

(CTI 19/2008T Project)

SCSC - APEC

August 09, 2008 Cusco, Peru

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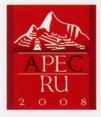
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Asia-Pacific Economic Cooperation



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Foreword

Mercedes Araoz
Minister
Ministry of Foreign Trade and Tourism (MINCETUR), Peru

Peru's exports reached US\$ 28 billion in 2007 and over the past five years have been growing at an annual rate of 32.5%. This outstanding expansion is a fundamental pillar to achieve economic growth, efficiency and job creation, and therefore to improve the quality of life and reduce poverty in our country.

MINCETUR is convinced that technical regulations, metrology, standards and conformity assessment procedures (including accreditation) are key tools for promoting exports. Their sound development and effective implementation enable sustainable development, improve welfare and facilitate trade. However such activities may also act as impediments to market access for goods and services. As a result, there is an increasing awareness of the need to discuss, compare and improve countries' abilities to determine, maintain and improve their infrastructure, practices, as well as international compatibility and recognition in these areas.

The 5th Conference on Good Regulatory Practice, which took place on 9 August 2008 in the city of Cusco, Peru, provided an opportunity for APEC Member Economies to gain better knowledge on sound regulatory policies that meet regulatory needs and lead to reductions in regulatory barriers to trade. This knowledge should be considered as one of the means for assisting APEC Member Economies in meeting their international obligations under the WTO TBT Agreement and their commitment under the APEC Bogor Goals of free and open trade in the region.

I welcome the successful completion of the 5th Conference on Good Regulatory Practice, expressing my deep gratitude to all who have made it possible. My appreciation goes to our co-sponsors, Chile, New Zealand and the United States of America, to all speakers for making their excellent contributions, and the delegates from the APEC Member Economies for their active participation in the Conference and the ensuing discussions. We were very glad to welcome you all to Peru and hope you had a pleasant and fruitful time. Last but not least, I commend our team for the well-run organization of the Conference.

Conference Agenda

	V Conference on Good Regulatory F	Practice
	Saturday 9 August	
09:00-09:10	Introduction and w	elcome
Section 1	Regulatory Sys	tems
Time	<u>Topic</u>	<u>Speakers</u>
09:10 – 10:20	Experiences on coordination among regulatory bodies	
09:10 – 09:35	The Regulators' Forum: A New Zealand example of co-ordination among regulatory bodies	Ms. Sirma Karapeeva, Ministry of Economic Development, New Zealand
09:35 – 10:00	Chile Experience on Coordination among Regulatory Bodies	Ms. Carolina Ramirez, DIRECON, Chile
10:00-10:20	Questions and an	swers
10:20 – 10:35	Morning break	
10:35 – 13:00	Mechanisms of Coordination between standardization bodies and regulatory bodies	
10:35-11:00	Mechanism of Coordination: NTTAA and the U.S. Federal Government's Use of Consensus Standards	Jennifer Stradtman U.S. Department of Commerce United States
11:00-11:25	The Use of Standards in the Regulatory Regime: Canadian Experience	Mr. David Shortall, Standards Council of Canada
11:25-11:50	Standards and the regulatory efficiency agenda in Australia	Mr. John Tucker, Standards Australia
11:50-12:15	Mechanisms of Coordination between standardization bodies and regulatory bodies	Mr. Gary Kushnier, PASC

12:15 – 13:00	Questions and an	swers
13:00 – 14:30	LUNCH	
Section 2	Regulation and Trade	
<u>Time</u>	<u>Topic</u>	<u>Speaker</u>
14:30 – 14:55	Methodologies of regulatory impact analysis on trade	
	U.S. Perspectives on Incorporating Trade Considerations into the Regulatory Process	Ms. Julia Doherty, U.S.T.R.
14:55-15:20	Coordination mechanisms among regulatory bodies: harmonization vis a vis MRAs	
	The ASEAN (Association of Southeast Asian Nations) EE MRA and AHEEER – A Model for Trade Facilitation	Mr. Teo Nam Kuan, SPRING, Singapore
15:20-15:40	Questions and an	swers
Section 3	Performance Based R	Regulations
<u>Time</u>	<u>Topic</u>	<u>Speaker</u>
15:40-16:05	Performance based regulations vs prescriptive regulation: A case study of the European approach to wine regulation compared to APEC Economies	Mr. Tony Battaglene, Winemakers' Federation of Australia
16:05-16:15	Questions and an	swers
16:15-16:30	Afternoon bre	ak
Section 4	Good Regulatory Practices: APEC	Economies Experiences
16:30-16:55	PERU: Experience in Technical Regulations	Mr. Augusto Mello, INDECOPI, Peru
16:55-17:05	Questions and an	swers
	Quodilono ana an	400





Welcome Speech

Speaker Mr. Waldy Bejarano, Ministry of Foreign Trade and Tourism, Peru

Waldy Bejarano is an economist: He works for the Vice Ministry of Foreign Trade as Free Trade Agreement negotiator in the field of Sanitary and Phitosanitary Measures. He is the Head of the Peruvian Delegation to the APEC Sub Committee on Standards and Conformance as well as the Project Overseer for the 5th Conference on Good Regulatory Practice.

WELCOME SPEECH

On behalf of the Ministry of Foreign Trade and Tourism of Peru it is my pleasure to welcome you to the 5th Conference on Good Regulatory Practice, being held on 9 August 2008 in Cusco.

This conference has been organized by Peru together with the co-sponsoring economies Chile, New Zealand and the United States. Peru thanks these economies for supporting this project.

The organizers thank all the conference participants for attending this event. In particular, we thank the conference speakers, who are regulatory authorities from APEC member economies and the Specialists Regional Bodies (PASC) and who have participated in the implementation of sound good regulatory policies to meet trade and regulatory needs. I hope that you all enjoy your stay in the historical city of Cusco.

The APEC Sub Committee on Standards and Conformance has already taken significant steps in addressing Good Regulatory Practice. To note are the APEC Information Notes on Good Regulatory Practice developed in the 1990s as well as the GRP Conferences organized in the past, the last opportunity in Vietnam in 2006. This Conference is the continuation of these efforts.

The Conference's objectives are the following:

- Highlight the value that technical infrastructures have in achieving the APEC Bogor goal of free and open trade in the region through the reduction of business transaction costs
- Increase the awareness and visibility among high-level regulatory authorities of the contribution of SCSC's initiatives and achievements in facilitating trade and in responding to the new challenges emerged from the evolving international trade environment
- Increase the awareness and visibility among high-level regulatory authorities of the need for sound policies in each economy that allow for and promote the use of international standards and internationally accepted conformance practices to meet trade and regulatory needs
- Encourage government leaders to budget for, and actively participate in, international standards development activities to harmonize technical and procedural criteria
- Encourage regulatory authorities in each economy to consult and cooperate amongst themselves, with input from their private sectors, in the process of promulgating any new mandatory requirements and to reference compatible international standards in regulations wherever possible, and
- Promote a dynamic cooperation between SCSC and regulatory authorities in the APEC region.

This one-day conference is divided into four sessions. In the morning, we will address Regulatory Systems, focusing on coordination mechanisms both among regulatory bodies and between regulatory bodies and standards and conformance bodies. Australia, Canada, Chile, New Zealand, the United States and PASC will share their experiences.

In the afternoon we will have three sessions that will focus on regulation and trade, performance based regulations and the APEC member experiences in good regulatory practice. In these sessions we will have speakers from Australia, Peru, Singapore, and the United States.

The Conference seeks that the regulatory authorities present today express their evaluation and expectations related to current and future SCSC activities on the subject of Good Regulatory Practices, in particular, that they provide feedback with regards to increasing the value and relevance of the "APEC Information Notes on Good Practice for Technical Regulations", reviewing them if necessary.

I trust that this Conference and its outcomes will be very useful for all APEC economies and the SCSC work. Now, I would like to hand over the floor to Mario Sandoval, who will co-moderate the conference. Mr. Sandoval was responsible for the Peruvian National Standardization and Accreditation Bodies and is an expert on TBT matters, having advised Peru in its FTA negotiations with the United States, Mexico, Singapore, EFTA, the European Union and China.



Conference Moderator

Mr. Mario Sandoval, Peru

Mario Sandoval is a Mechanical Engineer with a Masters in Chemical Engineering from the Aachen University of Technology (RWTH) and a Diploma in Business Administration from the Australian Graduate School of Management. Having worked for the Royal Dutch Shell Group for 8 years in the Netherlands, Australia and the Unites States, he actively participated in the development of U.S., European and international standards for hydrogen and fuel cell technologies. He was the lead delegate of the Netherlands to IEC TC 105 Fuel Cell Technologies and ISO TC 197 Hydrogen Technologies, convener of the ISO TC 197 Working Group 9 "Hydrogen generators using fuel processing technologies" and a member of the U.S. DOE Hydrogen Codes and Standards Coordination Committee. More recently, he was the Technical Secretary of INDECOPI's Technical and Commercial Regulations Commission, which includes both the Peruvian National Standardization and Accreditation bodies. He represented Peru in international fora related to standardization, accreditation and technical barriers to trade and supported the work of the Ministry of Foreign Trade and Tourism in these areas as well as in Free Trade Agreement negotiations. In 2007 he was Vice Chair of the APEC Sub Committee on Standards and Conformance. Currently, he manages a private sector corporation and is a consultant on TBT matters.





Section 1

Regulatory Systems Topic Experiences on coordination among regulatory bodies

Presentation

The Regulators' Forum: A New Zealand example of co-ordination among regulatory bodies



Speaker

Ms. Sirma Karapeeva, Ministry of Economic Development, New Zealand

Sirma Karapeeva is a Senior Analyst with the Competition, Trade and Investment branch of the New Zealand Ministry of Economic Development. She has responsibility for policy development in relation to general standards and conformity assessment issues both domestically and internationally.

Sirma is involved with the negotiation and implementation of the Technical Barriers to Trade Chapters of New Zealand's free trade agreements as well as with a range of bilateral mutual recognition arrangements. Also, she represents New Zealand on the APEC Standards and Conformance Sub-Committee and has represented New Zealand at the WTO Committee on Technical Barriers to Trade.



The Regulators' Forum: A New Zealand example of co-ordination among regulatory bodies

Sirma Karapeeva 5th APEC Conference on Good Regulatory Practice 9 August 2008 Cusco, Peru



Agenda

- Background
- Structure, objectives, scope and role of the Regulators' Forum
- Specific tasks and work programme
- Experience to date
- Conclusions



Background

Review of NZ's standards and conformity assessment infrastructure completed in 2007

Objective was to assess how well the infrastructure supports NZ's regulatory and trade systems and the Government's economic transformation agenda

Review found that the infrastructure was fundamentally sound but there was room for improvement



Background

Review findings regarding regulatory co-ordination included:

- Regulators had different levels of awareness and understanding of the infrastructure as a tool to support quality regulations
- Regulators had limited understanding of their trade facilitation role and international obligations
- Diverse regulatory approaches
- Complexity of regulations
- Limited co-ordination of market surveillance and enforcement activities



Background

The strategy to overcome these challenges aims to:

- improve international linkages
- promote co-operation
- promote alignment between infrastructure bodies and regulatory agencies

A key element of the strategy is the establishment of the Regulators' Forum – model based on successful international experience (Chile and Mexico)



Establishing the Regulators' Forum

The Government approved the establishment of the Regulators' Forum in December 2007

Forum has met three times:

- 30 January 2008
- 31 March 2008
- 9 July 2008

Next meeting scheduled for October 2008



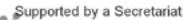
Structure of the Regulators' Forum

Forum comprises of:

- Policy and regulation makers
- Regulators
- Standards and conformity assessment bodies
- Others by invitation (e.g. academics and businesses)

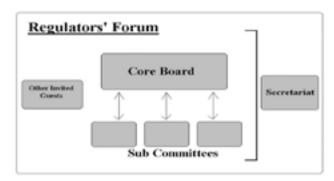
Operates as a two-tier system

- Core Board responsible for setting the agenda and leading the broader discussion on cross cutting issues
- Sub-Committees responsible for undertaking more detailed and technical work on specific issues as directed by the Core Board





Structure of the Regulators' Forum





Objectives of the Regulators' Forum

Aims to maximise the benefits of existing resources

Improve knowledge and awareness of the role of standards and conformity assessment in a developed economy

Promote improved use of infrastructure as a tool to support quality regulation, trade facilitation, innovation, sustainability and economic transformation

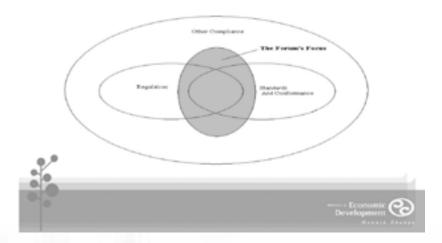
Promote better alignment and co-ordination across regulators, government agencies and infrastructure bodies

Establish a whole of government approach to good regulatory practice



Scope and Role of the Regulators' Forum

Focus of the Forum is on the interface between regulations, standards and conformity assessment



Scope and Role of the Regulators' Forum

The Forum operates as a <u>regulatory cluster</u> with 3 primary roles:

- To act as a sounding board
- To provide advice
- To commission work in areas of common interest

The Forum has specific tasks under each of its primary roles



Specific tasks of the Regulators' Forum

To act as a sounding board:

Foster debate, information sharing and peer review of regulatory approaches and models;

Promote better understanding of the role of standards and conformity assessment to support quality regulations, GRP and economic development

Promote awareness and compliance with international obligations

Promote discussions of the opportunities for international regulatory co-operation

Improve awareness among infrastructure bodies of the needs of regulators



Specific tasks of the Regulators' Forum

To provide advice:

Support peer review of regulatory proposals and support the Regulatory Impact Analysis regime

Develop solutions to problems where appropriate

Report to the Government on relevant issues discussed at the Forum which require Government action

Monitor and advise on the effectiveness of its role



Specific tasks of the Regulators' Forum

To commission work in areas of common interest:

Develop guidelines on the use of standards and conformity assessment to support quality regulation and regulatory objectives

Develop other documents for use by regulators and policy makers

Commission sub-committees to carry out analysis in particular areas

Provide a shared educational experience through interaction, workshops and seminars



Work programme of the Regulators' Forum

Work is progressed through sub-committees

Sub-committees are:

- established with a specific focus and terms of reference
- drawn from the network of entities involved in the Forum
- report findings to the Core Board
- 4 sub-committees have been established so far



Work programme of the Regulators' Forum

Standards related sub-committee is focused on:

Development of a national standardisation and conformity assessment strategy

Development of a "choice framework" of different approaches to using standards and conformity assessment in regulation

International obligations sub-committee is focused on:

Promoting better awareness of and compliance with NZ's international obligations e.g. WTO TBT Agreement

Considering the development of operational guidance for compliance with international obligations



Work programme of the Regulators' Forum

Metrology sub-committee is focused on:

Identifying the risks and potential sources of failure inherent in the metrology infrastructure

Development of a metrology strategy and framework for dealing with metrology issues

Accreditation of standards development organisations subcommittee:

Worked on a specific issue raised during the Review of NZ's standards and conformity assessment infrastructure

Was disestablished after it completed its work



Experience to date

Still early to draw definitive lessons learned Positive experience to date as indicated by:

- Consistent and active participation from 16 agencies
- Well informed debate and free and frank discussion
- Willingness to share ideas and expertise and apply these to current issues
- Enthusiasm to work together particularly in subcommittees
- Strong work programme focused on delivering outputs that can make a significant contribution to achieving the Forum's main objectives



Conclusion

Regulators' Forum was established to meet challenges of co-ordination and alignment between regulatory agencies

It is based on international models and experience

It aims to:

- Promote improved use of infrastructure to support quality regulation, trade facilitation, innovation, sustainability and economic transformation
- Promote better alignment and co-ordination
- Establish a consistent approach to good regulatory practice

Structure and work programme has flexibility to respond to issues as they arise

Experience so far shows enthusiasm and willingness among participants to ensure success of the Forum



Thank you for your attention

Sirma Karapeeva sirma.karapeeva@med.govt.nz



Section 1

Regulatory Systems Topic Experiences on coordination among regulatory bodies

Presentation

Chile Experience on Coordination among Regulatory Bodies



Speaker

Ms. Carolina Ramirez, DIRECON, Chile

Carolina Ramirez has her Masters of Economics and Statistical Engineering from the University of Santiago. Since May 1st 2008, she is Adviser on Technical Barriers to Trade in the Market Access Department, General Directorate of International Economic Affairs, Ministry of Foreign Affairs of Chile. She also worked as Adviser of Foreign Trade Department and Adviser of Productive Development Division, Ministry of Economy.





Chile Experience on Coordination among Regulatory Bodies

Carolina Ramírez Joignant Adviser on Technical Barriers to Trade General Directorate of International Economic Affairs Ministry of Foreign Affairs





Objectives of Technical Regulations

Technical Regulations set the rules that products must fulfill so the protection level defined by the society through the competent authorities is achieved.

- Their interventions should not distort the market performance.
- One aspect that is determinant is the coordination among regulatory bodies.
- The coordination among regulatory bodies is important to comply with the Good Regulatory Practices (GRP)





The National Commission on Technical Barriers to Trade

It was created in 1997.

- It is headed by the General Directorate of International Economic Affairs (DIRECON), the Ministry of Foreign Affairs.
- It is conformed by the representatives of the Ministries and Public Agencies that develop, adopt and apply technical regulations and conformity assessment procedures
- Officials from the Ministry of Foreign Affairs
- The National Standardization Institute (INN)

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The Mission

To coordinate and provide consistency to the work of the institutions involved with technical regulations and conformity assessment procedures

- To strengthen the market surveillance
- To ensure its application and setting the appropriate conditions so standards become an instrument that promote technical innovation and assure the fulfillment of all obligations.

BILLY NORTH		
MINISTRY OR GOVERNMENTAL AGENCY	AREA	WEB SITE
Transport	Vehicles	www.mtt.cl
Telecommunications	Telecommunications	www.subtel.cl
General Direction of Public Works	Road and Construction	www.mop.cl
Housing Planning, Urban Development and National Goods	Construction materials, seismic design, fire prevention, etc.	www.minvu.cl
Ministry of Agriculture SAG	Agriculture products and animal products, pesticides, fertilizers, seeds, alcohol, meat, fruits, etc.	www.agricultura.gob/ www.sag.cl
CONAMA (Environment)	Environment	www.conema.cl
Superintendence of Electricity and Fuel (SEC)	Electric products and fuel	www.sec.cl
SERNAPESCA (Fishing National Service) SUBPESCA (Undersecretary of Fishing)	Fishing	www.sernapesca.cl www.subpesca.cl
Ministry of Health ISP (Public Health Institute)	Health Pharmaceuticals products Cosmetics	www.minsal.cl www.ispch.cl
Ministry of Economy Consumer National Service	Labeling	www.sernac.cl www.economia.cl
INN (National Institute of Standardization)	Voluntary Area	www.inn.cl
Superintendence of Sanitary Services	Sanitary Services	www.siss.cl
Ministry of Defense	Arms, Defense	www.defensa.cl





Themes

- Review and analysis of the general standardization, regulation and conformity assessment systems outstanding in Chile.
- 2) Periodical updates of the WTO/TBT activities for its implementation and application in Chile.
- 3) Identification and analysis of the topics on WTO/TBT and other fora that require a national position.





Themes (Cont.)

- 4) Analysis and follow up of the free trade agreement negotiations with Australia, Turkey, Malaysia, among others. Support on the administration of the current agreements, mainly by providing technical information about particular sectors.
- Review and analysis of national technical regulations' public availability.





Themes (Cont.)

- Measures to strengthening market surveillance through better coordination.
- 7) Evaluation the possibility to be a member of IEC
- Review and evaluation of the existing MRA under the SCSC in APEC.
- Implementation of a network of focal points in the different agencies to coordinate work and to respond to information requirements.
- 10) Capacity building requirements





Outcomes - Trade Negotiations

Each of the trade negotiations that have been carried out and that address TBT matters has been analyzed, discussed and commented by its members.

 This work allows for a prompt implementation of the measures agreed and their straightforward application in all sectors.





Outcomes - Legal Matters

Throughout 2003 the Commission worked on the elaboration of a Decree regarding the implementation of Law No 19.912.

- This Law ensures compliance with TBT principles and procedures. The text of the Decree (Decree 77/2004: Requirements for the Preparation, Adoption and Application of Technical Regulations and Conformity Assessment Procedures) was agreed by consensus.
- The scope of the Law, and therefore of the Decree, relates to the principles of the TBT Agreement and good regulatory practices (GRP).





Outcomes - Legal Matters (Cont.)

The Decree has allowed enhancing awareness among the Chilean agencies regarding:

- The benefits of having clear and uniform rules on how technical regulations and conformity assessment procedures (CAP) should be developed, adopted, and applied.
- The process for its elaboration gave the opportunity to answer the agencies inquiries and to share the main concerns.





Outcomes - Legal Matters (Cont.)

- The Decree establishes principles of the TBT Agreement such as: use of international standards, nondiscrimination, avoidance of unnecessary barriers to trade and transparency.
- It includes a broad system of consultation of draft regulations with the community and a time period for comments (60 days)
- It requires to keep relevant information available to the public (objective of the measure, alternatives considered, advantages and disadvantages, etc.)





Outcomes - Legal Matters (Cont.)

- Technical regulations and/or CAP must allow a reasonable time between the date of their adoption and their application. A reasonable time shall be understood to mean a period of no less than six months.
- The Ministry or agency with regulatory powers shall analyze the comments received and take said written comments into account. In addition, it must make available to the public responses to any significant comments it received.
- The Decree 77 is available in: http://www.reglamentostecnicos.cl/OtroDocumento/C omisionNacional

(Spanish and English version)

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Outcomes - Internal Topics

A Topic that have been discussed at the Commission was the implementation of GHS.

- Another topic that was considered in the Commission is the REACH system, proposed by the European Union for the trade and imports of chemicals.
- New topics: Measures that affects our exports of sodium nitrate and potassium nitrate (USA and Germany) and our exports of borates (EU)

*



Outcomes - SCSC

The subscription by Chile of the First Part of the Electrical MRA and the Arrangement for Exchange of Information on Toy Safety was facilitated by the previous discussion in this assembly.

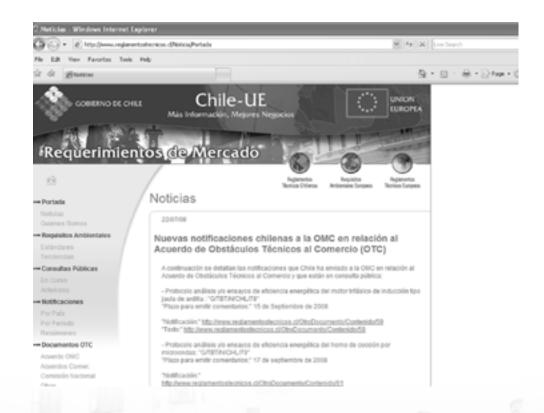
- Food Sectoral MRA (analyses with the competent Authorities)
- APEC Food Safety Cooperation Initiative (analyses with the competent Authorities)





Outcomes - Others

- Regarding public availability of technical regulations, the agencies have been improving the information contained in their websites.
- With resources obtained from a cooperation program with the EU there is website containing all the Chilean technical Regulations and CAP, and related information (www.reglamentostecnicos.cl)







Outcomes- Others (Cont.)

The market surveillance is an important matter to assure the right application of technical regulations to national products and imports.

O A program to share information is being settled with the Customs Service to improve the control of imported products. The first area where this program is being applied is the electrical and fuel products and pharmaceuticals/cosmetics products.

* * *

*



Others

Training on the implementation of <u>Decree 77/2004</u> and its regulation to Ministries and Agencies.

- Training of the implementation of the web site contains all technical regulations and conformity assessment procedures
- The WTO/TBT Contact Point send every week all WTO/TBT Notifications of the rest of the WTO Members and private sector (exporters)
- The Commission is working in the elaboration of a "Guide proposed of Procedures to follow in relation to the comments received of Chilean proposed technical regulations and CAP"





Others

About the "Guide":

- The proposed regulation has to be in a web site or it has to be available (public access)
- Send to the WTO/TBT Contact Point a copy of the proposed technical regulation and CAP
- A period of no less than 60 days for comments
- The institution has to give a <u>Standardized Form</u> for the received comments by theme, articles of the proposed regulation, sections or others kinds of classification





Others

About the "Guide" (cont.):

- Identify the relevant comments
- Evaluate the comments
- About international comments the Ministry or agency with regulatory powers shall analyze the written comments and inform to the WTO/TBT Contact Point how they will take into account the written comments
- Make a "Table" containing the relevant comments received and the answers to these comments. This Table will be available for public access.





Future Work

Continue the Training On the TBT Agreement to agencies and entrepreneurs.

- Continue the Training On the Decree of GRP (Decree 77/2004) to agencies.
- Current regulations to consumers.
- Continue the evaluation of the possibility to be a Member of IEC





Future Work (Cont.)

Improve the web site of technical regulations and CAP

- Create the National Public-Private Commission on Technical Barriers to Trade
- Finalize the "Guide proposed of Procedures to follow in relation to the comments received of Chilean proposed regulations"





Challenges

- To improve our system.
- To move toward the optimization of our system.
- Obtain permanent training on GRP
- Identify other national coordination schemes to share experiences and improve our work.
- To improve mechanism on GRP.





Chile Experience on Coordination among Regulatory Bodies

Carolina Ramírez Joignant Adviser on Technical Barriers to Trade General Directorate of International Economic Affairs Ministry of Foreign Affairs

Section 1

Regulatory Systems Topic Mechanisms of Coordination between standardization bodies and regulatory bodies

Presentation

Mechanism of Coordination: NTTAA and the U.S. Federal Government's Use of Consensus Standards



Speaker

Jennifer Stradtman, U.S. Department of Commerce, United States

Jennifer Stradtman has worked for seven years at the US Department of Commerce in various roles, including her current position in the Standards Liaison's Office, and previously as a WTO TBT Specialist. Prior to working for Commerce, Ms. Stradtman was the Director of the Microbiology Analytical Chemistry Section of the American Council of Independent Laboratories. Ms. Stradtman has her Masters degree in International Trade from University of Bufalo.

APEC SCSC Fifth Conference on Good Regulatory Practice

Mechanisms of Coordination: NTTAA & The U.S. Federal Government's Use of Consensus Standards

Ajit Jillavenkatesa, Ph.D.

National Institute of Standards and Technology
U.S. Department of Commerce
USA

August 9th, 2008

APEC SCSC: 5th GRP Conference Cusco. Peru

Outline

- □ Introduction
- The U.S. Federal government's relationship to standards development
- Law and policy
- □ Examples
- □ Conclusions

August 9th, 2008

The U.S. Standards System Is voluntary, market-driven and private sector led Works through cooperation and communication among stakeholders: Standards organizations Industry Government Federal law and supporting policy encourage Federal government agencies use of consensus standards In lieu of government unique standards For procurement, supporting regulatory needs and meeting emerging national priorities Agencies retain authority to choose the standard that best meets their needs The voluntary consensus process is called out specifically as offering benefits

U.S.Federal Government's Relationship To Standards Development

- Standards user:
 - In product purchases
 - Through incorporation into regulations
- Participant in standards development through the voluntary process
 - Does not receive any special treatment/privileges for participation
- Contributes to the technical underpinning for standards

Goal: Standards that meet Federal government agencies' needs

August 9th, 2008

Government's Use of Standards: Benefits

- Eliminates the cost of developing and maintaining standards that meet government requirements
- □ Decreases cost of goods purchased
- Promotes efficiency and economic competition
- Decreases burden on regulated communities
- Furthers the policy of reliance on the private sector to supply goods and services that meet government needs

August 9th, 2008

APEC SCSC: 5th GRP Conference Cusco, Peru

The National Technology Transfer and Advancement Act (NTTAA)

- All Federal agencies should use private sector standards in lieu of agency unique standards
 - Agencies must annually report use of agency unique standards and provide explanation of use
- Federal agencies should participate in standards developing activities
- Identifies NIST as the coordinator of Federal standards and conformity assessment activities with those of the private sector

August 90, 2008

Policies of OMB Circular A-119 Encourage Federal agencies to benefit from the expertise of the private sector Promote Federal agency participation in such bodies to ensure the creation of standards that are useable by Federal agencies Reduce reliance on government unique standards where private sector standards would suffice No preference among types of standards Use commercial off the shelf products regardless of source of underlying standard

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Major Sources of Standards Used by the U.S. Federal Government ASTM International □ Institute for Printed Circuits American Society of Mechanical Engineers (ASME) National Fire Protection Association (NFPA) □ Society of Automotive Engineers Underwriters Laboratories, Inc. American Petroleum Institute □ International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) □ International Maritime Organization (IMO) Compressed Gas Association August 9th, 2008 APEC SCSC: 5th GRP Conference Cusco, Peru

Example: U.S. Government Agency Participation in Standards Development

- More than 3200 Federal agencies staff participate in private sector standards development activities
- □ NIST has identified:
 - 9207 citations of standards incorporated by reference (regulation); more than 6500 are non-government standards
 - 10559 standards incorporated by reference by agencies for procurement purposes

(minor overlap between the two lists – trend of dependence on private sector standards is unambiguous)

Searchable database:

http://standards.gov/sibr/query/index.cfm?fuseactio

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Example: NIST Participation In Nanotech Standards Development

- NIST has active involvement in nanotechnology standards development activities
- Emphasis on developing relevant standards to enable reliable measurements (e.g., toxicological properties of nanopowders)
- NIST experts provide technical expertise in highly accurate and precise measurement, and provide measurement standards (reference materials) that underlie documentary standards
- NIST staff participate in ASTM E42, ASTM E56, IEC TC113, ISO TC229, ISO TC201, ISO TC202, ISO TC213, IEEE-P1650, IEEE-P1690, JEDEC, SEMI, OECD-WPMN: all focusing on standards and test method development relevant to nanotechnology

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Example: The U.S. Environmental Protection Agency

Since the introduction of the NTTAA in 1996 requiring Federal agencies to use voluntary standards wherever possible, the EPA has benefited from:

- Greater ease in meeting regulatory obligations, with voluntary standards meeting the technical requirements of about half of the 600-900 EPA rules written each year
- Increased collaboration between government and private sector technical experts on the environment
- Opened paths of communication with industry to advance the agency's objectives

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Conclusions

- Coordination between the U.S. Federal govt. and standards developers has led to numerous benefits for all involved
- The coordination is backed by U.S. Federal law and supporting policy.
- Federal agencies' use of standards is a key element of the U.S. Standards Strategy*

*http://publicaa.ansi.org/sites/apdl/Documents/Standards%20Activitie s/NSSC/USSS-2005%20-%20FINAL.pdf

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Conclusions (2) ☐ Individual Federal agencies make effective use of private sector standards in many applications ☐ Agencies must consider whether the use of standards helps them accomplish their missions, increases efficiency, reduce the burden on regulated and other communities and whether there is an impact on trade ☐ Greater use of standards with global acceptance facilitates both least burdensome regulatory approaches and trade August 9°, 2008 APEC SCSC: 5° GRP Conference

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Section 1

Regulatory Systems
Topic

Mechanisms of Coordination between standardization bodies and regulatory bodies

Presentation

The Use of Standards in the Regulatory Regime: Canadian Experience

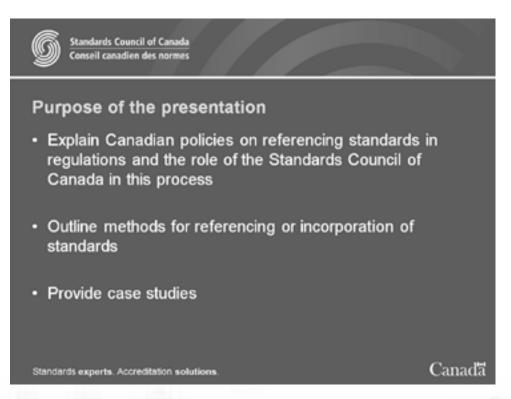


Speaker

Mr. David Shortall, Standards Council of Canada

David Shortall is a consultant in the area of standardization, trade and regulatory policy. Among his clients are the Organization for Economic Cooperation and Development (OECD) and the World Bank. He acts as an advisor to the Standards Council of Canada and is a member of Canada's delegation to the WTO Technical Barriers to Trade Committee. Mr. Shortall served as convenor of ISO/CASCO Working Group 22 which undertook revision of ISO/IEC Guide 60, Code of Good Practice for Conformity Assessment. In his previous career Mr. Shortall served as Canada's delegate to the TBT Committee and to the APEC Subcommittee on Standards and Conformance.







Government of Canada: New Regulatory Policy (2007)

- Government of Canada's Cabinet Directive on Streamlining Regulation (CDSR) which requires Government Departments to make use of national and international standards and conformity assessment procedures when they fulfill intended policy objectives.
- Cabinet Directive on Streamlining Regulation http://www.regulation.gc.ca

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Standards and Regulations in the CDSR

- Encourages regulators to use standards and conformity assessment as the basis of regulations
- Directs regulators to maintain compliance with international trade obligations (WTO TBT and SPS Agreements)
- · Promotes cooperation with provincial and territorial governments
- · Encourages the use of performance based measurements

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Standards and Regulations: A Comparison

Standards	Regulations
Standards Development Process	Regulatory Development Process
Standards development organizations (SDOs) facilitate the development of standards in response to requests from proponents	Governments take the lead in developing regulations
SDOs seek consensus on the content of standards	Governments consult interested parties, but do not necessarily seek consensus
Conformity Assessment	Compliance Assurance
Certification bodies, testing laboratories and management systems certification bodies carry out conformity assessment activities	Regulations may require testing and certification by accredited CABs
	Governments enforce their regulations themselves or remain accountable for enforcement when they rely on others to carry it out

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How do standards get incorporated in regulations?

- Incorporated directly into statutes
 - . i.e. the statute reproduces the wording of the standard
- · Incorporated by reference into statutes
 - i.e. the statute refers to a particular standard, but does not reproduce the wording of the standard
- Reproduced directly in regulations
- Incorporated by reference into regulations
- Used as guidelines to elaborate rules found in statutes or regulations

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Standards development (1)

- · Inclusiveness: Interest groups participation
 - Regulators
 - Producers and Consumers
 - Academics
- · "Balanced Matrix": Equal representation of interest groups in:
 - Standards development and approval
 - Maintenance/review
- Consensus

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Standards development (2)

- Scope of standard
 - Only requirements essential for regulatory reference
 - Only technical issues
- Structure
 - Consistent and identifiable sections
 - Non-technical issues outside of normative content
- Language
 - Avoiding recommendations
- References
 - Clear indication of the preceding version

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Regulatory adoption process

Referencing options

- Complete reference
- Qualified reference
- Partial reference
- Reference as good practice
- Reference as alternate
- Inclusive reference to standard

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Procedures for updating standards in regulations

- Periodical review of standards to determine relevance to current technology
- Notification from the SDOs to interested regulatory authority prior to the maintenance action
- Monitoring of status of referenced standards by regulatory authority
- RegWatch

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What is RegWatch?

- · Search tool for identifying Canadian, foreign and international standards referenced in Canadian federal law
- · Provides links to the full text of Canadian regulations that cite standards, and links to additional information about the referenced standards
- Allows to:
 - Search by keyword or standard number, developer, regulation
 - Find bibliographic information on Canadian, US and international standards referenced in Canadian legislation

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Canada a



Example: ISO Standards in Canadian Regulations

- Title of Standard: <u>Qvality Management Systems Fundamentals and Vocabulary</u> Standards Developer: ISO Standards Developer: ISO
 CS Code: 03.120.10: Quality management Systems - Fundamentals a
 CS Code: 03.120.10: Quality management and quality assurance
 Winister Responsible: Minister of Health
 Regulation: Medical Devices Regulations
 Enabling Statute: Food and Drugs Act
 Location Within Legislation: section 1

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Example: Canadian National Standards in Regulations

- Title of Standard: Risk Management: Guideline for Decision-Makers
- Standards Developer: Canadian Standards Association (CSA)

 ICS Code: 03.120.99; Other standards related to quality

 Minister Responsible: Minister of Transport

 Regulation: Canadian Aviation Regulations

 Enabling Statute: Aeronautics Act

 Location Within Legislation: section 1

The Minister may, in writing, on application by the operator of a designated airport, authorize the operator to cease providing an aircraft fire-fighting service if the operator demonstrates by means of a risk analysis based on Standard CAN/CSA-Q850-97 entitled Risk Management: Guideline for Decision-makers as amended from time to time that the cessation of the aircraft fire-fighting service will not result in an unacceptable risk to aviation safety."

Link to Legislation:

- http://laws.justice.gc.ca/en/A-2/SOR-96-433/index.html
 Link to Standards Information:
- - http://www.standardsstore.ca/eSpecs/index.jsp?language=en

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Example: Foreign Standards in Canadian Regulations

- Title of Standard: Safety Standard for Conveyors and Related Equipment
 Standards Developer: American Society of Mechanical Engineers (ASME)
 ICS Code: 13: ENVIRONMENT. HEALTH PROTECTION. SAFETY
 53: MATERIALS HANDLING EQUIPMENT
 Minister Responsible: Minister of Labour
 Regulation: Marine Occupational Safety and Health Regulations
 Enabling Statute: Canada Labour Code

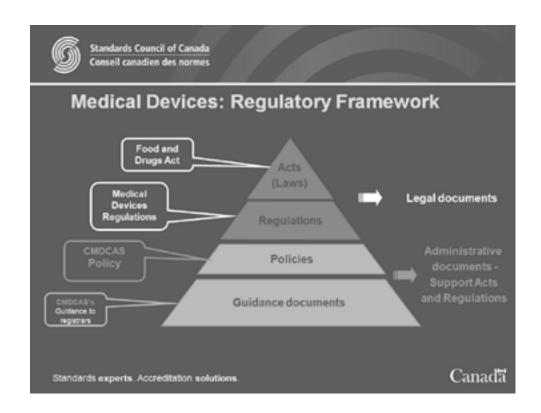
- Location Within Legislation: section 12.19

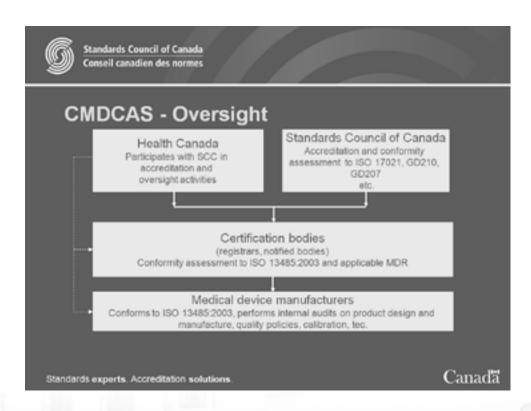
"Equipment used in the mechanical transmission of power shall be guarded in accordance with sections 7 to 10 of ANSI Standard ANSI B15.1-1972, Safety Standard for Mechanical Power Transmission Apparatus, dated July, 1972."

- Link to Legislation: http://laws.justice.gc.ca/en/L-2/SOR-87-183/index.html
 Link to Standards Information: http://www.global.ihs.com/

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Medical Devices: Role of SCC Accreditation

- •Ensures that only those certification bodies who can meet both accreditation and Health Canada requirements are utilized
- · Ensures consistent application of CMDCAS requirements by certification bodies originating from different countries and
- · Enables Health Canada to recognize the certification body and its certificates
- An accredited certificate under CMDCAS substantially raises Health Canada confidence in the manufacturer

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Related Links

- Standards Council of Canada:
 - see: www.scc.c

Guide for regulators on using standards
 Key Considerations in the Development and Use of Standards in Legislative Instruments

- see: http://www.scc.ca → "Publications"
- Use of International standards in technical regulations (ISO/IEC)
 - see: http://www.ifan.org
- Canadian Medical Devices Conformity Assessment System
 See: http://www.hc-sc.gc.ca → Home → Drugs & Health Products → Medical Devices → Quality Systems (ISO13485)
- Accreditation programs:
 - see: http://www.scc.ca → "Products and Services" → Accreditation programs

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Section 1

Regulatory Systems Topic

Mechanisms of Coordination between standardization bodies and regulatory bodies

Presentation

Standards and the regulatory efficiency agenda in Australia



Speaker

Mr. John Tucker, Standards Australia

John Tucker is an experienced company director, having formerly held statutory appointments in the fields of health, OHS and workers' compensation, including:

- memberships of Australia's National Occupational Health and Safety Commission and the NSW Health Minister's Quality Reference Group; and
- directorships of the NSW Work Cover Authority, Coal Mines Insurance Pty. Ltd. and the NSW Mines Rescue Service

In 2004, John Tucker joined Standards Australia as Chief Executive Officer. John has had a diverse career path traversing public and private sectors, political advising and has held CEO positions in the fields of injury management, OHS risk management and industry association management.



Standards and the regulatory efficiency agenda in Australia

John Tucker Chief Executive Officer Standards Australia

5th SCSC Conference on Good Regulatory Practice Cuzco, Peru 9 August 2008

History

- · Federalism: nine governments
- 'A talent for bureaucracy' leads to 'a tangle of red tape'
- The Council of Australian Governments (COAG): 'hotspots' but lack of action
- The Productivity Commission and the Banks Review
- · The role of Standards

No action | Nonregulatory regulation (incl. standards) | Policy solutions | Risk assessment | Public expectation/politics | What we said | Quasiregulation (incl. standards regulation (incl. standards redersed by govt) | Policy solutions | Risk assessment | Public expectation/politics | Public expectation/politics |

9

A change in 2007

- · Labor Governments across the country
- 'I want COAG to be a work horse not a dead horse': Kevin Rudd, Prime Minister
- · 'Hotspots' list gets longer
- · New Ministers with enthusiasm
- Renewed government interest in 'alternative approaches to regulation'

What we did

- Lobbied COAG members and Office of Best Practice Regulation: 'the Standards alternative to black-letter regulation'
- · Offered workshops and seminars
- · Spoke to new Ministers and their advisers
- Wrote letters
- · Liaised with other business groups

5

Example: Product Safety Framework

- Productivity Commission reports
- · Range of existing Standards
- Pilot study in nursery products sector
- · 'Hazard based'
- Replicable
- · COAG action
- What happens next: Australian Competition and Consumer Commission

Example: Construction industry

- · Building Code of Australia
- Wiring Rules
- Other sectors: gas, plumbing, communications
- · COAG and 'National Construction Code'
- What happens next: many stakeholders

7

Next steps

- Continuing contact with nine governments and their advisers: 'Alternative approaches'
- Strengthen liaison with industry allies
- Continue to show that Standards Australia can deliver: New Business Model (rigour and Net Benefit; accredited alternative Standards developers)
- · None of this is easy!

Following up

- Standards Australia: http://www.standards.org.au/
- Accreditation Board for Standards Development Organisations: http://www.absdo.org.au/
- Net Benefit Guide: follow the links from http://www.standards.org.au
- Contact:
 - Dr David Stephens
 Government & Stakeholder Relations Consultant to Standards Australia

clamshred@ozemail.com.au

Section 1

Regulatory Systems

Topic

Mechanisms of Coordination between standardization bodies and regulatory bodies

Presentation

Mechanisms of Coordination between standardization bodies and regulatory bodies

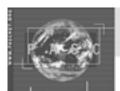


Speaker

Mr. Gary Kushnier, Pacific Area Standards Congress (PASC)

Gary W. Kushnier became Vice President, International Policy, of the American National Standards Institute in January 1995. Mr. Kushnier is responsible for overall liaison and policy coordination of ANSI's activities with international and regional organizations, for example, the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC), the three European Standards Organizations, the Pacific Area Standards Congress (PASC), and the Panamerican Standards Commission (COPANT), as well as their national member bodies. He also serves as Chair of the PASC Standing Committee.

Prior to becoming Vice President of International Policy, Mr. Kushnier had served as Vice President of ANSI's Brussels Office.



Mechanisms of Coordination Between Standardization Bodies and Regulatory Bodies

Gary Kushnier

Chair - Executive Committee Pacific Area Standards Congress (PASC)

> August 9, 2008 Cusco, Peru

> > 2008 O PASC Slide 1



Pacific Area Standard Congress (PASC)

- · PASC is the:
 - APEC Specialist Regional Body for Standardization
 - Composed of 21 APEC economies and 3 additional economies
 - APEC link to international standardization bodies including ISO, IEC and others
- · The standing objective of PASC is to increase the value of international standards to regulators as well as to industry.

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Pacific Area Standard Congress (PASC)

- PASC does not develop standards, but rather is a forum to:
 - Strengthen international standardization programs of the ISO and IEC and to improve the ability of the Pacific Rim standards organizations to participate in these programs effectively
 - Improve the quality and capacity of standardization in economies in the region
 - Support free trade within the region with economies in other regions
 - Support improvement of economic efficiency and development of the region through the promotion of standardization
 - Interact with other bodies that represent elements of the standardization technical infrastructure, industry, consumers and government
- PASC strongly encourages each of its member economies to use international standards rather than develop regional standards which PASC does not do.

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Importance of Standards

- Facilitate Trade:
 - Provide agreed-upon specifications for products, services and systems, reducing compliance costs
 - Driven by the marketplace involvement breeds usefulness and increases the likelihood that the standard will be sensible
 - Enable innovation, competitiveness, and economic growth
 - Protect health, safety, the environment, and national security
 - Can be changed relatively quickly
- Versatile Multi-purpose Multi-level
 - Legislation
 - Regulation
 - Adjunct to Regulation
 - Alternative Solution
 - Good/Retter/Rest?
- Provide a link between industry, consumer and regulator (almost never wholly public or private)

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Trends in Standardization

- International harmonization of standards
- Standards in international free trade
 - Standards under WTO-TBT Agreement
 - Standards under WTO-SPS Agreement
 - International standards
- Public acceptance of international private-sector standards
- Public influence in international private-sector standards
- Convergence of technology
- Faster....better user relevance (regulators and business)

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Types of Coordination

- The relationship between PASC member standards bodies and PASC member regulatory bodies in each PASC member economy is different.
- · Each relationship depends upon the governing structure of the standards body.
- The three different types of governing structures for standards bodies are:
 - Governmental
 - The majority of Asian economies in PASC have governmental standards bodies.
 - · Quasi Governmental
 - Private Public Partnership
 - Non Governmental
- Better cooperation = Better international alignment

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PASC Member Economies

- Australia (SA)
- Brunel Darussalam (CPRU)
- Canada (SCC)
- Chile (INN)
- · China (SAC)
- Colombia (ICONTEC)
- Fiji (FTSQCO)
- Hong Kong China (ITCHSKAR)
- Indonesia (BSN)
- Japan (JISC)
- Republic of Korea (KATS)
- Malaysia (DSM)

- Mexico (DGN)
- Mongolia (MASM)
- New Zealand (SNZ)
- Papua New Guinea (NISIT)
- Peru (INDECOPI)
- Philippines (BPS)
- Russia (GOST-R)
- Singapore (SPRING SG)
- · South Africa (SABS)
- Thailand (TISI)
- USA (ANSI)
- Vietnam (STAMEQ/TCVN)

Governmental Standard Bodies in Blue Quasi – Governmental Standards Bodies in Red Non-Governmental Standards Bodies in Black

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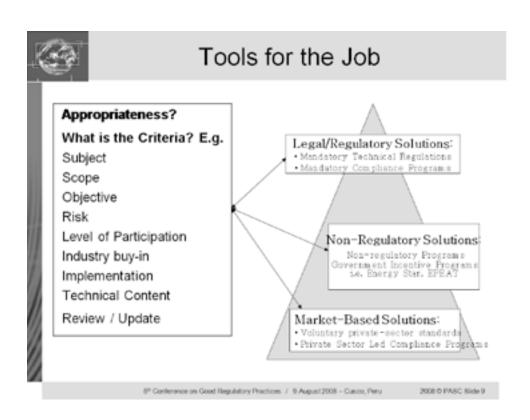


Types of Coordination

- Each PASC member economy has the freedom to choose the appropriate tools for coordination between standardization bodies and regulatory bodies.
- · PASC supports adherence to the WTO principles.
- Depending upon the subject matter, industry, objective, etc. a member economy has several tools at their disposal:
 - Technical Regulations
 - Mandatory specifications, which may include (or reference) particular standards or conformity assessment procedures.
 - Standards
 - Market driven specifications for a product, service, person, process or system, voluntary in application or incorporated into a law.
 - Conformity Assessment
 - Processes used to verify the compliance of a product, service, person, process or system to either a standards or a regulation (i.e. Suppliers Declaration of Conformity (SDoC) to 3rd Party Testing and Certification)

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Issues in Standardization

- · Certification / Liability
- Public and industry understanding of "mandatory" and "voluntary"
- Regulator needs to be at the table and communicating with the Technical Committees and their standards organizations
- Standards process v. political risk
- Adopting standards as part of legislation
 - Process
 - Access for free?

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Summary: Standards - the Regulators Friend

- Encourages innovation and productivity allows alternative solutions
- Increases efficiency best practice
- The process promotes acceptance of the completed standard
- Regulation is therefore effective (relevant, flexible, responsive)
- Alternative to regulation allows less regulation reduced compliance costs

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Section 2

Regulation and Trade Topic Methodologies of regulatory impact analysis on trade

Presentation

U.S. Perspectives on Incorporating Trade Considerations into the Regulatory Process



Speaker

Ms. Julia Doherty, U.S. Trade Representative, United States

Ms. Julia Doherty is responsible for developing, coordinating and implementing U.S. trade policy positions on international standards, conformity assessment procedures, technical regulations and other non-tariff matters.

She represents the United States on the trade issues in the World Trade Organization (WTO), the Asia-Pacific Economic Cooperation (APEC) and other international organizations. Prior to working on standards and conformance issues, Ms. Doherty coordinated U.S. trade policy related to the negotiations on the Doha Development Agenda of the World Trade Organization. She has also worked on international economic issues at the U.S. Office of Management and Budget, the Joint Economic Committee of the U.S. Congress and the investment bank of Kidder, Peabody & Co. She holds a Masters of Arts in Economics from the University of Maryland.

APEC SCSC 5th Conference on Good Regulatory Practices

"U.S. Perspectives on Incorporating Trade Considerations into the Regulatory Process"

Julia Doherty Senior Director Office of the U.S. Trade Representative

Outline

- Review of APEC work on good regulatory practice, including SCSC GRP work with particular relevance to trade issues
- Survey of elements of the U.S. regulatory system relevant when assessing international trade impacts
- Summary of recommendations in recent joint OMB-EC review of EU and US Regulatory Impact Assessment guidelines relating to international trade issues
- □ Conclusions

APEC Good Regulatory Practice

- APEC/OECD work in 1990's produced consensus on principles to guide regulatory decision making and reform programs.
- Recommended that regulations should:
 - serve clearly identified policy goals and be effective in achieving goals;
 - have a sound legal and empirical basis;
 - produce benefits that justify costs
 - minimize costs and market distortions;
 - promote innovation through market incentives and goal-based approaches:
 - be clear, simple, and practical for users;
 - be consistent with other regulations and policies; and
 - be compatible as far as possible with competition, trade and investment-facilitating principles at domestic and international levels.

SCSC Good Regulatory Practice

- In 1997, the SCSC links specific GRP principles with corresponding WTO TBT obligations in its "Guidelines for the preparation, adoption and review of technical regulations."
 - E.g., GRP principle of "clearly identify goal" is directly related to the "legitimate objectives" of TBT Article 2.2.
 - Goal of regulation must meet criteria in Art 2.2.
- SCSC produces "APEC Information Notes on Good Practice for Technical Regulation" in 2000.

Recent APEC work on GRP Efforts to design and apply longer term improvements to regulatory quality, including in developing economies. Country "case studies" and "self assessments" regarding OECD/APEC Checklist. Sectoral initiatives, including the Chemical Dialogue's work on principles for chemical regulation, and the new Wine Regulatory Forum in the SCSC.

SCSC GRP Work on Trade

- Foster regulatory policies, institutions and tools designed to reduce unnecessary obstacles to trade.
- Improve consistency and transparency of regulations, standards and conformance to facilitate trade across economies.
- Promote adherence to WTO TBT and SPS Agreements.

Key U.S. Regulatory Policies with Trade Nexus Administrative Procedure Act - Mandates an open, transparent process of public notice and comment. Executive Order 12866 - Establishes the framework for decision making and oversight to ensure regulation brings the greatest possible net benefit. OMB Circular A-4 - Provides guidance on conducting regulatory impact analyses, including cost-benefit analysis and risk assessment.

Administrative Procedure Act

- Requires that agencies go through a "notice and comment" process open to all interested parties, both foreign and domestic.
- Before agencies can issue a final regulation, they must respond to the comments, make sure that the final regulation follows logically from the proposal and the public record, and is not arbitrary or capricious.
- The public record may be used by the courts in settling any challenge to the regulations brought by interested parties.

Executive Order 12866 1993 Presidential statement establishing the philosophy, principles and process for regulatory planning and review Recognizes that private sector and private market are the best engines for growth Constrains regulatory action to that necessary by law, to interpret law or compelling public need Requires cost-benefit analysis, both quantifiable and qualitative measures, of regulatory initiatives Establishes OMB as central oversight body responsible for ensuring regulations are consistent with the law, the President's priorities and principles, and do not conflict with actions taken by other agencies

Executive Order 12866 - Guiding Principles for Rulemaking by Regulatory Agencies

- □ Identify the problem
- □ Identify and assess alternatives to direct regulation
- Consider the degree and nature of the risks posed
- Design regulation in most cost-effective manner to achieve regulatory objective
- Propose or adopt a regulation only upon a reasoned determination that the benefits justify the costs.
- Base decisions on the best scientific, technical and economic data available.
- Specify performance objectives, rather than specifying behavior or manner of compliance
- □ Tailor regulations to impose the least burden on society
- Avoid regulations that are inconsistent or incompatible with those of other agencies

Guides agencies in developing more beneficial, less intrusive and more cost-effective rules Well-done analyses provide exceptionally valuable decision-making tools for policy makers Consideration of impact on economy -- including international trade -- required for economically significant rules Centralized review of significant regulations by OMB, interagency participation and public participation, result in regulations that are much less likely to create trade barriers

Circular A-4: Guidance on Regulatory Analysis Provides detailed guidance on regulatory analysis to agencies Standardizes the way benefits and costs of regulatory actions are measured and reported Provides a formal way of organizing the evidence on key effects of various regulatory alternatives

Circular A-4: Good Regulatory Analysis Statement of the need for federal regulatory action Market failure or other social purpose Presumption against economic regulation An examination of alternative approaches Market oriented approaches Statutory discretion Enforcement options/Compliance dates Informational measures Evaluation of the costs and benefits -- quantitative and qualitative -- of proposed action and main alternatives

Circular A-4 - Trade Aspects

- While focus is on domestic impacts, trade considerations are covered, including evaluating concerns that new U.S. rules could act as non-tariff barriers to imported goods and looking at effects beyond the border
- Requires consideration of the role of regulation in facilitating U.S. participation in global markets
- Acknowledges importance of strong Federal regulatory role in harmonization of U.S and international rules
- RIA methodology is not explicit on how to evaluate effects beyond the borders

OMB-EC Dialogue on Regulatory Issues Dialogue established in 2005 between the OMB and relevant experts in the European Commission Focus is to address methodological issues (e.g., impact assessment) in order to improve understanding of each others' regulatory systems and practices Final report, "Review of RIA Guidelines on the Analysis of Impacts on International Trade and Investment" published in May 2008.

OMB-EC Dialogue - Report Conclusions

- Value of timely announcement of planned legislative and regulatory initiatives, and of transparency in the associated impact analyses.
- Importance of transparency in impact assessment procedures and guidelines, accompanied by rigorous system of quality control.
- Making policy proposals and impact assessments public to allowing governments and stakeholders to respond in cases of where significant trade impact is expected.

OMB-EC Dialogue: Further Work

- Report concluded that guidance should be provided on the type of analysis needed to provide decision makers with information on international trade and investment impacts and their multilateral context.
- □ This could include:
 - an analysis demonstrating the need for any proposed regulation that might directly impede international trade or investment
 - an analysis of the degree to which different groups (foreign and domestic businesses and consumers) are affected by such a proposal or
 - a recommendation that existing international standards or regulatory approaches, if applicable, should be analyzed as an explicit regulatory alternative.

Conclusions

- As economic integration increases, domestic regulatory policies have greater affects on trading partners.
- Policy trade-offs can be better managed through a more thorough understanding of linkages that enable careful design of regulatory policies.
- APEC, and the SCSC, can continue to assist policy makers and the business community by furthering its work in identifying and exploring trade-related GRP issues.

J.S. communications to WTO TBT Committee	
	"Good Regulatory Practice"
	G/TBT/W/258 - October 2005
	"Determining the Need to Regulate"
	G/TBT/W/285 - March 2008

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- Listing of OIRA's meetings with outside parties on regulations under OMB review: www.whitehouse.gov/omb/oira/meetings.html
- OMB guidance to agencies on Regulatory Analysis (September 17, 2003): www.whitehouse.gov/omb/circulars/a004/a-4.pdf
- Review of the Application of EU and US Regulatory Impact Assessment Guidelines on the Analysis of Impacts on International Trade (May 2008): http://www.whitehouse.gov/omb/inforeg/reports/sg-omb_final.pdf

Section 2

Regulation and Trade Topic

Coordination mechanisms among regulatory bodies: harmonization vis a vis MRAs

Presentation

The ASEAN (Association of Southeast Asian Nations) EE MRA and AHEEER – A Model for Trade Facilitation



Speaker

Mr. Teo Nam Kuan, SPRING, Singapore

Teo Nam Kuan is the Group Director of Quality & Standards Group, SPRING Singapore, covering standardization, accreditation, consumer product safety and weights & measures. He has been involved in standardization work since 1985 when he was in charge of standardization and certification programs in the then SISIR. He represents SPRING Singapore in international meetings in ISO, IEC and regional standardization for such as the ASEAN Consultative Committee on Standards and Quality (ACCSQ), Pacific Area Standards Congress (PASC), and the APEC Sub-committee on Standards and Conformance (SCSC). Mr Teo has also participated actively in MRA negotiations at the G-to-G level.

The ASEAN (Association of Southeast Asian Nations) EE MRA and AHEEER – A Model for Trade Facilitation

Teo Nam Kuan Group Director (Quality and Standards)

9 August 2008



What is ASEAN?

- Association of Southeast Asian Nations (ASEAN)
 grouping of 10 Member States with population of more than 560 million in Southeast Asia
- □ Member States are: Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Philippines, Singapore, Thailand and Vietnam
- □In 2003, the ASEAN Leaders resolved that an ASEAN Community shall be established comprising three pillars, namely, ASEAN Security Community, ASEAN Economic Community and ASEAN Socio-Cultural Community



Outline

- □ ASEAN Sectoral Mutual Recognition Arrangement for Electrical & Electronic Equipment (ASEAN EE MRA)
- ☐ Agreement on the ASEAN Harmonised EEE Regulatory Regime (AHEEER)



ASEAN EE MRA - Background

- Developed by EPWG (Electrical Product Working Group)
 - EPWG was formed in 1999 and comprises ASEAN EEE regulators
 - main objective to develop the ASEAN EE MRA to support free trade initiatives
- MRA signed by ASEAN Economic Ministers (AEM) in 2002
- □ JSC EE MRA replaced EPWG upon signing of MRA by AEM
 - Key objective to implement the MRA
 - Serves as platform by each member state to provide latest update on its EEE Regulatory Regime
 - Designation of testing laboratories and certification bodies



Elements of the ASEAN EE MRA (1/2)

- ☐ Participation in acceptance of Test Reports
 - Regulator's acceptance of testing undertaken by listed Testing Laboratories to Mandatory Requirements imposed by the regulators
 - Underpinned by the IECEE CB Scheme and the APLAC Multilateral MRA
 - Participation: ALL 10 Member States
 - Implementation: 14 Testing Laboratories listed (Indonesia-4, Malaysia-1, Philippines-1, Singapore-2, Thailand-4, Vietnam-2)



Elements of the ASEAN EE MRA (2/2)

- Participation in acceptance of Certification
 - Regulator's acceptance of certification by listed Certification Bodies to Mandatory Requirements imposed by the regulator
 - Underpinned by the IECEE CB FCS and PAC Multilateral MRA for Product Certification
 - Participation: 7 Member States
 - Implementation: 2 Product Certification Bodies listed (Singapore and Vietnam)



Agreement on the ASEAN Harmonised EEE Regulatory Regime (AHEEER) - Background

- □ Developed by JSC EE MRA Taskforce to support the realisation of the ASEAN Economic Community
- ☐ Common regulatory requirements for ASEAN members so as to facilitate intra-ASEAN trade and reduce cost and technical barriers to trade
- ☐ First draft discussed in 2004
- ☐ Finalised and signed by ASEAN Economic Ministers (AEM) on Dec 2005
- □Agreement to be fully implemented by 31 Dec 2010



AHEEER - Who's responsible for implementing it? (1/2)

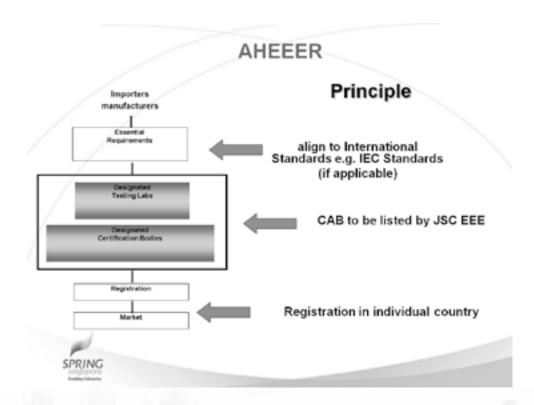
- ☐ JSC EEE (Joint Sectoral Committee for Electrical and Electronic Equipment)
- □ Formed after signing of AHEEER; replaced JSC EE MRA
- Key objectives
 - Oversees implementation of AHEER
 - Sets up the principle for acceptance of International Standards, e.g. IEC standards (where applicable), including based on specific edition as well as any newer editions



AHEEER - Who's responsible for implementing it? (2/2)

- ☐ Key objectives (continued)
 - Designation of CABs to harmonised standards meeting Essential Requirements
 - Transpose national legislation to achieve harmonised regime
 - Harmonise conformity assessment procedures





AHEEER - Key elements (1/5)

- ☐ Essential Requirements for EEE
- ☐ Conformity Assessment Procedures



AHEEER - Key elements (2/5)

- ☐ Essential Requirements for EEE
 - Safety
 - · Environment (e.g. energy efficiency)
 - · Electromagnetic Compatibility
- ☐ Listed standards are deemed to meet Essential Requirements

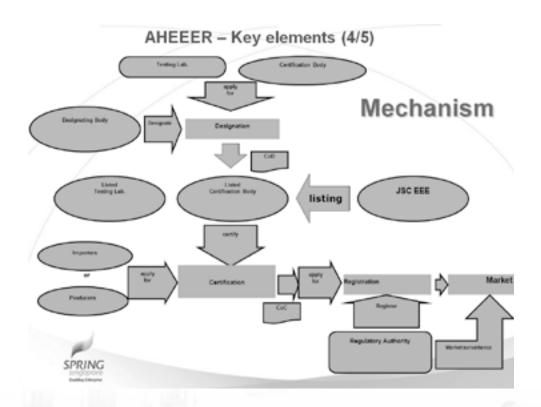


AHEEER - Key elements (3/5)

☐ Conformity Assessment Procedures, Registration of EEE and Designation of CABs

- Mechanism
- Product Certification System





AHEEER - Key elements (5/5)

Harmonise conformity assessment procedure:

- □ Medium Risk EEE → System 1 (Type Testing)
- ☐ High Risk EEE → System 5 (Type Testing + Factory Inspection)



Differences between ASEAN EE MRA and AHEEER

ASEAN EE MRA

- Technical Regulation / Mandatory Standards not required to be harmonised
- Conformity Assessment Procedure
- Laws & Administrative Provision may not require to be changed

AHEEER

- Harmonised Technical Regulation / Mandatory Standards
- Harmonised Conformity Assessment Procedure
- Harmonised Laws & Administrative Provision

SHALL be in line with the Agreement



AHEEER - Outcome

- Supports ASEAN Economic Community common market of more than 560 million people across 10 Member States
- Enhanced free flow of goods in the region as reduction in TBTs expected



Thank you for your attention.



Section 3

Performance Based Regulations

Presentation

Performance based regulations vs prescriptive regulation: A case study of the European approach to wine regulation compared to APEC Economies



Speaker

Mr. Tony Battaglene, Winemakers' Federation of Australia

He has direct responsibility for government liaison, policy extension, all trade-related issues, R&D issues, development of industry policy and general wine industry strategy for the Winemakers Federation of Australia. He represents the Australia wine industry in the government to government bilateral negotiations between Australia and the European Union on wine, and leads the Australian industry delegation in a number of international fora including the World Wine Trade Group (WWTG) and the International Organization of Wine and the Vine (OIV).



Performance based regulations vs prescriptive regulation: A case study of the European approach to wine regulation compared to APEC Economies

CONFERENCE ON GOOD REGULATORY PRACTICES 9 August

Tony Battaglene

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Why do we need wine regulation?

- Regulations exist to protect consumers and producers and to create a fair trading environment.
- These regulations can be developed by global organizations (WTO, CODEX), regional country groups, nation states, or local governments.
- Self-regulations (e.g. Codes of Best Practice) can be created by producer associations or influential corporate entities.



Influences over wine regulation?

- Governments set regulations to achieve policy outcomes
- Special interest groups often have significant influence over regulations.
- Examples of these special interests are environmental groups, consumer groups, nutrition and health advocates, and pro-trade groups, such as the WWTG.

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Wine regulation meets a number of policy objectives

- Social policy
- Fiscal policy
- Consumer protection
- Consumer information
- Health and safety
- Quality Đ Trademarks, Geographic Indications, Brands



Social policy

- Standard drinks
- Health warnings
- Allergen labelling
- Recycling symbols

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Standard drinks

- Used to provide advice to drinkers on how to moderate their consumption
- Many different definitions, usually based on grams of alcohol per amount of beverage
- Can be linked to drink driving programs
- Can be a symbol or statement in different jurisdictions



Health warnings

- Used to provide advice to drinkers on harmful effects of alcohol consumption
- Different countries require different warnings
- Often linked to pregnancy / foetal alchol syndrome
- Can be a symbol or statement in different jurisdictions

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Allergen labeling

- Used to provide advice to drinkers on presnce of potential allergenic material including eggs, milk, nuts, fish and sulphites.
- Regulations based on international recommendations from the Codex Alimentarius Commission
- Sulphites can be described using INS numbers in some countries.
- Issues surrounding language of declaration



Recycling symbols

- Used to provide information to consumers.
- Regulations based on horizontal legislation

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Fiscal policy

- Used to collect taxes and tariffs
- Used for revenue raising purposes
- Some economies impose taxes/tariffs to try to reduce consumption (ineffective instrument that creates trade distortions; illegal trade and production and potential serous consumer impacts)



Health and safety

- Regulate additives and processing aids
- Regulate chemical usage on vineyards and residues in wine
- Hygiene standards
- Worker health and safety regulations

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Consumer protection

- Ensure what is in the bottle is reflected in the label declaration
- Regulate production methods so consumers know what they are getting
- Harmonise regulations across producing economies



Quality – Trademarks, Geographic Indications, Brands

- TRIPS Agreement provides basis for GI and trademark protection Đ multilateral obligation for WTO members
- Key element in purchase decision and for consumer loyalty
- System requires integrity for consumer protection

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Why are rules & regulations different?

- 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, in requiring different production methods, and in terms of logistics.
- Differing regulations also increases the possibility of consumer confusion.



What are the drivers to reduce these barriers?

- WTO agreements specifically instruct member governments to reduce technical barriers to trade arising from differing national regulations.
- Industry and producer groups also promote these activites because of their potential to reduce costs, facilitate trade flows and reduce consumer confusion.

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What are the mechanisms to reduce these barriers?

The WTO identifies three mechanisms for facilitating trade:

- 1. Harmonisation
- 2. Equivalence
- 3. Mutual recognition/mutual acceptance

These three mechanisms are closely related, but not interchangeable



Harmonisation

- Involves the adjustment of standards, regulations and procedures until they are the same.
- This can be done by:
 - **D** Upward harmonisation
 - **Downward harmonisation**
 - **D** Compromise harmonisation (new standard)

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Mechanisms to harmonise

- Bilateral agreements eg. Chile-European
 Free Trade Agreement
- Multilateral agreements
- International Standard Setting Organisations
 D International Organisation for Standardisation (ISO)
- International Reference bodies OIV; OIML



Equivalence

- Does not require adjustment of national standards (key difference to harmonisation)
- Requires a determination that the two standards/procedures address similar regulatory objectives or achieve similar results even though they are not identical.

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Mutual recognition

- · Also known as mutual acceptance
- Vehicle for regulatory cooperation
- Can be based on harmonisation, equivalence or external criteria



What is an MRA?

- The parties to a MRA agree to accept the other parties standards because they are:
 - **Đ** Equivalent; or
 - **Đ** Harmonised; or
 - **Đ Meet some other mutually identified criteria**
- Most MRAs based on equivalence or external criteria

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Why is harmonisation difficult?

- Differing regulatory philosophy
- Harmonisation requires regulatory change

 ⊕ Bureaucrats don⊕ like change
- Regulatory change can create precedents for other goods /services
- Differing policy objectives



The origin of MRA

- A result of the creation of the European Union
- Extended now to underpin international trade negotiations
- Fundamental principle of WTO
- Underpins APEC

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The Mutual Recognition Principle _

Mutual Recognition is the principle of law under which
Member States must allow goods that are legally sold in
another Member State to be sold within their own territory.
Member States are only allowed to derogate from this
principle if they adopt their own national technical rules
which are proportionate and which are justified by the EU
Treaty or by Òverriding requirements of public interestÓas
defined by the European Court of Justice.



Mutual Recognition in the WTO context

- · Mutual recognition is encouraged in the WTO.
- Article 7 of GATS encourages signatories to adopt measures, by way of bilateral agreements or "autonomously", in order "to recognise the education or experience obtained, requirements met, or licences or certification obtained in a particular country".
- Under the TBT agreement "Members are encouraged, at the request of other members, to be willing to enter into negotiations for the conclusion of agreements for the mutual recognition of results of each other's conformity assessment procedures...(article 6.3)."
- The TBT also includes a stronger obligation regarding unilateral recognition of equivalence: "6.1. Members shall ensure, whenever possible, that results of conformity assessment in other Members are accepted, even when those procedures differ from their own ... (article 6.1)."

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Regulatory philosophies

- D In the past the regulatory philosophies of the ÒOld WorldÓ economies differ markedly from those of so called ÒNew WorldÓwine production economies.
- D Most issues arise when production standards within a country are applied as market standards for imported products.
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Proposed wine market reform in Europe

- **Đ Proposals to adopt similar regulatory** philosophy to the **Ôlew WorldÕ**

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Common to all proposals are:

- D The rigidity of procedures for adopting and adapting Winemaking practices hinders competitiveness.
- **EU regulations are too complex, notably on definitions and Winemaking practices.**
- D No reference in Community legislation to the concept of @eographical indication as defined by the WTO Trade Related Aspects of Intellectual Property Rights (TRIPs) Agreement.
- **D** 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.

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This new found commonality between the producing economies means that we now have a real chance of harmonising trade restrictive regulations or through mutual recognition facilitating trade.



To sum up.....

- Mutual recognition is a mechanism that allows access to markets after standards have been set.
- Harmonisation and equivalence allow a wine producer to make and present wine in a single fashion in all markets.

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Effective Regulations

- An appropriate instrument that is sufficient to meet the objective (whether treaty, regulation, code of practice etc) in clear and easily understood language, taking into consideration the compliance requirements of both local and foreign producers.
- Each instrument is reviewed periodically to assess current relevance.
- The goal is to ensure that the overall framework of regulation is appropriate, effective, and not duplicative or overly-burdensome.



Components of the Regulatory Framework

Intergovernmental Standards

- International agreements adopted by bodies such as Codex Alimentarius have grown in significance and often serve as a catalyst to the formation of regional and national regulations.
- Allergen labeling provides a recent example of this, being adopted into the Codex Alimentarius food labeling standard in the late 1990s and stimulating member countries (beginning with Australia) to require such labeling for foods (including wine) in national regulations.
- Even where the agreements of such bodies are not directly translated into regulation, they are still important reference texts on the subjects covered, and may be used to help resolve trade disputes between WTO member countries.

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Bi-lateral and Multi-lateral Agreements

- There is a plethora of agreements that help to shape the global trading environment for wine.
- Some of these are Free Trade Agreements between countries, some are commodity-specific, such as the WWTG Mutual Acceptance Agreement on Oenological Practices or the many bilateral wine trade agreements that have been negotiated between the EU and its principal trading partners.
- These play a significant part in the overall global regulatory framework for wine



Government regulation

- This type of regulation can impose a huge burden on producers without commensurate benefits Da fact that is acknowledged in the recently proposed EU wine reform package.
- The recognition of this potential imbalance between legislative burden and beneficial outcome has led to the development among governments in Europe of the concept of ÖBetter RegulationÓ specifically for government regulations, but containing principles of general application across all facets of the regulatory framework:

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General principles of 'Better regulation'

- Regulate as a last resort and not as a first resort.
- Regulate only after all other options have been excluded.
- Be clear about the cost of regulatory proposals.
- Regulate only when the overall benefit outweighs the burden and cost to individuals and businesses



Specific principles of 'Better regulation'

Proportionate The remedy must match the risk

Accountable To all stakeholders

Consistent With other regulations and risks

• Transparent Keep it simple, clear and open

Targeted Focus on the problem

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Industry self-regulation

- In a complete regulatory framework, there will always be a place for well constructed and targeted guidance documents, Codes of Practice etc.
- These can enter into greater detail than might be possible or desirable and can also generally be prepared and revised more rapidly than is possible for formal regulations. In the wine sector, FIVS has produced several documents of this type, including:
 - **Đ** Guiding Principles for Advertising and Marketing Practices for Alcohol Beverages
 - **Đ** Good Fining Practice Guidelines
 - **D** Global Wine Sector Environmental Sustainability



Retailer "regulation"

- As retailers extend their distribution outside of national boundaries and fight for competitive positions, a new tier of technical requirements has begun to appear, as retailers have imposed their own standards on their suppliers.
- These requirements are in areas such as quality management and sustainable practices but may also include labeling to supply customers with additional data, such as nutritional or health information.

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Conclusion

- APEC has led the world in establishing mutual recognition systems.
- The WWTG is also providing leadership in the field of mutual recognition for the grape and wine sector.
- MRAs are good for producers and consumers.
- MRAs allow traditional methods to be maintained while facilitating trade.



The role of APEC

- APEC contains major consuming and producing wine economies
- The SCSC has set up a wine regulatory forum
- APEC has led the world in establishing mutual recognition systems.

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Wine Regulatory Forum

- The WRF will commence dialogue and exchange ideas on wine regulation.
 - D These experts would share experiences and knowledge, in particular in relation to involvement and obligations with the various relevant international fora, including *inter alia*, the Codex Alimentarius Commission, World Trade Organisation (WTO), International Organisation of Wine and the Vine (OIV), and the World Wine Trade Group (WWTG).
 - D This consultation would also look at the benefits for APEC Economies and the APEC region, in particular the benefits to consumers by improving consumer protection through better wine regulation, without forming a barrier to trade. A key thrust of these consultations would be to provide capacity building in the area of wine regulation.
 - D This group could then bring forward a project proposal for Trade & Investment Liberalization & Facilitation (TILF) funding to be considered inter-sessionally. This would enable the holding of training workshops for wine regulators.



DRAFT TERMS OF REFERENCE

- · Goal
 - Đ To examine options to simplify and harmonise wine regulation across the APEC region, reduce technical barriers to trade and protect consumers.
 - $\boldsymbol{\mathfrak{D}}$. To share information and build capacity in wine regulation across the APEC region.
 - **Đ** Communications and Administrative Arrangements
 - D Contact details of wine regulation focal points to be provided by member economies to the Australian contact point by the end of 14 March 2008
 - $\bar{\rm D}$ $\,$ The Wine Regulatory Forum will report to SCSC via presentation and/or written statements tabled at SCSC plenary.
 - D The work of the Wine Regulatory Forum will, wherever possible, be carried out via electronic communications.

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DRAFT TERMS OF REFERENCE (2)

- Modalities for Cooperation
 - Establishment of a Wine Regulatory Forum, under the auspices of SCSC, to undertake a stock take on existing wine regulations and recommend action on future cooperation and harmonisation opportunities.
 - D The Wine Regulatory Forum initially to be chaired by Australia and include representatives from all interested APEC economies.
 - D The Food Safety Forum has a strong relationship with the intended activities of the Wine Regulatory Forum (in particular the sub-theme: Legal and technical drafting to support the development of food laws and regulations harmonized with international standards). The Wine Regulatory Forum should seek to consult with and coordinate with the activities of the Food Safety Forum to facilitate the best use of capacity building activities and ensure maximum efficiency of time and resources between both Forums.
 - Đ Participation from domestic and regional wine regulatory agencies is encouraged.
 - D The Wine Regulatory Forum will place high priority on an examination of capacity building needs in the region. It will also consider the potential benefits of running capacity building training workshops in the field of wine regulation with the support Trade & Investment Liberalization & Facilitation (TILF) funding.



Other SCSC activities

- This activity has a strong relationship with the Food Safety Forum.
- The Food Safety Forum has produced a strategic approach for SPS
 activities that has four key strands, including one on Food safety
 regulatory systems, with a sub-theme: Legal and technical drafting to
 support the development of food laws and regulations harmonized
 with international standards. This activity, which links the wine
 industry engagement with food regulators fits within that strand.
- This activity is a model case study for capacity building with a view to regulatory alignment, where you have an industry that is keen to foster trade, and governments keen to protect consumers, rather than use regulation as a form of protectionism.

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And APEC?....

- WRF provides APEC with a springboard to reduce trade barriers for wine; strengthen regulatory capacity and develop better policy.
- · Areas of activity could include:
 - **Đ** Carbon accounting protocols
 - **D** Capacity building
 - **D Better Regulation** O
 - **Đ** Relationships between regulators

Section 4

Good Regulatory Practices: APEC Economies Experiences

Presentation

Peru: Experience in Technical Regulations



Speaker

Mr. Augusto Mello, INDECOPI, Peru

Augusto Mello is an economist. He is the Technical Secretary of INDECOPI's Technical and Commercial Regulations Commission, which includes both the Peruvian National Standardization and Accreditation Body. He has represented Peru in international fora related to standardization, accreditation and technical barriers to trade.

He supports the work of the Ministry of Foreign Trade and Tourism in these areas as well as in Free Trade Agreement negotiations.

From 2000 to 2004 he was President of the MLA Committee of the Inter American Accreditation Cooperation (IAAC). Currently he is Chair of the APEC's Sub Committee on Standards and Conformance.



PERU: Experience in Technical Regulations

Augusto Mello Technical Secretary, Technical and Commercial Regulations Commission INDECOPI

Cusco, August 2008

INDECOPI suma esfuerzos al servicio del mercado

CONTENTS

- Introduction
- Legal Framework
- National Experience
- Conclusions

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INTRODUCTION

Why to improve Technical Regulations?

Purpose of public policy: Rigorous production of Technical Regulations by authorities. A systematic process based on:

- Analysis of alternative regulations
- · Inclusive and equilibrated public consultation
- · Cost benefit analysis
- Accountability

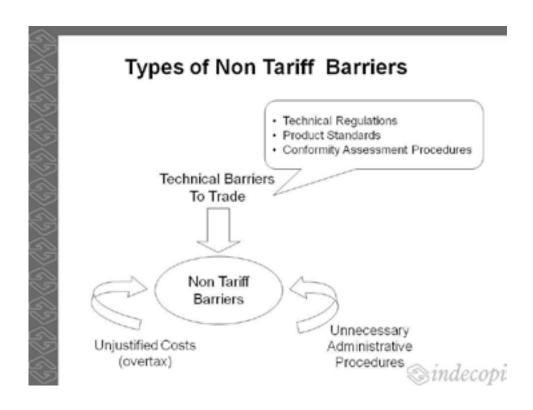
Improvement in regulations results in benefits: a more competitive country.



INTRODUCTION

- A badly designed technical regulation implies:
 - Costs exceed benefits
 - Judicial uncertainty
 - Possible generation of Technical Barriers to Trade
 - Unnecessary, complex and costly administrative procedures
 - Possible corruption
 - Proliferation of administrative legal protection
 - Non resolution of problems and rising of new ones: solution is sought through new regulations (vicious circle)
- Bad regulations infringe the rule of law

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LEGAL FRAMEWORK

Peru: Evolution in Technical Regulations

National Framework:

 In the 1990s: Laws related to obligations associated to non tariff commercial barriers

Supranational Framework:

 Inclusion of WTO TBT Agreement and Andean Community Decisions

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LEGAL FRAMEWORK

Peru: Evolution in Technical Regulations

- Peruvian Political Constitution (1993), Article 63°
 - Investment without discrimination
 - Free production and trade
- Legislative Decree 668 (September 1991)
 - Guarantees for free domestic and international trade
 - Transparency Non discrimination in laws and regulations
 - Proscription of Non Tariff Barriers, except for legitimate objectives



LEGAL FRAMEWORK

Peru: Evolution in Technical Regulations

- Law Decree 25629 (July 1992)
 - Restrictions to trade only via Supreme Decree and ratification by the Ministry of Economics and Finance -MEF
- Law Decree 25868 (November 1992)
 - Creation of the National Institute for the Defense of Competition and the Protection of Intellectual Property -INDECOPI and its Technical and Commercial Regulations Commission - CRT
 - CRT: Defense of free trade laws, may revoke non-tariff restrictions (ex-post)

LEGAL FRAMEWORK

Peru: Evolution in Technical Regulations

- Legislative Resolution 26407 (January 1995)
 WTO Agreements are integrated into Peruvian legislation
- Supreme Decree N°058-2005-EF. (May 2005)
 Only MEF or a delegate entity issues import authorizations.
 Reiteration of Law Decree 25629
- Supreme Decree N°149-2005-EF (November 2005)
 WTO TBT Agreement provisions are regulated
- Ministerial Resolution N°639-2006-EF (November 2006)
 Guidebook for economic and legal analysis of regulations issued by the Ministry of Economics and Finance MEF



Supreme Decree N° 149-2005-EF

Purpose: To regulate WTO TBT Agreement provisions, as well as the WTO General Agreement on Trade in Services (GATS) provisions.

- Administrative procedures that affect free trade are approved by Supreme Decree with ratification by MEF and any other Ministry involved (Art.1).
- It defines: Technical Regulation, Standard and Procedures for conformity assessment, based on WTO TBT Agreement and Andean Decision 562 (Art.2).

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Supreme Decree N° 149-2005-EF

The authority which issues the technical regulation must:

- a) Supervise compliance (Art.3).
- Establish procedures to certify compliance.
 Equivalent requirements for nationals and foreigners.
 (Arts. 4 y 9).
- c) Publish the project 90 days before enactment
- d) Publish the Technical Regulation at least 6 months before its coming into force (Art.7).



Supreme Decree N° 149-2005-EF

 Proof of Compliance with Technical Regulation with one year validity. May be renewed (Art.10).

Additional Comments: This Supreme Decree does not affect the scope of sanitary and phytosanitary measures

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Ministerial Resolution N°639-2006-EF

- · Guidebook to promote the efficient development of regulations:
 - Homogeneous Criteria and procedures
 - Implementation of effective and trustworthy filters
- · It is backed by the following principles:
 - Need (prior evidence of the need to regulate)
 - Effectiveness (clear objective and means to achieve it)
 - Proportionality (cost-benefit analysis or impact)
 - Transparency (prior publication)
 - Consistency (regulations are duly coordinated)
- It applies to all dispositions issued by MEF and is starting point to analyze Technical Regulations before they are ratified.



LEGAL FRAMEWORK

Peru: Evolution in Technical Regulations
Supranational Framework (Andean Community):

- Decision 419: Andean System for Standardization, Accreditation, Testing, Certification, Technical Regulations and Metrology
- Decision 506: Recognition of product certificates (with technical regulation) issued by accredited or recognized bodies

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LEGAL FRAMEWORK

Peru: Evolution in Technical Regulations

Supranational Framework (Andean Community):

- Decision 562: Legal framework for the development, adoption and implementation of technical regulations by members
- Decision 615: Andean Community Information System for Notification of Technical Regulations -SIRT



Decision 562

A Technical Regulation must include:

- 1. Objective and purpose
- 2. Products covered
- Technical Regulation specific technical contents: definitions, description of products' general characteristics, requirements and reference to standards
- Administrative procedure for its application, including conformity assessment procedures
- 5. Date of entry into force

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Decision 562

(...)

- Authorized Conformity Assessment bodies
- Authority in charge of supervising compliance with technical regulation
- 8. Type of supervision and/or control
- 9. Sanctions regime

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NATIONAL EXPERIENCE

Developing and implementing Technical Regulations

- MEF: Ex-ante control through ratification
- MINCETUR: International commercial negotiations, Notifies Technical Regulations to the WTO. Gives opinion on Technical Regulations' contents
- INDECOPI: Ex-post control. May revoke regulations which qualify as non-tariff restrictions

MEF: Ministry of Economics and Finance

MINCETUR: Ministry of Foreign Trade and Tourism

INDECOPI: National Institute for the Defense of Competition and the Protection of

Intellectual Property

NATIONAL EXPERIENCE

Developing and implementing Technical Regulations

Notification (TBT – WTO)

- Responsible: MINCETUR-Vice ministry of Foreign Trade
 - makes consultations and coordinates with competent authorities
 - Proposes rectifications
- Notification at two levels
 - a) SIRT (Andean Community CAN) → All Technical Regulations, including legal text
 - b) TBT (WTO) → Technical Regulations which differ from international standards

(...)

⊗indecopi:

NATIONAL EXPERIENCE

Developing and implementing Technical Regulations

Notification (TBT – WTO):

- From 1999 to 2007 21 TR were notified
- Main sectors: Health, Agriculture, Industry and Energy

Information Service (TBT – WTO):

 Enquiry Point: INDECOPI – Technical and Commercial Regulations Commission

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NATIONAL EXPERIENCE

Developing and implementing Technical Regulations

Technical Regulations Inventory

- MINCETUR manages the Technical Regulations data base
- To develop the inventory, a guide was prepared to identify TR from other regulations. It is based on the WTO TBT and Andean Decision 562. The guide includes:
 - a) Criteria to identify TR
 - b) Steps to follow for identification
 - c) TR Examples
- Soon there will be access to the TR Inventory through the Internet.







NATIONAL EXPERIENCE

Developing and implementing Technical Regulations

- Activities to raise awareness among competent authorities, providing guidelines and best practices for the development of technical regulations (MINCETUR, INDECOPI)
- Progress with users (consumers, exporters, importers) regarding knowledge of WTO TBT Agreement: scope, procedures and mechanisms
- The APEC Good Regulatory Practice Guide has been used.
- There has been progress, but there is still work to be done.



Criteria which guide good regulatory practices

Indecopi establishes if TR is illegal or irrational and may declare it inapplicable

Indecopi has issued administrative resolutions which have established regulation evaluation criteria:

- Justification: Facts that justify it
- Proportionality: Does it relate to the objectives it intends to protect?
- Non discrimination: Does the Technical Regulation apply to all products, regardless of their origin?
- Adoption of the least restrictive measure: Is the selected Technical Regulation the least restrictive among the alternatives?



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INDECOPI suma esfuerzos al servicio del mercado

Closing Remarks

Mr. Waldy Bejarano, Foreign Trade and Tourism, Peru

On behalf of the Ministry of Foreign Trade and Tourism of Peru it is my pleasure to close the 5th Conference on Good Regulatory Practice. This Conference is one of the activities under the APEC Sub Committee on Standards and Conformance. It was organized by Peru, and co-sponsored by Chile, New Zealand and the United States of America.

Most of over 100 delegates from the government agencies, industries, academia and standards and conformance bodies of 19 APEC Member Economies have attended this conference. Member economy speakers from Australia, Canada, Chile, New Zealand, Singapore, United States of America, as well as a representative from the Specialists Regional Bodies (PASC) made presentations.

The Conference was divided into four sessions. The first session highlighted the need for sound regulatory policies and coordination in each economy that allow for and promote Good Regulatory Practice, in particular the use of international standards and internationally accepted conformance practices to meet trade and regulatory needs.

The second session highlighted that guidance is required on the type of analysis needed to provide regulators with information on international trade and investment impacts and their multilateral context. It also highlighted that harmonization as well as MRAs can be effective in enhancing trade in the region by reducing TBTs. The third session underlined the fact that performance based regulations can effectively serve APEC economies as a basis for harmonization and MRA's.

The fourth session highlighted the need of raising the awareness and visibility among high-level regulatory authorities of the need of sound regulatory practice and the use of using as guidance the "APEC Information Notes on Good Practice for Technical Regulations".

An issue highlighted during the different sessions was the importance of a system approach to the development of regulations, with adequate institutional structures and consistency and alignment among all participants and taking into account an effective participation in international standards and conformance organizations and multilateral agencies in order to harmonize technical and procedural criteria. This required capacity building tools and mechanisms to continuously train and guide personnel from the government agencies, industries, academia and standards and conformance bodies on the different aspects of Good Regulatory Practice, including on the type of analysis needed to provide regulators with information on international trade and investment impacts and their multilateral context.

Participants put forth the following recommendations for further SCSC work on Good Regulatory Practice:

- Stock take of APEC/SCSC work on Good Regulatory Practice to assist in determining whether the guidance documents produced are current or in need of updating, including in relationship to specific developing economy needs.
- Review the WTO Technical Barriers to Trade Committee work on Good Regulatory Practice.
- Gather information documents on Good Regulatory Practice from APEC Member Economies and make them available through an APEC public website.

The Conference provided an opportunity for APEC Member Economies to gain better knowledge on sound regulatory policies that meet regulatory needs and lead to reductions in regulatory barriers to trade. This

knowledge should be considered as one of the means for assisting APEC Member Economies in meeting their international obligations under the WTO TBT Agreement and their commitment under the APEC Bogor Declaration.

The 5th Conference provided an opportunity for APEC Member Economies to exchange information on regulatory systems and share experiences in establishing Good Regulatory Practice.

The Conference also contributed to help APEC Member Economies to further consider the priorities for capacity building in the area of Good Regulatory Practice in the future, and interact with the private sector to explore the potential for future collaborative capacity building activities on Good Regulatory Practice.

As Chair of this Conference and Project Overseer, at the upcoming SCSC meeting I will recommend that the SCSC:

- Note that the APEC funded Conference organized by Peru, entitled 5th Conference on Good Regulatory Practice held on 9 August in Cusco, Peru involving over 100 delegates from the government agencies, industries, academia and standards and conformance bodies of 19 APEC Member Economies.
- Note the Report of the Conference, including the recommendations contained therein.
- Agree that the SCSC will give effect to these recommendations in its work program.
- Report the outcomes of this Conference as an important activity under SCSC to the CTI meeting in this August.

These important outcomes of the Conference were possible thanks to the support of the co-sponsoring economies Chile, New Zealand and the United States of America, the speakers from 6 APEC Member Economies and PASC, and the attendance of delegates from the government agencies, industries, academia and standards and conformance bodies of 19 APEC Member Economies, to all of you, my recognition and gratitude for your active cooperation and participation.

Thank you very much.

The venue, the people



Waldy Bejarano, Conference Chair



Conference Speakers



Conference Moderator and Conference Speaker



Conference Moderator, Conference Chair and Speakers



Conference Participants



Conference Participants



Conference Speaker



Conference Speaker



Press Conference



Machu Picchu



Thanks for your participation!

Participant List 5th GRP

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