonized internationally, moving to the forefront as market access issues.

It is quite clear that regulatory interventions most of the time are necessary to safeguard consumer health and safety, to avoid deceptive practices and to protect the environment. However, misused or excessive regulation may harm international trade, by increasing the cost of trade and limiting competition. Therefore, the implementation of so called public

policies that avoid discrimination, promotion of fair trade and reduce the impact of potential market failures are encouraged

In this scene, the SCSC's main objective is to facilitate trade by promoting policies and practices that reduce transaction costs and stimulate competition. For the Trade globalization, the development of standards and technical regulations according to the WTO TBT principles are encouraged by SCSC in order to protect economy's own markets, as well as, assure access to third markets...

As a part of its work, the Standard and Conformance Sub-Committee has developed guidelines for the preparation, adoption and review of technical regulations, which are based on WTO principles that recognize the legitimate objectives of regulations. By promoting similar approaches, consistency and transparency of technical regulation may play an important role in reducing unnecessary obstacle to trade. Another step forward is the draft Guide for Good Regulatory Practice, which contains a number of practices that set goals for future regulatory environment.

Good regulatory practices improve economic wellbeing, and create an economic environment that facilitates competition and trade. They also are providing clear and fair rules for the markets, granting the conditions to achieve economic development and foster innovation in order to impose unnecessary transaction costs, avoid market protectionism.

The SCSC conference on GRP is organized every two years, and considered as valuable contribution of the SCSC in seeking and attaining good regulatory practices in APEC region. It is a good opportunity where we can exchange and share our practice and experiences or create the new ideas on the large fields of the GRP and to recommend the actions to be implemented in the Future

This conference also is aiming to magnify SCSC positive impact on business community by contributing to further development of "APEC Information Notes on Good Practice for Technical Regulations" which draw on best practice principles and complement guideline core and principles established on "Guide for Alignment of APEC Economies' Standards with International Standards" and "APEC Guidelines for Preparation, Adoption and Review of Technical Regulations".

The 4th SCSC conference is continual efforts of SCSC member economies. It has the intention to support and deepen the work already done before in previous conferences and to remark the importance of elements related to Good Regulatory Practice and its impact on trade flows. Special importance will be given to performance regulations and its effects in regulatory regimes.

The 4th SCSC Conference on GRP provides an additional opportunity for economic cooperation and capacity building that strengthens the performance of the economies in the

region. During this Conference, we will share information about regulatory systems, Analyze the conditions that allow regulations to become trade facilitators rather than technical obstacles to trade; Talk about case study on the practices of using different models or mechanisms like Regulatory Impact analysis to develop infrastructure that is necessary to successfully ensure regulation conformance etc.

Lastly, I hope we will have very productive discussion at the conference so that every participant can get his benefits by active participation in the conference

I would like to wish you all in good heath and conference every success, and I also do hope that you will have a nice stay in this nice sunny beach Danang city

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Session I: Regulation and Trade

Asia-Pacific
Economic Cooperation

2006/SOM3/SCSC/GRP/002

Development and Implementation of the APEC Work Program on Trade Facilitation in Information Technology Products

Submitted by: Ann Rollins, Vice President, Technology & Trade
Information Technology Industry Council (ITI)

4th Conference on Good Regulatory Practices
Da Nang, Viet Nam
4 September 2006

4th Conference on Good Regulatory Practices
APEC Sub-Committee on Standards and Conformance (SCSC)
Da Nang, Viet Nam
4 September 2006

Development and Implementation of the APEC Work Program on Trade Facilitation in Information Technology Products

Ann Rollins
Vice President, Technology & Trade
Information Technology Industry Council (ITI)

Information Technology Industry Council

ITI represents the leading global providers of information technology products and services.

Accenture
Agilent Technologies
AMD
Apple Computer
Applied Materials
Canon USA
Cisco Systems
Corning
Dell Computer
Eastman Kodak
eBay
EMC
Hewlett-Packard
Honeywell
IBM
Intel
Lenovo
Lexmark
Micron
Microsoft
National Semiconductor
NCR
Oracle
Panasonic
Qualcomm
SAP
Sony Electronics
Sun Microsystems
Symbol Technologies
Tektronix
Time Warner
Unisys
Verisign
Vonage

ICT Industry View on EMC, Safety and Telecom Legal Compliance

ICT companies want:

- **Safe, legal products fast, at low cost, for our customers**
- **Easy, cost-effective market access to the world for our global business units**

Every responsible ICT company manages …

Illustrative example marks on power supply or notebook

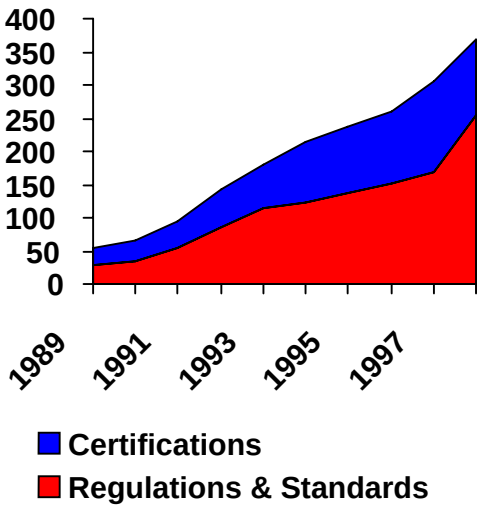
- **PRODUCT COMPLIANCE**
- Design requirements
- Product testing & certification
  - ✓ Testing & test reports
  - ✓ Compliance statements
  - ✓ Certifications
  - ✓ Marks & labels
- Government audit/surveillance
- Authority interface for recalls

CUSTOMER SALES & SUPPORT

Support for RFP's
After sales support
Customer incidents

Proliferating regulations in 1990's

7X increase in the '90's



Negatively impact Companies

- Limit flexibility of product design and innovation
- Limit scale economies by fragmented markets
- Delay market intro. for products w/ short lifecycles
- Increase complexity to manage compliance of OEM/ODM, contract manufacturers, and core technology partners
- Increase cost for redundant testing, certification, etc
- More surveillance that may stop shipments & damage brand

INFORMATION TECHNOLOGY INDUSTRY COUNCIL

1-1SDoC

- ***One Standard*:** Acceptance of an international standard (e.g. IEC 60950 for safety of IT equipment or CISPR 22 for electromagnetic emissions), or national standard with stated equivalency.

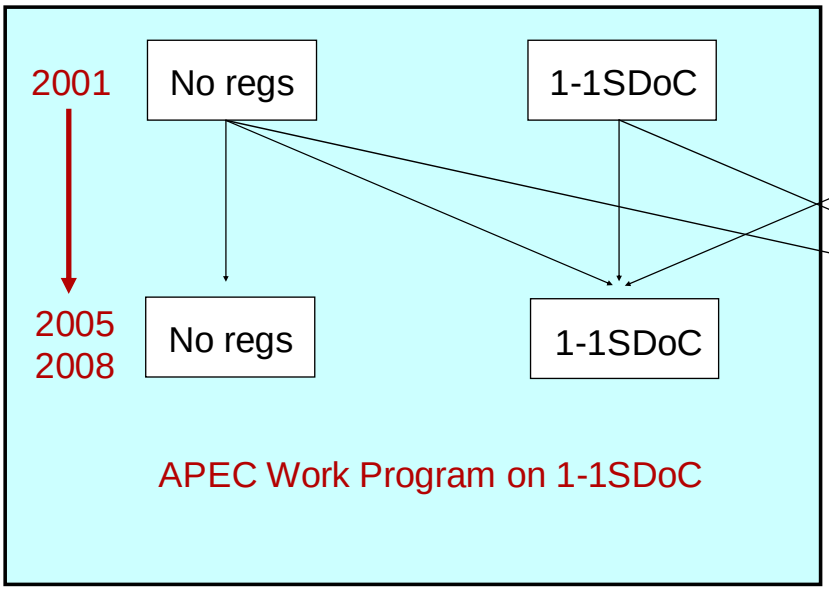
- ***One Test*:** Acceptance of test results conducted in any competent test facility (e.g., conforming to ISO/IEC 17025, accredited to ISO/IEC Guide 58, member of MRA, and/or IECEE CB Scheme member) regardless of the facility's geographic location.

- ***Supplier's Declaration of Conformity*:** Products may be marketed on the basis of a supplier's declaration of conformity that complies with ISO/IEC 17050 Part 1 and 2. The supplier shall retain compliance documentation (i.e., description of product, test reports, etc.) providing the basis for the supplier's declaration and make it readily available to the regulator upon request. Enforcement of regulatory requirements will be by means of post-market surveillance and non-compliance penalties.

SCSC Work Program on Trade Facilitation in Information Technology Products October 2000

"As part of the APEC SCSC Collective Action Plan, APEC members, on a voluntary basis, will positively consider permitting information technology products (specifically, computers and computer peripherals, such as printers, monitors, and storage devices) to be marketed in their economy on the basis of supplier's declaration of conformity, which states that products conform to the economy's technical standards aligned with the safety standard IEC 60950 and the electromagnetic interference (EMI) standard CISPR 22, based on testing in a competent test facility—in short, "One Standard-One Test, Supplier's Declaration of Conformity (1-1SDoC)."

“Starting Point” and “End Point” for an APEC member economy



Not achieving the APEC Work Program on 1-1SDoC

INFORMATION TECHNOLOGY INDUSTRY COUNCIL

Standards and Conformity Assessment Progress to 1-1SDoC

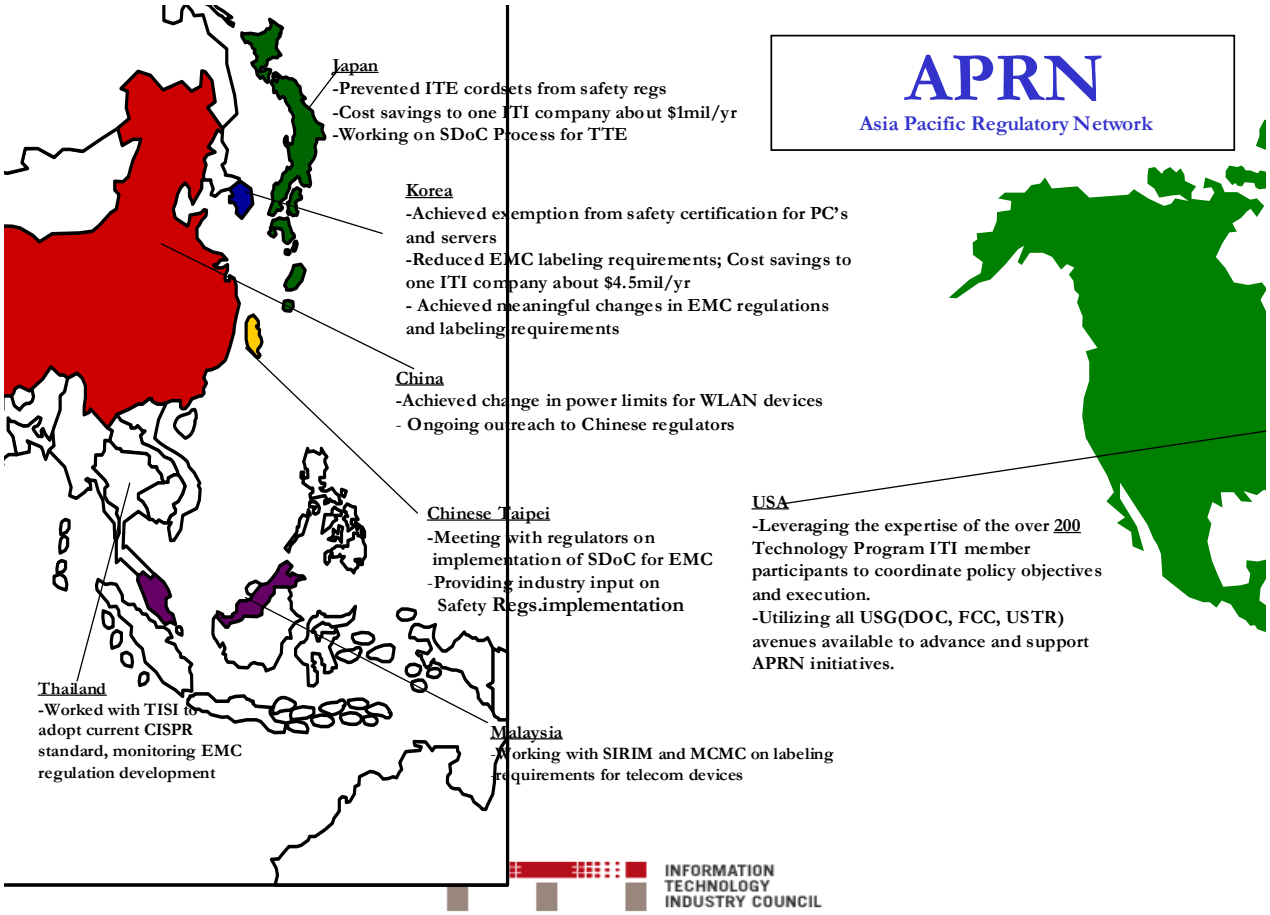
	Safety		EMC		Telecom	
	Std	CA	Std	CA	Std	CA
US						
Canada						
Argentina						
Brazil						
Chile						
Mexico						
Peru						

	Safety		EMC		Telecom	
	Std	CA	Std	CA	Std	CA
Australia						
Brunei						
Cambodia						
China						
Hong Kong						
India						
Indonesia						
Japan						
Korea						
Malaysia						
New Zealand						
Pakistan						
Philippines						
Singapore						
Sri Lanka						
Chinese Taipei						
Thailand						
Vietnam						

	Safety		EMC		Telecom	
	Std	CA	Std	CA	Std	CA
European Union (25 EU & 6 EU-like countries)						
Belarus						
Croatia						
Egypt						
Israel						
Jordan						
Kazakhstan						
Kenya						
Kuwait						
Lebanon						
Morocco						
Nigeria						
Russia						
Saudi Arabia						
South Africa						
Tunisia						
Turkey						
Ukraine						
Uzbekistan						

	Standards	Conformity Assessment
	Ref Int’l standards	SDOC, post market surveillance
	Ref regional standards	n/a
	Ref. unique standards	Certification, pre-market testing
	Emerging Requirements	
	No known requirements	

INFORMATION TECHNOLOGY INDUSTRY COUNCIL



Progress towards "1-1SDoC" Regulatory Model

- Established "two-way street" of communication and solid relationships with key regulatory authorities in Asia Pacific
- Rely on in-country company representatives to lead interaction with government officials and local industry
- Represent and advocate "global industry solutions." Made concrete changes in a number of regulations that affect ITI companies' market access
- Promoting APEC Work on 1-1SDoC in other multi-lateral organizations like
  - WTO TBT Workshop on SDoC 03/2005
  - WTO Guidelines on EMC/EMI Regulation 11/04
  - WTO EU Proposed Electronics Sectoral to address non-tariff barriers (NTBs) via promotion of SDoC (6/2006)
- Expansion of similar activities into Latin America

INFORMATION TECHNOLOGY INDUSTRY COUNCIL

Korea

- Exemption from safety certification for PC's and servers
- MIC revision of compliance marking requirement to MIC logo and approval number on product
- MIC allowance of family series approvals
- MIC allowance of wireless modular approvals with integrated antenna
- Acceptance of one approval number for identical product models from different factories
- Implementation of MRA with USA; witness testing for huge and complex products in other countries and ongoing consideration by RRL as to how to resolve in-country testing issue for manufacturers in countries without MRA.
- Revision of EMC compliance marking requirement to MIC logo and approval number on product. Manufacturers can apply the number in advance
- MIC consideration of SDoC system for EMC in process

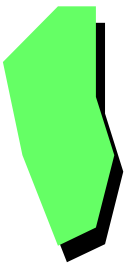
INFORMATION TECHNOLOGY INDUSTRY COUNCIL

Japan

- Continued strong relationship with VCCI and, share information and collaborate to deliver common messages and information to regulators around the world
- Working to promote implementation of the Japan-US MRA
- Working to implement SDoC for telecom terminal equipment
- Maintain exemption for safety certification of IT cordsets

INFORMATION TECHNOLOGY INDUSTRY COUNCIL

Chinese Taipei



- Seen changes in DGT approval process - modular approvals are accepted as are worst case tests for the same type of antennas.
- EMC compliance marking has been simplified, supplier code introduced process streamlined
- BSMI allows submission with electronic documents (CD) instead of traditional hard copy.
- 2003 BSMI implemented DoC for EMC on PC components
- BSMI announced acceptance of compliance to IEC 60950:1999 until 2006 for new BSMI safety requirements for IT equipment.
- BSMI spoke at APEC SCSC Feb2003 1-1SDoC event on DoC for EMC; also active in relevant WTO Committees (ITA, TBT) to promote the trade facilitating effects of implementing a 1-1SDoC system.

⇒ Industry needs to do more work here to support BSMI and regulators to find a way to increase awareness and understanding of SDoC and to conduct effective post-market surveillance.

INFORMATION TECHNOLOGY INDUSTRY COUNCIL

China

- CNCA acceptance of family series and CB reports
- CNCA exemption of service parts (now via separate process)
- CNCA allowance for factory printing of compliance label
- CNCA awareness of request for acceptance of foreign EMC reports
- Annual US-China ICT Standards, Conformity Assessment and Trade Facilitation Workshops held in Beijing, hosted by AQSIQ and US DOC - have helped industry in establishing a dialogue with Chinese government agencies and also US government to bring our standards and CA issues to the US-China trade/market access agenda.
- 2 ITI APRN China Team Members on CNCA Regulatory Advisory Committees

INFORMATION TECHNOLOGY INDUSTRY COUNCIL

Malaysia

Labeling requirements for Telecom Terminal Equipment

Industry approached SIRIM and Malaysian Communications and Multimedia Commission (MCMC) this year about streamlining these regulations. Industry is maintaining dialogue with Malaysian officials.

INFORMATION TECHNOLOGY INDUSTRY COUNCIL

Thailand

TISI postponed implementation of the new EMI standard until the internationally recognized and widely used CISPR22 revision is complete.

⇒ Industry interested in working with TISI on conformity assessment regime for new EMI regulations.

INFORMATION TECHNOLOGY INDUSTRY COUNCIL

Mexico

Mexican telecom regulator's (COFETEL) proposed conformity assessment procedures (PEC) will potentially have a negative impact on manufacturers importing into Mexico.

Draft EMC regulations (NOM 125) have been delayed, industry continues to work with COFETEL.

INFORMATION TECHNOLOGY INDUSTRY COUNCIL

Looking Forward

- Reinvigorate APEC SCSC 1-1SDoC Workplan
- Continue industry to government outreach and dialogues.
- Build momentum in APEC, WTO and other multilateral organizations.
- Establish linkages with domestic industry in countries.

INFORMATION TECHNOLOGY INDUSTRY COUNCIL

THANK YOU!

Ann Rollins
Vice President, Technology & Trade Policy
ITI
arollins@itic.org

Asia-Pacific
Economic Cooperation

2006/SOM3/SCSC/GRP/003

Good Regulatory Practice Guidance

Submitted by: John Henry, Director- International and Standardization Policy, Standards Australia

4th Conference on Good Regulatory Practices
Da Nang, Viet Nam
4 September 2006

4th Conference on Good Regulatory Practice
September 2006

Good Regulatory Practice Guidance

John Henry

Director- International and Standardization Policy

Standards Australia

Current APEC Guidance

- Principles and Features of Good Practice for Technical Regulation (2000)
- Informative Notes on Good Practice for Technical Regulation (2000)
- Guidelines for the Preparation, Adoption and Review of Technical Regulations

Why have GRP?

- To guide emerging new regulatory systems in developing economies
- To ensure both new and existing systems do not create unnecessary technical barriers to trade
- To ensure efficient regulatory systems that provide confidence in local markets
- Let's look at some of the key points in the current guidance:

GRP Principles (1)

- Before implementing mandatory requirements alternative mechanisms should be considered including reliance on systems of legal recourse; liability laws; liability insurance schemes; economic instruments such as taxes, fees and charges; education programs; co-regulation; voluntary standards; self-regulation; and codes of practice.

GRP Principles (2)

- The compliance regime used to ensure that the regulatory objectives are being met should be the least interventionist necessary to achieve the regulatory objective and are the least trade restrictive means of arriving at its goal.
- In selecting the most appropriate compliance regimes, member economies should take into account the risks associated in non-compliance

GRP Features (1)

Good regulations:

- are transparent and non-discriminatory;
- are performance based;
- reference international standards or internationally aligned standards where applicable, taking into account health, safety, technological, climate, developmental and other factors;

GRP Features (2)

Good regulations:

- reference only those standards, or parts there of, necessary to achieve the legitimate regulatory objective; and
- are subject to review to maintain flexibility and adaptability to modern needs.

Information Notes on Good Practice for Technical Regulation

- Regulation of Products
- Technical Regulation
- Conformity Assessment
- Regulatory Safety Nets
- Post-Market Surveillance
- Risk Assessment Techniques
- Establishing a Regulatory Regime

What can we say about the guidance?

- It's very much focussed on removing barriers to international/regional trade
- It doesn't address the legislation that provides the framework for national standardization and conformity assessment, including establishing the roles of S&C bodies
- It refers to 'common law' and liability laws that exist under the 'British' legal system

What can we say about the guidance?

- It assumes that imports and exports are treated the same way as products that are locally made for local consumption
- Technical regulation of services doesn't seem to be considered, eg construction
- Second hand products aren't mentioned

How does regulation operate?

- The actions of persons and corporate entities can be regulated
- Inanimate objects cannot themselves be regulated, it's their manufacture, supply, usage or possession by persons
- The guidance is a bit unclear and seems focussed on regulating the supply of products, but there are other alternatives such as usage that are not discussed

Some facts about APEC

- Of the 21 APEC economies, around one-third are developed, one-third are developing but with a mature S&C infrastructure, and one-third are at a relatively early stage of development
- There is no proposal to have a common treaty-based S&C infrastructure within APEC, so the guidance is simply informative and advisory

Some facts about APEC (2)

- Both Chile and Vietnam have recently reviewed the regulatory basis for their standards and conformance system, but neither found the good practice guidance particularly relevant
- However, it seems that these are just the type of economies that would benefit most from APEC advice and capacity building

Verdict on the Guidance

- It provides very useful explanations and guidance for application in a developed economy like Australia
- There are many irrelevant parts and some significant gaps when one seeks to apply it in a developing economy like Vietnam
- So it's probably only fully applicable in about one-third of APEC economies

Drivers for Technical Regulation

- Government working with its people to progressively improve the quality of products and create a better life
- Building consumer confidence in the local market
- Educating manufacturers and suppliers, especially SMEs, in what is acceptable
- Preventing deceptive practices
- Recognition that the local industry base may be ‘fragile’ and requires encouragement

Conclusions

- The guidance needs to be equally applicable to all APEC economies
- Perhaps its time to review the guidance, especially the information notes
- A capacity building element would complement the current trade facilitation focus
- It would need to include significant developing country input

Asia-Pacific
Economic Cooperation

2006/SOM3/SCSC/GRP/004

Benefits to the Wine Industry from Reducing Barriers to Trade and Improving Consumer Understanding Though the Harmonization of Labelling

Submitted by: Tony Battaglene, Director, International & Regulatory Affairs, Winemakers Federation of Australia, Australia

4th Conference on Good Regulatory Practices
Da Nang, Viet Nam
4 September 2006

Benefits to the Wine Industry from Reducing Barriers to Trade and Improving Consumer Understanding Though the Harmonization of Labeling

Tony Battaglene, Director, International & Regulatory Affairs, Winemakers Federation of Australia, Australia

Paper presented to 4th Conference on Good Regulatory Practices
APEC Sub-Committee on Standards and Conformance (SCSC)
Da Nang, Viet Nam
4 September 2006

Introduction

Differing labeling regulations between markets adds a major cost to producers. Costs are incurred, not just in the cost of printing different labels for different markets, but it terms of logistics. Differing label regulations also increase the possibility of consumer confusion, particularly in a globalised market where consumer regularly travel between markets.

The World Wine Trade Group (Australia, New Zealand, United States, Canada, Chile, Argentina, Mexico and South Africa) have been negotiating an agreement on labeling between the parties.

The key objective in the agreement is to harmonise labels for wine internationally. This is the first of what we hope will be a series of agreements that will eventually result in complete harmonization of all mandatory particulars, while still allowing individual countries to demand specific consumer information deemed desirable – however the agreement will prevent label requirements being used as a deliberate impediment to trade.

Why is labeling important?

Labeling is a key component of selling wine. On any retailer's shelf there are a large number of brands and the packaging is a key element in selling the bottle of wine.

Consumers are after a number of things in the label. They want to determine the provenance of the wine – that is, they want to know the grape variety, the region it came from and the country. They need to be informed of the mandatory items required under national legislation. These include the alcohol content; declaration of sulphides; and health warnings, such as the Surgeon-General's warning in the United States.

In addition, they may wish to be informed of supplementary information that may help in the purchasing decision. For example, historical details of the vineyard; what food the wine may be enjoyed with; or details of the winemaker.

From the winemaker's perspective, he wants all the information that the consumer wants on the label to be there. He wants consistency across markets so that he doesn't have to change labels for different outlets, be they different economies or different types of retail outlet.

Ideally, we would like a bottle to be labeled so it can be legally sold in any market in the world.

Practically, this cannot occur as consumers in different economies demand different mandatory information. However, it is possible to improve the situation. All economies want transparency in rules, so product is allowed unfettered access to markets.

Therefore, it is in the interest of the global wine industry to ensure that rules are clear and that labels are truthful, the information contained is verifiable and that the consumer has access to the information they need to make a choice.

Trade Barriers/Restrictions caused by labeling

The labeling rules that apply in each country reflect the history, culture and geography of that country. However in international trade terms differences in rules between economies give rise to barriers to trade. They include:

i. International trade in certain wines is prevented by labeling requirements in some markets.

ii. Different labels are required for different markets giving rise to additional costs

iii. Different blends are required for different markets giving rise to additional costs.

These distortions mean innovation is restricted, consumer choice is restricted and prices are raised. These restrictions are to the detriment of a healthy, competitive and vibrant wine market. The beneficiaries of such restrictions are those producers whose products would not be competitive in a more open market place. The biggest losers are the consumers, who face higher prices, less choice and a lack of information on which to make an informed choice.

Growing International Trade in Wine:

In the last 20 years, the global trade in wine has undergone enormous growth. Bulk and packaged wine is now bought and sold across international borders. The world's wine industries operate in a global market, in stark contrast to the regional production and consumption patterns of the past.

APEC as a producer and a consumer

Over the past 100 years the international wine trade has been focused on the traditional large wine consuming nations - in particular Western Europe and the America's. However, consumption in Western Europe and South America has been either stable or declining over the past decade. Clearly, in the next decade (2010 onwards) increasing focus will be on the Asia Pacific region and to a lesser extent the Eastern European markets. This is forecast to accelerate from around 2025 onwards (Ruthven, 2004).

The key drivers of this growth will be increasing economic growth in the Asian region, leading to higher incomes, increased consumption of consumer goods and resulting in increased demand for quality wine products.

APEC economies are very significant consumers and producers of wine. Grape based beverages are relatively new alcoholic beverages for most APEC economies. Australia has

the highest per capita consumption in the region of around 20.7 litres, followed by New Zealand (13.4), Canada, the United States (7.4 litres), Japan (2.2 litres), Singapore (1.6 litres), Chinese Taipei (1.4 litres), Hong Kong (0.8 litres) and China (0.3 litres).

However, in the last decade of the 20th century their has been a trend towards greater grape wine consumption among higher income consumers and this trend is expected to continue.

Increased wine consumption is being driven by several factors, including higher per capita incomes; appeal as a healthier lower alcohol beverage, liberalization of market access in some markets for better quality imported wines and better distribution within markets with modernization of food and beverage retailing.

Trade Impact of Wine Regulation:

As the global trade in wine increases, competition between producer economies for market share is increasing. Wine regulation is a potential source of advantage in the global wine trade war, allowing the creation of non-tariff trade barriers. These barriers are often couched in terms of "protecting the consumer', "respecting wine's heritage" and even "preserving the agrarian landscape".

The so-called "Old World" wine producing economies such as France, Italy and Spain have traditionally wielded a lot of power in the global regulatory scene. These economies are all members of the EU. While this group commands over 60% of world wine production and export volume, they are experiencing declining domestic wine consumption and, in most cases, declining export sales, especially in key growth markets such as the UK and USA.

The regulatory philosophies of the "Old World" economies differ markedly from those of so called "New World" wine production economies, such as Australia, the USA, Chile and South Africa. In the past this has inevitably led to conflicts that have significant potential impact on trade. Most issues arise when production standards within a country are applied as market standards for imported products. However, these differences are narrowing as government and industries in both the "Old" and "New" World begins to understand that inefficient and inconsistent regulation harms the industry as a whole.

In 2006, the European Commission launched a public debate on future wine policy in Europe. This was in response to a situation where European Union wine consumption has fallen significantly and steadily in recent decades. Since 1996 the volume of wine imports into the EU-25 has been growing at a rate of 10% a year, reaching almost 11.8 million hl in 2005. So-called "new world" wines have gained considerable market share from EU wines. The volume of wine exported from the Community has been increasing since 1996 but at a much slower rate than imports, to reach about 13.2 million hl in 2005. Overall, the EU remains a net wine exporter. However, the mid-term outlook for the EU wine sector is daunting. The European Commission estimates that until 2010/2011, under the assumption that the wine CMO is unchanged and on the basis of the expected trends in production, consumption and trade dynamics is that excess wine production will increase up to 27 million hl (15% of production)[1].

[1] European Commission (2006) Brussels, 22.06.2006 COM(2006) 319 final, Communication From The Commission To The Council And The European Parliament, Towards a sustainable European wine sector

In the face of over-supply, decreasing consumption and increased competition. The European Commission have put forward a number of proposals for wide ranging reforms to the wine sector to make European Union wine producers to become more competitive.

Common to all these proposals (which are currently under debate in Europe) are proposals to change wine making practices, geographical indications and labeling.

The European Commission believes that[2]:

- The rigidity of procedures for adopting and adapting Winemaking Practices hinders competitiveness.
- EU regulations are too complex, notably on definitions, Winemaking Practices, and classification, i.e. Quality Wine psr, table wine with a GI and table wine.
- On Quality wine psr, there is no '*quality*' concept at international level and no reference in Community legislation to the concept of 'geographical indication' as defined by the WTO's Trade Related Aspects of Intellectual Property Rights (TRIPs) Agreement. Besides, in recent decades, there has been an increase in the number of Quality wine psr and table wines with GIs, which leads to customer confusion, weakens the Community GI policy in the EU and abroad, and contributes to the decline of the market situation.
- On labeling:
  - consumers are confused by wine labels resulting from a complex legal system consisting of a mixture of legal instruments which deal differently with several wine categories and with some particulars depending on the product;
  - Inflexible labeling rules hamper the marketing of European wines. A major drawback is the prohibition of the indication of the vintage and the vine variety on table wine without a GI;
  - non-EU countries regularly criticise European labeling policy as far as the sales designation (for example, Quality wine psr, table wine with a GI and table wine), the use of optional indications, the reservation of bottle shapes and the policy on traditional terms are concerned. In that connection the review of the labeling rules should take into account their impact on imports from third countries and the EC's international obligations.
- Independent analysis suggests that appropriate liberalisation of wine-making practices, in line with International Wine and Vine Organisation (OIV) rules, and more consumer-oriented labeling would enable EU wine producers to expand their outlets and improve their marketing, thereby improving their competitiveness and reducing the structural imbalance.

This new found commonality between the producing economies means that we now have a real chance of harmonising trade restrictive labeling regulations.

GLOBAL APPROACHES TO WINE REGULATION.

A number of international bodies play a large part in influencing the international regulatory environment on labeling. These include **Codex Alimentarius Commission** (general labeling rules for food), the **World Trade Organisation, and the International Organisation on Legal Metrology** (type size and placement of volume statement) and the **World Intellectual Property Organisation**.

[2] European Commission (2006) Brussels, 22.06.2006 COM(2006) 319 final, Communication From The Commission To The Council And The European Parliament, Towards a sustainable European wine sector

There are also a number of international bodies that play a role in harmonization efforts for wine labeling regulations.

Office International de la Vigne et du Vin (OIV).

The OIV is an intergovernmental organisation created in 1924. The activities of the OIV include:

- drawing up and framing recommendations and monitoring implementation of such recommendations in liaison with its members; and
- contributing to the harmonisation and adaptation of regulations by its members or,
- Where relevant, facilitating mutual recognition of practices within its field of activities.

The resolutions of the OIV are recommendations only and are not immediately binding upon persons within its member states. They become so only as part of an adoption into internal legislation. The OIV presently has 42 member states and 14 observers (including four sovereign states, one region and nine NGOs). With a couple of notable exceptions (in particular, the United States, China and Canada), all major winemaking economies belong to the OIV. Resolutions of the OIV are not binding in the laws of member economies.

In June 2006, the OIV adopted a number of resolutions relating to labeling, with the objective of harmonisation. The most significant of these was adopting the single field of vision concept being proposed by members of the World Wine Trade Group (see below). However, a further significant resolution passed by the General Assembly in June related to the declaration of sulphites, recognised that alternative indications could be used to declare the presence of sulphites, opening up the prospect of pictograms, chemical symbols or other commonly used symbols.

World Wine Trade Group (WWTG).

The World Wine Trade Group includes representatives from Argentina; Chile; USA; Canada; Australia; South Africa; and New Zealand. Observers from a number of other economies including Uruguay, Brazil and Mexico also attend meetings. This is an industry - government group that meets twice a year with the objective of enhancing world trade in wine.

In December of 2001, the New World Wine Producers signed the Mutual Acceptance Agreement (MAA) on winemaking practices. In this historic agreement, members agreed to recognize one another's winemaking practices and the regulatory and enforcement mechanisms of the signatory economies. This binds the 'World Wine Trade Group' of economies to allow the importation of wines from each other provided the wine has been produced in accordance with practices legitimate in the country of origin, regardless of the legality of those winemaking practices in the country to which the wine is exported. The introduction of new technologies is far less likely to disrupt trade under this 'mutual acceptance' approach than under the arrangements previously favored by the EU.

This agreement is intended to encourage free trade in wine, through setting a benchmark standard to ensure consistent quality for wines and guaranteeing consumer health and safety. This agreement also foreshadowed a labeling agreement which would harmonise between the members of the WWTG labeling regulations to provide consumer certainty and increased production efficiency. A set of principles (Annex 1) were adopted by the WWTG in 2002 to provide a negotiating framework.

The last meeting of the WWTG was held in Washington in July 2006. At this meeting a treaty level labeling agreement was finalised. This agreement will be formally signed at the next meeting of the WWTG to be held in Canberra in January 2007.

The Labeling Agreement

Having different labels for different markets is expensive in terms of printing costs, inefficient in terms of economies of scale and prevents the introduction of advanced logistics systems i.e. product requires separate warehouse space, cannot be easily diverted between markets if a sale falls through and prevents a rapid adjustment to supply and demand imbalances.

However, it is not possible and will not be possible to sell wine in all world markets under a single label. The reason for this is that all jurisdictions have different national labeling requirements for consumer safety and protection purposes. For example, the United States mandates a government health warning; Australia requires a 'Standards Drinks' declaration and both Canada, Australia and the United States either do now or will in the future require the labeling of potential allergens.

What should be possible is that only one label needs to be changed on a bottle of wine for any market in the world. That is, is placement of mandatory information is not mandated, producers will have the flexibility to design a common label for any market and satisfy national and international requirements on a separate label.

Currently, in the major markets of the world the following countries mandate placement:

- Australia Mandates 'contents' statement on the principal display panel
- CanadaMandates 'contents' statement on principal display panel
- United States Mandates the Brand name must appear in conjunction with Class, type, or other designation and the Alcohol content

The key changes that will occur on signing of the agreement will be:

- The United States will remove the requirement to link the alcohol statement with the brand name and product designation
- Alcoholic strength will be able to be expressed as either x% alc/vol or alcx%vol
- The United States have clarified that if the varieties are named on one label, the requirement to state varietal percentages can appear on another label
- Canada and Australia will remove the requirement to have the contents statement on the 'principal display panel'
- Canada will remove the requirement to have bilingual requirements for country of origin and product designation on the principal display panel (although bilingual requirements will still apply)

- The use of the term 'icewine' will be restricted to product made from grapes naturally frozen on the vine, although terms such as 'Ice Riesling' will still be permitted.

The WWTG labelling agreement would allow wine producers to create a common principal label for all markets. The agreement introduces the "single field of vision" labelling concept. This would allow the four items of mandatory information – product name, country of origin, net contents and alcohol content – to be presented together on a label in a "single field of vision".

The proposed agreement will provide **significant benefits** to Australian wine exporters including estimated direct cost savings of at least $25 million per year and significant efficiencies in distribution and marketing in some of our key wine export markets.

The main benefits of a "single field of vision" approach to wine labelling include:

- substantial cost savings to the Australian wine industry alone of a minimum of $25 million, which equates to around 4% of the costs of production
- additional savings from using a common label for domestic and export sales
- shipments could be more easily diverted to other markets, less "over-stickering"
- reduced storage costs and storage space required for holding the same standard wine bottles for multiple markets
- an even greater proportional reduction in costs for smaller producers seeking to break into export markets for the first time
- improved presentation of all common mandatory information to consumers and the consolidation of this information
- marketing and promotional advantages for wine producers of an attractive common label

The signatory countries expected to sign the initial agreement account for over 39% of Australian wine exports by volume and 45% by value. The labeling regulations in the European market, which comprises a further 50% of the market for Australian wine by volume and 48% by value are also consistent with the WWTG labeling agreement, which moves us a long way towards a single label for all markets.

Other labeling issues

These are not the only labeling issues of interest to producers and consumer of wine. Of particular interest are:

- allergen labeling
- sulphites declaration
- vintage labeling
- use of geographical indications on a label

While the WWTG is currently focused on the issues covered by the draft Statement of Principles these other labeling issues would lend themselves to standardization, harmonization or mutual acceptance.

To that end the World Wine Trade Group has agreed that it will continue to discuss and consider the use of varietal, geographic and other descriptive terms and rules of trade dress, with a view to eliminating practices that constitute technical barriers to trade between members of the group and with other economies

Sulphites

Sulphites declaration on a label is a good example of how labeling can become trade restrictive. Due to the sensitivity of some consumers to sulphites most economies mandate the labeling for sulphites when the level is 10 mg/kg or greater.

In the European Union, Directive 2003/89/EC came into effect in November 2005, requiring the indication of allergens such as sulphur dioxide and sulphites on pre-packed food including alcoholic drinks. Sulphur dioxide and sulphites in alcoholic drinks may be indicated using the term "contains sulphur dioxide/sulphites", and use of the chemical symbol "SO_2" is not acceptable, although the term "sulfites" is acceptable.

The problem is that many European countries have introduced implementing regulations that will mandate the language of the sulphite statement must be of that member state. The result of this is that for export to Europe many wines are now required to carry a sulphite declaration in 22 languages or change the label for each different market.

While the wine industry supports all moves to ensure the health and safety of consumers, unfortunately the language issue will impact adversely on the principle of free trade within Europe.

This will particularly impact on intra-European Union trade, with increased costs for the big European wine producers and for the new Member States in particular. For example, French and Italian products will need to have the sulphite declaration in English for that market and German for Germany. This will create extra expense in printing labels and serious logistics problems for producers and traders.

New World Producers will be impacted to a much lesser extent as their major market is the United Kingdom.

We believe that the introduction of chemical symbols or the use of the INS number will permit an easily understandable indication for those sensitive consumers and will work towards this outcome.

This problem has the potential to be magnified if the European Union extends the labeling requirement to potential allergens (egg, milk or fish products) used as processing aids. This could create a label the size of the bottle, which will probably result in the consumer not reading it.

Conclusion

It is the view of the author of this paper that coping with the myriad different labeling requirements facing wine exporters as they go from one country to another unnecessarily complicates the international trade in wine, makes it considerably more expensive, impacts most adversely on small producers who cannot afford the numerous small production runs

needed to comply with the different requirements of individual nations and thereby constitutes a very real non-tariff barrier to trade.

It is also our view that all economies have developed their own labeling rules with a view to making sure that consumers receive truthful and accurate information about the product they are buying. The differences in approach to achieving that truth and accuracy reflect the different history, culture, geography and internal regulatory systems of each country. It is not that one approach is right and all the others are wrong. They are all right in their own way. Rather than trying to bludgeon economies into changing their long held positions, our view is that the best course is not to try to eliminate the differences but to recognize that they exist, accept them and build an international regulatory environment that respects them while at the same time also respecting other quite legitimate ways of achieving the same thing – and that is essentially a mutual acceptance approach.

The APEC economies are ideally placed to take a lead in reforming labeling restrictions. They incorporate a number of important producers as well as some of the quickest growing economies with high potential growth. In addition, consumers in many of these economies are not traditional consumers of grape wine and are seeking certainty in presentation. Adopting the principles proposed by the WWTG is a good way of encouraging the development of the wine industries in these economies and ensuring consumer protection.

ANNEX1: WORLD WINE TRADE GROUP

STATEMENT OF PRINCIPLES

Recognising the principle of mutual acceptance and that wine labels, and any regulations relating to them, should be designed to meet the various needs of consumers, producers and regulators, the New World Wine Producers Industry Group recommends that the following principles should be embodied in the proposed WWTG agreement on mandatory wine labeling requirements and practices.

1. All information contained on labels should be clear, accurate, truthful and not misleading.

2. The Universal Mandatory Information - currently Product Designation, Content Volume, Percentage Alcohol and Country of Origin - should appear on a label or labels that are in a single field of vision [i.e. they should be legible at the same time without having to turn the container].

3. Any other items of label information required by individual national laws may appear in the same field of vision as the Universal Mandatory Information or elsewhere on the container.

4. Optional additional information may appear in any field(s) of vision.

5. Provided the Universal Mandatory Information appears together in one field of vision it will be permissible for all or parts of it [or for any other information] to be repeated in any other field of vision.

6. All mandatory information [whether Universal Mandatory Information or individual national requirements] shall be legible and easily discernable to the consumer.

7. Pursuant to the prevailing principle of mutual acceptance

    a. Percentage alcohol may be expressed as _% Alcohol by Volume, _% alc/vol, alc_%vol or any variation or other abbreviation which accurately conveys the same meaning.
    b. the contents volume of the container may be expressed in centilitres (cl), millilitres (ml) or litres (l).
    c. minimum type sizes and any similar requirements will be subject to mutual acceptance.

8. Provided the foregoing requirements are met wine producers should be free to:

    a. provide consumers with accurate descriptive information in addition to the prescribed items.
    b. label their products as they see fit subject to applicable laws on geographical indications and intellectual property and to any information being verifiable.

Benefits to the Wine Industry from Reducing Barriers to Trade and Improving Consumer Understanding Though the Harmonization of Labeling

Tony Battaglene
Director, International & Regulatory Affairs
Winemakers Federation of Australia

Wine trade in the APEC Region

- **Consumption in Western Europe and South America has been either stable or declining over the past decade.**
- **In the next decade (2010 onwards) increasing focus will be on the Asia Pacific region and to a lesser extent the Eastern European markets.**
- **The key drivers of this growth will be increasing economic growth in the Asian region, leading to higher incomes, increased consumption of consumer goods and resulting in increased demand for quality wine products.**
- **APEC economies are very significant consumers and producers of wine.**

Major barriers to trade in wine

- Tariffs
- Labeling regulations
- Different oenological practices
- Inconsistent maximum residue levels for agrochemicals
- Certification and testing procedures

Labeling

- Labeling rules that apply in each country reflect the history, culture and geography of that country.
- Differences in rules between economies give rise to barriers to trade, by increasing costs of printing different labels for different markets,
- Also in terms of logistics.
- Differing label regulations also increases the possibility of consumer confusion,
- Different may be required for different markets giving rise to additional costs.

What can be done?

- The objective is to harmonise labels for wine internationally to minimise impediments to trade.
- However, not all labeling can be harmonised
- Individual countries to demand specific consumer information
- Therefore, aim to harmonise mandatory items and not mandate placement of any particulars.

Why is labeling important?

- Labeling is a key component of selling wine. On any retailer's shelf there are a large number of brands and the packaging is a key element in selling the bottle of wine.
- Consumers want to determine the provenance of the wine – that is, they want to know the grape variety, the region it came from and the country. In addition, they may wish to be informed of supplementary information that may help in the purchasing decision. For example, historical details of the vineyard; what food the wine may be enjoyed with; or details of the winemaker.

What does the winemaker want to put on the label?

- All the information that the consumer wants on the label to be there.
- Items to help the purchasing decision – 'a good story'
- Iterms the consumer needs to know for responsible drinking – volume, alchol content etc.
- Consistency across markets so that he doesn't have to change labels for different outlets, be they different economies or different types of retail outlet.

Mandatory items required on a label

- These include items necessary for consumer protection - the alcohol content; volume declaration of sulphites; health warnings; country of origin and product name.

Common mandatory items

- **Some items are common in all markets: alcohol content; volume; country of origin and product name.**

National mandatory items

- **Health warnings**
  - **Mandatory in US since early 90's**
  - **Recently introduced in Japan (minors)**
  - **Under consideration in Europe (warning pregnant women) and Australia**
- **Standard Drinks**
  - **Various definitions and formats.**

Regulatory philosophies

- In the past the regulatory philosophies of the "Old World" economies differ markedly from those of so called "New World" wine production economies.
- Most issues arise when production standards within a country are applied as market standards for imported products.
- These differences are narrowing as government and industries in both the "Old" and "New" World begin to understand that inefficient and inconsistent regulation harms the industry as a whole.

Proposed wine market reform in Europe

- In the face of over-supply, decreasing consumption and increased competition. The European Commission have put forward a number of proposals for wide ranging reforms
- Proposals to adopt similar regulatory philosophy to the 'New World'.

Common to all proposals are:

- The rigidity of procedures for adopting and adapting Winemaking practices hinders competitiveness.
- EU regulations are too complex, notably on definitions and Winemaking practices.
- No reference in Community legislation to the concept of 'geographical indication' as defined by the WTO's Trade Related Aspects of Intellectual Property Rights (TRIPs) Agreement.
- Customer confusion about what a geographic indication means.

Common labeling proposals:

- Consumers are confused by wine labels resulting from a complex legal system which deal differently with several wine categories and with some particulars depending on the product;
- Inflexible labeling rules hamper the marketing of European wines.
- Non-EU countries regularly criticise European labeling policy as far as the sales designation, the use of optional indications, the reservation of bottle shapes and the policy on traditional terms are concerned.

This new found commonality between the producing economies means that we now have a real chance of harmonising trade restrictive labeling regulations.

Global Approaches to Wine Regulation.

- **A number of international bodies play a large part in influencing the international regulatory environment on labeling including the Codex Alimentarius Commission (general labeling rules for food), the World Trade Organisation, the International Organisation on Legal Metrology (type size and placement of volume statement) and the World Intellectual Property Organisation.**

International bodies that play a role in harmonization efforts for wine labeling regulations

- **Office International de la Vigne et du Vin (OIV)**
- **World Wine Trade Group (WWTG)**

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An intergovernmental organisation created in 1924.

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- **contributing to the harmonisation and adaptation of regulations by its members or,**
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Office International de la Vigne et du Vin (OIV)

- **Resolutions of the OIV are recommendations only and are not immediately binding upon persons within its member states.**
- **In June 2006, the OIV adopted a number of resolutions relating to labeling, with the objective of harmonisation. The most significant of these was adopting the single field of vision concept being proposed by members of the World Wine Trade Group.**

World Wine Trade Group (WWTG).

- **The World Wine Trade Group includes representatives from Argentina; Chile; USA; Canada; Australia; South Africa; and New Zealand. Observers from a number of other economies including Uruguay, Brazil and Mexico also attend meetings.**
- **This is an industry - government group that meets twice a year with the objective of enhancing world trade in wine.**

- December 2001 - Mutual Acceptance Agreement on Oenological Practices (MAA) between Australia, US, Canada, NZ, Chile and Argentina.
- Key features of MAA:
  - Each country will permit the importation of wines from another signatory country as long as the wine is made in accordance with the producing countries' domestic laws on oenological practices.
  - Subject to human health and safety protection.
- MAA also commits parties to negotiate an agreement on labelling.
- Labelling agreement has the potential to provide the participating wine industries with more flexibility in labelling in key markets. Potential savings of 10's of $A millions

WWTG Labeling Agreement

- The last meeting of the WWTG was held in Washington in July 2006.
- At this meeting a treaty level labeling agreement was finalised.
- This agreement will be formally signed at the next meeting of the WWTG to be held in Canberra in January 2007.

Objective of the WWTG Labeling Agreement

- **Only one label needs to be changed on a bottle of wine for any market in the world.**
- **That is, is placement of mandatory information is not mandated, producers will have the flexibility to design a common label for any market and satisfy national and international requirements on a separate label.**

Currently, in the major markets of the world the following countries mandate placement:

- **Australia Mandates 'contents' statement on the principal display panel**
- **Canada Mandates 'contents' statement on principal display panel**
- **United States Mandates the Brand name must appear in conjunction with Class, type, or other designation and the Alcohol content .**

Single field of vision" labelling concept

- The WWTG labelling agreement would allow wine producers to create a common principal label for all markets.
- This would allow when the four items of mandatory information – product name, country of origin, net contents and alcohol content – are presented together on a label in a "single field of vision", the label is deemed to meet placement requirements for these items.

The main benefits of a "single field of vision" approach to wine labelling include:

- substantial cost savings to the Australian wine industry of a minimum of $25 million, which equates to around 4% of the costs of production
- additional savings from using a common label for domestic and export sales
- shipments could be more easily diverted to other markets, less "over-stickering"
- reduced storage costs and storage space required for holding the same standard wine bottles for multiple markets
- an even greater proportional reduction in costs for smaller producers seeking to break into export markets for the first time
- improved presentation of all common mandatory information to consumers and the consolidation of this information
- marketing and promotional advantages for wine producers of an attractive common label

A global solution?

- The signatory countries expected to sign the initial agreement account for over 39% of Australian wine exports by volume and 45% by value.
- The labeling regulations in the European market, which comprises a further 50% of the market for Australian wine by volume and 48% by value are also consistent with the WWTG labeling agreement, which moves us a long way towards a single label for all markets.
- Need adoption by consumer markets in Asia

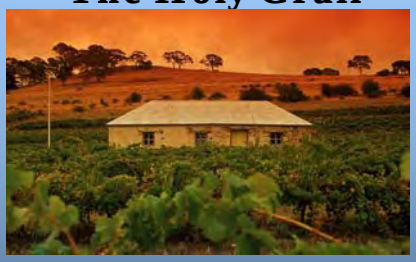
Where does APEC fit in?

- The APEC economies are ideally placed to take a lead in reforming labeling restrictions. They incorporate a number of important producers as well as some of the quickest growing economies with high potential growth.
- In addition, consumers in many of these economies are not traditional consumers of grape wine and are seeking certainty in presentation.
- Adopting the principles proposed by the WWTG is a good way of encouraging the development of the wine industries in these economies and ensuring consumer protection

- THANK YOU -

www.wfa.org.au

The Holy Grail



2002

Cabernet 80% Merlot 20%

Langhorne Creek

13.0% alc/ vol Wine of Australia 750 ml

Crafted in the traditional style, this wine displays strong varietal characters. The wine was matured in new and one year old French oak for fifteen months. 13%alc.vol.

GOVERNMENT WARNING: (1) According to Surgeon General, women should not drink alcoholic beverages during pregnancy because of the risk of birth defects. (2) Consumption of alcoholic beverages impair your ability to drive a car or operate machinery, and may cause health problems.

Imported By: Trail Blazers NY

Contains Sulfites

Produced By: The Grail Wines
23 Waite Road Sevenhill SA

Alcohol format defined

To claim vintage or variety need GI

Brand Label – 4 Mandatory Items

GI to be shown in direct conjunction with designation - % for multi-varietal

Sulfite Statement

Govt warning

The Holy Grail

Cabernet Merlot
Langhorne Creek

Common Mandatory Information

Crafted in the traditional style, this Langhorne Creek Cabernet Merlot has strong varietal characters and a lingering palate.

National Mandatory Information

The Holy Grail

2002
Cabernet Merlot
Langhorne Creek

13.0% vol Wine of Australia 750 ml

Crafted in the traditional style, this wine displays strong varietal characters. The wine was matured in new and one year old French oak for fifteen months. 13%alc.vol.

Imported by, AWBC Wines
Northern Ireland BT70 3HD

Contains Sulphites

Produced By: The Grail Wines
23 Waite Road Sevenhill SA

GI if Vintage or Variety
Wine in conjunction with C of O
Alcohol Format
4 mandatory items SFV

Produced - Imported By:
No Std Drinks–'Contains Sulphites'
Can't have protected GI's

The Holy Grail

Crafted in the traditional style, this Langhorne Creek Cabernet Merlot has strong varietal characters and a lingering palate.

National Mandatory and Common Mandatory Information

The Holy Grail

Cabernet Merlot
Langhorne Creek

Crafted in the traditional style, this Langhorne Creek Cabernet Merlot has strong varietal characters and a lingering palate.

National Mandatory and Common Mandatory Information

Session II:
Performance Based Regulation

Asia-Pacific
Economic Cooperation

2006/SOM3/SCSC/GRP/005

Guide on Establishing Technical Regulation Based on Application of Indonesian National Standard(SNI)

Submitted by: National Standardization Agency of Indonesia (BSN)

4th Conference on Good Regulatory Practices
Da Nang, Viet Nam
4 September 2006

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GUIDE ON ESTABLISHING TECHNICAL REGULATION BASED ON APPLICATION OF INDONESIAN NATIONAL STANDARD (SNI)

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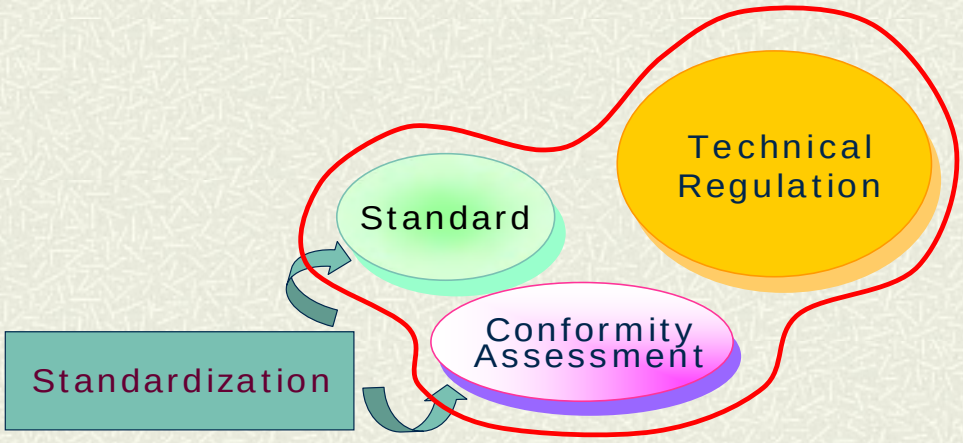

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Application of standard :

- Technical Regulation (± 70%)
- Without Technical Regulation (± 30%)

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Technical Regulation :

- To facilitate trade
- Not intended to create unnecessary technical barrier

- APEC issued a publication on “Information Note on Good Regulatory Practice”
- ASEM published “Best Regulatory Practice”

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A good Technical Regulation is the one that is formulated based on standard

GRP ~ Application of Mandatory Standard

(Standard : Consensus based)

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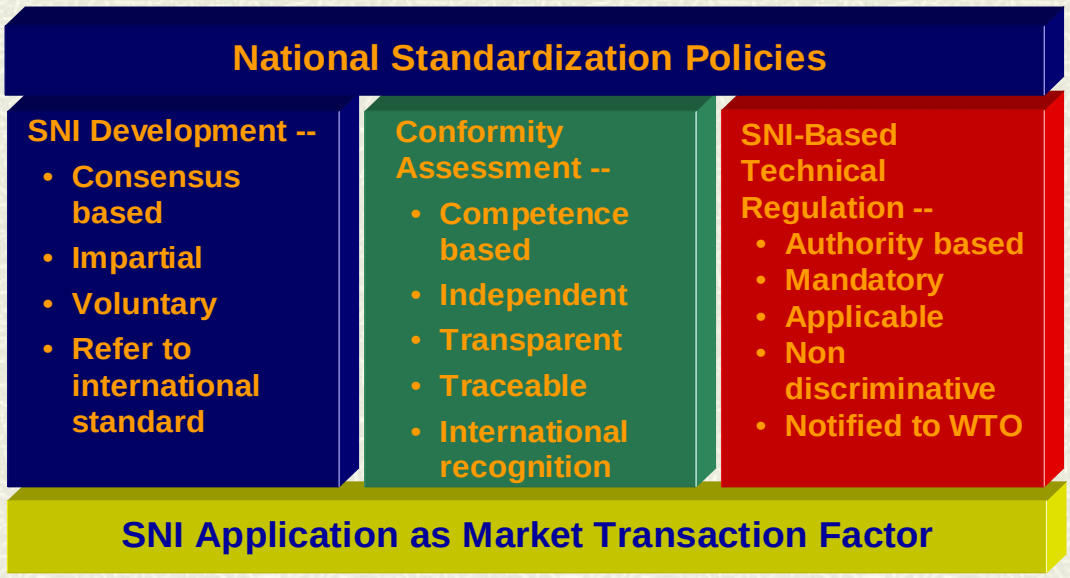
Standardization Elements



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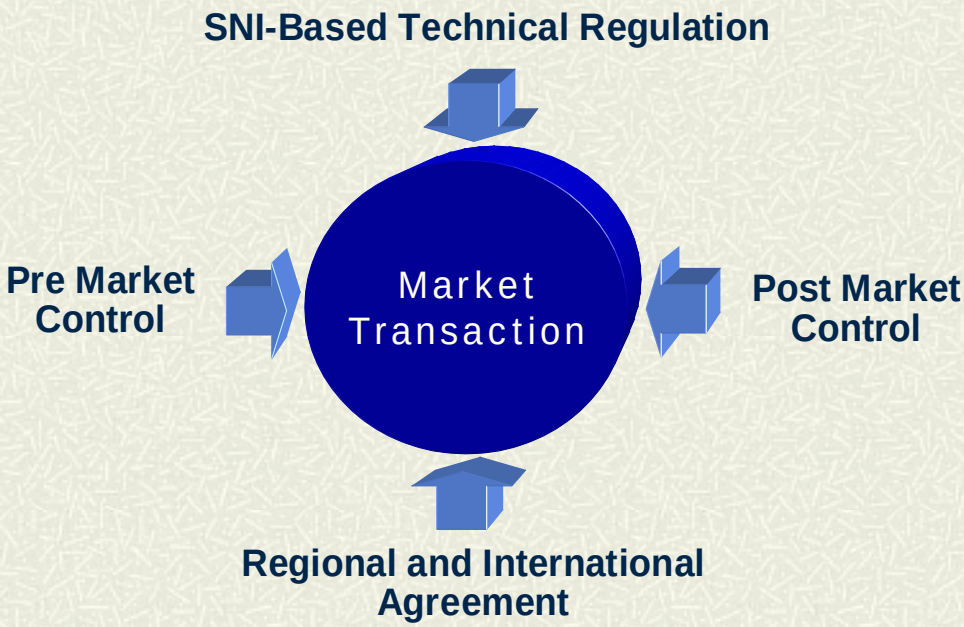
Factors that affect SNI application :



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A Guide on Establishing Technical Regulation Based on Application of Indonesian National Standard (SNI) has been issued since 2003.

References :

- APEC Information Notes on Good Practice for Technical Regulation
- WTO Agreement on Technical barrier to trade
- ASEM Best Regulatory Practices

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Consideration in Establishing Technical Regulation (Mandatory SNI)

- Government must ensure that goods being traded do not :
  - create risks to consumer safety, health and security;
  - create threats to the sustainability of environment;
  - influence the operation or safety of other products.
- Government must ensure market certainty and fair market competition

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"Side Effects" of Mandatory SNI

- Exclusion of business enterprises who are not able to comply
- Create negative effects :
  - to barrier business enterprises – particularly SMEs – if the requirement is too high;
  - limited access to a competition if it can only be complied by small number of producers;
  - create a protest from other country due to unnecessary barrier to trade

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Requirements of Mandatory SNI Application

- In line with related laws and regulations
- Do not create unnecessary barrier to :
  - development of industries;
  - trade and competition;
  - development of other economic factors
- Must be in line with regional and international agreement (e.g. ASEAN, APEC)

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Preparatory Aspects in Mandatory SNI Application

- Purpose must be clear and well understood by business enterprises
- The SNI must, as much as possible, align with international standards
- Analysis must be done on the followings :
  - its effectiveness in achieving the goal and its posibilty in creating negative impact
  - alignment with related laws and regulation, TBT/SPS Agreement and other relevant regional and international agreement
  - control system to be applied
  - readiness of producers and CABs

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Stipulation of Mandatory SNI Application

- Must be agreed by related ministers and agencies before stipulated
- At least 6 month notice prior to its implementation
- The preparation period depends on :
  - Readiness of domestic producers
  - Readiness of CABs
  - Preparation of post market control system to be applied

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Pre Market Control (Preventive)

According to Government Regulation No 102, CABs must be accredited or recognized by KAN

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TBT-WTO Requirements :

- Conformity assessment procedures should be in accordance with those developed by relevant international organization
- To accept system from other country if the purpose can be achieved
- Establish MRAs
- To permit foreign CABs to conduct conformity assessment in their economies

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Requirements and Obligation of CABs

- Fulfill ISO/IEC Guide 65 and be accredited by National Accreditation Body of Indonesia (KAN) or by KAN's MRA partners
- Provide and conduct certification scheme in accordance with :
  - Conformity assessment scheme stipulated in Mandatory SNI
  - Relevant ISO/IEC Guides
- Hold the responsibility on the validity of certificate as well as maintain and provide relevant records for the need of confirmation

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Product Certification System (ISO/IEC Guide 67)

Elements of product certification	1a	1b	2	3	4	5	6	n
1 Selection (sampling) as applicable	x	x	x	x	x	x		
2 Determination of characteristics, as applicable, by: ▪ Testing (ISO/IEC 17025) ▪ Inspection (ISO/IEC 17020) ▪ Design appraisal	x	x	x	x	x	x	x	
3 Review (evaluation) & Decision	x	x	x	x	x	x	x	
4 Licensing (attestation) –		x	x	x	x	x	x	
5 Surveillance, as applicable: ▪ Testing or inspection of sample from market ▪ Testing or inspection of sample from factory ▪ Quality system audits combined with random tests or inspections ▪ Assessment of production process or service			x	x x	x x	x x x	x	

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Post Market Control

- Done by market authority and to recall products that not comply with requirements
- Scope of control :
  - Products that have not been certified or registered
  - Products using counterfeit certificate or other conformity mark
  - Products that have been certified but after certification be potential to create risks

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Consideration for Post Market Control

- Needed for :
  - Take action against dishonest business enterprises
  - To form a fair market competition and transparency
  - To build a good government integrity
- Need a good plan :
  - Affected by many factors : product properties, geographic market and distribution system
  - Expensive and require credible product testing infrastructures
- Producers must take correction to products which do not comply with the requirements

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Example of SNI-Based Technical Regulation

PRODUCTs	SNIs	REGULATORs
Wheat flour for human consumption	SNI 01-3751-2000	Ministry of Industry and Trade
Ammonium sulfate fertilizer	SNI 02-1760-1990	Ministry of Industry and Trade
Ammonium chloride fertilizer	SNI 02-2581-1992	Ministry of Industry and Trade
Electrical lamp – Safety requirement	SNI 04-6504-2001	Ministry of Industry and Trade
Tire for Passenger Vehicles	SNI 06-0098-2002	Ministry of Industry and Trade
Etc		

*) Some products have been regulated based on SNI before 1995 and some of them are not effectively implemented

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THANK YOU

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2006/SOM3/SCSC/GRP/006

Relationships Between Business Sectors and Regulatory Bodies in Vietnam

Submitted by: Le Dang Doanh, Advisor to the Minister of Planning and Investment and Consultative Member of the Prime Minister's Research Commission for Social-Economic Issues (PMRC)

4th Conference on Good Regulatory Practices
Da Nang, Viet Nam
4 September 2006

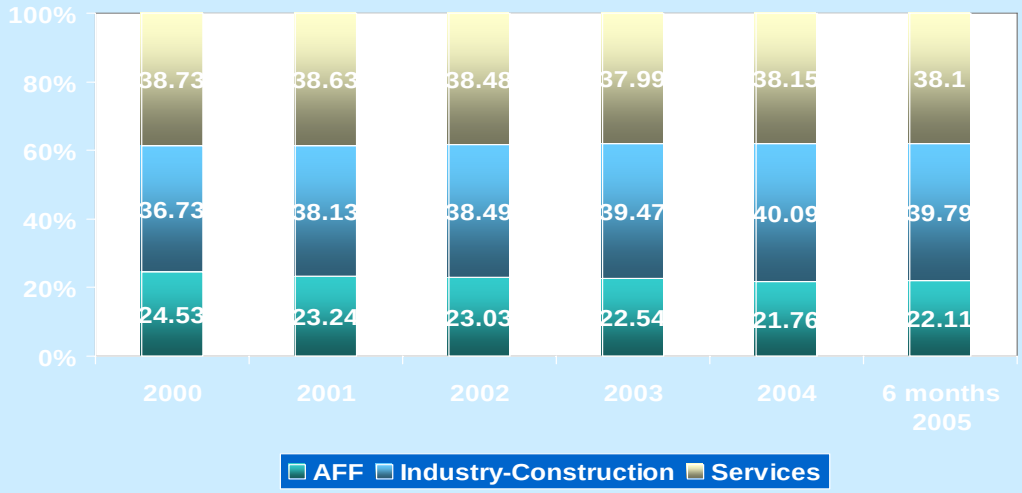
APEC 4th Conference on GRP Danang, September the 4 2006

Relationships between business sectors and regulatory bodies in Vietnam

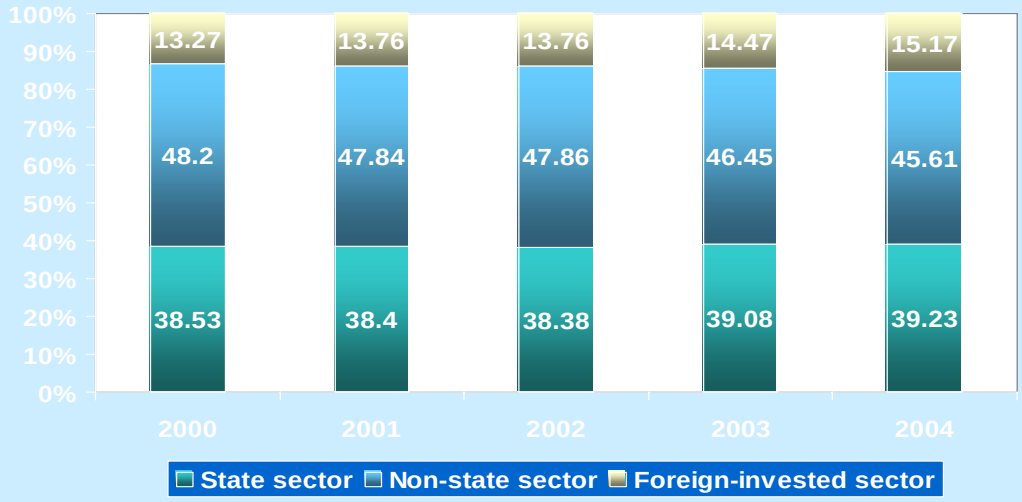
Le Dang Doanh

Population: 83.12 million (2005)
GDP: US$ billion 53 (2005)
GDP/capita: US$ 640(2005)
GDP/capita(PPP): US$ 3141
GDP-Growth rate 8,4%
Export: US$ billion 32.442 (2005)
Import: US$ billion 36.978 (2005)
CPI: 8.4%(2005)

GDP composition by economic sector 2000-05 (%)



GDP composition by ownership (%)



Progress on legal framework

- As an economy in transition from centrally planning to market economy with socialist orientation and integrated into the world economy, Vietnam has made tremendous progress and established the main pillars of market economy and reforming the public administration into a market-friendly one.
- Nevertheless Vietnam has to continue its efforts for further improvement of business environment: preventing and fighting against corruption, established the E.Government and E.Business etc.

Legal Framework

- The Enterprise Law (EL) 1999 and the EL2005 implemented the freedom to make business according to laws and simplifying the market entry.
- The Bankruptcy Law regulates the termination of business but its implementation is weak.
- The Competition Law aims to regulates fair competition and controlling monopoly but the impacts in the practical business life is limited.

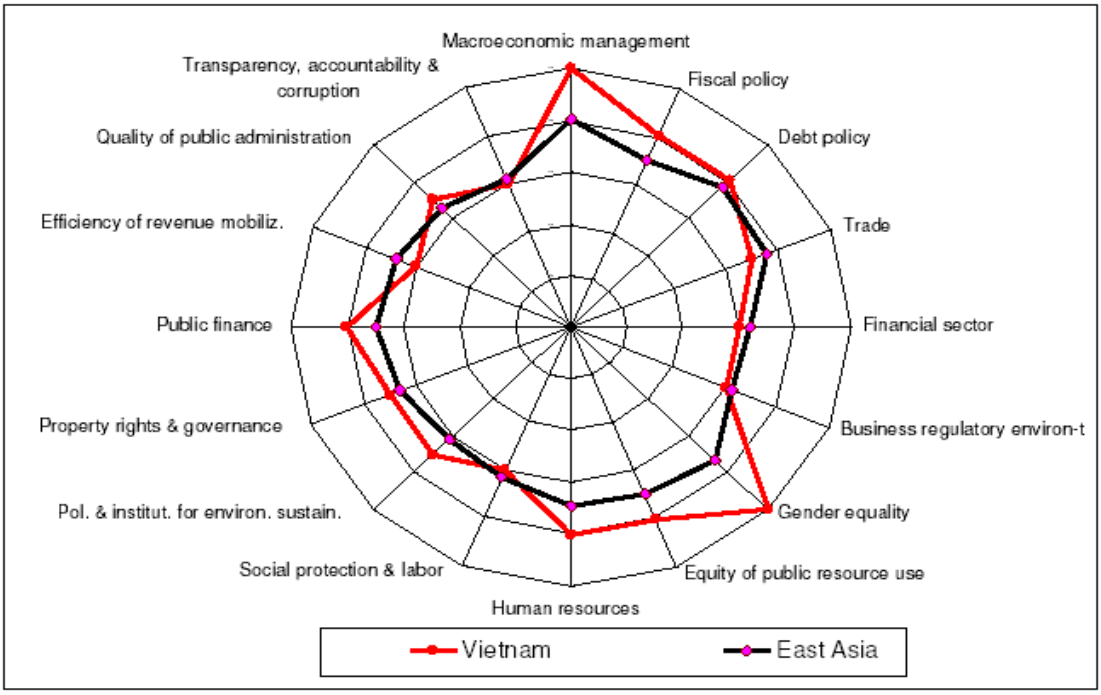
Other legal regulations

- Other laws regulating distinct businesses require business licenses, certificate of business conditions, professional certificate, insurance, capital requirement etc.
- Business operations depend on in-puts and out-puts like public utilities, land, infrastructure, human resources, information. They are regulated by other laws and provided by agencies and state-owned companies.

STATE MANAGEMENT OVER BUSINESSES

- Chapter IX of the EL regulates the tasks, responsibilities, duties of state agencies toward enterprises.
- Inspections have to be conducted according to laws.
- Business Registrar should be organized to an unified system.
- Violations from enterprises and state agencies should be strictly punished.

WB evaluation of Vietnam's Strengths and Weaknesses



Source: Based on data from the World Bank.

Binding Constraints to Growth

Based on a representative sample of enterprises

Constraint	East Asia	Vietnam	The World
Access to finance	17.4 **	37.4	30.1 **
Access to land	9.9 **	26.4	14.5 **
Labor skills and education	23.8	22.3	20.4 *
Transportation	15.2 **	21.6	12.4 **
Macroeconomic stability	34.1 **	16.8	40.2 **
Corruption	28.6 **	12.8	36.8 **
Labor relations	17.4 **	10.9	17.3 **
Legal system	27.3 **	5.5	21.6 **
Crime and theft	19.3 **	4.0	25.7 **
Licenses and permits	14.4 **	1.4	15.9 **

Corruption in the East Asian region

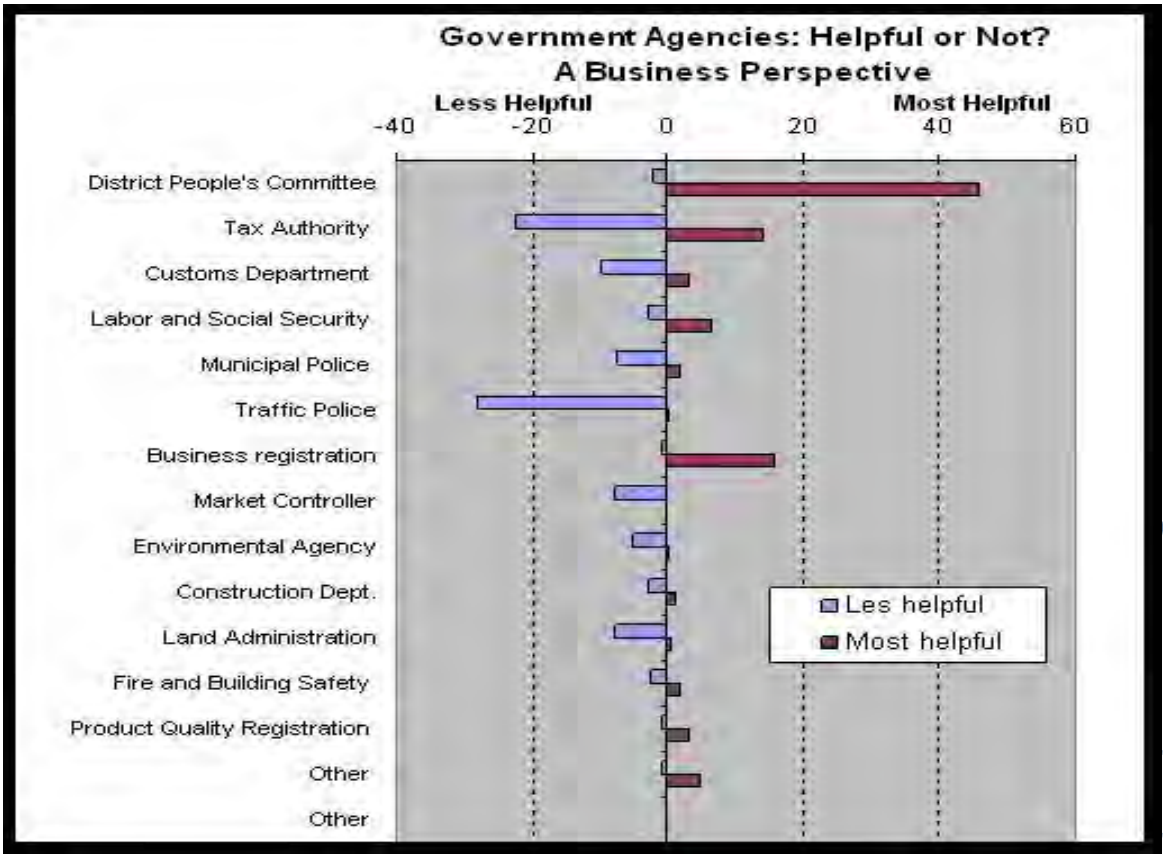
	Is corruption a constraint to business? (percent of responses)		
	No	Minor	Severe or major
Cambodia	4.7	39.4	55.9
China	24.1	48.5	27.3
Indonesia	29.3	29.2	41.5
Malaysia	53.8	31.7	14.5
Philippines	40.6	24.3	35.2
Thailand	49.7	32.1	18.3
Vietnam	52.3	17.8	14.2

Source: ICS database of the World Bank, using un-weighted averages.

Which are the most Corrupt Government Agencies in Vietnam?

Investment Climate Survey	Diagnostic Study on Corruption
Traffic police	Land administration agency
Customs department	Customs department
Tax department	Traffic police
Land administration agency	Tax department
Market controller	Regulators in construction
Construction permit authorities	Construction permit authorities
Import/ export license authorities	Health care
	Planning and investment agencies
	Regulators in transportation
	Economic police

Source: Based on data from ICS by the World Bank and on Communist Party of Vietnam (2005). In the case of the ICS, rankings are based on the share of respondents declaring that corruption is widespread or gifts are required to get a favorable decision. Only agencies with a share in excess of 5 percent are reported.



Legal regulations on services

- There are ca.80 legal regulations on different kinds of services.
- Nearly every service is subjected to license, business condition, professional certificate.
- Some regulations are vague, conditions are not precise and concrete, creating a fertile soil for abusing of power.
- Administrative Tribunal has been established but rarely used.

Implementation of legal regulations

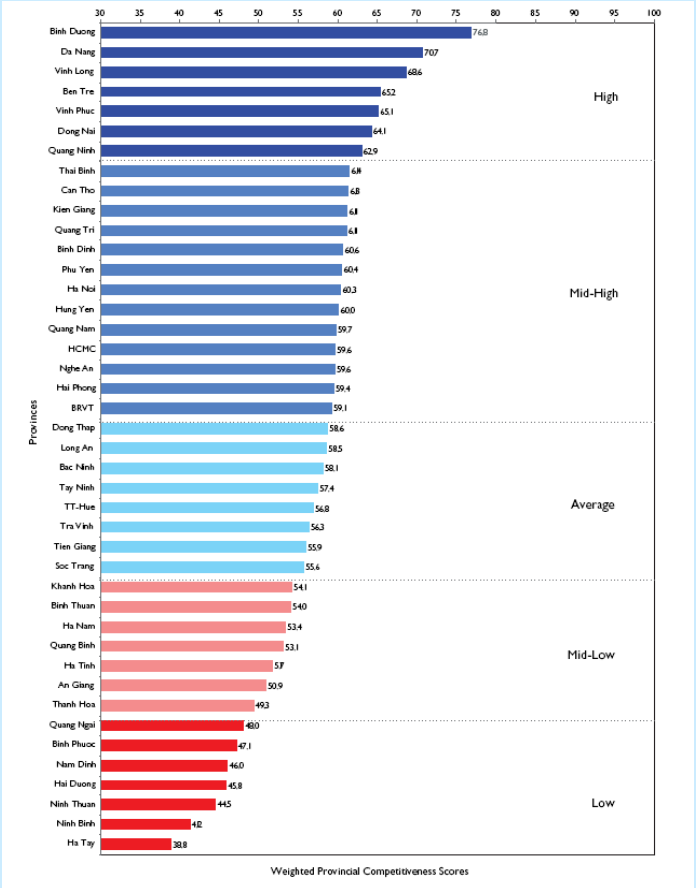
- The hierarchical structure of legal regulations (law, decree, directive) provides different interpretation and implementation.
- Lacking of transparency and openness provides space of arbitrary application of legal regulations.
- Regardless efforts of deregulations in 2001-2002, canceling 186 licenses, in the years 2003-2005 the number of licenses and permits have increased to more than 300.
- A powerful institution monitoring the licenses is needed.

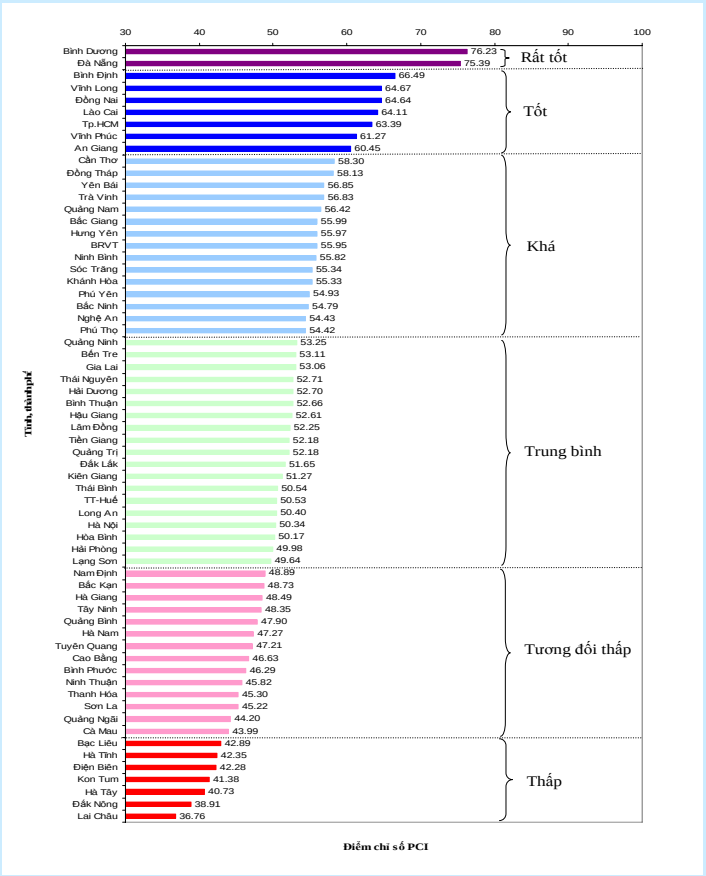
Monopolies and Regulatory Agencies

- There are in Vietnam many monopolies and de-facto monopolies in public utilities: electricity (EVN), water supply but also fixed telephone (market predominant position of VNPT), airline etc.
- Only one Regulatory Agency for electricity has been established. The Agency is not independent but reporting to the Minister of Industries like EVN.
- Until now there is no efficient regulation or monitoring for monopolies in Vietnam.

Provincial Competitiveness Index (CPI)

- Since 2005 the VNCI (Vietnam Competitiveness Initiative) in cooperation with VCCI has conducted a survey on PCI.
- Under the very same legal framework there are a huge gap between the best and the worse provinces, indicating a big potential for improvement.
- In most provinces legal institutions have been rated with under 5 scores. Business community doesn't trust the legal institutions much and prefer to use other





Prospect

- It is expected that Vietnam could join the WTO in October 2006.
- WTO should be a vehicle for reform of legal regulations, their implementation.
- General application of RIA (Regulation Impact Assessment) and other best practices could help Vietnam to improve the relations between business and regulatory bodies.

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Economic Cooperation

2006/SOM3/SCSC/GRP/007

A Case Study of Regulatory Impact Analysis (RIA)

Submitted by: Jennifer Fang-Yu Huang, Council for Economic Planning and Development, Chinese Taipei

4th Conference on Good Regulatory Practices
Da Nang, Viet Nam
4 September 2006

A Case Study of RIA

The 4th Conference on Good Regulatory Practices
Da Nang, Vietnam
September 4, 2006

Jennifer Fang-Yu Huang
Council for Economic Planning and Development
Chinese Taipei

Outline

- The Legal Basis for RIA
- Operational Flowchart for General Law Proposal
- The Assessment Checklist for Law Proposal
- A Case Study: Commodity Inspection Act
- Operational Flowchart for Significant Law Proposal
- The Lessons

2

The Legal Basis for RIA (1/2)

- In 2002, the Innovative Service Mechanism Group submitted a document concerning the establishment of Regulatory Impact Analysis (RIA) in the hope of effectively utilizing government resources in accordance with related economic analyses.
- In 2003, the CEPD presented a research report entitled "A Feasibility Study on Administrative Organizations' Implementation of RIA."
- Methods for implementing regulatory reform:
  (1) Establishing an outside-in mechanism via hosting meetings with the European and American Chambers of Commerce on a regular basis
  (2) Enhancing a bottom-up mechanism via granting the Golden Axe Awards.

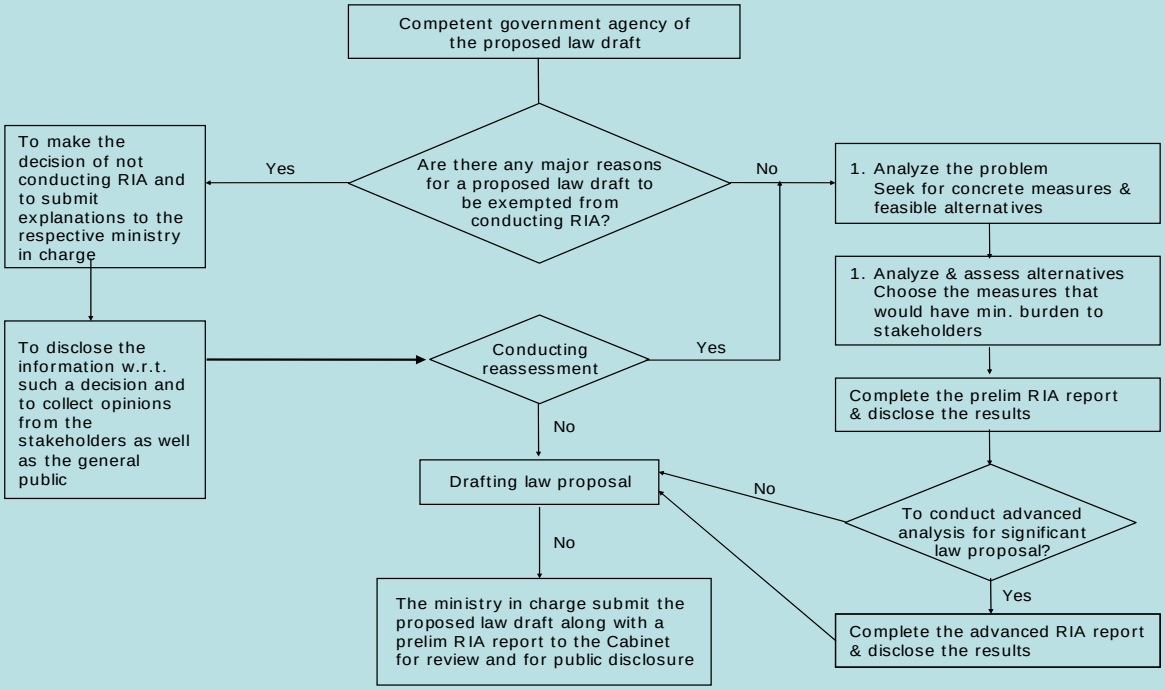
3

The Legal Basis for RIA (2/2)

- Administrative Procedure Act (1999)
- Guidelines on Central Administrative Agencies' Legal Matters (1977, 2004)
- Guidelines for Bills Submitted by Cabinet Agencies for Review (2004)

4

Operational Flowchart for General Law Proposal



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Content Guidelines for a Prelim RIA Report

- What is the Contending Issue of the Proposed Law?
- Provide the Background Information
- Set the Objectives and Targets to be Achieved
- To Identify the Possible Alternative Measures
- To Conduct the Impact Analysis
- Clear Description of the Consultation Process
- Choose the Policy Measure to be Implemented

6

The Assessment Checklist for Law Proposal (1/3)

1. Describing Issues of the Proposed Law
   - (1) Related issues being involved
   - (2) Any reasons for being exempted from this checklist assessment procedure
2. Providing the Background Information
   - (3) The current legal environment
   - (4) The possible agencies, industries, people being impacted by the proposed law in terms of costs, obligations and rights, as well as change in welfare
3. Formulating the Problem
   - (5) Is the matter a set government policy or a legal obligation for amendment?
   - (6) Any difficulties or obstacles occurred in the current social or market mechanism?
   - (7) Any difficulties or obstacles occurred in current government institutions or legal operations?
   - (8) Other causes?

7

The Assessment Checklist for Law Proposal (2/3)

4. Setting the Targets to be Achieved
   - (9) Clear delineation for the scope of the problem and the linkage with the matter to be resolved
5. Identifying the Possible Alternative Measures
   - (10) Maintaining the status quo
   - (11) Possible extrajudicial alternatives
   - (12) Possible judicial alternatives
   - (13) Other measures
   - (14) List of Prelim-formulated alternatives
6. Conducting Regulatory Feasibility Assessment (RFA)
   - (15) If SMEs are involved, it is to conduct the Regulatory Feasibility Assessment for them.

8

The Assessment Checklist for Law Proposal (3/3)

7. Engaging in Pubic Consultation Process
   (16) whether or not consultation documents are well prepared and public opinions are being solicited?
   (17) Active opinion consultation
   (18) Records for the consultation process
8. Undertaking policy assessment
   (19) Compilation of the public opinion and records of consultation
   (20) Conducting CBA for each possible alternatives
9. Choosing the Policy Measure to be Implemented
   (21) The concrete contents for the chosen measure
   (22) The reason for the particular choice
   (23) Whether or not to conduct the advanced analysis

9

A Case Study – Amendment of the Commodity Inspection Act (1/4)

- Participating agencies:
  - Committee of Laws and Regulations, The Cabinet
  - Council for Economic Planning and Development (CEPD)
  - Research, Development, and Evaluation Commission
  - Bureau of Standards, Metrology, and Inspection, MOEA
- 6 meetings (3 hours long) + 175 men hour
- 17 proposed amendments are reviewed via the aforementioned process
- 2 of the 17 proposed amendments are dropped after the process
- 3 of the 17 proposed amendments are chosen as materials for writing a demonstrating RIA report

10

A Case Study – Amendment of the Commodity Inspection Act (2/4)

- To amend Article 12 of the Act so that the commodity inspection mark could be placed on qualified commodities according to the special characteristics of the goods

[Note: Article 12 of the Act states that the obligatory inspection applicant shall place the commodity inspection mark on commodity's body.]

⇨ To amend the law !

11

A Case Study – Amendment of the Commodity Inspection Act (3/4)

- To amend Article 14 of the Act so that the management system is to be in conformity with the requirements being prescribed by the BSMI

[Note: Article 14 of the Act states that in order to upgrade the management of commodity or service in terms of quality, environment, safety or health, the BSMI may implement certification system in connection with products or management authority. ……]

⇨ To amend the law !

12

A Case Study – Amendment of the Commodity Inspection Act (4/4)

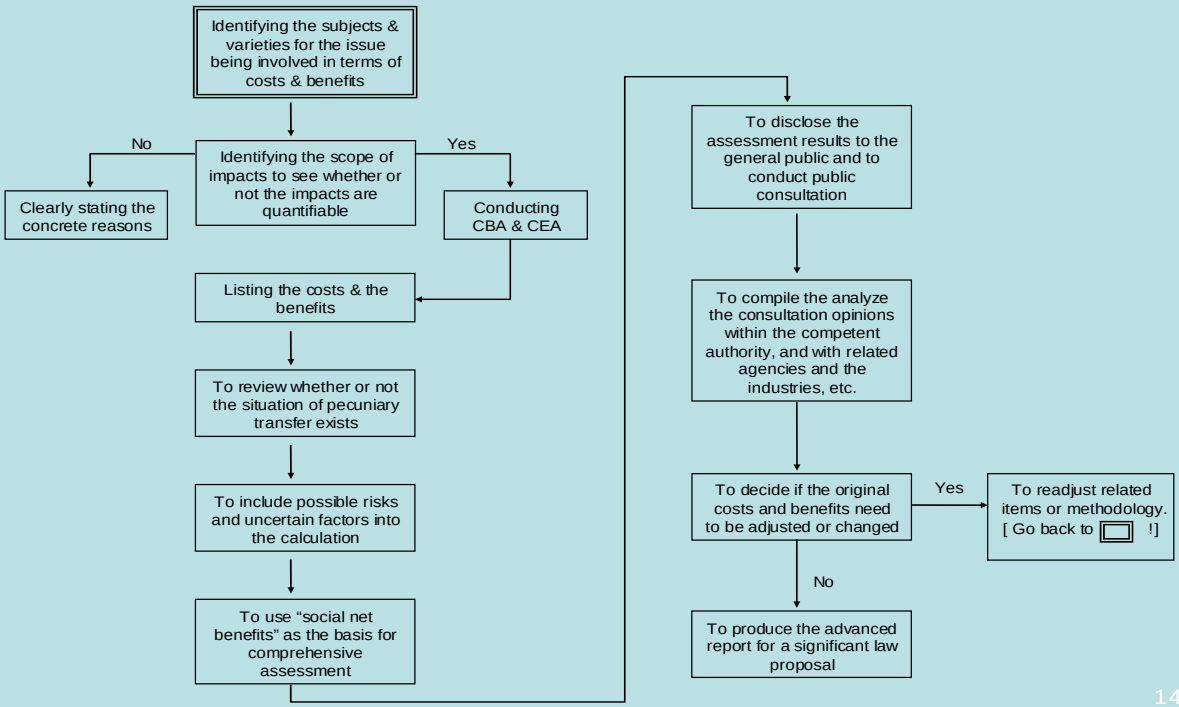
- Regarding seal-up disqualified commodities to be stored at a designated place

  [Note: Article 50 of the Act states that The BSMI may proceed to … seal up the suspect commodity and place it under the custody of the representative …
  or to request the representative … to store the suspect commodity at a designated place. ……]

⇨ To maintain the status quo !

13

Operational Flowchart for Significant Law Proposal



14

The Lessons

- Awareness raising and capacity building programs
- Cross-agency coordination and cooperation
- Mechanism for clear accountability assigning
- Accumulation of know-how with a designed institutional arrangement
- Adequate incentives for civil service providers
- PP² (for Public & Private Partnership)

15

Thank you very much for your kind attention

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16

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Australian Performance-Based Regulatory System

Submitted by: Ivan Donaldson, General Manager, Australian Building Codes Board

4th Conference on Good Regulatory Practices
Da Nang, Viet Nam
4 September 2006

Australian Performance-based Regulatory System

Ivan Donaldson
General Manager, Australian Building Codes Board

ABSTRACT

This paper discusses various aspects of a performance-based building regulation system drawing mainly on Australian experience. Australia has established and operated a performance-based building regulatory system for the last 10 years. Issues to be discussed in this paper include:

- The development of a performance-based building code
- Issues that have arisen in its application
- Education and training of practitioners
- Relationship between regulations and standards (such as ISO and national standards)

CONTENT

0. Introduction

1. What is performance-based regulation?

2. Why did we adopt it?

3. What are the components of the system?

4. How does it work?

5. What are the issues in drafting and application?

6. What are the impacts?

OUTLINE

0. Introduction

- Australia has operated a performance-based building code for more 10 years
- Purpose of paper is to share this experience with other participating economies

1. What is performance-based regulation?

- **WTO-TBT**: 'Wherever appropriate, Members shall specify technical regulations based on product requirements in terms of ***performance*** rather than design or descriptive characteristics.' (Clause 2.8)
- **'Performance-based Regulation'**: A regulation system that has:

- specific requirements (*performance requirements*) to ensure achievement of the regulatory objectives without compulsory prescription of specific technical solutions
- means for demonstrating compliance with the performance requirements for any proposed solution

2. Why did we adopt it?

- **Flexibility** for construction industry:
  - To promote innovation
  - To adopt new technologies
  - To optimize designs to suit specific buildings

- **Cost saving** by allowing the use of alternative materials, forms of construction or designs

- **Regulatory reform**:
  - Clear indication of what regulation is trying to achieve
  - Principles of good regulation - COAG

- **International trade**: to remove technical trade barriers

3. What are the components of the system?

For the system to operate effectively:

- **Technical Development**: building codes and supporting referenced documents

- **Administrative Development**: building control agencies and building surveyors

- **Educational Development**: of technical and administrative professionals

4. How does it work?

The technical development of the Building Code is the core element of the system. The structure of the Building Code of Australia is a typical example. It consists of the following components:

i) Objectives
ii) Functional Statements
iii) Performance Requirements
iv) Building Solutions

The *Objectives* and *Functional Statements* are considered as Guidance i.e. as an aid to interpretation of what the provisions are trying to achieve.

The *Performance Requirements* are mandatory i.e. a *Building Solution* is considered as complying only if it satisfies the *Performance Requirements*.

The *Building Solutions* are grouped into two types:

a) Deemed-to-Satisfy Solutions(DTS): if these solutions are followed then the building works are considered as complying and no further assessment is necessary.
b) Alternative Solutions: Any solutions that are at variance with the DTS solutions are classified as *Alternative Solutions*. They will be assessed for compliance with the *Performance Requirements.* There are various methods for doing this*:*

- If the *Performance Requirements* are **quantified**, then it is possible to use a *Verification Methods* to demonstrate compliance.
- If the *Performance Requirements* are **not quantified**, then two options are available for demonstrating compliance:
    - Comparison with the DTS solutions
    - Expert Judgment

5. What are the issues in drafting and application?

- **Scope, roles and objectives** of the building code must be clearly defined: Life-saving objectives are generally not in dispute but the role of regulation in property protection, consumer protection etc. are debatable. Degrees of overlap between various jurisdictions are also possible cause for conflict.
  More recently, issues such as sustainability and societal needs are emerging.

- **Qualitative vs. Quantitative performance requirements**: Quantification of performance requirements is a desirable goal but it must be realized that it is not possible to quantify all requirements. The effort is continuing but progress is limited by the development of related sciences and practical consideration of developing appropriate verification methods.

- **Relationship with referenced documents**: A building code needs to be supported by other documents such as standards. The role of these supporting documents must be clearly defined and its drafting must be suitable for regulatory adoption. While a policy of adopting international standards (such as ISO Standards) is desirable, the adoption of some ISO Standards may be difficult because of the regulatory frameworks in some economies.

6. What are the impacts?

KPMG Study (1999):

- Cost saving: 1% to 5%
- Designs are better able to meet functional, financial and aesthetic requirements
- Flexibility in accommodating new products and materials therefore encouraging innovation
- Scope for abuse of system
- Lack of understanding by suppliers and other building professionals

Productivity Commission Research Report (2004)

- Greater flexibility in satisfying regulatory objectives
- Performance requirements needs to be clarified/quantified
- More pressure on expertise of certifiers
- Problems of insurers unable to assess the risks of performance-based solutions resulting in higher premium

AUSTRALIAN PERFORMANCE-BASED REGULATORY SYSTEM

Ivan Donaldson
General Manager
Australian Building Codes Board

CONTENT OF PRESENTATION

0. Introduction
1. What is performance-based regulation?
2. Why did we adopt it?
3. What are the components of the system?
4. How does it work?
5. What are the issues in drafting and application?
6. What are the impacts?

Introduction

- Australia has operated a performance-based building code for more 10 years
- Purpose of presentation is to share this experience with other participating economies

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PERFORMANCE-BASED REGULATION

- WTO-TBT: 'Wherever appropriate, Members shall specify technical regulations based on product requirements in terms of **performance** rather than design or descriptive characteristics.' (Clause 2.8)
- 'Performance': 'Behaviour (of a product) related to use' (ISO 6241)

Building Australia's Future

PERFORMANCE-BASED REGULATION

Two components:

- Specific requirements (P**erformance requirements**) to ensure achievement of the regulatory objectives without compulsory prescription of specific technical solutions
- **Means for demonstrating compliance** with the performance requirements for any solution

Australian Building Codes Board

Why did we adopt it?

- **Flexibility** for construction industry:
  - To promote innovation
  - To adopt new technologies
  - To optimize designs to suit specific buildings
- **Cost saving** by allowing the use of alternative materials, forms of construction or designs

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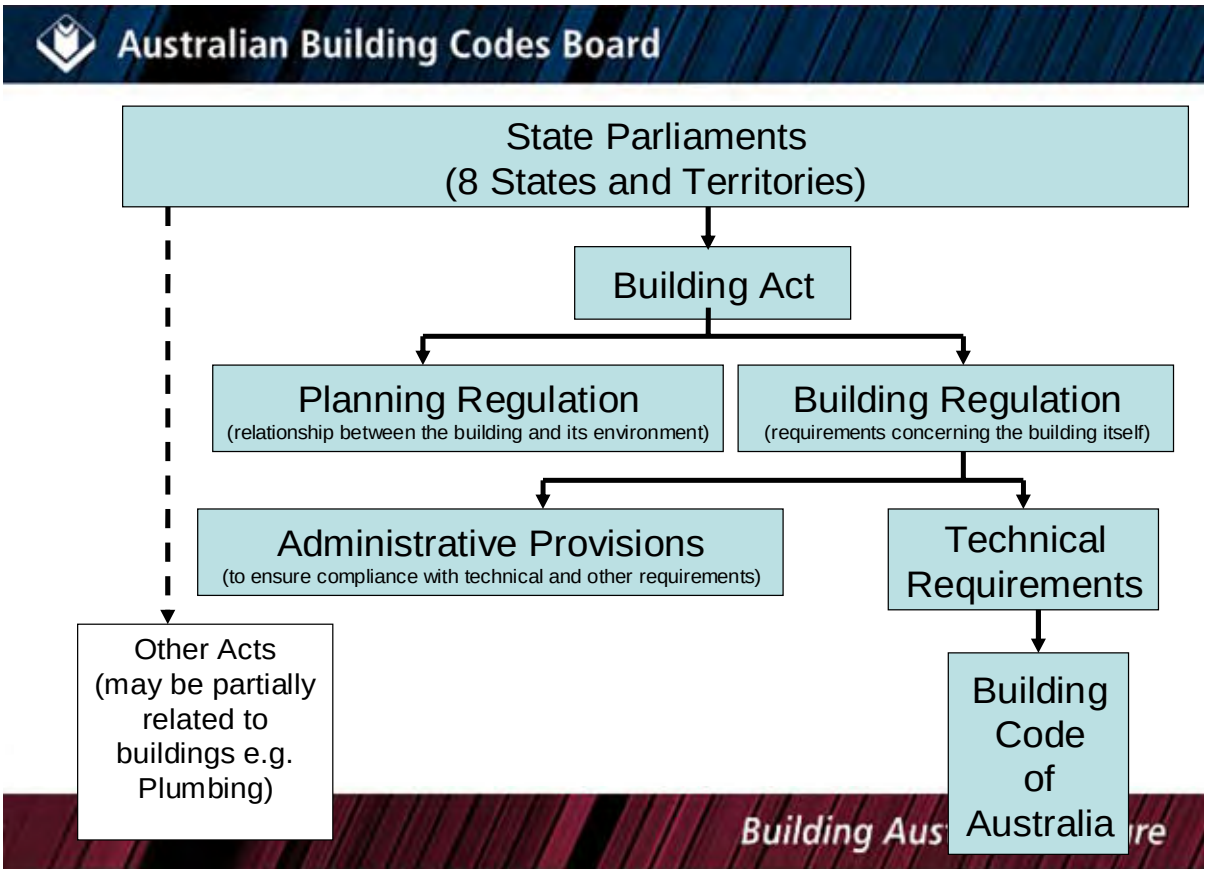
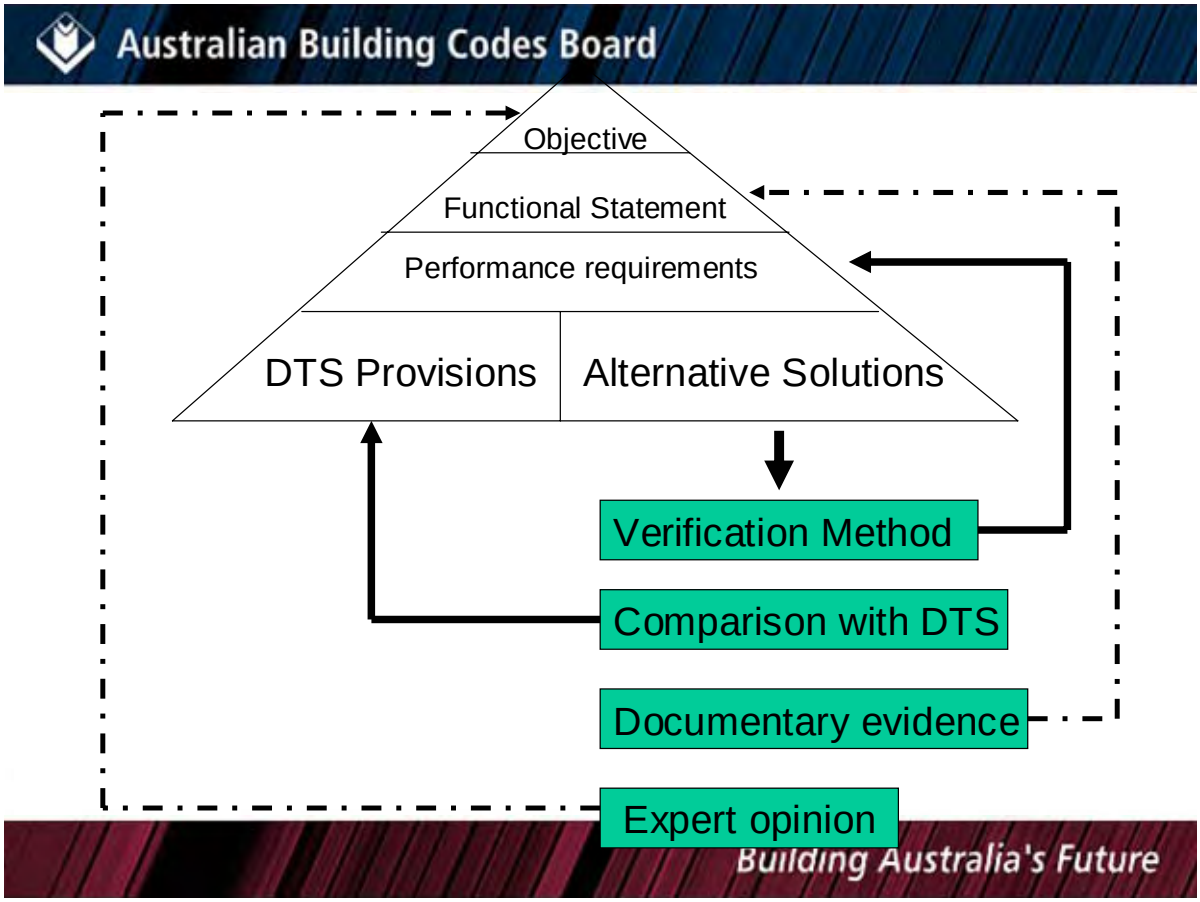
Why did we adopt it?

- **Regulatory reform**:
  - Clear indication of what regulation is trying to achieve
  - Principles of good regulation - COAG
- **International trade**: to remove technical trade barriers

Components of the system

- **Technical Development**: building codes and supporting referenced documents
- **Administrative Development**: building control agencies and building surveyors
- **Educational Development**: of technical and administrative professionals


Australian Building Codes Board
State Parliaments
(8 States and Territories)
Building Act
Planning Regulation
(relationship between the building and its environment)
Building Regulation
(requirements concerning the building itself)
Administrative Provisions
(to ensure compliance with technical and other requirements)
Technical Requirements
Other Acts
(may be partially related to buildings e.g. Plumbing)
Building Code of Australia


Australian Building Codes Board
Objective
Functional Statement
Performance requirements
DTS Provisions
Alternative Solutions
Verification Method
Comparison with DTS
Documentary evidence
Expert opinion
Building Australia's Future

Issues in drafting and application

- **Scope, roles and objectives of the code:**
  - Life-saving – generally accepted
  - Property protection ?
  - Consumer protection ?
  - Overlaps between jurisdictions
- **Recent issues:**
  - Sustainability
  - Societal needs

Australian Building Codes Board

Issues in drafting and application

- **Qualitative vs Quantitative requirements**:
  - Quantification is a desirable goal
  - Not possible to quantify all requirements
  - Limited by the development of related sciences and practical consideration of developing appropriate verification methods

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Issues in drafting and application

Relationship with referenced documents:

- Need to be supported by referenced documents such as standards
- The role of these must be clearly defined and its drafting must be suitable for regulatory adoption
- The adoption of international standards (such as ISO Standards) is desirable but may be difficult because of the regulatory frameworks in some economies

Impacts of performance-based regulation

KPMG Study (1999):

- **Cost saving**: 1% to 5%
- **Better designs**: to meet functional, financial and aesthetic requirements
- **Flexibility** in accommodating new products and materials therefore encouraging innovation
- **Abuse potential**
- **Lack of understanding** by suppliers and other building professionals

Impacts of performance-based regulation

Productivity Commission Research Report (2004)

- Greater flexibility in satisfying regulatory objectives
- Performance requirements needs to be clarified/quantified
- More pressure on expertise of certifiers
- Problems of insurers unable to assess the risks of performance-based solutions resulting in higher premium

Concluding Remarks

- Brief outline of the Australian performance-based regulatory system
- In operation for more than 10 years with good outcomes for industry
- Will be continuously improved as part of government regulatory reform process

Thank you for your attention.

Appendix

Asia-Pacific
Economic Cooperation

2006/SOM3/SCSC/GRP/009

Information Notes on Good Regulatory Practice for Technical Regulation

Purpose: Reference
Submitted by: Australia

4th Conference on Good Regulatory Practices
Da Nang, Viet Nam
4 September 2006

INFORMATION NOTES ON GOOD PRACTICE FOR TECHNICAL REGULATION

SEPTEMBER 2000

TABLE OF CONTENTS

INFORMATION NOTES ON GOOD REGULATORY PRACTICE FOR TECHNICAL REGULATION 1

1. INTRODUCTION 1

2. REGULATION OF PRODUCTS 3

What is Regulation? 3

Forms of Regulatory Responses 3

Choosing the Appropriate Regulatory Response 6

Guidelines on Technical Regulation 8

3. TECHNICAL REGULATION 9

Performance Based Technical Regulations 9

Referencing Voluntary Standards 10

Alignment with International Standards 10

Equivalency 11

Minimising the Trade Restrictive Effects of Technical Regulation 12

4. CONFORMITY ASSESSMENT 13

Conformity Assessment Regimes 13

Types of Conformity Assessment Regimes 14

Choosing the Appropriate Conformity Assessment Regime 16

Recognising the Results of Conformity Assessment Activities 16

5. REGULATORY SAFETY NETS 18

Types of Regulatory Safety Nets 18

6. POST-MARKET SURVEILLANCE 21

APPENDIX 1 - RISK ASSESSMENT TECHNIQUES 25

APPENDIX 2 - ESTABLISHING A REGULATORY REGIME 30

INFORMATION NOTES ON GOOD PRACTICE FOR TECHNICAL REGULATION

These Information Notes provide member economies with resource materials for reference when preparing, adopting or reviewing their regimes for the regulation of products according to the Principles and Features of Good Practice for Technical Regulation compiled by the APEC Sub-Committee on Standards and Conformance (SCSC). The reference material contained in these Information Notes is intended to assist member economies in the adoption of efficient regulatory arrangements, which should lead to reductions in regulatory barriers to trade. Use of these Information Notes should be considered as one of the means for assisting member economies in meeting their international obligations under the WTO TBT Agreement and their commitment under the APEC Bogor Declaration.

These Information Notes will be revised for their improvement and augmented, over time, by a number of case studies and the outcomes of issue specific seminars.

1. INTRODUCTION

With the reduction in tariffs, non-tariff barriers to trade are moving to the forefront as market access issues. Of these, differences in the regulatory requirements of individual economies are among those which have the greatest impact on trade. In certain situations, regulatory requirements may actually impede gains from trade liberalisation.

While economic literature is replete with estimates of the welfare losses from tariffs and the benefits of market liberalisation, studies that identify and quantify the effects of non-tariff barriers are generally lacking. The information that is available tends to be limited to particular markets and industries in which disputes have arisen or in which case studies have been undertaken. Much of this information appears to be subjective and anecdotal. This noted, the information and studies available do agree that regulatory reform in the form of adoption of good regulatory practices can generate gains in terms of trade facilitation.

In an APEC Economic Committee study in November 1997 entitled *The Impact of Trade Liberalisation in APEC* existing trade facilitation programs (such as those relating to standards and conformance) were estimated to generate gains of about 0.26 percent of real GDP to APEC (or about US$45 billion) whereas gains from trade liberalisation (ie. tariff

reductions) would only amount to about 0.14 percent of real GDP, or half that achievable through trade facilitation measures.

The APEC Sub-Committee on Standards and Conformance (SCSC) has already taken significant steps in addressing standards and conformance related barriers to trade by developing and endorsing:

- a Guide for Alignment of APEC Member Economies' Standards with International Standards;
- accelerated alignment of member economies' standards with international standards in agreed priority areas; and
- APEC Guidelines for the Preparation, Adoption and Review of Technical Regulations;

The impact of the work of the SCSC in alignment of standards and the development of mutual recognition arrangements on conformity assessment will be magnified if good regulatory practice is adopted by member economies.

2. REGULATION OF PRODUCTS

What Is Regulation?

Regulation can be defined as any measure or intervention implemented under government authority that acts to control the behaviour of individuals or groups that come within the ambit of that authority. Regulation includes the primary laws and subordinate instruments developed by government and the rules issued by government and non-government agencies under delegated powers.

The Organisation for Economic Cooperation and Development (OECD) identifies three categories of regulation:

- economic regulations which intervene directly in market decisions.
- social regulations which protect public interests such as health and safety, the environment and social cohesion; and
- administrative regulations which are administrative and paperwork requirements through which governments collect information and impact on individual decision making through the requirement for licensing et cetera.

The regulatory environment for governments and regulators is one in which there is an increasing focus on systematic analysis and review of both existing and new regulatory proposals. This focus is emanating from three main drivers - the desire of governments themselves to efficiently and effectively manage their regulatory responsibilities; the desire of those to which the regulation applies for efficient and effective regulatory and compliance regimes; and the increasing recognition of the benefits that can be realised from regulatory cooperation between governments.

Forms of Regulatory Responses

The greatest economic gains occur as governments move towards open and transparent marketplaces where community interests are supported without excessive regulation being imposed on business. Therefore, before implementing mandatory requirements, governments should consider all available regulatory options and should favour the adoption of the minimum effective regulation necessary to achieve the desired outcomes.

While not limiting the forms of regulatory responses available, the most recognised are identified and briefly discussed below.

Status Quo

The status quo should always be considered as an option. Alternatives may not always result in an outcome that is better than the status quo.

Legal Recourse

Governments can take a "hands off" approach to regulation and rely on common law to ensure the appropriate behaviour of individuals and business. By providing access to legal remedies, parties can enforce their rights rather than relying on government action. Legal remedies can, however, be uncertain, slow or too costly to be an efficient method of modifying behaviour.

To belay the costs of legal remedies, some economies have developed product liability insurance schemes which protect certain groups (eg. consumers) against specific risks. Such insurance schemes, which may be developed, promoted or required by government, can contain in-built health and safety considerations. In such cases, the insurance scheme sets the appropriate level of control without the direct intervention of government.

Liability Laws

As governments place an increasing emphasis on preventative measures, the regulatory responses they choose are designed to reduce risks. Yet risk by itself is not sufficient reason for governments to intervene in the market place. Technical regulations may not be necessary if those who are able to reduce the risk of accidents and/or injury face effective incentives to do so. This can be achieved through laws which make the manufacturer/supplier accountable for any damage caused through their actions. Robust, transparent liability laws create strong incentives for manufacturers or suppliers to educate consumers, workers, and others about risks that may be outside the realm of their direct experience.

Economic Instruments

Economic instruments seek to influence market behaviour by altering the relative prices of goods. These instruments can be more efficient than prescriptive regulation because they allow individuals to make their own cost-benefit trade-offs in pursuing certain behaviour. Therefore, they can achieve desired regulatory outcomes in a way that imposes the least cost on them. By using such economic instruments, the costs of enforcing behaviour can be reduced.

Market behaviour can be influenced either directly (for example, through a tax or user charge), or indirectly (for example, through controlling the overall level of supply). The most common use of economic instruments is as a response to externalities. Economic instruments are a means of "internalising" the costs of externalities, so that they will be taken into account in production and consumption decisions.

Education Programs

This option improves the functioning of the market by allowing individuals to make decisions that better match their requirements through improved knowledge. The main advantage of

this option is that it allows individuals to choose what is best for them, given the information available, rather than imposing one solution on all.

This type of approach does not set legally binding rules of behaviour. Instead objectives are reached through education and persuasion.

The provision of information or education may be as effective as coercion for obtaining desired results. Information can be disseminated through government action by requiring companies to disclose information on certain features or attributes of the product to consumers, and through the government collecting and disclosing information to the public.

Education programs can improve outcomes while still preserving consumer choice. Even poorly-informed consumers have more information than governments about their preferences, their financial situation, their skills and so on. Governments, on the other hand, can obtain critical information for consumers. It is far easier to provide information to consumers than to try to collect all of the information that would be required for the government to substitute its own judgement about when and how goods should be used. For example, it may be better to label appliances with energy-use information than to set energy-efficiency standards, since the government does not know whether a furnace will be installed in a well- or poorly-insulated house; whether an air conditioner will be used daily, or only on weekends; how many people will be taking showers from a water heater; how many people will be contributing laundry to a washing machine. All these conditions change the cost-benefit analysis of specific energy-use decisions.

It should be noted, however, that the administrative burdens of collecting and maintaining information under mandatory disclosure schemes can be high. Furthermore, disclosed information should be easily understood or interpreted by consumers.

Voluntary Standards

In the context of the social infrastructures that exist, Government endorsement of, or support for, a voluntary standard or compliance regime may be as effective as a mandated regime without the compliance costs to government associated with a mandated conformity assessment regime. Voluntary standards established with the consent of all the stakeholders should be assumed to fulfil the necessary requirements for the products to be placed on the market. Consequently, a compliance regime with voluntary standards should be considered as an effective alternative tool to mandatory regulation. Needless to say, maximum efforts should be given to align these voluntary standards with the international standards.

Industry Self-Regulation

Self-regulation can be defined as an arrangement in which an organised group (such as an industry association) regulates the behaviour of its members. The advantages of self-regulation are that rules may be more likely to be observed if they are made by members of the group, changes and updating can be more rapid, and it is cheaper for the governments because the group bears the costs of regulating.

Government oversight may be needed to ensure that the public is being protected, rather than the private interest of the regulated group.

Codes of Practice

Voluntary schemes may be established by a private body or group of private bodies in the form of codes of practice. These can cover issues such as standards, information requirements, or dispute resolution mechanisms. Codes of practice can be effective tools for building consumer confidence, and providing effective communication between consumers and suppliers. The effectiveness of codes of practice depends on how many members are in the scheme, the sanctions for non-compliance and the degree to which consumers are involved in developing and monitoring the scheme.

Codes of practice are often developed by consensus between those who will be applying them. In addition, codes of practice tend to be developed by those with a good knowledge of market conditions, and so should be better suited to economic and competitive conditions than technical regulations. Care needs to be taken that codes of practice are subject to effective competition laws so that codes of practice will not be used to reduce competition or create de facto cartels.

Technical Regulation

A technical regulation is a document adopted by an authority that provides binding technical requirements, either directly or by referencing or incorporating the content of a standard, technical specification or code of practice. Technical regulations may specify the type of product that is not allowable, the type of product that is allowable, or the outcome that is required. By their very nature, technical regulations have an effect on the type of products that can be manufactured.

Technical regulations are the most stringent form of government control and should ideally be used only in situations where none of the other options for the regulation of product, outlined above, will ensure the adequate protection of health, safety and the environment.

Choosing the Appropriate Regulatory Response

Whilst regulation will continue to be an important tool for preserving and advancing public interests, it is recognised that regulations can become an obstacle to achieving the very economic and social well-being for which they are intended.

The OECD notes that regulatory arrangements can impede innovation and create unnecessary barriers to trade, investment and economic efficiency. They may involve duplication between regulatory authorities and different layers of government, and between governments of different economies. They may also promote the influence of vested interests seeking protection from competition. Similarly, regulations that are outdated or poorly designed to achieve their intended policy objectives contribute to inefficient regulatory arrangements.

In discussing the rationale for reviewing regulation, a recent OECD study stated:

> *Inappropriate regulations can potentially result in substantial costs or inefficiencies being imposed upon both the sector and the economy as a whole ... the direct results of inappropriate regulation in a particular sector are likely to be higher costs, higher prices, misallocation of resources, a lack of product innovation and poor service quality.*

Given this, it is evident that the economy-wide gains that can be captured by pursuing regulatory best practice may be significant. The same OECD study estimated economy-wide effects of regulatory reform in eight economies and found the potential for significant gains in labour and capital productivity and potentially significant economy-wide increases in GDP and real wages.

The challenge for all economies is to achieve the objectives of the government, in terms of protecting the health and safety of the community, while keeping regulatory intervention to a minimum. By keeping regulatory intervention to the minimum necessary to achieve the regulatory objective, member economies will not stifle innovation and competition amongst businesses and thereby ensure benefits to consumers and to the community in general.

This challenge is encapsulated in Article 2.2 of the WTO TBT Agreement which states:

> *Members shall ensure that technical regulations are not prepared, adopted or applied with the view to or with the effect of creating unnecessary obstacles to international trade. For this purpose technical regulation shall not be more trade restrictive than necessary to fulfil a legitimate objective.*

Accordingly, to maximise economic well-being, member economies should adopt the least restrictive regulatory response possible to achieve their legitimate regulatory objectives.

Tools for Regulatory Analysis

Cost-benefit analysis is a useful tool for policy-makers to decide whether a particular regulatory response is the most appropriate in a given situation. It enables decision-makers to make judgements about the reasonableness of a regulation and the practicalities for those who will be required to comply. It also allows regulations to be designed so that they impose the lowest costs and yield the greatest benefits. A major consideration when undertaking a cost-benefit analysis is the assessment of risk[1]

By quantifying and comparing the total benefits and costs of a proposal, it is possible to determine whether a proposal has a net benefit, that is, whether the benefits outweigh the costs. Those proposals with a net benefit result are potentially attractive and the proposal with the greatest net benefit should be selected and implemented.

Monitoring the Effectiveness of Regulatory Responses

Member economies should be mindful of the fact that the market place is a dynamic environment and that problems are seldom resolved completely in the first instance. Accordingly, member economies should have mechanisms for the ongoing evaluation of the success of the chosen regulatory response.

[1] A discussion of Risk Analysis Techniques is to be found in Appendix 1.

Guidelines on Technical Regulation

Recognising the potential gains from the pursuit of regulatory good practice, all economies are coming under increasing pressure to adopt good regulatory practice, as applied at both the domestic and international level. Many governments have moved to establish central agencies to oversee the development and review of regulation. Similarly, many governments have moved to adopt standardised, systematic analytical tools to aid their decisions in relation to the review of current regulation and the vetting of new regulatory proposals.

The *APEC Guidelines for the Preparation, Adoption and Review of Technical Regulations*[2] provides one such analytical framework. It is a simple but effective analytical tool. The checklist developed as part of the Guidelines asks the following questions in relation to a regulatory proposal:

- Has the problem been clearly identified?
- Have all the options to address the problem been considered?
- Has the design and implementation of technical regulations been considered?
- Have performance-based regulations and/or standards been considered?
- Have international standards and obligations been considered?
- Have compliance mechanisms been considered?
- Have provisions for review and monitoring of the technical regulation been considered?
- Has consultation taken place?

In developing this framework, member economies recognise that the development of complementary analytical frameworks for regulatory review will facilitate good regulatory practice.

[2] These Guidelines have been endorsed by APEC Senior Officials and referred to other APEC fora for consideration and use where appropriate.

3. TECHNICAL REGULATION

Performance-Based Technical Regulations

There are two main types of technical regulations. These are:

- prescriptive - which specify the means for attaining the specified outcome; and
- performance-based - which specify the desired objective in precise terms but allow the regulated entity to determine their own technique for achieving the outcome.

Prescriptive regulations focus attention on only one means of achieving the desired objective. As such, prescriptive regulations can create an obstacle to trade and economic development. Firms are locked into a single solution with no opportunity to utilise alternative, and possibly more cost efficient, compliance solutions. Prescriptive regulations may suppress innovation and create barriers to the uptake of new technology.

Prescriptive regulations do, however, provide certainty for those being regulated and for those whose role it is to determine whether the desired objective has been met. Because of the implications that result from reduced flexibility, prescriptive regulations should only be applied when there are extremely limited ways of achieving a desired objective or when the problem that the regulation addresses is static. In these cases, certainty may be more important than flexibility.

On the other hand, performance-based regulations represent a more flexible approach and allow regulated entities to devise the most efficient and effective method of compliance.

Performance-based technical regulations are generally preferred over prescriptive requirements as they provide flexibility while ensuring that the objective is achieved. Performance-based regulations are a less trade restrictive form of regulation and are endorsed by APEC member economies through their adoption of the *APEC Guidelines on Preparation Adoption and Review of Technical Regulations*, and by members of the WTO, through Article 2.8 of the WTO TBT Agreement which states:

> *Wherever appropriate Members shall specify technical regulations based on product requirements in terms of performance rather than design or descriptive characteristics.*

The major advantage of performance-based regulations is that they can accommodate a range of technical solutions provided the outcomes are the same. Performance-based regulations provide flexibility for manufacturers in terms of demonstrating compliance with outcomes, thus providing scope for firms to innovate and adopt new technology.

However, in its analysis of performance-based regulation, the OECD has highlighted that performance-based regulatory solutions:

- may introduce uncertainty regarding what constitutes acceptable compliance;
- are suitable only in situations where the regulated entity is in a better position than the regulator to understand and address the potential causes of problems which the regulation is designed to address; and
- may pose difficulties for regulators to monitor and enforce compliance.

These concerns go to the level of uncertainty created by allowing flexibility in methods of achieving compliance. It can be argued that performance-based regulations disadvantage some firms, particularly small and medium sized enterprises, which may need or prefer more guidance on how to meet the regulatory requirements of both the domestic and export markets. Small to medium businesses may, therefore, prefer the legal certainty provided by approved or recommended methods of compliance as opposed to the costs of legal advice and liability insurance that are often associated with compliance with performance-based regulations.

One method of addressing this problem is for regulators to provide performance-based regulations that include references to optional prescriptive standards (called 'deemed-to-comply solutions'). These prescriptive standards can be effectively used as examples with the view to lessening the compliance burden of small-medium sized enterprises. Compliance can be achieved either by using the prescribed deemed-to-comply solutions or by using an alternative solution that can be demonstrated as achieving the regulatory objectives. This approach offers the flexibility and speed to market of performance-based regulations as well as the certainty of prescriptive regulations for those who wish to continue to use that option.

Referencing Voluntary Standards

Having noted the benefits of performance-based technical regulations, and the referencing of standards and sanctioned guidelines as deemed to comply solutions where a greater degree of certainty is desirable, member economies should be cautious as to the manner in which such referencing occurs.

Standards, in particular voluntary standards, developed by both domestic and international standardisation bodies, are not necessarily written with a view to possible endorsement or reference by mandatory requirements. As a result, voluntary standards can contain aspects which are not essential to the legitimate objective of the regulations that reference them.

Accordingly, only those parts of a standard that represent the minimum necessary to fulfil the regulatory objective should be referenced by the regulations.

Alignment with International Standards

The adoption of common standards reduces the trade restrictive effects of regulation. Manufacturers benefit through the removal of the artificial segmentation between markets that differences in standards create. Instead of having to produce numerous small batches for each of the markets they may wish to enter, manufacturers can produce a single version of the

product that is acceptable in all markets. This can lead to significant cost savings through economies of scale.

The WTO TBT Agreement endorses the adoption of international standards as a mechanism for eliminating technical barriers to trade. In particular, the TBT Agreement states that where technical regulations are prepared, adopted or applied in accordance with the relevant international standards, there shall be a presumption that the regulations do not create an unnecessary obstacle to international trade.

International standards, however, should be drafted in a transparent, open and non-discriminatory manner. They should also have relevancy, responding to market and regulatory needs, scientific and technological developments, and should not distort global market competition. Furthermore, International standards should be continuously reviewed to confirm that they are fulfilling those requirements.

Within APEC, member economies have committed to:

- aligning their standards with international standards, wherever possible[3], by the year 2010 in the case of industrialised economies and 2020 in the case of developing economies;
- aligning their standards for radios and their parts, televisions, video apparatus, refrigerators, air-conditioners, industrialised robots, rubber surgical and examination gloves, rubber condoms and food labelling by the year 2000 in the case of industrialised economies and the year 2005 in the case of developing economies; and
- aligning their standards 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.

Equivalency

In the absence of international standards, member economies can still achieve similar benefits through the use or recognition of standards from other economies. Acceptance of the technical regulations or standards of another economy, even where the standards are not exactly identical, can result in significant efficiency gains for industry and regulators. For industry, the practice results in the removal of segmentation effects caused by different standards. The problems faced by regulatory authorities in one economy are often the same as those faced in another economy. The regulatory responses adopted by either economy, while they may be different, generally achieve the same level of protection of health and safety for their respective communities. Accordingly, it should be possible for member economies to reference compliance with the standards of another economy as an acceptable solution provided they are satisfied that these standards adequately fulfil the objectives of their own regulations. This might be achieved by referencing the standards of another economy as a deemed to comply solution (see performance-based technical regulations above).

[3] The 'wherever possible' caveat was inserted to allow member economies to deviate from international standards for reasons of national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment (see WTO TBT Article 2 and Annex 3)

This process for reducing the burden to industry and trade is encouraged within the terms of the WTO TBT Agreement, which states:

> *Members shall give positive consideration to accepting as equivalent technical regulations of other Members. even if these regulations differ from their own, provided they are satisfied that these regulations adequately fulfil the objectives of their own regulations.*

In summary, there are a number of steps which can be taken to minimise the trade restrictive effects of technical regulations. These steps include:

- the adoption of performance based, rather than prescriptive, technical regulations;
- ensuring that, when voluntary standards are referenced, only those standards, or parts of standards that are necessary to achieve the legitimate objective are referenced;
- reducing the differences in regulatory requirements through the adoption of, or alignment with, international standards; and
- accepting the standards and/or technical regulations used by other member economies, provided these standards and/or technical regulations adequately fulfill the objectives of the accepting economy's regulations.

4. CONFORMITY ASSESSMENT

Conformity Assessment Regimes

Conformity assessment regimes typically fall into two broad categories. The first category includes regimes that require products to be assessed prior to entry into the market. Such conformity assessment regimes or requirements are often called 'pre-market' conformity assessment regimes and often take the form of product approvals, product registrations, licences (import/practice) or inspections.

Pre-market conformity assessment requirements, by their very existence, delay the entry of goods onto the market. In some cases, these delays can constitute a significant barrier to entry and may prevent the uptake of new, innovative and more efficient technologies. This is not to say that pre-market conformity assessment is inherently bad. In high risk areas, for example medical devices and pharamceuticals, pre-market assessment of a product's conformity may be essential to give adequate sureties that the products do not pose a risk to the health or safety of the community.

The second category of conformity assessment regimes relies on the manufacturer or supplier, rather than the regulatory agency, taking on the responsibility for ensuring that products entering the market comply with the relevant mandatory technical regulations. Conformity assessment regimes in this category are typically referred to as supplier declaration regimes.

Supplier declarations should not, however, be confused with no conformity assessment at all. A manufacturer or supplier still needs to undertake some form of conformity assessment to show that due diligence has been undertaken prior to placing the good onto the market. This is a necessary step for manufacturers so that they are in a defensible position should the conformity of their products with the required technical regulations ever be questioned by a regulatory body, during the course of a post-market surveillance exercise, or by the courts in the case of a product liability or negligence action.

Supplier declarations provide significant advantages to industry. Suppliers are no longer required to seek approvals from a regulatory agency prior to the placement of goods onto the market. Instead, suppliers can choose from any number of conformity assessment bodies or, in some cases, use their own internal conformity assessment mechanisms to ensure compliance.

However, as recognised by the WTO Committee on Technical Barriers to Trade, reliance on supplier declarations is not appropriate in all cases. As previously discussed, there remain

instances where a pre-market conformity assessment requirement is necessary to give adequate confidence that the product conforms with the technical regulations.

Types of Conformity Assessment Regimes

While not limiting the types of conformity assessment regimes available to governments, the most common conformity assessment regimes are described below.

Inspection

Inspection involves the assessment of each individual product. In cases where a product may deteriorate over time (for example: gas cylinders, motor vehicles and marine vessels), inspection may occur a number of times over the product lifecycle.

Inspection is a highly stringent conformity assessment regime and places a significant burden on industry and consumers. Inspection should, therefore, only be used in high risk situations or in instances where the product or device is constructed on-site and does not reach final form until ready to be put into use (for example, lifts, cranes, large boilers and buildings).

Licensing

Licensing individuals or companies is a conformity assessment regime that assesses the competence of an individual or a company to undertake a specific task. Licensing is applicable in situations where the performance characteristics of the product are not readily discernible and confidence that the product conforms with the applicable technical regulations can only be achieved if the product was manufactured by appropriately qualified individuals or companies. Such individuals or companies would be licensed and, where appropriate, subject to review of their licence to ensure maintenance of competencies. Typically, licensing applies to trade professionals and quality management systems of companies.

Batch testing

Batch testing involves a sample test of each batch or shipment of mass produced product. In terms of the conformity assessment spectrum, batch testing lies somewhere between 'inspection' - which involves the assessment of each product – and 'type approval' - which involves the assessment of only one sample of the product which is applicable to future batches.

Batch testing is declining in popularity as a conformity assessment regime. This is because of the uptake of quality management systems by manufacturers that ensures each product made is of the same quality, and has the same characteristics, as the original batch or sample.

Batch testing should, therefore, only be used where the regulator has little confidence that each individual product will be of the same quality as the original or sample product.

Approvals

Approvals are currently the most common form of pre-market conformity assessment. Approvals typically involve the assessment of a sample of a product. In many economies, the

regulatory body undertakes the assessment of the product, whereas in others the conformity assessment is undertaken by competent test facilities or laboratories. However, in both cases the regulatory body retains the final decision, based on the test report, to approve or otherwise the sale and/or use of the product.

Approval systems are usually augmented by a post-market surveillance mechanism (see Chapter 7) to ensure that the goods being placed on the market are the same as those for which the original approval was given.

Certification

Typical certification systems involve initial testing of products and ongoing product surveillance. In some cases, an initial assessment of the manufactures' premises/manufacturing practices is also undertaken. Manufacturer's quality management system may also be assessed during the course of certification.

Governments in a number of economies are choosing to rely on certification programs delivered by competent third party product certification bodies who operate in a competitive environment. Such regimes have the advantage of delivering a conformity assessment regime whose costs are reduced through competition while maintaining the same, or possibly better, level of control/regulation of the market place as that offered through the approval system.

Listing/registration

Listing/registration is similar to approvals except that there is no direct activity by the regulatory agency before a product is placed onto the market. Manufacturers and suppliers submit the appropriate documentation, together with supporting evidence, such as test reports, to the regulatory body. The regulatory body, following an assessment of the documentation, lists the product on a register or gazette of approved/recognised products.

Listing/registration of products provides the regulatory body with a quick reference for identifying the manufacturer/supplier of any product on the market. Should an instance of non-conformity arise, the regulator can quickly and easily identify the relevant party and take necessary actions. However, for less critical products there are other mechanisms that can be used to facilitate the easy identification of the manufacturer/supplier without the need for a pre-market approval step to be taken.

Supplier Declarations

As outlined previously, supplier declarations do not equate with no conformity assessment at all. Supplier declarations still require the manufacturer or supplier to undertake some form of conformity assessment. This assessment can be undertaken, at the choice of the supplier, by any one of a number of conformity assessment bodies, or by the supplier's own internal test facility in some cases. All the supplier needs to demonstrate is that due diligence has been exercised prior to placing the product onto the market. This will place suppliers in a defensible position should the conformity of their products with the required standards or technical regulations ever be challenged by a regulator or a court.

Supplier declarations provide significant advantages to industry. In particular, they give manufactures and suppliers the choice of agency used to demonstrate conformity with the mandatory requirements that apply. Suppliers are not required to seek approvals from a regulatory agency prior to the placement of goods onto the market. This can lead to significant time and cost savings to industry and consumers and may represent a significant reduction in regulatory burden.

A mechanism to ensure that the declarations made by suppliers are valid is an essential element of supplier declaration regimes.

Choosing the Appropriate Conformity Assessment Regime

Regulatory measures should contain compliance strategies which ensure the greatest degree of compliance at the lowest level of government intervention. By doing so, member economies encourage the establishment of effective and open markets that will, in turn, provide economic benefits and stability. (see also Chapter 2)

Member economies should, however, be mindful of the risk non-compliance may pose to human health, the safety of animal and plant life, and the environment. Accordingly, the least interventionist conformity assessment regime may not be the most appropriate in all circumstances. As outlined above, there are situations/sectors where the more interventionist conformity assessment regimes, such as inspections, are not only warranted but necessary.

In addition to the type of conformity assessment regimes chosen, member economies should consider the specifics of any conformity assessment regime. For example, the number of licenses, certifications, approvals, authorities et cetera. should be kept to the minimum necessary to achieve regulatory objectives. The regulatory burden for industry can be reduced if the level of interaction between individuals or companies, and the government, is kept to a minimum. This can be achieved through measures such as one-stop shops, better forms and process design.

Recognising the Results of Conformity Assessment Activities

It is accepted that member economies may require assurance that products placed on their market comply with the technical regulations they have determined as essential to ensure the health and safety of their citizens. This need for positive assurance of conformity with technical regulations does, however, place an inherent burden on manufacturers. This burden manifests itself most noticeably for manufacturers who are required to have products re-tested or re-certified even though they have already been tested or certified in another economy. This requirement can substantially increase costs for manufactures to enter the market. As a result; manufacturers may choose not to enter a market; the number of products available in the importing economy can be limited; and the degree of competition faced by domestic manufacturers, and hence the level of innovation and technological advances made in the importing economy, restricted. This has a negative effect on the prosperity and economic stability of the importing economy. This is particularly noticeable for those products with a relatively short market life, for example high technology IT products, where the additional time delays associated with product testing and certification in the importing country can severely impact on their marketability.

Costs to manufacturers and limitations to the importing member economies' economic prosperity, can be reduced and/or eliminated if member economies unilaterally accept the results of conformity assessment activities undertaken by competent bodies in other member economies. Such a move would reduce the amount of re-testing that occurs, and therefore the cost, in addition to reducing the workload for the regulatory agencies.

There are a number of mechanisms that can be used for acceptance of the results of conformity assessment. The key factor, however, governing any recognition arrangement at government level is the **confidence** that regulatory authorities in the importing economy have in the **technical competence** of the conformity assessment bodies in the exporting economy to assess product to the **importing economy's requirements.**

Whichever mechanisms for the acceptance of the results of conformity assessment is used it must, for the purposes of the WTO TBT Agreement, meet the essential WTO TBT principles of transparency and non-discrimination and take into consideration national and most favoured nation treatment.

Mutuality, even though supported by the WTO TBT Agreement[4], is not necessary for the recognition of overseas test reports and/or certificates. Indeed, it has been said that mutual recognition arrangements are nothing more than a structured set of unilateral arrangements in which each party unilaterally accepts the result of the conformity assessment activity undertaken in the other party(ies).

The concept of unilateral recognition arrangements, sometimes called national treatment of laboratories, is embodied in the WTO TBT Agreement. The WTO TBT Agreement states, at Article 6.1, that:

> *Without prejudice to the provisions of paragraphs 3 and 4, Members shall ensure, whenever possible, that results of conformity assessment procedures in other Members are accepted... provided they are satisfied that those procedures offer an assurance of conformity with applicable technical regulations or standards equivalent to their own procedures.*

These principles are supported by the WTO TBT Agreement, which states that:

> *Prior consultations may be necessary in order to arrive at a mutually satisfactory understanding regarding, in particular adequate and enduring technical competence of the relevant conformity assessment bodies in the exporting Member, so that confidence in the continued reliability of their conformity assessment results can exist; in this regard, verified compliance, for instance through accreditation, with relevant guides or recommendations issued by international standardising bodies shall be taken into account as an indication of adequate technical competence.*

There exist a number of commonly used mechanisms for determining the technical competence of conformity assessment bodies. Such mechanisms include accreditation; peer assessment; and government designation.

[4] WTO TBT Agreement – Article 6.3

5. REGULATORY SAFETY NETS

The nature of any general consumer protection or product liability regimes based in either legislation or civil law (referred to as regulatory safety nests in this chapter) plays a significant role in the choices of regulatory responses and conformity assessment regimes.

The strength of the regulatory safety net which applies in an economy will influence the types of regulatory responses taken and conformity assessment regimes implemented by an economy in their consideration of issues relating to the suitability or otherwise of particular goods.

In the absence of a strong regulatory safety net, governments may consider it necessary to adopt a more interventionist approach such as mandatory pre-market conformity assessment regimes with stringent post market surveillance techniques to ensure that there is no possibility of non-compliant product entering their market.

Where regulatory safety nets are strong, however, governments can adopt light handed approaches to product regulation such as listings and supplier's declarations (see Chapter 4). It is only when the non-compliance associated with a particular type of product poses a significantly high risk to health and safety that separate, more stringent regulation may be required.

Strong regulatory safety nets promote both economic efficiency and consumer protection while allowing manufacturer's to carry on their business without being overly burdened by government regulation. An effective regulatory safety net can provide manufacturers and suppliers with an incentive to make their goods safe, consumers with a good level of protection and recourse and governments with a means of dealing with potentially hazardous products in the market.

Types of Regulatory Safety Nets

In general terms, regulatory safety nets are of two basic forms. Firstly, those which are created through statute-based consumer protection or product liability laws that can provide ways to limit and deal with hazardous products without demanding compliance with strict technical specifications. Secondly, those that exist due to the operation of case law arising from instances of negligence actions. Case law systems provide private rights of action to consumers and businesses that enable redress to be sought through the legal system. Both statute-based and case law-based systems are capable of creating a strong regulatory safety net.

Statute-Based Regulatory Safety Nets

Consumer Protection Laws

General consumer protection laws relating to product safety can sometimes be found embedded in laws relating to trade practices, commerce or fair trading legislation. The features of such laws are that:

- they create an obligation on the manufacturer and/or supplier to ensure that the goods they place on the market are safe and/or fit for the purpose for which they are offered for sale or use; and
- suppliers must not engage in conduct or practices that are misleading or deceptive including misrepresenting the safety of a product or that the goods are of a particular standard or quality.

Most of these obligations can be enforced whether or not there has been any personal injury or property damage, as the obligations create a strict liability regime which must be adhered to by suppliers regardless of fault or damage. In some instances enforcement agencies may also be able to take actions against suppliers particularly where there is potential for widespread consumer detriment. Actions of this nature normally do not have criminal consequences and are predominantly of a civil nature resulting in civil remedies such as damages, injunctions or rescission of contracts. Enforcement agencies may also require remedies such as corrective advertising or enforceable undertakings.

Product Liability Laws

These types of laws normally provide an individual with a private statutory right of action to obtain damages for personal injury or property losses caused by defective products. The advantage of this type of regime is that liability on suppliers is strict - in other words there is no need for an individual to prove that the supplier has been negligent in the supply of the goods, merely that the defective goods have caused injury or loss. The defectiveness of goods will normally be judged on an objective basis of commonly accepted community standards. A regime of this type thus provides strong incentive for manufacturers to supply safe products.

The strength and success of a statute-based regulatory safety net is, however, dependent on the methods used to detect unsafe product. If the methods used to detect unsafe product, and remove it from the market place, are poor then the pressure for manufacturers and supplier to take full responsibility for their product is reduced and the strength of the regulatory safety net eroded.

Civil Law Systems

Civil law, or tort, based systems are to be found in the body of case law built up over time within an economy's judicial system. Civil law based regulatory safety nets derive their strength from the cost faced by the manufacturer or supplier should they ever be subject to litigation due to injury or damages caused by the products they place on the market. Where the potential costs of litigation are high, the prudent manufacturer will take all necessary steps, including undertaking conformity assessment activities to substantiate the safety of the product, to ensure that the products placed on the market are safe and do not pose any threat to health or the environment.

In cases where the costs of litigation become so high as to potentially destroy a manufacturer, the manufacturer may resort to taking out product liability insurance to cover any potential losses. In these situations, the insurer is likely to require the manufacturer to demonstrate the safety of the product through assessment of conformity to relevant voluntary standards. In essence, the requirement for conformity assessment is set by the insurer and, in effect, the insurer acts like a regulator operating in a pre-market approval regime.

The benefits of this type of regulatory safety net are that the government can take a light-handed, non-interventionist approach and that the manufacturers/suppliers have greater levels of choice as to the methods of determining that their products are safe to place on the market.

There are, of course, some disadvantages to a case law system because the very nature of case law is reactive rather than pro-active. In addition, litigation procedures can be long, costly, and are slow to respond. Such systems require actual injury or damage to occur and the litigation procedures tend to be drawn-out such that the final result may not be determined for some time.

That said, both statute law and case law based regulatory safety nets are capable of providing the same level of consumer protection and risk abatement necessary for governments to adopt low interventionist type conformity assessment regimes.

6. POST-MARKET SURVEILLANCE

The assessment of products after they have been placed onto the market is the integral part of many conformity assessment regimes. The assessment is often called post-market surveillance and is undertaken to ensure that products comply, or continue to comply, with the relevant regulatory requirements.

Post-market surveillance is essential to conformity assessment regimes where there is no in-built assurance of continued compliance. For example, it is necessary in approval regimes to ensure that the product being offered for sale in the market place has the same performance characteristics as the sample for which the original approval was given. Post-market surveillance is also necessary in supplier declaration regimes to ensure that the supplier's declarations are valid.

In conformity assessment regimes, such as inspection, licensing or batch testing, post-market surveillance is not as critical. The degree of post market surveillance may also depend on whether the conformity assessment regime requires internal auditing and surveillance. For example, where quality management systems are mandated or encouraged, the level of post-market surveillance could be less than would otherwise occur. Conformity assessment regimes which rely on product certification, where the certification body undertakes some degree of post-market surveillance or auditing as well as quality management system assessment, may also attract a lower level of post-market surveillance by regulatory bodies.

Characteristics of an effective post-market surveillance regime

There are two essential characteristics of any effective post-market surveillance regime:

- significant penalties for non-conformity; and
- an expectation by suppliers that non-compliant products will eventually be detected.

Without these two essential elements, suppliers may be tempted to take risks regarding the compliance of their products with required regulations. As a result the health and safety of the community could be endangered through non-compliant products entering the market.

In the first instance, if the penalties for non-compliance are minimal, suppliers may choose to take risks, even though the possibility of non-compliant products being detected may be high. Attracting a penalty or fine may be viewed by suppliers as an annoyance and not as an incentive for compliance.

In the second instance, where the likelihood of detection is low, suppliers may choose to take risks even though the potential penalties for non-compliance, if detected, are high. The likelihood of detection will be balanced against the costs associated with ensuring compliance.

If the likelihood of non-compliant products being detected, in conjunction with the potential penalty, is less than the costs associated with ensuring compliance, then suppliers will be more likely to accept risks associated with potential non-compliance.

In addition to the essential characteristics of an effective post-market surveillance regime described above, the effectiveness of a post-market surveillance regime can be enhanced if the regime attaches responsibility for non-compliant products to all of those involved in the supply chain (manufacturer/importer, wholesaler and retailer). The advantage of this characteristic is that the retailers are more likely to place pressure on their wholesalers or manufacturers to supply only those products which comply with the mandatory requirements. This involvement of retailers in applying pressure to manufacturers/importers and wholesalers assists in achieving compliance with mandatory requirements, while reducing surveillance costs to government.

Penalties for Non-Compliance

Mandatory regulatory instruments should contain appropriate sanctions or remedies to enforce compliance and penalise non-compliance.

Remedies may include:

- Fines
- Injunctions
- Corrective advertising
- Damages (private actions)
- Withdrawal of products
- Product recalls
- Court enforceable undertakings
- Negotiated settlements
- Representative actions by regulators

Some of these remedies may require those suppliers detected as supplying non-compliant products to incur substantial costs which may exceed any fines levied against them.

For example, costs of withdrawing or recalling goods typically include:

- corrective advertising;
- loss of profits on withdrawn or recalled products;
- freight charges;
- repair costs; and
- company downtime.

Other costs include legal fees and additional loss of sales due to loss of reputation through bad publicity.

These potential detection costs act as an incentive to suppliers to do the right thing and produce products which are safe and comply with mandatory requirements.

Enforcement options should differentiate between the good corporate citizen and the renegade, to ensure that 'last resort' penalties are used most effectively and model behaviour encouraged. Enforcement measures should not have the effect of encouraging otherwise good corporate citizens to subvert compliance measures.

To maximise flexibility in the penalties, member economies should consider a wide variety of remedial actions and sanctions. A regulator can then apply differing levels of penalties dependent on:

- the seriousness of the safety hazard;
- the quantities that the product is supplied in;
- whether the supplier's conduct is blatant; and
- the level of cooperation from the supplier.

Flexibility of response has advantages for the regulator, business and consumers alike as it allows for the implementation of remedies that can not only differentiate between varying levels of risk but also take into account the conduct of suppliers. For example, minor breaches of a standard by a supplier with a good compliance record may result in a regulator applying a low-level administrative solution. However at the other end of the scale, suppliers may be prosecuted and fined where their conduct has been blatant and resulted in serious breaches. By using flexible remedies in this way, a regulator can encourage good corporate behaviour by suppliers, and help prevent non-compliant products from entering the market.

It is also recognised that flexibility of response is important as it allows regulators to take into account the effect of non-compliance and penalties on all affected parties in an industry as a whole. For instance, certain remedies may be undesirable because of their effect on the availability of certain products to consumers.

A further advantage of having flexible remedial actions or sanctions is that enforcement options can be chosen, such as corrective advertising, which may facilitate public awareness of non-complying products thus leading to an increased likelihood of non-compliance being detected.

Detecting Non-Compliance

As outlined above, post-market surveillance regimes must be sufficient to convey to suppliers that there is a likelihood that non-compliant behaviour will be detected, appropriate actions taken and penalties imposed.

Detection of non-compliant behaviour is normally achieved through two main detection strategies:

- a pro-active program based on risk management principles; and
- a re-active program based on complaints from various sources.

The Risk Management Approach

This approach involves the use of risk assessment criteria relating to potential injury severity, the probability of the hazard occurring and the level of product availability. Risk assessment based on these criteria is used to decide on priorities for market surveys and further investigation of non-compliant products.

Essentially market surveys need to be planned around maximising opportunities, particularly where a regulator's resources are limited. The use of risk assessment criteria is crucial in identifying those products most appropriate to be surveyed either because of priorities or their availability.

The complaints-based approach

Specific complaints may be received from numerous sources – consumers, competitors of suppliers, other regulatory agencies, and organisations such as accreditation or consumer organisations.

Non-compliant products may also be detected by checking media sources such as newspapers, press clippings and radio or television broadcasts.

Methods for detecting non-compliance

The most commonly used methods to detect non-compliance are:

- Random audits of documentation used by suppliers to substantiate their self-declaration of conformity with the relevant regulations. Regulatory bodies may require copies of test reports from competent laboratories or product certification bodies. Alternatively, regulators may be satisfied with test reports undertaken by the manufacturer where those tests are undertaken in an appropriate manner.
- Audits of documentation following a complaint relating to a regulated product. In such cases, the regulator should first substantiate the complaint to eliminate any nuisance or unfounded complaints before conducting an audit of the supplier.
- Visual examinations of regulated products which are the subject of market surveys or complaints. In many cases, particularly where mandatory regulations apply to labelling or packaging requirements, a simple visual check is sufficient to establish whether a product is compliant.
- Mandatory re-testing of products either on a random basis during a survey or as a result of a complaint. This method generally involves the regulator requiring the supplier to seek, at their own expense, an independent test report, or certificate, to demonstrate compliance of the product. Such a method minimises costs to the regulator. However, where the choice of the sample to be re-tested is left up to the supplier, there may be a tendency for the supplier to provide a 'rolls-royce' for testing.
- Independent sampling of product by the regulator. This method avoids the problem associated with 'rolls-royce' samples but leads to higher costs for the regulator. The independent sampling technique usually involves the regulator purchasing a sample from the market place, without the knowledge of the supplier, and subjecting it to the appropriate assessments of conformity. Depending on the results of the tests, the regulator can then take the appropriate action and levy the relevant penalties.

Appendix 1 RISK ASSESSMENT TECHNIQUES

Operating in a dynamic and volatile environment, regulatory bodies are increasingly presented with the need to identify and respond to the multitude of risks that prevail in the marketplace.

It is through the systematic assessment of risk that regulators seek to ensure effective allocation and utilisation of resources in the face of competing obligations.

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 process by which risk is analysed is to identify the specific hazards, the mechanisms that cause its existence, and the probability that the repercussions of the risk will be felt. The analysis of risk is comprised of well-defined steps designed to enhance decision-making by contributing to a greater insight into risks and their potential consequences. The differing needs of governments dictate that the design and implementation of regulatory regimes will be specific to the environment where it is administered.

Beyond analysis of conceivable events, decision makers are concerned with the degree of risk associated with following a particular course of action and the response required to control the impact of the hazard. Comprehensive analysis of activities will identify those risks where government intervention will produce the greatest gains or where the directing of government resources will generate only marginal gains.

The following seeks to provide a generic framework to facilitate the identification, analysis, evaluation, treatment and monitoring of risk for regulatory bodies.

The Risk Assessment Process

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.

Figure 1 is a graphical depiction of the risk assessment process.

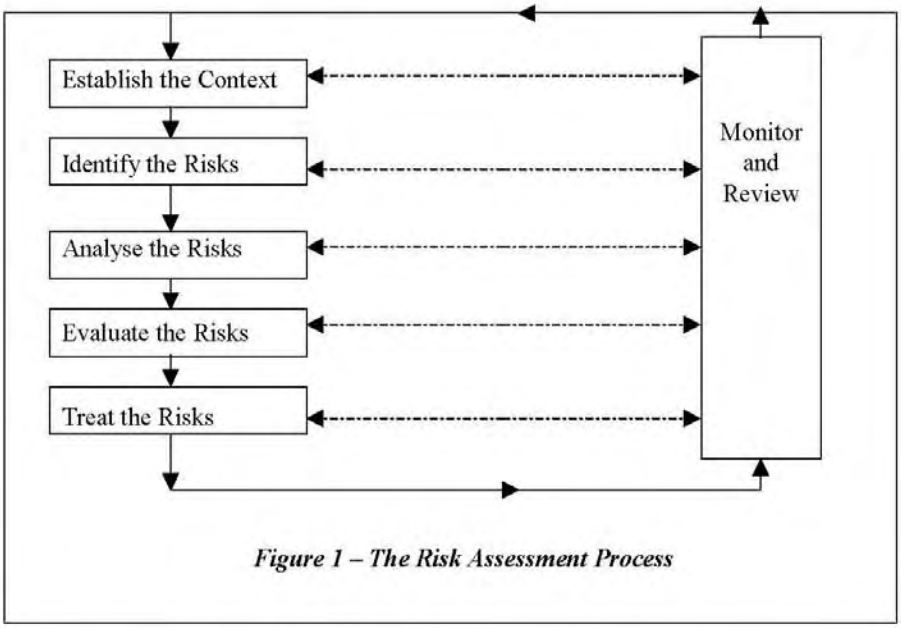


Figure 1 – The Risk Assessment Process

Establishing the context

The strategic and organisational context within which the processes for risk assessment are to take place must be established by the regulator. Part of this process is to prioritise risks according to their significance to the regulatory body. The structure of regulatory compliance regimes should therefore reflect risk assessment processes whereby risks are identified, assessed and strategically managed. A well structured systematic risk assessment process provides the basis for engaging in best regulatory practice. Monitoring and reviewing the performance of the regulatory regime in managing the risk is essential to ensure the strategies employed continue to reflect the priorities of government.

Considering the multitude of risks faced on a daily basis it is necessary to distinguish between these risks in terms of the probability of the hazard occurring and their potential to cause harm. Not only must the regulator understand why the hazard came into existence and what the potential consequences are, but they must also comprehend the magnitude of the risk involved. It is advisable for the regulatory body to have identified certain criteria against which they can assess the probability of the risk causing harm.

Inherent in developing an understanding of the potential risk factors is an acknowledgment of the existing control barriers in place to guard against potential hazards. Analysis of the existing regulatory infrastructure, coupled with an understanding of the environment in which the regulatory body operates, will combine to produce an estimated level of risk.

The identified risks are then placed in perspective against those risks previously regarded as government priorities. Certain hazards for example, may be particularly inauspicious but have a low risk or likelihood of occurring. Other hazards however, may have a smaller detrimental effect but have a high risk or probability of occurring. The perceived level of risk will direct

government resources where they will produce the greatest gains. Low priority risks may be accepted and monitored accordingly, while higher priority hazards may require the development and implementation of risk management strategies.

Risk identification

Identifying sources of risk and areas of impact provides a framework for risk analysis. The following sources of risk are generally identified as generic in nature:

- Legal environment - the ability of regulators to take action and the ability of injured parties to take action;
- Size of manufacturers - the likelihood that small opportunistic organisations might produce defective products, or that large organisations will systematically undermine the regulatory regime based on their own risk strategies;
- Reliance of citizens on the regulatory regime - the degree to which consumers do not make individual separate assessment of a product's safety;
- Political and international factors - relationships between economies which may impede or assist direct action against imports from another economy;
- Technological growth - the degree to which the rate of technological growth can introduce new products on to the market place;
- Self regulation - the degree of controls internal to an industry and the manner in which the behaviour of business in that industry is regulated; and
- Business culture - the extent to which businesses place importance on trade names, trade marks and commercial goodwill.

Analysis of the likelihood and consequences of a risk occurring is a subjective task, founded on judgements and assumptions where information may be incomplete. To minimalise subjective biases, the analysis should be based on information gathered from past records; relevant experience; industry practice and experience; relevant published literature; test marketing and market research; experiments and prototypes; economic, engineering or other models; and specialist and expert judgements.

A well structured systematic process is critical to identifying those risks that will require government attention. Risk identification therefore involves the use of both prospective and retrospective intelligence to develop an appreciation of existing and developing risks.

A preliminary screening of the identified risks provides for an efficient allocation of resources between low consequence risks and those requiring a more detailed review. Identification of risks at this stage is critical to ensure they are not excluded from analysis at a later stage. Following identification of the risks, it is necessary to generate a comprehensive list of events to consider the causes and scenarios that may eventuate. The specific nature of the risk can then be assessed against a standard list of events.

Approaches to risk identification may range from basic management practices to scientific engineering techniques. Standard checklists, records, flow charts, brainstorming, systems analysis, scenario analysis and systems engineering techniques can all be employed to assist in the identification of risks.

Risk analysis

In addition to ensuring accurate information from which to conduct risk analysis, it is essential that the techniques employed to gather the information are reliable and authoritative. Recognised practices include: structured interviews with experts in the area of interest; the use of multi-disciplinary groups of experts; individual evaluations using questionnaires; the use of computer and other modelling; and the use of fault trees and event trees.

Depending on the information and the data available on the risks identified, risk analysis can be undertaken to varying degrees of refinement. The complexity and costs of these analyses increase in range from qualitative, semi-quantitative to quantitative analysis. In practice, qualitative analysis is preferred as an initial screening activity to identify risks that require more detailed analysis. Qualitative analysis utilises the word form or descriptive scales to describe the probability of an event arising and its consequences. Such analysis is often conducted where the level of risk does not justify the time and effort required for a more detailed study.

Semi-quantitative analysis produces a more substantial account of the relationship between the probability and the consequence of an event occurring. Semi-quantitative analysis attributes values to the scales identified in qualitative analysis, seeking to reflect relativities in the data under analysis. The number allocated to each description is not required to reflect an accurate relationship between the magnitude of the likelihood or consequence of the event. The numbers can thus be combined by any one of a range of formulae provided that the system used for prioritisation matches the system chosen for assigning numbers and combining them. Inconsistent outcomes may result, however, if the numbers chosen do not reflect existing relativities.

The likelihood and consequences of a risk occurring can also be assessed on the basis of quantitative analysis. Quantitative analysis provides for consequences to be estimated by modelling the outcomes of an event or set of events. The consequence, or impact, of risk may be quantified in terms of dollars, technical, human, or other criteria. As such, the quality of the analysis will depend on the accuracy and completeness of the numerical values assigned. Considering the nature of quantitative analysis and the capacity for imprecise measures of estimates, a sensitivity analysis should be conducted to test the effect of changes in assumptions and data. Sensitivity analysis is designed to establish the capacity for the results of the risk assessment process to change in accordance with variations in the assumptions upon which the research was based.

Risk evaluation

Risk evaluation is concerned with the comparison of the level of risk identified during the analysis process with previously established risk criteria. Risk evaluation produces a prioritised list of risks upon which further action to manage the events can be based. In order to ensure meaningful comparisons, it is necessary to ensure risk evaluation employs the method of research utilised in the preceding stages of risk analysis. Qualitative evaluation thus involves comparison of a qualitative level of risk against qualitative criteria, while quantitative evaluation estimates level of risk against criteria which may be expressed as a specific number or value.

Risk evaluation should be performed with the view of acquiring a broad perspective of the context of the risk, including detailed consideration of the tolerability of the risks borne by elements within the broader community. While minimal treatment may be required if a risk is deemed to be of low or acceptable proportions, such risks should be subject to additional monitoring and review on a periodical basis to ensure they remain at acceptable levels.

Risk treatment

Risk treatment defines the process of identifying the range of options available for treating risk, assessing those options, and the preparation of plans for risk treatment and its implementation. The decision to follow a particular course of action, such as the institution of pre-market conformity assessment processes, will require analysis of the various contributors to the overall risk and evaluation of how to effectively manage that risk.

The allocation of resources for the purpose of risk assessment should be considered according to the ability of the regulatory body to manage the effects of the risk and/or the potential to benefit from opportunities that may flow from the risk. The allocation of resources should take account of the need to carefully consider the cost of providing additional funding against the benefits that can be derived from doing so. Rare but consequential risks for example, may require significant resource allocations that are not justifiable on strictly economic grounds.

A plan for risk treatment should identify in detail the responsibilities, schedules, the expected outcome of treatments, budgeting, performance measures and the review processes that are to be set in place. Within this plan it is essential that a mechanism for assessing the implementation of the options against performance criteria and objectives be established to monitor critical stages within the implementation process.

Monitoring and review

The systematic review of risk strategies is an integral part of the risk management process. In addition to assessing risks, the effectiveness of risk treatment plans and strategies should be evaluated as a means of reviewing the implementation process. Risks and effectiveness of control measures need to be monitored to ensure they reflect the risk priorities and strategic plans of management. The risk assessment process must be regularly reviewed to ensure the likelihood and consequences of an event remain current, and the suitability or cost of the treatment remains unchanged.

Appendix 2 ESTABLISHING A REGULATORY REGIME

This annex is to provide guidance to member economies in implementing good regulatory practices. It works through the elements of good regulatory practices with respect to the electrical and electronic equipment sector.

While this annex focuses on electrical and electronic equipment, it will serve as a guide to the implementation of good regulatory practices in other sectors.

Risks

All products pose an inherent risk to health and safety. Some products pose high risks (for example: pharmaceuticals, medical devices and foods) while others pose low risks (for example: mechanical hand tools). Even within a sector, such as electrical and electronic equipment, products have varying degrees of risk. Electrical and electronic products in which there is the potential for direct and/or indirect contact with 'live' elements (for example: toasters, room heaters, water heaters and track lighting) have a higher risk than other electrical and electronic equipment.

Regulatory Safety Net

As indicated in Chapter 5, the nature of any regulatory safety net plays a significant role in the choice of alternatives to regulation and in any risk assessment in relation to the setting of technical regulations and the choice of conformity assessment regimes.

The variance in the risk posed by electrical and electronic equipment is graphically represented by the dotted line in Figure 1. The strength of different regulatory safety nets is depicted in Figure 1 by the horizontal lines I, II and III.

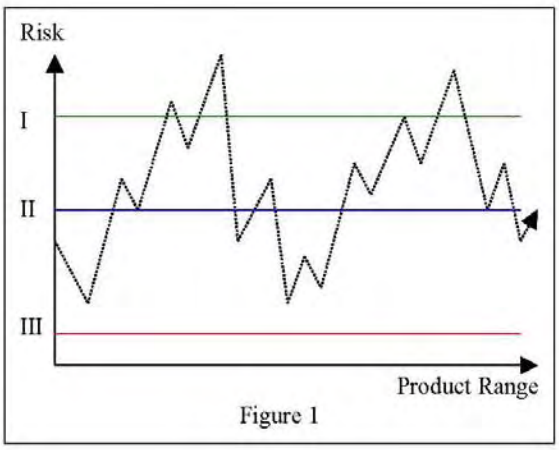


Figure 1

Where the regulatory safety net is strong (as depicted by Line I), member economies can adopt more flexible and efficient standards and conformity assessment regimes which promote technical and economic development. As the strength of the regulatory safety net reduces, the level of risk which the regulatory safety net can account for decreases. That is, the gap between the risk which can be accommodated by the regulatory safety net and the risk posed by the product increases.

In Figure 1, this is shown by an increase in the area under the dotted 'risk' line as the 'regulatory safety net' lines (I, II and II) drop. Regulation is the means often used by governments to mitigate or regulate this risk gap.

Regulating the Risk Gap

Before looking at the regulatory solutions to mitigating the risk gap, it should be remembered that there are mechanisms, other than the development of technical regulations and mandatory conformity assessment regimes, that can be used. These alternative mechanisms are outlined in Chapter 2 of the *Information Notes on Good Regulatory Practice.*

However, should none of these alternative methods achieve the objective of government, and regulatory intervention become necessary, the following discussion outlines the steps to be taken in selecting the appropriate conformity assessment regime.

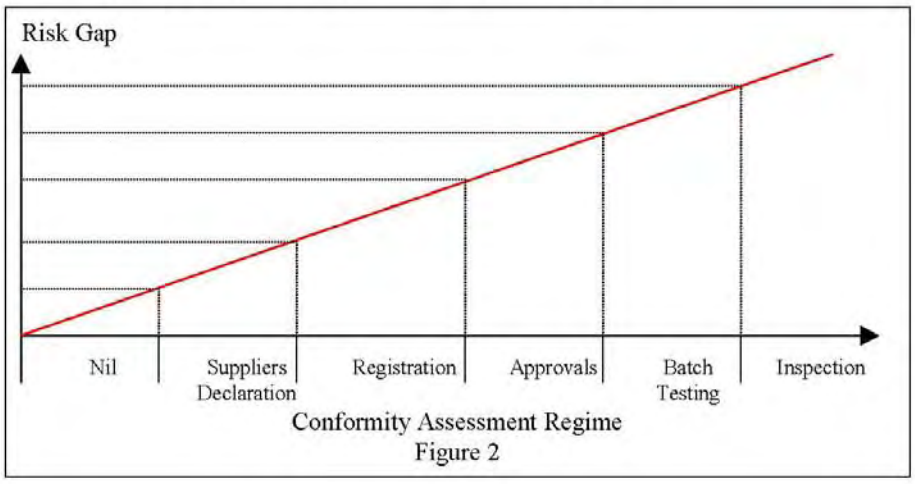
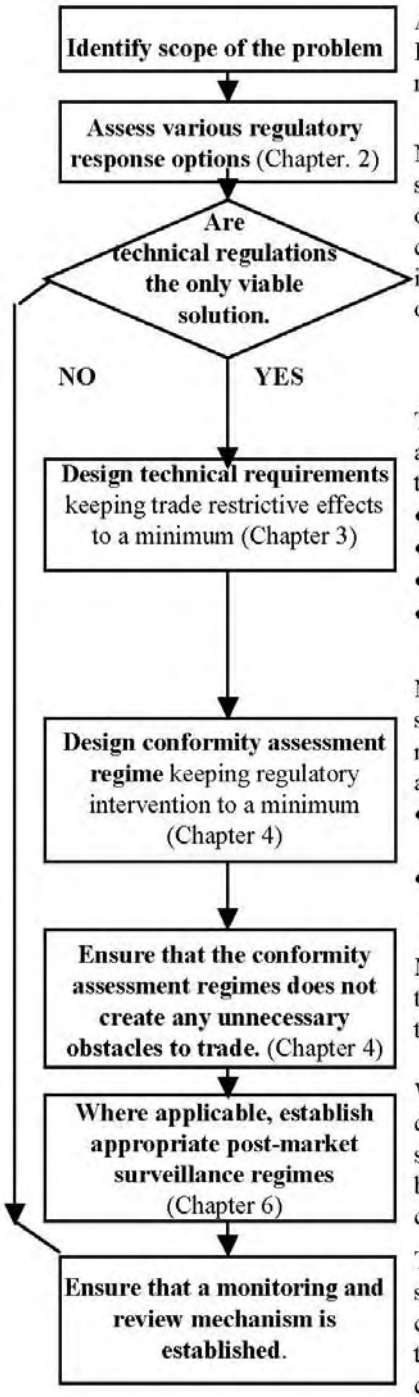


Figure 2

As outlined in Chapter 2 of the *Information Notes on Good Regulatory Practice*, the choice of appropriate conformity assessment regime is dependant on the level of risk, or risk gap, that needs to be regulated and controlled. As depicted in Figure 2, for low level risk less invasive and more efficient conformity assessment regimes such as suppliers' declarations can be used. As the level of risk increases, then more invasive conformity assessment regimes such as approvals and inspections may need to be employed.

It should be remembered, however, that the conformity assessment regime chosen need only apply to those electrical and electronic equipment products for which there is a higher level of risk. The chosen conformity assessment regime need not apply to all products within this sector.



A clear definition of the problem to be addressed is essential. Problems described in the broad may lead to unnecessarily restrictive regulatory responses.

Noting the existing mechanisms available, such as regulatory safety nets (See Chapter 5) assess the relative merits of a range of possible regulatory responses. The regulatory response chosen should be the one with the greatest net benefit and that is not more restrictive than necessary to fulfil the regulatory objective.

Technical regulations should not be prepared, adopted or applied with the effect of creating unnecessary barriers to trade. Member economies should therefore, consider:

- the use of performance based regulations;
- the appropriateness of referencing voluntary standards;
- the use of international standards; and
- the use of other member economies standards where international standards do not exist or are inappropriate

Noting existing mechanisms available such as regulatory safety nets (See Chapter 5), assess the relative merits of a range of conformity assessment regimes. The conformity assessment regime should be the one:

- with the least level of interaction between government and business; and
- which is the least interventionist possible taking into account the risk posed by potential non-compliance.

Member economies should give consideration to recognising the results of conformity assessment activities undertaken by technically competent conformity assessment bodies.

Where member economies have chosen low interventionist conformity assessment regimes (eg type approvals and suppliers declaration) post-market surveillance regimes may be necessary to ensure that products comply, or continue to comply, with the relevant technical regulations.

The world is a dynamic environment and member economies should have in place formalised mechanisms for review of the chosen regulatory response and conformity assessment regime to ensure that they take into account technological and other changes.