



Asia-Pacific  
Economic Cooperation

# 2004:

## Key APEC Documents



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December 2004

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## INTRODUCTION

**Key APEC Documents 2004** is the eleventh in a series produced by the APEC Secretariat to provide a reference set of the key policy decisions and initiatives endorsed by APEC Leaders and Ministers each year. Collectively, these documents frame the policy directions for APEC's annual work programmes.

This issue presents a compilation of the statements from each of the APEC Ministerial Meetings held during 2004 together with the APEC Economic Leaders' Declaration from their recent meeting in Santiago, Chile. The Executive Summary of the annual APEC Business Advisory Council Report to APEC Economic Leaders is also included for easy reference.

The enclosed CD provides the complete text of all documents contained in this publication together with supplementary policy papers and selected key APEC 2004 Reports.

The APEC website, [www.apec.org](http://www.apec.org), offers a further source of documentation and information relating to the wide-ranging activities of APEC.

APEC Secretariat  
December 2004



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## **APEC Business Advisory Council**

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## **ADDITIONAL DOCUMENTS FOUND IN THE ATTACHED CD-ROM:**

### **Policy/Strategy papers referred to in Leaders' and Joint Ministerial statements as follows:**

1. APEC Best Practices for RTAS/FTAS (2004/AMM/003)
2. APEC Course of Action on Fighting Corruption and Ensuring Transparency (2004/AMM/033rev2)
3. APEC Guidelines on Controls and Security of Man-Portable Air Defense Systems (MANPADS) (2004/AMM/035)
4. APEC Key Elements for Effective Export Control Systems (2004/AMM/036)
5. APEC Life Sciences Innovation Forum (LSIF): Strategic Plan (2004/AMM/009)
6. APEC Privacy Framework (2004/AMM/014rev1)
7. APEC Reform: Reforms for Immediate Action (2004/AMM/022)
8. APEC's Strategies and Actions toward a Cross-Border Paperless Trading Environment (2004/AMM/004)
9. Comprehensive Action Initiative Recognising the Need For Strengthening The APEC Energy Security Initiative - Energy Security, Sustainable Development And Common Prosperity (CAIRNS) (2004/AMM/030rev1)
10. Fighting Against Aids in APEC (2004/AMM/021)
11. Intellectual Property Rights (IPR) Policy Progress Mapping And Follow-up Report On "Comprehensive Strategy On IPR In APEC" (2004/AMM/011)
12. Implementing the e-APEC Strategy - Progress and Recommendations for Further Actions: Overview Report
13. Leaders' Agenda to Implement Structural Reform (LAISR) (2004/AMM/020)
14. Report to the 16th APEC Ministerial Meeting on Preparation for Mid-term Stocktake of the Bogor Goals (2004/CSOM/018rev1)
15. Santiago Commitment to Fight Corruption and Ensure Transparency (2004/AMM/032rev1)
16. Santiago Agenda on Entrepreneurship (2004/SMEMM/014)
17. Statement to Implement APEC Policies on Trade and the Digital Economy (2004/AMM/027)

### **CTI, EC and ESC Annual Reports:**

18. 2004 APEC Committee on Trade and Investment: Annual Report to Ministers
19. 2004 APEC Senior Officials Report on Economic and Technical Cooperation
20. APEC Economic Committee Publications
  - *2004 APEC Economic Outlook*
  - *Realising Innovation and Human Capital Potential in APEC, 2004*
  - *Trade Facilitation and Trade Liberalisation: From Shanghai to Bogor, 2004*

### **Other Reports:**

21. Senior Officials' Meeting (SOM) Report to Ministers (2004/AMM/029)
22. APEC Business Advisory Council: Report to APEC Economic Leaders 2004  
*Bridging the Pacific: Coping with the Challenges of Globalization*

## 12TH APEC ECONOMIC LEADERS' MEETING

Santiago de Chile  
2021 November 2004

### SANTIAGO DECLARATION “ONE COMMUNITY, OUR FUTURE”

We gathered in Santiago for the 12<sup>th</sup> APEC Economic Leaders' Meeting, under APEC's 2004 theme, “One Community, Our Future”. We reaffirmed our commitment to achieve sustainable and equitable growth and reduce economic disparities for the well-being of our people by meeting the Bogor Goals of trade and investment liberalization and facilitation, enhancing human security, and promoting good governance and a knowledge-based society.

#### **Advancing Development through Trade and Investment Liberalization**

We reaffirmed the primacy of the rules-based multilateral trading system, which allows us to pursue trade liberalization on a global scale. We welcomed the new momentum acquired by the Doha Development Agenda (DDA) negotiations resulting from the July Package adopted by the General Council of the World Trade Organization (WTO). We pledged to provide leadership to continue this momentum. With a view toward fulfilling the development objectives of the DDA, we agreed:

- To work with a renewed sense of urgency to achieve a balanced overall outcome that will meet the high levels of ambition set for these negotiations, while respecting flexibility and taking into account the principles of special and differential treatment. Particularly in the core areas of agriculture, non-agricultural goods, services, and rules, the outcome should be substantially greater market access and fewer distortions;
- To seek substantial results at the Sixth WTO Ministerial Conference and instruct our Ministers and officials to work in earnest toward this goal. Our Ministers will review progress of the DDA negotiations at their next meetings;
- To contribute to negotiations on trade facilitation by sharing our considerable experience within APEC with the rest of the WTO and strengthening our work in this area;
- To redouble our efforts to provide technical assistance and capacity building -in a more strategic manner- thus underpinning progress in the WTO through full and effective participation of all Members; and
- To support efforts to conclude promptly the accessions of the Russian Federation and Viet Nam to the WTO.

We call on all WTO Members to join us in this endeavor.

With regard to Regional Trading Arrangements and Free Trade Agreements (RTAs/FTAs), we agreed that they play a constructive role in accelerating liberalization in the region, thus contributing to the achievement of the Bogor Goals and advancing the WTO process. To strengthen this contribution and ensure high-standard agreements, we welcomed the *APEC Best Practices for RTAs/FTAs* which are a meaningful reference for APEC members when undertaking RTAs/FTAs negotiations. We also committed to greater transparency in RTAs/ FTAs to facilitate public understanding of the scope and effect of these agreements.

We recognized that improved protection and enforcement of Intellectual Property Rights contribute to the promotion of investment, innovation and economic growth. We welcomed APEC's work on



the *APEC Comprehensive Strategy on Intellectual Property Rights* and encouraged further progress in 2005.

### **Santiago Initiative for Expanded Trade in APEC**

We agreed to launch the *Santiago Initiative for Expanded Trade in APEC* to complement the achievement of free and open trade in the region. An overarching dimension of the Initiative is capacity building so that all economies can implement and benefit from their work on trade liberalization and facilitation.

The Initiative has two components:

- *Trade and Investment Liberalization*: Ministers will recommend to us next year how to further liberalize trade and investment in the region, taking into consideration progress made in the WTO DDA negotiations, the mid-term stock take of the Bogor Goals, APEC work on RTAs/FTAs, and other unilateral and collective market-opening actions;
- *Trade Facilitation*: We will continue our work to reduce business transaction costs by cutting red tape, embracing automation, harmonizing standards and eliminating unnecessary barriers to trade. We will also work together to advance the trade facilitation negotiations in the WTO, promote secure trade, and build on the *APEC Best Practices for RTAs/FTAs* in the area of trade facilitation;

ABAC presented us two relevant proposals: a joint scoping study for a Trans-Pacific Business Agenda; and a study of the feasibility and potential scope and features of a Free Trade Area of the Asia-Pacific.

We welcomed the inputs from our business community, including ABAC's resolve for expanding trade, and we share its view on the critical importance of trade facilitation. We look forward to the continued participation of ABAC as we implement the *Santiago Initiative*. In particular, we invited ABAC to provide its views on emerging trade facilitation issues as well as on the benefits and challenges that arise for business from the increasing number of RTAs/FTAs in the region and ways that these can be addressed.

### **Enhancing Human Security – Underpinning Economic Growth**

We recalled the heinous acts and terrible consequences of terrorism as tragically manifested in Beslan and Jakarta during this past year. We reaffirmed our determination to advance the prosperity and sustainable growth of our economies and the complementary mission of ensuring the security of our people.

We encouraged relevant APEC economies to take measurable steps towards the ratification and implementation of, or the commitment to ratify, all basic universal antiterrorist conventions, so as to demonstrate APEC's unmistakable resolve to collectively confront the threat of terrorism and its disastrous effects on the people and also the economies of the region. In this context, we agreed to take steps to cut off terrorists' access to the international financial system, including implementing standards and agreements on combating terrorist financing and money laundering.

We commended the additional APEC work this year to help enhance the security of our people. We also commended the success of the APEC process and informal consultations in building consensus on these issues. We welcomed the further consensus arrived at by Ministers, and agreed to take the appropriate individual and joint actions to follow up on this consensus, in line with our respective circumstances. We welcomed the following actions adopted by APEC economies this year:

- Steps to advance compliance with the International Maritime Organization's new Ship and Port Security Standards through cooperative efforts;

- Financial contributions made to the Asian Development Bank's Regional Trade and Financial Security Initiative;
- Progress in implementing business mobility initiatives, including the Advance Passenger Information systems (API), the development of a Regional Movement Alert List System (RMAL), and cooperation for the issuance of machine readable travel documents by 2008;
- Cooperation on the supervision of exported and imported food, to prevent hidden hazardous or toxic materials; and
- Efforts to strengthen the public health system to respond to regional health threats.

We expect to review progress on our commitments to dismantle trans-national terrorist groups, eliminate the danger posed by proliferation of weapons of mass destruction, their delivery systems and related items, and confront other direct threats to the security of our region in the future.

We endorsed the initiative on *Fighting against AIDS in APEC*, and pledged our political commitment to work together, at the regional and global levels, to combat the further spread of the AIDS pandemic. We support efforts to increase access to health care and safe and affordable drugs for all people living with AIDS.

We encouraged new efforts during 2005 by APEC to address the specific threats posed by infectious diseases such as Severe Acute Respiratory Syndrome (SARS), avian flu, pandemic influenza, tuberculosis, malaria and polio in the Asia Pacific Region and to strengthen the research into and production of relevant vaccines. We also welcomed and endorsed the strategic plan to promote life sciences innovation in the region to improve the health and well-being of our people.

As a response to global concerns about high oil prices, and in keeping with our commitment to promote energy security, sustainable development and common prosperity within the APEC region, we instructed Energy Ministers to continue to implement and enhance the *APEC Energy Security Initiative*.

### **Promoting Good Governance and a Knowledge-Based Society**

Corruption is a serious threat to good governance and deters investment. Therefore, fighting corruption is essential to the development of our economies for the benefit of our people. We welcomed the timely commitments and recommendations of ABAC in this regard.

Accordingly, further to our agreement in Bangkok to fight corruption, we endorsed the *Santiago Commitment to Fight Corruption and Ensure Transparency*. We also endorsed the *APEC Course of Action on Fighting Corruption and Ensuring Transparency* which develops and implements it, including through the APEC anticorruption initiative *From Santiago to Seoul*.

Reaffirming our political commitment to promote structural reform, and recognizing its value for achieving sustainable economic growth, including through improving the functioning of markets, we adopted the *Leaders' Agenda to Implement Structural Reform (LAISR)*.

We underscored the need to deepen capacity building initiatives in the region through private/public partnerships and increased interaction with international financial institutions.

We welcomed APEC's efforts in the field of education, in particular work undertaken to promote the use of English and other languages as tools for small and medium enterprises, and the use of information technology tools to assist the learning process.

We called upon our officials to advance toward an APEC Sustainable Development Framework, that will build on the work being carried out by APEC and ensure that the growth and development of

the region is enjoyed by future generations. We instructed them to report on progress by the time we meet in 2005.

We welcomed Ministers' report on the progress made this year to strengthen APEC. We reaffirmed the need to continue to make APEC more efficient and responsive to all stakeholders.

**We endorsed in full the Joint Statement agreed by Ministers at the 16th APEC Ministerial Meeting.**

## SIXTEENTH APEC MINISTERIAL MEETING

**Santiago, Chile  
17–18 November 2004**

### JOINT STATEMENT

Ministers from Australia; Brunei Darussalam; Canada; Chile; the People's Republic of China; Hong Kong, China; Indonesia; Japan; the Republic of Korea; Malaysia; Mexico; New Zealand; Papua New Guinea; Peru; the Republic of the Philippines; the Russian Federation; Singapore; Chinese Taipei; Thailand; the United States of America; and Viet Nam, representing economies which collectively account for 47 percent of world trade and over 60 percent of global GDP, gathered in Santiago, Chile, on 17–18 November 2004, in order to participate in the Sixteenth Asia Pacific Economic Cooperation (APEC) Ministerial Meeting. The APEC Secretariat was also present. The Association of Southeast Asian Nations (ASEAN) Secretariat, the Pacific Economic Cooperation Council (PECC) and the Pacific Islands Forum (PIF) attended as observers.

The meeting was chaired by H.E. Ignacio Walker, Minister of Foreign Affairs and Trade of the Republic of Chile.

Ministers met and discussed issues under Chile's main theme, "One Community, Our Future". They agreed that collective responses are essential to meet common challenges facing the APEC Region in fundamental areas like trade, security, transparency, anti-corruption, human resource development, health, the knowledge-based economy, and sustainable development. They pledged their efforts towards achieving an open trading system aimed at creating new opportunities in a dynamic and inter-dependent Asia Pacific Region. They reaffirmed their commitment to achieve the Bogor Goals of free and open trade and investment by 2010/2020. APEC Foreign and Trade Ministers appreciated the opportunity to meet in APEC sessions and in meetings on the margins of APEC.

Ministers reviewed the key achievements of the APEC 2004 Year hosted by the Republic of Chile and agreed upon initiatives to be undertaken during the APEC 2005 Year, to be hosted by the Republic of Korea.

The key outcomes of the Sixteenth APEC Ministerial Meeting are organized in accordance with the theme "One Community, Our Future" and seven sub-themes of the APEC 2004 Year.

Ministers agreed to the following during their deliberations in Santiago:

#### **A COMMITMENT TO DEVELOPMENT THROUGH TRADE AND INVESTMENT**

##### **World Trade Organization (WTO)**

Ministers reaffirmed their commitment to the improvement of and liberalization within the multilateral trading system. They fully endorsed the July Package adopted by the WTO General Council, recognizing it as a breakthrough for the Doha Development Agenda (DDA) negotiations. In this regard, Ministers highlighted APEC member economies' contribution to reaching the July Package and their commitment to moving forward the DDA negotiations.

Ministers stressed that development is at the core of the DDA negotiations and, underlining the importance of achieving a balanced overall outcome, agreed to work together for a successful conclusion to these negotiations. They concurred that such an outcome will strengthen the multilateral trading system and promote economic growth and poverty reduction, particularly amongst developing economies.

Ministers reiterated that high levels of ambition and respect for flexibility must be maintained in all areas of the DDA negotiations, in accordance with the mandates approved in Doha. Consequently, Ministers:

- Stressed the importance of agricultural reform, including the abolition of all forms of agricultural export subsidies and unjustifiable export prohibitions and restrictions at an early date, substantial reduction of trade-distorting domestic support, as well as substantial improvements in market access;
- Confirmed the need for substantially improved market access for non-agricultural goods, through the reduction or, as appropriate, elimination of tariff and non-tariff barriers;
- Highlighted the growing importance of services trade and called on all members to submit improved revised offers by May 2005. Members, which have not done so, should table initial offers expeditiously;
- Reaffirmed the importance of the clarification, strengthening and improvement of WTO rules.

Ministers welcomed the launching of negotiations on trade facilitation and agreed to work together to advance these negotiations in the WTO. They agreed that these negotiations should take into account the principle of special and differential treatment for developing and least developed economies. They recognized that trade facilitation plays a critical role in ensuring that the benefits from greater market liberalization are fully reaped. Therefore, the introduction of clearer and transparent multilateral rules on trade facilitation will bring greater certainty, reduce costs and delays, and provide more competitive import and export conditions for industry and business. Ministers agreed that APEC's practical and vast experience in this area could be shared with other WTO members, so as to contribute towards the achievement of positive results. They endorsed the APEC Business Advisory Council's statement that transparency, efficiency, simplification, non-discrimination, procedural fairness, cooperation and capacity building should be core elements of this negotiation.

Ministers reaffirmed the importance of effective demand-driven WTO capacity building, and the effective implementation of special and differential treatment in promoting progress in WTO DDA negotiations. This would allow developing Members to fully participate in DDA negotiations. Ministers called on APEC economies to maintain and increase capacity building efforts, particularly in areas where APEC can best add value. Ministers noted with satisfaction plans to evaluate APEC's past capacity building activities using existing evaluation work by APEC economies and sub-fora, and to improve thereby the effectiveness of future activities. Ministers commended the APEC Seminar on WTO Trade Facilitation held in Bangkok in November and looked forward to the APEC/WTO Roundtable on Trade Facilitation to be held in Geneva in early 2005 and the trade facilitation capacity building in Kuala Lumpur in February 2005. They also welcomed the WTO Capacity Building Group's intention to devote more attention to policy-oriented discussions related to WTO capacity building.

Ministers reaffirmed that support for and consultation among APEC economies regarding the DDA negotiations must be maintained and reinforced. In this context, they welcomed the work undertaken by the APEC Geneva Caucus this year, and instructed it to continue its consultations, as well as to improve communication between APEC and Geneva Officials in order to share their experience and contribute to the WTO work program. Ministers committed to convening the APEC Geneva Caucus regularly between now and the WTO's Sixth Ministerial Conference, to be held in Hong Kong, China in December 2005.

Ministers welcomed the progress that has been made in the WTO accession negotiations of Viet Nam and the Russian Federation and called for a prompt conclusion of the accession negotiations, including through the provision of capacity building assistance.

Ministers noted that the particular concerns of recently acceded Members to the WTO should be given due consideration in the DDA negotiations.

Ministers reaffirmed the need to facilitate access by developing countries to medicines required to address public health problems such as HIV/AIDS, TB, malaria and other epidemics. In this context, they underlined the need for appropriate action, including those pursuant to the consensus reached by the WTO General Council on August 30, 2003 on TRIPS and Public Health.

Ministers agreed that at their next meeting, to be held in Korea in mid 2005, they should review progress in the DDA negotiations and provide clear guidance to negotiators regarding the preparations and objectives for the Sixth WTO Ministerial Conference.

Ministers stressed the importance of maintaining momentum in the DDA negotiations. APEC should continue to provide leadership in this regard. Ministers acknowledged that substantial technical work remains to be done in all areas of the negotiations. They instructed officials to intensify their efforts in this respect so that the anticipated WTO stock-taking in the first part of the year is positive, thus setting the scene for a productive 2005.

### **Regional Trading Arrangements / Free Trade Agreements**

Ministers welcomed the substantial progress that has been achieved to maximize the contribution of RTAs/FTAs to achieving the Bogor Goals, including an APEC policy response, concrete measures to enhance transparency and targeted capacity building. Ministers noted that the need for greater transparency in RTAs/FTAs was an important issue raised by ABAC.

Ministers endorsed the “APEC Best Practices for RTAs/FTAs” which are a meaningful reference for APEC members in their RTAs/FTAs negotiations and highlighted their importance as a means to achieve high standard agreements in our region. These Best Practices will help to ensure that RTAs/FTAs contribute to the achievement of the Bogor Goals and are consistent with, and build upon, existing WTO commitments. Ministers recognized that these Best Practices are a timely policy response to the challenges arising from the growing number of RTAs/FTAs, as identified by the business community. Furthermore, they agreed that these Best Practices are a valuable reference for the current negotiations to clarify and improve existing WTO rules, and practices relating to regional trade agreements.

To enhance transparency, Ministers approved a new IAP reporting template to enable economies to share information on their RTAs/FTAs beginning in 2005. They instructed Senior Officials to take the template into account in the context of IAP Peer Reviews and as part of the Mid-term Stocktake. Ministers also welcomed the inclusion of links to official information on APEC economies’ RTAs/FTAs on the APEC Secretariat’s webpage, and instructed Senior Officials to study the feasibility of developing an APEC RTAs/FTAs database for the use of business, policy makers and other stakeholders.

Ministers supported demand-driven capacity building assistance to ensure that all economies can undertake the analytical and negotiating tasks involved in conducting FTA and RTA negotiations, and welcomed the workshops on negotiating free-trade agreements to be held in Viet Nam, Brunei Darussalam and China.

Ministers welcomed the results of the Second Policy Dialogue on RTAs/FTAs held in Chile, and endorsed the decision by Senior Officials to hold a Third SOM Policy Dialogue on RTAs/FTAs next year in Korea.

### **Interaction with the Business Community**

Ministers noted with satisfaction that the partnership between APEC Officials and ABAC representatives has increased substantially during 2004. They also took note of ABAC’s active

engagement in the DDA and expressed appreciation for their continued work to provide views, proposals and recommendations to both Ministers and Senior Officials to help ensure tangible benefits in the pursuit of APEC goals.

Ministers commended ABAC's closer relationship with other APEC fora, including through the Second STAR Conference; the Expanded Dialogue on Trade Facilitation; the APEC Customs-Business Dialogue; and the Policy Dialogue on Standards and Conformance. Ministers expressed appreciation for the 2004 ABAC Report to APEC Economic Leaders.

In particular, Ministers took note of ABAC's proposals to APEC Economic Leaders on a joint scoping study for a Trans Pacific Business Agenda and the examination of the feasibility and the potential scope and features of a Free Trade Agreement of the Asia Pacific. In this regard, they agreed to recommend to Leaders to undertake action toward an enhanced trading environment in the Asia Pacific Region.

### **Trade and Investment Liberalization and Facilitation**

Ministers commended and endorsed the 2004 Committee on Trade and Investment Annual Report on APEC's Trade and Investment Liberalization and Facilitation activities, including the Collective Action Plans developed by CTI sub-fora.

Ministers commended the Committee on Trade and Investment's work in advancing trade facilitation and the progress made by members in implementing the Trade Facilitation Action Plan (TFAP). Ministers welcomed the outcomes of the Expanded Dialogue on Trade Facilitation (EDTF) that was held on 1 October 2004, chaired by the ABAC Chair, and that involved the participation of other stakeholders. They endorsed a series of recommendations in three areas (as described in Appendix 1 of the CTI Annual Report to Ministers): deepening and better monitoring the implementation of the Trade Facilitation Action Plan; better interaction with business; and advancing trade facilitation negotiations in the WTO. Ministers asked Senior Officials to report progress on the implementation of these recommendations by the 2005 MRT.

Ministers noted a report prepared by an expert on the mid-term review of the TFAP implementation. Ministers were pleased with the review findings which showed APEC economies to be on track towards the objective of achieving 5 percent reduction in transaction costs by 2006. Ministers directed Senior Officials to intensify efforts to deepen the implementation of the TFAP.

Ministers took note of the various studies dealing with measuring the benefits of actions APEC members take to facilitate trade and reduce transaction costs, including the completion of the *Study on the Mutually Supportive Advancement of APEC's Trade Facilitation and Secure Trade Goals post September 11*, and the *Study on the Assessment of the Effectiveness in implementing APEC Trade Facilitation Actions*, which highlighted several areas where APEC could work to build capacity and enhance domestic and international cooperation. Ministers encouraged members to continue to identify suitable methodologies to measure these benefits. In this regard, Ministers welcomed steady progress on Time Release Surveys as one of the proxies for measurement.

Ministers recognized the relevance of standards, technical regulations and conformity assessment for trade facilitation, in particular for Small and Medium Enterprises (SMEs), and encouraged member economies to participate actively in the development of standards at the international level, including on product-related environmental standards. Ministers noted China's initiatives on food safety to promote cooperation among APEC economies in areas such as the application of Hazard Analysis and Critical Control Point principles. We encourage analysis of the food safety activities of relevant international organizations, such as the World Health Organization and the Food and Agriculture Organization of the United Nations, with the aim of determining how APEC, through work in the relevant APEC subfora, might complement the ongoing work of these organizations.

Ministers also endorsed the Transparency Standards on Government Procurement for incorporation into the Leaders Statement to Implement APEC Transparency Standards, thus completing the mandated Leaders' area-Specific Transparency Standards. In this context, Ministers approved a new Transparency IAP template for reporting the Leaders' General Transparency Standards and revisions to the existing IAP templates for reporting the Leaders' area-Specific Transparency Standards for use beginning in 2005. Ministers emphasized the importance of well-targeted and demand-driven capacity building and instructed officials to develop concrete capacity building programs in 2005, which aim to assist member economies to implement the APEC Transparency Standards. Progress in this area should be reflected in relevant Collective Action Plans.

Ministers acknowledged that expeditious implementation of Pathfinder initiatives can invigorate progress towards the Bogor Goals. In this context, Ministers welcomed the adoption of new Guidelines on Pathfinders as approved by Senior Officials and noted that these guidelines will help ensure that pathfinders support the achievement of APEC's Bogor Goals and attract the widest possible participation of APEC's member economies.

Ministers welcomed the increasing participation of member economies in existing Pathfinders including the Advance Passenger Information (API) Pathfinder, with almost half of all economies having implemented or committed to implement an API system in 2005. They also welcomed Australia, Canada and China as new participants in the Pathfinder on the Digital Economy. They welcomed the work of economies in the CTI to update their digital economy templates to report their progress to implement Leaders' objectives on e-commerce, services critical to e-commerce, intellectual property, and tariffs. Ministers also welcomed Russia's support for this initiative as well as its decision to participate in the Pathfinder on the Revised Kyoto Convention on the Simplification and Harmonization of Customs Procedures.

In the context of the Pathfinder on Trade and the Digital Economy, and its attachments, Ministers agreed on a list of three IT products (multi-chip integrated circuits, digital multifunctional machines and modems) to forward to the WTO for consideration and possible tariff elimination as part of a balanced outcome of negotiations, including comparable liberalization of other products of interest to economies. Ministers welcomed Mexico's list of IT products for unilateral tariff elimination. Economies take this action without prejudice to the positions they may adopt in relevant WTO negotiations and accessions.

Ministers stressed the importance of effective intellectual property rights protection and enforcement regimes, and their contribution toward promoting investment, innovation and economic growth. They agreed on the need to build on the APEC Comprehensive Strategy on Intellectual Property Rights in 2005 including to reduce piracy, trade in counterfeit goods and online piracy, and increase cooperation and capacity building.

Ministers welcomed the work undertaken under the Pathfinder on Trade and the Digital Economy to survey economies' best practices for combating optical disc piracy and encouraged taking steps to implement the APEC Effective Practices for Regulation Related to Optical Disc Production.

Ministers welcomed the progress on the IPR Policy Progress Mapping and the follow-up report on the "*Comprehensive Strategy on IPR in APEC*" as measures to strengthen business confidence in the region. They also welcomed progress on the establishment of IPR Service Centers and encouraged their establishment in all member economies as soon as practicable.

Ministers encouraged economies to hold training seminars on intellectual property enforcement based on the guidelines set out in the Comprehensive Strategy. In this context, they welcomed China's initiative to host a high-level symposium on IPR in 2005.



## **e-APEC and the Information Society**

Recognizing the importance of the development of effective privacy protections, that avoid barriers to information flows, to continued trade and economic growth in the APEC region, Ministers endorsed the APEC Privacy Framework and the Future Work Agenda on International Implementation of the APEC Privacy Framework. Ministers also endorsed APEC's Strategies and Actions Towards a Cross-Border Paperless Trading Environment and its recommendations.

Ministers welcomed the Telecommunications and Information Working Group's (TEL) work on "*Progress Towards Adopting and Implementing the WTO Reference Paper on Basic Telecommunications*" and "*Best Practices for Implementing the WTO Reference Paper*", and noted the value of this work in the context of WTO capacity building.

Ministers welcomed the report on the implementation of the e-APEC Strategy and instructed Senior Officials to study its findings and report back to the relevant APEC Ministerial meetings in 2005. Ministers noted the significant improvements in e-infrastructure through, for example, the benefits of increased competition and market-oriented policies. Ministers acknowledged that building skills and capacity in optimizing information technology is the most pressing need for APEC economies to reduce the digital divide and to facilitate trade. In this context, they welcomed the progress that has been made by the APEC Digital Opportunity Center (ADOC). Ministers restated their commitment to the Brunei Goals on tripling internet access by the end of 2005.

Ministers welcomed the report of the 2nd APEC High-Level Symposium on e-Government held in Mexico in October 2004 and the convening of the APEC E-commerce Fair and the First APEC E-commerce Business Alliance Forum held in China in June 2004.

Ministers recognized the importance of the second phase of the World Summit on the Information Society (WSIS), to be held in Tunisia in November of 2005, for continuous development of the global information society, and instructed Senior Officials, through the TEL, and other relevant fora, to formulate APEC's input to the WSIS.

## **Industry Dialogues**

Ministers acknowledged the work carried out this year by the Chemical Dialogue and its steering group in APEC. Ministers encouraged additional capacity building efforts for the implementation of the United Nations Globally Harmonized System of Classification and Labeling (GHS).

While noting that standards and regulations can effectively address environmental objectives, Ministers expressed concern over the growing number of EU product-related environmental regulations, including the EU's proposed chemical regulations (REACH) because of the adverse implications of this complex regulatory system for industry. Ministers encouraged APEC economies to work together to ensure that the views of their respective stakeholders will be duly considered by the EU in the development of its regulations.

Ministers welcomed the results of the Sixth Automotive Dialogue hosted by the People's Republic of China and looked forward to the Seventh Dialogue to be hosted by the Philippines. Ministers noted the work to date undertaken by the Chemical and Automotive Dialogues on non-tariff measures and encouraged these groups to continue this work with a view to contributing to the DDA.

They encouraged other fora to use the Automotive and Chemical Dialogues as models for promoting harmonization of standards, transparency, trade facilitation, and the identification of non-tariff measures. Ministers welcomed the establishment of the new APEC Dialogue on Non-Ferrous Metals and endorsed convening its first full-fledged meeting in May 2005.

## Life Sciences Innovation

Ministers commended the outcomes of the Second APEC Life Sciences Innovation Forum (LSIF) held in Malaysia in September 2004. They endorsed the Strategic Plan for Promoting Life Sciences Innovation which aims to help APEC economies reach their full potential in researching, developing and marketing effective diagnostics, medical devices and modern and traditional medicines, and to promote cooperation in developing effective health services.

They noted that implementation of the basic principles of the strategic plan should contribute to improving health, and achieving social and economic goals related to life sciences innovation in the region, contributing to a more coordinated approach to identifying and addressing health treatment priorities.

Ministers welcomed the APEC LSIF's participation in the Global Cooperation Group of the International Conference on Harmonization.

## Individual and Collective Action Plans

Ministers reaffirmed their commitment to achieve the Bogor Goals through actions outlined in their respective Individual Action Plans (IAPs). They endorsed the 2004 IAPs and welcomed the measures undertaken by individual economies to liberalize and facilitate trade.

Ministers welcomed the successful conclusion of the 2004 IAP Peer Reviews of Chile, China, Peru, Singapore, Chinese Taipei and the United States. Ministers reaffirmed their commitment to complete all twenty-one IAP peer reviews by the First Senior Officials' Meeting (SOM I) in 2005 in order to support preparations for the mid-term stock-take to be conducted in 2005 on overall progress towards meeting the Bogor goals.

Ministers welcomed the progress made on the implementation of Collective Action Plans (CAPs) and instructed Senior Officials to keep reviewing and progressively improving the CAPs to ensure that they produce tangible benefits to the business community and meet the Bogor Goals. They noted that these actions will also contribute to the mid-term stock-take process next year.

## Structural Reform

Recognizing that structural reform improves the functioning of markets so as to enhance living standards and realize the economic potential of the APEC region in a sustainable way, Ministers stressed the importance of promoting structural reform as a priority within the APEC agenda.

Ministers welcomed the work undertaken by Senior Officials in responding to Leaders' instructions to review the implementation of the Structural Reform Action Plan. In this context, they applauded the success of the APEC High Level Conference on Structural Reform held in Tokyo in September 2004, which provided positive momentum by identifying future steps to implement the APEC Structural Reform Action Plan.

Ministers also welcomed the achievements made in the area of strengthening economic legal infrastructure (SELI), capacity building and business outreach projects on competition policy, corporate governance and debt collection regimes. They also acknowledged progress on the SELI reporting mechanism, submitted voluntarily by member economies.

Ministers approved the "*Leaders' Agenda to Implement Structural Reform*" (LAISR) for adoption by Leaders as further clear guidance to promote structural reform in APEC in the following possible priority areas: regulatory reform, strengthening economic legal infrastructure, competition policy, corporate governance and public sector management, in 2005 and beyond. Ministers instructed Senior Officials to continue working, in close consultation with Finance Ministers, to identify an effective institutional mechanism to address structural reform in APEC.

## **Anti-Corruption and Transparency**

Ministers recognized that corruption is one of the most serious threats to good governance and the proper development of economic systems in the APEC region, and globally. Ministers agreed that APEC's commitment and leadership to prevent and combat corruption, including through ensuring transparency, is indispensable in strengthening the integrity of enforcement and the core foundations of our collective values in society, in particular in the areas of economic development, growth, and prosperity.

Ministers commended the success of the APEC Anti-Corruption Experts Meeting, held during SOM III in Santiago. They approved, for endorsement by Leaders, its recommendations for the "*Santiago Commitment to Fight Corruption and Ensure Transparency*" and an "*APEC Course of Action on Fighting Corruption and Ensuring Transparency*" (COA).

Further, they recommended that Leaders agree to the implementation, beginning in 2005, of the concrete actions outlined in the COA, including that APEC economies: take all appropriate steps, consistent with their different status, towards ratification of, or accession to, and implementation of the United Nations Convention Against Corruption (UNCAC); strengthen effective measures to prevent and fight corruption and ensure transparency; deny safe haven to officials and individuals guilty of public corruption, those who corrupt them, and their assets; fight both public and private sector corruption; promote public-private partnerships; nurture cooperation to combat corruption in the region; and implement, in accordance with the fundamental principles of each economy's legal system, the concrete actions contained under the item "*From Santiago to Seoul*".

Ministers endorsed the experts' recommendation to establish an Experts' Task Force in 2005 on implementation of such commitments, and instructed Senior Officials to develop its terms of reference by the first Senior Officials' Meeting (SOM I) in 2005.

Ministers also welcomed the experts' recommendation for effective and results-oriented synergies and partnerships with other multilateral and regional organizations, particularly on donor coordination on training, capacity building and exchanges of technical expertise.

## **Economic and Technical Cooperation and Capacity Building**

Ministers welcomed the 2004 Senior Officials' Report on Economic and Technical Cooperation and endorsed its recommendations, in particular that working groups be assessed to ensure that they are responsive to APEC's current work priorities and contribute to the achievement of the Bogor Goals.

Ministers approved a new Quality Assessment Framework, which will replace the ECOTECH Weightings Matrix, as a tool to foster good quality project proposals and an efficient allocation of APEC resources. They recognized that strengthening assessment, monitoring and evaluation of APEC's ECOTECH activities has the potential to help attract external resources, such as from International Financial Institutions as well as from the private sector.

Ministers noted that APEC's growing work program is generating greater demand on its capacity-building resources. Accordingly, they instructed officials to consider ways to broaden APEC's funding base, and endorsed the establishment of an APEC Support Fund, which could attract funds from government as well as non-government sources.

Ministers recognized that English and other languages constitute critical operational tools for SMEs, micro enterprises, youth and women. They welcomed the results achieved to date by ABAC and other APEC Fora to foster capacities in language skills and looked forward to consolidating and developing specific actions aimed at achieving the full potential of this communication tool and promoting entrepreneurship, mutual understanding and increased opportunities in a digitalized region.

Ministers instructed Senior Officials, through the SOM Committee on ECOTECH, to oversee the work to be developed by the Education Network from the Human Resources Development Working Group, so as to establish a Strategic Action Plan for English and other Languages in the APEC Region, with the support of all relevant fora, aimed at creating competitive human capital, and to report progress in 2005.

Given the importance of expanding APEC's relationships with International Financial Institutions (IFIs), the private sector, and other relevant international organizations, Ministers welcomed the collaboration between the APEC Secretariat and the World Bank's Global Development Learning Network (GDLN). They looked forward to concrete outcomes from the Second APEC/IFIs Roundtable Dialogue on ECOTECH to be held in Korea in 2005, focusing on the areas of SMEs and education, and called for close consultation with the Finance Ministers process.

In the context of social safety nets and workforce retraining, Ministers commended the initiatives undertaken in APEC, aimed to empower vulnerable people, ensuring more equitable distribution of the benefits brought about by globalization. In this regard, they welcomed the outcomes of two meetings this year on these issues, co-hosted respectively by Thailand and Korea and the People's Republic of China and Korea. Ministers welcomed Korea's offer to hold a symposium in 2005, with a view to making the results of the Social Safety Nets – Capacity Building Network's (SSN-CBN) research projects widely known.

Ministers instructed Senior Officials to redouble their efforts on strengthening social safety nets and workforce retraining programs through the Human Resources Development Working Group (HRDWG) and the SSN-CBN. In this context, they noted the launching of a pilot project entitled "*Workforce Retraining through Digital English Instruction Media*".

Ministers noted the importance of capacity building activities addressing the social dimension of globalization, with regards to the poverty alleviation aspects of micro, small and medium size enterprises.

Ministers acknowledged the Science and Technology Ministerial Meeting's emphasis on the importance of interlinking activities of governments, researchers, entrepreneurs, and investors to ensure that each economy gains the maximum benefit from science, technology, and innovation.

Ministers urged further initiatives aimed at bringing together policy makers and the scientific community, to promote cooperation under the knowledge-based economies priority of fostering innovation, as discussed at the APEC Workshop on Development of Science and Technology Intermediary Mechanism hosted by China and Thailand in Beijing in February 2004.

## **SHARING BENEFITS THROUGH BETTER PRACTICES: ENHANCING HUMAN SECURITY**

### **Counter-Terrorism and Secure Trade**

Ministers reaffirmed that terrorism is a threat to human security, stability and growth in the region and the imperative need to combat terrorism - in all its forms and manifestations - in accordance with the purposes and principles of the Charter of the United Nations and international law, in particular humanitarian and human rights law, and bearing in mind United Nations Security Council anti terrorism resolutions, including Resolution 1566 (2004).

They valued APEC's on-going work to confront effectively the risks posed by trans-national terrorism and to strengthen capacity building and technical assistance efforts in order to meet collectively the challenges posed by this threat.

Ministers condemned, in the strongest terms, all acts of terrorism, including the most recent barbarous acts in Russia and Indonesia, and expressed their condolences to their peoples and governments.

Ministers reiterated the commitment of each APEC member economy to fight terrorism and secure trade flows, and that these efforts should complement APEC's core business of trade and investment liberalization and facilitation and economic and technical cooperation. While noting work by relevant APEC fora on the economic impacts of terrorism, Ministers also noted the concerns flagged by the business community on the additional costs generated by security-related measures. Ministers therefore underscored the need to secure trade while removing obstacles to trade and minimizing costs on businesses.

Ministers continued their work to take action to eliminate the danger of proliferation of weapons of mass destruction and their means of delivery. They noted the important contribution of informal consultations in building consensus on these issues. They identified key elements of effective export control systems, and committed to continue work in APEC to unite economies and the private sector to facilitate the flow of goods to legitimate end users while preventing illicit trafficking in weapons of mass destruction, their delivery systems and related items. They established guidelines on the control of Man-Portable Air Defense Systems (MANPADS), and economies committed to work individually to develop measures consistent with these guidelines and, as appropriate, with efforts taken at the United Nations, its agencies and other relevant international organizations, to prevent terrorists from obtaining and using these weapons to attack civilian aviation. Ministers also recognized that all APEC economies are implementing, have concluded, or aim to conclude an Additional Protocol with the International Atomic Energy Agency by the end of 2005, reflecting their determination not to allow illicit nuclear activities in our region through their collective commitment to expanded transparency on nuclear-related activities.

Ministers noted the progress made by the Counter-terrorism Task Force (CTTF) in implementing the 2003 APEC Leader's Human Security commitments, especially those aimed at facilitating secure and efficient trade within the region, such as the implementation of the International Ship and Port Facility Security Code (ISPS Code). Endorsing the agreements reached within the CTTF, Ministers:

- Recognized the need for cooperation among member economies on the supervision of imported and exported food in order to prevent and better respond to possible bio-terrorist attacks, including attacks through toxic or hazardous material in food supplies;
- Called for increased commitments, including efforts through the Health Task Force (HTF), on strengthening the public health system and enhancing public awareness to help member economies respond to regional health threats;
- Called for cooperation to ensure that all APEC economies will begin issuing Machine Readable Travel Documents (MRTDs), if possible with biometrics, by 2008, and, on a best endeavours basis, to accelerate replacement of Non-MRTDs by MRTDs as well as implement ICAO travel document security standards;
- Agreed to continue to implement existing business mobility initiatives, and welcomed efforts to implement the Advance Passenger Information (API) system and the cooperative program of Immigration Liaison Officer in the region. Ministers noted the completion of a feasibility study for an automated Regional Movement Alert List (RMAL) System as an important counter-terrorism initiative. They agreed to pilot the RMAL in 2005 and agreed to work on an enhanced version of the Customs Asia-Pacific Enforcement Reporting System (CAPERS) to address legal issues.

Ministers welcomed Senior Officials' decision to extend the mandate of the CTTF until the end of 2006. They welcomed the Philippines and Chile as CTTF Chair and Vice Chair, respectively, for the next two years.

Ministers committed their efforts to advance the ongoing work in adopting all necessary steps to control the cross-border movement of dual use equipment and materials, as well as people and

financial resources, involved in terrorist activities while, at the same time, enhancing the free flow of legitimate travellers, trade and investment.

Ministers reaffirmed the willingness of all economies to cooperate -where appropriate and in accordance with APEC practices- with international organizations with common goals, such as the International Civil Aviation Organization (ICAO), the International Maritime Organization (IMO), the World Customs Organization (WCO), the Counter-Terrorism Action Group (CTAG) and the International Labour Organization (ILO) so as to develop concrete, result-oriented actions to neutralise threats to the security of our economies.

Ministers noted the Transportation Ministers' statement to focus on implementing an inter-modal supply chain security initiative in the next two years and to continue implementation of maritime and aviation security measures, consistent with international law, with emphasis on the implementation of the International Ship and Port Facility Security Code (ISPS Code) and working to support international efforts, including those by multilateral agencies, to control access to MANPADS and other potential threats to civil aviation. Ministers welcomed on-going technical and capacity building efforts to implement thorough baggage inspection for air and maritime passengers.

Ministers welcomed the Finance Ministers' statement to support actions to combat terrorism, including through increased compliance with accepted international standards to counter money laundering and terrorist financing, and fostering closer cooperation through the exchange of financial intelligence among financial intelligence units and customs. Meanwhile, Ministers urged the Financial Action Task Force to make progress, as appropriate, in the enlargement of its membership.

Ministers looked forward to an enhanced capability in the region to develop and implement regional counter terrorism capacity building initiatives as a result of the establishing the Asian Development Bank's Cooperation Fund for Regional Trade and Financial Security Initiative (FRTFSI).

Ministers welcomed the outcomes of the Second Secure Trade in the APEC Region (STAR) Conference Chile in March 2004 and looked forward to the Third STAR Conference, to be held in Korea in March 2005. They valued the capacity building and best practices sharing work that member economies, along with representatives from the private sector, are able to achieve through this on-going APEC initiative.

Ministers took note of work undertaken by the Telecommunications and Information Working Group (TEL) regarding Cyber Security and Cyber Crime within the scope of securing telecommunications through the exchange of experiences and good practices. They agreed to strengthen their respective economies' ability to combat cybercrime by enacting domestic legislation consistent with the provisions of international legal instruments, including the Convention on Cybercrime (2001) and relevant United Nations General Assembly Resolutions; increasing cooperation among economies' Computer Emergency Response Teams (CERTs), law enforcement, and the public and private sectors; training SMEs in network security; and increasing law enforcement capacity-building.

### **Health Security**

Ministers recognized that outbreaks of infectious diseases, such as SARS in 2003 and avian influenza in 2004, have a profound impact on both the peoples and the economies of the region. They encouraged continued vigilance and preparedness so as to detect, respond to, and mitigate the impact on the economy of public health threats.

Ministers welcomed the efforts of the HTF in enhancing preparedness and planning for pandemic influenza, and activities underway and planned at the Regional Emerging Disease Intervention Center. Ministers encouraged the HTF to enhance cross-sector cooperation with other relevant APEC fora in order to address avian influenza and to strengthen, in coordination with APEC members, the work on research and development of relevant vaccines and antiviral drugs. They underscored the importance of using information technology to better face threats to health in the region and, in this

context, welcomed the HTF's project on e-Health Initiative. Ministers instructed Senior Officials, through the HTF, as well as other relevant fora, to include appropriate actions in the area of Health Security in their work plans, ensuring that such actions complement, without duplicating, work being conducted in other international fora.

Ministers noted with concern the economic and social impact that HIV/AIDS continues to have in the APEC region, and approved the initiative "*Fighting against AIDS in APEC*" for endorsement by Leaders, with the aim of encouraging greater cooperation in the region to prevent HIV/AIDS and promote access to safe and affordable medicines and treatment for people living with AIDS.

Ministers welcomed the outcomes of the XV International AIDS Conference held in Bangkok in July 2004. They underlined the need for APEC to work with relevant international organizations, such as UNAIDS, WHO and the Global Fund to fight AIDS, Tuberculosis and Malaria, in accordance with APEC practices, so as to collectively support actions to address the spread of HIV/AIDS in the region. They appreciated the leading role of Thailand and others on this issue. Ministers looked forward to the active participation of APEC economies in the next International AIDS Conference, which will be held in Canada in August 2006.

Ministers also noted the international effort to eradicate polio by 2005 through the WHO/UNICEF-led global Polio Eradication Initiative. They stressed the importance of all economies making efforts to close the financial gap that faces this effort.

### **Energy Security**

Ministers noted the impact of current high oil prices on the economies of APEC and emphasized that access to adequate, reliable and affordable energy is fundamental to achieving the region's economic, social and environmental objectives.

Ministers acknowledged the achievements of the APEC Energy Security Initiative and supported the outcomes of the APEC Energy Ministers' meeting in June this year, including their call for adequate supply to help stabilize the oil market, and efforts to enhance energy security by preparing for energy supply disruptions, facilitating energy investment, using energy more efficiently, expanding energy choices and capitalising on technological innovation. They also noted the outcomes of the APEC Meeting of Ministers Responsible for Trade in June calling for closer cooperation between Energy Ministers and Trade Ministers. In this context, they instructed Senior Officials to work with the Energy Working Group to examine the impact of high energy prices on trade and economic activity in the region.

Further, Ministers endorse the "*Comprehensive Action Initiative recognizing the need for strengthening the APEC Energy Security Initiative – energy security, sustainable development and common prosperity*" (CAIRNS Initiative), which aims to improve data transparency, energy emergency responses, energy investment, energy efficiency, the development of renewable and alternative energy, and to promote energy for sustainable development and poverty reduction.

### **Invasive Alien Species**

Ministers noted the difficulty and cost of dealing with problems caused by Invasive Alien Species (IAS). Ministers agreed that APEC should identify opportunities for cooperation and capacity building to detect, monitor, and manage invasive pests in the Asia-Pacific region, using science-based criteria in accordance with international standards. Ministers also agreed that a shared awareness and understanding of the risks that invasive marine pests pose to regional growth and sustainability is urgently needed, along with coordinated regional action to help prevent their spread. Ministers welcomed the progress on the development of the Regional Management Framework for Control and Prevention of Introduced Marine Pests by the Marine Resources Conservation Working Group. They noted that IAS problems cut across sectors and, therefore, called on Senior Officials to instruct relevant APEC fora to work together to evaluate how APEC can best contribute on this matter and to

report the results in 2005. In this context, Ministers welcomed the APEC Symposium to prevent the spread of the Golden Apple Snail held in Chinese Taipei in September 2004 and the APEC Workshop on Introduced Marine Pests held in Chile in May 2004.

## **GROWTH AND STABILITY: KEYS FOR APEC INTEGRATION**

Ministers welcomed the outcomes of the APEC Finance Ministers' Meeting, and supported its conclusions, in particular with regard to the importance of disciplined and sustainable fiscal policies for their contribution to long-term growth and macroeconomic stability; the need for policies and institutions that lead to sustainable, broad-based and equitable growth in the region; and the contribution that financial integration can make to growth and economic development. However, Ministers also recognized that freer capital flows can heighten vulnerabilities, especially in emerging market economies, increasing the importance of sound economic policies, strong institutions, and appropriately sequenced liberalization.

### **Macroeconomic Issues**

Ministers endorsed the Economic Committee's Report for 2004; the 2004 APEC Economic Outlook; the KBE/New Economy project titled "*Realizing Innovation and Human Capital Potential in APEC*"; and the TILF project titled "*Trade Facilitation and Trade Liberalization: From Shanghai to Bogor*".

Ministers welcomed the 2004 APEC Economic Outlook, particularly its structural chapter on FTAs/RTAs. Ministers instructed the Economic Committee to further contribute to the understanding of FTAs and RTAs issues in the Asia-Pacific region as a catalyst for achieving the Bogor goals and advancing the WTO process. They also welcomed the initiative on "*Realizing Innovation and Human Capital Potential in APEC*", recognizing that these factors are two key drivers of growth in the new global economy. Ministers acknowledged the importance of the TILF project titled "*Trade Facilitation and Trade Liberalization: From Shanghai to Bogor*" that attempted to provide methodology to implement the Shanghai Accord. Ministers further instructed the Economic Committee to continue to work on TILF related and KBE/New Economy studies that will help to achieve the Bogor Goals.

Given the importance of the issue of terrorism and its direct impact on an economy's welfare, Ministers welcomed the Economic Committee's efforts to undertake a research project on this topic noting that the structural theme of the 2005 APEC Economic Outlook will be the Economic Impact of Counter-Terrorism in the APEC Region.

Ministers commended the Economic Committee's efforts to provide an analytical basis for increasing the economic benefits arising from structural reforms. Ministers agreed on the need to make the agenda of the Economic Committee more policy and action oriented in consultation with other APEC fora and Finance Ministers' process while maintaining its analytical functions.

## **SKILLS FOR THE COMING CHALLENGES**

Ministers welcomed the outcomes of the Third APEC Education Ministerial Meeting (AEMM), with its theme of "Skills for the Coming Challenges". Ministers appreciated its emphasis on improving the learning of English and other foreign languages at the school level as well as among workers and small business entrepreneurs and the use of technology for teaching and learning. Ministers also commended EDNET for organizing a summit of researchers and policy-makers in Beijing in January 2004 in preparation for the Third AEMM.

Ministers expressed their appreciation to the APEC Education Foundation (AEF) for its initiatives in advancing cyber education and ICT capacity building of small and micro-enterprises. Ministers also recognized the Foundation's potential as a useful vehicle to enhance APEC education and human



capacity building cooperation, and encouraged member economies, business, academia and other stakeholders to strengthen partnerships and cooperation with the AEF.

Ministers supported the outcomes of the Fourth APEC Science Ministers' meeting, with its theme "Enhancing the capacity of science, technology & innovation to deliver sustainable growth across the APEC region". They welcomed the mandate given to the Industrial Science and Technology Working Group to progress a range of important activities on human capacity building (in conjunction with the Human Resources Development Working Group) connecting research and innovation, international science and technology networks and technological cooperation.

Ministers acknowledged the importance of promoting science and technology cooperation and noted that improved education and training in math, science and technology is of critical importance in order to ensure the long-term economic growth of APEC economies, and to support global efforts to address significant sustainability issues.

Ministers welcomed the work of the HRDWG to prepare people for the new skills required in the 21st century. These efforts include promoting improved curricula, teaching methods, policy and transparent governance methods for quality basic education, lifelong learning, and training and retraining opportunities to improve the quality of the labor force.

Ministers welcomed the concept of an APEC Business Schools' Network (ABSN) proposed by ABAC, which aims to build partnerships among regional tertiary training institutions, so as to encourage academic and educational exchanges; develop common standards; share resources and identify best practices. They encouraged economies to nominate business schools in the region to be part of ABSN.

## **OPPORTUNITIES FOR ENTREPRENEURIAL GROWTH**

### **Small and Medium Enterprises**

Ministers emphasized that Small and Medium Enterprises (SMEs) and Micro-Enterprises (MEs) are engines for innovation, wealth and employment among APEC economies and urged member economies to establish sound business environments that encourage the creation and growth of enterprises through policies that are consistent with APEC and WTO principles.

Ministers welcomed the "*Santiago Agenda on Entrepreneurship*" adopted at the Eleventh APEC Ministerial Meeting on SMEs, which identified best entrepreneurial practices and reinforced the need for their implementation.

Ministers considered SMEs to be a cross-cutting issue for APEC and welcomed the dialogues held with other relevant fora and the initiatives of economies to host events aimed at improving dialogue with SMEs. They encouraged the SMEWG to continue to improve its role in coordinating APEC's work to promote the growth and competitiveness of SMEs and to further promote the APEC SME Coordination Framework.

Ministers welcomed the SME Ministers' commitment to enhance regional support to advance the business environment of MEs and their commitment to strengthen the role of MEs in the APEC region, through the advancement of the micro-enterprise Development Action Plan as an integral part of the SME WG's Micro-enterprises Subgroup. Likewise, Ministers encouraged an open dialogue with regional International Financial Institutions (IFIs), in coordination with the SOM Committee on ECOTECH, to advance joint initiatives that specifically benefit MEs, including through microfinance.

## Gender

Ministers noted that APEC needs to formulate and implement policies that promote the development of women-owned and -managed SMEs and MEs, including business development and export support services that target women's enterprises in the region.

They recognized the need for women-specific programs to develop technical and digital skills, as well as to strengthen women's business development at all levels, and welcomed the recommendation to support the APEC project "*Initiative for APEC Women's Participation in the Digital Economy*".

Ministers noted the important role of the Gender Focal Point Network for the implementation of the Framework for the Integration of Women in APEC. They recognized the need to reinforce and promote gender integration in APEC through studies, research and collaborative projects among APEC fora aimed at strengthening the participation of women in trade within the region. They welcomed the continued participation of the Women Leaders Network (WLN) in the APEC process and commended its commitment towards the advancement of women and gender issues throughout APEC, including through establishment of a gender advisory group within each economy's coordinating mechanism.

Ministers commended the valuable contribution of the CTI project "*Supporting Potential Women Exporters*" in identifying how APEC's trade liberalization and facilitation agenda can be inclusive of gender considerations. They looked forward to follow-up activities by CTI and other APEC fora that will increase trade and advance gender equality. Ministers asked Senior Officials to report on follow-up to the project's recommendations by the 2005 MRT.

## Youth

Ministers welcomed the 2004 APEC International Youth Camp held in Chinese Taipei in August 2004. Ministers recognized the commitment of the participants to work towards an innovative and entrepreneurial society. They also recognized the need to enhance youth entrepreneurship through special education, and the creation of programs to facilitate the start up and operation of youth-owned and managed businesses.

Ministers encouraged more APEC youth activities so as to build mutual understanding and cooperation in the region. Ministers welcomed Korea's proposal to organize the 2005 International Youth Camp.

## COMMITMENT TO SUSTAINABLE GROWTH

### Sustainable Development

Ministers recognized the need to revitalize APEC's agenda on sustainable development and welcomed the work undertaken by various APEC fora on this issue. They recognized that these initiatives have shed light upon the relationship between economic, environmental and social issues from the widest range of perspectives and that they have contributed to a better understanding of what sustainable development implies for the APEC region.

Ministers highlighted the cross-cutting character of this theme and welcomed the work achieved this year in the First Meeting of APEC Ministers Responsible for Mining; SME Ministerial Meeting; the Third APEC Tourism Ministerial Meeting; and the Fourth APEC Ministers Meeting on Regional Science and Technology Cooperation. Ministers welcomed the recommendations on sustainable development, including the need for more cooperation with other international fora, and instructed the SOM Committee on ECOTECH (ESC) to take these into consideration in coordinating and developing future work in this area. Ministers looked forward to the results of a study on sustainable development that will be undertaken by SOM, as well as the preparations for an APEC High-Level Meeting on Sustainable Development in 2005-2006.

Noting the conclusions of the APEC workshop on environmental impact analysis of trade liberalization measures, and other activities undertaken this year, Ministers emphasized the value of environmental impact analysis as a means both to increase understanding of the implications of trade liberalization measures, and to strengthen public support for trade liberalization by reducing uncertainty.

### **Agricultural Biotechnology**

Ministers welcomed the 2004-2006 Work Plan of the APEC High Level Policy Dialogue on Agricultural Biotechnology and acknowledged its importance in realizing the benefits of agricultural biotechnology through increased agricultural productivity, improved food security, and protection of environmental resources.

Ministers instructed Senior Officials to continue the Policy Dialogue to advance discussions in the areas of policy and information exchange, intellectual property rights and technology transfer, economic and human resource investment, and agricultural biotechnology public policy development. In this regard, Ministers welcomed the convening of a 4th APEC High Level Policy Dialogue on Agricultural Biotechnology in the margins of SOM I in Korea in 2005.

### **EXPERIENCING OUR DIVERSITY**

Ministers welcomed the “*Patagonia Declaration on Tourism in the APEC Region*” and noted the achievements reached during the four years of the Tourism Charter.

Ministers underscored the importance of tourism to the well-being of the region. In addition to being a significant employer through many micro, small and medium enterprises, tourism is a key vehicle for promoting mutual understanding and respect for our natural resources.

Ministers acknowledged that the work on each policy goal of the Tourism Charter is underpinned by the importance of strengthening cultural, environmental and economic sustainability. They recognized that member economies must continue to work in partnership with other APEC fora and the private sector to address these issues.

Ministers instructed Senior Officials to continue to explore ways to broaden opportunities to experience diversity among member economies in areas beyond tourism such as cultural diversity.

### **FROM SANTIAGO TO BUSAN: PENDING TASKS**

#### **APEC Reform**

Ministers welcomed the package of reforms agreed by Senior Officials for immediate implementation. They noted that these reforms contribute towards making APEC more focused and policy-oriented, ensuring that APEC’s work responds directly to the instructions of Ministers and Leaders, streamlining meeting arrangements and other processes, improving coordination between fora, and improving dialogue with the business community and other stakeholders, including labour representatives.

Ministers also welcomed the efforts of individual fora to evaluate and reform their own processes under the leadership of Senior Officials. Ministers instructed Senior Officials that reform should be a continuous process to ensure APEC retains its accountability and the flexibility to respond to a rapidly changing environment and to the needs of all APEC’s stakeholders. In this context, they welcomed the agreement by Senior Officials to work further next year on the additional issues identified during 2004 and to explore new areas for possible institutional reform.

Ministers welcomed decisions by Senior Officials to address immediate and emerging funding issues related to APEC operation. Ministers instructed Senior Officials to give high priority to developing a

sustainable financial strategy for APEC and its Secretariat. This strategy should take into consideration the annual instructions of Leaders, Ministers and Senior Officials; improvements in efficiency of the assessment, monitoring and evaluation of projects; improvements in efficiencies on savings and management of the Secretariat; the possibility of new and additional funding sources; and an analysis of the affordable level of contributions from Member economies.

### **Mid-Term Stock-take**

Ministers commended Senior Officials for their work on the preparation for the Mid-term Stocktake of overall progress towards the Bogor Goals, and endorsed the recommendation on the work program. Ministers instructed Senior Officials to provide a preliminary progress report to the APEC Meeting of Ministers Responsible for Trade in 2005 and bring the final results of the Mid-term Stocktake to the 17th APEC Ministerial Meeting so that Ministers may report to Leaders on the final outcomes. They underscored that the result should comprise an assessment of APEC's progress towards the Bogor Goals based on members' evaluation, IAP Peer Reviews process, inputs from fora, and stakeholders such as ABAC, the APEC Study Center Consortium, PECC, and include Senior Officials' policy recommendations for future activities that need to be taken to achieve the Bogor Goals.

### **Approval of SOM Report**

Ministers approved the SOM Report, including the decision points therein, in particular, the proposed APEC budget and the assessment of members' contributions for 2005.

### **APEC Secretariat**

Ministers noted with satisfaction the Report of the Executive Director of the APEC Secretariat and commended the Secretariat for its efforts throughout the year.

### **APEC 2005**

Ministers thanked the Republic of Korea for its briefing on preparations for the 17th AMM and the 13th APEC Economic Leaders' Meeting in 2005 and Viet Nam for its presentation on the preparations for the 2006 APEC year.

### **Future Meetings**

Ministers noted that future APEC Ministerial Meetings will be held in Viet Nam in 2006, Australia in 2007, Peru in 2008 and Singapore in 2009

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## 3RD APEC TOURISM MINISTERIAL MEETING

Punta Arenas, Patagonia, Chile  
14 October 2004

### PATAGONIA DECLARATION ON TOURISM IN THE APEC REGION

Recognizing the growing importance of the tourism industry to all the economies in the Asia Pacific Region, we, APEC Ministers and their representatives for Tourism from Australia; Brunei Darussalam; Canada; Chile; the People's Republic of China; Hong Kong, China; the Republic of Indonesia; the Republic of Korea; Malaysia; Mexico; New Zealand; the Republic of the Philippines; the Russian Federation; Singapore; Chinese Taipei; Thailand; the United States and Viet Nam, met under the APEC Chile 2004 theme of "One Community, Our Future", in Punta Arenas, Chile, on 13–14 October 2004, under the chairmanship of H.E. Mr. Jorge Rodriguez, Minister Responsible for Tourism for Chile.

The meeting was also attended by the Executive Director of the APEC Secretariat as well as by the distinguished observer from the Pacific Islands Forum, PIF.

We undertook valuable discussions during our Retreat Session on board the MN "Mare Australis", navigating through the southern Chilean channels located in Tierra del Fuego, as well as in a Plenary Session in Punta Arenas.

We adopted the following:

1. The Tourism Charter established by APEC Tourism Ministers in Korea, in July 2000, provides a long-term vision for tourism across the APEC region. The Charter includes a comprehensive set of policy goals that guide the work of the APEC Tourism Working Group (TWG) to enhance the economic, cultural, social and environmental well-being of APEC member economies, which are as follows:
  - a. Remove impediments to tourism business and investment;
  - b. Increase mobility of visitors and demand for tourism goods and services;
  - c. Sustainable manage tourism outcomes and impacts; and
  - d. Enhance recognition and understanding of tourism as a vehicle for economic and social development.
2. We note the work of the TWG and their report on their achievements during the first four years of the Tourism Charter. In particular, we took note of:
  - a. Fourteen projects completed across all four policy goals;
  - b. Four best-practice case studies of particular importance to less developed economies on topics such as safety and security, development of tourism satellite accounts, e-commerce for SMEs, and the special needs of travellers with restricted physical ability; and
  - c. The establishment of the APEC International Centre for Sustainable Tourism (AICST), which provides technical support to complement the work of the TWG.
3. To maximize progress towards implementing the Tourism Charter, we instruct the TWG to undertake a strategic review to ensure a work program that addresses challenges affecting tourism in the coming years, for consideration by the Ministers in 2006. Such challenges should include but not be limited to:

- a. Safety and security;
  - b. Policy and regulation;
  - c. Measuring sustainability;
  - d. Classification and accreditation;
  - e. Infrastructure and
  - f. Niche product development, such as sports tourism, health tourism and others.
4. We encourage all APEC member economies to continue work on Tourism Satellite Accounts to measure the precise value of tourism in their economies and underline the need to implement crisis management plans and to facilitate intra regional cooperation. We also encourage member economies to promote timely infrastructure development and information exchange within the APEC Region.
  5. We acknowledge that the theme of this Third APEC Tourism Ministerial Meeting, “Exploring our Diversity”, is very significant and important to the tourism development of the APEC member economies. The work of each and every policy goal is underpinned by the importance of strengthening cultural, environmental and economic sustainability. We recognize that member economies must continue to work in partnership with the private sector to address these issues.
  6. We recognize that collaboration and cooperation occurs within APEC as much as with external partners. To this end, we encourage the TWG to enhance ties with the APEC Small and Medium Enterprises Working Group; the Human Resources Development Working Group; the Health Task Force and the Counter Terrorism Task Force and other such fora that are of particular relevance to tourism, for increasing mobility and the safety and security of business people, tourists as well as response to crisis situations affecting the region. In addition, there should be closer ties with the APEC Women’s Leaders’ Network to foster the greater inclusion of women as travellers and tourism entrepreneurs.
  7. We welcome the results of the Third APEC Education Ministerial Meeting, whereupon ministers stressed the need for APEC member economies to foster capacities in language skills. As such, we recognize that English and other languages constitute important operational tools for business in the tourism industry.
  8. We underscore the importance of tourism to the economic, social, cultural and environmental well-being of Asia-Pacific. In addition to being a significant employer through its many small and medium enterprises, tourism is a key vehicle for promoting mutual understanding and respect for the natural environment throughout the region.
  9. We were pleased to have as guests at this Ministerial Meeting, representatives from the following organizations:
    - a. World Tourism Organization, WTO
    - b. World Travel and Tourism Council, WTTC
    - c. APEC International Centre for Sustainable Tourism, AICST

We appreciate their contribution during the meeting and we look forward to further collaboration with these organizations, and others such as the Pacific Asia Travel Association, PATA. Involving other public and private sector experts broadens the basis of dialogue within the tourism forum.

We acknowledge the contribution and the hospitality provided by the host Government of Chile; the Regional Government of Magallanes and the Chilean Antarctic, as well as the work undertaken by the APEC Tourism Working Group and the APEC Secretariat, for the success of this Ministerial Meeting.

## **APEC SMALL AND MEDIUM ENTERPRISE MINISTERIAL MEETING**

**Santiago, Chile  
6–7 October 2004**

### **JOINT MINISTERIAL STATEMENT “OPPORTUNITIES FOR ENTREPRENEURIAL GROWTH”**

APEC Ministers and their representatives responsible for Small and Medium Enterprises (SMEs) from Australia; Brunei Darussalam; Canada; Chile; the People's Republic of China; Hong Kong, China; the Republic of Indonesia; Japan; the Republic of Korea; Malaysia; Mexico; New Zealand; Papua New Guinea; Peru; the Republic of the Philippines; Russian Federation; Singapore; Chinese Taipei; Thailand; the United States of America; and Viet Nam, met in Santiago, Chile, on 6–7 October 2004, under the chairmanship of H.E. Jorge Rodriguez, Minister of Economy, Chile.

The meeting was also attended by the Executive Director of the APEC Secretariat as well as by distinguished observers from the Pacific Economic Cooperation Council, the Pacific Islands Forum and the ASEAN Secretariat.

In line with the Chile APEC 2004 theme of “One Community, Our Future”, the policy theme was “Opportunities for Entrepreneurial Growth”. The aim was to identify the best entrepreneurial practices in the APEC community.

The approach to organize a separate retreat session for the Ministers, prior to the formal plenary sessions, was deemed to be a success. There were lively discussions and meaningful exchange of views by the Ministers on the “Santiago Agenda for Entrepreneurship” and on SMEs as a cross-cutting policy issue within APEC. The retreat format allowed more relaxed and theme-oriented discussions. Ministers recommended that this approach be adopted for future meetings to allow Ministers to fully deliberate issues that are of concern to APEC economies.

#### **APEC Agenda for Entrepreneurship**

Ministers adopted the “Santiago Agenda on Entrepreneurship” which is published in a separate document.

Ministers recognized that SMEs are key generators of innovation, wealth and employment among APEC economies. The future of dynamic knowledge-based SMEs is core to the future of APEC.

The Agenda recognized two significant factors that allow SMEs to flourish.

First, is the enabling business environment that encourages the formation and growth of enterprises. Such an environment is characterized by stable macro and microeconomic policies that are business-friendly; legal and governance systems that uphold the rule of law; a regulatory framework that is facilitative of sustainable business growth; and, a culture that supports and rewards entrepreneurial endeavors.

Secondly, Governments should assist in realizing the potential of the SMEs in their economies by providing support for SME growth and by removing barriers that impede their growth.

With regard to the latter the Agenda identified:

- the need to develop the business expertise of entrepreneurs and to encourage the creation of an entrepreneurial culture that also recognizes the contribution of women, rural and micro-enterprises (MEs), minorities and young people, to business and economic growth;



- a role for Governments and financial institutions in facilitating access to finance for credit-worthy SMEs and MEs on affordable terms and which allows for access to professional advice for business improvement;
- the rapid diffusion of technological innovations and the realization of their value through effective commercialization as key contributors to economic growth; and
- the need for member economies to continue their efforts to strengthen both the local and international markets to which SMEs provide products and services through the removal of regulatory impediments to business development and trade.

Ministers will submit the “Santiago Agenda on Entrepreneurship” to the meetings of the APEC Foreign and Trade Ministers as well as Economic Leaders to be held in November in Chile, as a concrete outcome of the 11th APEC SME Ministerial Meeting. An endorsement by the Foreign and Trade Ministers, and Leaders will underline the importance of the APEC process in developing and supporting the requisite policy environment for the emergence of MEs and SMEs with the region. It will also enhance the linkage between the entrepreneurial process, job creation, and income generation for the wider APEC population.

### **APEC Micro-enterprise Action Plan**

Ministers welcomed the report of the Micro-enterprise Sub Group (MESG) on the outcomes of the Third Meeting of the Sub Group.

Ministers reaffirmed their commitment to the MESG and commended the progress made by the Sub Group in further strengthening its role. Greater focus on the objectives as outlined in its Terms of Reference will improve the work of this Sub Group.

In recognizing ME is a unique sector of the economy, Ministers noted the need for better participation by ME specialists in the Sub Group. They encouraged economies to invite appropriate ME agencies and experts to be the Sub Group focal points. These experts can contribute to technical and policy development projects undertaken.

The Ministers thanked those economies that provided studies, activities, and papers to better advance the support of ME, both urban and rural, in the APEC region.

Ministers commended Thailand’s efforts in raising environmental management issues as one of the critical factors in enhancing APEC ME development. Ministers welcomed Thailand’s offer to organize a self-funded seminar on “Environmental Management for APEC Micro-enterprises: Toward Sustainable Development” in 2005. Ministers look forward to receiving recommendations for better ME and SME initiatives which incorporate environmental awareness.

Ministers took note of the USA paper on International Financial Institutions (IFIs) and instructed the MESG to maintain an open dialogue with IFIs to study ways to develop and advance joint initiatives that would specifically benefit MEs in the Asia Pacific region. Ministers welcomed the MESG proposal for such a dialogue during the 2005 meeting in Korea. These activities can be undertaken independently from any future APEC/IFI Round Tables that may take place.

Ministers commended Viet Nam’s proposal for a project to better quantify the contributions of IFIs and other international organisations in building capacity for the ME sector. They also welcomed Viet Nam’s project on enhancing the business environment in the APEC region.

Ministers noted that in 2005, Peru will take forward its project “Micro and Small Enterprise Financing: A Tool for Mainstreaming the Informal Sector” with the purpose of analyzing the different aspects of formalization including the regulatory framework and how they affect the financing of micro, small and medium enterprises in APEC economies.

Ministers discussed the importance of creating a sound regulatory environment for ME development and called on economies to share information and best practices as well as to make an inventory of regulatory best practices. To this end, Ministers encouraged economies to support Indonesia's initiative to hold a workshop on this issue in 2005.

In enabling the creation of an entrepreneurial society, Ministers emphasized the need for promotion of technology-based incubators, as well as incubators for the resources-based economy, especially in agriculture.

Recognizing the work done by the Women Leaders Network (WLN), Ministers noted the recommendation that the MESHG and WLN jointly conduct a research project on the participation of women in MEs. In capturing such sex-disaggregated data, economies can better understand the participation and economic contribution of women, including indigenous women, in MEs in the APEC region.

### **APEC SME Coordination Framework**

Ministers reiterated the importance of coordinating APEC efforts and activities directed towards promoting the growth and competitiveness of SMEs across all fora. This echoes the objectives approved by SOM, as outlined in the "APEC SME Coordination Framework".

Ministers applauded the work of the SMEWG in this regard. They noted that early progress had been made towards the proposed measures to improve coordination, including:

- a joint initiative by the SMEWG and the Committee on Trade and Investment (CTI) Sub-Committee on Standards and Conformance in addressing compliance with standards and conformance for SMEs;
- the Trade Policy Dialogue (TPD) on market access impediments facing SMEs held with experts from the Market Access Group (MAG) and the collaborative activities to develop strategies to overcome challenges faced by SMEs' access to Government Procurement Markets with the Government Procurement Experts Group (GPEG); and
- the first annual meeting of the signatories of the MoU on Cooperation Among APEC Financial Institutions Dealing with SMEs hosted by Thailand on 28 July 2004 and the APEC Conference on Promoting APEC Entrepreneurs: The Financiers' Perspective.

Ministers encouraged the SMEWG to continue its coordination role and to make efforts to further publicize/promote the Framework across all APEC fora. The SMEWG should also request that other fora communicate on a regular basis on proposals that will benefit SMEs and seek the input of the SMEWG as necessary. This will give recognition that the SMEWG has expertise in SME matters and that it will provide direction and add value to the efforts undertaken by all fora regarding SMEs.

Ministers noted the concerns raised in the report of the SMEWG Chair about the current management arrangements. Ministers looked forward to receiving a firm proposal to address that matter in 2005.

### **Cooperation with OECD Working Parties on SMEs and Entrepreneurship**

Ministers welcomed the report of activities being undertaken by the OECD Working Party on SMEs & Entrepreneurship. The SME Ministerial Meeting acknowledged the recent creation of the OECD Centre for Entrepreneurship; the celebration of The 2nd OECD Conference of Ministers responsible for SMEs held on 3-5 June, 2004, in Istanbul, Turkey; and "The Istanbul Ministerial Declaration on Fostering the Growth of Innovative and Internationally Competitive SMEs".

Ministers encouraged the SMEWG to continue to cooperate with the OECD through sharing of information, and to explore opportunities for further collaboration.

### **Collaboration with Other Related Organizations**

Ministers thanked APEC Business Advisory Council (ABAC), WLN, Pacific Economic Cooperation Council (PECC) and Inter-American Development Bank (IDB) for the ongoing contributions to the SMEWG and the MESG and noted the importance of the private sector perspective.

Ministers welcomed the continued participation of the WLN in the MESG and commended its commitment to the advancement of women and gender issues throughout APEC. They noted that the WLN is seeking support and requested SOM and APEC Secretariat to explore how this can be achieved. Ministers agreed that APEC needs to formulate and implement policies that promote the development of women-managed SMEs and MEs and business development services for those firms. Ministers also encouraged the sharing of best practices across APEC and welcomed the participation of WLN in the SMEWG and Ministerial Meetings.

### **English and Other Languages as Business Tools**

Ministers welcomed the results of the Third APEC Education Ministers' Meeting, and especially their work on best practices for the teaching of English and other languages as business tools. Ministers requested that their officials cooperate with the Education Network (EDNET) in order to identify specific actions towards the collective development of a Strategic Plan for English and other Languages in the APEC Region. This will encourage greater mobility and assist SMEs and MEs in meeting the challenges posed by globalization.

### **Secure Business Environment**

Ministers recognized that terrorist attacks in the APEC region have engendered new requirements to secure the movement of people and goods. These are affecting the business environment for SMEs in the region. They supported APEC's commitment to undertake security measures related to trade, but recognized the need to address the business community's concerns about the increasing costs generated by security-related measures.

### **Review of Projects Underway in SMEWG**

Ministers commended the progress and implementation of APEC funded and self-funded projects which offer valuable contributions to understanding the elements needed for entrepreneurship to flourish. Projects are listed below.

- The two phases of Chinese Taipei's project "From Income Generation to Patent Creation: Incubating Innovative Micro-enterprises", which focused on entrepreneurship promotion through incubation of innovative new ventures, and the "Symposium on Industrial Clustering for SMEs" were also commended. Ministers expected the industrial clustering symposium to develop best practice guidelines.
- Russia's International Conference on "Small and Big Business Interaction", which offered a valuable exchange and networking opportunities.
- The second stage of the Canada/Philippines APEC-IBIZ project on "Implementation and Program Enhancement" has been successful in expanding the network of business counselors and national institutes.
- The Bank Rakyat Indonesia (BRI) International Visitor Training Program implemented by Indonesia exemplified of how developing economies advance their role in international cooperation. Ministers thanked the Indonesian Government and BRI for funding, hosting and

implementing a very professional and advanced training program, which focused on the benefits of commercial microfinancing.

- Indonesia's project "The Need and Availability of Micro-Finance Services for Micro-Enterprises: Bringing Multi-Level Good Practices into Local Context" was also commended.
- Korea's multi-phased project "Enabling e-Micro-enterprise Environment: Through Survey and e-Community Based Capacity Building", which involved a survey, forum and training workshop was commended for initiating a new model of cooperation to promote SME informatization among the APEC economies.
- USA's Voluntary Visitors Program for APEC SME Government Officials, which included a Standards Training Program module, was welcomed as an example of public-private sector cooperation in capacity building.
- Brunei's workshop for SME Managers on Reducing SMEs Compliance Cost, which will address issues related to the cost of compliance to Standard and Conformance processes for SMEs to gain access to overseas markets, and Australia's SME Impediments Monitoring System, were welcomed as steps to ease barriers to SMEs in international trade.
- The 7th APEC SME Business Networking Promotion Forum and the APEC Meeting for Cooperation among SME Policy-Implementing Agencies, both hosted by Japan External Trade Organization (JETRO), to be held in October in Sendai, Japan are commended as practical steps to improve networking among agencies, SME organizations and SMEs themselves.
- Ministers welcomed China's efforts to host the 3rd APEC SME Technology Conference and Fair, and the 2nd APEC SME Service Alliance Forum (SMESA) in Ningbo. Ministers recommended China to further coordinate the efforts of the SMESA with the SMEWG and the APEC process in general. The SMESA is able to play a valuable role in the APEC process, especially enhancing the place for SMEs in it.

### **Promoting Innovation of SMEs**

Ministers welcomed Korea's theme for 2005 "Promoting Innovation of SMEs". The theme recognises that innovation is a practical response to the fast-changing international business environment. There will be three sub-themes:

- Human resources and technology development through industry and academia linkages
- Enhancing availability of capital to innovative SMEs
- Networking and clustering for innovative SMEs

Ministers took note that the next SME Ministerial and related meetings, such as the WLN and the business forum will be held in Daegu, Korea, from 28 August to 3 September 2005. In conjunction with the meetings, the "Innovative Technology Show 2005" (Inno Tech Show 2005) will be held as a showcase for innovative SMEs to open new business opportunities and enhance public awareness of their state of the art technology.

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# 11TH APEC FINANCE MINISTERS' MEETING

2–3 September 2004  
Santiago, Chile

## JOINT MINISTERIAL STATEMENT

### I. Introduction

We, the Finance Ministers of the APEC economies, convened our eleventh annual meeting in Santiago, Chile, on 2–3 September 2004. Mr. Nicolás Eyzaguirre, Chile's Minister of Finance, served as Chairman. The meeting was also attended by the Managing Director of the International Monetary Fund, the President of the Inter-American Development Bank, the Vice Presidents of the World Bank and the Asian Development Bank, and the Deputy Executive Director of the APEC Secretariat, as well as by representatives from the private sector.

We met under the policy themes of *"Fiscal policies for growth and stability in an open APEC region"* and *"Institution building in a world of free and volatile capital flows"*. In discussing the themes, we emphasized that to reap the benefits of enhanced openness and integration, member economies must have in place policies and institutions that lead to sustainable, broad-based and equitable growth in the region.

### II. Global and Regional Economic Developments

We note with satisfaction the strengthening of this year's global economic growth and the continued favorable outlook for 2005, notwithstanding the risks associated with high oil prices. We stress the important fact that investment and trade are the leading factors behind the global economic recovery. In our view, both factors are crucial for stronger and broader based growth and for spreading the benefits of globalization. We also note that restored confidence in financial markets, revealed in lower spreads, has contributed to the recovery. Despite higher growth and increases in a number of commodity prices including oil, inflation is expected to remain moderate in most economies.

We also observe that the APEC region is growing faster than the world economy. Though the developed APEC economies are driving this recovery, it is the emerging economies within the region that are showing the highest growth rates, reflecting the sound macroeconomic policies instituted, buoyant exports and the recovery of domestic demand.

In pointing out that trade is one of the key factors pushing growth in the region and the world, and in consonance with the Bogor Goals, we reiterate our support for the WTO Doha Round. We welcome the Decision Adopted by the General Council on 1 August 2004 and call for reaching prompt and concrete results in the negotiations.

Ministers note that terrorism remains a threat to growth and stability and support actions to combat terrorism including increased compliance with accepted international standards to counter money laundering and terrorist financing, as well as other measures including fostering closer cooperation among financial intelligence units and customs. In this context, we urge FATF to make progress, as appropriate, in the enlargement of its membership.

### III. 11th APEC FM Process Policy Themes

Looking forward to the Bogor Goals, the discussions under the two policy themes underscored the importance of sound policies and robust institutions to successfully meet the challenges of globalization.

### *Fiscal Policies for growth and stability in an open APEC region*

We acknowledge the importance of disciplined and sustainable fiscal policies for their contribution to long-term growth and macroeconomic stability. Sustainable fiscal policies keep public indebtedness within limits that help to ensure continued access to international capital markets and reduce external vulnerability. At the same time, such policies allow social and investment expenditures to be maintained during economic downturns. Fiscal discipline will also help governments to better face the future fiscal challenges associated with population ageing.

Transparency is a key element for fiscal credibility and accountability, and hence for good governance. We underscore the need for strong institutions to ensure fiscal discipline while granting sufficient flexibility to manage economic shocks. We recognize that there is no single way of inducing fiscal discipline and that properly designed fiscal rules can be useful tools to guide fiscal policy.

We are pleased with the significant progress being made in a number of APEC economies in strengthening fiscal institutions. Such progress has improved our economic resilience and helped our region to both weather successfully the economic slowdown of the past years, and be in the forefront of world economic recovery. We agree to continue building on the progress made in order to address current and future challenges to fiscal sustainability.

### *Institution building in a world of free and volatile capital flows*

We stress that financial integration can contribute to growth and economic development through benefits that include reductions in the cost of capital, greater technology transfers, increased investment opportunities, improved competitiveness in domestic financial markets and lower consumption volatility. However we also recognize that freer capital flows can heighten vulnerabilities, especially in emerging market economies, increasing the importance of sound economic policies, strong institutions, and appropriately sequenced liberalization. We note also that additional efforts at the international level can be helpful in this regard.

At the domestic level, economies are encouraged to promote deep and broad financial systems for developing alternative sources of financing and diversification of risks, well-supervised financial institutions, improvements in transparency for authorities and market participants and good governance in general, in combination with a sound macroeconomic policy framework.

At the international level, additional efforts should be made by the IFIs to provide, as appropriate, liquidity to emerging economies with sound economic policies and fundamentals at times of distress originating from external shocks, along with their efforts to help economies achieve sound policies and institutions for growth. We welcome the growing number of economies that include collective action clauses in their international sovereign bonds and the convergence toward collective action clauses as a market standard.

We also note the increasing importance of remittances as a steady source of financial flows that can benefit emerging markets and urge continued work on analyzing and reducing the institutional and regulatory impediments to remittance flows.

Ministers welcome steps being taken at the regional and national levels to develop capital markets and strengthen banking systems, which would over time facilitate freer and more stable capital flows and the choice to move to an exchange rate regime with greater flexibility, in some economies, if they deem appropriate.

We highlight the importance of enhancing the resilience of markets and institutions to growing capital flows. We reaffirm our support for the Bogor Goals as useful tools to promote sustainable and broad-based growth in the APEC region.

#### **IV. Other Matters**

We welcome the dialogues with the APEC Business Advisory Council (ABAC), and the Pacific Economic Cooperation Council (PECC) Finance Forum. They have provided valuable insights from the private and academic perspectives, as well as support for the work under the themes of this 11<sup>th</sup> APEC Finance Ministers' Process.

We would like to thank the Chilean Government and the Ministry of Finance for the arrangement of this APEC Finance Ministers' Process and the Chilean people for their hospitality.

We will meet again for the 12th APEC Finance Ministers' Meeting in Jeju, Korea, on 8–9 September 2005.



# 11TH APEC FINANCE MINISTERS' MEETING

2–3 September 2004  
Santiago, Chile

## ANNEX A: POLICY INITIATIVES REVIEW

### **a) Voluntary Action Plan for Supporting Freer and More Stable Capital Flows. (Canada, New Zealand and Chile)**

#### **Policy Dialogue on Deposit Insurance**

The first APEC Policy Dialogue on Deposit Insurance was held in Kuala Lumpur, Malaysia on 16–18 February 2004. The Dialogue was chaired by the Canada Deposit Insurance Corporation and hosted by Bank Negara Malaysia.

The participants discussed three important issues affecting deposit insurers and other financial system safety net participants: (1) legal protection and indemnification for individuals working for deposit insurers and other financial safety net participants; (2) governance and interrelationship management among safety net participants; and (3) trigger mechanisms for prompt corrective action when dealing with troubled deposit-taking institutions.

The Policy Dialogue allowed participants to exchange views on topics related to deposit insurance.

#### **Policy Dialogue on Financial Disclosure**

In February 2004, the APEC Finance Ministers' Process held a Policy Dialogue on Financial Disclosure in Kuala Lumpur, Malaysia. The Policy Dialogue was co-chaired by Chile's Ministry of Finance and the Reserve Bank of New Zealand, and hosted by Bank Negara Malaysia. Its purpose was to provide a forum for exchanging views on the importance of high quality financial disclosure in the corporate and financial sectors and the means by which such disclosure can be promoted.

The Policy Dialogue noted the importance of high quality disclosure in the corporate and financial sectors of our economies. It was noted that disclosure plays a number of important roles, including: encouraging sound corporate governance and risk management; facilitating sound investment decisions and resource allocation; promoting a more robust financial system; and assisting in promoting economic growth.

Effective financial disclosure requires a number of underlying foundations, including: leadership by government authorities in adopting high quality standards for their own financial reporting; robust accounting standards; sound accounting practices, supported by a culture of fair, accurate and timely disclosure and ethical business practices; robust auditing standards and practices, supported by a culture of professionalism and ethical behavior in the auditing profession; effective monitoring and enforcement of accounting and auditing standards by bodies that have the required authority, resources, independence and credibility; sound corporate governance practices that underpin effective financial disclosure; strong market-based incentives that promote high quality disclosure; and structures and practices that encourage and assist the users of financial information to make greater use of financial disclosure.

## **b) APEC Financial Regulators Training Initiative: Progress Report (ADB and United States)**

The Finance Ministers in their last meeting in Phuket endorsed an extension of this Initiative for a 6th year with the aim of: (i) delivering additional training courses at the regional level to help build a critical mass of potential trainers; (ii) organizing the transfer of training programs and products developed under the Initiative to training institutions at the regional and national levels; and (iii) maintaining its Advisory Group (AG) structure.

In place since May 1998, the Initiative has the objective of developing and providing broad-based training to junior and mid-level financial sector regulators and supervisors. Regulatory and supervisory authorities in APEC economies and the ADB have supported this initiative. An APEC Advisory Group (AG) representing bank supervision and securities regulatory agencies from member countries and other interested parties (separate membership exists for bank supervision and securities regulation) provide oversight of the work done under this Initiative.

The 2004 training program includes 5 regional courses and assumed a reduced need for direct foundation and intermediate-level training on core topics under the Initiative (i.e. bank analysis, credit risk analysis, market risk analysis, and risk management and internal controls), given previous regional and national training seminars in these areas. Based on feedback obtained from AG members, the banking supervision component of the 2004 program comprises regional courses on emerging supervisory issues of risk-focused supervision and anti-money laundering, for which most supervisory organizations in the Region currently have comparatively little in-house training capacity. These courses are using instructors and content from the US Federal Reserve System.

At the 19 July meeting in Manila, the Advisory Group appointed Malaysia to the first of a two-year rotating chair (for the period 2004–2006). Bank Negara Malaysia will oversee the banking supervision component and the Securities Commission Malaysia will oversee the financial markets training component. It is also expected that training programs during this period will be hosted and facilitated by Malaysia.

## **c) Pathfinder Initiative on Corporate Governance (Australia)**

Australia proposed this initiative at the Oaxaca (Mexico) TWG in June 2002 and will table the final report to Finance Ministers in Santiago. The initiative's Core Group Members include Australia, Korea, Malaysia, Mexico, New Zealand and Singapore. The Pathfinder is a peer review process that aims to encourage greater participation in the IMF and World Bank Reports on the Observance of Standards and Codes (ROSC) process, and report on members' achievements and plans for corporate governance reform. The Pathfinder's goal is to encourage all APEC economies to actively improve their corporate governance standards. The report details the achievements of the Core Group economies and discusses areas for further improvement.

## **d) Insolvency Law (Thailand and Korea)**

After the APEC Initiative on Insolvency Law was instigated at the 5th APEC FMM in Canada in 1998, several advances have been achieved at a satisfactory level. A symposium on "Insolvency System in Asia" was held in Sydney in 1999. A series of meetings on "The Forum of Asian Insolvency Reform (FAIR)" were held afterwards. The FAIR I was hosted by Indonesia in 2001, FAIR II was hosted by Thailand in 2002, and FAIR III was hosted by the Republic of Korea, jointly with the OECD, several International Financial Institutions, and the Korean Ministry of Finance and their authorities in 2003.

Given that each economy has achieved a considerable level of domestic Insolvency Law reform and that the interest among APEC economies to participate in discussions on this topic has slowed down, the Meeting noted that the discussion on Initiative on Insolvency Law was complete, unless any member economies volunteer to lead the cooperation under this initiative.

#### **e) APEC Initiative on Remittance Systems (Japan, Singapore, Thailand and United States)**

Building on the APEC Alternative Remittance Systems Initiative from 2003, the APEC ARS Working Group (WG) Co-Chairs (United States, Thailand, Japan and Singapore) advanced their work on remittances in 2004 through holding a successful remittance symposium, supporting additional country case studies and presenting a summary of the main policy conclusions to the APEC Finance Ministers in September 2004. The APEC WG was renamed the “Remittances Initiative” in order to emphasize the development aspects of remittances. This new comprehensive approach will address the issues of shifting to formal funds transfer mechanisms and maximizing the social and economic impact of remittances.

The APEC ARS WG Co-Chairs and World Bank technical assistance team, in collaboration with the Asian Development Bank and Japanese Ministry of Finance, organized the APEC Remittance symposium and policy dialogue entitled “Shaping the Remittance Market by Shifting to Formal Systems”, 3–4 June 2004, in Tokyo, Japan. The symposium provided a unique opportunity for governments, international organizations, non-governmental organizations and private sector entities to participate in discussions on issues of formal and informal remittance systems and to hear presentations from a wide range of stakeholders in the remittance arena.

The key findings include a need for a more comprehensive and well-organized approach to information gathering to bring transparency to the market on critical features and challenges of industry. Regulations should be applied transparently and consistently to result in a level playing field for market competitors and should be made compatible across jurisdictions to minimize impediments. Increased investment in technology will also be useful in widening access to faster, cheaper, and convenient remittance services. The research also illustrates the importance of studying individual remittance corridors, since the social, cultural and economic nuances that have shaped an economy’s remittance landscape play a key role in determining how to develop formal channels.

In this meeting, the APEC Finance Ministers will be asked to welcome the 2004 APEC Remittance initiative report and support upcoming activities as proposed in the report, including a second Remittance Symposium and work toward improving data on remittances.

#### **f) APEC Finance and Development Program (P.R. China and the World Bank)**

Under the overarching three-year theme Improving Financial Intermediation for Economic Growth, Development and Stability, three workshops were successfully held under the APEC Finance and Development Program (AFDP) since the last December.

According to the AFDP 2004 work plan, its Annual Forum will be held in Sanya, Hainan Province, P.R. China, on 28 November 2004. About 100 delegates, including senior government officials, renowned scholars and private sector representatives from APEC member economies and IFIs are expected to attend the Forum and to share their experiences and observations. In addition, focusing on ‘SME Financing in the Asia Pacific Region’ and co-sponsored by the AFDP, Thailand Ministry of Finance and Korean Ministry of Finance and Economy, the third workshop of this year will be held in mid-December.

According to the proposal adopted in 2001, the three-year trial period of the AFDP will end in 2004. Given that member economies in the Asia-Pacific Region are encountering increasingly complex challenges in the areas of finance and development, and that there is still a need for institutional capacity building, it is crucial to continue the AFDP initiative. Based on this consideration, the Deputies agreed to extend this initiative for another three years. They welcomed the P.R. China’s contribution to capacity building and in this regard they took note of the P.R. China’s intention to create a permanent institution that will provide training workshops, organize forums, and finance research projects on specific issues of member economies’ common interest.

### **g) APEC Future Economic Leaders' Think Tank (Australia)**

Australia proposed the annual Think Tank, which was formally launched at the Beijing TWG (December 2000) without a sunset limit. This initiative aims to facilitate the building of relationships and networks among the future financial and economic leaders in APEC; and to provide an experiential program that facilitates networking, problem-solving and the development of creative solutions for priority regional economic and financial challenges. The 2004 Think Tank was held on 30 June–2 July and the theme was Managing Capital Flows: the Domestic and Regional Policy Responses. Twenty-five delegates from fourteen APEC economies considered the reform challenge posed by capital flows within APEC and proposed a roadmap for reform. Delegates called for enhanced policy dialogue to develop consistent macroeconomic approaches to address the character of regional capital flows; policy dialogue to identify reform sequencing appropriate to different stages of economic development; and the need to extend capacity building to strengthen domestic financial institutions

### **h) Development of Securitization and Credit Guarantee Markets (Hong Kong, China; Korea; and Thailand)**

The APEC Initiative on Development of Securitisation and Credit Guarantee Markets is co-led by Hong Kong, China; Thailand and Korea and sponsored by the World Bank. Since the launch of the Initiative, two policy dialogues and six panel visits (two each to Thailand, China and Mexico) were held. The Initiative is successful in promoting the development of domestic securitisation and credit guarantee markets, especially in the three economies receiving expert advice. The experts panels have recommended concrete action plans to the national authorities for removing market impediments and considerable progress has been made in the implementation of market reforms. The co-chairs encourage APEC member economies to continue with their efforts and momentum in developing the markets by implementing the action plans and panel experts' recommendations.

As the Initiative is intended for a two-year term till September 2004, on behalf of the two co-chairs and the World Bank, the Initiative would be formally drawn to a close in this Finance Ministers Meeting. In light of the momentum generated to develop the securitisation and credit guarantee markets, some follow-up work on the Initiative may continue into the next year. The co-chairs and panel experts stand ready to continue to provide advice to the three advice-receiving economies upon request.

### **i) Initiative on APEC Financial Institutions Dealing with SME (Thailand)**

The Ministers welcome the new Initiative on APEC Financial Institutions dealing with SMEs. Following the signing of a Memorandum of Understanding on Cooperation among APEC Financial Institutions Dealing With SMEs on 5 September 2003, during the Tenth APEC Finance Ministers Meeting in Phuket, Thailand, the signatory member institutions convened their First Annual Meeting on 28 July 2004 at Hua Hin, Thailand, under the chairmanship of SME Development Bank of Thailand.

The Ministers noted the success of the first annual meeting and the conference held in Hua Hin, Thailand. The Ministers stressed that greater cooperation among APEC financial institutions dealing with SMEs would bring about a better environment for micro, small and medium enterprises of participating economies. The Ministers also encourage other financial institutions from APEC economies to participate in the cooperation.

The Ministers noted that the China Development Bank would host the Second Annual Meeting in the year 2005. Subsequent annual meetings will be hosted on economy name rotation basis, thus Hong Kong, China, is scheduled to host the 2006 annual meeting.

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## 4TH APEC TRANSPORTATION MINISTERIAL MEETING

27–29 July 2004  
Bali, Indonesia

### JOINT MINISTERIAL STATEMENT

We, the Ministers Responsible for Transportation in the APEC Region, met in Bali, Indonesia, on 27–29 July 2004, to continue progress towards achieving the goals of free and open trade and investment in Asia-Pacific by 2010 for developed economies and 2020 for developing economies set out by our APEC Economic Leaders' Declaration at Bogor. In this regard, we strive for the highest possible standards of efficiency, safety, security and environmental sustainability for our transportation systems.

Since September 11, 2001, we have witnessed a number of terrorist attacks around the world, including in the APEC Region. We condemn, in the strongest terms possible, such attacks and the targeting of transportation systems to inflict terror on civilians. We are united in our determination to enhance regional cooperation on transportation security.

In Bali, we considered ways and means of reducing impediments to trade and investment, while enhancing security and safety, including progressively liberalizing transportation services, engaging in economic and technical cooperation, and building human and institutional capacity. We recognized that through the Secure Trade in the APEC Region (STAR) initiative, APEC economies are building a transport and trade system in our Region that strengthens security while facilitating the movement of people and goods.

Recognizing the rapid increase of road traffic fatalities and injuries worldwide, especially in the APEC Region, which accounts for over 40 percent of the 1.2 million global fatalities, we commit to working together in combating this rising transportation, public health and economic problem.

We benefited from an open dialogue with the leaders of the Region's transportation industry, and we call upon industry and our officials to continue to work together to promote economic prosperity and a secure, safe, efficient and integrated transportation system for all member economies.

The Transportation Working Group (TPT-WG) is the instrument by which both APEC Leaders' and Ministers' goals and directions in the transport field are implemented collectively. We noted the report of the activities of the TPT-WG, and expressed our satisfaction with the work that it has accomplished since our meeting in 2002, and endorsed its Operational Plan.

#### OUR PRIORITIES FOR THE FUTURE

Reaffirming that a principal aim of cooperation in APEC for transportation is trade liberalization and facilitation as well as economic and technical assistance;

According high priority to ensuring a safe, secure, efficient, integrated and environmentally sustainable transportation system for the Region;

Recognizing that the capacity constraints of our transportation systems need to be reduced so that our people, goods and services can move safely and freely;

Recognizing that transnational organized crimes increasingly pose serious threats to the security and safety of aviation, land, and maritime transportation and preservation of environment;

Recognizing that a focus on intermodalism would permit the possibility of exploring innovative solutions to transportation challenges in the region; and

Mindful of the priorities established by Chile, as APEC Host Economy for 2004, with respect to encouraging progress towards a community based on sustainable development;

We state our priorities for all modes of transportation as being:

- Implementing the Bogor Goals on free and open trade and investment;
- Harnessing new technologies and best practices to facilitate travel and trade;
- Improving transport safety in the region;
- Implementing the goals of the Leaders' Statement on Counter Terrorism, including efforts to curb terrorist threats against all modes of transportation;
- Implementing the Secure Trade in the APEC Region (STAR) and other security related initiatives consistent with international law;
- Improving human capacity and institutional development, with a particular focus on developing concrete results-oriented actions of economic and technical assistance and capacity building to ensure the balanced advancement between economic and technical cooperation and trade and investment liberalization and facilitation;
- Cooperating with international organizations with common goals in accordance with APEC rules, such as the International Civil Aviation Organization (ICAO), the International Maritime Organization (IMO) and the International Labor Organization (ILO) without duplication of the work undertaken by those organizations; and
- Supporting the World Trade Organization (WTO) through trade facilitation measures.

## **IMPLEMENTATION PLAN**

In implementing these priorities, we recognize the continuing work and action being undertaken within the Working Group on all modes of transport and infrastructure as well as their integration. Without limiting the initiative of the Working Group, we direct it to give particular focus to the following concrete actions:

- Develop a roadmap consistent with APEC principles, to be reported to Ministers six months before our next meeting, describing the remaining work required for reaching the Bogor Goals of trade liberalization and facilitation as well as economic and technical assistance in all modes of transportation;
- Implement a road safety technical assistance initiative to establish a model traffic safety data collection and evaluation system to better target road safety policies and strategies and combat road safety hazards;
- Support the continuing implementation of maritime and aviation security measures, with emphasis on
  - the implementation of the International Ship and Port Facility Security Code (ISPS Code);
  - working to support international efforts, including those by multilateral agencies, to control access to MANPADS and other potential threats to civil aviation;
- Implement an intermodal supply chain security initiative over the next two years;

- Establish a web-based learning and technical information exchange system; and establish a professional exchange program to assist training and education and the mobility of transport professionals;
- Implement a Global Navigation Satellite System test bed in all areas of the APEC region;
- Implement arrangements for the structured exchange of information among member economies on safety and security best practices and measures;
- Develop a proposal to support the secure transport of dangerous goods, that would include an inventory of economies' regimes pertaining to transportation of dangerous goods and other appropriate actions;
- Develop concrete and specific action plans to carry forward economic and technical cooperation between APEC developed economies and developing economies to assist in establishing an efficient, safe, secure and environmentally sustainable transportation system;
- Enhance cooperation with the World Bank and the Asian Development Bank, through appropriate APEC channels, to improve member economies' transport infrastructure and the capabilities of their transport professionals, including in the area of international security commitments. We note the existence of the APEC-Asian Development Bank (ADB) Regional Trade and Financial Security Initiative in this regard; and
- Implement our Leaders' directives with regard to sustainable development.

We direct the TPT-WG, within the next 12 months, to take stock of the organization, activities and business practices of the Working Group to identify approaches and actions that will further support its ability to provide concrete and productive advice to Ministers in support of the Leaders' Declarations.

In addition, we instruct the TPT-WG to continue its work in implementing the attached Operational Plan with all deliberate speed, and to work with other relevant APEC fora as appropriate in order to implement APEC Leaders' and Ministers' Declarations.

#### **CLOSING REMARKS**

We agreed to meet again in 2006. We instruct the TPT-WG to provide a comprehensive report on its progress towards implementation of our priorities six months before our next Meeting.

We expressed appreciation to the Minister of Indonesia for hosting this 4th APEC Transportation Ministerial Meeting and for the warm hospitality provided. We also thank the Chair for the efficient management of the meeting and the APEC Secretariat for its supportive work.



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# FIRST MEETING OF APEC MINISTERS RESPONSIBLE FOR MINING

**Antofagasta, Chile  
16–17 June 2004**

## JOINT STATEMENT

### Introduction

1. We, the Ministers Responsible for Mining representing APEC's member economies, convened our First Meeting in Antofagasta, Chile, on 16–17 June 2004, under the Chairmanship of H.E. Alfonso Dulanto, Minister of Mining, Chile.
2. We noted that the Asia Pacific region is the main driver of global economic growth and a significant producer and user of minerals and metals; that many economies derive important economic and social benefits from their development, trade and use; and that the mining and metals industry can effectively be an engine for development.
3. We confirmed that the development of the mining and metals industry has great importance in promoting employment and economic growth.
4. We discussed and analyzed two main issues for minerals and metals:
  - A. Sustainable development.
  - B. Trade and investment liberalization and facilitation.
5. We acknowledged that this meeting was a great opportunity to give minerals and metals in APEC a new impetus and to discuss the challenges that face a key productive activity for the development of APEC economies and the world, at the highest level.
6. We acknowledged that development in an interdependent world supposes complex challenges to the mining and metals industry. The most important is related to how society can meet its demands for the mining and metals industry while complying with social, environmental and economic standards that are sustainable in the long term.
7. We acknowledged that challenges are arising for producer and consumer economies from the increasing demand for minerals and metals globally, and the development of new technologies and applications which require new material.
8. We observed that resource endowment and minerals and metals usage varies considerably between APEC member economies which makes relationship among economies more necessary.
9. We recognized the work conducted by the Expert Group on Minerals and Energy Exploration and Development (GEMEED) in minerals, metals and energy related issues since 1996 through the Energy Working Group (EWG).
10. We confirmed our commitment to the economic, environmental, and social dimensions of sustainable development and recognized the importance of the mining and metals industry as a fundamental platform for reaching greater development in many APEC economies as well as the contribution of minerals and metals as essential elements of modern economies.
11. We confirmed our commitment to trade and investment liberalization and facilitation of minerals and metals by recognizing, as a global industry, the need for free flow of trade and investment.

## **Sustainable Development**

12. We agreed that the sustainable development of the mining and metals industry in the APEC Region enhances wealth creation, environmental outcomes and socially responsible development and result in enhanced value for society. To give substance to this, we recognized:
  - A. The need to support and promote initiatives that contribute to meet sustainable development in the mining and metals industry.
  - B. The importance and the need for promoting a cleaner and more efficient production, building on the significant efforts being made by the industry globally to address the environmental, economic and social impacts and benefits of minerals and metals.
  - C. That best practices can be fostered through collaboration between member economies in such areas as technical and capacity-building support to address small scale mining and legacy issues including rehabilitation of mining sites.
  - D. The need of promoting a culture of harmony between the mining industry and local populations influenced by mining operations. This concept should be based on a continued dialogue, the respect for local institutions and authorities and a shared understanding of sustainable development aimed to encourage opportunities for human development beyond the mining activities in the long run.

## ***Trade and Investment Liberalization and Facilitation***

13. We acknowledged that trade and investment liberalization and facilitation of minerals and metals improve the economic and social conditions of APEC economies. These actions need to move forward based on the Bogor Declaration and in the premise of discussions at APEC Meeting of Ministers Responsible for Trade.
14. In order to meet trade and investment liberalization and facilitation of minerals and metals, we:
  - A. Considered it necessary to identify the tariff and non tariff related issues for minerals and metals in the APEC context.
  - B. Recognized the importance of detecting future prospects for trade and investment facilitation in the mining and metals industry.
  - C. Assumed the need to identify, analyze and foresee regulatory trends for minerals and metals.
  - D. Recognized the desire of APEC economies to expand trade in minerals, metals and mining-related goods, services and technologies.
  - E. Recognized the importance of working towards facilitating investment in the mining and metals industry and therefore the balance between supply and demand in order to support development of APEC economies.
  - F. Recognized the importance of the mining and metals industry to APEC economies development goals and the need to understand the supply and demand outlook for minerals and metals, and the ability of this industry to meet this demand.
15. We welcomed the launch of the APEC Non-Ferrous Metals Dialogue, as proposed by Russia, particularly the outcome of the first Steering Group Meeting of the Dialogue held in Pucón, Chile, on 25 May 2004 and encouraged APEC members to work towards identifying measures

to contribute to implementing decisions and recommendations made at this ministerial meeting, including through capacity building, exchange of information and best practice. We expressed the hope that the Dialogue will contribute to effective cooperation between Government and Business sectors in minerals and metals and related areas.

### Action Items

16. We agreed to work in a collective manner to raise the profile of the mining and metals industry in APEC, as well as to encourage sustainable development and trade and investment liberalization and facilitation in the sector.
17. We agreed to develop a working plan in order to make future collaboration among APEC economies more precise and effective in order to guide decisions on the minerals and metals sector at the future Meetings of Ministers Responsible for Mining.
18. We tasked GEMEED to develop and coordinate this working plan which will be reported to Ministers Responsible for Mining and should include the following issues:
  - A. Increase, improve and coordinate the flow and exchange of information and experiences in the mining and metals industry, including the restructuring of the GEMEED's Minerals and Energy Information Network, in order to:
    - Demonstrate the contribution of minerals and metals to sustainable development.
    - Recognize the efforts to improve society's appreciations of the mining and metals industry.
  - B. Promote cooperation of scientific and technological research and development in minerals and metals, within the framework of APEC-ECOTECH principles, in order to:
    - Move forward towards a stronger interrelationship among APEC member economy governments, researchers and firms.
    - Improve international scientific and technological networks.
    - Improve the workforce capability, including the needs of indigenous people, promoting the exchange of professionals and researchers among APEC economies.
    - Assess and evaluate the current situation of the workforce resources in the mining and metals industry in APEC economies.
  - C. Examine mechanisms to work more closely with the industry, including through the APEC Business Advisory Council (ABAC), in order to:
    - Generate synergies among the minerals, metals and related sectors taking into account that productive linkages (clusters) are an important contribution of mining to sustainable development.
    - Develop small and medium enterprises, which will reaffirm the above mentioned and multiply effects due to a higher generation of jobs and to the greater development of economies.
    - Generate a business network which allows cooperation among its members, as well as the analysis of new opportunities for minerals, metals and its related sectors within the APEC region.
  - D. Promote minerals and metals issues in other APEC Fora.
  - E. Undertake an assessment of the state of trade and investment liberalization and facilitation of minerals and metals in APEC economies.
19. We agreed to express our concern to the European Union (EU) over possible EU trade restrictions imposed on minerals and metals by the proposed New Chemicals Policy (REACH). The proposed policy is not commensurate with the scale of the problem, particularly with

respect to the potential impact on the mining and metals industry, and would impose unnecessary costs.

20. We decided to communicate to the World Bank our concern about the outcome of the Extractive Industries Review (EIR) report, and our interest in working with the Bank to respond to the report.
21. We requested the Chairman to report on conclusions reached at the First APEC Ministers Responsible for Mining Meeting, at the next meeting of APEC Economic Leaders in Santiago, Chile, on 20–21 November 2004, in order to ensure that the contribution that the mining and metals industry makes to economic development and prosperity in the APEC region is recognized by Leaders.
22. Finally, we welcomed the opportunity for joint discussion on important issues in the minerals and metals sector. Ministers have committed to meet again when the working plan has been developed.

## SIXTH MEETING OF APEC ENERGY MINISTERS

Manila, The Philippines  
10 June 2004

### ENERGY SECURITY IN APEC: COOPERATION FOR A SUSTAINABLE FUTURE

#### ***Message from APEC Energy Ministers***

*We, Energy Ministers of the APEC economies, gathered for the 6th time in Manila, the Philippines, on 10 June 2004 under the theme “Energy Security in APEC: Cooperation for a Sustainable Future”.*

*We agreed that access to adequate, reliable and affordable energy is fundamental to achieving the region’s economic, social and environmental objectives, that energy security challenges faced by the APEC region are constantly evolving, and that our efforts to enhance energy security must be flexible and responsive.*

*The importance of these efforts is further highlighted by the recent rise in global oil prices and its potential impact on economic growth and sustainable development within the APEC region. Having concern for the impact of recent high oil prices on our economies, we welcome efforts by oil producers to provide adequate supply to help stabilise the oil market. We recognise, however, that a variety of factors influence global markets, and in that context we commit our own efforts to enhance energy security.*

*We agreed that common ground exists for strong cooperation on energy security, with regional and global benefits. We agreed that our cooperation must acknowledge the individual circumstances of each member economy, and that our diversity of views is the foundation for meaningful dialogue.*

*We instruct the Energy Working Group (EWG) to continue its broad-based approach to energy security. We commit to continued development of response mechanisms for short-term disruptions while pursuing longer-term energy security objectives. We agreed that initiatives should be developed and implemented in close cooperation with the business, research and financial communities.*

*These initiatives include:*

- *preparing for energy supply disruptions;*
- *facilitating energy investment;*
- *using energy more efficiently;*
- *expanding energy choices; and*
- *capitalising on technological innovation.*

#### ***Responding to Our Energy Security Challenges***

We respond to the direction by APEC Economic Leaders in their 2003 Bangkok Declaration, to “accelerate the implementation of the Energy Security Initiative by endorsing its Implementation Plan and, as appropriate, a new Action Plan to enhance regional and global energy security.” We also commit to the continued implementation of our Type II Partnership Initiative, “Energy for Sustainable Development”, submitted to the World Summit on Sustainable Development in 2002.

**Prepare for Energy Supply Disruptions.** Oil remains the region’s dominant fuel and oil demand, particularly for transport, is growing rapidly. APEC has oil exporters and importers, but as a whole the region is a growing net oil importer. Historical experience indicates that oil supplies can be seriously interrupted by factors such as geopolitical instability, natural disasters, piracy on key sea lanes, terrorism, and the intrinsic infrastructure and production features of oil supply systems. Today,

power plants, pipelines, port facilities, transmission hubs, hydroelectric structures and other parts of our energy infrastructure face some inherent vulnerabilities. Our challenge is to protect our economies from the adverse effects of oil supply disruptions and infrastructure damage.

To meet this challenge:

- We commit to having emergency mechanisms and contingency plans in place, appropriate to our individual member economies' energy situations, that will provide us with the capacity to respond to energy emergencies, including oil supply disruptions, and damage to our infrastructure systems.
- We commit to establishing and maintaining, as appropriate to the needs of individual member economies, readiness to respond to oil market disruptions and oil market volatility by sharing data, information and experiences, and to cooperate and communicate as appropriate during emergencies.
- We direct the EWG to continue to build the capacity of member economies to collect data and report to the Joint Oil Data Initiative, to monitor efforts to strengthen sea-lane security and respond as appropriate, and to implement the Real-Time Emergency Information Sharing System. We encourage interested member economies to move towards best practice as identified in 'Best Practice Principles for the Establishment and Management of Strategic Oil Stocks'; encourage consideration of the feasibility of joint stocks among interested parties; and encourage continued cooperation under the Earthquake Response Cooperation Initiative.

**Facilitate Energy Investment.** To meet the APEC region's energy needs significant investment is required, and finance from the private sector and financial institutions is essential. Our challenge is for economies to find ways to engage the private sector and financial institutions and to reduce investment risk through policy and regulatory mechanisms that help create an environment to facilitate investment in the full range of energy projects, including energy efficiency, renewable energy and energy infrastructure.

To meet this challenge:

- We direct the EWG to implement the recommendations of the 'Energy Investment Report: Facilitating Energy Investment in the APEC Region', recognising the important contribution of the private sector and financial community in developing the recommendations.
- We reaffirm our commitment to encourage the implementation of best practices previously endorsed for investment in the natural gas and electricity sectors.

**Use Energy More Efficiently.** The potential to reduce energy use through more efficient production, distribution and consumption of energy is great, with energy efficiency enhancing regional energy security and sustainable development through lower energy demand, reduced energy costs and lesser environmental impacts. Cooperation between member economies has proved effective in facilitating improved energy efficiency through the sharing of information and experiences on policies and programs in individual economies. Our challenge is to continue and build on these efforts.

To meet this challenge:

- We commit to implement, as much as possible, an invigorated energy efficiency Pledge and Review Program that includes exploring ways to monitor the implementation of policies and programs.
- We encourage all member economies to participate in the Energy Standards and Labelling Cooperation Initiative and the web-based APEC Standards Notification Procedure aimed to facilitate trade in efficient energy using equipment used within the region.

- We also encourage broadening the scope of work on energy efficiency to include other energy intensive sectors, and to monitor the development of new technologies that could have significant impacts on, and synergy with, energy efficiency and conservation.

**Expand Our Energy Choices.** Energy diversification broadens our choice of energy sources and technologies and in doing so, strengthens energy security and sustainable development within the APEC region. The region's move towards a more diverse energy mix includes a growing demand for natural gas, through cross-border pipelines and Liquefied Natural Gas (LNG), recognition that, for some member economies, nuclear power plays a significant role in their energy mix, and increased development and deployment of renewable energy technologies. In the longer term, research on methane hydrates may yield an important complement to other sources of natural gas. Our challenge is to continue to diversify in ways that support the region's economic, social and environmental objectives.

To meet this challenge:

- We support the creation of a competitive and transparent marketplace for gas trade and encourage member economies to move towards best practice as identified in 'Facilitating the Development of LNG Trade in the APEC Region', recognising the important contribution of the private sector in developing these principles, and direct the EWG to implement its recommendations. We also direct the EWG to continue work to improve the security of natural gas supply by identifying vulnerabilities, supporting trade promotion and establishing convenient information links to gas market data available in existing data systems.
- Recognising that some Member Economies consider nuclear power as an option for their energy mix, while others do not, interested Member Economies are encouraged to cooperate on the nuclear framework as endorsed by the EWG. We emphasise that security, seismic and health concerns, including trans-border effects, should be adequately addressed'
- We support research on the potential of methane hydrates as a future energy source and direct the EWG to communicate research developments within their economies.

**Capitalise on Technological Innovation.** Innovative technologies enable us to discover, produce, transport and use energy in new and more efficient ways, increasing our access to more adequate, reliable and affordable energy. They also strengthen energy security and sustainable development through energy diversification, lower energy costs and the provision of cost-effective solutions to reduce environmental impacts. Innovations include technologies for cleaner and more efficient fossil energy production, carbon dioxide capture and geological sequestration, the production, storage and distribution of hydrogen for use in fuel cell vehicles and electricity generation, and the development of renewable energy technologies and alternative transportation fuels. Our challenge is to capitalise on these and other technological innovations.

To meet this challenge:

- We direct the EWG to continue its work in the areas of clean fossil energy, carbon dioxide capture and geological sequestration and, under the 21st Century Renewable Energy Development Initiative, renewable energy, working closely with the EWG Business Network and the APEC business and research communities.
- We direct the EWG to implement the recommendations identified in the 'Interim Framework Document on Hydrogen and Fuel Cells' that highlights the potential for a hydrogen economy in the APEC region. In doing so we note that APEC Science Ministers, at their meeting in New Zealand in March 2004, directed the Industrial Science and Technology Working Group and the APEC Center for Technology Foresight to collaborate with the EWG in its research on the hydrogen economy, and ask that the EWG support these efforts.
- We call for accelerated cooperation on the development of alternative transportation fuels.



To meet all of these challenges, we call upon the EWG to work closely with the APEC business and financial communities, including through the EWG Business Network, and to draw upon the expertise and resources of the EWG Expert Groups and APERC, of which we endorse the APERC strategic plan that outlines the cooperation sought from member economies for further improving its research activity.

We encourage the EWG to continue cooperation with other organisations, where it is in our interest to do so, and commit to making our activities and achievements known, as appropriate, to other relevant fora.

## MEETING OF APEC MINISTERS RESPONSIBLE FOR TRADE

Pucón, Chile  
4–5 June 2004

### STATEMENT OF THE CHAIR

We, the APEC Ministers Responsible for Trade, representing 21 member economies collectively responsible for 47 percent of world trade and over 50 percent of global GDP, met in Pucón, Chile, on 4–5 June 2004, under the chairmanship of H.E. Maria Soledad Alvear, Minister of Foreign Affairs and Trade, Chile.

The meeting was also attended by the Director General of the World Trade Organization, Dr. Supachai Panitchpakdi, the Executive Director of the APEC Secretariat as well as by distinguished observers from the Pacific Economic Cooperation Council; Pacific Islands Forum and the ASEAN Secretariat. The APEC Business Advisory Council (ABAC) was represented by Mr. Hernán Somerville, Chairman of ABAC 2004.

We met under the policy theme of “A Commitment to Development through Trade and Investment” with the aim of fostering closer economic and commercial ties in the Asia Pacific region. The main policy theme supports the Chile APEC 2004 Theme of “One Community, Our Future”.

#### **Strengthening the Multilateral Trading System**

##### **APEC support to the WTO process**

In accordance with our separate statement on the Doha Development Agenda (DDA) negotiations, we emphasized the need for a successful conclusion of the DDA negotiations as strengthening the multilateral trading system is of the major importance for the achievement of Bogor Goals of free and open trade and investment by all APEC member economies.

We welcomed plans for an APEC/WTO Roundtable on Trade Facilitation in Geneva, to share APEC’s positive experiences in this area with non-APEC economies.

We expressed our satisfaction with the latest developments regarding the accession process of the Russian Federation and VietNam to the WTO. We recognized the importance of APEC WTO capacity building programs aimed at supporting their accession and committed ourselves to encourage the earliest possible conclusion of their accession negotiation processes. The support by the Russian Federation and VietNam to the Ministerial Statement on Doha Development Agenda (DDA) is without prejudice to their accession negotiations to the WTO.

Taking into consideration the contributions made by recently acceded Members to the WTO, their particular concerns should be given due consideration in the DDA negotiations.

In line with the recommendations of the APEC Workshop on WTO Capacity Building Best Practices, we instructed officials to identify best practices and build the capacity of APEC members in the areas of multi-stakeholder and intra-governmental consultations on trade negotiations, in order to help developing economies to fully participate in WTO DDA negotiations and enjoy the full benefits of WTO membership. We instructed officials to identify best practices and build the capacity of APEC members in the areas of multi-stakeholders and intra-governmental consultations on trade negotiations.

## Trade and Security

We noted that terrorist attacks in the APEC region and elsewhere underscore the necessity for timely and meaningful action to secure the movement of both people and goods, as well as an appropriate business environment, which are essential requirements to enhance the prosperity and security of its people.

We reiterated the commitment of APEC member economies in undertaking security measures related to trade, in areas such as air and maritime transport security. The many actions being developed in the field of trade and security attest to the fact that the Asia Pacific Region is striving –through collective action- to provide a safer environment to conduct business.

We realized the need to address the rising concerns flagged by the business community on the increasing costs generated by security-related measures. We noted that implementation of secure trade measures, particularly through effective cooperation, can lead to long-term economic efficiencies. Therefore, we underscore the importance of facilitating travel and trade while enhancing our security.

We recognized the importance of energy on economic stability and security, and called for a mechanism to be set up to promote greater coordination and exchange of information between the APEC Trade and Energy Ministers, in order to ensure that the work in both fora will complement each other to effectively and systematically tackle the ramification of higher energy prices on trade. In addition, we stressed the need for an informal linkage between APEC and OPEC to be established in order to monitor and exchange views and information on the global oil situation and therefore, be in a better position to adjust to the current, as well as any future predicament in the world oil prices.

We stressed the need to strengthen capacity building initiatives, including those aimed at supporting the implementation of air and maritime security measures and safeguarding the mobility of people, and strengthening financial systems against terrorist financing. We encourage the establishment of concrete public/private partnerships in those areas identified for action by government, business and academia representatives at the Second APEC Secure Trade in the APEC Region (STAR) Conference.

We took note of the work being undertaken by the APEC Counter Terrorism Task Force and instructed our officials to intensify their efforts to ensure APEC produces a set of concrete deliverables in 2004 in response to Leaders' Bangkok commitments.

We welcomed the substantial progress achieved in implementing the Advanced Passenger Information (API) pathfinder, and encouraged greater participation in the initiative. We were also pleased to note the exploratory work on a Regional Movement Alert system (RMAL) which has the potential to make a major contribution in enhancing regional security.

We welcomed the establishment of a Regional Trade and Financial Security Initiative within the Asian Development Bank (ADB) and encouraged member economies to contribute to the Fund. We called upon them to identify programs to be financed through the ADB as well as other International Financial Institutions that can add value to APEC's on-going work in the field of trade and security, particularly on capacity building.

We were in agreement that the overarching threat posed by terrorism should not preclude action against other menaces affecting the secure environment we want for our peoples and our trade. In particular, we stressed the need to effectively neutralize – through collaborative and concerted action – all manifestations of international organized crime, including drug trafficking, money laundering and smuggling.

## **Free Trade Agreements and Regional Trade Arrangements (FTAs/RTAs)**

We recognized the contribution that bilateral and regional free trade arrangements can make towards achieving the Bogor Goals and promoting multilateral trade liberalization. We agreed that this contribution is enhanced if regional trade arrangements are open, comprehensive and consistent with WTO rules and disciplines and APEC goals and principles. We welcomed the report of Senior Officials on their Second Policy Dialogue on FTAs/RTAs, including their decision to explore possible FTAs/RTAs best practices and develop specific measures to enhance the contribution of FTAs/RTAs to APEC's goals and principles.

## **Trade and Investment Liberalization and Facilitation**

### **1. Trade and Investment Facilitation**

We welcomed progress achieved so far in the implementation of concrete measures and actions by member economies in the areas of customs, standards, business mobility and e-commerce, that will contribute to the five per cent reduction in transaction costs by 2006, as agreed by APEC Leaders in Shanghai in 2001.

Lower transaction costs will improve business competitiveness and foster economic growth. We highlighted the importance of capacity building efforts to assist APEC developing economies in implementing trade facilitation measures. We further endorsed the revised work plan on Trade and Investment Facilitation (including IPR) which lays down the framework for carrying out the Mid-Term Review and the Expanded Dialogue on Trade Facilitation to be held in September 2004, which provides for wide participation from APEC member economies, the business community, including small and medium enterprises and experts from international organizations. We committed our best efforts to take action to accelerate implementation on the basis of this review.

We instructed officials to accelerate their efforts to identify and, if necessary, undertake new work, including capacity building and greater interaction with the private sector. Such work can help develop methodologies on how to assess quantitative and qualitative reductions in transaction costs, and contribute to the full implementation of the Trade Facilitation Action Plan (TFAP).

Regarding Intellectual Property Rights (IPR), we agreed that their proper protection underpins technical innovation as well as for fair competition amongst market oriented economies, thus contributing to sustainable economic development in the APEC region. We agreed that member economies should take all necessary actions to protect IPR collectively as well as individually. In order to achieve these goals, we called for the early establishment of IPR Service Centers in our economies with close cooperation among members, and instructed our officials to report on the progress of the Comprehensive Strategy on IPR in APEC, and to report on IPR Policy Progress Mapping at the APEC Ministerial Meeting in November 2004.

We welcomed the results of the Third APEC Education Ministers' Meeting, and especially their work on best practices for the teaching of English and other languages as business tools. We instructed our officials to engage all relevant fora, including the Educational Network (EDNET) in order to identify specific actions, such as building bilateral partnerships, geared towards the collective development of a Strategic Plan for English and other Languages in the APEC Region, progress of which will be reported to APEC Economic Leaders in November, 2004.

We affirmed that the Strategic Plan for English and other languages for the APEC region will encourage greater mobility and will assist SMEs and micro-enterprises in meeting the challenges posed by globalization.

## **2. APEC Transparency Standards**

We endorsed the Transparency Standards on Government Procurement and took note of the work in progress for assessing economies' performance in incorporating Leaders' Transparency Standards into their domestic legal regimes. We emphasized the importance of demand-driven capacity building to assist all member economies in complying with the Transparency Standards, as agreed to by APEC Economic Leaders in Bangkok. We welcomed efforts underway to incorporate the Standards into the Individual Action Plan for economies to use in their IAP reporting this year.

We endorsed Senior Officials' plan to consult ABAC in developing an early harvest of concrete results on transparency in 2004, and committed to do our utmost to address the transparency issues raised by the business community by the time of the 2004 APEC Economic Leaders' Meeting.

## **3. Pathfinder Initiatives**

We underlined the importance of increasing economies' participation in existing pathfinder initiatives and called for their expeditious implementation in order to contribute to the achievement of the Bogor goals. Pathfinders facilitate increased trade for business and we call for the on-going development of new pathfinders initiatives.

We welcomed Australia's decision to become the eighteenth economy to participate in the Leaders' Statement to Implement APEC policies on Trade and Digital Economy. We recalled our agreement last year in Bangkok to work on the basis of economies' proposals to identify additional information technology products on which tariffs could be eliminated. We noted some Economies proposals now under consideration by officials and encouraged other economies to identify further products, including new products that have come on to the market since the Information Technology Agreement was concluded in 1996. We instructed officials to prepare a list of information technology products for consideration at the 16<sup>th</sup> APEC Ministerial Meeting.

We Ministers of economies belonging to the Trade and the Digital Economy Pathfinder encouraged other economies to join.

## **4. Individual and Collective Action Plans**

We reaffirmed APEC's commitment to achieve the Bogor Goals through actions outlined in Collective Action Plans and member economies' Individual Action Plans.

We welcomed the completion of peer reviews of the People's Republic of China; Chile; Peru and the United States of America have undergone. We looked forward to having completed all peer reviews of Individual Action Plans by the first Senior Officials' Meeting in 2005. We took note that this process constitutes a strong instrument to assess progress towards the achievement of the Bogor Goals, in the context of the Mid Term Stock-take.

## **5. Structural Reform**

We reaffirmed our determination to continue pursuing structural reform in the APEC region in order to ensure sustainable economic growth and development by improving economic efficiency and raise our competitiveness. We called upon officials to work towards the implementation of the APEC Structural Reform Action Plan and to report on progress achieved at the AMM in Santiago in November 2004. We instructed officials to promote synergies between the implementation of the APEC Structural Reform Action Plan and the work undertaken by APEC Finance Ministers. We welcomed progress on the preparations of the APEC High-Level Conference on Structural Reform, to be held in September 2004, and requested that officials report back on its outcomes at the AMM.

We welcomed progress in APEC's joint work with the OECD on the development of regulatory reform checklist, and looked forward to the completion of this work by the time of our meeting next year.

We instructed Officials to provide guidance to relevant fora on structural reform priorities, taking advantage of the High Level Conference on Structural Reform to be held in September 2004, in Japan.

## **Economic and Technical Cooperation**

We reaffirmed the utmost importance of economic and technical cooperation (ECOTECH) as one pillar of the APEC agenda and urged our officials to develop concrete results-oriented actions to implement the ECOTECH priorities and to ensure the balanced advancement between economic and technical cooperation and trade and investment liberalization and facilitation.

We underscored the importance of developing stronger links with International Financial Institutions (IFIs) and the private sector and engaging them in APEC's economic cooperation and capacity building activities. In improving coordination of APEC activities we acknowledged the importance of strengthening collaboration with the SME Working Group in particular.

We expressed our satisfaction with the preparations being undertaken for the Second APEC/ International Financial Institutions roundtable, at the margins of the Third Senior Official Meeting. We concurred that the areas to be addressed during this meeting, SMEs, micro enterprises and Education, are fundamental to the achievement of long term economic development in the region.

The knowledge of the different languages used by our communities can contribute to create more business opportunities in the region. Therefore, we instructed Senior Officials to work with the APEC Education Network, EDNET, so as to develop with their counterparts responsible for SMEs and Tourism, a Strategic Plan for English and Other Languages in the APEC Region that takes into account each economy's context.

We took note of the intention to explore sustainable development synergies across issues such as fisheries and marine resources; tourism; forestry; biodiversity, mining, SMEs, and micro enterprises. We looked forward to the development of a comprehensive plan on sustainable development that takes into account the work being done in this area in other international fora, and to report progress to Economic Leaders in November.

We welcomed the progress in developing the evaluation frameworks for APEC projects. Such frameworks contribute to the efficient use of APEC financial resources .

## **Preparations for the Mid Term Stock-take of the Bogor Goals**

We welcomed APEC Senior Official's decision to commence the Mid-term Stock take of progress in the achievement of the Bogor Goals. We urged Senior Officials to conduct a forward looking review which demonstrates the contribution that APEC has made -and will continue to make- towards regional integration, greater openness and economic growth in the Asia-Pacific Region.

## **Interaction with the Business Community**

### **1. Dialogue with the APEC Business Advisory Council (ABAC)**

We welcomed the increased interaction with the APEC Business Advisory Council (ABAC), as reflected by the ABAC Chair's active participation in Senior Officials and ministerial meetings in the APEC 2004 Year, and through ABAC's recommendations.

We took note of ABAC's preliminary report to APEC Economic Leaders and requested that officials consider ABAC's recommendations on the WTO, Trade Facilitation, Transparency, FTAs/RTAs, Trade and Security and anti-corruption. We welcomed ABAC's contribution to APEC's Mid-term stock-take process, to ABAC's leadership of an Expanded Dialogue on Trade Facilitation, and to ABAC's assistance in identifying priorities for early implementation of the Leaders Transparency Standards, as described in the "Early Harvest" plan.

## **2. Public/Private Initiatives**

We welcomed the work undertaken by Officials on business related activities, in particular the positive work achieved by business and governmental representatives in the Automotive, Biotechnology, Life Sciences, Chemical and Non Ferrous Metals Dialogues.

We expressed continuing concern over the EU's proposed chemical regulations (REACH) and the adverse implications of this complex regulatory system. We also noted the relevance to our WTO priorities of the Chemical Dialogue's work to address non-tariff measures.

We welcomed the work of APEC's Life Sciences Innovation Forum in promoting global trade and investment in innovative life sciences products and services. We looked forward to reviewing its strategic plan in November .

## MEETING OF APEC MINISTERS RESPONSIBLE FOR TRADE

Pucón, Chile  
4–5 June 2004

### MINISTERIAL STATEMENT ON DOHA DEVELOPMENT AGENDA (DDA) NEGOTIATIONS

1. We, the APEC Ministers Responsible for Trade, strongly support the efforts now underway to move the Doha negotiations forward expeditiously. We urge all WTO members to intensify their efforts in coming weeks to agree by July 2004 on the key issues that will provide a clear way forward for the Doha negotiations. We emphasize the continued importance of the mandate agreed by Ministers in the Doha Development Agenda (DDA) and the need for high levels of ambition and respect for flexibility contained therein to be faithfully reflected in the way forward.
2. Consequently, bearing in mind that the development dimension permeates all areas of the negotiation, we commit and direct our officials to work with a sense of urgency to achieve by July 2004 results that include:
  - a negotiating framework for agriculture that provides an ambitious approach to market access with the necessary flexibility; substantial reductions of trade-distorting domestic support; and includes a specific commitment to abolish all forms of export subsidies by a date certain;
  - a negotiating framework for non-agricultural market access, on the basis of the Derbez text, that is balanced and provides for real improvements in market access and addresses non-tariff barriers;
  - an agreement to launch negotiations on trade facilitation within the single undertaking, recognizing APEC's special contribution in this area;
  - the tabling of services offers by members that have not done so by July 2004, a timeframe for improving offers, as well as making progress in the rule-making areas of services; and,
  - a reaffirmation on the need to make substantial progress in all areas, including work in the Negotiating Group on Rules in accordance with the Doha mandate and the Bangkok Leaders' Declaration;
3. We reaffirm that a high level of ambition in all areas of the DDA must be accompanied by a strong and renewed emphasis on development. In line with this ambition we also want prompt results in the on-going efforts aimed at making existing special and differential treatment more precise, effective and operational. We commit to enhancing technical assistance and capacity building for developing members.
4. We instruct the APEC Geneva Caucus to intensify their efforts to support the key areas of the July package. Recognizing that agricultural market access is lagging behind export subsidies and domestic support, we further instruct that special attention be given to finding a way forward.



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## 3RD APEC EDUCATION MINISTERIAL MEETING

Santiago, Chile  
29–30 April 2004

### JOINT STATEMENT “SKILLS FOR THE COMING CHALLENGES”

#### I. Introduction

1. We, the Education Ministers representing APEC’s 21 Member Economies, convened our Third Meeting in Santiago, Chile, on 29–30 April 2004, under the Chairmanship of H.E. Sergio Bitar, Minister of Education, Chile.
2. We met under the policy theme of “Skills for the Coming Challenges”, to foster linkages and to strengthen collaborative initiatives in the field of education. We agreed to promote equitable and sound opportunities for our communities to make the most of their potential to achieve our goals of greater economic integration, openness, and prosperity for our peoples.

#### II. Recent Developments in the APEC Region

3. Since we last met in Singapore, on April 7, 2000, APEC’s Economic Leaders have met on four occasions and the overall APEC vision remains the same: *Achieving stability, security, and prosperity for our people*. Through the Human Resources Development Working Group (HRDWG), the Education Network (EDNET) has been able to implement initiatives endorsed by the Senior Officials Meeting (SOM) in February 2003 and in Part II of the Osaka Action Plan (OAA), including: Quality basic education, Lifelong learning, Improved curricula, Teaching methods and instructional materials for the 21st century, Enhanced quality of the labor force and mobility of qualified persons.
4. We recognized the challenge in balancing the economic goals of education and training, through the preparation of a skilled labor force to stimulate sustainable economic growth, and the non-economic goals including personal development and fostering civic education and cultural identity, within the APEC Region.
5. We renewed our commitment to support EDNET within HRDWG and recognized that it is a driving force that can add positive value in collaborative initiatives in the field of education-related issues in the APEC Region. Work that is being accomplished through EDNET can bring forward better education and training opportunities to develop the needed skills that will allow our communities to face the challenges of the 21st century.
6. We acknowledged the accomplishments of EDNET towards the goals we outlined in 2000 and note in reviewing those strategic areas that were prioritized at our Second APEC Education Ministers’ Meeting in Singapore, we have been able to successfully complete joint initiatives in the field of Information Technology; Teacher Preparation; Education Management and the enhancement of cooperation as well as the exchange of experts and expertise. A list of completed and current EDNET projects is attached as Annex A.
7. We observed how EDNET has matured as an organization since 2000. Participation has continued to grow; the organization has gained greater focus; strategic alliances with the private sector, other international organizations in the region and across APEC fora have been made; and EDNET has made progress towards the Leaders’ priority of building knowledge-based society.

8. We acknowledged that EDNET organized a successful summit of researchers and policy-makers in Beijing in January 2004 in preparation for this 3rd AEMM to ensure recommendations reflect the most up-to-date research and policy trends. In this regard, we noted the generic signals that emerged from studying the four theme reports prepared for this meeting. These signals should guide our officials as they continue to work through EDNET: ensuring gender analysis and perspectives, encouraging a mix of actors, overcoming resource constraints, emphasizing professional training, encouraging community and parental support, and improving transparency and sharing assessments.

### **III. Facing Educational Challenges with Collaborative Strategies**

9. Building upon the successful work to date, we defined the following four priority areas for future network activities: Teaching English and Other Foreign Languages; Stimulating Learning in Mathematics and Science; Using Technology for Teaching and Learning; and Governance and Systemic Reform in Education.
10. The wealth of knowledge and experience that exists in the APEC Region in the four areas was demonstrated through the discussions and deliberations in Santiago. This was specially demonstrated through the existence of the Knowledge Bank of Education Policy and Practices, ([www.apecneted.org/knowledgebank](http://www.apecneted.org/knowledgebank)), an APEC site that is currently available publicly through the Asia Pacific Network for Education Web Portal ([www.apecneted.org](http://www.apecneted.org)) - a joint initiative of APEC Cyber Education Cooperation (ACEC), the APEC Education Foundation (AEF), and the APEC Education Network (APEC EDNET). To share the benefits of the Knowledge Bank, the use of languages other than English is also encouraged.
11. A number of challenges emerged under the four key themes discussed at the meeting:
  - Improving the learning of English and other foreign languages at the school level is essential to ensure long-term impact. This will be achieved by setting and measuring clear standards and implementing context-relevant strategies for professional development of teachers. However, the importance of learning of English and other foreign languages is not limited to traditional students; it extends to workers, small business entrepreneurs, women, and disadvantaged groups, to enable them to interact successfully in a globalized world.
  - Curriculum reform, notably in Languages, the Sciences and Mathematics, must be considered in the context of the community as a whole to overcome the weaknesses in a given system, while preserving the existing strengths.
  - While basic instruction in ICT is important to learn, ICT's strength appears to be in supporting other subjects. More research is needed to elucidate the factors affecting learning in this context.
  - Establishing strong pedagogical foundations for the use of ICT in education will facilitate the integration of ICT into the school curriculum. Sustainable communities of practice among teachers, students, researchers and other stakeholders will allow us to leverage on each other's experience, knowledge and research findings on innovative uses of ICT in learning and teaching.
  - Economies need effective governance including transparent, accountable, regulatory, accreditation, and quality assurance systems, and also policy and program delivery in order to provide the best educational outcomes. Better connections between researchers and policy makers will support the successful application of governance models, school and curriculum reforms within economies' education systems. More comprehensive, longitudinal studies are needed in order to obtain helpful data for decision-making.

#### IV. Putting Words into Action

12. We have therefore instructed our senior officials to evaluate and prioritize the recommendations highlighted in each of the four priority areas in Annex B.

For a successful collaboration, EDNET will use the following guidelines:

- Undertaking joint research projects addressing fundamental cognitive, empirical and policy matters in the four main priority areas.
  - Identifying and sharing of promising practices on the four priority areas through on-site and online networking communities to connect researchers, students, teachers, children, adult learners and common interest groups.
  - Promoting student and professional mobility as well as joint professional development resources and exchange opportunities, to allow for extended use of limited resources on the four priority areas.
13. We requested that EDNET give careful attention to identifying specific mechanisms required to effectively implement our prioritized recommendations. This includes investigating the rich internal resources available in each of our economies, including our research organizations and universities and building on the activities already taking place in our Ministries to achieve these shared goals.
14. A point stressed by many economies was the need to capitalize on and add value to work related to education being done by other international groups, such as OECD, OAS, SEAMEO and UNESCO. A special concern was the economic pressure being felt in each economy and, therefore, the need to focus limited resources on high quality projects and partnerships.
15. We requested that EDNET work with other relevant APEC Fora, including APEC Business Advisory Council (ABAC), to develop a Strategic Plan for English and Other Languages in the APEC Region that would take into account each economy's context. We encourage our counterparts responsible for Trade, SMEs and Tourism, to instruct their senior officials so as to collectively develop the Plan for the APEC Region, taking on board the strengths that these sectors can offer for the positive, long-term development of this initiative, with an aim of presenting a progress report to APEC Economic Leaders when they meet in Santiago on 20–21 November 2004.
16. We requested that EDNET, through the HRD Working Group, report on conclusions reached at the 3rd Education Ministerial Meeting at the next meeting of the APEC Economic Leaders in Santiago, Chile on 20–21 November 2004, and provide the Ministers with an Annual Report of Progress towards the goals we have established.

## 3RD APEC EDUCATION MINISTERIAL MEETING

Santiago, Chile  
29–30 April 2004

### JOINT STATEMENT “SKILLS FOR THE COMING CHALLENGES”

#### ANNEX A LIST OF PROJECTS BY PRIORITY AREA ACCORDING TO THE 2ND AEMM (SINGAPORE, APRIL 2000)

##### I. Using Information Technology

###### Current

- ACEC including the Asia Pacific Network for Education Web Portal and the Knowledge Bank of Education Policy and Practice - (U.S., Korea, Hong Kong and New Zealand) - [www.apecneted.org](http://www.apecneted.org) and [www.apecneted.org/knowledgebank](http://www.apecneted.org/knowledgebank)
- APEC Cyber Academy (Chinese Taipei) - <http://linc.hinet.net/apec>
- eLearning Strategic Plan (Chinese Taipei and the U.S.) - <http://apec.linc.hinet.net/>

###### Completed

- APEC Links (Singapore)
- APEC Education Exchange Programme (Singapore)
- Integration of Information and Communications Technologies Through Teacher Professional Development and Pre-service Teacher Training (Canada)

##### II. Improving Teaching Systems

###### Current

- Best Practices in Math and Science Seminars - Elementary and Secondary School Levels (Malaysia)

###### Completed

- Vocational Teacher Standards and the Formulating Method (China)
- Best Practice Workshop on School-to-work Transitions in APEC Member Economies for Youth at Greatest Risk of Unemployment (Canada)

##### III. Reforming Education Management

###### Current

- Best Practice in Governance Case Studies (Australia)
- Best Practices for Promoting Life Long Learning (Chinese Taipei)

###### Completed

- Improving Institutional Capacity in Joint Schools (China)
- Achieving High Performing Schools (China and the U.S.)

##### IV. Promoting Cooperation and the Exchange of People and Expertise

###### Current

- Learning About Each Other (U.S. and Chinese Taipei)
- APEC Learning Community Builders - ALCoB (Korea) <http://alcob.com/new/index.html>

- University Mobility in Asia and the Pacific - UMAP (Australia)
- APEC Education Hubs (Singapore)

Completed

- APEC Sister Schools Project (Thailand)
- Towards Mutual Recognition of Qualifications for Stage 3- Engineering (Australia)
- Improving the Understanding of Culture in APEC - We Are APEC (Australia)
- Promoting New Exchanges in Higher Education for the 21st Century (Japan)
- Exchange of Education Professionals Among APEC Member Economies (Korea)
- Cross-Cultural Comparison on Open-Learning System in APEC Member Economies (Korea)
- KDI School as an APEC Education Hub (Korea)
- APEC Youth Networking: Youth Preparation for the APEC Society in the Next Millennium (Thailand)
- Modalities of University-Industry Cooperation in the APEC Region (Thailand)

## 3RD APEC EDUCATION MINISTERIAL MEETING

Santiago, Chile  
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### JOINT STATEMENT “SKILLS FOR THE COMING CHALLENGES”

#### ANNEX B RECOMMENDATIONS SUBMITTED BY EACH SUB THEME PAPER AT THE 3RD AEMM (SANTIAGO, APRIL 2004)

##### English and Other Foreign Languages

###### *1. Curriculum & Standards*

It is important to achieve a balance between existing programs and emerging needs. Key priority should be given to develop clear standards and testing system to support teacher language accreditation, and to define clear standards for student learning and appropriate assessment systems.

###### *2. Exchange & Development*

It is recommended to build on strengths of each economy through networking and collaborative initiatives such as the following:

- Compile a resource inventory including foreign/second language reference materials, resources and teacher exchange information and on-line training programs linked to EDNET Knowledge Bank.
- Link APEC Foreign Language Teachers with internationally recognized language teaching association, such as IATEFL or TESOL, to organize English language teachers' workshops, symposium and other training programs relevant to foreign language teaching, research and publication under the auspices of APEC EDNET (as endorsed by APEC HRDWG)
- Support APEC-wide events to create a 'language star culture' that lauds achievement in foreign language (such as offering rewards, sponsoring contests, debates, etc.)
- Promote e-learning strategies for language teachers' professional development and creativity in classroom instruction
- Create network of returning graduate students and exchange of foreign language educators and students within APEC economies.

###### *3. Research:*

Cooperate in relevant research projects, with clear identification of collaborative roles. The following initiatives are recommended:

- Study use of foreign language e-language learning, web sites and distance education programs to compensate for limited number of teachers and resources
- Assessment of communication skills, especially in large classes, and the possibility of collaborative assessment tools, along with associated impact studies
- Development of a collaborative foreign language teachers' standards assessment and accreditation program, along with associated impact studies

###### *4. Resource Leverage*

Make the best use of resources available for research, networking and collaborative initiatives by:

- Implementing the Knowledge Bank

## Math and Science Instruction

1. Build an online professional development network. Online professional development can be used to enhance teachers' knowledge about mathematics and science. For example, teachers in more developed economies could share their knowledge of how to teach science or how to use ICT to improve instruction with teachers in less developed economies. If done well, online professional development could be as effective as and more cost effective than face-to-face professional development. APEC should explore opportunities for providing online professional development in mathematics and science, and in foreign languages and ICT.
2. Use all opportunities to share knowledge. APEC can create opportunities to share information about mathematics and science education. APEC should sponsor a seminar to discuss case studies: suggested seminar themes might include effective practices for teaching and assessing 21st Century skills and effective practices for training mathematics and science teachers. After the seminar, findings could be even more widely disseminated through the *APEC Network for Education Knowledge Bank*. The Knowledge Bank is a powerful tool that can be used by APEC economies to share information on policies, research, and effective practices. The Knowledge Bank could also house an online bank of assessment questions that measure students' mathematics and science skills in a variety of different formats (multiple choice, short answer, open-ended), including assessments at key grades and college entrance exams.
3. Research how best to integrate instruction in science, technology, and mathematics. Technology is more available than ever in APEC economies. Consequently, it is important to determine how this technology can be used to change instructional techniques and improve student achievement. APEC should encourage research to provide educators with evidence-based methods for integrating ICT with mathematics and science instruction. Without such research, ineffective instructional practices could be inadvertently promoted.
4. Promote the use of evidence-based educational policies and practices throughout APEC. Using the *APEC Network for Education Knowledge Bank*, economies will be able to share information on *evidence-based* best practices in science and mathematics education with one another. APEC is moving toward a research-based focus in its education work, reaching agreement on what constitutes a promising practice and what constitutes an evidence-based practice. Economies should identify their promising practices and rigorously evaluate them to see if they are evidence-based. They should then share proven methods with the other APEC economies.
5. Build on existing cognitive research. APEC should work to determine how recent brain research could be used in teaching mathematics and science concepts, to determine appropriate sequencing of concepts, and to help students of different ages retain mathematical and science concepts. APEC or APEC members should also consider ways to use information collected in UNESCO and OECD brain research projects.

## Using ICT for Teaching and Learning

1. Establishing communities of practice, both on line and on site to share knowledge among students, teachers, researchers, parents, policy makers and other stakeholders among APEC communities.
2. Collaborate on research and development (R&D). APEC economies can share and collaborate with one another on how technology tools can yield high pedagogical impact with low investment, and how such tools can be widely accessible and widely adopted, especially in regions where the digital divide in schools is an issue.



3. Towards the Integration of ICT Literacy into Teaching and Learning. In the long run it is recommended that a holistic approach can be adopted in assimilating ICT into all aspects of teaching and learning to promote ICT literacy. Hence, the focus for future EDNET discussions and projects should be on close integration of the ICT sub theme into the other sub themes, namely English and Foreign Language, Mathematics and Science, and Governance.

### **Governance and Systemic Reform in Education**

1. To have effective governance including transparent, accountable, regulatory, accreditation and quality assurance systems and also policy and program delivery.

These will depend on the economies' political and cultural context, level of economic development and international engagement. Information can be gained from other economies including outside the region.

2. To build the capacity of individuals and at the local and central levels of government;

Decentralization and other reforms cannot occur without appropriate resource and skills shifts and capacity at local level. There is a need to balance local autonomy with national goals and aims.

3. To strengthen ties between schools/education training institutions and local communities;

This encompasses moves to greater school based management systems (often including the building of social capital in schools), increased accountability of schools and greater community involvement.

4. Higher Education Reform. To share best practices including quality assurance systems and international benchmarking.

## 3RD APEC EDUCATION MINISTERIAL MEETING

Santiago, Chile  
29–30 April 2004

### JOINT STATEMENT “SKILLS FOR THE COMING CHALLENGES”

#### ANNEX C THE APEC EDUCATION NETWORK’S ACCOMPLISHMENTS 2000 THROUGH 2004

##### GENERAL PROGRESS

###### Support Leaders Priority of a Knowledge-Based Society

- There was an obvious movement by the EDNET members toward a research-based agenda from 2000–2004 for all EDNET business
- This movement toward a research-based agenda is best exemplified by the participation of 18 out of 21 economies at the APEC Education Summit, “Striking Balance from East and West.”
- In addition, there was a huge response to the policy surveys developed for the 3rd AEMM in each of the four priority areas: 16 in math, 15 in English, 11 number in IT, 13 number in governance. This is in stark contrast to a total of 7 surveys submitted in IT for the 2000 Ministerial.
- EDNET members agreed upon an adopted a common core of definitions for promising practice and evidence-based practice.
- The Knowledge Bank provides the opportunity to access research-based information in each of the priority areas by economy, as well as topic area

###### Growing Participation

- EDNET projects represented 50 percent of all HRDWG funded projects over the last four years.
- EDNET participation is broadening to offices beyond MOEs’ International Cooperation offices to frontline developers and implementers of policy reform and research within the Ministries.

###### Increased Focus

- The group has decisively moved beyond general cooperation to cooperation in key areas of common concern (particularly improving teaching in key content areas – Math and Science, Language Instruction).
- There is one gateway into all APEC education projects—across Fora—via the portal: Knowledge Bank of Policy and Practices.

###### Strategic Cooperation

- Together: Economies chaired each of the four sub-themes at the Summit and have served as a management team for the Ministerial
- With Foundations: AEF on ACEC, Hewlett Foundation and Sun Wah
- With each other: Building on bi-national partnerships formed out of APEC cooperation (e.g., e-language)
- With the research community: Economy researchers able to talk with one another via email in their own language and have it translated via the Knowledge Bank.

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# 4TH APEC MINISTERS' MEETING ON REGIONAL SCIENCE AND TECHNOLOGY COOPERATION

Christchurch, New Zealand  
10–12 March 2004

## COMMUNIQUÉ

### Introduction

We, the Science Ministers and other Heads of Delegation of Australia, Brunei Darussalam, Canada, Chile, the Peoples' Republic of China, Hong Kong China, Indonesia, Japan, Korea, Malaysia, Mexico, New Zealand, Papua New Guinea, the Republic of the Philippines, Russia, Singapore, Chinese Taipei, Thailand, the United States, and Viet Nam met from 10–12 March 2004. Representatives from the APEC Secretariat were also present.

We are grateful to the New Zealand Minister for Research, Science & Technology, Hon Pete Hodgson, for his generous hospitality and effective chairing of the meeting. We also commend the organisers of the ministerial meeting and the two associated events for their efficient arrangements, which have ensured a productive and enjoyable event.

We welcomed the participation of Pacific Economic Cooperation Council (PECC) and the European Commission.

### Connecting Science, Policy and Business

The activities of governments, researchers, entrepreneurs and investors need to be closely interlinked to ensure each economy gains the maximum benefit from science, technology and innovation.

Therefore, we welcomed New Zealand's initiative in arranging for our meeting to be held in conjunction with the APEC R&D Leaders' Forum and an Innovation Showcase. These associated events have enabled us to benefit from interaction with research leaders, innovative businesses, and investors.

Ministers enjoyed discussing a wide range of issues with leading R&D people from the APEC region. The report of the R&D Leaders' Forum is attached.

We commend the hosts of future meetings of APEC Science Ministers to consider a similar programme of events.

### The Theme of the Ministerial Meeting

The theme for our meeting, agreed by the Industrial Science and Technology Working Group (ISTWG) in May 2003, was:

Enhancing the capacity of science, technology and innovation to deliver sustainable growth across the APEC region.

Within that heading are four agreed key policy issues, i.e.:

- human capacity building,
- international Science and Technology (S&T) networks,
- connecting research and innovation,
- strengthening technological cooperation and encouraging best practice in strategic planning.

We appreciate the role which Korea, Australia, Canada and Thailand have played in leading the drafting groups on these issues.

### **Outcomes From This Meeting**

Recent statements by APEC Leaders and Ministers recognise the importance of promoting S&T cooperation in order to ensure the long-term economic growth of APEC economies, and of supporting global efforts to address significant sustainability issues.

During the Ministerial Retreat, which focussed on science and society, we:

- agreed there needed to be more and better engagement between the scientific community and society in APEC economies, including the communication of benefits and risks arising from research; and
- welcomed the offer by Australia's National Science and Technology Centre, to coordinate the development and implementation of a project to study the impact of science centre programmes and activities, and capture and disseminate best practice.

We want ISTWG to base its future programme of activities on the four key policy issues, coordinating its efforts with other APEC working groups where that would lead to a more effective and cohesive programme of work.

We also welcome the broader perspective which ISTWG now takes on the policy aspects of S&T and the contribution which science, technology and innovation make to sustainable growth, arising from work initiated at the Penang Policy Forum in 2001.

At the same time, we note that any consensus about future activities of ISTWG and other APEC working groups must take into account that individual economies are at varying stages of economic and technological development.

We need to look particularly to measures that can be adopted by governments, and areas where collaboration among economies can help address both individual and regional priorities.

Our main directions for ISTWG's future work programme are attached.

### **Current challenges in the sector**

This is the first time that there has been an APEC Science Ministers' meeting since 1998. Since then, developments in science and technology have continued to move at a rapid pace. In seeking to ensure that science and innovation realises its potential, APEC economies face several key challenges, including:

- Globalisation facilitated by the rapid spread and use of information and communication technology gives rise to such issues as (i) how scientists, researchers and policy makers work with each other; and (ii) the availability and use of scientific and technological information, in particular balancing effective protection of intellectual property rights against ensuring the appropriate availability of public good information derived from research and development.
- Increasing complexity, cost and pace of science and innovation, which have spurred international cooperation, particularly in areas of science requiring large scale facilities and/or sharing of large databases and research tasks. This requires economies to ensure their science and innovation systems are open, competitive and attractive.
- The blurring between science and industry; effective interaction between public and private sector researchers requires the appropriate scientific and innovation skills; appropriate patenting, licensing and spin off arrangements to be in place; and for the private sector to play appropriate roles in the science and innovation system.

- Maintaining adequate funding to sustain the economy's science base, so individual economies can play a role in wider science and innovation systems.
- Ensuring an adequate supply of appropriately skilled science and innovation personnel to maintain the basic sciences, work in multidisciplinary teams, and effectively manage science and innovation processes.
- Ensuring that science and innovation optimise their contributions to sustainable growth through the public and private sectors playing appropriate roles.

APEC Ministers responsible for other sectors, such as human resources, small and medium enterprises and energy, should be aware of our decisions and where our respective working groups should coordinate their activities in order to make the most efficient use of APEC resources.

### **Sustainability**

The concept of sustainable growth is very broad, and extends well beyond the responsibilities of science portfolios and of ISTWG. However, we are well aware that science and technology will play a pivotal role in APEC's ability to deliver sustainable growth. Science Ministers requested that ISTWG promote S&T cooperation for sustainable growth.

To ensure sustainability issues are taken into account in a wider context, we attach a number of recommendations to the 16th APEC Ministerial Meeting in November 2004.

### **Developing a Programme of Work**

Ministers ask ISTWG to base its future work programme on a limited number of principles, which should include critical mass and prioritisation. Policy work differs in character from research projects, on which ISTWG has tended to concentrate in the past. The benefits from policy work depend upon a sufficient number of economies participating. ISTWG needs to ensure that the planned work programme does not exceed available resources.

### **Human Capacity Building**

For S&T to fulfil its part in delivering sustainable growth to APEC economies, effective human capacity building policies must be developed and implemented, to make sure the right range of skills is in place.

We underscored the need to ensure the workforce within APEC economies is equipped to meet the scientific and technological needs of today and the challenges of the future, and that it draws on the widest pool of talent, now and in the future.

To this end we discussed some specific challenges, including: the importance of facilitating mobility of research skills; identifying future skill sets required for science & technology; obtaining necessary information to guide study and career choices; the public image and perception of science and technology; the strengthening of education in science, mathematics, and engineering for all segments of the population; recruiting and retaining sufficient people with research and scientific skills; facilitating the active participation of women and other under-represented groups in the S&T workforce; encouraging lifelong learning; and the need for researchers to achieve a shared vision with society over the ethical aspects and value of their work.

Ministers appreciated the opportunity to interact with a group of young students and scientists on the factors that encouraged people to study and work in S&T.

We also acknowledge the importance, for democratic governance, of a public that is informed on scientific and technical issues. Ministers endorsed cooperation across the APEC region in scientific and technological research and education.

Ministers agreed that human capacity building is a top priority for economies as they become increasingly reliant on knowledge-based industries, and as more traditional industries become knowledge-intensive. To facilitate consideration of specific initiatives, we ask ISTWG as an initial step to assemble sufficient data to allow a thorough analysis and evaluation of the current situation across the APEC region.

As Science Ministers we are pleased to note that the APEC Education Ministers, meeting in April 2004, will consider issues arising in science and technology education. We commend this communiqué to them and invite them to inform us of the outcomes of that meeting.

### **Connecting Research and Innovation**

Economies need to have in place policies which facilitate the efficient operation of national science and innovation systems.

We discussed the role which government policies can play in fostering research and development, the importance of public/private partnerships in managing the convergence of science and innovation, and APEC mechanisms which could help build research-based partnerships that serve the innovation needs of economies.

The blurring of boundaries between basic and applied research, and the importance of efficient interaction between science and industry as a driving factor behind the performance of innovation systems increase the need for interdisciplinary approaches and collaboration among key players.

Ministers reaffirmed the high priority of investment in fundamental research as an engine for technological innovation and economic growth.

### **International S&T Networks**

Networking is increasingly important because of the increasing complexity, cost and speed of science and innovation. At the same time, advances in information and communications technology (though not yet available evenly throughout the APEC region) are making effective networking increasingly possible.

The rapidly increasing pace of technological change and the convergence of technologies and disciplines were reflected in our discussions on:

- the most appropriate role for governments in facilitating the establishment and operation of successful international S&T networks;
- factors that are needed to successfully establish and operate international S&T networks;
- ways in which economies can identify areas of science where the maximum mutual benefit would result from the establishment of international S&T networks.

Ministers noted the important role modern communications technologies can play in facilitating more effective international networking in S&T, and in this context affirmed the critical role of the APEC Science and Technology website (ASTWeb), and the need for ISTWG to ensure it operates effectively.

### **Strengthening Technological Cooperation and Encouraging Best Practice in Strategic Planning**

Noting that many of today's major technological challenges create inter-dependence among innovation systems within the APEC region, and the need for clear directions towards delivering sustainable growth, we discussed ways in which policy decisions can best be informed by strategic intelligence and planning. Many of these require a critical mass of expertise, credible foresighting techniques, and access to sophisticated equipment and resources which cross traditional disciplines.

Establishing mechanisms for multilateral cooperation and leveraging the APEC project knowledge base should enable a more effective identification of the opportunities to address high priority S&T issues in the region.

Ministers acknowledged that the APEC Center for Technology Foresight provides a vehicle to assist with progress towards refining and developing strategic intelligence and planning tools.



## **APEC SCIENCE MINISTERS MEETING 2004: MINISTERIAL STATEMENT ON THE ISTWG WORK PROGRAMME**

APEC Science Ministers, meeting in Christchurch, New Zealand on 10-12 March 2004, tasked the Industrial Science & Technology Working Group (ISTWG) to include in its work programme the following range of activities, coordinating its activities with other APEC working groups where appropriate.

### **Human Capacity Building**

Science, technological and entrepreneurial capabilities are central to economic growth and social wellbeing. Some evidence suggests that most economies face difficulties in training and retaining people with the needed science and technology (S&T) skills. We ask that ISTWG and other APEC working groups including the Human Resource Development Working Group (HRDWG) work together and consider how to promote further research on the supply and demand of needed science and technology skills within APEC economies.

The focus of this study should be whether there is a world-wide shortage of S&T skills, or a mismatch between available skills and changing demands.

Depending on the results of this work, topics that could be considered for information exchange and further study by the two working groups are:

- The demand for S&T skills in relation to the capacity of economies to educate and train researchers, scientists and secondary & tertiary teaching staff.
- The main factors that encourage people to study and work in the S&T field (or discourage them from doing so).
- The key factors behind skilled S&T staff moving across borders, either within APEC or to other countries.

To ensure their S&T workforce reflects the demography of each economy and makes best use of the range of skills available, ISTWG, HRDWG and other relevant APEC fora should consider the need for programmes that promote the active participation of women, ethnic communities and other under-represented groups in science and research.

We recognise the value to individuals and to economies of broadening skills and work experience, though we are also concerned at the impact when skilled staff are lost elsewhere for the long term. A balance is needed.

We have agreed that ISTWG, in conjunction with the HRDWG and other working groups as necessary, should:

- Consider how APEC can facilitate the exchange of S&T staff.
- Identify successful policies to promote mobility of individual S&T staff, drawing on the work relating to the APEC Architect and APEC Engineer programmes where relevant.
- Consider the development of curricula that incorporate science, research and technology with business and innovation.

We exchanged experience in identifying curricula, educational materials, governance systems, teaching and facilities to meet the needs of future S&T students. We task ISTWG with continuing that sharing of experience, to help identify and disseminate best practice and positive case studies.

We agreed on the importance of cooperation to raise S&T awareness among all sections of the population. We welcomed the efforts of member economies working together to enhance the

contribution which science centres and museums make to increasing communities' knowledge of the benefits of science and of science careers.

### **International S&T Networks**

Globalisation has profound implications for S&T. As economies become increasingly knowledge-based and subject to international flows of goods, services, people, investment and ideas, governments have a critical role in encouraging collaboration among universities, research institutions and business.

We want to ensure that the contribution that collaborative activities can make to sustainable economic growth is recognised.

We endorse ISTWG's earlier work which identified the following characteristics of successful international S&T networks as:

- being researcher driven,
- having the potential to enhance skills and knowledge,
- having clear goals and appropriate levels of accountability,
- dealing with issues of mutual interest for the economies involved, and
- encouraging the involvement of all interested parties that have the capacity to make a positive contribution.

To facilitate the creation of networks of this sort within APEC, the future work programme of ISTWG should:

- Address those framework issues over which governments have control and where intervention could remove impediments to the establishment of successful international S&T networks. These could include, for example, intellectual property arrangements and the international mobility of researchers.
- Study existing networks within APEC, to identify best practice principles that underlie the establishment and operation of successful networks. This could include encouraging other bodies to compile information from past collaborations, to serve as a guide.
- Explore the establishment and strengthening of international S&T networks in areas of science that have broad implications across economies and society including monitoring and prediction of climate, clean energy, the biological sciences, the nanosciences, and the information and communication technology sciences. Such networks will need to be mindful of other activity already underway.

Ministers recognised the importance across a wide range of sectors of existing networks, noting the work of the APEC Climate Network (APCN) and the Asia-Pacific International Molecular Biology Network (A-IMBN) as examples, and the proposed initiatives of "APEC Climate Center (ACC)" and "electronic International Molecular Biology Laboratory (eIMBL)" for furthering advancements in these areas.

### **Connecting Research and Innovation**

We endorse the idea of ISTWG taking a more targeted and concerted approach to innovation policy. We ask the working group to review the work of the OECD Committee for Science & Technology Policy, which may provide a relevant model for developing and funding innovation policy studies.

Agreed indicators to measure the successful performance of science/industry relationships are an essential component of arriving at best practice. We would like ISTWG to review ways in which public research institutions are evaluated and to consider the need for additional factors to be measured, such as commercialisation outputs.

Consistent with its strengthened policy focus, which Ministers warmly support, we encourage ISTWG to enhance its work on the research/innovation interface. We leave it to ISTWG to decide on the appropriate mechanism for this, as part of its planned review of the structure of the working group. The important thing is to identify and exchange information that will assist policy development and benchmarking in relation to innovation and commercialisation. This could, for instance, comprise a series of comparative policy studies, focussing on innovation and intermediary mechanisms within member economies.

We also task ISTWG with the development of programme options on ways to bridge the gap between the S&T capabilities of the various APEC economies. Ministers highlighted the importance of identifying the digital opportunities to leverage the S&T resources among the APEC economies to build the collective capacity in the region.

Ministers welcomed the outcomes of the APEC Workshop on Development of S&T Intermediary Mechanisms and asked ISTWG to consider its recommendations. Ministers also encourage further sharing of best practices and cooperation among APEC economies in the field of innovation to enhance APEC economic development and long-term prosperity.

### **Strengthening Technological Cooperation and Encouraging Best Practice in Strategic Planning**

Strategic planning is important for all S&T stakeholders – public and private alike – and it must be driven by those who have a vested interest in securing quality outcomes.

Having discussed ways in which policy decisions can best be informed by strategic intelligence and planning, we agreed that ISTWG should:

- Initiate a comparison of current practices in national strategic planning, including foresighting techniques, with the intention of trying to define best practice that is most relevant for member economies.
- Review the current directions and topics for APEC-wide foresight studies, which were last set in 1997, and consider the need for a new survey of economies to identify possible revisions.

Ministers acknowledged the work of the APEC Center for Technology Foresight, and the value of effective coordination between the activities of the Center and other groups within APEC.

### **Sustainability**

We have noted the potential of hydrogen and fuel cell technologies to improve the region's energy, environment and economic security, and that the Energy Working Group is developing a framework document on hydrogen and fuel cell technologies as directed by APEC Leaders. We ask ISTWG and the Center for Technology Foresight to continue to collaborate with the Energy Working Group in its research on the hydrogen economy.

Ministers noted the first Earth Observation Summit that was held in the United States in July 2003, and the work of the ad hoc Group on Earth Observations (GEO) which was charged to develop an international 10 year plan for a coordinated earth observation system. The Ministers were informed that as many APEC economies as possible should participate in the Earth Observation Summit II in Japan in April 2004 and contribute to the development of the Global Earth Observation System of Systems (GEOSS) implementation plan for comprehensive, integrated and sustained global Earth observations through a variety of mechanisms and measurements.

Ministers reaffirmed the importance of science and technology to the health sector. They encouraged cooperation among the Science Ministers, the ISTWG, APEC Senior Officials and the new APEC Health Task Force regarding needs, opportunities, and potential contributions of APEC's science and technology sector related to APEC health priorities.

## **Concluding Remarks**

Recognising the importance and challenges of the four policy issues for sustainable growth in the region, Ministers noted the need to: (1) identify the opportunities in the four policy areas in a coherent fashion; (2) initiate targeted efforts under APEC mechanisms; and (3) ensure relevant APEC activity is leveraged to build the capability of economies throughout the region.

## **RECOMMENDATIONS ON SUSTAINABILITY TO THE 16TH MEETING OF APEC MINISTERS' (AMM), NOVEMBER 2004**

APEC Science Ministers' Meeting in Christchurch, New Zealand on 10–12 March 2004 agreed to recommend to the 16th meeting of APEC Ministers, to be held in November 2004:

- That the current review of the organisational structure of APEC should consider the most effective ways of including sustainable growth concepts and priorities within the responsibilities of the bodies that comprise APEC, while avoiding unnecessary duplication of activities which take place within other international organisations;
- That working groups take particular account of the potential value of information exchange and cooperative pilot projects on sustainable growth, the need for managers and technical personnel in enterprises within APEC economies to be aware of the principles of sustainability, and the establishment of information exchange networks on sustainable growth issues between large companies and SMEs;
- That consideration be given to endorsing within the overall APEC structure the following working definition of sustainable growth: “growth that meets the needs of the present without compromising the ability of future generations to meet their own needs” and to consider the development of a set of principles which would help guide APEC’s work;
- That business leaders within APEC be encouraged to adopt a positive approach towards sustainability concepts as a way of establishing goals that will release the creativity of engineers and scientists;
- That economies explore effective ways of sharing best practice in training, information management and other elements of enabling sustainable growth.

## **APEC SCIENCE MINISTERS MEETING 2004: REPORT TO MINISTERS BY DELEGATES TO THE 5TH APEC R&D LEADERS FORUM**

This paper summarises the main points emerging from the workshops and plenary discussions held by members of the APEC R&D Leaders Forum (Forum). The overarching theme of the Forum was “Capturing value from science”.

The Forum’s conclusions have been grouped according to the four policy issues that are being discussed at the Ministerial meeting.

They are as follows:

- Connecting Research and Innovation
- Human Capacity Building
- International S&T Networks
- Technological Co-operation and Best Practice in Strategic Planning

### **Connecting Research and Innovation**

- There are three dimensions to value
  - Economic
  - Environmental
  - Social
- Technology and science are different. Science uses wealth to create knowledge and technology uses knowledge to create wealth.
- Innovation must be set within a sustainable framework and “business as usual” without regional orchestration won’t achieve the change required.
- The Forum recommends Ministers consider achieving a level of harmony between regulatory and taxation regimes in different economies throughout the region to stimulate collaboration in regional research and commercialisation.
- Government plays a crucial role in providing an education system at all levels to ensure excellence of science and the necessary infrastructure to allow good research to flourish. There is a strong regional element to such a system.
- The Forum acknowledges the huge divide between developed and undeveloped economies within the region and the challenges it presents to commercialising science. The Forum was unable to offer any immediate solutions to this problem, but does commend it to Ministers as an area which warrants further consideration. Linking technology transfer to overseas aid to less developed economies was suggested by some delegates.
- Government and researchers play an important role in gaining public understanding of emerging technologies. The Forum was keen to avoid the difficulties that have been associated with the commercialisation of genetically modified crops.

### **Human Capacity Building**

- The Forum agreed this area as the most important challenge facing the APEC region.
- There is a great opportunity within APEC to facilitate this by moving people around the region in a targeted way, e.g. sharing best practice in commercialisation from universities such as staff training, use of patent pools, Intellectual Property.
- Scientists need new skills; traditionally they are trained in discovery but they need to be flexible, to work well in teams, to have HR, finance and leadership skills, and be business savvy.
- The Forum encourages APEC to explore opportunities for creativity and invention at the interface of indigenous and scientific knowledge systems.

### **International S&T Networks**

- The need to achieve more effective links with business groupings through APEC is crucial. This area needs to be fully explored and options developed as a matter of urgency.

- The possibility of establishing an APEC research council to coordinate research effort in areas of regional interest such as sustainable development was advocated. This should have as one of its objectives the need to establish links with comparable northern hemisphere bodies, in particular the European Union.
- Building on local and national initiatives to develop directories and programmes embracing business, venture capitalists and research communities, the Forum supports the establishment of an APEC based regional directory.

#### **Technological Cooperation and Best Practice in Strategic Planning**

- The Forum acknowledges the value of coordinated strategic planning but encourages ministers not to lose sight of the fact that much innovation has a strong element of chance to it and all economies need to be able to respond effectively to this.

## LEADERS' STATEMENT TO IMPLEMENT APEC TRANSPARENCY STANDARDS

**Los Cabos, Mexico  
27 October 2002**

**Bangkok, Thailand  
21 October 2003**

**Santiago, Chile  
21 November 2004**

We, the Economic Leaders of APEC, reaffirm the commitment made in the Shanghai Accord to pursue implementation of APEC's transparency principles. In so doing, we observe that transparency:

- is an important element in promoting economic growth and financial stability at the domestic and international levels;
- is conducive to fairer and more effective governance and improves public confidence in government;
- is a General Principle in the Osaka Action Agenda which requires its application to the entire APEC liberalization and facilitation process;
- is a basic principle underlying trade liberalization and facilitation, where the removal of barriers to trade is in large part only meaningful to the extent that the members of the public know what laws, regulations, procedures and administrative rulings affect their interests, can participate in their development, can participate in administrative proceedings applying them and can request review of their application under domestic law;
- in monetary, financial and fiscal policies, and in the dissemination of macroeconomic policy data ensures the accountability and integrity of central banks and financial agencies, and provides the public with needed economic, financial and capital markets data; and
- will be enhanced through well-targeted, demand-driven capacity building to assist developing economies make progress toward greater openness.

Accordingly, we are committed to implementing the following transparency standards, taking into account the General Principles in the Osaka Action Agenda. We recognize that implementation of these standards will be an important APEC-led contribution to achieving a successful outcome for the WTO Doha Development Agenda.

### **Transparency in Trade and Investment Liberalization and Facilitation**

#### General Principles

1. (a) Each Economy will ensure that its laws, regulations, and progressively, procedures and administrative rulings of general application respecting matters in Section C of Part One of the Osaka Action Agenda are promptly published or otherwise made available, for example via the Internet, in such a manner as to enable interested persons and other Economies to become acquainted with them.



- (b) Each Economy will have or designate an official journal or journals and publish any measures referred to in paragraph 1 in such journals. Each Economy will publish such journals on a regular basis and make copies of them readily available to the public.
  - (c) An Economy may comply with subparagraph (b) by publication on the Internet.
  - (d) Each Economy will promote observance of the provisions of this paragraph by the regional and local governments and authorities within its customs territory.
2. When possible, each Economy will:
- (a) publish in advance any measure referred to in paragraph 1 that it proposes to adopt; and
  - (b) provide where applicable interested persons a reasonable opportunity to comment on such proposed measures.
3. Upon request from an interested person or another Economy, an Economy will endeavor to promptly provide information and respond to questions pertaining to any actual or proposed measure referred to in paragraph 1.
4. Each Economy will ensure in its administrative proceedings applying any measure referred to in paragraph 1 that:
- (a) wherever possible, persons of another Economy that are directly affected by a proceeding are provided reasonable notice, in accordance with domestic procedures, when a proceeding is initiated, including a description of the nature of the proceeding, a statement of the legal authority under which the proceeding is initiated and a general description of any issues in controversy;
  - (b) such persons are afforded a reasonable opportunity to present facts and arguments in support of their positions prior to any final administrative action, when time, the nature of the proceeding and the public interest permit; and
  - (c) its procedures are in accordance with domestic law.
5. Where warranted, each Economy will ensure that appropriate domestic procedures are in place to enable prompt review and correction of final administrative actions, other than those taken for sensitive prudential reasons, regarding matters covered by these Standards, that:
- (a) provide for tribunals or panels that are impartial and independent of any office or authority entrusted with administrative enforcement and have no substantial interest in the outcome of the matter;
  - (b) provide parties to any proceeding with a reasonable opportunity to present their respective positions;
  - (c) provide parties to any proceeding with a decision based on the evidence and submissions of record or, where required by domestic law, the record compiled by the administrative authority; and
  - (d) ensure, subject to appeal or further review under domestic law, that such decisions are implemented by, and govern the practice of, the offices or authorities regarding the administrative action at issue.

6. For purposes of these Standards, administrative ruling of general application means an administrative ruling or interpretation that applies to all persons and fact situations that fall generally within its ambit and that establishes a norm of conduct but does not include: (a) a determination or ruling made in an administrative or quasi-judicial proceeding that applies to a particular person, good or service of another Economy in a specific case; or (b) a ruling that adjudicates with respect to a particular act or practice.

#### Specific Principles

7. Consistent with the above Standards, Economies will follow the transparency provisions contained in the following documents:
  - (a) APEC Group on Services Menu of Options for Voluntary Liberalization, Facilitation and Promotion of Economic and Technical Cooperation in Services Trade and Investment;
  - (b) APEC Investment Experts Group Options for Investment Liberalization and Business Facilitation to Strengthen the APEC Economies-For Voluntary Inclusion in Individual Action Plans;
  - (c) APEC Principles to Enhance Competition and Regulatory Reform;
  - (d) APEC Sub-Committee on Standard and Conformance objective to ensure transparency according to the WTO Agreements on Technical Barriers to Trade and Sanitary and Phytosanitary Measures, and the SCSC 1994 Declaration of an APEC Standards and Conformance Framework and 1998 Terms of Reference; and
  - (e) APEC Principles on Trade Facilitation.
8.
  - (a) APEC sub-fora that have elaborated the above transparency provisions should review these regularly and, where appropriate, improve, revise or expand them further.
  - (b) APEC sub-fora that have not developed specific transparency provisions should do so.
  - (c) APEC sub-fora that develop such new or revised transparency provisions should present them to Leaders upon completion for incorporation into this Statement.

#### **Transparency in Monetary, Financial and Fiscal Policies and the Dissemination of Macroeconomic Policy Data**

9. Prior to our agreement in the Shanghai Accord to implement APEC transparency principles, we agreed in Brunei Darussalam in 2000 to support the key standards identified by the Financial Stability Forum. Three of these key standards focus on transparency:
  - (a) Code of Good Practices on Transparency in Monetary and Financial Policies: Declaration of Principles;
  - (b) Code of Good Practices on Fiscal Transparency; and
  - (c) General and Special Data Dissemination Standards.
10. Following APEC Finance Ministers' decision to support the assessment of Economies' implementation of these transparency codes through the IMF led Reports on the Observance of Standards and Codes (ROSCs), Economies are encouraged to participate fully in the

ROSC program. As voluntary disclosure of ROSC modules promotes transparency, Economies should, where practicable, disclose the results of these assessments.

### **Confidential Information**

11. The provisions of this Statement will not require any Economy to disclose confidential information where such disclosure would impede law enforcement, the enactment of laws, or otherwise be contrary to the public interest or would prejudice the legitimate commercial interests of particular persons or enterprises.

### **Area-Specific Transparency Standards**

12. (a) Economies are committed to implementing the area-Specific Transparency Standards contained in Sections A-H below in a manner consistent with the Standards in paragraphs 1-6 and 11 above.<sup>1</sup>
- (b) Economies agree to review periodically the Area-Specific Transparency Standards contained in Sections A-H below and, where appropriate, improve, revise or expand them further.

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<sup>1</sup> Economies in accession to the WTO accept the area-Specific Transparency Standards on the understanding that this will neither influence the outcome of their on-going WTO accession negotiations nor prejudice the results of the relevant WTO negotiations.

## A. Services

### Introduction

Economies agree to implement, in respect of services, the General Principles contained in paragraphs 1-6 and paragraph 11 of the Leaders' Statement to Implement APEC Transparency Standards ("Leaders' Statement").

Economies believe that, in the services context, it is particularly important to emphasize Leaders' observation that transparency contributes to: good governance; improving public confidence in, and legitimacy of, regulatory regimes; better understanding of regulatory objectives; more efficient markets; and a more attractive investment climate in both small and large economies.

Economies take note of Leaders' recognition that implementation of these standards will be an important APEC-led contribution to achieving success in the WTO Doha Development Agenda (DDA) GATS negotiations.

### Transparency Standards on Services

1. (a) Each economy will, in the manner provided for in paragraph 1 of the General Principles in the Leaders' Statement, ensure that its laws, regulations, and administrative procedures related to applications for licenses or authorizations (including, inter alia, licensing procedures and requirements/criteria, qualification procedures and requirements, and technical standards) and their renewal or extension are promptly published or otherwise made available in such a manner as to enable interested persons and other Economies to become acquainted with them.
- (b) Economies will use the Internet as much as possible, and specifically, official government web sites, to fulfill this obligation.
2. Economies will publicize and maintain at least one enquiry point that will endeavor to promptly provide information and respond to questions from an interested person or another Economy pertaining to any actual or proposed measure. Economies will also make the names, official addresses, and other contact information (including website, telephone, facsimile) of its enquiry point(s) publicly available.
3. Economies will diligently complete and provide annual updates to their electronic Individual Action Plans (E- IAPs) for services sectors.
4. Regarding authorizations and licensing procedures, when possible:
  - (a) the competent authorities of an Economy will, within a reasonable period of time after the submission of an application considered complete under domestic laws and regulations, inform the applicant of the decision concerning the application. The competent authorities will establish deadlines for processing of completed applications under normal circumstances.
  - (b) at the request of the applicant, the competent authorities of the Economy will provide, without undue delay, information concerning the status of the application, including any reason for denial. Applicants will also be given the opportunity to resubmit or amend their application for further review, or file an appeal if an application is denied or found in violation of public regulations.

- (c) Economies will publish the time schedule for and costs of examinations required as part of the application process for a license or authorization in accordance with paragraph 1 of the Leaders' Statement.
- 5. These Standards should be administered in a reasonable, objective and impartial manner.

## **B. Investment**

### **Introduction**

On 27 October 2002, in Los Cabos, Mexico, APEC Leaders adopted the Statement to Implement APEC Transparency Standards (“Leaders’ Statement”), and directed that these standards be implemented as soon as possible, and in no case later than January 2005.

In paragraph 8 of the Leaders’ Statement, APEC Leaders instructed APEC sub-fora that have elaborated transparency provisions to review these regularly, and, where appropriate, improve, revise or expand them further. Economies were further instructed that such revised transparency provisions should be presented to Leaders upon completion for incorporation into the Leaders’ Statement. Accordingly, the following set of transparency standards on investment were developed for incorporation into the Leaders’ Statement. These principles flow from the General Principles on Transparency agreed to by APEC Leaders at Los Cabos and also build on the Options for Investment Liberalization and Business Facilitation to Strengthen the APEC Economies – For Voluntary Inclusion in Individual Action Plans. Economies agree to implement, in respect of investment, the General Principles contained in paragraphs 1 through 6 and paragraph 11 of the Leaders’ Statement.

These principles provide specific guidance for implementation within an investment context.

### **Transparency Standards on Investment**

1. Each Economy will, in the manner provided for in paragraph 1 of the Leaders’ Statement, ensure that its investment laws, regulations, and progressively procedures and administrative rulings of general application (“investment measures”) are promptly published or otherwise made available in such a manner as to enable interested persons and other economies to become acquainted with them.
2. In accordance with paragraph 2 of the Leaders’ Statement, each Economy will, to the extent possible, publish in advance any investment measures proposed for adoption and provide a reasonable opportunity for public comment.
3. In accordance with paragraph 3 of the Leaders’ Statement, upon request from an interested person or another Economy, each Economy will:
  - (a) endeavor to promptly provide information and respond to questions pertaining to any actual or proposed investment measures referred to in paragraph 1 above; and
  - (b) provide contact points for the office or official responsible for the subject matter of the questions and assist, as necessary, in facilitating communications with the requesting economy.
4. Where warranted, each Economy will ensure that appropriate domestic procedures are in place to enable prompt review and correction of final administrative actions, other than those taken for sensitive prudential reasons, regarding investment matters covered by these standards, that:
  - (a) provide for tribunals or panels that are impartial and independent of any office or authority entrusted with administrative enforcement and have no substantial interest in the outcome of the investment matter;
  - (b) provide parties to any proceeding with a reasonable opportunity to present their respective positions;

- (c) provide parties to any proceeding with a decision based on the evidence and submissions of record or, where required by domestic law, the record compiled by the administrative authority; and
  - (d) ensure subject to appeal or further review under domestic law, that such decisions will be implemented by, and govern the practice of, the offices or authorities regarding the administrative action at issue.
5. If screening of investments is used based on guidelines for evaluating projects for approval and for scoring such projects if scoring is used, in accordance with paragraph 1 of the Leaders' Statement each Economy will publish and/or make publicly available through other means those guidelines.
  6. Each Economy will maintain clear procedures regarding application, registration, and government licensing of investments by:
    - (a) publishing and/or making available clear and simple instructions, and an explanation of the process (the steps) involved in applying/government licensing/registering; and
    - (b) publishing and/or making available definitions of criteria for assessment of investment proposals.
  7. Where prior authorization requirement procedures exist, each Economy will conduct reviews at the appropriate time to ensure that such procedures are simple and transparent.
  8. Each Economy will make available to investors all rules and other appropriate information relating to investment promotion programs.
  9. When negotiating regional trade agreements and free trade agreements that contain provisions with an investor/state dispute settlement mechanism, each Economy should consider whether or not to include transparency provisions.
  10. Each Economy will participate fully in APEC-wide efforts to update the APEC Investment Guidebook.

## **C. Competition Law and Policy and Regulatory Reform**

### **Introduction**

In October 2002, in Los Cabos, Mexico, APEC Leaders adopted the Statement to Implement APEC Transparency Standards (“Leaders’ Statement”), and directed that these standards be implemented as soon as possible, and in no case later than January 2005.

In paragraph 8 of the Leaders’ Statement, APEC Leaders instructed that APEC sub-fora that have not developed specific transparency provisions should do so, and further instructed that such new transparency provisions should be presented to Leaders upon completion for incorporation into the Leaders’ Statement. Accordingly, the following set of transparency standards on competition and deregulation for incorporation into the Leaders’ Statement were developed.

These principles flow from the General Principles on Transparency agreed to by APEC Leaders at Los Cabos, and provide specific guidance for implementation within the context of competition law and policy and regulatory reform.

### **Transparency Standards on Competition Law and Policy**

1. In furtherance of paragraph 1 of the General Principles of the Leaders’ Statement, each Economy will ensure that its competition laws, regulations, and progressively, procedures, administrative rulings of general application and judicial decisions of general application are promptly published or otherwise made available in such a manner as to enable interested persons and other Economies to become acquainted with them.
2. In furtherance of paragraphs 4 and 5 of the General Principles of the Leaders’ Statement, each Economy will ensure that before it imposes a sanction or remedy against any person for violating its national competition law, it affords the person the right to be heard and to present evidence, except that it may provide for the person to be heard and present evidence within a reasonable time after it imposes an interim sanction or remedy; and that an independent court or tribunal imposes or, at the persons request, reviews any such sanction or remedy. Proceedings subject to this paragraph are to be in accordance with domestic law.

### **Transparency Standards on Regulatory Reform**

1. In furtherance of paragraph 1 of the General Principles of the Leaders’ Statement, each Economy will ensure that its laws, regulations, procedural rules and administrative rulings of general application relating to regulatory reform are promptly published or otherwise made available in such a manner as to enable interested persons and other economies to become acquainted with them.
2. In furtherance of paragraphs 2 and 3 of the Leaders’ Statement, Economies recognize the importance of ensuring transparency in the regulatory reform process and of soliciting and responding to inquiries from interested persons and other Economies. Accordingly, each Economy will, where possible (a) publish in advance regulatory reform measures that it proposes to adopt, and (b) provide where applicable interested persons a reasonable opportunity to comment on such proposed measures. In addition, upon request from an interested person or another Economy, each Economy will endeavor to promptly provide information and respond to questions pertaining to any actual or proposed regulatory reform measure.



## **Confidential Information**

Economies agree that nothing in these standards requires any Economy to disclose confidential information.<sup>2</sup>

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<sup>2</sup> The Leaders' Statement includes a provision for the protection of confidential information. This statement is included here to emphasize the importance of the protection of confidential information in the contexts of both competition law and policy and regulatory reform.

## D. Standards and Conformance

### Introduction

On 27 October 2002, in Los Cabos, Mexico, APEC Leaders adopted the Statement to Implement APEC Transparency Standards (“Leaders’ Statement”), and directed that these standards be implemented as soon as possible, and in no case later than January 2005.

In paragraph 8 of the Leaders’ Statement, APEC Leaders instructed that “APEC sub-fora that have not developed specific transparency provisions should do so,” and further instructed that such new transparency provisions should be presented to Leaders upon completion for incorporation into the Leaders’ Statement. Accordingly, the Subcommittee on Standards and Conformance (SCSC) developed the following set of transparency standards for incorporation into the Leaders’ Statement.

These principles flow from the General Principles on Transparency agreed to by APEC Leaders at Los Cabos and the obligations of the WTO Agreements on Technical Barriers to Trade and on the Application of Sanitary and Phytosanitary Measures.

### Transparency Standards on Standards and Conformance

1. In accordance with paragraph 1 of the Leaders’ Statement, and the WTO Agreements on Technical Barriers to Trade (TBT) and on the Application of Sanitary and Phytosanitary (SPS) Measures, each Economy will:
  - (a) promptly publish or otherwise make available to all interested parties, through readily accessible, widely available media, for example via the Internet, information on its laws, regulations, policies, administrative rulings, certification, qualification and registration requirements, technical regulations, standards, guidelines, procedures and practices relating to standards and conformance; and,
  - (b) have or designate an official journal or journals and publish in them information on technical regulations, sanitary and phytosanitary measures and related conformity assessment procedures on a regular basis and make copies of them readily available to the public.
2. As far as practicable, each Economy will maintain one centrally located website for the information referred to above.
3. In accordance with paragraph 2 of the Leaders’ Statement and the WTO TBT and SPS Agreements, each Economy will publish in advance any standards or conformance requirement that it proposes to adopt and provide interested persons a reasonable opportunity to comment on such proposed measures and take those comments into account before a final measure is adopted. Each Economy that is a WTO member will notify proposals to the WTO as required by the TBT and SPS Agreements.
4. In accordance with paragraph 3 of the Leaders’ Statement, upon request from an interested person or another Economy, each Economy will endeavor to promptly provide information and respond to questions pertaining to any actual or proposed standards and conformance measure.
5. Recognizing that standards and conformance measures can have an adverse impact on trade and development, each Economy will ensure that such measures are developed and administered in a transparent manner, and in compliance with WTO TBT/SPS obligations, as well as the APEC Guidelines for the Preparation, Adoption and Review of Technical Regulations, and the APEC SCSC Principles and Features of Good Practice for Technical Regulations so as to prevent the creation of unnecessary or arbitrary barriers to trade.

6. Each Economy will promote awareness of and compliance with the transparency provisions of the WTO TBT and SPS Agreements.
7. Each Economy that is a WTO Member will cooperate in the Triennial Reviews of the TBT Agreement to promote awareness of and compliance with the transparency provisions of the TBT Agreement, the APEC Guidelines for the Preparation, Adoption and Review of Technical Regulations, and the APEC SCSC Principles and Features of Good Practice for Technical Regulations.
8. Each Economy will continue to provide updated information for the SCSC Contact List which is maintained on the APEC Secretariat's website and includes a range of contacts for each economy relevant to standards and conformance activities.
9. Each Economy will, as appropriate, promote the observance of these transparency standards by the regional and local governments, and non-governmental standardizing bodies within its territory.

## **E. Intellectual Property**

### **Introduction**

On 27 October 2002, in Los Cabos, Mexico, APEC Leaders adopted the Statement to Implement APEC Transparency Standards (“Leaders’ Statement”), and directed that these standards be implemented as soon as possible, and in no case later than January 2005.

In paragraph 8 of the Leaders’ Statement, APEC Leaders instructed that “APEC sub-fora that have not developed specific transparency provisions should do so,” and further instructed that such new transparency provisions should be presented to Leaders upon completion for incorporation into the Leaders’ Statement. Accordingly, the Intellectual Property Experts Group (IPEG) developed the following set of transparency standards on intellectual property for incorporation into the Leaders’ Statement.

These principles flow from the General Principles on Transparency agreed to by APEC Leaders at Los Cabos, and provide specific guidance for implementation within an intellectual property context.

### **Transparency Standards on Intellectual Property**

1. In accordance with paragraph 1 of the Leaders’ Statement, each Economy will promptly publish in its domestic language or otherwise make available its laws, regulations, and progressively, all procedures concerning the protection, including enforcement, of intellectual property rights in such a manner as to enable interested parties to become acquainted with them.
2. Furthermore, each Economy will clarify procedures and practices regarding application, issuance, and registration of intellectual property rights by publishing the following information:
  - (a) Clear and simple instructions, and an explanation of the steps involved regarding the application and registration process,
  - (b) Examination guidelines and assessment criteria used to review an application for approval, if applicable,
  - (c) Contact points for inquires on standards, technical regulations, and other requirements,
  - (d) Provisions that are directed to SMEs.
3. Each Economy will also provide a system for the registration of industrial property, which shall include:
  - (a) Providing to the applicant a communication in writing, which may be electronic, of the reasons for any refusal to register a trademark or grant a patent;
  - (b) Providing to the applicant an opportunity to respond to communications from the relevant government authorities, to contest an initial refusal, and to have a higher authority review any refusal to register a trademark or grant a patent;
  - (c) An opportunity for interested parties to petition to oppose or to challenge a trademark or patent application or to seek cancellation after a trademark has been registered or a patent has been granted; and
  - (d) A requirement that decisions in opposition or cancellation proceedings be reasoned and in writing.

4. Each Economy will provide that final judicial decisions or administrative rulings, those where appeals are no longer possible, of general applicability pertaining to the protection, including enforcement, of intellectual property rights shall be communicated to the parties to the proceedings. Each Economy will also provide for publication of such decisions or rulings, or where such publication is not practicable, made publicly available, in a domestic language in such a manner as to enable governments and rights holders to become acquainted with them.
5. In accordance with paragraph 2 of the Leaders' Statement, each Economy will, when possible, publish in advance any proposed changes to laws, regulations, and progressively, all procedures concerning the protection, including enforcement, of intellectual property rights, and provide where applicable interested persons a reasonable opportunity for public comment. Each Economy will also make available to all interested parties timely updates of changes to intellectual property law statutory regimes, including as appropriate via the APEC Secretariat.
6. In addition to paragraphs 3, 4, and 5 of the Leaders' Statement, each Economy will conduct as appropriate periodic reviews of administrative regulations, rules, and procedures to ensure they are simplified, consistent, and transparent. Outstanding issues raised by the reviews will be resolved where possible in a timely manner.
7. Where possible, each Economy will publish information on its efforts to provide effective enforcement of intellectual property rights in its civil, administrative and criminal system, including any statistical information that the Economy may collect for such purposes.
8. Each Economy will conduct regular briefings in appropriate fora to provide updates on the status of intellectual property protection and enforcement as well as future policy direction, if appropriate

### **Confidential information**

Nothing in the provisions of this statement shall require an Economy to disclose confidential information which would impede law enforcement or otherwise be contrary to the public interest or would prejudice the legitimate commercial interests of particular enterprises, public or private.

## **F. Customs Procedures**

### **Introduction**

On 27 October 2002, in Los Cabos, Mexico, APEC Leaders adopted the Statement to Implement APEC Transparency Standards (“Leaders’ Statement”), and directed that these standards be implemented as soon as possible, and in no case later than January 2005.

In paragraph 8 of the Leaders’ Statement, APEC Leaders instructed that “APEC sub-fora that have not developed specific transparency provisions should do so,” and further instructed that such new transparency provisions should be presented to Leaders upon completion for incorporation into the Leaders’ Statement. Accordingly, the United States proposes that the Sub-Committee on Customs Procedures develop the following set of transparency standards on customs for incorporation into the Leaders’ Statement.

The following customs transparency standards flow from, and are to be read consistently with, the General Principles on Transparency agreed to by APEC Leaders in Los Cabos, and provide specific guidance for implementation within the customs context.

### **Transparency Standards on Customs Procedures**

1. In furtherance of paragraph 1 of the Leaders’ Statement, each Economy, will promptly publish and make available on the Internet, information on its customs laws, regulations, procedures and administrative rulings of general application in such a manner as to enable interested persons to become acquainted with them.
2. In furtherance of paragraph 2 of the Leaders’ Statement, each Economy will, to the extent possible, publish in advance any regulations of general application governing customs procedures proposed for adoption, and provide a reasonable opportunity for comments from interested persons.

In furtherance of paragraph 4 of the Leaders’ Statement, and taking into account Economies’ individual circumstances, upon request from an interested person in its territory, each Economy wherever possible will provide for the issuance, of advance rulings based on specific facts and circumstances provided by such requester prior to the importation of a good into its territory, for areas such as:

- (a) tariff classification;
  - (b) the application of the provisions set forth in the WTO Agreement on Customs Valuation;
  - (c) the application of duty drawback;
  - (d) country of origin marking requirements;
  - (e) the application of rules of origin under free trade agreements and other preferential tariff regimes; and
  - (f) admissibility requirements.
4. Subject to domestic confidentiality requirements, each Economy, will make such advance rulings publicly available for purposes of ensuring application of the rulings to other goods where the facts and circumstances are the same as those under which the rulings are issued.

5. In furtherance of paragraph 5 of the Leaders' Statement, where warranted each Economy will maintain procedural transparency and fairness in customs procedures by:
  - (a) providing for the prompt review and correction of customs administrative actions;
  - (b) ensuring that importers are provided with the right to a level of administrative review independent of the employee or office issuing the determination subject to review; and
  - (c) maintaining the availability of judicial review of customs administrative determinations.
  
6. Each Economy will, maintain one or several contact points to which interested parties can address questions concerning customs matters, and shall make available on the Internet information concerning the procedures for making such inquires.

## **G. Market Access**

### **Introduction**

On 27 October 2002, in Los Cabos, Mexico, APEC Leaders adopted the Statement to Implement APEC Transparency Standards (“Leaders’ Statement”), and directed that these standards be implemented as soon as possible, and in no case later than January 2005.

In paragraph 8 of the Leaders’ Statement, APEC Leaders instructed that “APEC sub-fora that have not developed specific transparency provisions should do so,” and further instructed that such new transparency provisions should be presented to Leaders upon completion for incorporation into the Leaders’ Statement. Accordingly, the Market Access Group developed the following set of transparency standards on market access for incorporation into the Leaders’ Statement.

These principles flow from the General Principles on Transparency agreed to by APEC Leaders at Los Cabos, and provide specific guidance for implementation within a market access context.

### **Transparency Standards on Tariff and Non-Tariff Measures**

1. (a) In accordance with paragraph 1 of the Leaders’ Statement, each Economy will promptly publish or otherwise make available to all interested parties, through readily accessible, widely available media (for example via the Internet), information on its laws, regulations, and progressively, procedures and administrative rulings relating to tariff and non-tariff measures.
  - (b) Such information could include publication of the following measures:
    - (i) tariff schedules, with current applied tariff rates, on the Internet;
    - (ii) details of preferential tariff programs;
    - (iii) tariff rates applicable under Free Trade Agreements and Regional Trade Agreements; and
    - (iv) NTMs maintained by member economies.
2. In accordance with paragraph 2 of the Leaders’ Statement, when possible each Economy will endeavour to publish in advance any tariff or non-tariff measure that it proposes to adopt, and provide interested persons a reasonable opportunity to comment on such proposed measures.
3. In accordance with paragraph 3 of the Leaders’ Statement, upon request from an interested person or another Economy, each Economy will endeavour to promptly provide information and respond to questions pertaining to any actual or proposed measures referred to in paragraph 1 above.
4. Each Economy will endeavour to ensure that non-tariff measures are administered in a transparent manner, so as to mitigate their effect on the trade and development of other Economies.
5. Each Economy that is a WTO Member will, where possible, provide information on non-tariff measures when requested by other WTO Members in the context of the WTO negotiations on market access and will participate actively in these negotiations as they move forward.
6. Each Economy that is a WTO Member will comply with notification procedures under the WTO Agreement on Import Licensing Procedures.



7. Each Economy that is a WTO Member will submit its updated tariff data (both bound, and, where possible, current applied) and trade data to the WTO Integrated Data Base on a timely basis. Economies in the process of acceding to the WTO will, where possible, submit current applied tariff and trade data to the WTO Integrated Data Base. Each economy will also submit current applied tariff data to the APEC tariff database in a timely manner.
8. Each Economy will provide to the APEC Secretariat for inclusion on the website of the Market Access Group (MAG) links to individual government websites, including, where possible, links to specific officials responsible for developing, administering, implementing and/or enforcing policies related to tariff and non-tariff measures. Each Economy further agrees to provide current information on import regulations for the MAG's Import Regulation website. Each Economy will also provide as much information as possible on rules and procedures, and details of enquiry points, in its e-Individual Action Plan.

## H. Business Mobility

### Introduction

Since its inception, the APEC Business Mobility Group (BMG) has recognized that transparent and predictable business mobility procedures are essential to a stable and open trading regime. As a consequence many BMG initiatives have facilitated openness, transparency and information exchange in an effort to ensure that APEC members make immigration measures (new and amended, including those in international agreements) publicly available to all interested parties. Economies have provided up to date, information on rules and procedures governing temporary residency, processing standards and contact points in the *APEC Business Travel Handbook* and have shared information on immigration legislation, trade agreements, policies and technologies on the BMG web site.

On 27 October 2002, in Los Cabos, Mexico, APEC Leaders adopted the “Statement to Implement APEC Transparency Standards” (hereinafter referred to as the “Leaders’ Statement”), and directed that these standards be implemented as soon as possible, and in no case later than January 2005. In paragraph 8 APEC Leaders instructed that “APEC sub-fora that have not developed specific transparency provisions should do so,” and further instructed that such new transparency provisions should be presented to Leaders upon completion for incorporation into the Leaders’ Statement.

The following Business Mobility Standards relate to immigration laws, regulations, policies, administrative rulings, procedures and practices related to the temporary entry and stay of business persons, at the pre-arrival, entry, stay and departure phases.

### Transparency Standards on Business Mobility

#### **Publication and Access**

1. In accordance with paragraph 1 of the Leaders’ Statement, each Economy will promptly publish or otherwise make available to all interested parties, through readily accessible, widely available media, for example via the Internet, information on its immigration laws, regulations, policies, and progressively, administrative rulings of general application, procedures and practices as they relate to business persons, collectively referred to as “immigration measures”. Economies will ensure that immigration regulations and requirements based on policy are clear, concise, current, simple, transparent and readily available, and meet applicable Standards for Pre-Arrival and Entry and will:
  - (a) Provide user-friendly application forms, instructions and reference materials.

#### **Consultation**

2. In accordance with paragraph 2 of the Leaders’ Statement, each Economy will, when possible, publish in advance using the media and other mechanisms as appropriate proposed immigration measures that might affect business mobility and where applicable provide interested persons a reasonable opportunity to comment on such proposed measures. Such measures should include:
  - (a) A set of rules and regulations that provide sanctions for the production, sale and use of fraudulent documents;
  - (b) Effective rules and regulations that are precise in specifying what constitutes document fraud and what the sanctions are for producing, selling or using fraudulent documents; support inspectors, investigators and prosecutors in apprehending and taking action against fraudulent document producers, vendors and users; and promote business facilitation as well as protect the country’s inhabitants;

- (c) In respect to professional service, a comprehensive Code(s) of Conduct that sets out in very practical terms the behavior expected of all immigration officials, including employee's responsibilities, service policies and standards, clear guidance and practical examples, and that is developed in consultation with internal and external stakeholders as appropriate; and
- (d) Mechanisms for reporting or filing complaints on code of conduct breaches without fear of reprisal or prejudice.

### **Information Services**

- 3. In accordance with paragraph 3 of the Leaders' Statement, upon request from an interested person or another Economy, each Economy will endeavor when possible to promptly provide information and respond to questions pertaining to any actual or proposed immigration measures and will provide:
  - (a) Points of inquiry for business persons or businesses with questions;
  - (b) Simple, quick and user-friendly application processes with clear information and instructions on requirements relating to any exemptions, fees and charges;
  - (c) Information that is easily accessible to internal/external stakeholders (Customer Help Desks/Call Centres or Industry Consultative Committees, Internet, displays and signs); and
  - (d) Where appropriate, will provide mechanisms so that stakeholders' service charters are developed which clearly state the level of service they can expect, and are displayed in public areas such as airports, Immigration offices and overseas missions.

### **Decision Making**

- 4. In accordance with paragraph 4 of the Leaders' Statement, each Economy will ensure that immigration measures are administered in a transparent manner, including, wherever possible, reasonable notice in accordance with domestic procedure when a proceeding is initiated, and an opportunity to present facts and arguments in support of their positions, when time, the nature of the proceeding, and the public interest permit, and that the procedure is in accordance with domestic law. Economies shall
  - (a) Strive for transparency in decision-making that is based on an economy's prevailing employment and immigration policies and procedures and, where applicable, provide decisions that are in writing and denials that provide reasons based on requirements and information on any right of appeal or waivers;
  - (b) Strive for reasonable processing times for decision-making in an effort to avoid unnecessary delay or uncertainty on the part of business travelers;
  - (c) Ensure that decisions are consistent with published guidelines and requirements through regular quality control reviews;
  - (d) Ensure that employees are trained in decision-making procedures and have access to current written guidelines and instructions relating to interpretation of regulations and laws;
  - (e) Ensure that authority to make decisions includes appropriate checks and balances, and is strictly controlled to prevent abuse of power;

- (f) Provide periodic review mechanism of systems and procedures to ensure uniformity and consistency in decision making; reviews undertaken in consultation with employees to eliminate “red tape;”
- (g) Develop and implement mechanisms which monitor and evaluate the organization’s performance against established service standards;
- (h) To the extent possible, have a system in place for monitoring consistency between different offices, provinces or regions concerning decisions, procedures and information provided;
- (i) Where appropriate, clearly define and make publicly available the basis or criteria upon which discretionary power is exercised by officials; and
- (j) To the extent possible, convey reasons for decisions to applicants and document grounds for decisions clearly and retain these for monitoring and review.

**Review**

- 5. In accordance with paragraph 5 of the Leaders’ Statement and its own immigration laws, where warranted, each Economy will provide procedures that are simple, consistent, and easily accessible for review and appeal of immigration decisions and, where warranted, prompt correction of final administrative actions, regarding immigration measures which provide parties to the proceeding with a reasonable opportunity to present their respective positions, a decision based on the evidence and submissions in the administrative record, tribunals or panels that are impartial and independent of any office or authority entrusted with administrative enforcement and have no substantial interest in the outcome of the matter, and implementation of the final decision. To ensure transparent administrative regulations and decision-making, Immigration Administrations shall have
  - (a) To the extent possible, objective performance standards for managers to ensure compliance and accountability for the Standards on Professional Conduct;
  - (b) To the extent possible, guidelines and policies that clearly state management responsibilities in employee development and in the promotion and monitoring of ethical practices and integrity; and
  - (c) Selection criteria for managerial positions that include demonstrated ability to accept responsibility and accountability for implementation of the Standards on Professional Conduct.

## **I. Government Procurement**

### **Introduction**

The Government Procurement Experts Group (GPEG) was established in 1995 to consider ways to increase transparency of, and liberalise, government procurement markets in accordance with the goals of the Bogor Declaration. APEC identified and agreed a collective action plan for government procurement. A key component of the plan was to develop a set of non-binding principles on government procurement. This was in line with the APEC General Principle of flexibility, enunciated in the Osaka Action Agenda: "Considering the different levels of economic development among the APEC economies and the diverse circumstances in each economy, flexibility will be available in dealing with issues arising from such circumstances in the liberalisation and facilitation process".

In 1999 GPEG completed the Non-Binding Principles on Government Procurement (NBPs) that identify elements and illustrative practices on the principles of transparency, value for money, open and effective competition, fair dealing, accountability and due process, and non-discrimination. The NBPs have the support and commitment of all Economies and have been adopted as the basis of the Government Procurement section of APEC economies' annually revised Individual Action Plans recording progress towards the Bogor goals of free and open trade and investment.

The NBPs have been a major contributor to the success of Economies and GPEG in promoting transparency in government procurement. The majority of GPEG members have completed their voluntary reviews and reports of their government procurement systems against the non-binding principle of Transparency. Through this process, Economies are exploring how best to implement the principles and to voluntarily bring their systems into conformity with them. This general transparency principle applies to all aspects of government procurement, including the elements of the general operational environment, procurement opportunities, purchase requirements, bid evaluation criteria and award of contracts. Establishing and maintaining transparent procurement markets not only assists Economies to learn from each other but also enables industry to obtain a clear understanding of the procurement markets operating within member economies.

On 27 October 2002, in Los Cabos, Mexico, APEC Leaders adopted the "Statement to Implement APEC Transparency Standards" ("Leaders' Statement"), and directed that these standards be implemented as soon as possible, and in no case later than January 2005.

Paragraph 7 of the Leaders' Statement states that, consistent with the transparency standards in paragraphs 1-6 of the Leaders' Statement, Economies will follow the transparency provisions contained in the APEC Government Procurement Experts Group (GPEG) NBPs. In paragraph 8 of the Leaders' Statement, APEC Leaders instructed that "APEC sub-fora that have elaborated transparency provisions should review these regularly and, where appropriate, improve, revise or expand them further," and also instructed that such new transparency provisions should be presented to Leaders upon completion for incorporation into the Leaders' Statement. Ministers Responsible for Trade meeting in Khon Kaen on June 2-3 "instructed officials to complete work underway to develop area-specific Transparency Standards."

The Transparency Standards on Government Procurement, as set out below, are consistent with and fully reflect the General Principles in the Leaders' Statement and the transparency-related provisions of the NBPs. Implementation of both the Transparency Standards on Government Procurement and the NBPs will promote transparency in government procurement in the Asia-Pacific region.

### **Transparency Standards on Government Procurement**

Transparency in the government procurement context means that sufficient and relevant information should be made available to all interested parties consistently and in a timely manner through a readily accessible, widely available medium. This applies to all aspects of government procurement,

including the general operational environment, procurement opportunities, purchase requirements, bid evaluation criteria and award of contracts.

1. Consistent with paragraph 1 of the Leaders' Statement, each Economy will:
  - (a) ensure that its laws, regulations, and progressively judicial decisions, administrative rulings, policies (including any discriminatory or preferential treatment such as prohibitions against or set asides for certain categories of suppliers), procedures and practices (including procurement methods) related to government procurement (collectively referred to as "procurement rules") are promptly published or otherwise made available, for example, via the Internet, in such a manner as to enable interested persons and other Economies to become acquainted with them;
  - (b) designate an official journal or journals and publish the procurement rules in such journals on a regular basis and make copies of the journals readily available to the public (e.g., via the Internet); and
  - (c) promote observance of the provisions of this paragraph by the regional and local governments and authorities within its customs territory.
2. Each economy will disseminate information on its procurement rules, for example, by:
  - (a) publishing either a positive or negative list of the procuring entities subject to its rules; and
  - (b) providing a description of its procurement rules on the APEC Government Procurement Experts Group Home Page and linking its government procurement Home Page, where available, with the APEC Government Procurement Experts Group Home Page.
3. Consistent with paragraph 2 of the Leaders' Statement, when possible each Economy will publish in advance any procurement rules that it proposes to adopt; and provide, where applicable, interested persons a reasonable opportunity to comment on such proposed procurement rules.
4. Consistent with paragraph 3 of the Leaders' Statement, each Economy will endeavor upon request from an interested person or another Economy to promptly provide information and respond to questions pertaining to any actual or proposed rules. Each Economy will also establish contact points for such inquiries.
5. Consistent with paragraph 4 of the Leaders' Statement, in administrative proceedings applying to any procurement rule, each Economy will ensure that:
  - (a) wherever possible, persons of another Economy that are directly affected by a proceeding are provided reasonable notice, in accordance with domestic procedures, when a proceeding is initiated, including a description of the nature of the proceeding, a statement of the legal authority under which the proceeding is initiated and a general description of any issues in controversy;
  - (b) such persons are afforded a reasonable opportunity to present facts and arguments in support of their positions prior to any final administrative action, when time, the nature of the proceeding and the public interest permit; and
  - (c) its procedures are in accordance with domestic law.
6. Consistent with paragraph 5 of the Leaders' Statement, where warranted, each Economy will ensure that appropriate domestic procedures are in place to enable prompt review and

correction of final administrative actions, other than those taken for sensitive prudential reasons, regarding matters covered by these Standards, that:

- (a) provide for tribunals or panels that are impartial and independent of any office or authority entrusted with administrative enforcement and have no substantial interest in the outcome of the matter;
  - (b) provide parties to any proceeding with a reasonable opportunity to present their respective positions;
  - (c) provide parties to any proceeding with a decision based on the evidence and submissions of record or, where required by domestic law, the record compiled by the administrative authority; and
  - (d) ensure, subject to appeal or further review under domestic law, that such decisions are implemented by, and govern the practice of, the offices or authorities regarding the administrative action at issue.
7. Each Economy will endeavour to maximize transparency in access to procurement opportunities. This should be accomplished where possible by:
- (a) where open tendering is adopted, publishing procurement opportunities in a medium readily accessible to suppliers (e.g., on the Internet);
  - (b) making the same information on procurement opportunities available in a timely manner to all potential suppliers;
  - (c) publishing contact details of purchasers, and their product/ service purchase interests, for suppliers wishing to register their interest in being notified of bidding opportunities that may not be publicly advertised;
  - (d) making available early advice of complex high-value procurement needs through staged procedures such as public requests for information, requests for proposals and invitations for pre-qualification, and allowing adequate time for interested suppliers to prepare and submit a response;
  - (e) making publicly available requirements and procedures for pre-qualification of suppliers; and
  - (f) any time limits established for various stages of the procurement process.
8. Each Economy will make available for suppliers all the information required to prepare a responsive offer. This should include where possible:
- (a) providing in procurement notices the following information: the nature of the product or service to be procured; specifications; quantity, where known; time frame for delivery; closing times and dates; where to obtain tender documentation, where to submit bids, and contact details from which further information can be obtained;
  - (b) providing any changes to participating suppliers; and
  - (c) providing tender documentation and other information to suppliers promptly on request.

9. Each Economy will maintain transparent criteria for evaluating bids and evaluate bids and award contracts strictly according to these criteria. This should be done where possible by:
  - (a) specifying in procurement notices or tender documentation all evaluation criteria, including any preferential arrangements; and
  - (b) maintaining, for a predetermined period proper records of decisions sufficient to justify decisions taken in the procurement process.
10. Each Economy will award contracts in a transparent manner. This should be accomplished where possible by:
  - (a) publishing the outcome of the tender including the name of the successful supplier and the value of the bid; and
  - (b) as a minimum promptly notifying unsuccessful suppliers of the outcome of their bids and where and when contract award information is published, and debriefing unsuccessful suppliers on request.
11. Consistent with paragraph 11 of the Leaders' Statement, an Economy does not need to disclose confidential information where such disclosure would impede law enforcement, the enactment of laws, or that would be contrary to the public or national interest, or compromise security of the economy concerned or that would prejudice the legitimate commercial interests of particular persons or enterprises. Each economy will keep commercially sensitive information secure and prevent its use for personal gain by procurement officials or to prejudice fair, open and effective competition



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## APEC BUSINESS ADVISORY COUNCIL 2004

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### REPORT TO APEC ECONOMIC LEADERS 2004 BRIDGING THE PACIFIC: COPING WITH THE CHALLENGES OF GLOBALIZATION

#### EXECUTIVE SUMMARY

ABAC is encouraged by this year's brighter global economic picture, which gives the region the opportunity to move aggressively on measures to promote economic growth and prosperity. While ABAC anticipates stronger growth in the APEC region, there are continued risks and uncertainties with regard to global trade and investment.

In the 2004 ABAC Report, ABAC urges APEC Economic Leaders to take prompt and decisive action to promote global and regional free trade, ensure the growth of financial markets that underpin economic growth, and secure economic stability in all economies. ABAC's theme in 2004 is "**Bridging the Pacific: Coping with the Challenges of Globalization.**" In this report, ABAC makes recommendations to APEC Leaders in six key issue areas, as follows:

1. ABAC applauds the significant breakthrough achieved by the World Trade Organization (WTO) members on 31 July 2004 in approving a framework and other agreements that are considered the foundation for the continued negotiation in the Doha Round. It urges APEC economies to continue to work together to achieve an early and substantive outcome to the Doha Development Agenda. ABAC recommends that economies:
  - Present a collective approach to advance the WTO negotiations on agriculture involving improved market access through the reduction of tariffs, elimination of export subsidies and substantial reduction in trade distorting domestic support.
  - Develop a specific tariff reduction formula with comprehensive coverage for non-agricultural market access (NAMA), which should fully respect the Doha mandate.
  - Move quickly to table services offers in advance of the new May 2005 Doha Development Agenda deadline to bring balance to the negotiations, focusing on priority areas within the services negotiations including financial services, movement of natural persons, and recognition and regulation of professional standards.
  - Support revisions to the WTO Anti-Dumping Agreement to clarify and improve the rules and disciplines on anti-dumping.
  - Leverage APEC's trade facilitation agenda to bring definition to the WTO negotiations on trade facilitation with a view to concluding a comprehensive and binding agreement and ensuring capacity building assistance continues to be provided to WTO developing members. Support of initiatives, like the Trade Facilitation Alliance, is important to encourage the participation of businesses within the region.
2. The Bogor Goals are the cornerstone of APEC's trade and investment liberalization and facilitation agenda. This commitment has been constantly reaffirmed by the APEC Leaders. Yet it appears increasingly unlikely that the 2010 deadline set for developed economies to achieve the Bogor Goals of free and open trade and investment will be met. This is a major

concern to ABAC since it goes to the heart of APEC's credibility as a regional economic cooperation forum. ABAC recommends that economies:

- Ensure that regional trading arrangements (RTAs)/free trade agreements (FTAs) serve as 'building blocks' toward the achievement of the Bogor Goals by developing and adopting Best Practices for RTAs/FTAs in the APEC region with key principles, including consistency with WTO rules and procedures, with the Bogor Goals, and with other APEC principles such as those that apply to competition, regulatory reform, investment, government procurement and trade facilitation. To this end, establish public/private sectoral advisory groups to help develop best practices approach to RTAs/FTAs, beginning with the financial services sector.
  - Expand on the proposal for an integrated regional market by undertaking a joint scoping study with a view to launching, by the 2005 APEC Leaders Summit, an ambitious new Trans-Pacific Business Agenda.
  - Agree in Santiago in 2004 to further examine the feasibility and potential scope and features of a Free Trade Area of the Asia-Pacific (FTAAP). This process could be conducted by a high-level task force, which should be fully representative of APEC economies, and include government representatives as well as business and academic experts. Its task would be to examine the FTAAP concept in more detail with a view to presenting a report to APEC Leaders in 2005, taking into account the results of APEC's mid-term review and on-going progress in the WTO negotiations.
3. The new security environment has complicated progress on the trade facilitation action plan and brought additional costs to businesses in the APEC region. Security compliance costs risk jeopardizing APEC's commitment to reduce trade transaction costs by five percent by 2006. ABAC recommends that economies:
- Adopt a range of specific measures aimed at reaching the target of a five percent reduction in transaction costs, including streamlining of customs procedures, strengthening standards and conformance infrastructure, and expanding the APEC Business Travel Card scheme.
  - Balance trade and security requirements through consultation and information sharing with the business community on the application of new security requirements. Cooperate to provide technical assistance to assist developing economies with security compliance.
  - Facilitate investment by strengthening cooperation among enforcement agencies in protecting intellectual property rights, developing a robust economic legal infrastructure, adopting a common accounting framework, and enhancing transparency in investment regulations.
  - Support the development of the APEC Privacy Framework and encourage its adoption and implementation by all member economies.
4. The improved global economic outlook presents an excellent opportunity to strengthen the financial systems that support economic growth by accelerating reforms; helping vulnerable economies in APEC deal with potential adverse implications of volatile capital movements; securing a better understanding of what each economy needs to do to deepen capital markets; developing effective public/private partnerships to improve financial system security, governance and combat corruption; and, given the recent breakthrough in the WTO, taking major initiatives to promote financial services liberalization. While significant progress has been made in capacity building to improve financial standards and to address capital market issues, more work is needed. ABAC recommends that economies:

- Strengthen financial systems by increasing the capacities and resources of regulatory agencies to support the implementation of Basel 2 standards on capital adequacy in banking; endorsing the conclusions and recommendations of the report of the ABAC/PECC bond market conference and assisting economies to make self-assessments on progress; endorsing new international financial reporting standards and measures for the orderly convergence to those standards in member economies; implementing recommendations by the International Institute of Finance (IIF), Bank for International Settlements (BIS) and Financial Stability Forum (FSF) on policies to mitigate against adverse consequences arising from volatile capital flows and the activities of hedge funds and highly leveraged institutions; and endorsing IIF recommendations on corporate governance.
  - Improve financial system security by deepening the consultative processes between public agencies and regional and international bodies with private sector finance groups to build awareness and develop policies, laws and regulations to combat terrorist funding, corruption, and money laundering arrangements.
  - Support the role and objectives of the Advisory Group on APEC Financial System Capacity Building, and provide funding for the training of relevant officials to participate in APEC sponsored financial sector capacity building initiatives.
  - Establish a new APEC Ministerial Committee on Regional Technical Cooperation as recommended in ABAC's mid-term assessment of APEC.
5. Capacity building in the APEC region is essential to fulfilling the Bogor Goals, and must be conducted at the institutional, organizational and human level in order to succeed. As such, APEC economies must work together to address critical capacity building needs at all of these levels. ABAC recommends that economies:
- Enhance collaboration between health and trade negotiation delegations within APEC and encourage interaction between the APEC Trade Ministerial and Health Ministerial processes. Encourage APEC economies' health authorities to take a more proactive and strategic approach to ensure early consideration of public health issues as they relate to trade.
  - Enhance capacity building efforts in the area of standards and conformance, including undertaking independent assessments of standards and conformance infrastructure in each APEC economy to identify weaknesses and plan actions to rectify them and develop APEC-wide seminars to promote the business case for the establishment of a standards and conformance regime across the region. Provide other capacity building programs to ensure greater participation in international standards setting organizations.
  - Identify bottlenecks in regional supply chains associated with gaps in cross-border logistics infrastructure. Enhance the capability of logistics infrastructure to resist, respond, and recover from acts of terrorism and piracy; such efforts could include development of coordinated vessel and cargo monitoring systems in the APEC region.
  - Promote cooperation among enforcement agencies to protect intellectual property rights, including developing practical measures to share information, helping economies address new and emerging forms of intellectual property (IP)-related crimes, and increasing cross-border collaboration.
  - Strengthen capacity building efforts to support SMEs in the services sector, including providing technical assistance to APEC developing economies on services exporting, building regional best practices networks to support SME services trade, and addressing barriers to SME services exporters within WTO and APEC.

- Support the development of an APEC Business Schools Network (ABSN), which would aim to build partnerships among these institutions and promote English as the regional medium of business.
6. Given the changing landscape in the region, APEC must strengthen its efforts and strategies to remain relevant and effective. Above all, APEC must commit to the notion fundamental to and enshrined in the Bogor Goals, of “concerted” implementation of the trade and investment reform agenda.

APEC must strengthen its mechanism to ensure a higher level of implementation of APEC initiatives. ABAC offers a number of specific proposals for intensified implementation of APEC commitments set out in detail in the report. These include action with respect to Anti-Corruption in Government Procurement, the APEC Non-Binding Investment Principles, liberalization of air transportation cargo, the Digital Economy Statement, energy security, and environmental protection.

## ABBREVIATIONS

ABAC	APEC Business Advisory Council
ABSN	APEC Business Schools' Network
ACC	APEC Climate Center
ACEC	APEC Cyber Education Cooperation
ADB	Asian Development Bank
ADOC	APEC Digital Opportunity Center
AEF	APEC Education Foundation
AEMM	APEC Education Ministerial Meeting
AFDP	APEC Finance and Development Program
AICST	APEC International Centre for Sustainable Tourism
AIDS	Acquired Immune Deficiency Syndrome
A-IMBN	Asia-Pacific International Molecular Biology Network
AMM	APEC Ministers' Meeting
APCN	APEC Climate Network
APEC	Asia Pacific Economic Cooperation
APERC	Asia Pacific Energy Research Center
API	Advance Passenger Information systems
ASEAN	Association of Southeast Asian Nations
BIS	Bank for International Settlements
BMG	Business Mobility Group
CAPERS	Customs Asia-Pacific Enforcement Reporting System
CAPs	Collective Action Plans
CERTs	Computer Emergency Response Teams
CTAG	Counter-Terrorism Action Group
CTI	Committee on Trade and Investment
CTTF	Counter-terrorism Task Force
DDA	Doha Development Agenda
ECOTECH	Economic and Technical Cooperation
EDNET	Education Network
EDTF	Expanded Dialogue on Trade Facilitation
eIMBL	Electronic International Molecular Biology Laboratory
EIR	Extractive Industries Review
ESC	SOM Committee on ECOTECH
EU	European Union
EWG	Energy Working Group
FATF	Financial Action Task Force
FMM	Finance Ministers' Meeting
FRTFSI	Fund for Regional Trade and Financial Security Initiative (by ADB)
FSF	Financial Stability Forum
FTAAP	Free Trade Area of the Asia-Pacific
FTAs	Free Trade Agreements
GCG	Global Cooperation Group
GDLN	Global Development Learning Network
GEMEED	Group on Minerals and Energy Exploration and Development
GEO	Group on Earth Observations
GEOSS	Global Earth Observation System of Systems
GHS	Globally Harmonized System
GPEG	Government Procurement Experts Group
HIV	Human Immunodeficiency Virus
HRDWG	Human Resources Development Working Group
HTF	Health Task Force
IAPs	Individual Action Plans
IAS	Invasive Alien Species

ICAO	International Civil Aviation Organization
ICH	International Conference on Harmonization
IDB	Inter-American Development Bank
IFI	International Financial Institutions
ILO	International Labour Organization
IMO	International Maritime Organization
ISPS	International Ship and Port Facility Security
ISTWG	Industrial Science and Technology Working Group
JETRO	Japan External Trade Organization
LAISR	Leaders' Agenda to Implement Structural Reform
LNG	Liquefied Natural Gas
MAG	Market Access Group
MEs	Micro-Enterprises
MESG	Micro-Enterprise Sub Group
MRTD	Machine Readable Travel Documents
NAMA	Non-Agricultural Market Access
NBPs	Non-Binding Principles
OAA	Osaka Action Plan
PECC	Pacific Economic Cooperation Council
PIF	Pacific Islands Forum
R&D	Research and Development
REACH	Registration, Evaluation, Authorisation of Chemicals (New Chemicals Policy)
RMAL	Regional Movement Alert List System
ROOs	Rules of Origin
ROSCs	Reports on the Observance of Standards and Codes
RTAs	Regional Trading Arrangements
S&T	Science and Technology
SARS	Severe Acute Respiratory Syndrome
SCSC	Subcommittee on Standards and Conformance
SELI	Strengthening Economic Legal Infrastructure
SMEs	Small and Medium Enterprises
SMESA	SME Service Alliance Forum
SOM	Senior Officials' Meeting
SPS	Application of Sanitary and Phytosanitary
SSN-CBN	Social Safety Nets – Capacity Building Network's
STAR	Secure Trade in the APEC Region
TBT	Technical Barriers to Trade
TEL	Telecommunications and Information Working Group
TFAP	Trade Facilitation Action Plan
TILF	Trade and Investment Liberalization and Facilitation
TPD	Trade Policy Dialogue
TPT-WG	Transportation Working Group
TWG	Tourism Working Group
UNCAC	United Nations Convention Against Corruption
UNICEF	United Nations International Children's Emergency Fund (now United Nations Children's Fund)
WCO	World Customs Organization
WHO	World Health Organisation
WIPO	World Intellectual Property Organization
WLN	Women Leaders Network
WSIS	World Summit on the Information Society
WTO	World Trade Organization

# KEY APEC DOCUMENTS 2004

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## ADDITIONAL DOCUMENTS

Policy/Strategy papers referred to in Leaders' and Ministerial Statements



## **BEST PRACTICE FOR RTAS/FTAS IN APEC<sup>1</sup>**

RTAs/FTAs involving APEC economies can best support the achievement of the APEC Bogor Goals by having the following characteristics:

### **Consistency with APEC Principles and Goals**

- They address the relevant areas in Part I (Liberalization and Facilitation) of the Osaka Action Agenda (OAA) and they are consistent with its General Principles. In this way they help to ensure that APEC accomplishes the free trade and investment goals set out in the 1994 Bogor Leaders Declaration.
- They build upon work being undertaken by APEC.
- Consistent with APEC goals, they promote structural reform among the parties through the implementation of transparent, open and non-discriminatory regulatory frameworks and decision-making processes.

### **Consistency with the WTO**

- They are fully consistent with the disciplines of the WTO, especially those contained in Article XXIV of the GATT and Article V of the GATS.
- When they involve developing economies to whom the Enabling Clause applies, they are, whenever possible, consistent with Article XXIV of the GATT and Article V of the GATS.

### **Go beyond WTO commitments**

- In areas that are covered by the WTO, they build upon existing WTO obligations. They also explore commitments related to trade and investment in areas not covered, or only partly covered, by the WTO. By so doing, APEC economies are in a better position to provide leadership in any future WTO negotiations on these issues.

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<sup>1</sup> Regional Trade Arrangements (RTAs), Free Trade Agreements (FTAs), and other Preferential Arrangements

### **Comprehensiveness**

- They deliver the maximum economic benefits to the parties by being comprehensive in scope, and providing for liberalization in all sectors. They therefore eliminate barriers to trade and investment between the Parties, including tariffs and non-tariff measures, and barriers to trade in services.
- Phase-out periods for tariffs and quotas in sensitive sectors are kept to a minimum, and take into account the different levels of development among the parties. Thus, they are seen as an opportunity to undertake liberalization in all sectors as a first step towards multilateral liberalization at a later stage.

### **Transparency**

- By making the texts of RTAs/FTAs, including any annexes or schedules, readily available, the Parties ensure that business is in the best position to understand and take advantage of liberalized trade conditions. Once they have been signed, agreements are made public, in English wherever possible, through official websites as well as through the APEC Secretariat website.
- Member economies notify and report their new and existing agreements in line with WTO obligations and procedures.

### **Trade Facilitation**

- Recognizing that regulatory and administrative requirements and processes can constitute significant barriers to trade, they include practical measures and cooperative efforts to facilitate trade and reduce transaction costs for business consistent with relevant WTO provisions and APEC principles.

### **Mechanisms for consultation and dispute settlement**

- Recognizing that disputes over implementation of RTAs/FTAs can be costly and can raise uncertainty for business, they include proper mechanisms to prevent and resolve disagreements in an expeditious manner, such as through consultation, mediation or arbitration, avoiding duplication with the WTO dispute settlement mechanism where appropriate.

### **Simple Rules of Origin that facilitate trade**

- To avoid the possibility of high compliance costs for business, Rules of Origin (ROOs) are easy to understand and to comply with. Wherever possible, an economy's ROOs are consistent across all of its FTAs and RTAs.
- They recognize the increasingly globalized nature of production and the achievements of APEC in promoting regional economic integration by adopting ROOs that maximize trade creation and minimize trade distortion.

### **Cooperation**

- They include commitments on economic and technical cooperation in the relevant areas reflected in Part II of the OAA by providing scope for the parties to exchange views and develop common understandings in which future interaction will help ensure these agreements have maximum utility and benefit to all parties.

### **Sustainable Development**

- Reflecting the inter-dependent and mutually supportive linkages between the three pillars of sustainable development – economic development, social development and environmental protection – of which trade is an integral component, they reinforce the objectives of sustainable development.

### **Accession of Third Parties**

- Consistent with APEC's philosophy of open regionalism and as a way to contribute to the momentum for liberalization throughout the APEC region, they are open to the possibility for accession of third parties on negotiated terms and conditions.

### **Provision for periodic review**

- They allow for periodic review to ensure full implementation of the terms of the agreement and to ensure the terms continue to provide the maximum possible economic benefit to the parties in the face of changing economic circumstances and trade and investment flows. Periodic review helps to maintain the momentum for domestic reform and further liberalization by addressing areas that may not have been considered during the original negotiations, promoting deeper liberalization and introducing more sophisticated mechanisms for cooperation as the economies of the Parties become more integrated.

## **APEC COURSE OF ACTION ON FIGHTING CORRUPTION AND ENSURING TRANSPARENCY**

On 25–26 September, APEC government officials and senior experts met in Santiago to outline key recommendations to pursue the fight against corruption with a view to implement, synergize, and coordinate our efforts in adopting actions contained in the United Nations Convention Against Corruption (UNCAC) and other multilateral frameworks to fight corruption and ensure transparency, including the APEC Transparency Standards.

We reaffirm our commitment to cooperate in APEC to implement concrete actions to fight corruption and ensure transparency and accountability in the proper management of public affairs and public property, and we hereby agree to the following actions, where appropriate and within the means of each economy and in accordance with the fundamental principles of each economy's legal system:

### **I. Take All Appropriate Steps Towards Ratification of, or Accession to, and Implementation of the UNCAC\*:**

- Intensify our efforts to combat corruption and other unethical practices, strengthen a culture of transparency, ensure more efficient public management, and complete all appropriate steps to ratify or accede to, and implement the UNCAC.
- Develop training and capacity building efforts to help on the effective implementation of the UNCAC's provisions for fighting corruption.
- Work to strengthen international cooperation in preventing and combating corruption as called for in the UNCAC including extradition, mutual legal assistance, the recovery and return of proceeds of corruption.

### **II. Strengthen Measures to Effectively Prevent and Fight Corruption and Ensure Transparency by Recommending and Assisting Member Economies to:**

- Establish objective and transparent criteria that assure openness for merit, equity, efficiency for the recruitment of civil servants, and promote the highest levels of competence and integrity.
- Adopt all necessary measures to enhance the transparency of public administration, particularly with regard to organization, functioning and decision-making processes.
- Develop and implement appropriate public financial disclosure mechanisms or codes of conduct for senior-level public officials.
- Institute effective government measures aimed at preventing corruption and ensuring transparency, including the implementation of the APEC Leaders Transparency Standards in all areas endorsed by Leaders:
  - Government Procurement
  - Services
  - Investment
  - Competition Policy and Regulatory Reform
  - Standards and Conformance
  - Intellectual Property

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\* APEC member economies that are not members of the United Nations will positively consider and make efforts to achieve the measures, practices, and goals set out by the UNCAC through ways consistent with their respective status.

- Market Access
  - Customs Procedures
  - Business Mobility
- Afford one another the widest measure of mutual legal assistance, in investigations, prosecutions and judicial proceedings related to corruption and other offences covered by the UNCAC.
  - Designate appropriate authorities in each economy, with comparable powers on fighting corruption, to include cooperation among judicial and law enforcement agencies and seek to establish a functioning regional network of such authorities.

### **III. Deny Safe Haven to Officials and Individuals Guilty of Public Corruption**

- Promote cooperation among financial intelligence units of APEC members including, where appropriate, through existing institutional mechanisms.
- Encourage each economy to promulgate rules to deny entry and safe haven, when appropriate, to Officials and individuals guilty of public corruption, those who corrupt them, and their assets.
- Implement, as appropriate, the revised Financial Action Task Force (FATF) 40 Recommendations and FATF's Special Recommendations on Terrorist Financing.
- Work cooperatively, within the means of each economy, using mechanisms in the UNCAC, FATF, or other international initiatives and in accordance with domestic law, to investigate and prosecute corruption offenses and to trace, freeze, and recover the proceeds of corruption.

### **IV. Fight both Public and Private Sector Corruption**

- Develop effective actions to fight all forms of bribery, taking into account the OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions or other relevant anticorruption conventions or initiatives.
- Adopt and encourage measures to prevent corruption by improving accounting, inspecting, and auditing standards in both the public and private sectors in accordance with provisions of the UNCAC.
- Support the recommendations of the APEC Business Advisory Council (ABAC) to operate their business affairs with the highest level of integrity and to implement effective anticorruption measures in their businesses, wherever they operate.

### **V. Public-Private Partnerships**

- Involve, in accordance with each economy's domestic law, individuals and groups outside the public sector, such as civil society, nongovernmental organizations, community-based organizations, and the private sector in efforts to fight corruption, ensure transparency, promote good governance, strengthen public financial management accountability systems, and advance the rule of law.

### **VI. Cooperation Among APEC Member Economies to Combat Corruption and Ensure Transparency in the Region**

- Work together and intensify actions to fight corruption and ensure transparency in APEC, especially by means of cooperation and the exchange of information, to

promote implementation strategies for existing anticorruption and transparency commitments adopted by our governments, and to coordinate work across all relevant groups within APEC (e.g., SOM, CTI, GPEG, SCCP, and IEGBM).

- Coordinate, where appropriate, with other anticorruption and transparency initiatives including the UNCAC, OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions, FATF, the ADB/OECD Anticorruption Action Plan for the Asia Pacific region, and Inter-American Convention Against Corruption.
- Recommend closer APEC cooperation, where appropriate, with the OECD including a joint APEC-OECD seminar on anticorruption, and similarly to explore joint partnerships, seminars, and workshops with the UN, ADB, OAS, the World Bank, the Global Forum on Fighting Corruption and Safeguarding Integrity, and other appropriate multilateral intergovernmental organizations.
- Initiate and develop innovative, coordinated and targeted training and capacity building tools (e.g., an APEC Anticorruption and Transparency Training (ACT) Program), a region-wide public outreach program, or other initiatives that provide regional technical expertise and raise awareness).
- Encourage all relevant economies to sign bilateral and multilateral agreements that will provide for assistance and cooperation in areas covered by the UNCAC.

## **VII. From Santiago to Seoul**

- In 2005, establish an Experts' Task Force to serve in an advisory role to APEC Senior Officials. The terms of reference for the task force shall be developed for approval by SOM I in 2005, outlining a more concrete roadmap for accelerating the implementation and tracking the progress made of our commitments to fight corruption and ensure transparency:
  - Strengthen and further refine the APEC course of action adopted in the Santiago Commitment to Fight Corruption and Ensure Transparency towards effective implementation and monitoring by all APEC economies.
  - Encourage APEC Member Economies, where appropriate, to put into practice measures and mechanisms outlined in the UNCAC.
  - Help implement the APEC Transparency Standards by 2005 into domestic legal regimes.
  - Recommend any additional actions to fight corruption and ensure transparency, including further areas related to corruption involving the private sector and denying them of their safe haven.
  - Develop specific benchmarks to help ensure that each APEC Member Economy is taking all appropriate steps and measures to implement agreed upon commitments.
  - Organize an APEC Anticorruption and Transparency Symposium in Korea in 2005 to showcase the progress that APEC economies have done to fight corruption and ensure transparency and discuss further cooperation on any additional actions that need to be built into the APEC work program.

## **APEC Guidelines on Controls and Security of Man-Portable Air Defense Systems (MANPADS)**

APEC Leaders agreed in October 2003 to strengthen joint efforts to curb terrorist threats against mass transportation and confront the threat posed by terrorists' acquisition and use of man-portable air defense systems (MANPADS) against international aviation. In furtherance of this effort, APEC economies have agreed to adhere individually to the following guidelines for export control and security of MANPADS, and exchange information, when and as appropriate, in support of the efforts.

### **1. Scope**

MANPADS are defined as: surface-to-air missile systems designed to be man-portable and carried and fired by a single individual or individuals.

MANPADS controlled under these guidelines refer to complete systems, components, spare parts, models, training systems, and simulators, for any purpose, by any means, including licensed export, sale, grant, loan, lease, co-production or licensing arrangement for production (hereafter "export"). The scope of control regulations apply to research, design, development, engineering, manufacture, production, assembly, testing, repair, maintenance, servicing, modification, upgrade, modernisation, operation, use, replacement or refurbishment, demilitarisation, and destruction of MANPADS; technical data, software, technical assistance, demonstration, and training associated with these functions; and secure transportation, storage. This scope according to domestic legislation may also refer to investment, marketing, advertising and other related activity.

Any activity related to MANPADS within the territory of the producing economy is subject to domestic laws and regulations.

### **2. Domestic Control Measures**

Domestic measures designed to attain the requisite control and security include, but are not limited to, the following set of practices, or others that will achieve comparable levels of protection and accountability:

- When receiving MANPADS, written verification of receipt of MANPADS shipments.
- Inventory by serial number of the initial shipments of all transferred firing mechanisms and missiles, if physically possible; and maintenance of written records of inventories.
- Physical inventory of all MANPADS subject to transfer, at least once a month; account by serial number for MANPADS components expended or damaged during peacetime.

- Ensure storage conditions are sufficient to provide for the highest standards of security and access control. These may include:
  - a. Where the design of MANPADS permits, storing missiles and firing mechanisms in locations sufficiently separate so that a penetration of the security at one site will not place the second site at risk.
  - b. Ensuring continuous (24-hour per day) surveillance.
  - c. Establishing safeguards under which entry to storage sites requires the presence of at least two authorized persons.
- Transport MANPADS in a manner that provides for the highest standards and practices for safeguarding sensitive munitions in transit. When possible, transport missiles and firing mechanisms in separate containers.
- Where applicable, bring together and assemble the principal components - typically the gripstock and the missile in a launch tube - only in the event of hostilities or imminent hostilities; for firing as part of regularly scheduled training, or for lot testing, for which only those rounds intended to be fired will be withdrawn from storage and assembled; when systems are deployed as part of the point defenses of high priority installations or sites; and in any other circumstances which might be agreed between the receiving and transferring economies.
- Access to hardware and any related classified information will be limited to military and civilian personnel of the receiving economy who have the proper security clearance and who have an established need to know the information in order to perform their duties. Any information released will be limited to that necessary to perform assigned responsibilities and, where possible, will be oral and visual only.
- Adopt prudent stockpile management practices that include effective and secure disposal or destruction of MANPADS stocks that are or become excess to domestic requirements.

### **3. Export Control Conditions and Evaluation Criteria**

Decisions to permit MANPADS exports will be made by the exporting economy by competent authorities at senior policy level and only to foreign economies or to agents specifically authorized to act on behalf of an economy after presentation of an official End-User Certificate (EUC) certified by the receiving economy.

General licences are inapplicable for exports of MANPADS; each transfer is subject to an individual licensing decision.

Exporting economies will not make use of non-governmental brokers or brokering services when transferring MANPADS, unless specifically authorized to on behalf of the economy.



In order to authorise MANPADS exports, both exporting and importing economies will take into account:

- The need to protect against potential for diversion or misuse in economies;
- The need to ensure appropriate measures to protect against unauthorized re-transfers, loss, theft and diversion; and
- The need to ensure adequate and effective physical security arrangements for the protection of military property, facilities, holdings, and inventories.

Prior to authorizing MANPADS exports, the exporting economy will assure itself of the recipient economy's guarantees:

- not to re-export MANPADS except with the prior consent of the exporting economy;
- to afford requisite security to classified material and information in accordance with applicable bilateral agreements, to prevent unauthorized access or compromise;
- to inform promptly the exporting economy of any instance of compromise, unauthorized use, loss, or theft of any MANPADS material.

In addition, the exporting economy will satisfy itself of the recipient economy's willingness and ability to implement effective measures for secure storage, handling, transportation, use of MANPADS material, and disposal or destruction of excess stocks to prevent unauthorized access and use. The recipient economy's domestic procedures designed to attain the requisite security include, but are not limited to, the above set of practices mentioned in paragraph 2, or others that will achieve comparable levels of protection and accountability:

## **APEC Key Elements for Effective Export Control Systems**

Recognizing that:

Transnational terrorism and the proliferation of weapons of mass destruction and their means of delivery pose direct and profound challenges to APEC's vision of free, open and prosperous economies;

APEC leaders committed in October 2003 in Bangkok to eliminate the severe and growing danger posed by the proliferation of weapons of mass destruction and their means of delivery by adopting and enforcing effective export controls;

Effective export controls not only help prevent proliferation and terrorism but also facilitate and protect legitimate trade;

International cooperation, including through effective collaboration, technical assistance and capacity building, and cooperation between relevant international, regional and functional organizations, is essential to create an effective global export control system to prevent proliferation and terrorism and that such a system requires all responsible economies to adopt and implement effective export control systems;

APEC Ministers have adopted the following set of export control best practices and agreed to use it as a reference for individual actions to strengthen export control systems, and to work together to increase capacity in export controls in APEC in future years.

## **1. Legal and Regulatory Framework**

Comprehensive export control laws and regulations that control transfers of items, technology, and related services.

Laws and regulations that control technology in both tangible (blueprints, for example) and intangible (e-mails and verbal communications, for example) forms.

Controls that extend to items that are transiting or being transshipped through an economy.

Controls on foreign-origin items re-exported from an economy.

Controls on items temporarily transferred to another economy -- including commercial trade show demonstrations and equipment transfers to foreign-owned holdings.

Controls on arms brokering and other intermediary activities.

Comprehensive control lists and practices in harmony with the guidelines and control lists of the multilateral nonproliferation regimes, instruments and arrangements.

Controls on transfers of unlisted items, services, and technologies of potential concern, if the transfers are intended for programs involved in weapons of mass destruction, their delivery systems, or conventional weapons ("catch-all" controls).

Legal authorities that permit denial of licenses without excessive threat of appeal or demand for compensation by trade companies.

Criminal and civil penalties, including imprisonment, fines, and restriction or denial of trading privileges, and publicity of such actions, to deter and prevent future violations.

Provisions that protect the confidentiality of commercial information, while permitting information-sharing with other governments to enhance international efforts against proliferation.

## **2. Licensing Procedures and Practices**

Effective and transparent licensing organizations and processes to ensure adequate review of license applications for nonproliferation reasons.

Procedures, databases, and watch lists for evaluating parties involved in transfers, paying particular attention to those considered to be suspicious, unreliable, or presenting a high risk of diversion.

Processes to ensure that technical experts, intelligence experts, and policy officials from all legally entitled government agencies have the knowledge and opportunity to evaluate license applications for proliferation concerns.

Procedures to confirm, as appropriate, the legitimacy of stated end-users and end-uses.

Procedures to confirm, as appropriate, that licensed items have reached their stated end-users and are being used for their stated end-use.

### **3. Enforcement, Investigation, and Prosecution**

Policies, laws, and regulations to provide enforcement agencies the mission, authority, training, and resources necessary to detect, identify, and stop transfers that violate export control laws and regulations, as well as to investigate and prosecute export control violators.

Legal authorities to permit routine, advance review of detailed manifest data to analyze for suspicious transfers.

Procedures to apply risk management and targeting strategies, using trade information and intelligence, to detect suspect transfers and to minimize impediments to legitimate trade.

Effective cooperation among policy officials, enforcement agencies, licensing officials, technical experts, and intelligence agencies to establish whether specific transfers involve items or transactions that are controlled or are contrary to member economies' interests.

Cooperation among agencies responsible for export controls, including those responsible for licensing, investigation, and prosecution to ensure that laws are enforced effectively.

Use of inspection techniques and equipment to identify potential transfers of proliferation concern.

### **4. Industry Outreach**

Effective outreach to raise the awareness of companies and commercial individuals, universities, and centers of research and development -- including conventions and trade shows -- about their responsibilities under the economy's export control system, including penalties for violations.

Strong relationships with industry to identify suspect sales and deliveries.

Efforts to encourage industry to develop internal compliance practices that incorporate checks on end-users and end-uses of concern.

## APEC LIFE SCIENCES INNOVATION FORUM STRATEGIC PLAN

November 2004

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## Message to Leaders

APEC members face challenges to their healthcare systems and to ensuring public health as never before. We recognize that improving the health of our population involves early detection, prevention and innovation at many levels. Technological advances and continuing innovation in the life sciences sector offer hope, and a real opportunity to advance public health, while promoting economic productivity and development. The APEC region is poised to take a leadership role in developing a model for regional cooperation to promote and support bio-medical life sciences innovation to stimulate economic growth and improve the quality of life for its people.

Recognizing the potential of life sciences innovation as a new driver of economic growth and a potent contributor to socio-economic well being, and the benefits of a collective approach to this sector, you directed us to establish a life sciences innovation forum to develop a strategic plan for life sciences innovation in the region. You also asked that the plan “include, as a priority, addressing the challenges of risk detection and prevention, treatment and cure of the communicable and life-style diseases which afflict the people of the region.” In so doing, you stated that “investing in health will benefit economic growth, worker performance and productivity, and poverty alleviation” and that “we need to be more effective with our investment at every stage of the health care process, including primary prevention against disease risks and focusing on most vulnerable populations.”

With this mandate, we have developed for your review and endorsement a strategic plan, which serves as a set of best practices guidelines to promote life sciences innovation in the region. The imperative for implementation of this plan has been made all the more pressing by the current focus on health priorities in the region, something we have factored in to the plan to ensure both a responsive and a long-term perspective on health policy, and as a guide for more effective investment in innovation. The plan acknowledges the unique social and cultural environment of each economy.

Our overarching messages are that, the region’s competitiveness and the health and well being of our people, would benefit from (1) a top-level political commitment to this sector with appropriate resource allocation, and (2) an integrated approach taken to life sciences and health care policy making. Many different agencies have competing priorities and approaches. Coordination of these will maximize benefits to the community and efficiencies in the administration of government systems in this sector.

We also advocate a multidisciplinary and inclusive approach to health care and life sciences innovation policy-making, bringing together stakeholders from the government, industry, academia and the community to identify economy specific priorities and debate issues before they become counter-productive areas of contention. You established the Life Sciences Innovation Forum as a tri-partite mechanism. This has stimulated extremely productive debate, solid outcomes for the strategic plan, and innovative recommendations going forward.

The strategic plan is structured to (1) allow economies to determine the overarching regulatory and policy environment that would support social and economic goals related to life sciences innovation in the region and lay the foundation for a more coordinated approach to identifying and tackling health priorities; and, (2) allow an economy to decide how the four areas of the life

sciences innovation value chain (research, development, manufacturing and marketing, and health services) could be most productively developed and aligned to encourage economic growth and social well being.

We start with basic principles governing life sciences innovation, which were identified as common themes at the August 2003 inaugural Life Sciences Innovation Forum in Phuket, Thailand. These basic principles should be applied individually and collectively. Working with these basic principles Expert Working Groups developed goals, operating principles and best practices for each area of the life sciences value chain. The September 2004 2<sup>nd</sup> Life Sciences Innovation Forum in Penang, Malaysia developed recommendations for collective action going forward. To support implementation of the strategic plan, we have developed a Life Sciences Innovation Readiness Assessment template for interested economies to use to assess their strengths and capacity building needs in each area of the life sciences innovation value chain.

The Life Sciences Innovation Forum considers that implementation of this strategic plan will provide a model for a global approach to life sciences innovation. Our region already has a comparative advantage in this sector and we should capitalize on this. We believe that the people of our region will benefit significantly from a coordinated approach to this sector's development, and that resources will be spread more efficiently and evenly throughout the region. Our work has already attracted international recognition. Because of the forum's work on the harmonization of standards, the International Conference on Harmonization (ICH) invited the LSIF to send a permanent representative to the ICH Global Cooperation Group meetings. The LSIF now is an active member of the group. There is work underway to launch a series of Pacific Health Summits beginning in June 2005 to focus on early detection and disease prevention, which may give rise to outcomes consistent with your instructions in this critical area.

Finally, we stress the importance of continuing dialogue among all stakeholders during the implementation phase of the strategic plan. Industry and academia have many resources to help economies build capacity in this sector. Effective implementation also requires community involvement. We recommend that you endorse the concepts and principles in the strategic plan and instruct the Forum to develop, for interested economies, a road-map for implementation according to the attached schedule. In seeking your endorsement of these principles and recommendations, we also recognize the many ongoing activities within APEC that may support the recommendations of the LSIF. We further encourage interested Economies to develop specific implementation milestones and establish multidisciplinary implementation task forces involving all stakeholders to assess priorities, needs, enhance public awareness, and monitor progress.

Respectfully submitted  
H.E. Suwit Khunkitti  
Minister of Natural Resources and Environment, Thailand  
Chair, Life Sciences Innovation Forum  
November, 2004



## Background

At their October 27, 2002 meeting in Los Cabos, APEC Economic Leaders called for the establishment of a tri-partite Life Sciences Innovation Forum (LSIF) “to develop a strategic plan for life sciences innovation in the region”. Leaders mandated that “this should include, as a priority, addressing the challenges of risk detection and prevention, treatment and cure of the communicable and lifestyle diseases which afflict our people”. In so doing, Leaders acknowledged that “investing in health will benefit economic growth, worker performance and productivity, and poverty alleviation” and that “we need to be more effective with our investment at every stage of the health care process, including primary prevention against disease risks and focusing on most vulnerable populations”. Terms of reference were agreed for the LSIF (Appendix I) in Chang Rai, Thailand, in February, 2003. The inaugural forum was held August 14-15, 2003 in Bangkok, Thailand under the chairmanship of H.E. Suwit Khunkitti, then Deputy Prime Minister of Thailand. The second LSIF was held September 16-17, 2004 in Penang, Malaysia.

The forums attracted world-wide attention. Experts from government, academia and industry participated. Key outcomes of LSIF I are attached as Appendix II. LSIF II outcomes are reflected in the strategic plan. The first LSIF developed a framework for the strategic plan based on the four main elements of the life sciences innovation value chain: Research, Development, Manufacturing and Marketing, and Health Services. That forum recommended that because life sciences technology is fast moving, the strategic plan be finalized for review and endorsement by APEC Economic Leaders at their November 2004 meeting in Santiago. Ministers and Leaders agreed with this recommendation, among others from the forum at their October 2003 meetings in Bangkok, Thailand.

Ministers further recommended the establishment of Expert Working Groups to work on specific elements of the strategic plan covering each of the four areas of the value chain. Two meetings of the Expert Working Groups were convened: February 12-13, 2004 in Khon Kaen Thailand and June 11-12, 2004 in Washington DC. An ad hoc Planning Group open to representatives of all APEC economies met at each senior officials meeting throughout 2002 – 2004 to review and comment on progress. Ministers also “supported the forum’s recommendations to identify economy-specific strengths in life sciences and ways to promote trade and investment, economic and technical cooperation and government-business sector collaboration in life sciences innovation”. Accordingly, the Expert Working Groups developed a readiness assessment template to assess the strengths and capacity building needs of economies. In June 2004, APEC Trade Ministers broadened the mandate of the forum in acknowledging the potential of the strategic plan to promote global trade and investment in innovative life sciences products and services. Two APEC readiness assessment pilot projects were conducted in 2004 supported by APEC funds. The results were presented to LSIF II on September 16, 2004 in Penang, Malaysia.

This strategic plan has been developed from the work products of the first and second Life Sciences Innovation Forum, the Expert Working Groups and, the APEC Life Sciences Planning Group meetings. It has been reviewed by the second Life Sciences Innovation Forum in Penang, Malaysia and by APEC Senior Officials at their October 3-4, 2004 meeting in Santiago.

## Executive Summary and Recommendations to Leaders

- For the purpose of the strategic plan the term “life sciences” refers to bio-medical sciences as they relate to human health.
- The Life Sciences Innovation Forum has developed a strategic plan for endorsement by APEC Economic Leaders based on the common themes and principles that emerged from the 1<sup>st</sup> and 2<sup>nd</sup> Life Sciences Innovation Forums and the work product from the Expert Working Groups as instructed by Ministers and Leaders. The Forum agreed that investment in life sciences innovation by APEC member economies would contribute significantly to the longevity, wellness and economic potential of the region and help address critical areas of concern including early detection, prevention and treatment of diseases. Thus the plan has been constructed to provide guidance on how best to maximize the return on investment in health innovation and turn activities in this sector to the benefit of people in APEC economies.
- The LSIF recognizes the existence of many ongoing activities within the APEC organization that may already support the recommendations of the LSIF. The Forum does not intend to duplicate these activities, or activities of other organizations, but would support these activities to meet the goals of the LSIF. Because the LSIF is designed to create an enabling environment for life sciences innovation and encourage cooperation among the APEC economies to achieve the LSIF goals, LSIF recognition of these programs may help facilitate these activities, especially capacity building programs.
- The strategic plan covers the four key areas of the life sciences innovation value chain: research, development, manufacturing and marketing and health services. The chain has been described in this way to facilitate economies in identifying the differing needs and capacity building relevant to each, and also to emphasize the role of health services and health policy making as a mechanism for translating life science innovation into improved access to innovation and improved health for patients. This includes approaches both to health policy making and to the delivery of health services.
- In each of the four areas, principles and, where possible, best practices have been identified that would contribute to a more efficient, effective, and coordinated policy approach to support innovation and health in the region. This would enhance the productivity and well-being of the people and also help address the health challenges of existing and emerging diseases in the region that undermine the well-being of vulnerable populations and have the potential for large adverse impacts.
- Based on the output from the Forum and Expert Working Groups, the Forum developed a Life Sciences Readiness Assessment template so that interested economies can best decide how their investment in the life sciences sector would be the most productive and bring the most benefit.

**Recommendation:** Endorse the principles and concepts of the strategic plan as a best practices guideline for the region to follow individually and collectively in the life sciences sector to improve the health and well-being of citizens while supporting economic development goals.

**Recommendation:** Instruct LSIF to develop, for interested economies, a road-map for early implementation of the strategic plan based on the principles, concepts and best practices so identified and the attached implementation schedule.

**Recommendation:** Support and encourage interested economies to finalize and utilize the LSIF Readiness Assessment template, undertake readiness assessments in 2005 and, on that basis, help them develop economy-specific implementation schedules with clearly identified milestones.

### *Areas of Priority Focus*

- Efficient and effective investment in and support for life sciences innovation requires a transparent, coordinated, and holistic approach to policy and priority setting, and to resource level and allocation, with the involvement and commitment of all stakeholders (within government, industry, academia, and the community). In this way, in each economy, the needs of populations can be best identified and addressed and targeted activities can be more evenly spread to where they will be most productive.

**Recommendation:** Encourage each APEC Economy to consider establishing Economy-specific multidisciplinary taskforces to make recommendations on life sciences policy and priorities across all areas of the health care process.

**Recommendation:** Consistent with Leaders' commitments on transparency, encourage each Economy to publish for comment advance notice of policy development, policy review and outcomes covering this sector and establish a consultative mechanism involving all stakeholders.

**Recommendation:** Welcome Thailand's offer to host a Ministerial level meeting in the 2<sup>nd</sup> quarter of 2005 to discuss and examine examples of effective holistic approaches to life sciences innovation that result in more effective and coordinated actions aimed at meeting the health needs of all populations.

- Attracting and retaining a dynamic life sciences industry depends heavily on the existence of an enabling environment for innovation. As such, the protection of intellectual property and the existence of rule of law that protects innovators is viewed as a precursor to the development of a robust life sciences sector in the region.

**Recommendation:** Encourage APEC-wide enactment of WTO-TRIPs by all member economies with adequate and effective infrastructure and resources to enable rightholders to enforce their intellectual property rights and criminal prosecution of counterfeiters of medicines across the region.

### *Critical Infrastructure*

- Efforts towards critical infrastructure development to international standards (biomedical facilities and supporting information technology platforms) and human capital development in the life sciences sector can benefit from a regional approach involving activities including, but not limited to, public-private sector partnerships in the design, establishment and implementation of appropriate programs.

**Recommendation:** Building on current initiatives in APEC member economies, instruct officials to examine the feasibility and prospect of interested economies establishing a regional Molecular Biology Laboratory (drawing on the model of the European Molecular Biology Laboratory), as well as the prospect of other relevant regional facilities such as chemical pilot and production plants and analytical facilities.

**Recommendation:** Direct the Life Sciences Innovation Forum to commission a study of the potential for cooperative development of innovation and applications platforms for the life sciences. The study should include an examination of real needs of member economies and how these might be met by a cooperative program.

### *Education*

- Education and human capital development are recognized as necessary for the discovery of new innovation, the encouragement of the utilization of innovation and the subsequent appropriate use.

**Recommendation:** Encourage APEC Education, Health, and Science and Technology Ministers to give appropriate priority to life sciences education and continuing medical professional education and training as described in the strategic plan.

**Recommendation:** Encourage APEC members to develop and implement life sciences curricula at all education levels. Encourage exchange programs on life sciences among APEC Economies at secondary and tertiary levels. In so doing, develop coordinated post-doctoral fellowship programs dedicated to life sciences.

**Recommendation:** Encourage the development of patient information and education, such as disease awareness programs and information on the full range of treatment and management options for important disease areas (including, for instance, dietary and lifestyle advice, as well as self-care).

**Recommendation:** Without duplicating other organizations, encourage the establishment of a federation of regional life sciences professional societies that may in turn be recognized by international professional societies.

## *Capacity Building*

- Capacity Building in all areas will be critical to the successful implementation of the strategic plan. Multilateral, regional and bilateral public/private sector partnerships should be encouraged to this end. LSIF Readiness Assessments by interested economies will help identify economy-specific capacity building requirements.

**Recommendation:** Encourage capacity building in health technology assessment so that economies are able to make informed decisions on health care and the introduction of new health technologies.

**Recommendation:** Endorse the establishment of expert taskforces on life sciences capacity building to conduct the Readiness Assessments in conjunction with facilitators and to use the assessments to identify gaps and facilitate the provision of necessary life sciences capacity building.

**Recommendation:** Welcome the establishment of a life sciences innovation *ad hoc* Technical Working Group to support the further development and the implementation of the Life Sciences Readiness Assessment and note that the first meeting of the Technical Working Group will be hosted by Thailand in the 2<sup>nd</sup> quarter of 2005.

## *Access to Capital*

- Access to capital was identified as a key factor in supporting the development of innovative products and services in the region. Among other things, it is a determinant on whether an innovation can be developed and brought to the consumer efficiently and effectively.

**Recommendation:** Instruct officials in interested APEC economies and the private sector to jointly explore the prospect of establishing a Regional Venture Capital facility directed at accelerating devices, diagnostics, medicines and other treatments for the diseases of the developing economies, and at emerging prospects from developing member economies.

- In consultation with the Technical Working Group of the Finance Ministers process, interested APEC economies should establish task force of experts to develop options for consideration by economies individually and collectively.

**Recommendation:** Examine the feasibility of establishing a Cooperative Program between Member Economies' Health Research Funding Bodies to identify and fund high quality research in member economies as described in the strategic plan.

**Recommendation:** Explore best practices for economy-specific fiscal incentives to attract R&D, manufacturing and commercial operations into the region consistent with existing international obligations.

## *Harmonization*

- Harmonization of standards for life sciences products and services (Appendix X provides an indicative list) and mechanisms for collaboration and the exchange of information among

economies were recognized as critical elements in all areas of the life sciences value chain and a basic principle going forward. To maximize the region's ability to address the region's health needs in the four areas of the value chain, policies, standards and regulatory mechanisms should be reviewed against international best practices, in accordance with APEC principles on harmonization.

**Recommendation:** Instruct the Forum to develop a mechanism for reviewing progress and the harmonization of standards against international best practices.

**Recommendation:** Noting that APEC LSIF has permanent representation on the Global Cooperation Group (GCG) of the International Conference on Harmonization (ICH) and that APEC member economies also participate in other Life Sciences standards bodies such as the Global Harmonized Task Force for medical devices, APEC Leaders agree in principle to move toward a regional harmonization process amongst APEC economies with a view to achieving close collaboration, international standards and global best practices through collaboration with bodies such as the GHTF, the Agenda for Leadership Program and Health Care Accreditation (ALPHA), and the ICH GCG and instruct LSIF to develop a roadmap to achieve this goal for life sciences products and for services.

**Recommendation:** Encourage information sharing among regulators with regard to safety issues, counterfeit products and other risks.

### ***Detection and Prevention***

- Building on the strategic plan, cooperative projects are underway to develop the necessary innovations to address early detection and prevention of diseases in the region. For example, an independently supported Pacific Health Summit will be held in June 2005 to focus on new technologies in early detection and prevention of diseases and policies to support these emerging technologies. The APEC Health Task Force also is addressing health priorities, including health security threats in the region, and independent initiatives are being promoted by major research organizations in the region.

**Recommendation:** APEC Leaders welcome the launching of a series of independently supported Pacific Health Summits beginning in June 2005 involving stakeholders in the early detection and prevention of diseases in the region and discussion of policies to support associated emerging technologies.

**Recommendation:** Where appropriate, LSIF should ensure that cooperative programs are conducted in coordination with the APEC Health Taskforce.

**Recommendation:** APEC Leaders to note that a number of APEC member economies have expressed interest in participating in a major molecular diagnostics initiative to help reveal the early onset of chronic diseases and an associated large scale cohort and monitoring program to gather essential information for the assessment of risk and early disease intervention.

## *Health Care Policy and Health Service Delivery*

- Improved approaches to health care policy making and priority setting has been identified by the LSIF as a key part of the process to improving the health of populations in APEC economies and reducing inequalities. This brings important social and economic benefits. For life science innovation to support this, economies not only have to consider how they support the development of innovation, but also how those innovations are put into practical use to bring benefits to patients. Securing patients appropriate access to innovation happens most effectively when policy making, research development, the allocation of health resources and the delivery of health care is coordinated in a way that is focused on the needs of populations.

**Recommendation:** Encourage economies to identify and prioritize the health needs of the populations and to identify mechanisms for meeting those needs. This includes the use of health surveys and needs assessment, which should also focus on inequalities within economies, as well an informed approach to the most effective ways of tackling these needs. Health system benchmarks can be used to prioritize resource use and measure progress.

**Recommendation:** Support economies in taking an integrated approach to health care policy making. Policy makers should engage with all stakeholders in their health systems (including patients) about the level, allocation and use of resources for health care. Economies should consider how incentives and approaches to budget setting can support the best use of resources and encourage access to the most appropriate care and use of life science (and other) innovation.

**Recommendation:** Economies should recognize the role of primary health care (health care provided outside a hospital setting) including in prevention and treatment, as an efficient and accessible way of treating many patients and providing good access to life science innovation. This includes use of general practitioners (family doctors), pharmacists and other health care professionals. Resource allocation, budget setting and medical training need to reflect these priorities.

## I. The Strategic Plan: Basic Principles

The inaugural Life Sciences Innovation Forum (LSIF I) developed a framework for the strategic plan based on the key elements of the life science value chain (Research, Development, Manufacturing and Marketing, and Health Services). A number of common themes emerged that were considered vital elements and basic principles of the plan. Member Economies agree that:

**Policy makers should consider life sciences innovation oriented to the identified health needs of APEC member populations as an investment rather than a cost.**

- Life sciences innovation is a critical area of growth and socio-economic development because healthy people produce healthy economies.
- Demonstrated productivity gains outweigh the costs of developing innovative products that address the health needs of the population.
- New product development and use can contribute to longevity, wellness and economic potential when linked to the health needs of the population.
- Sustainable health care policies are critical to realizing the value of life science innovation, and an informed approach to policy making that recognizes long term benefits of innovation is critical.

**A successful life sciences industry requires political leadership and commitment from the top. Key areas of this commitment include:**

- An integrated internal approach to health care policy making.
- An established process for inter-agency coordination on life sciences policy- and regulation-making among a broad range of government agencies including those responsible for Health, Science and Technology, Finance, Trade and Economic and Education
- Recognition of the importance of mechanisms to enhance innovation, such as public-private partnerships
- Consultation with key stakeholders: government, industry, academia and the community on priority setting
- Building human capacity through education and training
- Equitable, efficient and effective delivery of patient focused products and services
- Developing the necessary infrastructure to support life sciences innovation
- Policies that foster and reward innovation, and facilitate commercialization supporting health and economic benefits

**The policy and regulatory environment most conducive to investment in life sciences innovation should be governed by the following basic principles:**

- Transparency
- Efficiency
- Responsiveness and meaningful dialogue with all stakeholders
- Recognition of due process
- The priority health needs of the population
- Decisions based firmly on evidence of safety, efficacy and quality



**Capacity Building and Human Capital Development will be critical to successful implementation**

- Commitment to enhance life sciences programs in curricula at all levels of education
- Commitment to increase the pool of top quality scientists, regulatory policy experts and health services professionals; commitment to policies that foster, reward and encourage the retention and/or return of skilled professionals to the region
- Education mechanisms such as appropriate public-private sector partnerships to develop skills levels in each area of the life sciences value chain
- Collective programs to pool expertise and appropriate infrastructure
- Commitment to continuing medical and other professional education
- Programs for the continuing education of health professionals, including regulators
- Commitment to develop capacity building programs. The outcome of the APEC supported Life Sciences Readiness Assessment tool can serve as a guide for this purpose.

**The cutting edge infrastructure necessary to support bio-medical life sciences innovation must be developed and maintained**

- Verifiable and accurate top quality research, development, manufacturing and marketing and health services facilities meeting international standards that are supported by appropriate information technology platforms
- Centers of excellence
- Technology clusters
- A regional approach to critical infrastructure development

**Harmonization of standards for life sciences products and services according to international best practices across all four segments of the value chain will give the APEC region a competitive edge and expand opportunities for the rapid development of innovation**

- Agreement to harmonize quality standards for life science products and services according to international best practices (2003).
- Recognize the APEC principle that where there are existing international standards these will be the basis for harmonization in APEC and where appropriate international organizations exist for developing international standards, APEC economies will focus their coordinated efforts on promoting the development of international standards through these bodies.
- Efficient and robust clinical trial regulatory regime focused on safety, efficacy and ethical standards
- APEC LSIF “permanent representative” to the Global Cooperation Group (GCG) of the International Conference on Harmonization (ICH)
- International standards and best practices such as the Global Harmonization Task Force (GHTF) for devices, diagnostics and treatments

**Collaboration and networking among APEC economies is important to assure efficiencies and that the region remains at the cutting edge of life sciences innovation**

- Institutions specializing in life sciences innovation
- Funding institutions
- Health services institutions
- Networks such as the Asia-Pacific International Molecular Biology Network (AP-IMBN)
- Regional research initiatives such as the emerging molecular diagnostics initiative.
- Regional approach to existing and emerging diseases

**Access to capital is a critical factor in determining the viability of life sciences innovation**

- Venture Capital
- Seed funding
- Public-private partnerships
- Exploration of regional approaches to access to capital
- Government funding and multilateral development banks
- Foundations

**Implementation of the Strategic Plan should include collective and Economy-specific actions**

- Economy-specific implementation task forces including stakeholders
- Pathfinder approach as appropriate
- APEC-wide harmonization of standards for quality, safety and efficacy for life sciences products and services according to international best practices
- Human capital development
- Infrastructure development
- Access to capital
- Assessment of the strength of each APEC economy to identify those areas where contributions to life sciences innovation may be established quickly and effectively

**Economies are encouraged to identify investment, research and health policies that address the needs of all populations.**

- Commitment to processes that support the identification of the health needs of all populations
- Commitment to policies that support the development and use of innovative products and services that provide the greatest health and economic benefits
- Budget setting and incentive structures that support the treatment of patients using appropriate interventions and in the most appropriate location of care
- Promote research that is responsive to the priorities of a sustainable health care system
- A sustainable approach to decision making, based around efficient and effective use of resources. This should recognize the value of primary-level health care, supported by treatment approaches that recognize the long term benefits of an intervention to patients, the health system and the economy.

## II. The Strategic Plan: Goals, Operating Principles and Best Practices

Based on the outcomes of LSIF I (the basic principles) and agreements by Ministers and Leaders, this operational section of the strategic plan was developed from a matrix of goals and supporting operating principles, which was developed by the first Expert Working Group in Khon Kaen, reviewed by the Chair and Vice Chairs and reported to the LSIF Planning Group. The second Expert Working Group refined these goals and operating principles and developed best practices, where appropriate, that Economies should consider adopting, taking into account the rich diversity among and within Economies. The operational section was further reviewed by LSIF II, among other things to factor in recommendations for collective action going forward. Where possible, specific examples are given of successful models of cooperation, technology advances and implementation. So as to avoid duplication of effort, where possible principles, guidelines and best practices have been bench-marked against international best practices including those featured in the WHO, WTO, WIPO, GHTF and ICH, among others.

In terms of coverage, the goals, operating principles and best practices apply to all bio-medical life sciences products and services, including information technology platforms and supporting microtechnology, devices, diagnostics, medicines and treatments.

There is overlap and in some cases duplication in the goals, operating principles and best practices among the four areas of the life sciences innovation value chain. As one aspect of implementation will include economies determining their capacity building needs and prospects for economy specific or cooperative development, each segment of the value chain stands alone from that perspective and thus areas of overlap and duplication are maintained. Because significant interest was expressed by economies in the area of clinical trial regulation, this topic in the Development segment of the value chain has been substantially expanded to provide a best practices road map for developing capacity in clinical trials.

The following section of the strategic plan should be reflected in the LSIF Readiness Assessment Templates. As noted in the implementation schedule, interested economies are encouraged to conduct the readiness assessments as the first important step in implementing the strategic plan. Readiness assessments by interested economies should be completed by June 2005.

## 1. RESEARCH

### Goals

- To promote high-quality research<sup>1</sup> in all areas of the life sciences value chain.
- To promote the sustainable application<sup>2</sup> of the outcomes of research.

### Supporting Operating Principles<sup>3</sup> and Best Practices

#### Policies, priorities and strategies

- Member economies should, individually and collectively, develop research policies, priorities and strategies that are:
  - Based on identified health priorities<sup>4</sup> and economic objectives
  - Based on detailed policy research and evidence
  - Based on realistic assessment of research quality and capabilities
  - Subject to periodic reviews.
- *Best Practices*
  - Based on health and economic needs
  - Not duplicative
  - Capturing value through clearly defined outcomes
  - Consultative process involving all stakeholders
  - Inputs from international experts
  - Utilize best practice, peer review processes in the assessment of research
  - Regularly assess research practices and outcomes

#### Human capital and education

- Member economies should give priority to sufficient number of skilled researchers in life sciences.
  - The development of human capital should be pursued:
    - at all education levels
    - through collaboration among economies
    - through public and private collaborations
    - life sciences education curricula must include Good Laboratory Practice (GLP)

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<sup>1</sup> All forms of research including basic, applied, and development research, in both public and private sectors

<sup>2</sup> Broadly defined as encouraging the many different forms of applications, e.g., more research, translation, commercialization, communication of research to the public, and use of the results in formulating government policy

<sup>3</sup> In most, if not all, of these areas, capacity building will be of prime importance

<sup>4</sup> Having regard to the existing burden of disease and emerging disease and vulnerable population groups

- *Best Practices*
  - Policies to encourage skilled professionals (including returnees)
    - infrastructure, remuneration, recognition and qualifications
    - Ensure appropriate mechanisms are in place to enable research to be conducted by qualified personnel
  - Strong life sciences curricula starting from primary level
  - Inter disciplinary approach
  - Cooperation among APEC economies through shared educational programs

### Collaboration and networking

- Collaboration and networking are best achieved when based on trust, openness, complementarities, shared benefits and partnership
- Member economies should work together to:
  - Support research that leads to improved health outcomes
  - Encourage and facilitate collaboration and networks at all levels and between public and private sectors
  - Build on existing APEC networks in other APEC Working Groups such as the ISTWG, HRDWG, Health Task Force and networks such as the AP-IMBN

- *Best Practices*
  - Between economy-wide and international research funding agencies on specific priorities
  - High level commitment among collaborators

### Infrastructure and coordination

- Member economies should, individually and together, work to:
  - Develop strong and viable organizations and other infrastructure to support research track
  - Establish centers of excellence with critical mass around research priorities
  - Provide adequate infrastructure to support research priorities
  - Encourage coordination between national research agencies
  - Develop mechanisms to align research activities on health priorities.

- *Best Practices*<sup>5</sup>
  - Technology platform for pharmacogenomics studies. Examples include Thailand's TCELS-Oracle
  - Technology platform for pre-clinical studies. Examples include Thailand's TCELS, MBC and Malaysia's Progenix
  - Establishment and accessibility of laboratories consistent with relevant international standards
  - Partners to provide technology and investment
  - Research to support health services. Examples include Thailand's TCELS, MBC
  - Strong and appropriate structure for clinical trials. Examples include Thailand's TCELS, MBC
  - Public contributions to support professional bodies
  - Information and resource exchange and networking. Examples include the European Molecular Biology Organization (EMBO)
  - Ensure constant quality standards of research facilities

#### Ethics and regulation

- Member economies should, individually and together, work to ensure:
  - Appropriate and transparent ethical frameworks for research on health
  - Appropriate and transparent regulatory frameworks for research on health
  - Appropriate systems and mechanisms to support good research practices according to international best practices
  - Adequate training of personnel in the regulatory and ethical frameworks
  - Protection and enforcement of intellectual property according to agreed upon multilateral standards and obligations (TRIPS).
- *Best Practices*
  - Clinical trials comply with international standards
  - Regulation of research is undertaken by qualified personnel
  - Recognition of diversity across economies
  - Harmonization of diversified practices is required (WHO's GTN)
  - TRIPs compliance

#### Financing of research

- Member economies should, individually and together, work to:
  - Determine and provide adequate financing of research on health priorities according to respective capabilities and other priorities
  - Encourage public-private partnerships in financing research on health priorities
  - Improve access to private funding for the application of research outcomes

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<sup>5</sup> Involves organizations, knowledge networks, and access to equipment, technology, and services

- *Best Practices*
  - Pooling of resources toward a common goal (GFATM, NHMRC/MRC/Wellcome)
  - Appropriate incentives to promote philanthropic initiatives
  - Appropriate incentives to create venture capital (such as Tax, Capital gains) as well as other forms of funding

#### Public awareness, confidence and support

- Member economies should, individually and collectively, work to
  - Communicate widely research policies, priorities, strategies and outcomes
  - Consult with and involve the community in research activities
  - Inform and consult the community on specific research issues
  - Consult with all stakeholders (government agencies, academia, industry, community) in the development of research priorities, policies, plans and implementation
- *Best Practices*
  - Public awareness portals (NIH website, Life Sciences Center in Newcastle-UK)

## 2. DEVELOPMENT

Goals and operating principles are listed below. The area of clinical trials has been selected as an example of a best practices approach to development and a roadmap is provided which has the potential to expand capacity, competence and expertise in conducting clinical trials throughout the 21 APEC economies. The area of clinical trials was chosen as a concrete example of an area where contributions to life sciences innovation may be established quickly and effectively, in accordance with Leaders' instructions. This approach can advance APEC's strategy to enhance public health and welfare through innovation in human health life sciences. In so doing, member economies should strive to create a supportive environment for clinical trials that encourages collaboration. among economies.

### Goals

- Effective regulatory framework and infrastructure that ensures the safety, efficacy and quality of new products, while encouraging innovation.
- Partnership in working towards harmonizing regulatory practices and policies according to international best practices and standards
- Improved scientific and technical infrastructure
- Effective mechanism that promotes access to innovation

### Supporting Operating Principles

#### Human Capital

- Member economies should work to encourage investment in collaborative research grant programs between APEC economies.
- Member economies should encourage collaborative public-private research grant programs to support the development of human capital in LSIF.
- Member economies should work to develop government/public sector core competencies
- Member economies should work to improve human capital stock through:
  - *Best Practices*
    - a clear implementable plan for continuous improvement of core competencies
    - Integration of life sciences as part of the school curriculum
    - Investment in domestic PhD and postdoctoral grant programs
    - Public Education & Awareness Programs

#### Organizational Infrastructure and coordination

- Member economies should establish a legal and regulatory framework incorporating interagency review of new policies, guidance and regulations
- Member economies should work to establish Centers of Excellence around research priorities
- Member economies will work to establish clinical trials registries, accessible to all interested parties



### Physical Infrastructure

- Member economies will work to establish an IT structure that includes:
  - high speed grid computing networks
  - high performance computing capability
  - high speed telecommunications infrastructures that are based on open standards, which are secure, robust and facilitate real time collaboration between academic institutions, governments and the private sector
- Member economies will work to invest in adequate research facilities through mechanisms such as public-private partnerships

### Environment for Investment in Research and Commercialization

- Member economies acknowledge the importance of adequate human, organizational and physical resources, including:
  - a transparent, predictable and science-based regulatory framework to enable the transition of basic research to applied science
  - mechanisms for commercial partnerships to enable transition from basic to applied research and commercialization
  - access to capital markets

### Protection of Intellectual Property

- Member economies will work to implement a legal framework that is TRIPS compliant
- Member economies will work to provide adequate infrastructure and resources for enforcement of laws and regulations.
- *Best Practices*
  - Administrative and judicial frameworks that are fair, predictable, effective and efficient for concerned stakeholders
  - Intellectual property cases should be reviewed by appropriate judicial bodies with IP trained judges, evidence discovery frameworks, as well as mature injunction and bonding mechanisms to allow effective adjudication.

### Legal and Regulatory Framework with Due Process

- Member economies will work to establish rule of law that includes an adequate mechanism for right of appeal
- Member economies will work to establish a transparent legal and regulatory framework that incorporates adequate notice and comment into regulatory development

### Regulatory Framework: Sound Science

- Member economies will work to establish a regulatory framework that includes the following best practices:
- *Best Practices*
  - Includes assessment of current practice relative to international best practices (e.g., ICH, WHO, ISO, GHTF, ALPHA)
  - Provides a regulatory process based on safety, efficacy, and quality
  - use of public scientific advisory panels for specific scientific issues

### Regulatory Framework: Transparency

- Member economies should establish a clear, published process for drug and device development regulatory review, that includes the following best practices:
- *Best Practices*
  - Clearly defined requirements for drug and device development process
    - Available through print and electronic media.
    - Mechanism for Industry Consultation
    - Mechanism for appeal

### Regulatory Framework: Risk-and Evidence-based

- Member economies will work to implement clear, established data requirements consistent with international best practices
- *Best Practices*
  - Data requirements based on international standards (ICH, ISO, WHO), available through print and electronic media
  - Risk-based criteria with reference to safety, efficacy and quality for determining data requirements

### Regulatory Framework: Predictability

- Member economies should establish published indicative timelines for regulatory processes and review of clinical data consistent with international best practices and regulatory guidelines

### Good Clinical Practices

- Member economies will work to establish clinical trials requirements according to international standards
- Member economies will work to ensure adequate training of regulatory and clinical personnel, which may include:
  - The establishment and surveying of Independent Ethics Committees/ Institutional Review Boards (IECs)
- Member economies will work to release clear guidance to regulated community on clinical trial approval process
  
- *Best Practices*
  - Consider/adopt ICH GCP and WHO guidelines (when revision is completed) as a standard for clinical trials requirements

### Good Manufacturing Practices

- Member economies will work to ensure:
  - The adequate training of government personnel, including inspectors
  - Assessment of current domestic practices in relation to international practice (e.g., WHO guidance)
  - Establishment of regulatory framework that recognizes manufacturers adhering to GMPs
  - Performance assessment criteria based on international best practices—adequate infrastructures , indicators and criteria for inspection at the level of the ICH/PICS

### Environment for Capital Investment

- Member economies will work to ensure:
  - Effective and adequate IP protection defined as being TRIPS-compliant
  - Science-based, transparent, predictable, regulatory environment
  - Effective and adequate resources (human, organizational and physical)
  - Transparent market mechanisms including regulations
  - Mechanisms for public-private partnerships

### Services Environment

- Member economies will work to establish a services environment that:
  - Has an inclusive, open and transparent process
  - Is supported by interagency involvement and coordination
  - Is consistent with GLP
    - Ethics committees/Independent Ethics Committees/Institutional Review Boards (IECs)
    - GLP/ISO 17025 Laboratory
    - OECD GLP Laboratory

## **A Best Practices Roadmap for Interested Economies for Clinical Trials: The Necessary Elements and steps.**

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve human subjects. Compliance with GCP assures that the rights, safety, and well-being of trial subjects are protected and that the clinical trial data are credible. In addition to fulfilling the necessary elements of political leadership and regulatory system requirements indicated below, an economy wishing to establish GCP should be prepared to adopt and perform at the level of related internationally accepted standards including those expressed by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, (ICH), the Pharmaceutical Inspection Cooperation Scheme, (PIC/S), the World Health Organization, (WHO) and the World Trade Organization, (WTO) as appropriate.

Tools are available to become acquainted with GCP and the related regulatory review, monitoring and inspection activities. For example, details on good clinical practice standards, procedures for audit and inspection of clinical trials (compliance programs) information to be included in a report of a clinical study conducted in human subjects, guidance to facilitate the mutual acceptance of clinical data by the regulatory authorities, dealing with the influence of ethnic factors and other clinical study –related guidance is available in ICH and other guidelines at <http://www.ich.org>. Also, see <http://www.who.int> and search GCP. Note that WHO GCP guidelines are undergoing revision. For information on the Pharmaceutical Inspection Cooperation Scheme, see <http://www.picscheme.org>.

### **Elements**

#### **Political leadership from the top.**

A member economy in concert with industry, academia and others as appropriate will develop a coordinated strategy to promote life sciences innovation. The commitment to achieve and sustain Good Clinical Practices requires maintaining an environment that attracts investment, developing and applying legislation that is consistent with international standards, establishing public advisory boards and ensuring the provision of adequate financial and skilled human resources and facilities subject to monitoring, audit and avoidance of conflict of interest.

#### **Regulatory system requirements**

An adequately staffed healthcare infrastructure that includes a science-based regulatory system characterized by transparency, consistency, predictability and effectiveness that protects health while encouraging investment in innovation is essential. The staff should possess the regulatory review capacity to interpret reports of clinical trials and the skill set required to deal with human subject protection, and to conduct the inspection, auditing and monitoring required to assure GCP facility adequacy and practitioner capability to carry out clinical trials at an internationally acceptable level.

## **Roadmap Overview—Individual & Collective Actions**

- Readiness Assessment—Facilitated identification of capabilities and/or needs
- Evaluate current practice relative to international best practices (e.g., ICH E6 or revised WHO GCP)
- Develop common understanding of Regulatory Principles. Clinical trials principles: from regulatory authorization to GCP implementation
- Set priorities within APEC and within individual economies
- Establish a step by step, harmonization process for consensus building within APEC under the auspices of LSIF e.g.,
  - Agreement on principles for clinical studies
  - Common clinical trials application (CTA) format and content
- Coordinated program for “training the trainers” (regulatory agencies) within APEC—common curriculum
  - APEC economies share best practices
  - Develop training programs in each economy
- Form Technical Working Groups to advance objectives faster—creative use of technology to progress work program (e.g., videoconference, web cast)

## **Economy step-by-step implementation**

### **Step 1:**

Readiness Assessment—Economies willing to make the commitment necessary to achieve and sustain GCP should identify themselves. The initial step of an implementation plan for achieving GCP is an assessment of the capabilities, needs and willingness of an economy to achieve and sustain performance of both regulatory activities and clinical activities in conformance with internationally accepted standards. The assessment facilitators will review the economy’s coordinated strategy to achieve and sustain GCP and will evaluate current practice in the regulatory system and by clinical trial practitioners relative to international best practices (e.g., ICH E6 or the revised WHO GCP). The assessment summary will include recommendations for next steps.

### **Step 2:**

Based on recommendations from the Step 1 assessment, a training curriculum will be developed to ensure a common understanding of principles related to regulatory and clinical trial activities. Participants in training should include regulatory officials, individuals who may comprise an advisory board on GCP’s, and clinical trial practitioners. The curriculum will be applied as part of a coordinated program to “train the trainers” so that APEC economies will have the ability to conduct additional training, to share best practices and to form technical working groups to advance objectives faster. Use of technology such as videoconferences, webcasts and web-based training tools will be useful for Step 2 activities.

### **Step 3:**

Based on recommendations from the Step 1 assessment, with assistance from other APEC economies as needed, in a transparent manner, leaders of APEC economies will develop and enact legislation and guidance related to GCP and carry out other strategies designed to strengthen, manage and maintain GCP’s.

**Step 4:**

APEC economies continue to share best practices, perform monitoring and self-audits and obtain training as needed to ensure that both their regulatory system and clinical trial practitioners maintain the competence to perform in conformance with international standards. Based on certain indicators of success such as, but not limited to, the sample metric below, APEC economies may report on their progress at APEC LSIF meetings.

**Some Indicators of Success**

An attractive environment for innovation in life sciences can be measured qualitatively and quantitatively to show progress toward meeting the goals, for example through:

1. The number and sites for clinical trials should increase.
2. The types of trials should be reflective of the innovation an economy wants to attract, e.g., more multinational than local trials, trials for products/indications important to advancing the public health of the particular APEC economy.
3. Increased numbers of patients recruited to studies
4. Increased number of applications and approvals for clinical trials.
5. The review timeline should shorten.
6. Increased level of compliance to regulatory requirements /best practices

*Example of a Metrics Chart*

- Number of trials and/or sites
- Type of trials: Multinational vs. local / Phase I, II, or III /Bioequivalence
- Patient recruitment
- Number of applications
- Number of approvals
- Review timelines
- Level of compliance to Regulatory requirements / Best Practices

### 3. MANUFACTURING AND MARKETING

#### Goals

- To ensure a transparent and science-based regulatory framework for the manufacturing and marketing of innovative life sciences products that will assure the safety, quality and efficacy of the products.
- To ensure the ability of patients to have timely and effective access to appropriate innovative products.

#### Supporting Operating Principles and Best Practices

##### Transparent Regulatory Framework

- Member economies will work to establish a legal framework that incorporates adequate notice and comment into regulatory development:
  - Actual time-frame must be reflective of extent and impact of proposal and provide all parties with ample time for analysis of proposal and preparation of responses.
  - An adequate mechanism for right of appeal
  - Sponsor access to regulatory findings, especially in case of negative findings
  - An open and transparent process without risk of abuse to the regulatory authority, with adequate information to support its findings without being subject to repeated rounds of questioning on the same topic
  - The opportunity to input with the expectation of being heard
- Member economies will work to adopt the principles of due process in their regulatory framework
- *Best Practices*
  - Notice of regulatory development made to all stakeholders (patients, regulators, industry)
  - Notice includes description of contemplated regulation
  - Public rationale provided for the decisions surrounding the proposed regulatory development
  - Framework for due process that includes access to regulatory findings, the right of recourse, and a mechanism for stakeholders to consult with regulators
  - All parties agree on comment period according to a published process.
  - Mechanism for fast-track review of important new life-sciences products

##### Science-Driven Decisions

- Member economies will work to implement a science-based regulatory framework where decisions are made firmly on the basis of safety, efficacy and quality and equal treatment is provided to foreign and domestic applicants.
  - Framework should contain predictability and published timeframes for regulatory processes
- *Best Practices*

- Regulatory framework emulates appropriate international standards and international best practices such as ICH, WHO, ISO, and other international bodies working toward harmonization such as the Global Harmonization Task Force (GHTF) for devices.
- Takes into account on-going developments in the quality area for pharmaceuticals, devices and other health care products (including ICH guidelines Q8, Pharmaceutical Development and Q9, Risk Management currently under development, device (GHTF) and diagnostics standards)
  - Allows for further developments in the area of quality management beyond the cited ICH guidelines.
- A clear and published process for life sciences products and services development and regulatory review, a mechanism for industry to consult with regulatory authorities, and a mechanism for appeal
- Consistent application of standards leading to predictable outcomes
- Decisions based on the data presented (not on who is presenting the data) and independent of the individual reviewer or the inspector making the decision
- Use of public scientific advisory panels for specific scientific issues related to a marketing application, new technology, or new regulatory initiatives

#### Capable and Sufficient Human Resources

- Member economies will work to create an infrastructure supporting all levels of education
- Member economies will encourage investment in collaborative research grant programs between APEC economies that:
  - may be used to support investigations into both technology and policy; and
- Member economies will work to establish collaborative public-private research grant programs to support the development of human capital in LSIF.
- Member economies will work to encourage human resource development in the private sector; that is, continuing education for employees, that:
  - provides an opportunity for partnerships involving professional societies that are already established in the APEC economies
  - may lead to the establishment of an APEC-wide federation of those professional societies that support the life sciences industry in a region
- *Best Practices*
  - Collaborative research grant programs based on the model established by the World Health Organization (WHO)
  - Apparent mechanisms for continuing education that allow domestic and international professional societies to have a role
  - Centers of excellence
  - Public-private research collaborations
  - Promotion of exchange of people and ideas



### Adherence to Good Manufacturing Practices (GMP)

- Member economies will work to adopt an international baseline guidance for interpreting Good Manufacturing Practice (GMP).
  - Adherence to baseline good manufacturing practice should be acceptable in most cases
- Member economies will work to establish a regulatory framework that recognizes manufacturers that comply with GMP:
  - Performance based on international best practices
  - PICS (Pharmaceutical Inspection Cooperation Scheme) as a mechanism for training, documentation and information exchange across APEC economies at the bilateral and/or multilateral level.
- Member economies will, individually and together, work to provide adequate training of government personnel, with the same training to be delivered to inspectors and industry personnel
  - Training design should take into account both current domestic practices and international best practices
  
- *Best Practices*
  - Commitment to reviewable, contemporary quality systems such as ICH Q7A, WHO, PICS, 21 CFR 210-211, and applicable EMEA standards
  - Cooperative activities, for example through PICS extended to all APEC economies

### Respect for Intellectual Property Rights

- Member economies will implement a legal framework for patent protection, adequate infrastructure, and resources for enforcement of laws and regulations in order to protect intellectual property.
  - Mechanism that provides for the enforcement of those rights
  - Mechanism for public notice of submission prior to approval.
  - Information (including notice of marketing applications to holders of patents if a product is to appear on the market during the patent life of the original product) should be available and accessible to the holder of intellectual property rights, government agencies, and potential infringers
  - APEC-wide enactment of WTO-TRIPS by all member economies with adequate and effective enforcement of IPR, chance of apprehension, and criminal prosecution of counterfeiters across the region (such as based on the WHO guidelines for the development of measures to combat counterfeit medicines).
  - Acceptance of intellectual property rights must be consistent with WTO membership commitments.

- *Best Practices*
  - Enactment of laws consistent with WTO-TRIPS
  - Enforcement of those laws and regulations, including those laws against counterfeiting;
  - Cooperation among economies to combat counterfeiting
  - Marketing approvals should not lead to the infringement of intellectual property rights

#### Access to markets

- Member economies are encouraged to create an environment where there is adequate and timely access to markets for manufacturers and effective access for users in accordance with public health priorities.
- *Best Practices*
  - Market policies that reward innovation and maximize health benefits to society
  - Ability to discuss off-label uses with medical experts
    - In the spirit of scientific exchange
    - Consideration given to establishing a framework by regulators in an economy, where appropriate
  - Ability to communicate with consumers using balanced, ethical and good quality information and conduits

#### Physical Infrastructure

- Member economies will work to develop adequate information technology infrastructure that ensures the ability for regulators to communicate across economies
- *Best Practices*
  - high speed grid computing networks
  - high performance computing capability
  - high speed telecommunications infrastructures that are based on open standards are secure, robust and facilitate real time collaboration between academic institutions, governments and the private sector.

#### Environment for Investment in Research

- Member economies should establish a transparent, predictable, and science-based regulatory framework to enable the products of basic research to transition into use for applied science as one of the most important operating principles
- Access to capital markets likewise is a necessity for an APEC economy to implement successful manufacturing and marketing capacity

### Environment for Capital Investment

- To attract investment Member Economies will need to implement a science-based, transparent, and predictable regulatory environment that provides protection of intellectual property in order to encourage adequate capital investment

## 4. HEALTH SERVICES<sup>6</sup>

### Goals

- To create an environment that supports social and economic goals related to life sciences innovation
- To foster an inclusive, integrated, and sustainable approach to policymaking and implementation (policymakers need to co-ordinate their activities and consult with stakeholders)
- To monitor the quality and performance of health systems to ensure appropriate use of innovations
- To advocate accessibility, affordability, sustainability, and value from innovation in health services

### Supporting Operating Principles and Best Practices

#### Human capital and education

- Member economies should make necessary investments in human capital to ensure that economy is able to collaborate and lead research activities.
- Investments may include cross-country collaboration and public-private partnerships
- Within the economy, members will educate their science base to ensure appropriate utilization of innovations

#### Organizational infrastructure and co-ordination

- Member economies will measure and assure the quality of health services and research infrastructure

#### Physical Infrastructure

- Infrastructure is a key component of ensuring health systems create an environment that is conducive to the development and use of innovations. In particular, ensuring that different parts of the health system can “talk” to one another and that use of innovations, their impact, value and quality can be monitored is important. Member economies will invest in IT systems and infrastructure to ensure this is so.

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<sup>6</sup> Endorsement and implementation of this section is subject to constitutional power in respect of health services residing at the federal level of government, and is without prejudice to member economies’ division of responsibilities between central and local authorities or agencies of government.

- *Best Practices*
  - IT systems that are coordinated, with interoperability and common standards across the health system
  - transparent and efficient tendering is used to procure IT infrastructure
  - There are feedback mechanisms to ensure objectives are being met and quality standards enforced

#### Protection of intellectual property

- Member economies will commit to ensuring a legal and regulatory framework to guarantee IP standards is in place and enforced. The Health Services Group endorses the recommendations made by others in this respect, with the additional recommendation that mechanisms should be in place to discourage the prescribing or use of counterfeit products in clinical practice.
- *Best Practices*
  - Continuing public and physician education to promote awareness of the harmful effects of counterfeits
  - Reimbursement mechanisms that do not reward the use of counterfeits (e.g. there are cases where a cheap counterfeit is dispensed, yet reimbursement is sought at full cost)

#### Transparent regulatory framework

- Member economies are encouraged to:
  - Implement a transparent, timely and consistent framework for governing reimbursement decisions
  - Monitor the time from authorization to reimbursement decision
- *Best Practices*
  - Member economies are encouraged to:
    - Institute a clear and efficient process for public reimbursement decisions
    - Institute a transparent, objective, and science-based reimbursement decision-making process
    - Provide an opportunity for innovator and clinical experts to have input into the reimbursement decision-making process
    - Where there is a governmental reimbursement process, have government retain overall control over specific reimbursement decisions, on advice from an independent body as appropriate, but there is clarity over who makes which decisions/recommendations.
    - Allow products to be available privately as soon as they have marketing authorization, with consideration for public reimbursement via a clear and consistent process

### Good clinical practices

- Member economies are encouraged to work towards health systems with well-trained regulatory and clinical personnel who have clear guidance over processes. Ensuring quality of innovations is an important part of this process.
- *Best Practices*
  - There should be mechanisms for reporting adverse events related to the use of innovations, which should be collated and considered centrally.
  - Regulatory responses to data on adverse events should be driven by regulators and not politicians, with an emphasis on ensuring decisions are proportionate to the risks.

### Empowered Patients

- Member economies will take proactive steps to ensure patients have access to comprehensive information so that they can make balanced judgments about when and how to access health care.
  - Patients should have the opportunity to be involved in decisions about disease management, choice of treatment, and use of innovations
- *Best Practices*
  - There should be mechanisms that provide easily accessible, accurate, fact-based, unbiased, and comprehensive information to patients (e.g. internet, patient information leaflets)
  - Innovators should make information publicly available to consumers and patients about medicines while respecting the regulatory requirements and the ethical principles that govern this type of relationship

### Evidence-based medicine

- Noting that evidence-based medicine can be defined as the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients, and that the practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research, Member economies are encouraged to:
  - create strong communication channels between physicians, government, patients, and innovators to report adverse events and to understand the use of products in a real clinical setting
  - apply evidence-based medicine consistently across the health system, to the full range of interventions.
  - allow for clinical guidance based on robust evidence
  - promote accountability of all parties in the distribution chain by clarifying their roles and responsibilities
  - Promote guidance, which enables clinical freedoms
  - ensure physician knowledge is continually updated about the benefits of new innovations
- As a general principle, cooperation across APEC economies to develop and co-ordinate the application of evidence-based medicine is recommended
- *Best Practices*
  - Information about adverse events must be assessed by the government, regulatory review bodies and independent health experts in a fair and balanced manner
  - Evidence-based medicine should be applied to all products and health care interventions
  - Evidence-based medicine should be considered a valuable tool for informing clinical decisions
  - Physicians should be engaged in continuing medical education.
  - There should be ongoing review of evidence-based guidance
  - Procedures should be in place for collecting information on the use of innovations in practice

### Efficient use of resources

- Member economies are encouraged to:
  - Take an holistic approach to how they decide on the level of resource flowing into health care and on how it is allocated
  - Assess the health care needs of local populations, which should in turn inform decisions about the level of resources flowing in to health care
  - In conjunction with stakeholders, identify the specific needs of vulnerable populations and how these might be addressed in a fair and equitable manner
  - Have resource allocation reflect all these needs, which should include a national dialogue to understand the priorities of the population as well as local flexibilities
  - Take a long-term focus to allocating resources. This includes supporting preventative medicines and healthy lifestyles. It also includes a consistent approach to budget and priority setting over time

- Use health targets to help prioritize resource use. These targets must reflect the needs of the population and be based on sound evidence about what interventions work effectively
- Make incentive structures compatible with ensuring that physicians base their decisions around the clinical needs of the patient taking account of the resource constraints of the health system. This includes physicians taking a long-term view to treatment options, and recognizing that expenditure in one part of the system (e.g. primary care) can often generate savings in another (e.g. secondary care)
- Avoid setting budgets in a compartmentalized way (e.g. keeping prescribing budgets totally separate from other primary care budgets and secondary care budgets)
- Note that compartmentalized budget setting may be harmful for health services innovations in that:
  - A risk exists that physicians in one part of a health system are reluctant to use an efficient innovation because it imposes a cost on their budget but the savings are realized elsewhere or many years in the future
  - An innovation that is efficient from the health system perspective may be under-used because individual physicians do not see their budgets or the benefits from the perspective of the whole system
  
- *Best Practices*
  - Regular survey and other exercises to understand the underlying disease burden and its distribution in the population and prioritize health needs, and to understand the priorities of citizens
  - Resource allocation processes that reflect these needs (e.g. there should be a planning process for allocating resources to the right parts of the health system to maximize health benefits, given the needs identified)
  - Programs that emphasize health promotion and disease prevention. These should be focused both on encouraging citizens to live healthier lives and on ensuring physicians have good incentives, with support and incentives to detect and treat illness at an early stage
  - A well-developed primary care system, with holistic approaches to health teams (and hospital) reimbursement, that are consistent with managing patients outside the hospital setting where this is efficient and in the interests of patients. This includes making good use of all health professionals.
  - Targets can help to meet some of these objectives, but where used they should not be an over-riding constraint that distorts decision-making

### Prescribing Behavior

- Member economies are encouraged to ensure prescribing decisions are based around clinical needs to maximize the health and well-being of the population



- *Best Practices*
  - Separation of prescribing from dispensing
  - Remove financial incentives from prescribing decisions
  - Fees/physician reimbursement should be consistent with goals of effective resource use (see above), particularly in terms of the incentives they imply
  - Reimbursement mechanisms should be consistent with ensuring patients have good access to medicines and that prescribers have incentives to use them appropriately.

#### Use of traditional remedies

- Member economies will, where evidence shows sound clinical and efficiency benefits, work to make appropriate use of all types of health intervention, whether modern or traditional

#### Quality assurance programs

- Member economies are encouraged to work towards the mutual acknowledgement of quality assurance systems, such as hospital accreditation systems
- Member economies should be encouraged to move towards common standards
- *Best Practices*
  - National programs for the external evaluation of health care, with incentives to encourage continuous improvement of safety and quality of health care
  - Feedback to encourage dissemination of good practices

### III. Conclusions and Recommendations for Collective Action Going Forward

#### **Conclusions**

Implementation of the basic principles of the strategic plan will provide benefits to health and well being by creating an environment conducive to promoting global trade and investment, economic and technical cooperation and government-business sector collaboration in life sciences innovation according to Ministers' and Leaders' instructions. Ensuring that economies work towards harmonizing standards for life sciences products and services, and that resource needs are addressed, will allow the region to assume a global leadership role in this sector. An integrated, multi-disciplinary approach to policy-making involving all stakeholders is critical to success.

Implementation by economies of the basic principles and the goals, operating principles and best practices in the strategic plan will help accelerate the processes of risk detection, prevention and cure of the communicable and life-style diseases that afflict the people of the region. These goals, operating principles and best practices have been selected to attract top quality investment in targeted products and services that will meet the health and economic needs of the region and serve as a global model of cooperation to address pressing health policy issues, including the needs of vulnerable populations. In addition the goals, operating principles and best practices for each of the four areas of the value chain have been developed to ensure that investments made in every stage of the health care process by governments, industry and academia are more effective, including primary prevention against diseases risks and focusing on most vulnerable populations in accordance with Leaders' instructions.

Implementation of the Life Sciences Innovation Readiness Assessments will allow interested member economies to identify where to place their resources most effectively and efficiently and define their capacity building needs in accordance with Ministers and Leaders instructions.

The region has a clear comparative advantage in life sciences research, development and health services. But competencies and resources are not spread evenly. The area of clinical trials has significant potential for further development given the rich diversity of the region. A roadmap to build capacity and competence in clinical trials is provided as an example of where contributions to life sciences innovation can be established quickly and effectively according to Ministers' and Leaders' instructions. Building partnerships to harmonize clinical trial regulations and practices according to international best practices will be critical to success.

There is room for significant enhancement of research capabilities through collaboration, networking, pooling resources, and examining the prospect of cooperative funding initiatives.

Ministers recognized that there was a need to improve manufacturing and marketing standards and consistency throughout the region. Thus they agreed in principle to harmonize quality standards for life sciences products and services according to international best practices. The strategic plan provides a best practices approach to implement that commitment.

Health services is an area where some economies in the region are rapidly developing world class systems. But there is room for substantial improvement. Health services accreditation systems according to international best practices are to be encouraged in the region to promote the highest quality care for patients. But this is only one part of the process. Access to innovation needs to be strong for their benefits to be realized, which needs to be supported by transparent and efficient regulatory and budgetary processes. Approaches to priority setting and the allocation of resources also needs to be sufficiently flexible to address emerging disease problems.

There is potential for a broader effort at harmonization in the life sciences area through collaboration with relevant international standards bodies and initiatives, which would address the harmonization of regulatory standards and practices for life sciences products and services.

## Recommendations for Collective Action Going Forward

**Access to capital** was identified as a key factor in supporting the development of innovative products and services in the region. Among other things, it is a determinant on whether an innovation can be developed and brought to the consumer efficiently and effectively.

### *Recommendations*

1. Instruct officials in interested APEC economies and the private sector to jointly explore the prospect of establishing a Regional Venture Capital facility directed at accelerating devices, diagnostics, medicines and other treatments for the diseases of the developing economies, and at emerging prospects from developing member economies.
  - In consultation with the Technical Working Group of the Finance Ministers process establish a taskforce of experts to develop options for consideration by economies individually and collectively.
2. Establish a Task Force of experts including medical research funding bodies to examine the feasibility of establishing a Cooperative Program between National Health Research Funding Bodies to identify and fund high quality research in member economies. The Task Force should:
  - Report its findings back to appropriate Ministers.
  - Draw on experience in cooperative programs of the national research funding bodies such as the National Institute of Health in USA, the National Health and Medical Research Council (NHMRC) in Australia and comparable bodies in other economies.
  - Programs should be focused on:
    - Research on health issues particularly relevant to developing economies but not being adequately resourced such as dengue fever, malaria.
    - Areas of particular promise in developing member economies and/or on cooperative programs that bring together researchers from several economies.
    - Leveraging programs such as the REDI, the cooperative US-Singapore facility for training and response to emerging diseases in the region
  - Funding options include:
    - Member governments
    - Private grant funding (e.g. Wellcome, other foundations)
3. Explore best practices for fiscal incentives to attract R&D, manufacturing and commercial operations into the region consistent with existing international obligations

It is widely recognized that **education and human capital development** in the life sciences is critical. Education is increasingly becoming traded internationally, but a cooperative program within APEC focused on the life sciences could accelerate this process in relevant areas. This issue keeps recurring, and is certainly worth further detailed investigation as a major potential outcome from the Forum.

#### *Recommendations*

4. Encourage APEC Education, Health, and Science and Technology Ministers to give appropriate priority to life sciences education and continuing medical professional education and training as described in the strategic plan.
5. Encourage APEC members to develop and implement through appropriate training, region-wide life sciences curricula at all education levels. Encourage exchange programs on life sciences among APEC economies at secondary and tertiary levels. In doing so develop coordinated post-doctoral fellowship programs dedicated to life sciences.
6. Encourage programs for continuing education of all health professionals, including regulators.
7. Without duplicating other organizations, encourage the establishment of a federation of regional professional societies that may in turn be recognized by international professional societies.
8. Encourage the development of patient information and education such as disease awareness programs and information on the full range of treatment and management options for important disease areas, (including, for instance, dietary and lifestyle advice, as well as self-care).

Some facilities for the development of biomedical products from the R&D stage (e.g. toxicology, protein production) may be beyond the capacity of an individual economy but can be effectively provided on a regional basis. **Cooperative development of regional biotechnology and supporting information technology infrastructure** consistent with relevant international standards, including contract research organizations (CRO's) and contract manufacturing organizations (CMO's) could be an efficient way of pooling resources in the region.

#### *Recommendations*

9. Building on current initiatives in APEC member economies, examine the feasibility and prospect of interested economies establishing a regional Molecular Biology Laboratory (drawing on the model of the European Molecular Biology Laboratory)
10. Consider the prospect of other regional facilities such as chemical pilot and production plants and analytical facilities.

11. Direct the Life Sciences Innovation Forum to commission a study of the potential for cooperative development of innovation and applications platforms for the life sciences that includes but is not restricted to IT and related platforms, and advanced genomic and proteomic infrastructure. The study should include an examination of real needs of member economies and how they might be met by a cooperative program.

**Harmonization of standards** for life sciences products and services (Appendix X provides an indicative list) was recognized as a critical element in all areas of the life sciences value chain and a basic principle going forward. To maximize the region's ability to address the region's health needs in the four areas of the value chain, policies, standards and regulatory mechanisms should be reviewed against international best practices, in accordance with APEC principles on harmonization.

#### *Recommendations*

12. Noting that APEC LSIF has permanent representation on the Global Cooperation Group (GCG) of the International Conference on Harmonization (ICH) and that APEC member economies also participate in other Life Sciences standards bodies such as the Global Harmonized Task Force for medical devices, APEC Leaders agree in principle to move toward a regional harmonization process amongst APEC economies with a view to achieving close collaboration, consistency with relevant international standards and global best practices through collaboration with bodies such as the GHTF, the Agenda for Leadership Program and Health Care Accreditation (ALPHA) and the ICH GCG and instruct LSIF to develop a roadmap to achieve this goal for life sciences products and for services.
13. Instruct the Forum to develop a mechanism for reviewing progress and the harmonization of standards against international best practices.
14. Encourage programs for information sharing among regulators with regard to safety issues, counterfeit products and other risks

Building on the strategic plan, cooperative projects are underway to develop the necessary innovations to address early **detection and prevention of diseases** in the region. For example, an independently supported Pacific Health Summit will be held in June 2005 to focus on new technologies in early detection and prevention of diseases and policies to support these emerging technologies. The APEC Health Task Force also is addressing health priorities including health security threats in the region, and independent initiatives are being promoted by major research organizations in the region

#### *Recommendations*

15. APEC Leaders welcome the launching of a series of independently supported Pacific Health Summits beginning in June 2005 involving stakeholders in the early detection and prevention of diseases in the region and discussion of policies to support associated emerging technologies. LSIF to consider representation at this Summit.

16. Where appropriate, cooperative programs should be conducted in coordination with the APEC Health Taskforce.
17. APEC Leaders to note that a number of APEC member economies have expressed interest in participating in a major molecular diagnostics initiative to help reveal the early onset of chronic diseases and an associated large scale cohort and monitoring program to gather essential information for the assessment of risk and early disease intervention.

## Implementation Schedule

Some APEC member economies may choose to move more quickly than others in terms of implementing the strategic plan consistent with APEC's flexible, voluntary and consensus-oriented approach. For member economies choosing to move quickly to implement the strategic plan, the following implementation schedule is provided for endorsement by Ministers and Leaders:

### **January, 2005**

(i) Intersessional review and revision of Life Sciences Readiness Assessment template by LSIF Drafting Group.

### **February, 2005:**

(i) Develop a budget and associated criteria for APEC support for economy-specific Life Sciences Readiness Assessments.

(ii) Outreach to other APEC groups, including the ISTWG, HRDWG, Health Task Force, Finance Ministers TWG.

### **April 2005:**

1<sup>st</sup> meeting of the Ad Hoc Technical Working Group on Life Sciences Readiness Assessments.

### Objectives:

- review and refine the readiness assessment templates to be consistent with strategic plan best practices guidelines;
- develop guidance for economies and facilitators.

### **April/May 2005:**

(i) Launch economy specific readiness assessments.

(ii) Ministerial-level meeting. Objectives: review examples of best practices of a holistic approach to life sciences innovation to ensure that resource levels and allocations maximize the return on investment in terms of economic and health benefits; discuss ways of outreach to stakeholders, including within governments, academia, industry and the community.



**June 2005:**

- (i) Member economies factor the basic principles of the strategic plan into their policy-making infrastructure going forward.
- (ii) Possible LSIF representation at the Pacific Health Summit on early detection and disease prevention

**July 2005:**

- (i) Completion of readiness assessments by those economies who wish to develop a specific area of the value chain and/or undertake actions to stimulate the availability of innovative products and services.
- (ii) Complete first draft of ways to implement collective actions and recommendations going forward for presentation to Ministers, including priority areas.
- (iii) Economies finalize economy specific and collective milestones for implementation.

**August, 2005:**

- (i) Submission of statements of intent and capacity building needs.

**September, 2005:**

- (i) Presentation of progress to LSIF III and finalization of implementation steps going forward

**November, 2005:**

- (i) Progress report to Ministers and Leaders/Recommendations for implementation of priority collective actions going forward, including any relevant outcomes from the Pacific Health Summit.

## Appendices

- I Terms of Reference
- II Report of the Inaugural Life Sciences Innovation Forum: August 14-15, 2003, Phuket, Thailand
- III Report of the 2<sup>nd</sup> Life Sciences Innovation Forum: September 16-17, Penang, Malaysia
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**The APEC Life Sciences Innovation Forum  
Terms of Reference**

**1. The Mandate for the Forum**

At the October 2002 Joint Ministerial Meeting and Leaders meeting in Los Cabos, Mexico, Ministers and Leaders endorsed the establishment of a Life Sciences Innovation Forum in APEC. Specifically, in their Decisions approved at Los Cabos, Ministers:

“... recognized members’ interest in promoting public health improvement, and have made the life-sciences sector a high priority by approving the establishment of a Life-Science Innovation Forum in APEC.”

*Economic Leaders:*

“... acknowledged that investing in health will benefit economic growth, worker performance and productivity, and poverty alleviation. We need to be more effective with our investment at every stage of the health care process, including primary prevention against disease risks, and focusing on most vulnerable populations.”

*Leaders called for:*

“the establishment of a life-sciences innovation forum comprising government, private sector, and academia representatives to develop a strategic plan for life-sciences innovation in the region. This should include, as a priority, addressing the challenges of risk detection and prevention, treatment and cure of the communicable and lifestyle diseases which afflict our people”.

**2. The Purpose of the Forum**

2.1. As instructed by Leaders the primary goal of the Life Sciences Innovation Forum (LSIF) is to bring together representatives of the government, private sector and academia to promote life-sciences innovation in support of human health in the region in accordance with the Ministers and Leaders mandate. The Forum will provide a unique avenue to promote innovation in the life-sciences sector and at the same time support the overall APEC trade and investment agenda. Accordingly, the Forum will discuss, identify and promote a policy environment to foster the growth of life-sciences innovation and the improvement in public health in the Asia-Pacific region. In so doing, the Forum will strive to enhance the flow of information among APEC economies regarding life-sciences issues to help foster

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<sup>4</sup> 2003/SOM1/CTI/025

life-sciences innovation in the region and will not duplicate current and ongoing efforts of other APEC fora.

2.2. Based on these discussions, the Forum will develop recommendations for a strategic plan to address the health challenges and economic development goals identified by Leaders, including identifying the factors that are critical to success in each segment of the life-sciences value chain. For the purpose of this Forum, the life-sciences value chain encompasses all the value-added steps in a life-sciences product development cycle, beginning with research, continuing with development (R&D), to manufacturing and marketing, and through to consumer or patient use.

2.3. The Forum will also develop recommendations for economic and technical cooperation, including capacity building, and explore avenues to promote public-private sector collaboration in life sciences innovation. Some APEC Member Economies may choose to move more quickly than others in terms of implementing recommendations as is consistent with APEC's flexible, voluntary and consensus oriented approach to trade facilitation and economic and technical cooperation.

### 3. The Structure of the Forum

3.1. The LSIF will be held annually, with the inaugural meeting in August 2003. The work program and progress of the Forum will be reported initially to the Committee on Trade and Investment (CTI) and, where appropriate, to APEC Senior Officials, Ministers and Leaders. In the course of its work program, the LSIF may consult with other APEC specialty fora, including the APEC Industrial Science and Technology Working Group (ISTWG), the APEC Business Advisory Council (ABAC), and international and regional fora as appropriate. The work program and outcomes may also be conveyed to the ISTWG, the ABAC and other relevant APEC fora. Using the APEC reporting structure, through the CTI, to Senior Officials, and Ministers and Leaders when appropriate, progress towards the identification of critical issues in the life-sciences value chain and recommendations to address these will be reviewed annually. The LSIF terms of reference will be reviewed in 2006.

3.2. The Forum will be supported at the working level by an ad hoc Planning Group, comprising interested representatives from the private sector, academia and government officials. The ad hoc Planning Group will meet as needed before the Forum to determine the scope and operational structure of the Forum, define the agenda, determine the schedule of meetings, and facilitate the Forum. Schedules of meetings will be determined annually to allow flexibility. The proposed schedule of meetings in any one year, including the annual Forum meeting, will be agreed and deposited with the APEC Secretariat in a timely manner for inclusion in the APEC calendar.

3.3. The annual Forum will involve appropriate senior representatives of the life-sciences/human health sector and of APEC member economies as mandated by Leaders.

#### 4. Administration of the Forum

4.1. The Forum will be managed by a Chair and two Vice-Chairs representing the life-sciences industry, academia and the public sector. The Chair and Vice-Chairs will coordinate views and positions. They will be selected by the Forum from a list provided by the Planning Group to serve for a term of up to two years.

4.2. A Coordinator for the Forum will be identified to disseminate information, Chair Planning Group meetings, and coordinate with the APEC Secretariat, ISTWG, ABAC, appropriate APEC Sub-Committees, other Working Groups and Experts Groups, and international bodies as appropriate and as identified by the Forum.

4.3. To facilitate the work of the Chair and Vice-Chairs of the Forum each member economy is invited to designate up to two contact points to coordinate that member economy's participation in the Forum.

4.4. The names of the Chair and Vice-Chairs and contact details will be deposited with the APEC Secretariat by the Forum coordinator.



APPENDIX II: Report of the Inaugural Life Sciences Innovation Forum:  
August 14-15, 2003, Phuket, Thailand

**Key Outcomes – Life Sciences Innovation Forum**  
**14-15 August 2003**

The inaugural meeting of the APEC Life Sciences Innovation Forum (LSIF) was held August 14-15 in Phuket Thailand chaired by H.E. Suwit Khunkitti, Deputy Prime Minister, Thailand. Over 200 participants drawn from academia, government and industry discussed implementation of the APEC Leaders instructions to develop a strategic plan for Life Sciences innovation in the region. Several key themes emerged that were considered vital elements of a framework for the plan.

Life Sciences innovation was recognized as a critical area of growth and socio-economic development--healthy people produce healthy economies. Productivity gains far outweigh the costs of developing innovative products. New product development and use adds significantly to longevity, wellness and economic potential.

Successful Life Sciences industry requires political leadership and commitment from the top and depends on the proper policy environment, public-private partnership, human capacity, and efficient and effective delivery of patient focused products and services. Guiding principles moving forward must include transparency, meaningful dialogue with stakeholders and recognition of due process. Capacity building will be critical to successful implementation.

Because life sciences technology is fast moving it was recommended that the strategic plan be finalized by the time of the APEC Leaders Summit in 2004. It also was recommended that expert groups work intersessionally to develop a road map encompassing best practices for each of the four main segments of the life sciences innovation value chain: research; development; manufacturing and marketing and health services for endorsement by Leaders at their 2004 Summit.

A number of immediate outcomes were identified as recommendations for Leaders endorsement at their October 20-21 meeting in Bangkok including: agreement in principle to harmonize quality standards for life sciences products and services according to international best practices; and, an assessment of the strength of each APEC economy to identify those areas where contributions to life sciences innovation may be established quickly and effectively.

**Elements of the Framework for the Life Sciences Innovation Strategic Plan**

LSIF recommended the following key elements for inclusion in the framework for the Life Sciences Innovation strategic plan.

**1. Research**

**Objective 1: Promote quality scientific research**

- Physical & Intellectual infrastructure
- Human capital – brain train not drain

- Integration into international & APEC Networks
- Research priorities –economy specialization, disease specific
- Centers of Excellence
- Realistic assessment of capabilities
- Efficient use of research\_funding – research audits for quality outcome
- Tech transfer groups

### **Objective 2: Translational Research**

- Commercially viability
- Patient focus
- GMP-based CMOs
- Rewards for institution and scientists
- Collaboration

### **Objective 3: Commercialization**

- IP
- Environment and structure for commercial partnerships (NIH-type structure)
- Business development unit – Alliances, Spin offs
- Technology transfer
- International competitiveness
- Incubation centers
- Capital – seed funding

### **Objective 4: Investment in Education & Training**

- Education structure – life science in primary school curriculum
- Awareness/Communication with public and financial institutions
- Training

### **Recommendations to APEC Leaders**

- Make life science a priority and commitment
- Increase R&D funding
- Efficient and consistent policy environment
- Inter-governmental collaborations and networks
- Create APEC ‘APMBL’
- Attract private equity institutions and pharmas

## **2. Development**

### **Regulatory Practices Supporting Innovation**

- Transparency
- Efficiency
- Flexibility
- Responsiveness
- Protects IP
- Efficient & Robust Clinical Trial Regulation



## HARMONIZATION

- To expand opportunities for rapid development of innovative medicines
- Example of ICH as success in Harmonization
- Harmonization, not “homogenization”
- ICH “Mickey Mouse” model
- Move to globalize ICH activities through ICH GCG
- Clinical Trials
- Opportunities in Asia – Large patient base, unique and unmet medical needs, large pool of professionals, IT infrastructure
- Challenges –
- Varied social systems, cultures, traditions
- Different regulations, processes – new & existing
- Insufficient GCP training
- Possible players to Unify standards – Charitable research organizations, APEC
  
- **APEC - Development**
- Different levels of development of regulations in economies across APEC
- Possible groupings within APEC based on similar standards and needs – e.g. Korea, Chinese Taipei and Japan’s cooperation on ICH E5
- Suggested permanent representative of APEC on ICH GCG
  
- **Development--Harmonized Guidelines or ‘Commonality in Regulatory Guidelines’**
- Clinical Trials – infrastructure; regulation; patient safety
- Training, capacity building and education
- IPR – data exclusivity; IP issues in the regulatory framework
- Other topics: Examine ICH and the aim/value of partnership  
Examine policies – regulatory systems
- Examine and agree core principles of regulation
- **Tripartite Self Assessment**
- Core competencies
- ‘Needs assessment’ – training, education, infrastructure etc
  
- **Principles of Operation**
- Activities should be under the umbrella of APEC
- ‘APEC-wide’
- Terms of Reference will be prepared
- Participation should be open to regulators (government), industry and academia
- Any activities/agreements will be flexible and should take account of societal or cultural needs
- Participation in topic discussion should be voluntary
- Participation and activities will be contingent on resources
- Any economy can raise new related topics
- Meetings should leverage other international fora to most efficiently use resources

### **3. Manufacturing and marketing**

#### **Broad and lively discussion in three main areas**

- a. Role of regulation in assuring quality products
- b. Counterfeit drugs and their impact on society
- c. Trade and investment in life sciences

#### **Guiding Principles**

- Transparency of process
  - Public notice
- Dialogue
  - Meaningful input into development of regulation
  - Active collaboration among all groups: regulators, academics, industry
- Due Process
  - Including right of appeal

#### **Role of Regulation**

- Quality standards assure safe and effective medical products throughout the APEC region
  - For entire supply chain
- Quality standards to assure integrity of product use
- Not command and control but trust and verification
- Uniform adherence to high level of quality

#### **Role of Regulation: Actions**

- Conduct self-assessment to determine current status relative to best practice
  - WHO 1992
  - ICH Q7A
  - ISO 13485
  - National standards
- Identify gaps and build capacity as needed
- Establish an expert working group to recommend a uniform quality standard

#### **Counterfeit Medical Products**

- Now not only a health risk but an actual impact on health
- Now not a cost of doing business but a cause of destruction of business
- Long-range goal is to shift from combating counterfeiters to preventing counterfeiting

#### **Counterfeit Medical Products: Actions**

- Conduct self assessment to determine extent of counterfeiting and to understand scope of impact
- Build on WHO network of contact points among APEC economies to share information and to deal with crises
  
- Create public-private sector partnerships within and among APEC economies to combat counterfeiting
  - Identify most significant resources of counterfeiters
  - Share best practices, including dealing with internet fraud
- Establish uniform enforcement, penalty, and risk of being caught

### **Trade and Investment**

- Sound investment built on legitimate claims of quality, safety, and efficacy
  - From herbal medicinals to products of recombinant technology
- Branded products produced with the certainty of quality under agreed upon standards

### **Trade and Investment: Actions**

- Conduct self-assessment to identify one or more areas within each APEC\_economy where contributions to life sciences innovation may be established most quickly and effectively
  - Consistent, transparent market regulations
  - Regulatory framework based on sound science and international practice

## **4. Health Services**

The Health Services breakout session agreed on the importance of ensuring the recognition and value of life sciences innovation in health care delivery systems, with the ultimate aim of improving health and quality of life of patients in APEC. There was a general agreement that in order to achieve this end, APEC policy makers initiate a process that helps APEC members achieve the following objectives:

- Develop more inclusive, open and transparent processes for setting health care policies, which solicit and take into account the concerns of the range of stakeholders, including the life sciences industry, patients, and health care providers;
- Develop a more integrated internal approach to policy making on health care delivery issues, in which relevant government agencies such as health, finance, trade and investment and other agencies work together to develop more coordinated approaches;
- Develop better means of monitoring performance and quality of health care delivery systems, including for example, accreditation systems.

As a first step, the group recommends that APEC members meet in the coming year to develop a menu of best practices in these areas, as well as discussing other possible concrete means of cooperation.

APPENDIX III: Report of the 2<sup>nd</sup> Life Sciences Innovation Forum:  
September 16-17, Penang, Malaysia

Representatives of 13 APEC economies (Australia, Canada, China, Hong Kong China, Indonesia, South Korea, Malaysia, Mexico, New Zealand, Singapore, Chinese Taipei, Thailand, United States) participated in the second APEC Life Sciences Innovation Forum (LSIF II) held on September in Penang, Malaysia under the Chairmanship of H.E. Suwit Khunkitti. The forum was hosted jointly by the State Government of Penang and the Malaysian Ministry of Science, Technology and Innovation (MOSTI). Life Sciences experts from Europe contributed to discussion.

The main objective of LSIF II was to review the draft strategic plan, discuss best practices that could be included in the plan, and identify collective actions going forward. There was agreement that the strategic plan was on the right track, that it accurately reflected the work of LSIF I and Expert Working Groups, and that the plan would benefit from expanding on some of the concepts. LSIF II plenary and discussion forums thus expanded and added more clarity to the recommendations. Best practices covered creating incentives for innovation; a holistic approach to life sciences innovation; and technology and infrastructure for Life Sciences. Opportunities for collective action in life sciences were identified as including financing innovation; harmonization initiatives; cooperation for human capital development; and prospects for cooperative projects to develop the necessary innovations to address the early detection and prevention of diseases in the region.

Presentations on these topics were made by distinguished experts, including Malaysia's Minister of Science, Technology and Innovation, H.E. Dato Dr. Jamaluddin Jarjis; the Chief Minister of Penang, H.E. Tan Sri Dr. Koh, Tsu Koon; H.E. Minister Suwit Khunkitti, Chair LSIF; and, Nobel Laureate Dr. Lee Hartwell, President and Director of the Fred Hutchinson Cancer Research Center (FHCRC). Among other things Dr. Hartwell invited LSIF member economies to participate in cooperative research projects on the early detection of chronic diseases, as a contribution to outcomes on Leaders instructions in this area. Four APEC economies (South Korea, Malaysia, Singapore and Thailand) are currently considering participating in these projects with the FHCRC. A series of independently supported Pacific Health Summits will be launched in June 2005 focusing on early detection and prevention and policies that would support associated emerging technologies. It was recommended that APEC welcome the launching of the Pacific Health Summits and that consideration be given to LSIF representation at these Summits. Mexico drew attention to the Global Health Summit that Mexico is hosting in November, 2004 in conjunction with the WHO.

LSIF II discussed and proposed recommendations in all these areas for inclusion in the strategic plan. These recommendations were subsequently developed in breakout discussion forums and included in the draft strategic plan (attached). Interestingly, revisions to the strategic plan included points in common from the four discussion forum groups (research, development, manufacturing and marketing, and health services) in 9 specific areas. These were:

1. The strategic plan should provide guidelines for economies to support life sciences innovation and thus the tone of recommendations to Leaders should reflect that objective.

2. Greater specificity in the scope, coverage and definition of life sciences innovation products and services reflected in the plan extending to information technology/biometrics; scientific and medical devices; diagnostics; medicines; health care services; and, treatments.
3. A redefinition of a cooperative approach to the harmonization of standards to better reflect the intent to move towards a global system of international best practices and guidelines.
4. The need to recognize and build on activities already on-going in the region.
5. Greater definition of the need for LSIF activities to link with other relevant APEC working groups and taskforces such as the ISTWG and Health Taskforce, and the work of other international bodies.
6. The need for a competitive approach to fiscal incentives for R&D consistent with the WTO.
7. A common understanding on the goals of cooperative initiatives such as the Pacific Health Summit and their relevance to LSIF activities.
8. Strengthen education recommendations and proposed activities to include continuing education programs for all life sciences professionals.
9. The desirability of continuity in the composition of expert groups.

Representatives from Chinese Taipei and Thailand presented the outcomes of the APEC LSRA pilot projects conducted in August and September with the assistance of expert facilitators Dr. Edward Bramley-Harker (NERA), Dr. Stephen Cook (GSK), and Professor Dr. Ellick Wong (University of Singapore). It was felt that (1) the readiness assessments needed to be revised to better reflect the goals, operating principles and best practices of the strategic plan; (2) more specific guidance needed to be given to economies on how to approach the assessments; (3) there was a continuing need for expert facilitators to assist economies in the assessment process; and, (4) examples of best practices needed to be provided. LSIF II agreed to a proposal from the Chair of LSIF II that technical experts from interested APEC economies convene in Bangkok in the 2<sup>nd</sup> quarter of 2005 to ensure that economies understood what was needed to successfully complete a life sciences readiness assessment and review examples. Chinese Taipei and Thailand undertook to provide LSIF with comprehensive reports on their experience with LSRA and suggestions for improvement.

LSIF II discussed the need for specific guidance to Leaders on ways to implement the strategic plan and the need to secure “buy in” from a broad range of public and private sector agencies and entities. To that end the LSIF Chair proposed that he convene in Bangkok an informal meeting of APEC Ministers Responsible for Life Sciences in parallel with the technical experts group in the 2<sup>nd</sup> quarter of 2005 with the intention of communicating the results of that meeting through the LSIF to Trade and Finance Ministers, among others. LSIF II revised the implementation schedule in the strategic plan accordingly.

Finally, in order to meet the deadline of November 2004 set by Ministers and Leaders for the presentation of the strategic plan, LSIF II requested senior officials at SOM III to endorse the draft strategic plan in principle and instruct LSIF to finalize the plan by October 18, 2004 for intercessional review by the SOM preparatory to transmittal to Ministers and Leaders at their November 2004 meetings.

## APPENDIX IV Reports of the Life Sciences Innovation Planning Group

### **Report to the LSIF Planning Group 9/27/04**

#### REPORT OF THE LIFE SCIENCES INNOVATION FORUM PLANNING GROUP

1. The Life Sciences Innovation Forum (LSIF) Planning Group met on September 27, 2004 in Santiago, Chile, chaired by Barbara Norton of the United States, and assisted by Dr. Sumol Pavittranon of Thailand as the National Focal Point and LSIF secretariat representative. Attending the meeting were officials from 11 economies: Australia, Canada, Chile, China, Indonesia, Korea, Malaysia, Mexico, Chinese Taipei, Thailand and the United States. Australia indicated that it would provide comments on the LSIF draft Strategic Plan after a new government was in place.

#### REPORT OF THE 2ND LIFE SCIENCES INNOVATION FORUM

2. The Planning Group Chair reviewed the background to the development of the strategic plan, noting that the basic elements and framework for the plan emerged from LSIF I in August 2003 and were endorsed by Ministers at their October 2003 meeting in Bangkok. At that time Ministers and Leaders also requested that the strategic plan be finalized for review by Ministers and Leaders at their November 2004 meetings in Santiago. In response to Ministers instructions, Expert Groups worked throughout this year to add the required detail to the basic principles and framework. The work of the Expert Groups was reviewed by the LSIF Planning Group meeting at SOM I, and by the LSIF Chair, Vice Chairs and Discussion Forum Chairs and was incorporated into the strategic plan which was submitted to the September 16-17 LSIF II in Penang for review. Comments made at LSIF II were assimilated by the Discussion Forum Chairs and incorporated by the small drafting group into strategic plan (2004/SOMIII/LSIF/0003) which was circulated in draft form to the Planning Group in advance of the September 27 meeting.

3. Dr. Sumol Pavittranon reported on the outcome of LSIF II (attached), noting that presentations were made at the forum by a number of distinguished Ministers and the 2001 Nobel Laureate in Medicine, Dr. Lee Hartwell. She observed that LSIF II considered that the plan was on track with Ministers and Leaders instructions and enumerated the nine general comments in common that emerged from the Discussion Forums, noting that these were reflected in the latest version of the strategic plan, including, importantly, ensuring that the scope of the plan covered medical devices and diagnostics as well as pharmaceuticals and treatments.

4. Because of the need to provide specific guidance on the LSIF Readiness Assessment (LSRA) template as a means of implementing the strategic plan, the LSIF II seeks APEC endorsement of LSIF Chair's intention to host a technical working group in the 2nd quarter of 2005 to ensure that economies understand what is needed to successfully complete a LSRA and review examples. Because of the need to secure good communication with a broad range of public and private sector agencies and entities to ensure successful implementation of the strategic plan, and provide guidance to Leaders on implementation, LSIF II also seeks APEC endorsement of LSIF Chair's intention to hold an informal Meeting of Ministers Responsible for Life Sciences in the 2nd quarter of 2005 in Bangkok. The Planning Group agreed with this approach.

## REVIEW OF THE STRATEGIC PLAN

5. Comments on the strategic plan were made in the Planning Group by Mexico, Thailand, Malaysia and Chile. Mexico requested clarification of the goals of the Pacific Health Summit and how the plan would be implemented. The Chair assisted by an expert explained that LSIF II agreed to welcome independent initiatives such as the June 2005 Pacific Health Summit and Mexico's November 16-20, 2004 Global Health Forum and would examine the outcomes of those forums as part of LSIF intention to draw on and not duplicate the work of other international meetings that was relevant to the LSIF mandate. It was also noted that implementation of the strategic plan would largely be conducted through addressing capacity building needs that emerged from the LSRAs. Mexico suggested that the plan emphasize the importance of creating a good business environment for life sciences innovation.

6. Chile indicated that President Lagos would endorse the plan subject to a few changes including ensuring the plan was TRIPs consistent and a few revisions in wording such as in the health services section. Chile will submit those comments in writing. Dr. Sumol clarified certain points of substance on health services.

7. The Planning Group Chair requested that comments from economies be submitted no later than October 18 so that these could be incorporated for intersessional review by the SOM and endorsement for transmittal to Ministers and Leaders in November. In so doing, she noted that the strategic plan had already been substantively reviewed by economies, Chair LSIF, Vice Chairs, the Chair of the Expert Groups, and Discussion Forum Chairs.

8. Thailand noted that it planned to table a paper on fighting AIDs for APEC's possible future consideration.

## LSIF READINESS ASSESSMENTS

9. Chinese Taipei and Thailand presented their reports on the LSRA pilot projects they had conducted with the help of expert facilitators in August-September 2004. It was noted that LSRAs needed to be revised to make them more user-friendly and consistent with the LSIF strategic plan. Thailand outlined its progress and intentions on the readiness assessment for developing the four areas of the Life Sciences Innovation value chain: research, development, manufacturing and marketing, and health services. The Planning Group Chair noted that the LSRAs were an important step in the implementation of the plan and that some economies may require the assistance of facilitators to complete the LSRA template.

## ICH SELECTION CRITERIA

10. LSIF PG Chair reported on discussions with representatives of the International Conference on Harmonization's Global Cooperation Group (ICH GCG) in Penang, concerning LSIF representation at ICH, which will require a significant revision of the draft ICH selection criteria to reflect ICH GCG desire for continuity in representation at the same time as ensuring that there was adequate rotation among APEC economies, and addressing resource allocation. ICH is offering two seats for LSIF at the ICH GCG meetings. However, ICH will only meet the cost of one participant. The Planning Group agreed that LSIF Vice Chair Dr. Pakdee would

attend the November 4 ICH GCG meeting in Yokahama, funded by the ICH and accompanied by a second representative, who would attend the spring 2005 ICH GCG meeting. The Chair noted that formal nominations and resumes had been received from two of the five economies that had indicated interest in participating in the ICH GCG and requested that nominations be forwarded to her by October 15. The APEC Secretariat would then draw up a slate of candidates, which would then be circulated to the Planning Group. In the meantime, the selection criteria would be revised for intersessional review by the Planning Group. Australia indicated its intention to clarify the status of its intended nominee.

#### OTHER BUSINESS

11. The Planning Group welcomed the support of the medical life sciences industry for the strategic plan and the industry's invitation for APEC officials and Ministers to participate in a reception on November 18, 2004 hosted by Johnson and Johnson at the Marriott Hotel to celebrate the presentation of the LSIF strategic plan to Ministers and Leaders. The APEC Secretariat will include this event on the APEC calendar.



## **Report of the Life Sciences Planning Group 2/28/04**

1. The Life Sciences Planning Group met on February 28, 2004 in Santiago, Chile. Fourteen economies were represented at the meeting: Australia; Canada; Chile; China; Hong Kong, China; Indonesia; Japan; Korea; Mexico; New Zealand; Philippines; Chinese Taipei; Thailand; and United States.
2. The Planning Group Chair (United States) recalled the instructions of Ministers and Leaders instructing the Life Sciences Innovation Forum to draft a strategic plan for life sciences for review and endorsement by Ministers and Leaders in November 2004. The Chair noted that drafting the strategic plan was an ambitious undertaking, and thanked Thailand for its excellent leadership which was keeping the initiative on schedule toward the ultimate goal of developing the strategic plan by November 2004.
3. The Chair next reported on outcomes of the Life Sciences Experts Meeting, which the chair of the Life Sciences Innovation Forum, Thai Deputy Prime Minister H.E. Suwit Khunkitti, had convened in Khon Kaen on 12-13 February 2004. She noted that participants at the Experts meeting had agreed that a further Experts meeting would be needed, and that this would be held in Washington DC in June on the margins of other international life sciences meetings, including the International Conference on Harmonization.
4. The Chair then reported on the status of the capacity-building initiative which had been circulated and approved by Planning Group members in January. The proposal for facilitators to assist volunteer economies in conducting readiness assessments will be sent to CTI and SOM for endorsement, and then to the Budget Management Committee for consideration at their meeting at the end of March. The Chair noted that several economies had already expressed interest informally in volunteering to take part in the readiness assessment project, and invited economies to formally indicate their interest.
5. The United States reported that the International Conference on Harmonization, Global Cooperation Group (ICH GCG), had sent a letter on December 18, 2003 to the LSIF Chair inviting APEC to nominate one member to serve as a permanent representative to its meetings. The LSIF Chair had acknowledged the letter indicating that it would be discussed at the LSIF Planning Group in Santiago. There was discussion of the prospect of an interim representative pending the development of a selection process.
6. Thailand confirmed the interest of the Government Vice Chair of the LSIF, Dr. Pakdee Pothisiri in serving as the interim representative to the ICH GCG meeting in June, and also indicated that Dr. Pakdee would like to be considered as the permanent representative. Australia, China, Korea, and Chinese Taipei each reported that they also had candidates interested in serving as APEC's permanent representative to the ICH GCG.
7. The Planning Group agreed on a three-point plan of action: (1) The Planning Group supports APEC being permanently represented on the ICH GCG and requests SOM endorsement; (2) the three LSIF Vice-Chairs should expeditiously (and intersessionally)

draw up a list of criteria by which to judge the suitability of the various candidates, and to consider the terms and possible rotation schedule for APEC permanent representatives to the ICH GCG; and (3) In the meantime, Dr. Pakdee would serve as the coordinator and the interim representative for the purpose of the June 7, 2004 ICH-GCG meeting in Washington DC and the ICH GCG should be so informed as soon as possible.

8. The Planning Group Chair noted that the next meeting of the Life Sciences Planning Group would take place during the SOM II period. She further noted that the second Life Sciences Innovation Forum would take place in mid-September, and that Malaysia had informally expressed interest in hosting this event.

### Attachment

#### **LSIF: Report to LSIF Planning Group**

At their October 17-18, 2003 meeting in Bangkok, Thailand, APEC Ministers instructed the Life Sciences Innovation Forum (LSIF) to convene expert groups intersessionally to develop the strategic plan for life sciences innovation in the region for review and endorsement by APEC Ministers and Leaders at their November 2004 meetings. Accordingly, the Chair of the LSIF, H.E. Suwit Khunkitti convened a small expert group meeting February 12-13, 2004 in Khon Kaen, Thailand under the chairmanship of Dr. Pakdee Pothisiri, Government Vice-Chair of the LSIF, supported by industry Vice-Chair Richard Smith and Academic Vice Chair Dr. Peter Sheehan. Participants were identified by LSIF Vice Chairs in consultation with LSIF I Discussion Forum chairs and the LSIF Planning Group. A participants list is attached.

The four expert groups (research, development, manufacturing and marketing and health services) made an excellent start in identifying the specific goals and operating principles applicable and of priority to their particular area of expertise based on the outcomes of LSIF I (see attached). A draft working matrix of LSIF I outcomes developed by the LSIF Planning Group Chair in consultation with LSIF Chair and Vice Chairs was used as a guide (see attached draft matrix). It was felt that a further meeting of expert groups was needed to review, further refine and elaborate on the preliminary outcomes from Khon Kaen. The current proposal is to hold this meeting in June in Washington DC as many senior regulators, academics and industry representatives will convene in Washington at that time for other international life sciences related meetings. In the meantime, expert group chairs will work intersessionally in consultation with the LSIF Chair, Vice Chairs and the LSIF Planning Group chair to further develop a draft framework for the strategic plan for review at the June meeting. A progress report will be presented to CTI/SOM II.

LSIF Planning Group members are asked to identify an appropriate expert who will be participating in the June series of meetings in Washington DC. LSIF Chairs and Vice Chairs believe that we should not restrict expert participation to APEC economies as there are a number of world experts in the life sciences area upon whom the forum should draw. For example, the Khon Kaen expert group meeting included Dr. Edward Bramley-Harker, a world renowned health services expert who chaired that group in Khon Kaen and made a significant contribution to advancing the APEC LSIF agenda.

The Expert Group meeting in Khon Kaen also had preliminary discussions on the December 18, 2003 invitation to the LSIF from the International Conference on Harmonization (ICH) to nominate a permanent representative to its Global Cooperation Group (GCG). It was felt that this was an historic first for APEC. The LSIF Chair has responded in the affirmative on an interim basis, indicating that the government Vice Chair would coordinate APEC's response pending discussion at SOM I and related meetings in Santiago. A number of APEC economies have indicated interest in serving as the LSIF representative to the GCG.

Finally, the Expert Groups discussed ways of preparing life sciences innovation readiness assessments and the proposal to the APEC Budget and Management Committee for capacity building assessments.

#### 2004 Next Steps

- Expert groups work intersessionally to further develop the strategic plan framework and readiness assessments.
- BMC approval of capacity building pilot project
- Progress report to SOM II.
- Expert groups convene in Washington, DC in June
- Draft strategic plan circulated intersessionally in July/August
- Draft strategic plan and results of pilot readiness assessments presented to LSIF II in mid-September
- Draft strategic plan approved by SOM III for transmission to Ministers and Leaders
- Strategic plan presented to Ministers and Leaders for endorsement at their November meetings in Santiago.

## **Report of the Life Sciences Innovation Forum (LSIF) Planning Group 5/26/04**

The LSIF Planning Group met on May 26, 2004. Representatives attended from Australia, Canada, Chile, China, Hong Kong China, Indonesia, Malaysia, Papua New Guinea, the Philippines, Chinese Taipei, Thailand and the United States.

The Planning Group Chair briefed on developments since the February 28 Planning Group Meeting and provided a summary overview of the agenda. The U.S. reported on preparations for the June 11-12, 2004 Expert Working Group Meeting in Washington D.C. and noted that an updated agenda will be circulated shortly. Approximately 50 experts from Australia, Canada, China, Chinese Taipei, Hong Kong, Malaysia, Singapore, Thailand and the U.S. have already registered. The Chair noted that additional experts from economies would be welcome.

The Planning Group Chair reviewed the draft LSIF Readiness Assessment template that will be discussed by the June EWG meeting for further definition of the operating principles and targets. The template will be circulated again for review prior to the July-August commencement of pilot project assessments. The drafting committee representative clarified that the template is a working document that could be further refined as a result of the project assessments. Chile requested that all acronyms on the template be identified. Thailand confirmed its interest in conducting a pilot readiness assessment. China, Chinese Taipei, and the Philippines all indicated provisional interest.

The Planning Group Chair reviewed progress on developing the LSIF Strategic Plan noting that it will be based on the consolidated outcomes from LSIF I and Khon Kaen EWG. The June EWG meeting will further define the best practices that support the operating principles. The June EWG will provide an overview tied to the goals of the LSIF, and an executive summary and explanatory notes. The Chair noted that the Vice Chairs reviewed the consolidated outcomes and that comments from the Government Vice Chair were subsequently incorporated. This set of documents will constitute the Strategic Plan, which is due by the 2004 Ministers and Leaders Meeting. The draft plan will be circulated to the Planning Group for review in the third week of June with comments due by July 31. The drafting committee will incorporate comments and forward the revised plan to the Chair and Vice-Chairs for review and presentation to LSIF II with final review at SOM III.

The Planning Group discussed the ICH selection criteria and process for LSIF's participation at the ICH Global Cooperation Group's meetings. The group agreed to a minor modification to the selection criteria and agreed to revise the selection process as follows: the Planning Group would draw up an annual slate of candidates based on nominations from APEC economies. Nominations must include CVs and a letter of justification. The APEC Secretariat will serve as a clearinghouse for this process and will forward the nominees to the LSIF Chair and Vice-Chairs for final selection. The group agreed that an alternate would be appointed from the slate of candidates. The LSIF representative would serve for a term of one year. A revised document reflecting the changes to the selection criteria and process will be circulated to the Planning Group for further review.

The U.S. reported progress on a possible fiscal year 2005 U.S.-funded capacity building project on Good Clinical Practice.

Malaysia confirmed its offer to host LSIF II in Penang on September 15-16, 2004. More information will be circulated intersessionally including a call for suggestions for participants and speakers.

Report to the APEC SOM on the Life Sciences Innovation Forum  
by Professor Dr. Pakdee Pothisiri  
Deputy Permanent Secretary, Ministry of Public Health of Thailand  
Vice-Chair of the Life Sciences Innovation Forum  
22 August 2003, Phuket

Thank you Mr. Chairman,

On behalf of the APEC Life Sciences Innovation Forum Chairman, Mr. Suwit Khunkitti, Deputy Prime Minister of Thailand, I would like to present a brief report on key outcomes of the Forum, which held its inaugural meeting in Phuket during 14-15 August this year.

The Forum was convened with a view to implementing the APEC Leaders' instructions on the development of a strategic plan for life sciences innovation in the region. It was attended by over 200 high level participants from 17 economies drawn from academia, government and industry. The Forum attracted experts and noted policy makers such as Her Excellency Ms Sudarat Keyuraphan, the Thai MOPH Minister, HE Mr. Manual Dayrit, the Secretary of Health of the Philippines, Juan Enriquez, Harvard Business School, the author of the book "As the Future Catches You"

The Forum was held as plenary as well as panel discussion and break-out sessions to address and identify areas of cooperation in the four main segments of the life sciences innovation value chain, namely, research, development, manufacturing and marketing, and health care services. Several key themes emerged that were considered vital elements of a framework for the strategic plan. The written report of the key outcomes of the Life Sciences Innovation Forum has already been submitted to SOM.

The Forum recognized life sciences innovation as a critical area for growth and socio-economic development. The promotion of life sciences requires political leadership and commitment from the top, and depends on the proper policy environment, public-private partnership, sound basic education, human capacity, and efficient and effective delivery of patient-focused products and services. Transparency, meaningful dialogue with stakeholders and recognition of due process are among guiding principles to move forward the development of life sciences. Capacity-building will also be critical.

A number of immediate outcomes were identified as recommendations for Leaders' endorsement in October 2003, including, among others, agreement in principle to harmonize quality standards for life sciences products and services according to international best practices; and an assessment of the strength of each APEC economy to identify those areas where contributions to life sciences innovation may be established quickly and effectively.

As for the time-frame for the development of the strategic plan, given that life sciences technology is fast moving, the Forum recommends that the strategic plan be finalized by the time of the APEC Leaders Summit in 2004. It also recommends that expert groups work intersessionally to develop a road map encompassing best practices for each of the four main

segments of the life sciences innovation value chain for endorsement by Leaders at their 2004 Summit.

In all, the Forum was an excellent start for enhancing APEC's cooperation in the life sciences sector. I therefore hope that SOM will endorse the recommendations of the Forum.

Mr. Chairman,

I wish to add that Thailand takes the issue of life sciences innovation seriously. As a concrete step to promote life sciences innovation, we are establishing Thailand Center of Excellence for Life Sciences, which, as announced by Deputy Prime Minister Suwit during the Forum's meeting, will become operational in January 2004. This Center will complement our efforts to enhance cooperation in this area within APEC as well.

Finally, I would like to take this opportunity to thank the United States for this timely initiative and for their cooperation in making the first meeting of the Forum a real success.

Thank you.

**Summary Report of Life Sciences Innovation Forum (LSIF) Planning Meeting to CTI May 2003**

Purpose: For Consideration  
Submitted: US

The ad hoc LSIF Planning Committee was convened by the Chair, Barbara Norton, May 21, 2003 in Khon Kaen. A participant list is attached (from Catherine Wong, APEC Secretariat).

The first Life Sciences Innovation Forum will be held August 14-15, 2003, in Phuket Thailand as part of SOM III and related meetings. The Forum is expected to attract up to 300 participants and speakers. The Planning Group engaged in extensive discussion of the Forum Program, Speakers, Chair and Vice-Chairs. An updated program has been drafted, which reflects input and suggestion from the Planning Group (see attached for your review). Several economies indicated great interest in the LSIF from all three involved sectors--academia, private sector and government. Additional speakers names and nominations for Chair and Vice-chairs are continuing to be submitted up to the deadline of May 30. The Planning Group agreed that invitations to speakers would be issued in the first week of June. Each economy will be responsible for registering participants from their economy. A number of nominations have been received for Chair and Vice-chairs. The Planning Group will continue to work intersessionally to finalize the speakers, the placement of the speakers on the agenda, and Chair and Vice-chairs

Action requested: Endorse Life Sciences Innovation Forum Program as a working agenda to organize the Forum.

### **Report to CTI on Life Sciences Innovation Planning Forum February 2003**

1. The meeting was called to order by the Chair. Economies attending included Australia; Canada; Chile; China; Hong Kong, China; Indonesia; Japan; Korea; Malaysia; Mexico; New Zealand; Singapore; Chinese Taipei; Thailand; and the United States. The APEC Secretariat also attended the meeting.
2. An expert in the field made a presentation on the Life Sciences Value Chain.
3. The Chair opened the floor to discussion of the Terms of Reference (TOR), noting that these would need to be finalized at the February meetings, so that the Forum can be held in conjunction with SOM III and substantive work can begin intersessionally on the agenda and scope of the Forum. Extensive comment and discussion ensued, resulting in suggested amendments to the TOR and suggestions of topics for the Forum to cover. It was agreed that a further Planning Group meeting would be held in conjunction with SOM II.
4. The Chair adjourned the meeting, informing participants that a new draft, incorporating comments raised in the discussion would be distributed to all economies' boxes, asking for further comments on the new draft by end of day Feb 14.



APPENDIX V: Goals, operating principles and best practices:  
Report of the Expert Working Groups

Consolidated Outcomes from June 2004 meeting in Washington DC

**RESEARCH GROUP**

Goals

- To promote high-quality research<sup>7</sup> in all areas of the life sciences value chain<sup>8</sup>.
- To promote the application<sup>9</sup> of the outcomes of research.

Operating Principles<sup>10</sup>

- Policies, priorities and strategies
  - Member economies will, individually and together, develop research policies, priorities and strategies that are:
    - based on identified health priorities<sup>11</sup> and economic objectives
    - based on detailed policy research and evidence
    - subject to periodic reviews.
- Human capital and education
  - Member economies will give priority to sufficient number of skilled researchers in life sciences.
  - The development of human capital will be pursued
    - at all education levels
    - through collaboration among economies
    - through public and private collaborations.
- Collaboration and networking
  - Collaboration and networking will be based on trust, shared benefits and openness.
  - Member economies will work together to:
    - Support research that leads to improved health outcomes
    - Encourage and facilitate collaboration and networks at all levels and between public and private sectors.
- Infrastructure and coordination

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<sup>7</sup> All forms of research including basic, applied, and development research, in both public and private sectors

<sup>8</sup> This covers research in all four aspects of the life sciences value chain

<sup>9</sup> Broadly defined as encouraging the many different forms of applications, e.g., more research, translation, commercialization, communication of research to the public, and using of the results in formulating government policy

<sup>10</sup> In most, if not all, of these areas, capacity building will be of prime importance

<sup>11</sup> Having regard to the existing burden of disease and emerging disease

- Member economies will, individually and together, work to:
      - Develop strong and viable organizations and other infrastructure to support research
      - Establish centers of excellence with critical mass around research priorities
      - Provide adequate infrastructure to support research priorities
      - Encourage coordination between national research agencies
      - Develop mechanisms to align research activities on health priorities.
- Ethics and regulation
  - Member economies will, individually and together, work to ensure:
    - Appropriate and transparent ethical frameworks for research on health
    - Appropriate and transparent regulatory frameworks for research on health
    - Appropriate systems and mechanisms to support good research practices according to international best practices
    - Adequate training of personnel in the regulatory and ethical frameworks
    - Protection of intellectual property.
- Financing of research
  - Member economies will, individually and together, work to:
    - Ensure adequate financing of research on health priorities
    - Encourage public-private partnerships in financing research on health priorities
    - Improve access to private funding for the application of research outcomes.
- Best practices
  - Member economies will, individually and together, work to:
    - Utilize best practice peer review in the assessment of research
    - Ensure research is conducted by qualified personnel
    - Ensure clinical trials comply with relevant international standards
    - Ensure regulation of research is undertaken by qualified personnel
    - Regularly assess research practices and outcomes
    - Ensure consistent quality standards of research facilities.
- Public awareness, confidence and support
  - Member economies will, individually and together, work to
    - Communicate widely research policies, priorities, strategies and outcomes
    - Involve the community in research activities
    - Inform and consult the community on specific research issues.

## DEVELOPMENT GROUP

### Overall Goals

- Effective Regulatory Infrastructure that enhances innovation
- Harmonization of regulatory practices and policies according to international best practices
- Improved clinical trials infrastructure
- Effective Mechanism that enhances access to innovations

### Operating Principles

- Human Capital
  - Member economies will work to encourage investment in collaborative research grant programs between APEC economies.
  - Member economies will establish collaborative public-private research grant programs to support the development of human capital in LSIF.
  - Member economies will work to develop government/public sector core competencies, including:
    - a clear implementable plan for continuous improvement of core competencies
  - Member economies will work to improve human capital stock through:
    - Integration of life sciences as part of the school curriculum
    - Investment in domestic PhD and postdoctoral grant programs
    - Public Education & Awareness Programs
- Organizational Infrastructure and coordination
  - Member economies will establish a legal framework incorporating interagency review of new policies, guidance and regulations
  - Member economies will work to establish Centers of Excellence around research priorities
- Physical Infrastructure
  - Member economies will work to establish IT structure that includes:
    - high speed grid computing networks
    - high performance computing capability
    - high speed telecommunications infrastructures that are based on open standards are secure, robust and facilitate real time collaboration between academic institutions, governments and the private sector.
  - Member economies will work to invest in adequate research facilities through publi-private partnerships
- Environment for Investment in Research
  - Member economies will acknowledge the importance of adequate human, organizational and physical resources, including:
    - Transparent, predictable and science-based regulatory framework for transition from basic research to applied science with WHO criteria for ethical standards and ICH GCP
    - Mechanisms for commercial partnerships for transition from basic to applied research and commercialization
    - access to capital markets
- Protection of Intellectual Property

- Member economies will work to implement a legal framework that:
      - is defined as TRIPS consistent for patent protection
      - includes data exclusivity in regulatory process
      - provides for the protection of proprietary data
    - Member economies will work to provide adequate infrastructure and resources for enforcement of laws and regulations -- An integrated and linked administrative and judicial framework that is fair, predictable and efficient for concerned stakeholders. Intellectual property cases should be reviewed by IPR courts with trained judges/experts, evidence discovery frameworks, as well as mature injunction and bonding mechanisms to allow effective adjudication.
  - Legal framework with due process
    - Member economies will work to establish rule of law that includes an adequate mechanism for right of appeal
  - Transparency in development of regulations
    - Member economies will work to establish legal framework that incorporates adequate notice and comment into regulatory development
  - Regulatory Framework: Sound Science
    - Member economies will work to establish a regulatory framework that:
      - includes assessment of current practice relative to international best practices (e.g., ICH, WHO, ISO)
      - provides a regulatory process based only on safety, efficacy, and quality without additional requirements
      - includes use of public scientific advisory panels for specific scientific issues
  - Regulatory Framework: Transparency
    - Member economies will establish a clear, published process for drug development regulatory approval, <sup>6</sup> including:
      - a drug development process clearly specifying requirements for content, processes for advice, consent, and consultation; available through print and electronic media.
      - Mechanism for Industry Consultation
      - Mechanism for appeal
  - Regulatory Framework: Risk-and Evidence-based
    - Member economies will work to implement clear, established data requirements consistent with international best practices
      - Data requirements based on international standards (ICH, WHO, US FDA, EU CPMP), available through print and electronic media
      - Risk-based criteria with reference to safety, efficacy and quality for determining data requirements
  - Regulatory Framework: Predictability
    - Member economies will establish published timelines for regulatory processes and review of clinical data package consistent with international best practices and regulatory guidelines
  - Good Clinical Practices
    - Member economies will work to establish clinical trials requirements according to international standards and adopt ICH GCP and WHO guidelines as a standard for clinical trials requirements

- Member economies will work to ensure adequate training of regulatory and clinical personnel; including:
    - The establishment of Internal Review Boards (IRBs)
  - Member economies will work to release clear guidance to regulated community on clinical trial approval process
- Good Manufacturing Practices
  - Member economies will work to ensure:
    - the adequate training of government personnel, including inspectors
    - Assessment of current domestic practices in relation to international practice (e.g., WHO guidance)
    - Establishment of regulatory framework that recognizes manufacturers with history of adhering to GMPs
    - Performance assessment criteria based on international best practices—adequate infrastructures , indicators and criteria for inspection at the level of the ICH/PICS
- Environment for Capital Investment
  - Member economies will work to ensure:
    - Adequate IP protection defined as consistent with TRIPS
    - Science-based, transparent, predictable, regulatory environment
    - Adequate resources (human, organizational and physical)
    - Transparent market mechanisms including regulations
    - Mechanisms for public-private partnerships
- Services Environment
  - Member economies will work to establish a services environment that is:
    - Inclusive, open and transparent process
    - Interagency involvement and coordination
    - Accreditation systems
      - Ethical committee
      - GLP/ISO 17025 Laboratory
      - OECD GLP Laboratory

## MANUFACTURING AND MARKETING GROUP

### Goals:

- To ensure a transparent and science-based regulatory framework for the manufacturing and marketing of innovative life sciences products that will assure the safety, quality and efficacy of the products.
- To ensure the ability of patients to have timely access to innovative products.

### Operating Principles

- Human Capital
  - Member economies will invest in collaborative research grant programs between APEC economies that:
    - may be used to support investigations into both technology and policy; and
    - are based on the model established by the World Health Organization
  - Member economies will establish collaborative public-private research grant programs to support the development of human capital in LSIF.
  - Member economies will work to encourage human resource development in the private sector; that is, continuing education for employees, that:
    - provides an opportunity for partnerships involving professional societies that are already established in the APEC economies
    - may lead to the establishment of an APEC-wide federation of those professional societies that support the life sciences industry in a region
- Physical Infrastructure
  - Member economies will work to develop adequate information technology infrastructure that ensures the ability for regulators to communicate across economies
- Environment for Investment in Research
  - Member economies will establish a transparent, predictable, and science-based regulatory framework for transition from basic research to applied science as one of the most important operating principles
  - access to capital markets likewise is a necessity for an APEC economy to implement successful manufacturing and marketing capacity
- Protection of Intellectual Property
  - Member economies will implement a legal framework for patent protection, adequate infrastructure, and resources for enforcement of laws and regulations in order to protect intellectual property.
  - Acceptance of intellectual property rights must be consistent with WTO membership commitments.
- Legal Framework with Due Process
  - Member economies will work to establish rule of law that includes:
    - An adequate mechanism for right of appeal
    - Access to regulatory findings, especially in case of negative findings
    - An open and transparent process without risk of abuse to the regulatory authority

- A forthcoming regulatory authority with adequate information to support its findings without being subject to repeated rounds of questioning on the same topic
- Transparency in Development of Regulations
  - Member economies will work to establish a legal framework that incorporates adequate notice and comment into regulatory development
- Regulatory Framework: Sound Science
  - Member economies will work to implement a science-based regulatory framework where decisions are made firmly on the basis of safety, efficacy and quality and that:
    - Emulates appropriate international standards and international best practices such as ICH, WHO, ISO
    - Includes a clear and published process for drug development and regulatory approval, a mechanism for industry to consult with regulatory authorities, and a mechanism for appeal
    - Contains predictability and published timeframes for regulatory processes, with an aim to have a similar timeframe timelines for all Member economies
    - Takes into account ICH guidelines Q8, Pharmaceutical Development and Q9, Risk Management currently under development
  - When appropriate, public scientific advisory panels should be used for specific scientific issues related to a marketing application, new technology, or new regulatory initiative
- Good Manufacturing Practices (GMP)
  - Member economies will, individually and together, work to provide adequate training of government personnel, with the same training to be delivered to inspectors and industry personnel
    - Training design should take into account both current domestic practices and international best practices
  - Member economies will establish a regulatory framework that recognizes manufacturers with a history of compliance to GMP, with:
    - Performance based on international best practices
    - PICS (Pharmaceutical Inspection Cooperation Scheme) as mechanism for documentation and mutual recognition across APEC economies
  - Member economies will adopt an international baseline guidance for interpreting GMP.
    - Adherence to baseline good manufacturing practice should be acceptable in most cases
- Environment for Capital Investment
  - Member economies will implement a science-based, transparent, and predictable regulatory environment that provides protection of intellectual property in order to encourage adequate capital investment

## HEALTH SERVICES GROUP

### Goals

- To create an environment that is conducive to trade and investment in life science innovations
- To foster an inclusive and integrated approach to policymaking and implementation (policymakers need to co-ordinate their activities and consult with stakeholders)
- To monitor the quality and performance of health systems to ensure appropriate use of innovations

### Operating Principles

- Human capital and education
  - Member economies will make necessary investments in human capital to ensure that economy is able to collaborate and lead research activities.
  - Investments may include cross-country collaboration and public-private partnerships
  - Within the economy, members will educate their science base to ensure appropriate dissemination of new innovations
- Organizational infrastructure and co-ordination
  - Member economies will measure and assure the quality of research infrastructure
- Physical Infrastructure
  - Member economies will invest in IT systems and infrastructure that are:
    - coordinated, with interoperability and common standards across the health system
    - transparent and efficient tendering
    - equipped with feedback mechanisms to ensure objectives are being met and quality standards enforced
- Protection of intellectual property
  - Member economies will commit themselves to ensuring a legal and regulatory framework is in place to ensure IP standards are ensured and enforced
- Transparent regulatory framework
  - Member economies will work to implement a transparent process for deciding whether an innovation will be available in a health system that includes:
    - fast approval for public reimbursement (e.g. rapid inclusion on a national formulary)
    - efficient price negotiations
    - in the case of a pharmaceutical products, a clear and efficient process for obtaining marketing approval
  - A sensible benchmark is for products to be available privately as soon as they have marketing authorization, with approval for public reimbursement soon after via a clear and consistent process
- Good clinical practices
  - Member economies will work towards health systems with well-trained regulatory and clinical personnel who have clear guidance over processes that include:
    - mechanisms for monitoring quality



- mechanisms for reporting adverse events
- Portability of health insurance
  - Member economies will ensure that, where agreed, patients are able to make choices over where they have treatment
  - Member economies will also encourage the dissemination and take-up of innovations as health care providers start to compete in a broader market for patients
- Informed Patients
  - Member economies will encourage the provision of information about a variety of dimensions of health care, including quality and outcomes of different interventions, health care providers, physicians and patient experience so that patients may:
    - be involved in decisions about choice of treatment
    - be responsible users of innovations they need to know about their treatment (evidence suggests that compliance with treatment regimes is improved where patients are partners in the treatment process and are informed)
- Informed physicians
  - Member economies will work to ensure policymakers are willing and capable of:
    - disseminating good quality information to physicians
    - ensuring the continuing medical education of physicians
- Evidence-based medicine
  - Member economies will work to:
    - encourage evidence-based medicine subject to the condition that it is applied consistently across the health system, to the range of interventions and not just, for example, to new innovations
    - allow for clinical guidance based on good quality effectiveness and cost information
    - discourage mandatory guidance, which can limit clinical freedoms
- Budget setting
  - Member economies will work to:
    - adopt an integrated approach to budget setting
    - avoid setting budgets in a compartmentalized way (e.g. keeping prescribing budgets totally separate from other primary care budgets and secondary care budgets)
  - Compartmentalized budget setting may be harmful for health services innovations in that:
    - A risk exists that physicians in one part of a health system are reluctant to use an efficient innovation because it imposes a cost on their budget but the savings are realized elsewhere or many years in the future
    - an innovation that is efficient from the health system perspective may be under-used because individual physicians do not see their budgets or the benefits from the perspective of the whole system
- Separation of prescribing from dispensing
  - Member economies will work to separate prescribing from dispensing in order to:
    - ensure prescribing decisions are based around clinical needs
    - prevent financial motives from distorting prescribing behavior
- Balanced approaches to cost containment

- Member economies will work to focus on long-term efficiency and sustainability, not on short term cost containment
- Use of traditional remedies
  - Member economies will, where evidence shows sound clinical and efficiency benefits, work to make appropriate use of all types of health intervention, whether modern or traditional

## Summary Outcomes of the February 12-13, 2004 Expert Groups Meeting in Khon Kaen.

### 1. Strategic Plan

It was felt that the strategic plan should be based on clearly identified goals and operating principles supporting these goals. Best international practices should be utilized in developing the strategic plan. The strategic plan should allow individual economies the ability to clearly identify their strengths and weaknesses in segments of the life sciences value chain and provide a basis for developing individual and, where possible, collective APEC action plans, including identification of possible capacity building programs for implementation of the plan, beginning in 2005. Participants agreed that Ministers and Leaders need a document that is both workable and readily understood. As such, the strategic plan would include an executive summary that describes the goals and ways of achieving these goals from a strategic policy perspective.

### 2. Readiness Assessments

The development and implementation of life sciences innovation readiness assessments was endorsed by Ministers and Leaders in October 2003. It was felt that more work needs to be done on developing specific guidance in each area of the life sciences value chain before the readiness assessments can be fully developed. The expert groups heard a presentation on APEC's E-Commerce readiness assessments and determined that while that may be a valid model, the life sciences innovation sector did not lend itself to the quantifiable standards of the E-Commerce readiness assessments in all areas of the value chain. It was also felt that the life sciences innovation readiness assessments should avoid a questionnaire approach, instead it would be of more value to economies to clearly identify a menu of best practices options that supported the goals. Accordingly, the expert groups recommend that the life sciences innovation readiness assessments be drawn up for review by APEC economies and after the proposed meeting in June. In the meantime, the expert groups recommended that APEC call for 2 or 3 volunteers to participate in a readiness assessment pilot project for presentation to LSIF II in mid-September.

### 3. Expert Groups

#### a) Research

The Research Group was chaired by Academic Vice Chair, Dr. Peter Sheehan in the absence of Research Discussion Forum Chair Kim Sze Tan (Malaysia). The group considered in some detail the goals for life sciences research in the proposed strategic plan. This discussion took place in the context of the overall objectives of the APEC Life Sciences Innovation Forum to generate improved health outcomes and stronger economic development in member economies. The group identified two main goals: 1) To promote high quality research in all areas of the life sciences value chain and 2) To promote the application of the outcomes of the research. The proposed goals emphasized the promotion of research broadly defined, including basic, applied and development research in both the public and private sectors, and the application of this research to all elements of the life sciences value chain.

After detailed discussion of the matrix, the group developed draft operating principles to achieve these goals in eight areas, namely:

- policies, priorities and strategies,
- human capital and education,

- collaboration and networking,
- infrastructure and coordination,
- ethics and regulation,
- financing of research,
- best practices, and
- public awareness, confidence and support.

The principles developed in these areas are ones on the basis of which member economies might, both individually for national benefit and together for the benefit of the APEC region as a whole, identify and implement programs of action to achieve the goals. The starting point for such programs should be the identified health priorities of member economies, based on the actual burden of disease, and the contribution of improved capability in life science innovation to addressing those priorities.

#### b) Development

The Development Group was chaired by Dr. Suwit Wibulpolprasert, Senior Advisor on Health Economics, MOPH Thailand in the absence of Development Discussion Forum Chair John Lim (Singapore). The group held a robust discussion on the appropriate goals and operating principles that supported these goals. It was recommended that the goals as outlined in the matrix be amended to reflect the forward-looking nature of this group. As such, the group proposed three main goals: 1) Effective regulatory infrastructure that enhances innovation; 2) Harmonization of regulatory practices and policies according to international best practices; and, 3) Improved clinical trials infrastructure. The group also recommended a further goal – effective mechanisms that enhance access to innovations – in recognition that this goal might be better placed under health services. The group added an operating principle – public education and awareness programs, reasoning that these were a critical element necessary to achieve all the goals. Operating principles were further modified to reflect consistency with TRIPs with respect to IPR protection.

It was considered that IPR protection underpinned the success of life sciences innovation development in all areas, as did a regulatory framework grounded in sound science with the regulatory process based solely on safety, efficacy and quality. A legal framework with due process, risk and evidence-based procedures, transparent and predictable governmental processes and industry consultation in the regulatory framework were also considered critical factors in the development of life sciences innovation. These critical elements formed the basis for further detailed discussion by the group.

The group considered that an integrated and linked administrative and judicial framework dedicated to IPR protection was essential. The need for clear published process for drug development clearly specifying requirements including advice, consent and consultation available through print and electronic media was highlighted as an example of predictability in the regulatory environment. Other examples discussed by the group included the need for data requirements to be based on international standards (e.g. ICH/WHO); an adequate performance assessment infrastructure including indicators and criteria for inspection based on ICH/PICS; the adoption of ICH GCP and WHO guidelines as a standard for clinical trials; and, accreditation systems based on ethical guidelines and international standards such as OECD/GLP and

GLP/ISO 17025. The group recognized that an adequate and flexible IT infrastructure was an absolute requirement for life sciences product development.

The group concluded that more work needed to be done to flesh out the best practices that would support the operating principles and goals.

c) Manufacturing and Marketing

The group was chaired by Dr. James McArdle, Manufacturing and Marketing Discussion Forum Chair. The group recognized that its relatively small size would necessitate an additional meeting of experts. The group emphasized the need to invest in human capital, including developing the human resource in the private sector through continuing education programs; considered that a transparent, predictable and science-based regulatory framework was one of the most important operating principles that applied to all goals within manufacturing and marketing; and highlighted the need for WTO consistent IPR protection. As with the development group, there was discussion of the need for risk and evidence based procedures; and the adoption of international guidelines and best practices with respect to GMP. Access to capital was considered of importance across all areas of the value chain.

d) Health Services

The group was chaired by Dr. Edward Bramley-Harker in the absence of Dr. Frank Lichtenberg. It looked at the principles and mechanisms within a health system that impact on the incentives to develop and use life science innovations. Within this, the group identified three broad goals: 1) to create a conducive environment for life science innovation, trade and investment; 2) to encourage policymakers to develop inclusive approaches to policymaking and implementation; and 3) to ensure, through monitoring, that the health system is making good use of life science innovations and promoting quality in health care delivery. Many principles within the matrix were considered relevant to this. It was felt that human capital development was important to ensure knowledge transfer, both across APEC health systems and to filter information down to the level of individual clinicians.

IP and regulatory processes are important - strong IP and transparent and timely regulatory and reimbursement processes encourage early launch of life science innovations, with benefits to innovators, patients and health systems. Links to the broader health policy environment also impact on our goals for health services. For example, the provision of accessible information to patients is important, as is making sure physicians are informed about new innovations. The way budgets are set, and encouraging policymakers to consider spending in a whole-systems sense is also important (i.e. not to compartmentalize budgets, without making links between investment in one part of the health system and savings in another). Other influences on the health care environment include approaches to the application of evidence-based medicine, as well as the need to distinguish between short-term cost containment (often damaging to innovation) and long term sustainability. Within the APEC economies, the group considered there was a need to recognize that these principles apply to traditional (e.g. herbal and complementary) therapies. The group also proposes that APEC economies consider the portability of public health insurance as one operating principle.

APPENDIX VI: Example of draft LSIF Readiness Assessment Template (substance of template awaits endorsement of the strategic plan)

## LIFE SCIENCES INNOVATION FORUM READINESS ASSESSMENT TEMPLATE

Competencies for each phase of the life sciences value chain—research, development, manufacturing & marketing, and health services—are enumerated below. Through investigation and discussion, the facilitators will help each pilot economy determine their current status and the capacity building needs to reach the target.

Goal:

To conduct an assessment of the strength of each APEC economy to identify those areas where contributions to life sciences innovation may be established quickly and effectively.

## LIFE SCIENCES INNOVATION FORUM

Readiness Assessment: Segment of Value Chain (Research, Development, Manufacturing & Marketing, Health Services)

(ECONOMY)

Segment Goals:

- 
- 

Operating Principle	Target <small>(Identified Best Practice)</small>	Status	Technical Assistance/ Capacity Building <small>(Steps necessary to achieve target)</small>

## **Summary Report on the GCG Meeting**

**By**

**Professor Dr.Pakdee Pothisiri**  
**Deputy Permanent-Secretary, Ministry of Public Health**  
**Vice-Chairman of the APEC-LSIF**  
**Chairman of LSIF Expert Groups**

**To**

The APEC Life Sciences Innovation Forum Expert Group Meeting  
Washington DC, USA  
June 11-12, 2004

GCG stands for Global Cooperation Group and was established in March 1999, 9 years after the start of ICH, as a sub-committee of ICH Steering Committee, desiring to establish the link of the ICH with the Non-ICH region. At the beginning, its members are 6 ICH Parties, Public and Private organization from each ICH member; Japan, EU, and the US. The membership also include 2 Observers; the WHO and Health Canada, and the ICH Secretariat.

Starting point of the APEC-LSIF in the GCG was when the GCG invited the Chair of APEC-LSIF to nominate a Permanent Representative of a group to the GCG. Then, the Chair has designated a Vice-Chair Government, Professor Dr.Pakdee Pothisiri, as an Interim Permanent Representative for GCG.

The first participation of the APEC-LSIF was in the GCG Meeting, on 7 June 2004. This June 7 meeting of the GCG was the 1<sup>st</sup> Meeting of GCG with 5 Non-ICH Regional Harmonization Initiatives participants; namely ASEAN(Association of South East Asia Nations), GCC(Gulf Cooperation Council), PANDRH(Pan American Network for Drug Regulatory Harmonization, SADC(South African Development Community)(by telephone), and APEC. In this first Meeting, both a new Term of Reference or TOR, as well as Mandate of the GCG has been confirmed. It was also in this meeting that each Regional initiative formally presented its activities. In addition, the Non-ICH Regional initiatives identified an Areas of their particular interest. Finally, the Meeting also discussed the GCG next steps.

The GCG-TOR(Term of Reference) is important and has stated clearly the following;

1. The ICH GCG will act as the primary representative of ICH Steering Committee outside the ICH Region.
2. The ICH GCG will invite other non-ICH harmonization initiatives (rather than individual economies) to be “Permanent Representative”.
3. The ICH GCG will invite nomination of “Permanent Representative” to the ICH GCG from those harmonization initiatives that undertake activities meeting criteria established by the ICH GCG and ICH Steering Committee, as following;

The initiative should ;

- Be founded on the principle of harmonizing drug regulation across a defined group of economies
- Be science-based, with clear scientific harmonization objectives



- Be Currently active with meetings/activities regularly scheduled
- Have available, or establish, a mechanism to disseminate information on its activities with the ICH GCG to its member

**4. The ICH GCG will open its meeting in the future to the “Permanent Representative” of non-ICH partner initiatives unless, on occasion procedural discussion are required.**

To ensure complete transparency of activities, GCG will ;

- Public Summaries of its Meetings and other associated Document on public ICH website
  - Establish a ‘mailbox’ on the ICH website to receive questions for the GCG
- 5. The ICH GCG will use its meeting to identify, with the partner initiatives, topics and process issues associated with harmonization for discussion, collaboration, and potential development into a joint program of activities.**  
The ICH GCG will meet regularly (2-3 times / year), at the time of ICH Steering Committee, and at the time of Expert Working Group meeting.
6. On a case by case basis, the ICH GCG will invite other initiatives not meeting the criteria in point 3 above to present to the GCG on a specific topic of interest and relevance to the ICH GCG
  7. ICH Steering Committee will be consulted for approval on all proposed ICH GCG activities before they are undertaken.

And the Outcome of the GCG meeting could be summarized, as following;

1. Presentation of *APEC Interim Permanent Representative* on “Draft Criteria for APEC Participation in ICH GCG” has well been accepted and acknowledged by the Meeting.
2. This GCG Meeting was a very fruitful meeting and had allowed a better knowledge and understanding with active participation of non-ICH region initiative.
3. A two-way process of the Meeting had facilitated a flow of information, comments, and proposals.
4. Several Topics of Common Interest were identified.
5. The Meeting defined some actions on specific topics.
6. The Meeting also discussed for a development on exchanges, communication and procedures.
7. Lastly, the Meeting expressed a Positiveness and has welcome the further activities in the following months before the Yokohama meeting, as well.

The ultimate outcome from the GCG meeting was its report and proposal to the ICH Steering Committee was warm acknowledged and adopted. Its Term of Reference has been formally endorsed by the ICH Steering Committee.

APPENDIX VIII: Officers of the Life Sciences Forum and Expert Working Groups

Chair
H.E. Suwit Khunkitti Minister of Natural Resources and the Environment Thailand

Vice-Chairs	
Government & Chair of the Expert Working Groups	Professor Dr.Pakdee Pothisiri Deputy Permanent-Secretary Ministry of Public Health Thailand
Academia	Dr. Peter Sheehan Director Centre for Strategic Economic Studies Victoria University of Technology Australia
Industry	Mr. Richard Smith President Eli Lilly Asian Operations Hong Kong

Discussion Forum Chairs (past and current)	
Research	Dr. Kim Sze Tan (current) Dr. Peter Sheehan
Development	Mr. Michael Ward (current) John Lim
Manufacturing & Marketing	Dr. James McArdle
Health Services	Dr. Edward Bramley-Harker (current) Dr. Frank Lichtenberg

## APPENDIX IX: GLOSSARY OF TERMS

APEC	Asia Pacific Economic Cooperation
AP-IMBN	Asia-Pacific International Molecular Biology Network
CMOs	Contract Manufacturing Organizations
CROs	Contract Research Organizations
CTA	Clinical Trials Application
EMA	European Medicines Agency
EMBL	European Molecular Biology Laboratory
EMBO	European Molecular Biology Organization
CHMP	EMA Committee for Medicinal Products for Human Use
GCG	Global Cooperation Group
GCP	Good Clinical Practices
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GLP	Good Laboratory Practice
GMPs	Good Manufacturing Practices
GTN	Global Training Network
HRDWG	APEC Human Resources Development Working Group
ICH	International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICH GCG	ICH Global Cooperation Group
IEC	Independent Ethics Committee
IPR	Intellectual Property Rights
IRBs	Institutional Review Boards
ISO	International Organization for Standardization
ISTWG	APEC Industrial Science and Technology Working Group
IT	Information Technology
LSIF	Life Sciences Innovation Forum
Life Science Value Chain	(Research, Development, Manufacturing and Marketing, and Health Services)
MBC	Thailand Medical Biotechnology Center
MRC	Medical Research Council
NIH	National Institutes of Health
NHMRC	National Health and Medical Research Council
OECD	Organisation for Economic Co-operation and Development
PICS	Pharmaceutical Inspection Cooperation Scheme
Progenix	Progenix Research
REDI	Regional Emerging Disease Intervention Center
R&D	Research and Development
TCELS	Thailand Center of Excellence for Life Sciences
TRIPs	Trade-related aspects of intellectual property rights agreement (WTO)
US FDA	United States Food and Drug Administration
Wellcome	The Wellcome Trust
WHO	World Health Organization
WHO GTN	World Health Organization Global Training Network on Vaccine Quality
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

APPENDIX X: GLOSSARY OF INDICATIVE STANDARDS HARMONIZATION INITIATIVES

<p>Agenda for Leadership in Programs for Healthcare Accreditation (ALPHA)</p>	<p>The International Society for Quality in Healthcare (ISQua) initiative ALPHA, (the Agenda for Leadership in Programs for Healthcare Accreditation) looks to ensure global standards for accreditation processes. (<a href="http://www.isqua.org.au/isquaPages/Alpha.html">http://www.isqua.org.au/isquaPages/Alpha.html</a>)</p>
<p>Global Harmonization Task Force (GHTF)</p>	<p>The Global Harmonization Task Force (GHTF) is a group of representatives from national medical device regulatory authorities and the regulated industry. The purpose of the GHTF is to encourage convergence in regulatory practices related to ensuring the safety, effectiveness / performance and quality of medical devices, promoting technological innovation and facilitating international trade, and the primary way in which this is accomplished is via the publication and dissemination of harmonized guidance documents on basic regulatory practices. The GHTF also serves as an information exchange forum through which countries with medical device regulatory systems under development can benefit from the experience of those with existing systems and/or pattern their practices upon those of GHTF founding members. (<a href="http://www.ghtf.org">www.ghtf.org</a>)</p>
<p>International Conference on Harmonization (ICH)</p>	<p>The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) brings together the regulatory authorities of Europe, Japan and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration. The purpose is to make recommendations on ways to achieve greater harmonization in the interpretation and application of technical guidelines and requirements for product registration in order to reduce or obviate the need to duplicate the testing carried out during the research and development of new medicines. (<a href="http://www.ich.org">www.ich.org</a>)</p>
<p>Trade-related aspects of intellectual property rights agreement (TRIPS)</p>	<p>The WTO's TRIPS Agreement is an attempt to narrow the gaps in the way intellectual property rights are protected around the world, and to bring them under common international rules. It establishes minimum levels of protection that each government has to give to the intellectual property of fellow WTO members. When there are trade disputes over intellectual property rights, the WTO's dispute settlement system is available. (<a href="http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm">http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm</a>)</p>
<p>World Health Organization Global Training Network</p>	<p>The World Health Organization (Access to Technologies Team (ATT) of the Department of Vaccines and Biologicals) Global Training Network (GTN) consists of several institutions located throughout the world that provide training to achieve quality vaccine production and control. The purpose of the GTN is "to ensure that all vaccines used in national immunization programmes are of assured quality. It provides National Regulatory Authorities (NRA), National Control Laboratories (NCL), and vaccine producers who meet a minimum set of criteria and training. The Network consists of 13 training centres which offer instruction in priority areas using approved syllabi and standardized documentation materials. (<a href="http://www.who.int/vaccines-access/quality/gtn">www.who.int/vaccines-access/quality/gtn</a>)</p>

APPENDIX XI: Extracts from Ministerial and Leaders Statements concerning Life Sciences  
Innovation

2004 APEC Trade Ministers Meeting

MEETING OF APEC MINISTERS RESPONSIBLE FOR TRADE

PUCÓN, CHILE  
4 - 5 JUNE 2004

...

“We welcomed the work undertaken by Officials on business related activities, in particular the positive work achieved by business and governmental representatives in the Automotive, Biotechnology, Life Sciences, Chemical and Non Ferrous Metals Dialogues.”

...

“We welcomed the work of APEC's Life Sciences Innovation Forum in promoting global trade and investment in innovative life sciences products and services. We looked forward to reviewing its strategic plan in November.”

2003 LEADERS' DECLARATION

Bangkok Declaration on Partnership for the Future

BANGKOK, THAILAND

21 OCTOBER 2003

...

“We encouraged the Life Sciences Innovation Forum to complete its strategic plan by 2004.”

...

2003 15th APEC Ministerial Meeting

FIFTEENTH APEC MINISTERIAL MEETING

JOINT STATEMENT  
SUMMARY OF KEY ISSUES

....

“Ministers welcomed the first Life Sciences Innovation Forum in Phuket, Thailand in August 2003. They took note of the progress in developing the draft Strategic Plan for promoting Life Sciences Innovation and requested that the forum and its expert groups finalize the plan for endorsement in 2004.”

....

FULL JOINT MINISTERIAL MEETING STATEMENT

....

Life Sciences Innovation

“Ministers recognized the importance of life sciences innovation to economic development and the well being of people. They welcomed the first APEC Life Sciences Innovation Forum in Phuket, Thailand in August 2003 and supported the forum’s recommendations to identify economy-specific strengths in life sciences and ways to promote trade and investment, economic and technical cooperation and government-business sector collaboration in life sciences innovation. Ministers took note of the progress in developing the draft Strategic Plan for Promoting Life Sciences Innovation and requested that the forum and its expert groups finalize the plan for endorsement in 2004. As an immediate outcome of the forum, Ministers endorsed an agreement in principle to harmonize quality standards for life science products and services according to international best practices. They requested that the 4th APEC Ministers’ Meeting on Regional Science and Technology Cooperation in New Zealand in 2004 be kept informed of the forum’s progress.”

....

2002 LEADERS' DECLARATION

LOS CABOS, MEXICO  
OCTOBER 27, 2002

....

“We called for the establishment of a life-sciences innovation forum comprising government, private sector, and academia representatives to develop a strategic plan for life-sciences innovation in the region. This should include, as a priority, addressing the challenges of risk detection and prevention, treatment and cure of the communicable and lifestyle diseases which afflict our people.”

FOURTEENTH APEC MINISTERIAL MEETING

LOS CABOS, MEXICO  
23-24 OCTOBER 2002

JOINT STATEMENT

...

“Ministers also recognized members' interest in promoting public health improvement, and have made the life-sciences sector a high priority by approving the establishment of a Life-Science Innovation Forum in APEC.”

...

ECONOMIC LEADERS' STATEMENT

LOS CABOS, MEXICO  
23-24 OCTOBER 2002

...

“We acknowledged that investing in health will benefit economic growth, worker performance and productivity, and poverty alleviation. We need to be more effective with our investment at every stage of the health care process, including primary prevention against disease risks, and focusing on most vulnerable populations.”

...

**APEC PRIVACY FRAMEWORK  
29 OCTOBER 2004**

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**CONTENTS**

- Part I. Preamble**
- Part II. Scope**
- Part III. APEC Privacy Principles**
- Part IV. Implementation**
-



# **APEC PRIVACY FRAMEWORK**

## **Part I. Preamble**

1. APEC economies recognize the importance of protecting information privacy and maintaining information flows among economies in the Asia Pacific region and among their trading partners. As APEC Ministers acknowledged in endorsing the 1998 Blueprint for Action on Electronic Commerce, the potential of electronic commerce cannot be realized without government and business cooperation “to develop and implement technologies and policies, which build trust and confidence in safe, secure and reliable communication, information and delivery systems, and which address issues including privacy...”. The lack of consumer trust and confidence in the privacy and security of online transactions and information networks is one element that may prevent member economies from gaining all of the benefits of electronic commerce. APEC economies realize that a key part of efforts to improve consumer confidence and ensure the growth of electronic commerce must be cooperation to balance and promote both effective information privacy protection and the free flow of information in the Asia Pacific region.
2. Information and communications technologies, including mobile technologies, that link to the Internet and other information networks have made it possible to collect, store and access information from anywhere in the world. These technologies offer great potential for social and economic benefits for business, individuals and governments, including increased consumer choice, market expansion, productivity, education and product innovation. However, while these technologies make it easier and cheaper to collect, link and use large quantities of information, they also often make these activities undetectable to individuals. Consequently, it can be more difficult for individuals to retain a measure of control over their personal information. As a result, individuals have become concerned about the harmful consequences that may arise from the misuse of their information. Therefore, there is a need to promote and enforce ethical and trustworthy information practices in on- and off-line contexts to bolster the confidence of individuals and businesses.
3. As both business operations and consumer expectations continue to shift due to changes in technology and the nature of information flows, businesses and other organizations require simultaneous input and access to data 24-hours a day in order to meet customer and societal needs, and to provide efficient and cost-effective services. Regulatory systems that unnecessarily restrict this flow or place burdens on it have adverse implications for global business and economies. Therefore, in promoting and enforcing ethical information practices, there is also a need to develop systems for protecting information privacy that account for these new realities in the global environment.
4. APEC economies endorse the principles-based APEC Privacy Framework as an important tool in encouraging the development of appropriate information privacy protections and ensuring the free flow of information in the Asia Pacific region.

5. This Framework, which aims at promoting electronic commerce throughout the Asia Pacific region, is consistent with the core values of the OECD's 1980 Guidelines on the Protection of Privacy and Trans-Border Flows of Personal Data (OECD Guidelines)<sup>1</sup>, and reaffirms the value of privacy to individuals and to the information society.
6. The Framework specifically addresses these foundation concepts, as well as issues of particular relevance to APEC member economies. Its distinctive approach is to focus attention on practical and consistent information privacy protection within this context. In so doing, it balances information privacy with business needs and commercial interests, and at the same time, accords due recognition to cultural and other diversities that exist within member economies.
7. The Framework is intended to provide clear guidance and direction to businesses in APEC economies on common privacy issues and the impact of privacy issues upon the way legitimate businesses are conducted. It does so by highlighting the reasonable expectations of the modern consumer that businesses will recognize their privacy interests in a way that is consistent with the Principles outlined in this Framework.
8. Finally, this Framework on information privacy protection was developed in recognition of the importance of:
  - Developing appropriate privacy protections for personal information, particularly from the harmful consequences of unwanted intrusions and the misuse of personal information;
  - Recognizing the free flow of information as being essential for both developed and developing market economies to sustain economic and social growth;
  - Enabling global organizations that collect, access, use or process data in APEC member economies to develop and implement uniform approaches within their organizations for global access to and use of personal information;
  - Enabling enforcement agencies to fulfill their mandate to protect information privacy; and,
  - Advancing international mechanisms to promote and enforce information privacy and to maintain the continuity of information flows among APEC economies and with their trading partners.

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<sup>1</sup> The 1980 OECD Guidelines were drafted at a high level that makes them still relevant today. In many ways, the OECD Guidelines represent the international consensus on what constitutes honest and trustworthy treatment of personal information.

## PRINCIPLES

## COMMENTARY

### **Part II. Scope**

The purpose of Part II of the APEC Privacy Framework is to make clear the extent of coverage of the Principles.

#### Definitions

9. personal information means any information about an identified or identifiable individual

9. The Principles have been drafted against a background in which some economies have well-established privacy laws and/or practices while others may be considering the issues. Of those with already settled policies, not all treat personal information in exactly the same way. Some, for example, may draw distinctions between information that is readily searchable and other information. Despite these differences, this Framework has been drafted to promote a consistent approach among the information privacy regimes of APEC economies.

This Framework is intended to apply to information about natural living persons, not legal persons. The APEC Privacy Framework applies to personal information, which is information that can be used to identify an individual. It also includes information that would not meet this criteria alone, but when put together with other information would identify an individual.

## PRINCIPLES

10. **personal information controller** means a person or organization who controls the collection, holding, processing or use of personal information. It includes a person or organization who instructs another person or organization to collect, hold, process, use, transfer or disclose personal information on his or her behalf, but excludes a person or organization who performs such functions as instructed by another person or organization. It also excludes an individual who collects, holds, processes or uses personal information in connection with the individual's personal, family or household affairs.

11. **publicly available information** means personal information about an individual that the individual knowingly makes or permits to be made available to the public, or is legally obtained and accessed from:

- b) government records that are available to the public;
- c) journalistic reports; or
- d) information required by law to be made available to the public.

## COMMENTARY

10. The APEC Privacy Framework applies to persons or organizations in the public and private sectors who control the collection, holding, processing, use, transfer or disclosure of personal information. Individual economies' definitions of personal information controller may vary. However, APEC economies agree that for the purposes of this Framework, where a person or organization instructs another person or organization to collect, hold, use, process, transfer or disclose personal information on its behalf, the instructing person or organization is the personal information controller and is responsible for ensuring compliance with the Principles.

Individuals will often collect, hold and use personal information for personal, family or household purposes. For example, they often keep address books and phone lists or prepare family newsletters. The Framework is not intended to apply to such personal, family or household activities.

11. The APEC Privacy Framework has limited application to publicly available information. Notice and choice requirements, in particular, often are superfluous where the information is already publicly available, and the personal information controller does not collect the information directly from the individual concerned. Publicly available information may be contained in government records that are available to the public, such as registers of people who are entitled to vote, or in news items broadcast or published by the news media.

## PRINCIPLES

### Application

12. In view of the differences in social, cultural, economic and legal backgrounds of each member economy, there should be flexibility in implementing these Principles.
13. Exceptions to these Principles contained in Part III of this Framework, including those relating to national sovereignty, national security, public safety and public policy should be:
- a) limited and proportional to meeting the objectives to which the exceptions relate; and,
  - b) (i) made known to the public; or,  
(ii) in accordance with law.

## COMMENTARY

12. Although it is not essential for electronic commerce that all laws and practices within APEC be identical in all respects, including the coverage of personal information, compatible approaches to information privacy protection among APEC economies will greatly facilitate international commerce. These Principles recognize that fact, but also take into account social, cultural and other differences among economies. They focus on those aspects of privacy protection that are of the most importance to international commerce.

13. The Principles contained in Part III of the APEC Privacy Framework should be interpreted as a whole rather than individually, as there is a close relationship among them. For example, the Use Principle is closely related to both the Notice and Choice Principles. Economies implementing the Framework at a domestic level may adopt suitable exceptions that suit their particular domestic circumstances.

Although recognizing the importance of governmental respect for privacy, this Framework is not intended to impede governmental activities authorized by law when taken to protect national security, public safety, national sovereignty or other public policy. Nonetheless, Economies should take into consideration the impact of these activities upon the rights, responsibilities and legitimate interests of individuals and organizations.

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### **Part III. APEC Information Privacy Principles**

#### **I. Preventing Harm**

14. Recognizing the interests of the individual to legitimate expectations of privacy, personal information protection should be designed to prevent the misuse of such information. Further, acknowledging the risk that harm may result from such misuse of personal information, specific obligations should take account of such risk, and remedial measures should be proportionate to the likelihood and severity of the harm threatened by the collection, use and transfer of personal information.

14. The Preventing Harm Principle recognizes that one of the primary objectives of the APEC Privacy Framework is to prevent misuse of personal information and consequent harm to individuals. Therefore, privacy protections, including self-regulatory efforts, education and awareness campaigns, laws, regulations, and enforcement mechanisms, should be designed to prevent harm to individuals from the wrongful collection and misuse of their personal information. Hence, remedies for privacy infringements should be designed to prevent harms resulting from the wrongful collection or misuse of personal information, and should be proportionate to the likelihood and severity of any harm threatened by the collection or use of personal information.

#### **II. Notice**

15. Personal information controllers should provide clear and easily accessible statements about their practices and policies with respect to personal information that should include:

- a) the fact that personal information is being collected;

15-17. The Notice Principle is directed towards ensuring that individuals are able to know what information is collected about them and for what purpose it is to be used. By providing notice, personal information controllers may enable an individual to make a more informed decision about interacting with the organization. One common method of compliance with this Principle is for

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- b) the purposes for which personal information is collected;
  - c) the types of persons or organizations to whom personal information might be disclosed;
  - d) the identity and location of the personal information controller, including information on how to contact them about their practices and handling of personal information;
  - e) the choices and means the personal information controller offers individuals for limiting the use and disclosure of, and for accessing and correcting, their personal information.
16. All reasonably practicable steps shall be taken to ensure that such notice is provided either before or at the time of collection of personal information. Otherwise, such notice should be provided as soon after as is practicable.
17. It may not be appropriate for personal information controllers to provide notice regarding the collection and use of publicly available information.

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personal information controllers to post notices on their Web sites. In other situations, placement of notices on intranet sites or in employee handbooks, for example, may be appropriate.

The requirement in this Principle relating to when notice should be provided is based on a consensus among APEC member economies. APEC member economies agree that good privacy practice is to inform relevant individuals at the time of, or before, information is collected about them. At the same time, the Principle also recognizes that there are circumstances in which it would not be practicable to give notice at or before the time of collection, such as in some cases where electronic technology automatically collects information when a prospective customer initiates contact, as is often the case with the use of cookies.

Moreover, where personal information is not obtained directly from the individual, but from a third party, it may not be practicable to give notice at or before the time of collection of the information. For example, when an insurance company collects employees' information from an employer in order to provide medical insurance services, it may not be practicable for the insurance company to give notice at or before the time of collection of the employees' personal information.

Additionally, there are situations in which it would not be necessary to provide notice, such as in the collection and use of publicly available information, or of business contact information and other professional information that identifies an

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individual in his or her professional capacity in a business context. For example, if an individual gives his or her business card to another individual in the context of a business relationship, the individual would not expect that notice would be provided regarding the collection and normal use of that information.

Further, if colleagues who work for the same company as the individual, were to provide the individual's business contact information to potential customers of that company, the individual would not have an expectation that notice would be provided regarding the transfer or the expected use of that information.

### **III. Collection Limitation**

18. The collection of personal information should be limited to information that is relevant to the purposes of collection and any such information should be obtained by lawful and fair means, and where appropriate, with notice to, or consent of, the individual concerned.

18. This Principle limits collection of information by reference to the purposes for which it is collected. The collection of the information should be relevant to such purposes, and proportionality to the fulfillment of such purposes may be a factor in determining what is relevant.

This Principle also provides that collection methods must be lawful and fair. So, for example, obtaining personal information under false pretenses (e.g., where an organization uses telemarketing calls, print advertising, or email to fraudulently misrepresent itself as another company in order to deceive consumers and induce them to disclose their credit card numbers, bank account information or other sensitive personal information) may in many economies be considered unlawful. Therefore, even in



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those economies where there is no explicit law against these specific methods, they may be considered an unfair means of collection.

The Principle also recognizes that there are circumstances where providing notice to, or obtaining consent of, individuals would be inappropriate. For example, in a situation where there is an outbreak of food poisoning, it would be appropriate for the relevant health authorities to collect the personal information of patrons from restaurants without providing notice to or obtaining the consent of individuals in order to tell them about the potential health risk.

### **IV. Uses of Personal Information**

19. Personal information collected should be used only to fulfill the purposes of collection and other compatible or related purposes except:

- a) with the consent of the individual whose personal information is collected;
- b) when necessary to provide a service or product requested by the individual; or,
- c) by the authority of law and other legal instruments, proclamations and pronouncements of legal effect.

19. The Use Principle limits the use of personal information to fulfilling the purposes of collection and other compatible or related purposes. For the purposes of this Principle, “uses of personal information” includes the transfer or disclosure of personal information.

Application of this Principle requires consideration of the nature of the information, the context of collection and the intended use of the information. The fundamental criterion in determining whether a purpose is compatible with or related to the stated purposes is whether the extended usage stems from or is in furtherance of such purposes. The use of personal information for “compatible or related purposes” would extend, for example, to matters such as the creation and use of a centralized database to

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manage personnel in an effective and efficient manner; the processing of employee payrolls by a third party; or, the use of information collected by an organization for the purpose of granting credit for the subsequent purpose of collecting debt owed to that organization.

### **V. Choice**

20. Where appropriate, individuals should be provided with clear, prominent, easily understandable, accessible and affordable mechanisms to exercise choice in relation to the collection, use and disclosure of their personal information. It may not be appropriate for personal information controllers to provide these mechanisms when collecting publicly available information.

20. The general purpose of the Choice Principle is to ensure that individuals are provided with choice in relation to collection, use, transfer and disclosure of their personal information. Whether the choice is conveyed electronically, in writing or by other means, notice of such choice should be clearly worded and displayed clearly and conspicuously. By the same token, the mechanisms for exercising choice should be accessible and affordable to individuals. Ease of access and convenience are factors that should be taken into account.

Where an organization provides information on available mechanisms for exercising choice that is specifically tailored to individuals in an APEC member economy or national group, this may require that the information be conveyed in an “easily understandable” or particular way appropriate to members of that group (e.g., in a particular language). However if the communication is not directed to any particular economy or national group other than the one where the organization is located, this requirement will not apply.

This Principle also recognizes, through

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the introductory words “where appropriate”, that there are certain situations where consent may be clearly implied or where it would not be necessary to provide a mechanism to exercise choice.

As is specified in the Principle, APEC member economies agree that in many situations it would not be necessary or practicable to provide a mechanism to exercise choice when collecting publicly available information. For example, it would not be necessary to provide a mechanism to exercise choice to individuals when collecting their name and address from a public record or a newspaper.

In addition to situations involving publicly available information, APEC member economies also agreed that in specific and limited circumstances it would not be necessary or practicable to provide a mechanism to exercise choice when collecting, using, transferring or disclosing other types of information. For example, when business contact information or other professional information that identifies an individual in his or her professional capacity is being exchanged in a business context it is generally impractical or unnecessary to provide a mechanism to exercise choice, as in these circumstances individuals would expect that their information be used in this way.

Further, in certain situations, it would not be practicable for employers to be subject to requirements to provide a mechanism to exercise choice related to the personal information of their employees when

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using such information for employment purposes. For example, if an organization has decided to centralize human resources information, that organization should not be required to provide a mechanism to exercise choice to its employees before engaging in such an activity.

### **VI. Integrity of Personal Information**

21. Personal information should be accurate, complete and kept up-to-date to the extent necessary for the purposes of use.

21. This Principle recognizes that a personal information controller is obliged to maintain the accuracy and completeness of records and keep them up to date. Making decisions about individuals based on inaccurate, incomplete or out of date information may not be in the interests of individuals or organizations. This Principle also recognizes that these obligations are only required to the extent necessary for the purposes of use.

### **VII. Security Safeguards**

22. Personal information controllers should protect personal information that they hold with appropriate safeguards against risks, such as loss or unauthorized access to personal information, or unauthorized destruction, use, modification or disclosure of information or other misuses. Such safeguards should be proportional to the likelihood and severity of the harm threatened, the sensitivity of the information and the context in which it is held, and should be subject to periodic review and reassessment.

22. This Principle recognizes that individuals who entrust their information to another are entitled to expect that their information be protected with reasonable security safeguards.

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### **VIII. Access and Correction**

23. Individuals should be able to:

- a) obtain from the personal information controller confirmation of whether or not the personal information controller holds personal information about them;
- b) have communicated to them, after having provided sufficient proof of their identity, personal information about them;
  - i. within a reasonable time;
  - ii. at a charge, if any, that is not excessive;
  - iii. in a reasonable manner;
  - iv. in a form that is generally understandable; and,
- c) challenge the accuracy of information relating to them and, if possible and as appropriate, have the information rectified, completed, amended or deleted.

24. Such access and opportunity for correction should be provided except where:

- (i) the burden or expense of doing so would be unreasonable or disproportionate to the risks to the individual's privacy in the case in question;
- (ii) the information should not be disclosed due to legal or security reasons or to protect

23-25. The ability to access and correct personal information, while generally regarded as a central aspect of privacy protection, is not an absolute right. This Principle includes specific conditions for what would be considered reasonable in the provision of access, including conditions related to timing, fees, and the manner and form in which access would be provided. What is to be considered reasonable in each of these areas will vary from one situation to another depending on circumstances, such as the nature of the information processing activity. Access will also be conditioned by security requirements that preclude the provision of direct access to information and will require sufficient proof of identity prior to provision of access.

Access must be provided in a reasonable manner and form. A reasonable manner should include the normal methods of interaction between organizations and individuals. For example, if a computer was involved in the transaction or request, and the individual's email address is available, email would be considered "a reasonable manner" to provide information. Organizations that have transacted with an individual may reasonably be expected to answer requests in a form that is similar to what has been used in prior exchanges with said individual or in the form that is used and available within the organization, but should not be understood to require separate language translation or conversion of code into text.

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- confidential commercial information; or
- (iii) the information privacy of persons other than the individual would be violated.
25. If a request under (a) or (b) or a challenge under (c) is denied, the individual should be provided with reasons why and be able to challenge such denial.

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Both the copy of personal information supplied by an organization in response to an access request and any explanation of codes used by the organization should be readily comprehensible. This obligation does not extend to the conversion of computer language (e.g. machine-readable instructions, source codes or object codes) into text. However, where a code represents a particular meaning, the personal information controller shall explain the meaning of that code to the individual. For example, if the personal information held by the organization includes the age range of the individual, and that is represented by a particular code (e.g., “1” means 18-25 years old, “2” means “26-35 years old, etc.), then when providing the individual with such a code, the organization shall explain to the individual what age range that code represents.

Where individual requests access to his or her information, that information should be provided in the language in which it is currently held. Where information is held in a language different to the language of original collection, and if the individual requests the information be provided in that original language, an organization should supply the information in the original language if the individual pays the cost of translation.

The details of the procedures by which the ability to access and correct information is provided may differ depending on the nature of the information and other interests. For this

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reason, in certain circumstances, it may be impossible, impracticable or unnecessary to change, suppress or delete records.

Consistent with the fundamental nature of access, organizations should always make good faith efforts to provide access. For example, where certain information needs to be protected and can be readily separated from other information subject to an access request, the organization should redact the protected information and make available the other information.

However, in some situations, it may be necessary for organizations to deny claims for access and correction, and this Principle sets out the conditions that must be met in order for such denials to be considered acceptable, which include: situations where claims would constitute an unreasonable expense or burden on the personal information controller, such as when claims for access are repetitious or vexatious by nature; cases where providing the information would constitute a violation of laws or would compromise security; or, incidences where it would be necessary in order to protect commercial confidential information that an organization has taken steps to protect from disclosure, where disclosure would benefit a competitor in the marketplace, such as a particular computer or modeling program.

“Confidential commercial information” is information that an organization has taken steps to protect from disclosure, where such disclosure would facilitate a competitor in the market to use or

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exploit the information against the business interest of the organization causing significant financial loss. The particular computer program or business process an organization uses, such as a modeling program, or the details of that program or business process may be confidential commercial information. Where confidential commercial information can be readily separated from other information subject to an access request, the organization should redact the confidential commercial information and make available the non-confidential information, to the extent that such information constitutes personal information of the individual concerned. Organizations may deny or limit access to the extent that it is not practicable to separate the personal information from the confidential commercial information and where granting access would reveal the organization's own confidential commercial information as defined above, or where it would reveal the confidential commercial information of another organization that is subject to an obligation of confidentiality.

When an organization denies a request for access, for the reasons specified above, such an organization should provide the individual with an explanation as to why it has made that determination and information on how to challenge that denial. An organization would not be expected to provide an explanation, however, in cases where such disclosure would violate a law or judicial order.



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### **IX. Accountability**

26. A personal information controller should be accountable for complying with measures that give effect to the Principles stated above. When personal information is to be transferred to another person or organization, whether domestically or internationally, the personal information controller should obtain the consent of the individual or exercise due diligence and take reasonable steps to ensure that the recipient person or organization will protect the information consistently with these Principles.

26. Efficient and cost effective business models often require information transfers between different types of organizations in different locations with varying relationships. When transferring information, personal information controllers should be accountable for ensuring that the recipient will protect the information consistently with these Principles when not obtaining consent. Thus, information controllers should take reasonable steps to ensure the information is protected, in accordance with these Principles, after it is transferred. However, there are certain situations where such due diligence may be impractical or impossible, for example, when there is no on-going relationship between the personal information controller and the third party to whom the information is disclosed. In these types of circumstances, personal information controllers may choose to use other means, such as obtaining consent, to assure that the information is being protected consistently with these Principles. However, in cases where disclosures are required by domestic law, the personal information controller would be relieved of any due diligence or consent obligations.

### **Part. IV. Implementation**

27. Part IV provides guidance to Member Economies on implementing the APEC Privacy Framework. Section A focuses on those measures Member Economies should consider in implementing the Framework domestically, while Section B sets out APEC-wide arrangements for the implementation of the Framework's cross-border elements. Section B will be addressed in the Future Work of the Privacy Sub Group.

## **A. GUIDANCE FOR DOMESTIC IMPLEMENTATION**

### **I. Maximizing Benefits of Privacy Protections and Information Flows**

28. Economies should have regard to the following basic concept in considering the adoption of measures designed for domestic implementation of the APEC Privacy Framework:
29. Recognizing the interests of economies in maximizing the economic and social benefits available to their citizens and businesses, personal information should be collected, held, processed, used, transferred, and disclosed in a manner that protects individual information privacy and allows them to realize the benefits of information flows within and across borders.
30. Consequently, as part of establishing or reviewing their privacy protections, Member Economies, consistent with the APEC Privacy Framework and any existing domestic privacy protections, should take all reasonable and appropriate steps to identify and remove unnecessary barriers to information flows and avoid the creation of any such barriers.

### **II. Giving Effect to the APEC Privacy Framework**

31. There are several options for giving effect to the Framework and securing privacy protections for individuals including legislative, administrative, industry self-regulatory or a combination of these methods under which rights can be exercised under the Framework. In addition, Member Economies should consider taking steps to establish access point(s) or mechanisms to provide information generally about the privacy protections within its jurisdiction. In practice, the Framework is meant to be implemented in a flexible manner that can accommodate various methods of implementation, including through central authorities, multi-agency enforcement bodies, a network of designated industry bodies, or a combination of the above, as Member Economies deem appropriate.
32. As set forth in Paragraph 31, the means of giving effect to the Framework may differ between Member Economies, and it may be appropriate for individual economies to determine that different APEC Privacy Principles may call for different means of implementation. Whatever approach is adopted in a particular circumstance, the overall goal should be to develop compatibility of approaches in privacy protections in the APEC region that is respectful of requirements of individual economies.
33. APEC economies are encouraged to adopt non-discriminatory practices in protecting individuals from privacy protection violations occurring in that Member Economy's jurisdiction.
34. Discussions with domestic law enforcement, security, public health, and

other agencies are important to identify ways to strengthen privacy without creating obstacles to national security, public safety, and other public policy missions.

### **III. Educating and publicising domestic privacy protections**

35. For all Member Economies, in particular those Member Economies in earlier stages of development of their domestic approaches to privacy protections, the Framework is intended to provide guidance in developing their approaches.
36. For the Framework to be of practical effect, it must be known and accessible. Accordingly, Member Economies should:
- a) publicise the privacy protections it provides to individuals;
  - b) educate personal information controllers about the Member Economy's privacy protections; and,
  - c) educate individuals about how they can report violations and how remedies can be pursued.

### **IV. Cooperation between the Public and Private Sectors**

37. Active participation of non-governmental entities will help ensure that the full benefits of the APEC Privacy Framework can be realized. Accordingly, Member Economies should engage in a dialogue with relevant private sector groups, including privacy groups and those representing consumers and industry, to obtain input on privacy protection issues and cooperation in furthering the Framework's objectives. Furthermore, especially in the economies where they have not established privacy protection regimes in their domestic jurisdiction, Member Economies should pay ample attention to whether private sector's opinions are reflected in developing privacy protections. In particular, Member Economies should seek the cooperation of non-governmental entities in public education and encourage their referral of complaints to privacy enforcement agencies, as well as their continuing cooperation in the investigation of those complaints.

### **V. Providing for appropriate remedies in situations where privacy protections are violated**

38. A Member Economy's system of privacy protections should include an appropriate array of remedies for privacy protection violations, which could include redress, the ability to stop a violation from continuing, and other remedies. In determining the range of remedies for privacy protection violations, a number of factors should be taken into account by a Member Economy including:

- a) the particular system in that Member Economy for providing privacy protections (e.g., legislative enforcement powers, which may include rights of individuals to pursue legal action, industry self-regulation, or a combination of systems); and
- b) the importance of having a range of remedies commensurate with the extent of the actual or potential harm to individuals resulting from such violations.

## **VI. Mechanism for Reporting Domestic Implementation of the APEC Privacy Framework**

39. Member economies should make known to APEC domestic implementation of the Framework through the completion of and periodic updates to the Individual Action Plan (IAP) on Information Privacy.

## ANNEX I

### **FUTURE WORK AGENDA ON EFFORTS TO PROMOTE INTERNATIONAL IMPLEMENTATION 29 OCTOBER 2004**

The following items are general points of consideration for future work by the APEC ECSG Privacy Subgroup. Specific details on each of these issues are to be left up to discussion by the Subgroup in 2005.

#### **1. Information sharing among jurisdictions**

Taking into consideration existing, related international arrangements, Member Economies will endeavor to develop a multilateral mechanism for promptly, systematically and efficiently sharing information among APEC Member Economies. This will also include the designation of access point(s) within each Member Economy.

#### **2. Cross-border cooperation**

Member Economies should cooperate in relation to making remedies available against privacy infringements where there is a cross-border dimension. In order to contribute to this goal, Member Economies will endeavor to develop cooperative arrangements between privacy investigation and enforcement agencies of Member Economies.

#### **3. Cross-border privacy codes**

Member Economies will endeavor to support the development and recognition of organizations' cross-border privacy codes across the APEC region.

## **APEC REFORM REFORMS FOR IMMEDIATE ACTION**

### **AGENDA**

- Senior Officials will develop a clear set of initial priorities early in each APEC year based on Leaders instructions.
- However, Senior Officials will retain scope for a bottom-up approach to setting priorities on specific issues so that APEC remains responsive to emerging issues.
- Senior Officials will use the tasking database to monitor and follow-up the implementation of the instructions of Leaders and Ministers.

### **MEETINGS OF SENIOR OFFICIALS**

- Senior Officials Meetings will last for no more than two days.
- There will be no formal statements by official observers at SOMs (input by official observers may be sought on specific issues).
- The format introduced by Chile will be retained with a full day for informal discussion of priority issues. The plenary session and meetings of sub-groups on the second day will focus on overseeing the rest of the work program.
- Inter-sessional work will be improved, for example by use of videoconferences.
- Senior Officials will consider convening ad hoc meetings in response to urgent issues.

### **APEC MEETINGS OF LEADERS AND MINISTERS**

- The agenda for AMMs will be short and streamlined allowing maximum time for discussions in retreat format.
- “Information only” documents will not be formally presented.
- Leaders’ Declarations will be drafted as short, reader-friendly and results-oriented documents accompanied by stand-alone statements where appropriate.
- Joint press conferences of Leaders will be eliminated.

## **OUTREACH**

- Senior Officials will recommend to Leaders that the Bangkok model for dialogue between ABAC and Leaders be retained.
- The number of officials who can represent APEC at meetings of other organizations will be increased, subject to budgetary considerations.
- The Executive Director, Deputy Executive Director, SOM Chair and representatives from the SOM Chair's office will be allowed to represent APEC at meetings of other organizations without the approval of SOM.
- APEC host economy and Executive Director to reach out to stakeholders, including representatives of labour, and convey the outcomes to other economies, taking into account past practice.

## **COORDINATION**

- At the start of every year, APEC Senior Officials (or groups of Senior Officials) will discuss, at a meeting or through on-line communications, with Lead Shepherds of all Working Groups the priorities agreed by Leaders and Ministers and instruct them accordingly on the objectives they should pursue in the coming year.
- All fora will, in turn, review and streamline their work in light of APEC priorities.
- Senior Officials will review every three years the mandate and output of all fora, their consistency with APEC priorities and evaluate their continuing relevance.
- All Working Groups will include sunset clauses in their terms of reference. In addition, fora which do not attract a quorum (to be decided by Senior Officials) at two consecutive meetings will cease to exist.
- All working groups are encouraged to be evaluated by the ASCC, similar to the process undertaken by the Fisheries Working Group.
- The Economic Committee will be made responsible for the direction and oversight of the structural reform agenda under a mandate to be developed by Senior Officials.
- The BMC will continue to communicate with subsidiary fora to ensure that project proposals are in line with Leaders and SOM priorities.

## **APEC MANAGEMENT**

- Documents submitted by APEC members should follow a standard format that includes an executive summary and indicates clearly whether it contains proposals or is for information only.
- The 10-day rule for submission of new proposals will be reactivated.

# **APEC's Strategies and Actions toward a Cross-Border Paperless Trading Environment**

## **Electronic Commerce Steering Group**

30 September 2004

### **I. Background**

As demand for trade facilitation has been increasing throughout the business community due to the lowering of tariff barriers, more integrated manufacturing process involving different economies, and closer trade ties across the region, APEC has attached great importance to trade facilitation. In 2002, APEC Leaders and Ministers adopted the Trade Facilitation Action Plan (TFAP), which aims to reduce business transaction costs by 5% 2006. Ministers also approved a Trade Facilitation Menu of Actions and Measures and instructed relevant sub-fora to develop related capacity building and technical assistance or co-operation projects. The four categories for the reform cover the movement of goods, standards, business mobility and electronic commerce.

In its report to APEC Leaders in 2003, the APEC Business Advisory Council (ABAC) recommended APEC "implement paperless trading through the development of a single-window system that covers all import and export-related procedures." Member economies have demonstrated a strong willingness to achieve this goal, with many undertaking internal analyses of their trading systems and several implementing domestic paperless trading environments. In addition, several pilot projects based on the Pathfinders are being initiated among APEC economies. Plurilateral e-commerce alliances have been formed within the APEC region. The advance in ICT technology and the widespread use of the Internet, especially broadband, is assisting the process.

In September 2003, Chinese Taipei, together with Australia; Hong Kong, China; Japan; and Singapore, hosted the APEC Paperless Trading Symposium. The Symposium discussed the current impediments and the development of cross-border paperless trading, and considered pilot projects and capacity building initiatives to accelerate the progress to establish a paperless trading environment within APEC. Following the 2003 APEC Paperless Trading Symposium, China hosted the first Electronic Commerce Business Alliance Seminar in June 2004 and called for closer collaboration among business society to achieve the APEC paperless trading goal. Thailand hosted the APEC Symposium on ebXML for Paperless Trading and collaborative e-Business in June 2004 and urged harmonization on technical issues with other international organizations and among member economies. Furthermore, discussion on the implementation of the Electronic Certificate of Origin (ECO) Pathfinder and the Electronic Sanitary and Phyto-Sanitary Certificates (e-SPS) Pathfinder has been putting in progress.

### **II. Objectives and timelines**

Member economies aim to reduce and eliminate the required paper documents in trade administration, customs clearance, international transportation, and financial settlement. Ultimately a comprehensive paperless trading environment across the APEC region is to be established. To this end, member economies will endeavor to achieve the following objectives:

- |      |   |
|------|---|
| 2006 | As a part of the APEC Trade Facilitation Action Plan, interested member economies implement ECO and e-SPS Pathfinders for the cross-border transmission of electronic certificates of origin and electronic sanitary and phyto-sanitary certificates. |
| 2010 | Most member economies establish a domestic paperless trading environment and implement pilots for the cross-border electronic transmission of customs clearance data.   |



2020 APEC establishes a comprehensive paperless trading environment that enables the electronic transmission of trade related information across the region.

### **III. Strategies and issues**

The 2003 APEC paperless trading symposium recommended to adopt the following five strategies to achieve the goal of paperless trading:

- enhance public-private partnerships and commitments to achieve the APEC paperless trading goals;
- strengthen APEC's institutional arrangements and capacity building programs as well as experience sharing with international organizations and the business community;
- employ APEC Pathfinders as a valuable mechanism to initiate pilot programs;
- collaborate with international organizations to pursue common standards and procedures, elements, formats and interoperability frameworks; and
- achieve a balance between trade facilitation and security.

The environment for cross-border paperless trading requires the establishment of an interoperable framework for transmitting information in trade administration, customs clearance, international transportation and financial settlement. The framework includes business process, common data models, message standards and a platform for message exchange. The establishment of such a framework shall touch upon issues in legal, technical and procedural areas. Therefore, to accomplish such a framework, APEC shall launch pilot programs, while intensifying capacity building activities as follows:

#### **1. Pilot programs:**

- Ensuring the implementation of the existing APEC Pathfinders:
  - e-SPS, ECO, Revised Kyoto Convention
- Proposing new pathfinders for other priority areas:
  - cross-border electronic transmission of customs clearance data for express consignment based on WCO customs data model, followed by further initiatives for air cargos and ocean-going cargos
  - others

#### **2. Capacity building activities:**

- Reinforcing experience sharing among member economies in establishing a web-based single-window electronic access mechanism
- Increasing discussion on the legal, technical and procedural issues related to cross-border exchange of trade related e-documents
- Enhancing interactions with other international organizations on trade facilitation related issues
- Providing technical assistance programs for member economies

### **IV. The proposed work programs**

In spite of the ambition rendered by member economies, the lack of an overall picture and integrated plan for the implementation of pilot programs and capacity building activities continues to hinder the movement toward paperless trading. Coordination is required between the public and private sectors, including the harmonization of laws and standards among APEC members, as is collaboration between business and government. Therefore, ECSG proposes the following work programs to accelerate the progress in constructing a paperless trading environment within APEC:

#### **A. Ensuring the implementation of the existing APEC Pathfinders:**

- ECSG takes the responsibility to monitor the implementation of Electronic Certificates

- of Origin (ECO).
  - ECSG coordinates Agricultural Technical Cooperation Working Group (ATC WG) to implement Electronic Sanitary and Phyto-Sanitary Certificates (e-SPS).
  - CTI/SCCP shares information with ECSG on the progress of the adoption of the revised Kyoto Convention and the WCO customs data model and other paperless trading initiatives.
- B. Initiating new pathfinders for other priority areas:
- CTI/SCCP puts forward a project to harmonize customs declaration items among interested member economies.
  - CTI/SCCP launches a new Pathfinder on cross-border electronic transmission of customs clearance data for express consignment based on WCO customs data model, followed by further initiatives for air cargos and ocean-going cargos.
  - TEL Working Group discusses cross-recognition of PKI domains, aiming to establish a registry of APEC “recognized” certificate authorities (CAs) to provide a secured cross-border paperless trading environment.
- C. Intensifying capacity building activities:
- Relevant sub-fora carry out training programs to enhance experience sharing in establishing a web-based single-window for paperless trading.
  - Relevant sub-fora hold workshops to increase discussion on the issues related to cross-border exchange of trade related e-documents.
  - ECSG sponsors assessment and benchmarking of current practices in paperless trading.
  - ECSG organizes a paperless trading expert group and provides technical assistance programs for member economies.
- D. Collaborating with other international organizations:
- ECSG establishes a coordination mechanism with UN/CEFACT on international e-business standards.
  - ECSG coordinates with UN/CEFACT for the purpose of creating and ratifying the message standards of e-SPS, ECO and other possible initiatives.
  - Relevant sub-fora reinforce information sharing with international organizations to maximize and realize the harmonization and interoperability of required data elements, formats and frameworks.
- E. Achieving a balance between trade facilitation and security:
- CTI/SCCP promotes the application of advanced risk management technologies and information systems to facilitate trade and enhance security.
  - Member economies adopt advanced IT technologies to enhance anti-terrorism mechanism.
- F. Strengthening of public-private partnerships:
- Relevant sub-fora establish a mechanism to enhance public-private partnerships.
  - Member economies include in their FTAs a specific reference to promoting the use of paperless trading for cross-border transactions.
  - ECSG involves APEC Business Advisory Council (ABAC), Global Business Dialogue on e-Commerce (GBDe), Pan-Asian E-Commerce Alliance (PAA), Asia PKI forum, and other appropriate business societies in its proceedings as guests to nurture participation.

### **The recommendations**

- Senior Officials adopt the “APEC's Strategies and Actions toward a Cross-Border Paperless Trading Environment” and report to the 2004 Annual Ministerial Meeting for endorsement on the objectives and timelines to establish a paperless trading environment within APEC.
- Senior Officials endorse the proposed work programs as outlined in Section 4 and task relevant sub-fora to implement the programs.
- Member economies endeavor to establish a domestic paperless trading environment and implement bilateral or plurilateral pilots for the cross-border electronic transmission of customs clearance data.

## **COMPREHENSIVE ACTION INITIATIVE RECOGNISING THE NEED FOR STRENGTHENING THE APEC ENERGY SECURITY INITIATIVE – ENERGY SECURITY, SUSTAINABLE DEVELOPMENT AND COMMON PROSPERITY (CAIRNS)**

### **1. Background**

Energy is vital to realising the opportunities presented by economic growth and development for communities in the APEC region. Sustained economic growth is dependent on adequate, reliable and affordable supplies of energy.

At their meeting in 2000, the APEC Economic Leaders identified the risks to the world economy posed by volatility in the oil market and called for appropriate measures to promote stability in the mutual interests of energy consumers and producers.

In response, the Energy Working Group (EWG) developed the APEC Energy Security Initiative (ESI), which was endorsed by the APEC Economic Leaders at their meeting in 2001, held shortly after the events of September 11. Furthermore, the 'Recommendations of the APEC Energy Security Initiative' was endorsed at the fifth meeting of APEC Energy Ministers; both short-term and long-term measures were identified and encouraged for implementation.

At their meeting in 2002 the APEC Economic Leaders identified, in their 'Statement on Fighting Terrorism and Promoting Growth', the ESI as one of a number of collective activities underway in APEC to advance counter-terrorism commitments. In doing so, they "endorsed the strengthening of energy security in the region under the mechanism of the Energy Security Initiative".

To further implementation of the ESI the EWG developed, in 2003, an Implementation Plan including timeframes where appropriate. In light of this development, and in response to the region's energy security challenges and rising oil prices, the APEC Economic Leaders instructed, at their meeting in 2003, the EWG to "Accelerate the implementation of the Energy Security Initiative by endorsing its Implementation Plan and, as appropriate, a new Action Plan to enhance regional and global energy security."

The importance of the ESI, and the instructions from APEC Economic Leaders, was highlighted by the emergence of high global oil prices during 2004, and the potential impact on economic growth and sustainable development within the APEC region.

Having concern for the impact of high oil prices on our economies, APEC Energy Ministers, at their sixth meeting in June 2004 "recognised that a variety of factors influence global markets, and in that context we commit our own efforts to enhance energy security."<sup>1</sup> Energy Ministers also recognised "that access to adequate, reliable and affordable energy is fundamental to achieving the region's economic, social and environmental objectives, that energy security challenges faced by the APEC region are constantly evolving, and that our efforts to enhance energy security must be flexible and responsive." In this context, Energy Ministers "agreed that initiatives should be developed and implemented in close cooperation with the business, research and financial communities".

These initiatives include:

- preparing for energy supply disruptions;
- facilitating energy investment;
- using energy more efficiently;
- expanding energy choices; and
- capitalising on technological innovation.

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<sup>1</sup> "Energy Security in APEC: Cooperation for a Sustainable Future", Declaration from the Sixth Meeting of APEC Energy Ministers, Manila, the Philippines, 10 June 2004.

## **2. An enhanced APEC Energy Security Initiative**

In light of the directions from the APEC Economic Leaders and Energy Ministers, and in response to persistent high oil prices throughout 2004, Member Economies commit to implement and enhance the short and longer-term measures identified in the ESI, including measures to promote sustainable development and common prosperity. In addition, Members Economies agreed that it is important to assess the economic implications of high oil prices on the APEC region.

### **2.1 Implement the APEC Energy Security Initiative's short and longer-term measures:**

#### Short-term Measures

*Assess the economic implications of high oil prices on the APEC region* – In response to persistently high oil prices the EWG agrees that, whilst global economic fundamentals are sound, an important complement to the work currently being undertaken under the ESI is to assess the impact of high oil prices on trade within the APEC region. This assessment will not only support the EWG in its implementation of the ESI, it will also support efforts by other APEC fora to facilitate trade within the APEC region, for example the APEC Committee on Trade and Investment (CTI).

The assessment will commence in 2005, and be undertaken in close cooperation and with the support of the APEC business and research communities. It will analyse the impact of several scenarios for oil prices (eg business as usual, moderate sustained oil price rises, high sustained oil price rises) on key economic indicators in the APEC region, including trade in goods and services in the APEC region.

*Energy Emergency Response* – Encourage and assist Member Economies to have emergency mechanisms and contingency plans in place to provide the capacity to respond to energy emergencies, including encouraging the adoption of 'Best Practice Principles for the Establishment and Management of Strategic Oil Stocks' in interested Member Economies.

*Joint Oil Data Initiative* – Continue, through the EWG Expert Group on Energy Data and Analysis, to build the capacity of Member Economies to collect and report monthly oil data to the global Joint Oil Data Initiative, as a means to improve accuracy, coverage and timeliness of data and transparency in the global oil market.

*Real-Time Emergency Information Sharing* – Stress the importance of implementing the Real-Time Emergency Information Sharing System, including the development of an operational manual to assist Member Economies use the System.

*Sea-lane Security* – Monitor efforts to strengthen sea-lane security within the APEC region, and to respond and communicate with relevant bodies as appropriate.

#### Longer-term Measures

*Energy Investment* – Assist Member Economies to facilitate investment in energy infrastructure, energy efficiency and renewable energy projects by encouraging the implementation of the recommendations identified in the EWG's 'Energy Investment Report', working closely with the EWG Business Network and APEC business and financial communities. In addition, develop best practices to facilitate investment in the upstream oil producing sector.

*Natural Gas Trade* – Support the creation of a competitive and transparent marketplace for gas trade by encouraging Member Economies to adopt best practice as identified in 'Facilitating the Development of LNG Trade in the APEC Region', and to improve security of supply by identifying vulnerabilities, supporting trade promotion and establishing convenient links to gas market data available in existing data systems.

*Energy Efficiency* – Support the development and adoption of more energy-efficient technologies, policies and measures by encouraging information exchange and technology transfer, enhance the EWG's invigorated Pledge and Review Program by developing guidelines and support the Energy Standards and Labelling Cooperation Initiative. Strengthen the leading role of governments in energy saving, for example, by setting government standards and other mechanisms for government buildings or premises, facilitating the development of energy service companies and giving priority to energy saving products in government procurement.

*Renewable Energy* – Support the development and deployment of more economically viable new and renewable energy technologies by encouraging information exchange, technology transfer, capacity building, market development and other cooperation under the 21<sup>st</sup> Century Renewable Energy Development Initiative, working closely with the EWG Business Network and APEC business and research communities.

*Clean Fossil Energy* – Support the development and deployment of clean fossil energy and carbon dioxide capture and geological sequestration technologies, working closely with the EWG Business Network and the APEC business and research communities.

*Hydrogen and Alternative Transportation Fuels* – Follow the directions of APEC Energy Ministers in relation to hydrogen and alternative transportation fuels, such as biofuels, GTL and DME, including working with the APEC Industrial Science and Technology Working Group on the 'Future Fuels Foresighting Project'.

*Methane Hydrates* – Support research on the potential of methane hydrates as a future energy source by communicating research developments within Member Economies.

*Nuclear Energy* – Encourage interested Member Economies to cooperate on nuclear power in accordance with the EWG agreed framework, recognising that some Member Economies do not consider nuclear power as an option for their energy mix. Security, seismic and health concerns, including trans-border effects should be adequately addressed.

*Petroleum infrastructure/Crude oil and refined products* – Working closely with the EWG Business Network, identify problems and enhance efficiency in refining, transport and distribution of crude oil and petroleum products.

## **2.2 Promote Energy for Sustainable Development and Common Prosperity**

Recognising the essential link between energy and sustainable development and the environmental pressure imposed by ever-increasing energy consumption, Member Economies, through the EWG, commit to the coordination of energy, economic and environmental objectives as described in the EWG's Type II Partnership Initiative: Energy for Sustainable Development, which was submitted to the World Summit on Sustainable Development in 2002. This Partnership gives priority to the improvement of energy efficiency, enhanced development of renewable and new energy and the dissemination of environmentally friendly energy technologies in the APEC region.

Recognising that at present [200 million] people in the APEC region still have no access to electricity, Member Economies commit to undertake activities, through the EWG, to promote common prosperity by giving priority to increase the availability of affordable energy to all within the APEC community. Member Economies also recognise that efforts to strengthen coordination among energy development, poverty reduction, job creation and economic growth will enhance the region's energy security in the long term.

Member Economies recognise that implementing the enhanced Energy Security Initiative will maximise and promote sustainable development and poverty reduction, and improve the environmental amenity of energy production, transmission, distribution and use. Member Economies commit to emphasise and promote the capacity building and best practice aspects of the enhanced ESI.

## FIGHTING AGAINST AIDS IN APEC

The world first heard about HIV/AIDS in 1980s, and since then, 6 million people in the Asia-Pacific region alone have become infected and about 1,500 people died of AIDS every day in the late 1990's.<sup>1</sup> However, since 2001, the Asia-Pacific region has had a success story in reducing the prevalence of HIV, given the strong political commitment combined with strong support from the relevant international organizations, such as UNAIDS, WHO and the Global Fund to fight AIDS, Tuberculosis and Malaria, in exercising HIV intervention measures.

However, we cannot afford to be complacent, for although statistics show that the percentage of the adult population infected with HIV looks reassuringly low in Asia and the Pacific, more than 1 million people in the region became infected with HIV/AIDS in 2003. And more than 7 million people in the region are now estimated to have the virus and in 2003, half a million Asia-Pacific people died of it<sup>2</sup>. It is, therefore, crucial that more work and effort should be explored and implemented to prevent future epidemic growth within and outside the APEC region.

AIDS is a threat to the global economy and society as a whole. A strong political commitment from APEC is a prerequisite to successfully tackling this deadly infectious disease. Building upon the 2001 APEC Economic Leaders' initiative on "Infectious Disease in the Asia Pacific Region: A Reason to Act and Acting with Reason" and the 2003 Health Security Initiative, APEC will take the following measures:

1. Send a strong message from Leaders declaring APEC's commitment to fight AIDS regionally and globally:

*"We pledge our collective political commitment to combat the further spread of the AIDS pandemic. We commit our economies to work together at the regional and global levels. We support efforts to increase access to health care and safe and affordable drugs for all people living with AIDS."*

2. Call for collective efforts from all stakeholders in government, medicine, business and media to reinforce domestic campaigns and initiate or support, existing international campaigns against AIDS.

3. Consider effective actions to address:

- Gender inequalities that drive the HIV/AIDS epidemic. Action should recognize both the essential contribution of women and girls and address their unique needs;
- Protection of high risk populations and vulnerable groups from HIV infection through sexual transmission, injection drug use, mother-to-child transmission, and blood transfusions and those affected by AIDS such as children.

4. Instruct Senior Officials to request that relevant APEC fora incorporate work on AIDS into their work programs, with the APEC Health Task Force coordinating the effort, in order to support, not duplicate, global and regional efforts to expand access to treatment and to sustain and strengthen prevention efforts, including those directed at youth. Under all circumstances, the AIDS work program within APEC should only complement and add value to the work undertaken by competent international and regional organizations.

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<sup>1</sup> Report on HIV/AIDS in Asia and the Pacific Region 2001 by World Health Organization

<sup>2</sup> UNAIDS 2004. Report on the Global HIV/AIDS Epidemic. Geneva: UNAIDS

## IPR POLICY PROGRESS MAPPING AND FOLLOW-UP REPORT ON “COMPREHENSIVE STRATEGY ON IPR IN APEC”

### 1. Background

APEC recognizes the critical role of ensuring protection of intellectual property rights (IPR) in trade and investment facilitation from the following perspectives.

IPR protection plays an important role in member economies' efforts toward improving the trade and investment environment and is an essential factor which contributes to the achievement of APEC's goal of trade and investment facilitation. Absence of adequate protection of IPR would cause a serious damage to the reputation of an economy's trade and investment environment and would become an obstacle to the promotion of trade and investment.

Protection of IPR is an essential condition for promoting the creation, active utilization, and constant innovations of intellectual properties, and also for the sustained economic growth of APEC economies through innovations as well as for the realization of an IT-based economy in which widespread utilization of IT would accelerate intellectual creation.

Recognizing these critical factors, APEC has been undertaking a number of works on protection of IPR. Those works are also referred to in the IPR comprehensive strategy which was agreed on last year.

### 2. Overview and Objectives

This document consists of two parts: (1) the reports on each economy's IPR policy progress mapping and (2) the follow-up report on comprehensive strategy on IPR.

#### 2.1 IPR Policy Progress Mapping

The progress mapping is based on each economy's IAP and own input\*. The progress made by each economy is mapped to the following four areas/phases so that the information is organized in a concise and user-friendly manner.

- (A) Protection of IP Rights
- (B) Expeditious granting of IR rights
- (C) Strengthening of dispute settlement of IP rights
- (D) Strengthening enforcement of IP rights

In addition, citing references of recent enforcement records would illustrate member economies current status and progress.

IPR Progress Mapping has three objectives, as described below.

- (1) To inform the general public and the business community about member economies' progress and ongoing efforts.

APEC members, in general, have been vigorously engaged in strengthening IPR protection. Although IAPs do incorporate those actions taken by each member economy, due to the large amount of information

contained, IAPs are not necessarily organized in a user-friendly manner. Reports organized in a simplified and comparable manner will help to enhance the credibility of the business environment in the region for APEC stakeholders. Information on progress and outlook for businesspeople is also necessary in order for APEC to receive valuable input.

(2) To help identify the specific areas in which further capacity-building is needed

Although actions for IPR protection in general are making progress, due to varying financial conditions and human resource capacities, the amount of effort expended in specific areas differ greatly among economies. Most members have already made some progress on IPR protection by implementing the WTO TRIPs agreement, but further improvement may be required in the areas of expeditious granting and strengthening enforcement. The progress mapping report would help APEC to recognize the areas which require further capacity-building by highlighting each economy's strengths and weaknesses, and act as a tool for promoting efficient cooperation.

(3) As a pilot trial to modify the IAP format to make it readily used by general public

Since IAPs were originally designed for internal progress evaluation of each member's actions on trade and investment liberalization and facilitation, they cover a wide range of topics, have specific and detailed contents, and are not easily understood by the general public. In order to strengthen interaction with businesspeople, there is discussion about

exploring the possibility of improving IAP templates. The policy mapping report, which is based on the IPR chapter of IAPs, would be a pilot example for developing a more user-friendly format of IAP.

## 2.2 Follow-up Report on Comprehensive Strategy on IPR

The IPR Comprehensive Strategy aims to set guidelines for proper protection and enforcement of IPR in the region for the sake of better coordination and collaboration among APEC economies in this area. To improve IPR protection and its enforcement within the APEC region, it is important that individual economies undertake initiatives and a variety of cooperative efforts are pursued strategically within the APEC framework.

The Follow-up Report on Comprehensive Strategy on IPR requests lead economies of the APEC initiatives listed in the Strategy to submit progress reports of the initiatives. The 7 initiatives listed on the Comprehensive Strategy on IPR in APEC are as follows:

- Presentation on IPR Enforcement Situations (China)
- Illustrative Practices (Japan)
- Finalized Version of Survey (the Philippines)
- IP Toolkit (Australia)
- Digital Economy Next Steps (USA)
- Training Program (Vietnam)
- IPR Service Center (Japan)

## **3. Future Works**

The IPR Policy Progress Mapping incorporates member economies' efforts on IPR protection in a comparable manner and is designed to serve



as outreach to the stakeholders and as a basis for a policy discussion. In this context IPEG should consider the following future works as next steps;

- Make this report publicly available at the IPEG website in a readily accessible manner.
- Conduct a policy discussion on how to improve IPR protection among member economies based on the report.
- Discuss the contents of this report in IPEG meeting about how APEC can meet needs of the business community.
- Consider developing an improved method of reporting and promoting further policy discussion.
- Strengthen capacity-building especially in the areas where the report shows that further progress may be required.

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## **Part I. IPR Policy Progress Mapping**

Australia

Protection of IP Right	<p>Australian legislation is conformant to TRIPS Agreement.</p> <p>Recently Enacted Legislations</p> <p>Amendments to the <i>Patents Act 1990</i> in relation to novelty and inventive step criteria – 1 April 2002</p> <p>The <i>Intellectual Property Laws Amendment Act 2003</i> enables extension of time to be sought for errors or omissions by 3<sup>rd</sup> parties</p> <p>The <i>Designs Act 2003</i> took effect from 17 June 2004. It introduces a new regime for registration of industrial designs. Key features of the new system are:</p> <ul style="list-style-type: none"> <li>- a more streamlined registration process;</li> <li>- better enforcement and dispute resolution procedures;</li> <li>- stricter eligibility and infringement tests; and</li> <li>- clearer definitions.</li> </ul> <p><i>Designs Act 2003</i> - <a href="http://scaleplus.law.gov.au/html/comact/11/6753/top.htm">http://scaleplus.law.gov.au/html/comact/11/6753/top.htm</a></p> <p><i>Designs (Consequential Amendments) Act 2003</i> - <a href="http://scaleplus.law.gov.au/html/comact/11/6754/top.htm">http://scaleplus.law.gov.au/html/comact/11/6754/top.htm</a></p> <p>The <i>US Free Trade Agreement Implementation Act 2004</i> received Royal Assent on 16 August 2004 and is expected to commence on 1 January 2005. It is available on-line at <a href="http://scaleplus.law.gov.au/html/comact/12/6876/top.htm">http://scaleplus.law.gov.au/html/comact/12/6876/top.htm</a></p> <p>It contains a range of measures to further strengthen copyright law enforcement. The amendments will create:</p> <ul style="list-style-type: none"> <li>- wider criminal provisions, including for copyright infringement undertaken for commercial advantage or financial gain, and significant infringement on a commercial scale;</li> <li>- increased criminal and civil protection against the unauthorised receipt and use or distribution of encoded program carrying signals; and</li> <li>- a scheme for limitation of remedies available against Internet Service Providers (ISPs) for copyright infringement in relation to specified activities carried out on their systems and networks, provided certain conditions are met. A key feature will be an expeditious process to allow copyright owners to engage with ISPs to deal with infringing material on the Internet.</li> </ul>
Expeditious Granting of IP Right	<ul style="list-style-type: none"> <li>- IP Australia website provides lodgment of patent and trademark applications, search of public records, secure online payment, and searchable Trademark and Design journals</li> <li>- accession to the Madrid Protocol concerning international recognition of marks (11 July 2001)</li> <li>- Introduction of second tier patent system (Innovation Patent) to protect incremental inventions and to make other minor amendments to improve the efficiency of the legislation (24 May 2001)</li> </ul>
Strengthening of Dispute Settlement of IP Rights	<p>&lt;Civil Remedies&gt;</p> <ul style="list-style-type: none"> <li>- include injunctions, account of profits, damages (including additional damages), delivery up of infringing copies</li> </ul> <p>&lt;Criminal Sanctions&gt;</p> <ul style="list-style-type: none"> <li>- imposed for infringing copyright for commercial purposes, significant infringement of copyright on a commercial scale, intentional use of false trademarks and falsely claiming a patent right</li> </ul>
Strengthening of Enforcement of IP Rights	<p>&lt;Crackdown Measures&gt;</p> <ul style="list-style-type: none"> <li>- Copyright offences are enforced by the Australian Federal Police as well as the State and Territory police services.</li> <li>- The Australian Federal Police investigates criminal matters with prosecutions conducted by the Director of Public Prosecutions.</li> <li>- Border control provisions allow Customs authorities to seize infringing copies of copyright material being imported into Australia.</li> </ul>

- Monetary penalty for infringing importation was increased in the amendments in the Copyright Amendment Act 2003.
- <Public Awareness>
- IP portal, as the prime web based resource assisting user access to IP information, is available through the Australian Government. ([www.ipaccess.gov.au](http://www.ipaccess.gov.au))
- IP Australia has in place a comprehensive marketing program which aims to increase public awareness of IP issues and educate the community about the commercial benefits of protecting IP rights
- IP Australia has created a page on its website called "Attorney Central" aimed at meeting the needs of IP professionals and providing a means to ask questions of the Director-General of IP Australia ([http://www.ipaustralia.gov.au/attorney\\_central/index.shtml](http://www.ipaustralia.gov.au/attorney_central/index.shtml))
- The Department of Foreign Affairs and Trade has issued a booklet providing a background briefing on the TRIPS Agreement.
- IP Australia has in place a comprehensive marketing program which aims to increase public awareness of intellectual property issues and educate the community about the commercial benefits of protecting intellectual property rights.
- The Department of Communications, Information Technology and the Arts maintains an online copyright information resource
- The Attorney-General's Department initiatives include: comprehensive set of publications, booklet "Copyright Law in Australia", electronic newsletter "e-news on copyright"
- Seminars and publications by Arts Law Centre of Australia and the Australian Copyright Council (ACC)
- Regular presentations by Australian government agencies to workshops, conferences and universities about copyright issues
- Under funding received from APEC under its Trade and Investment, Liberalisation and Facilitation (TILF) program, IP Australia is managing a project to develop a public education and awareness program for Indonesia, Philippines and Vietnam. The program seeks to communicate the benefits of an effective intellectual property (IP) system for individuals and, business advantages for companies.
- The Australian Federal Police and Australian Customs Service delivered a workshop on Intellectual Property enforcement and border control in Hong Kong from 3 - 7 May 2004.
- Australia completed an enforcement database on the IPEG web site in 2003. (<http://www.apecipeg.org/enforcement/default.asp>)

Canada

Protection of IP Right	<ul style="list-style-type: none"> <li>- Fully implemented obligations of TRIPS Agreement.</li> <li>- Continuous participation in the negotiations of the multilateral system of notification and registration of geographical indications for wines and spirits.</li> <li>- Published "A Framework for Copyright Reform" for keeping pace with the technological and international developments, 2001</li> <li>- Domestic consultations held on the basis of two policy papers "Consultation Paper on Digital Copyright Issues" and "Consultation Paper on the Application of the Copyright Act's Compulsory Retransmission License to the Internet", early 2002</li> <li>- a comprehensive five year review of the Copyright Act tabled in the House of Commons</li> <li>- The last amendment to the Copyright Act: to clarify the rules for retransmitting the over-the-air signals of radio and television over the Internet</li> <li>- Amendment to the Patent Act: to extend the term of protection of certain "Old Act" patents (pre-1989)</li> </ul>
Expeditious Granting of IP Right	<ul style="list-style-type: none"> <li>- CIPO increased its operational capacity by hiring more examiners.</li> <li>- A new fee structure for patents, trademarks, industrial designs and copyrights has been approved. (come into force in January, 2004)</li> <li>- CIPO is offering the majority of the services and products through Internet.</li> <li>- CIPO has implemented electronic filing systems for all of IP built on the existing TM electronic filing system. All systems allow for secure online electronic payment of fees.</li> </ul>
Strengthening of Dispute Settlement of IP Right	<ul style="list-style-type: none"> <li>- Right holders may take legal action through the judicial system. Possible remedies include damages, injunctions and seizures of goods. There are also criminal enforcement mechanisms in relation to wilful trademark counterfeiting and copyright piracy on a commercial scale.</li> </ul>
Strengthening of Enforcement of IP Right	<p><i>&lt;Crackdown Measures&gt;</i></p> <p><i>&lt;Public Awareness&gt;</i></p> <ul style="list-style-type: none"> <li>- CIPO has in place an Outreach Program that will increase awareness, knowledge and effective use of IP by Canadians</li> <li>- Canada provided ongoing technical cooperation through advice and training for officials from intellectual property offices, participation in symposia, seminars and conferences on IP rights.</li> <li>- CIPO, in partnership with WIPO, organized a one-week Executive Workshop aimed senior officials from IP offices of the Asia-Pacific, Latin America and Caribbean regions.</li> </ul>

Chile

Protection of IP Right	<p>Basically in line with TRIPS Agreement except for some adjustments required</p> <p>* New laws are now being prepared for further compliance with TRIPS Agreement</p> <ul style="list-style-type: none"> <li>- Law No. 19.039 (Industrial Property Law): IP framework law; regulates offenses and sanctions against patents, utility models and industrial designs and regulates criminal offenses and sanctions against trademark offenders; contains minor modification to conventional IP related laws</li> <li>- Omnibus Bill: (*)</li> </ul>
Expeditious Granting of IP Right	<ul style="list-style-type: none"> <li>- Electronic filing and registration system available at the Industrial Property Department web page</li> </ul>
Strengthening of Dispute Settlement of IP Right	<ul style="list-style-type: none"> <li>- The current Chilean intellectual property legislation establishes civil and criminal provisions and procedures for the enforcement of intellectual property rights.</li> </ul>
Strengthening of Enforcement of IP Right	<p>&lt;Crackdown Measures&gt;</p> <p>&lt;Public Awareness&gt;</p> <ul style="list-style-type: none"> <li>- Seminars on the current norms for the protection of IP, protection of plant varieties, and the new IPR obligations acquired by the signature of the commercial treaties with EU, EFTA, South Korea and USA.</li> <li>- Hosting seminars in cooperation with WIPO and UN on the topics as IP national policy, technology transfer, creation of technology based companies, biotechnology, and patents as a part of the productive process</li> </ul>



People's Republic of China

Protection of IP Right	<p>-China is now fully in compliance with TRIPS requirements.          -China has amended major IPR related legislation.          Amended legislations are:          Patent Law(amended in 2000), trademark Law(2001), Copyright Law(2001)          Regulations on Computer Software Protection(2002),          Implementing Measure On the Procedure of Copyright Administrative Penalty”(2003)          -Also, China issued Regulations on Protection of Layout-Design of Integrated Circuit(2002)          In 2003 China promulgated “Regulations on Determination and Protection of Well-Known Marks”, “Measures for Registration and Administration of Collective and Certification marks”, “Measures for the implementation of International Registration of Mark Under the Madrid system”.</p>
Expeditious Granting of IP Rights	<p>SIPO Started to accept electronic filing system for patents on March 12,2004          SIPO enhanced its comprehensive capability in expedition of granting rights through recruiting more examiners and streamlined examination procedures</p>
Strengthening of Dispute Settlement IP Rights	<p>Right holders may take legal action against IPR violation with the People's court          Possible remedies include injunctions, damages and seizure of goods, there are also criminal sanctions imposed for infringement and counterfeit          Since 1992,China has se up special IPR courts within the People's Court system in Beijing, Shanghai and other places to handle IPR cases considering highly technical and special expertise required.</p>
Strengthening of Enforce of IP Right	<p>IP Right holders have access to both legal means and administrative means to seek protection.          Ministry of Public Security investigates criminal matters          Regulations on Customs Protection on Intellectual Property Right allows Customs authorities to seize infringed goods in and out of China          -Division for Border Protection of IPR is set up under Customs General Administration, and customs offices across China have designated their own teams and contact persons for IPR protection within respective precincts.          Patent: The State Intellectual Property Office(SIPO) and its local patent administrative authorities established in provinces, autonomous regions, municipalities directly under the government and other major cities. Local patent administrative authority handle patent infringement cases generally.          Copyright: National Copyright Agency and its local authorities allocated in provinces, autonomous regions, municipalities directly under the central government and other major cities. Generally, local copyright authorities handle the piracy cases.          Trademark: the Trade Mark Office is an agency under the State Administration for Industry and Commerce(SAIC).The SAIC has its local trademark administrative bodies established in provinces, autonomous regions, municipalities directly under the central government and other cities, prefectures, and counties.          Complaints lodged with local trademark administrative at or above the county level either where the infringement takes place or where the infringer is located. The Trademark Office of SAIC gives guidance to local SAICs in their handling of trademark infringement case when necessary.</p>

In April. 2004, the State Council Sets up a national working group for IPR protection composed of dozens of Ministries, Agencies and Courts. Such as SIPO, Trademark Office, National Copyright Agency, People's Supreme Court, People's Supreme Prosecution Court, Ministry of Commerce, Ministry of Public Security. Vice Premier, Madame Wuyi is the head of the working group. The function of the working group is to strengthen the enforcement of IPR through harmonizing the enforcement work between administrative agencies and judicial bodies, giving directives for national crackdown actions and providing public education and propaganda activities.

<public awareness>

-seminars, TV programs, and books for enhancement of public awareness

-IPR trainings for officials , heads of enterprises and technicians

Hong Kong China

<p>Protection of IP Right</p>	<p>Fully compatible with all obligations under the WTO TRIPS Agreement, constantly reviewing legislation for promoting the protection of IPRs.</p> <ul style="list-style-type: none"> <li>- Legislation in place for the protection of IPR in patents, trade marks, copyright, registered designs and the layout designs (topographies) of integrated circuits.</li> <li>- A new Trade Marks Ordinance came into operation in 2003.</li> </ul> <p>It gives increased protection to trade mark owners, and permits registration of sound and smell marks in addition to other categories of signs,</p> <p>There is also increased protection against infringement. The owner of a registered trade mark does not need to prove a likelihood of confusion if the infringing use is of an identical mark for identical goods or services. Infringing use is not restricted to visual (graphic) use. A person who applies a registered trade mark, or a sign similar to a registered trade mark, to materials intended to be used for labelling or packaging goods, or for advertising is treated as a party to any use of the materials which infringes. Infringement of a well-known mark extends to use for dissimilar goods or services if the use takes unfair advantage of or is detrimental to the distinctive character or repute of the mark. The owner of a well-known mark, even if he does not carry on business in Hong Kong, is entitled to an injunction against an infringing use of the mark for identical or similar goods which is likely to cause confusion.</p> <p>Defensive trade mark protection (for exceptionally well-known marks) is more widely available.</p> <p>On licensing, trade mark owners have effective protection even if they engage in merchandising (because licensing is de-restricted). Registration of collective marks is now available.</p>
<p>Expeditious Granting of IP Right</p>	<p>The Intellectual Property Department (IPD) is in charge of general IP matters of the HKSAR and sets performance target for processing applications for trade marks, patents and design.</p> <p>To raise transparency of trademark examination procedure, examination work manuals and FAQs have been uploaded on the website of IPD and workshops and briefings are organized by IPD.</p> <ul style="list-style-type: none"> <li>- A web-based and user-friendly e-business model for trademarks registration has been implemented. With automated processing, there has been reductions in fees (3-100% for trade marks, 73-100% for patents and 51-100% for designs).</li> <li>- Online search of trade marks, patents and registered designs data implemented.</li> <li>-E-publication of grant and registration of trade marks, patents and designs implemented.</li> <li>-E-filing for trade marks implemented. For patents and designs, e-filing is planned for the later part of 2004.</li> <li>- A five-year contract with IT private sector for in-house online support (on new applications development of trademarks, patents and designs) and front/back office support commenced in 2001.</li> </ul>
<p>Strengthening of Dispute Settlement of IP Right</p>	<p>The Secretary for Justice is responsible for criminal prosecution, including prosecution of IPR offences, in Hong Kong, China. Right holders may themselves initiate civil proceedings in court to enforce their IPR and seek remedies including damages, injunction, order for destruction or disposal of infringing goods as appropriate.</p> <p>Proof of copyright subsistence is often the stumbling block in civil and criminal proceedings against copyright infringements. To assist copyright owners in enforcement actions, section 121 of the Copyright Ordinance permits the use of an affidavit made and authenticated in a prescribed manner to be admitted without further proof in proceedings under the Ordinance. Such an affidavit has to be made by or on behalf of the owner of a copyright work and can be proof:</p> <p>(a) of the date and place of the making and first publication of the work;</p>

	<p>(b) of the name, domicile, residence or right of abode of the author of the work;  (c) of the name of the owner of the work;  (d) of the subsistence of copyright in the work; and  (e) that a copy of the work exhibited to the affidavit is a true copy of the work.</p> <p>In the absence of evidence to the contrary, the statements made in the affidavit are presumed to be true. Unless agreed by the parties, the affidavit has to be served not less than 10 days before the hearing at which the affidavit is to be tendered in evidence. The court may or upon the request of a defendant require the deponent to attend before the court and give evidence. In addition, presumptions as to authorship and ownership of copyright are provided under sections 115 and 116 of the Copyright Ordinance. Section 115 applies to literary, dramatic, musical and artistic works. Section 116 applies to sound recordings, films and computer programs.</p> <p>Under section 115 of the Copyright Ordinance, the person named as the author on copies of work is presumed to be the author and first owner of the copyright in the work. Where the publisher, and not the author, is so named on copies of the work as first published, the person named is presumed to be the owner of the copyright at the time of publication. Where the author is dead or his identity cannot be ascertained by reasonable inquiry, it is presumed that the work is an original work and allegations of the plaintiff as to the year and country in which there was first publication are correct.</p> <p>Under section 116 of the Copyright Ordinance, the person named as the owner of copyright on the label of a recording is presumed to be such owner as at the date when copies of the recordings are issued or made available to the public. The year and the country, in which there was first publication of the recording, where stated on such label, are also presumed to be correct. Similarly, in the case of a film, the persons named in a statement in a copy of a film as the director or producer, the principal director, the author of the screenplay, the author of the dialogue, the composer of the music specifically created for and used in the film and the owner of the copyright in the film as at the date when copies of the film are issued or made available to the public are presumed to be such parties. The year and the country in which there was first publication of the film are, where stated in the aforesaid statement, also presumed to be correct.</p> <p>With computer programs, similar presumptions as in the case with sound recordings apply where the information is set out in a statement in the copies of the program issued to the public in electronic form or made available to the public. The presumptions under section 116 also apply to infringement alleged to have occurred before the date on which the copies were issued or made available to the public.</p> <p>All the presumptions mentioned in the above are rebuttable ones, that is, they can be rebutted upon adduction of evidence to the contrary.</p>
<p>Strengthening of Enforcement of IP Right</p>	<p>&lt;Crackdown Measures&gt;</p> <ul style="list-style-type: none"> <li>- The Customs and Excise Department tackles criminal IPR infringements.</li> <li>- The Prevention of Copyright Piracy Ordinance was amended in 2001 to combat bootlegging of copyright works. Further amendment was made in 2002 to require licensing of the manufacture of stampers.</li> <li>-The Copyright Ordinance was amended in 2000 to clarify the criteria for offences that constitute infringement of copyright. In view of public concern that the dissemination of information in enterprises as well as in teaching activities in schools could be hampered, further amendments were made in 2001 to apply the amended criminal provisions, with a slightly narrowed scope, to computer programs, movies, television dramas and music recordings.</li> </ul> <p>&lt;Public Awareness&gt;</p> <p>The actions Hong Kong, China has taken to promote public awareness of IPR are as follows.</p> <ul style="list-style-type: none"> <li>- school visits and educational programs for school children</li> </ul>

	<ul style="list-style-type: none"><li>- publicity campaigns for general public “I Pledge” Campaign, “I Pledge” Concert (Nov., 2002), a comic series, broadcasting on TV etc., poster advertisement, interactive teaching kit on Web, participation in exhibitions (Comics Festival, Asia Game Show, Computer Festival etc.).</li><li>- annual benchmark survey to evaluate the change in public awareness level and the effectiveness of its publicity work and annual survey on business attitudes to intellectual property.</li><li>- organising and participating actively in regional workshops and training seminars</li></ul>
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Indonesia

Protection of IP Right	<p>Laws Recently Enacted or Amended</p> <ul style="list-style-type: none"> <li>- Copyrights Law: amended in July, 2002 (Database is covered as one of protected works; The use of any kind of means, wire or wireless, including the internet, to run optical disc products through audio, audiovisual, and/or telecommunication media;)</li> <li>- Trademarks Law: amended in August, 2001 (*)</li> <li>- Patents Law: amended in August, 2001 (*)</li> <li>- Layout Design of Integrated Circuits Law: enacted in December, 2000</li> <li>- Industrial Designs Law; enacted in December, 2000</li> <li>- Trade Secret Law: enacted in December, 2000</li> <li>- Protection of Plant Varieties; enacted in December, 2000</li> </ul>
Expeditious Granting of IP Right	<ul style="list-style-type: none"> <li>- The Development of an integrated automation/computerized system under the World Bank project is still in process.</li> </ul>
Strengthening of Dispute Settlement of IP Right	<ul style="list-style-type: none"> <li>- The amendment of Copyrights law introduced in the following settlement regulations and measures. The copyrights disputes can be settled by Commercial Court, Arbitrage, or Alternative Disputes Resolutions (ADR) Provisional Decision by the court to prevent a bigger loss of the rights holder</li> <li>- By the amendment of Copyrights Law the time limit was set for Commercial Court or Supreme Court to handle a civil case on copyrights and neighboring rights.</li> </ul>
Strengthening of Enforcement of IP Right	<p>&lt;Crackdown Measures&gt;</p> <p>&lt;Public Awareness&gt;</p> <ul style="list-style-type: none"> <li>- Activities Conducted by DGIPR, the Directors General of Intellectual Property Rights WIPO National Seminar on New Emerging Issues on Copyrights Protection and Enforcement in the Digital Era, Jakarta, April 25,2002 National Seminar on the Development and Current Issues of WTO/TRIPs Agreement "Bandung, July 1-2, 2002 WIPO National Roving Seminar on Enforcement of IP System Program in Medan (June 10-11, 2002; in Makasar, (June 13-14 2002); and in Pontianak (June 17-18, 2002)</li> <li>A series of trainings on IPR under the Indonesia Australia Specialized Training Project (IASTP Phase II)</li> <li>- The DGIPR in cooperation with the World Intellectual Property Organization (WIPO) will hold the WIPO Asia Pacific Sub Regional Workshop on the Benefit of Madrid Agreement and Hague Agreement for the Developing Countries, on June 3-5, 2003 in the city of Yogyakarta. The symposium will be attended by participants from 11 countries in the Asia Pacific region.</li> </ul>

Japan

Protection of IP Right	Japanese legislation is conformant to TRIPS Agreement.
Expeditious Granting of IP Right	<ul style="list-style-type: none"> <li>- Patent Law was amended to implement “Intellectual Property Policy Outline”. patent fee revision to correct imbalance among applicants, streamlining of dispute settlement, harmonization of Japanese Patent System with the global standard to encourage acquisition of foreign patents</li> <li>- Regular Trilateral Conference with patent offices in the United States and Europe for promoting international harmonization of legal frameworks</li> <li>- Reduction of the period for requesting examination from 7 years to 3 years by amending the Patent Law</li> <li>- Increases in the number of patent examiners, development of the Paperless Project (Electronic Filing and Administration System), and the outsourcing of prior art searches.</li> <li>- As for accelerated examination and accelerated appeal examination, the JPO has loosened eligibility requirements and simplified the procedure for a request.</li> <li>- JPO made the electronic patent application form pursuant to the PCT standard (XML form).</li> <li>- KIPO-JPO network established in 2002 to enable the data exchange of patent priority documents.</li> </ul>
Strengthening of Dispute Settlement of IP Right	<ul style="list-style-type: none"> <li>- Japan has an appeal system for industrial property rights, with the Appeals Department of the JPO dealing with the validity of rights.</li> <li>- Expansion of attorney’s role to act as attorney in intellectual property infringement lawsuits (revision of Patent Attorney law)</li> <li>- Unfair Competition Prevention Law was amended to implement “Intellectual Property Policy Outline”. reduction of burden of right holders to prove misuse of trade secret and its damage, clarification of definition of unfair competitions to adapt it to Internet and digital technology</li> </ul>
Strengthening of Enforcement of IP Right	<p><i>&lt;Crackdown Measures&gt;</i></p> <ul style="list-style-type: none"> <li>- Japan Customs have conducted border control based on the Customs Tariff Law consistent with TRIPS Agreement.</li> <li>- A help desk on counterfeits was established in the JPO in 1998.</li> <li>- Unfair Competition Prevention Law was amended to implement “Intellectual Property Policy Outline”. introduction of penalties for misuse and illicit acquisition of trade secret,</li> </ul> <p><i>&lt;Public Awareness&gt;</i></p> <ul style="list-style-type: none"> <li>- Computer database system of IPR related information such as the features distinguishing the genuine and the fake, and the characteristics of goods suspended in the past</li> <li>- Textbooks for school education provided in paper basis, CD ROMs and videos</li> <li>- International patent licensing seminars held by the National Center for Industrial Property Information</li> <li>- Local Copyright Seminars, Copyright Workshops and Copyright Training Programs Japan Copyright Office annually organizes for general public and experts</li> <li>- JPO’s seminars for office workers, researchers and entrepreneurs</li> </ul>

Republic of Korea

Protection of IP right	<p>Korea has fully implemented its obligation under the TRIPS Agreement.</p> <p>In 2003, the Copyright Act was amended to accommodate the digital environment more extensively. The amendments include protection of non-digital databases, limitation of Online Service Provider (OSP) liabilities, protection of technological measures and information on rights management, adjustment of the library exception, and recognition of the amount of damages.</p>
Expeditious granting of IP right	<p>Korea joined the Trademark Law Treaty (TLT) in February 2003 and the Madrid Protocol in April 2003.</p> <p>The Korean Intellectual Property Office (KIPO) recruited 89 examiners in 2002 and 73 examiners in 2003 and amended the Patent Act and the Utility Model Act to reflect the PCT revision.</p> <p>In 2002, Korea started to develop a system for the on-line registration of computer programs.</p>
Strengthening of dispute settlement of IP right	<p>Korea is operating the Korean Industrial Property Tribunal and the Patent Court to settle the disputes related to industrial property rights.</p> <p>MCT increased the maximum fine for infringing on copyrights of programs from 30 million won to 50 million won.</p>
Strengthening of enforcement of IP right	<ul style="list-style-type: none"> <li>- The Standing Inspection Team (SIT) staff under the Ministry of Information and Communication (MIC) has been granted special police powers to ensure the effectiveness of inspections.</li> <li>- KIPO distributed instructional materials to investigation agencies on how to identify counterfeit goods and trademarks.</li> </ul> <p>The 23 regional joint enforcement teams each at the branch public prosecutors' office in the respective region have continuously performed effective enforcement operation under the supervision of the Supreme Public Prosecutors' Office.</p>



Malaysia

Protection of IP right	<ul style="list-style-type: none"> <li>- Malaysian legislation is conformant to TRIPS Agreement.</li> <li>- The Protection of New Plant Varieties Act 2004 has been passed by Parliament on 1st July 2004.</li> <li>- Amendment to the Copyright Act 1987, enforced on 15 August 2003 confers the power of arrest to the Enforcement Officer of the Ministry, which includes arrest without warrant.</li> <li>- The provision for Patent Cooperation Treaty (PCT) has been incorporated in the Patents Act 1983 on 24 July 2003. The Instrument for PCT and Budapest Treaty will be deposited by end of this year.-To amend the Copyright Act 1987, which is, scheduled to be tabled in the Parliament before end of 2004 to enable Malaysia to accede both WIPO Copyright Treaty (WCT) and WIPO Performances and Phonograms Treaty (WPPT).</li> </ul>
Expeditious granting Of IP right	<ul style="list-style-type: none"> <li>- Intellectual Property Division (IPD) of Malaysia has been corporative on 3 March 2003 with its main objective to further improve the IPR system and services rendered.</li> <li>- Increased the number of officers and staffs including patent and trademark examiners.</li> <li>- Updated Manual Guidelines on patent, trademark and industrial design for examiners and IP practitioners.</li> <li>- Currently the Corporation has upgraded the computer system.</li> <li>- To provide on-line filing and on-line search facilities to the public by early of 2005.</li> <li>- Developing the Industrial Design Automation System and will be launched by end of 2004. Studying and analyzing information to develop Patent Document Search System Environment.</li> </ul>
Strengthening of Dispute settlement of IP right	<p>Appeal procedure for intellectual property rights is provided under the specific Acts and regulation related to IP.</p>

<p>Strengthening of Enforcement of IP right</p>	<p>&lt;Crackdown Measure&gt;</p> <ul style="list-style-type: none"> <li>- Malaysia has implemented forensic testing on Optical Disc product to trace the source of piracy.</li> <li>- Copyright Act 1987 has been amended to confer the power of arrest without warrant to the Enforcement Officers.</li> <li>- The Ministry has stopped the issuance of manufacturing licenses for optical discs since March 2003.</li> <li>- The prohibition of acquisition or importation of production machinery is still on going.</li> <li>- The producers of optical disc are required to submit monthly information report on optical discs produced, production volume and usage of raw materials for monitoring of legal operations.</li> <li>- Malaysia has been implementing a Reward Scheme of USD2, 631 (RM10, 000) to those who provide information leading to confiscation of each illegal production machine.</li> <li>- An enforcement initiative to curb optical disc piracy is still on going.</li> <li>-The respective task force has carried out regular joint operations with the government agencies concerned acting under the scope of the various laws enforced by them.</li> <li>-The Special Task Force To Combat Counterfeit Product was formed on 18 March 2002 to enable more effective action on counterfeit goods.</li> </ul> <p>&lt;Public Awareness&gt;</p> <ul style="list-style-type: none"> <li>- Awareness campaign for researchers, entrepreneurs, teachers, students, journalists and the general public. RM 7.5 million has been allocated for the IP Awareness campaign.</li> <li>- Initiate awareness programs at universities all over Malaysia.</li> </ul>
<p>(Reference) Latest records Of IPR related enforcement</p>	<ul style="list-style-type: none"> <li>- Number of open premises selling optical disc has been reduced from 2,386 in July 2001 to 147 in April 2004.</li> <li>- Since 1 April 1999 till 31 August 2004, 110,006 inspections have been done on the distribution center or store, shopping complex and retail outlets involving 31,483 cases with RM246.086 million values of the confiscation and 482 offenders.</li> <li>-Since 1 October 2003 till 30 April 2004, 289 offenders have been arrested without warrant.</li> <li>-All the cases regarding counterfeit includes various types of goods such as petroleum, foods, clothes, medicine, vehicle spare parts, watches, leather goods, electrical products and so forth.</li> <li>-At the end of July there are 775 cases with value of RM 62.7 million worth of counterfeiting goods seized.</li> </ul>

Mexico

Protection of IP Right	- Mexico has fully implemented TRIPS obligations.
Expeditious Granting of IP Right	<ul style="list-style-type: none"> <li>- implementation of Trademarks and Patents Systems in the Central Regional Office</li> <li>- implementation of the figurative search module for the Trademark system (by 4<sup>th</sup> quarter of 2002)</li> <li>- modification of the Trademark system to inform customers about the status of their applications via the Internet</li> <li>- Mexican Institute of Industrial Property (IMPI)'s fourth Regional Office opened in central part of Mexico in August, 2002.</li> <li>- CDs to provide complete bibliographic information of application and inventions for a search: Espace (collection of patent application), Data Access</li> </ul>
Strengthening of Dispute Settlement of IP Right	<ul style="list-style-type: none"> <li>- IMPI granted by the Industrial Property Law and the Federal Copyright Law, has the authority of substantiate and resolve IP infringement procedures.</li> <li>- Regarding Civil Procedure on Enforcement, once IMPI issues a resolution, the title holder could go before Civil Court to claim for damages.</li> <li>- As for criminal action, when evidence and presumptive responsibility/ liability of the accused person is accredited, the General Attorney's Office performs criminal action and submit the file for its resolution to the competent Federal Judge.</li> <li>- Criminal Offences on IP are federal matter. State authorities are not in the position of solving them.</li> <li>- Administrative infringements are punished by the IMPI.</li> <li>- Copyright infringements are punished by the National Copyright Institute. Copyright infringements related to commerce are punished by the IMPI.</li> </ul> <p>Note: In Mexico, legal claim procedure is called "Amparo", which indicates a legal instance that could be used when the corresponding authority infringes a person's individual right.)</p>
Strengthening of Enforcement of IP Right	<p>&lt;Crackdown Measures&gt;</p> <ul style="list-style-type: none"> <li>- Attorneys General Office (PGR) fights against piracy in cooperation with IMPI, INDAUTOR, Collective Societies, Interinstitutional Committee on Offenses Against Intellectual and Industrial Property</li> </ul> <p>&lt;Public Awareness&gt;</p> <ul style="list-style-type: none"> <li>- "Zero Tolerance" campaign for the use of legal software, 2002. Total 1,628 inspection visits were conducted.</li> <li>- Workshops, human resources training, and course on WCT and WPPT treaties</li> <li>- production of Gazettes, CD Espace, Collection, and Data Access Collection</li> <li>- Bar codes for areas of trademarks, patents and IP protection.</li> </ul>

New Zealand

Protection of IP Right	<ul style="list-style-type: none"> <li>- New Zealand's intellectual property regime is fully TRIPS-compliant .</li> <li>- Copyright Act: A review of the implications of digital technology for New Zealand's copyright legislation has been completed. A Copyright Amendment Bill is being prepared for introduction to Parliament.</li> <li>- Patents Act: A review of the Patents Act has been completed and an Amendment Bill is currently being drafted. Amendments include: strengthening the criteria for granting a patent; excluding human beings and medical treatment of human beings from patentability; establishment of a Maori Consultative Committee.</li> <li>- Plant Variety Rights Act 1987: A review of the Act has been completed and an Amendment Bill is currently being drafted for introduction to Parliament. The Bill will extend plant breeder's rights.</li> <li>- A Maori* Advisory Committee established under the Trade Marks Act 2002 advises the Commissioner of Trade Marks on whether the registration of trade marks containing Maori signs or imagery will be considered offensive to Maori.</li> </ul>
Expeditious Granting of IP Right	<ul style="list-style-type: none"> <li>- 12 month time limit is set for processing trade mark applications.</li> <li>- Over 80 % of applications are now made online, and all trade mark applications are electronically processed.</li> <li>- IPONZ (Intellectual Property Office of New Zealand. Former New Zealand Patent Office) examines applications within five working days of filing, and continuously reviews filing requirements to reduce compliance costs to business.</li> <li>- IPONZ website provides published, complete patent specifications in pdf or tif format.</li> <li>- IPOL website allows real-time access to the IPO database for registration, or payments of fees.</li> <li>- MED (Ministry of Economic Development) provides a website to incorporate elements identified in the APEC IPR Service Center standard.</li> </ul>
Strengthening of Dispute Settlement of IP Right	<p>&lt;Civil Remedies&gt;</p> <ul style="list-style-type: none"> <li>- include injunctions, account of profits, damages, delivery up of infringing copies. Reverse onus of proof in civil proceedings in importing computer programs, films and sound recording.</li> </ul> <p>&lt;Criminal Sanctions&gt;</p> <ul style="list-style-type: none"> <li>- specific criminal penalties for piracy and counterfeiting and commercial dealing in infringing items.</li> </ul>

<p>Strengthening of Enforcement of IP Right</p>	<p>&lt;Crackdown Measures&gt;</p> <ul style="list-style-type: none"> <li>- Border protection measures allow Customs to detain infringing trade marked/copyrighted goods when the right holder has lodged a notice and bond</li> <li>- s122 of the Copyright Act, 'Anton Pillar' orders, 'Metallica' orders: statutory and common law orders to help rights holders secure evidence and seize infringing articles</li> </ul> <p>&lt;Public Awareness&gt;</p> <ul style="list-style-type: none"> <li>- IPONZ and MED hold seminars and demonstrations (ex: agricultural shows and field days)</li> <li>- media statements, seminars, presentations, information accessible through government agencies' websites</li> <li>- free information booklet on granting IPR</li> <li>- free information line relating to the registration of IP rights</li> </ul>
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\* Maori: the indigenous people of New Zealand

Papua New Guinea

Protection of IP Right	<ul style="list-style-type: none"> <li>- Trade Marks Act (Ch, 385): reviewed, incorporated all TRIPS requirements, the amendment yet to be approved by parliament (*)</li> <li>- Patent and Industrial Designs Act, Copyright and Neighboring Rights Act: put into effect on July 1, 2002, basically TRIPS compliant, amended since the last IAP for further compliance with TRIPS Agreement (*)</li> </ul>
Expeditious Granting of IP Right	<ul style="list-style-type: none"> <li>- A cooperation Arrangement established between IPOPNG and IP Australia for assistance particularly in search and substantive examination</li> <li>- A new separate lodgement counter was established for clients to conduct search and file applications.</li> <li>- training for IPOPNG staff to improve skills and knowledge</li> <li>- plan of automated patent system awaiting APEC and other donor agencies to be persuaded to fund more</li> </ul>
Strengthening of Dispute Settlement of IP Right	
Strengthening of Enforcement of IP Right	<p><i>&lt;Crackdown Measures&gt;</i></p> <ul style="list-style-type: none"> <li>- the Customs of the Internal Revenue Commission: responsible for border measures, working on the rules and regulations for protection against IPR infringement</li> </ul> <p><i>&lt;Public Awareness&gt;</i></p> <p>No big activities due to funding constraints. Measures taken since the last IAP are as follows.</p> <ul style="list-style-type: none"> <li>- public awareness enhancement by means of pamphlets, newsletters, brochure, webpage, radio, daily newspapers</li> <li>- participated in activities conducted by other organizations to educate and disseminate information</li> <li>- intellectual property law as a course of UPNG law school.</li> </ul>

Peru

Protection of IP Right	- IPR protection of Peru is in accordance with the TRIPS Agreement.
Expeditious Granting of IP Right	- Internet service for IP agents established in 2002 - Download of application form available from INDECOPI website - The Copyright and Trademark Offices have delegated different functions (inspection, formal exam of TM registration) to INDECOPI's Decentralized Offices.
Strengthening of Dispute Settlement of IP Right	
Strengthening of Enforcement of IP Right	<p>&lt;Crackdown Measures&gt;</p> <ul style="list-style-type: none"> <li>- Officials from Copyright Office make twice per week inspections to sale and distribution stands where IP related articles (some of them without authorization of right holder) are sold.</li> <li>- A multi-sector commission has been established to combat infringement of IP Rights in the pharmaceutical sector.</li> <li>- A seminar on enforcement measures was held in July, 2003, for customs officers and public prosecutors</li> <li>- A chromatography laboratory has been inaugurated at the Metrology National Service (at INDECOPI) to allow for adequate quality verification of Peru's geographical indication "Pisco".</li> </ul> <p>&lt;Public Awareness&gt;</p> <ul style="list-style-type: none"> <li>- online device to give information on IPR implemented by INDECOPI and Contracopia Association</li> <li>- 7<sup>th</sup> National Inventions Contest was held at INDECOPI in 2002 to promote innovation, Peruvian creativity and protection of IP.</li> <li>- "Indecopi Educa" --- a training program addressed to school teachers</li> <li>- "Indecopi Empresa" --- a training program focused on SMEs</li> <li>- INDECOPI celebrated the "Intellectual Property Week" to increase awareness of IP.</li> <li>- INDECOPI co-organizes a technological innovation contest and the agricultural sector to promote technological innovation in Andean agricultural products.</li> <li>- "Cruzada de la Calidad" --- a campaign for quality and competitiveness in benefit of consumers and SMEs</li> <li>- Seminar on Protection of Plant Varieties in May, 2003</li> </ul>

INDECOPI : Instituto Nacional de la defensa de la competencia y Proteccion de la Propiedad Intelectual  
National Institute for the Defence of Competition and Protection of Intellectual Property)

The Philippines

<p>Protection of IP Right</p>	<p>RA 8293: the Intellectual Property Code of the Philippines; aligns existing legislation on patents, trademarks, geographical indications and copyrights with the WTO TRIPS Agreement.          Republic Act No. 8792: the Electronic Commerce Act, which took effect on June 14, 2000, brings IP protection to the digital environment.          - RA 9150: the Law Protecting Layout-Designs (Topographies) of Integrated Circuits was signed on August 6, 2001 and took effect on August 30, 2001. This law provides a registration system for the protection of layout designs.          RA 9168: Philippine Plant Variety Protection Act of 2002; The Implementing Rules and Regulations of the said Act was issued by the Department of Agriculture on 2 March 2003 and took effect on 1 April 2003 or thirty (30) days after its publication. This legislation provides a <i>sui generis</i> system of protection for new plant varieties and is administered by the Department of Agriculture.  <i>RA 9239: the Optical Media Act was signed into law on February 10, 2004 and took effect on March 2, 2004. The law is intended to address the problem of optical disc piracy by getting to the source – the manufacturers of pirated optical media and equipment used in the production thereof.</i>          WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty: Philippine Senate ratified Philippine membership to the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty on March 11, 2002. The Treaties took effect on October 4, 2002.          Patent Cooperation Treaty: Philippine Senate ratified Philippine membership to PCT on 5 February 2001 and took effect on 17 August 2001.          Rules on Search and Seizure in Civil Action for Infringement of IPR took effect on 15 February 2002 in compliance with Article 50 of the WTO TRIPS Agreement.          Rules on Electronic Evidence took effect on 1 August 2001 pursuant to RA 8792 or the Electronic Commerce Act.</p>
<p>Expeditious Granting of IP Right</p>	<p>- Modernization of IPR system: proactive implementation of the IPO Modernization Program based on its 2000-2004 Information System Strategic Plan (ISSP) in order to attain a significant streamlining and time reduction of the application processing mainly by full automation of IPO's IP processes and human resource development in the areas of: administrative, search and examination, IT-capability.          - Full automation of the patent and trademark administration processes/systems from filing of applications to grant/registration, including post-grant processes/maintenance.          - Industrial Property Digital Library (IPDL): full implementation of the web-based IPDL-Trademarks system and ongoing systems development of the IPDL-Patents System.</p>
<p>Strengthening of Dispute Settlement Involving IP Rights</p>	<p>- IPO pool of mediators: composed of 27 IPO employees and 3 practitioners from the private sector: tasked to encourage out of court settlement limiting the number of cases filed and hasten settlement of dispute as a result          - Civil and criminal actions are filed in courts known as Special Commercial Courts which hear and decide corporate and IPR cases.          - Disputes are resolved at the Documentation, Information and Technology Transfer Bureau (DITTB) involving author's rights and technology transfer agreements.          - Administrative complaints on violation in all other areas of IPR are handled by the Bureau of Legal Affairs (BLA) of the Intellectual Property Office.</p>



	- The Department of Trade and Industry, the Bureau of Trade Regulation and Consumer Protection and the Bureau of Legal Affairs of the Intellectual Property Office likewise address administrative complaints on IPR related cases.
Strengthening of Enforcement of IP Right	<p>&lt;Crackdown Measures&gt;  Intellectual Property Enforcement Unit under the Office of the Director General of the IPO, which is responsible for coordinating the enforcement activities of the IPO and the IP REAP members. The Intellectual Property Rights Enforcement Acton Panel (IP-REAP) is a new, broad-based coalition composed of government agencies and private organizations, which was formed to enhance enforcement action against piracy and counterfeiting.  Intellectual Property Unit: interim unit under the Bureau of Customs; establishment announced in CAO 24-2002; implement enforcement measures against the movement of counterfeit products and to supervise, monitor and implement IP border control policies set out on CAO 6-2002.  The Supreme Court of the Philippines issued Resolution No. 03-03-03-SC on 17 June 2003, identifying 65 Regional Trial Courts as Special Commercial Courts; incorporating the 34 previously designated Special IP Courts specified under the Supreme Court A.M. No. 02-1-11-SC and A.O. No. 113-95, stating that IP cases are commercial in nature.</p> <p>&lt;Public Awareness&gt;  - Seminars, workshops in regions, provinces, among educational institutions and SMEs; networking with science high schools of local government units (LGUs) to increase IP awareness among the high school students.  - Nationwide Essay Writing and On-the-spot Painting Contest on IPR, exhibits  - Basic information materials/brochures about the IP Code, IPO and its functions, IPO website and PCT</p>
IPO: Intellectual Property Office CAO: Customs Administrative Order	BOC: Bureau of Customs PCT: Patent Cooperation Treaty
	A.M.: Administrative Matter A.O.: Administrative Order

Russia

Protection of IP Right	<p>Russia is basically conformant to international standard of IP including TRIPS Agreement. For further compliance, the following Federal laws have been amended since the last IAP.</p> <ul style="list-style-type: none"> <li>- On the Legal Protection of Topographies of Integrated Circuits (July 24, 2002) (*)</li> <li>- Patent Law (March 11, 2003) (*)</li> <li>- On Trademarks, Service Marks, and Appellations of Origin of Goods (December 27, 2002) (*)</li> <li>- On the Legal Protection of Computer Programs and Databases (January 8, 2003) (*)</li> </ul>
Expeditious Granting of IP Right	<ul style="list-style-type: none"> <li>- Legal protection emerges without registration for computer programs, databases and topographies of IC early used for commercial purposes</li> <li>- Immediate grant of utility models following verification of an application's compliance with formal requirements</li> <li>- No documents required for granting inventions and industrial designs except for those relating directly to the substance of these subjects</li> </ul> <p>No information on right holders and manufacture of goods required to register trademarks</p>
Strengthening of Dispute Settlement of IP Right	<p>The Chamber of Patent Disputes was established in accordance with the Law "On trademarks Service Marks, and Appellations of Origin of Goods" and the Patent Law. The prime object of the Chamber is to secure protectable rights and interests of applicants and right holders and also legitimate interests of other persons and legal entities, when considering objections against examiner's decisions to refuse legal protection, objections against grant of the legal protection, statements to cease the legal protection and statements to recognize a mark as a well-known mark.</p>
Strengthening of Enforcement of IP Right	<p>&lt;Crackdown Measures&gt;</p> <ul style="list-style-type: none"> <li>- Special sub-units of the Ministry of Internal Affairs leads the combat against infringements in intellectual property domain.</li> <li>- Customs authorities can initiate an administrative investigation for IPR infringing imported articles. The actions they are admitted to take are suspension of the release of suspected goods, and hearing of any information from the right holder</li> <li>- In case of copyright infringement, the counterfeit product may be confiscated in addition to charging fine</li> <li>- Superior Arbitration Court issues a decision on confiscation and destruction in cases where the right holder does not request the goods to be transferred to him</li> </ul> <p>&lt;Public Awareness&gt;</p> <ul style="list-style-type: none"> <li>- Rospatent organized a conventional scientific and practical conference "Problems of Theory and Practice of Protecting Industry Property Rights and Certain Copyrights in the Russian Federation". - Rospatent website: access to databases for both internal and outside users, contains information on statutory acts in the field of IP. - Events of Russia-WIPO Cooperation Program - Training programs and events for specialists from outer organizations</li> <li>- Russian State Intellectual Property Institute (RGIIS): governmental educational establishment specialized in the problems of IP legal protection and commercial use, information on the training and raising the level of skill of experts on its website</li> <li>- Distance Learning under the Framework Agreement between Rospatent and WIPO - CD-ROM technology-based official publications</li> </ul>

Singapore

Protection of IP Right	<p>Singapore has been fully compliant with the TRIPS Agreement TRIPS-plus legislations implemented: Manufacture of Optical Discs Act 2004 ,</p> <p>PATENTS (changes with effect from 1 July 2004): Strengthening the conditions for grant of a patent, thus requiring an applicant to ensure that the application is in proper order for grant. Introduction of patent term extensions due to examination or grant delays at the patent office, delays at a foreign patent office of a corresponding application that is relied upon for grant in Singapore, or unreasonable curtailment of the opportunity to exploit a patent due to the marketing approval process for a pharmaceutical product. Introduction of post-grant search and examination provision to provide the opportunity for any party to obtain more information on the patent. Restrictions and clarifications on the government use and compulsory licensing provisions. Introduction of a Bolar provision to allow third parties to work a patent for the purposes of supporting an application for marketing approval of a pharmaceutical product. Introduction of a specific patient exception for patent infringement. Introduction of a provision restricting the parallel import of patented pharmaceutical products . Changes made to the grounds of revocation to remove relatively minor grounds and include more important grounds. Amendments were made to the Trade Marks Act to further improve upon the trade marks regime for trade mark owners and these amendments came into force on 1 July 2004. Protection for well-known marks is enhanced and well-known marks are now protected against dilution. Border enforcement measures for trade marks owners have also been enhanced to streamline search and seizure procedure for counterfeit goods that are imported into, exported out of or consigned to a Singapore party. For copyright, the term of protection for copyright works was extended by another 20 years to life plus 70 years for authors' works and 70 years from publication for secondary works.</p> <p>The new Plant Varieties Protection Act came into force on the 1 July 2004. The Act provides protection for new plant varieties. Singapore also deposited its instrument of accession to the International Convention for the Protection of New Varieties of Plants, 1991 or the UPOV 1991 Convention (Union internationale pour la Protection des Obstantions Vegetales) and became a member on the 30 July 2004.</p> <p>The Registered Designs Act has been amended in preparation for Singapore's accession to the 1999 Geneva Act of the Hague Agreement on the International Registration of Registered Designs; under our obligations with respect to the European Free States-Singapore Free Trade Agreement. The amendments to the Act also include provisions that assist in administration of the provisions in the Act. The amendments will come into force on the 1 Jan 2005.</p> <p>The Registered Designs Rules will be amended in order to provide the procedures for international applications and registrations, to align procedures across the different IPOS registries; as well as to provide the procedures for electronic on-line filing of designs which will be in place by mid 2005.</p>
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Expeditious Granting of IP Right	<p>The e-trademark system was enhanced with a new online e-Search portal introduced in January 2004. The e-Search portal now allows trade mark searches to be done online and members of the public from anywhere can have online access to Singapore's trade mark register and database.</p> <p>In addition, two sets of amendments have been made to the Trade Marks Rules to remove unnecessary hurdles and to make the registration process more efficient and responsive – one in October 2003 and the other, in July 2004. For instance, the requirement of 5 artwork copies for the representation of a mark has been removed. Further, the Registrar now has the power to amend trade mark forms through circulars without going through the formal procedure to gazette the amendments by the Minister. The grace period allowed for the renewal of marks that have expired has also been shortened to 6 months and the procedure streamlined.</p> <p>ePatents: Phase 2A launched on 1 August 2003 and phase 2B launched on 1 July 2004 providing electronic transaction functions for patent applications, thus improving the submission and processing of transactions relating to patent applications.</p> <p>PATENTS (2002): Extending the list of Prescribed Patent Offices to include the Japan Patent Office. PATENTS (changes with effect from 1 July 2004): Introduction of a 2-track system with a default fast track and an optional slow track to give the applicant greater flexibility in prosecuting his application. Allowing a Singapore national phase of a PCT application to proceed to grant in reliance on the IPRP (Chap I) or IPRP (Chap II). Removing the requirement to provide the prescribed details of all corresponding applications or corresponding international applications in the event that the applicant wishes to rely upon a corresponding application or corresponding international application for grant. Giving more time for the applicant to furnish the prescribed information of a corresponding application or corresponding international application, thus increasing the opportunity of an applicant not needing to request search and exam in Singapore. Removal of the mandatory requirement to furnish the priority documents. - Regular consultations with industry, IP professionals and members of public in order to strengthen IP infrastructure</p>
Strengthening of Dispute Settlement of IP Right	<p>- Amendments made to the Trade Marks Act, Patents Act and Registered Designs Act will enable an exclusive licensee or an IP owner to proceed with an action without enjoining the other party. This gives flexibility to the parties and facilitates an efficient settlement for disputes. In addition, the option for statutory damages is now available in civil suits against trade mark counterfeits.</p> <p>PATENTS (changes with effect from 1 July 2004): Introduction of new provisions giving the court or Registrar the discretion to restrict the relief that can be obtained in patent infringement proceedings if the patentee failed to comply with certain substantive examination conditions, thus encouraging patentees to put their application in order prior to grant..</p>
Strengthening of Enforcement of IP Right	<p>&lt;Crackdown Measures&gt; - Intellectual Property Rights Branch (IPRB): set up under the Criminal Investigation Dept of the Police Force in Jan., 2000; former IPR Warrant Unit; combats distribution and retail piracy - Cooperation of authorities and the industry to curb piracy.</p> <p>&lt;Public Awareness&gt; - IPOS has been conducting seminars, events, IP clinics, programs etc. to raise public awareness of IPR. - IP Academy: launched in Jan., 2003; a focal point for development of Singapore's IP capabilities; undertakes education and training for IP professionals, businesses and research organizations; promotes development in IP thought leadership</p>

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|  | <ul style="list-style-type: none"><li>- Intellectual Property Education and Resource Centre (iperc): set up in 2002; brands IPOS' education and capability-building programs</li><li>- Website: one-stop education resource with easy-to-comprehend IP information for school sectors</li><li>- Business Seminars: IP-Create, Exploit, Protect (IP-CEP) series of business seminars provided by IPOS; encourages local enterprises to effectively deploy IP concepts and strategies</li><li>- Publication: a series of informative handbooks on IP issued by IPOS</li><li>- IP Parade: launched in Mar., 2003; a series of offline roving IP exchanges to create marketplace for IP owners, services providers and investors; designed to complement IPOS' online promotional platform, SurfIP</li></ul> |
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Chinese Taipei

Protection of IP Right	Fully consistent with the requirements set out by TRIPS Acts Revised in 2003: Copyright Act(*), Trademark Act(*), Patent Act (adoption of formality system for new utility model patents ,*)
Expeditious Granting of IP Right	<p>Measures to Accelerate the IPR Application Process</p> <ul style="list-style-type: none"> <li>- Revision of Trademark Act: abolishment of examinations for renewal registrations, adoption of 3D and sound marks, multi-class application system, simplification of categories of TM, expanded protection of well-known TMs, change in method of registration fee payment, moving of opposition procedure from pre-registration to post-registration</li> <li>- Revision of Copyright Act: definition of “temporary reproduction” as “reproduction”, adoption of the right of public transmission, legislation of electronic rights management information, adopted the right of distribution</li> <li>- Amendment to the Patent Act: integration of the objection and petition systems, relaxation of legal requirements for application procedures, provisions for electronic applications etc.</li> <li>- “early disclosure of invention patents” system: Early Disclosure Gazette published in hardcopy and CD</li> <li>- fee reduction: for application for re-examination</li> <li>- website of Patent Network: patent related information and online search</li> </ul> <p>Education of people in IP sector: one to six month overseas training for patent examiners</p>
Strengthening of Dispute Settlement of IP Right	- Revise of Copyright Act: increase of civil remedy for general infringement, optical disk piracy, right of confiscation granted to police

<p>Strengthening of Enforcement of IP Right</p>	<p>&lt;Crackdown Measures&gt;</p> <ul style="list-style-type: none"> <li>- “IPR Action Year” announced in 2002 to strengthen IPR protection: Investigation Reporting Committee coordinated by MOJ</li> <li>- IETF: established in 2003; consists of 220 police; combats against piracy and counterfeiting</li> <li>- Approaches taken by Customs to effectively crack down on illegal importation/exportation of pirated and counterfeit goods: <ul style="list-style-type: none"> <li>[Patents] enforce the verdict or order given by the judicial authorities</li> <li>[Trademarks] enforce the Export Monitoring System of TM and the Guideline Governing TM and CR Protection</li> <li>[Copyrights] demand a security or equivalent assurance of applicants for suspending the release of pirated goods, enforce Export Monitoring System of Computer Program Related Products, Enforcement Task Force against the Export of Pirated Optical Disks, guidelines governing TM and CR Protection</li> <li>[Other Border Control Measures] inspection mechanism for optical disk manufacturing equipment and border control, and for export chip products with Mask-ROM</li> </ul> </li> </ul> <p>&lt;Public Awareness&gt;</p> <ul style="list-style-type: none"> <li>- Education of general public for IPR awareness: through media such as billboards at airports, on public transportation, radio, films, brochures, online games, sessions etc.</li> <li>- “Guidelines on MOEA Incentive for Information Against Pirated Optical Disk Manufacturer</li> <li>- Education at schools: study camp for teachers, university, high school and primary school students</li> <li>- National exhibitions of inventions to encourage innovation</li> <li>- Promoting the patent commercialization plan</li> <li>- Training of people in IP sector, in 2002-2003: seminars on IPR border control operations, workshops on Anti-counterfeiting for judicial officers, training programs for IETF, “Identifying Patent Infringement Workshop” for judges and patent infringement examiners etc.</li> </ul>
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\* MOJ: Ministry of Justice

MOEA: Ministry of Economic Affairs

IETF: Integrated Enforcement Task Force

Thailand

Protection of IP Right	<ul style="list-style-type: none"> <li>- The Trademark Act of B.E. 2534 (1991 A.D.) as amended by the Trademark Act (No.2) of B.E.2543 (2000 A.D.)</li> <li>- The Trade Secret Act B.E. 2545 (2002 A.D.)</li> <li>- The Copyright Act B.E. 2537 (1994 A.D.)</li> <li>- The Patent Act B.E. 2522 (1979 A.D.) as amended by the Patent Act (No. 2) B.E. 2535 (1992 A.D.) and the Patent Act (No. 3) of B.E. 2542 (1999 A.D.)</li> <li>- The Protection of Integrated Circuits Act B.E. 2543 (2000 A.D.)</li> <li>- The Protection of Geographical Indications Act B.E. 2543 (2003 A.D.)</li> <li>- The Plant Varieties Protection Act B.E. 2542 (1999 A.D.) under the Ministry of Agriculture and Cooperatives</li> <li>- The Traditional Medicine and Practice Act B.E. 2542 (1999 A.D.) under the Ministry of Public Health</li> <li>- The RTG has proposed for the enactment of the CD Products Controlling Bill.</li> </ul>
Expeditious Granting of IP Right	<ul style="list-style-type: none"> <li>- Thailand has set up a mobile unit project to give advice and to grant preliminary registration service for trademarks and patents in provinces throughout Thailand. The project is scheduled to last until the year 2005.</li> <li>- Thailand has established a facility for the electronic search of patents and trademarks in order to expedite the approval process. Electronic application filing is now planned to follow the search system.</li> </ul>
Strengthening of Dispute Settlement of IP Right	<ul style="list-style-type: none"> <li>- CIPITC (the Central Intellectual Property and International Trade Court): the first IP special court in Asia; started the operation in 1997</li> <li>- The Office of Dispute Prevention and Settlement of Intellectual Property was established in the year 2002.</li> </ul>
Strengthening of Enforcement of IP Right	<p>&lt;Crackdown Measures&gt;</p> <ul style="list-style-type: none"> <li>- Royal Thai Police: Watches and controls IPR infringement caused by pirated products. The IP related cases are handled mainly in ECID, Economic Crime Investigation Division.</li> <li>- The Royal Thai Police, in coordination with the DIP, Department of Intellectual Property, has setup teams of 5 police officers to monitor activities at major shopping centers reputed for IPRs infringement.</li> <li>- With the cooperation of Royal Thai Police, various governmental agencies have set up working groups such as Coordination Center for IPRs Enforcement.</li> <li>- Customs Department, the Ministry of Finance. Border control of import/ export products to protect trademarks and copyrights.</li> <li>- Modification of Price Disparity: The government is negotiating with IPR holders to lower the price of legitimate products in order to make them more attractive and competitive in sales against pirated products than now.</li> </ul> <p>&lt;Public Awareness&gt;</p> <ul style="list-style-type: none"> <li>-The Ministry of Education and the Ministry of University Affairs are consulting to make intellectual property a fixture of the official curriculum.</li> <li>- The DIP conducted a series of seminars to enhance the awareness of the importance of IP information and to encourage greater use of the Internet for patent information search.</li> <li>- Public awareness and education campaigns are conducted through the mass media and by means of visits to schools, universities and provincial chambers of commerce and industry. Government also organized an IP Festival Concert 2002 in August, 2002 in order to boost public awareness on the piracy problems and general importance of respecting others' IPRs.</li> <li>- WEB pages for children are provided to support distant learning of IP.</li> </ul>



The United States of America

Protection of IP Right	United States has been in full compliance with its TRIPS obligation since 1996. US laws ensure TRIPS-PLUS protection for IP.
Expeditious Granting of IP Right	<ul style="list-style-type: none"> <li>- EFS is electronic system for submitting patent applications, computer readable format (CRF) biosequence listings, and pre-grant publication submissions to the USPTO via the Internet. It includes:</li> <li>EFS-ABX – an authoring tool which assists the applicant in the preparation of a patent specification in XML and PDF formats</li> <li>ePAVE – (electronic packaging and validation engine) a software package which allows the applicant to assemble the various parts of the application and transmit the application to the USPTO via the Internet</li> <li>USPTO Direct PKI – a digital certificate to secure the transmission of the application to the USPTO.</li> <li>Trademark Electronic Application System (e-TEAS): electronical filing system for trademarks</li> <li>Electronic system for trademark trials and appeals (ESTTA): electronical system of Trademark Trials and Appeals Board (TTAB), filing of certain case-related documents and extension-of-time requests by e-mail available, more options being considered</li> <li>Trademark Trial and Appeal Board Inquiry System (TTABVUE): allows one to view a TTAB proceeding file by entering the proceeding number, or search for proceedings by application number, registration number, mark, party, or correspondent.</li> </ul>
Strengthening of Dispute Settlement of IP Right	<ul style="list-style-type: none"> <li>- The Copyright Office administers the Copyright Act including the registration of claims to copyright and the recordation of CR transfers. It also administers Copyright Arbitration Royalty Panels, which adjusts rates and distribute royalties under certain statutory licenses.</li> <li>- The federal trademark law (Lanham Act) authorizes suit for infringement of either registered or common law trademark rights.</li> <li>- Suit of Patents: Patent Owners can sue in federal court to stop parties from practicing a patented invention.</li> <li>- Suit of Copyright: Domestic authors must register their claims to copyright in order to bring a lawsuit for infringement in federal court while foreign authors need not register in order to bring such a suit.</li> </ul>

<p>Strengthening of Enforcement of IP Right</p>	<p>&lt;Crackdown Measures&gt;</p> <ul style="list-style-type: none"> <li>- IPR Center (National Intellectual Property Rights Coordination Center) mainly investigates major criminal organizations and those using the Internet to facilitate IP crime. It is a multi-agency of which core staffing is provided by Investigative personnel from the U.S. Customs Service and FBI.</li> <li>- Violations of federal IP statutes are prosecuted by the Office of the U.S. Attorney for the District in which the offense was committed. The Computer Crime &amp; Intellectual Property Section of the United State Department of Justice coordinates the national enforcement effort through prosecutors and prosecution units.</li> <li>- Economic Espionage Act of 1996 provides law enforcement including FBI with a tool to deal more effectively with trade secret theft.</li> <li>- International Trade Commission (ITC): authorized to order the Bureau of Customs and Border Protection to prevent the import of patent violating goods</li> </ul> <p>&lt;Public Awareness&gt;</p> <ul style="list-style-type: none"> <li>- The USPTO: sponsors with WIPO training seminars in IP enforcement for government officials worldwide; hosts digital video conferences with rights holding groups, government officials, and industry in various parts of the world; sponsors the Visiting Scholars Program and hosts IP officials from many countries for seminars.</li> <li>- For the public awareness, an electronic bulletin News@USPTO is released by USPTO, and the U.S. Patent and Trade Museum opened in 1995.</li> <li>- For children, the USPTO provides a website called "Kids' Pages", and funds and cosponsors Camp Invention.</li> <li>- The U.S. Copyright Office sponsors with WIPO the International Copyright Institute, a week-long training seminar in Washington, D.C, supplies expert speakers to numerous WIPO training programs and seminars around the world, and assists in organizing and supplies speakers for National Copyright Week, a public awareness program timed to coincide with World IP Day.</li> <li>- The US government through the USPTO has increased programs and efforts directed towards combating piracy and counterfeiting worldwide.</li> </ul>
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Viet Nam

Protection of IP Right	<p>- not yet a party to the WTO: almost in accordance with TRIPS/WTO Agreement, protecting all subject matters required by TRIPS</p> <p>- IP matters operated on Civil Code basis with supplement of Decrees and Circulars</p> <p>- Preparing to participate in some international treaties such as Bern Convention, Rome Convention, UPOV Convention;</p> <p>- Recently implemented legislations:          Ordinance No 3/2004/L/CTN of 5 April 2004 on Plant Varieties          Decree No. 42/2003/ND-CP; May. 2, 2003; G; on the protection of layout designs of integrated circuits;          Circular 29/2003/TT-BKHCHN; Nov 5, 2003; MOST; guiding the procedures for establishing industrial property right to industrial designs;          Circular 30/2003/TT-BKHCHN; Nov 5, 2003; MOST; guiding the procedures for establishing industrial property right to inventions/utility solutions.</p>
Expeditious Granting of IP Right	<p>Under current regulations, the time frame for application handling has been reduced (substantive examination of patents: 12 months; industrial designs: 6 months; trademarks: 6 months);</p> <p>Application examination process was expedited by setting the productivity targets for examiners, recruitment of new examiners, training and retraining of examiners, application of Industrial Property Administration System (computerized administration of applications);</p>
Strengthening of Dispute Settlement of IP Right	<p>Joint Circular No 01/2001/TTLT-TANHTC-VKSNDTC-BVHTT: May 12, 2001; People's Supreme Court, the People's Supreme Prosecution Institute and the Ministry of Culture and Information; guiding the implementation of some provisions of the Civil Code on the procedures for settlement of disputes at people's courts with respect to copyrights</p>
Strengthening of Enforcement of IP Right	<p>&lt;Crackdown Measures&gt;</p> <p>Instruction 18/2004/CT-BKHCHN of 14/7/2004 of Minister of Science and Technology on the strengthening of IPR Enforcement;</p> <p>At the instruction of the Government, a nationwide conference on the strengthening of IPR enforcement will be held in early September 2004 with the purpose of discussing strategic measures for enhancement of enforcement of intellectual property rights;</p> <p>Actions have been taken by IPR enforcement agencies to combat piracy of copyrights (especially computer softwares) and counterfeiting goods;</p> <p>The Customs Law No 29/2001/QH-10: passed by the NAV; Jun. 29, 2001; provisions concerning border enforcement of IP (Article 57,58,59);</p> <p>Decree No 31/2001/ND-CP: Jun. 26, 2001; G; administrative measures against violations in the field of culture and information (copyright)</p> <p>Decision No 127/2001/QD-TTg: Aug. 27, 2001; PM; establishment of a Committee for combating smuggling, counterfeiting and trade frauds</p> <p>Joint Circular 58/2003/TTLT-BVHTT-BTC of October 17, 2003 of the Ministry of Culture and Information and the Ministry of Finance guiding the copyright protection of exportations and importations at customs offices.</p> <p>&lt;Public Awareness&gt;</p> <p>Since April 2004, IP training courses have been conducted in Hanoi University, similar courses will be opened in other universities;</p> <p>Activities of education, training, dissemination of IP have been done through meetings, seminars, training courses and mass media.</p>

	The laws should be further systematized and extended in scale.
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G: Government	PM: Prime Minister	NAV: National Assembly of Vietnam
MOST: Ministry of Science and Technology	MARD: Ministry of Agriculture and Rural Development	MOF: Ministry of Finance
MOH: Ministry of Health	NOIP: National Office of Intellectual Property of Vietnam	UPOV: The International Union for the Protection

## Records of IPR Related Enforcement

Australia

Commonwealth Director of Public Prosecutions

Copyright Type Prosecutions

	<i>Designs Act 1906</i>	<i>Patents Act 1952</i>	<i>Trade Marks Act 1995</i>	<i>Copyright Act 1968</i>
<b>1999</b>				
Prosecutions	0	0	5	5
Convictions	n.a.	n.a.	5	4
Arrests	n.a.	n.a.	2	0
<b>2000</b>				
Prosecutions	0	0	6	7
Convictions	n.a.	n.a.	6	6
Arrests	n.a.	n.a.	3	1
<b>2001</b>				
Prosecutions	0	0	6	6
Convictions	n.a.	n.a.	6	5
Arrests	n.a.	n.a.	1	1
<b>2002</b>				
Prosecutions	0	0	7	5
Convictions	n.a.	n.a.	6	5
Arrests	n.a.	n.a.	4	3
<b>2003</b>				
Prosecutions	0	0	12	14
Convictions	n.a.	n.a.	12	13
Arrests	n.a.	n.a.	5	4

Note: These statistics do not include civil actions commenced by IPR owners

Statistics on border enforcement (seizures etc) are confidential and not available for public release.

**People's Republic of China**

Arrest, Prosecution and Conviction Statistics  
on Piracy and Counterfeiting Cases

Year	Type(example)	Intellectual Property Rights
1998	conviction cases	128
	conviction persons	213
1999	conviction cases	175
	conviction persons	301
2000	conviction cases	248
	conviction persons	379
2001	conviction cases	314
	conviction persons	509
2002	conviction cases	408
	conviction persons	702

## Hong Kong china

### 1. Arrest, Prosecution and Conviction Statistics on Piracy and Counterfeiting Cases

Year	Type(example)	Patent rights(including Utility model rights)(N.A.)	Design rights(N.A.)	Trademark rights	Copyrights	Others(N.A)	Total
1999	arrest case			651	2388		3039
	prosecution case			1108	1310		2418
	conviction (persons)			758	1077		1835
2000	arrest case			444	2356		2800
	prosecution case			843	3938		4781
	conviction (persons)			807	3410		4217
2001	arrest case			430	1381		1811
	prosecution case			654	1690		2344
	conviction (persons)			531	1958		2489
2002	arrest case			464	1108		1572
	prosecution case			535	1202		1737
	conviction (persons)			517	1323		1840
2003	arrest case			524	918		1442
	prosecution case			517	970		1487
	conviction (persons)			499	979		1478

2. Statistics on Import suspension of alleged infringing goods (Quantity of Seizure)

Type Year	Patent rights (including Utility model rights)	Design rights	Trademark rights	Copyrights	Total
1999	(N.A.)	(N.A.)	2009209	241352	2250561
2000			1139408	55639	1195047
2001			530100	113656	643756
2002			3362296	82181	3444477
2003			21245238	149743	21394981

\*NA : Hong Kong, China does not impose criminal liability on patents and designs infringements.



## Japan

### Statistics on import suspension of alleged infringing goods

Year	1999	2000	2001	2002	2003
Number of Cases	1,794	1,589	2,812	6,978	7,412
Number of Items (Unit:1,000)	994	1,099	1,010	993	771

Year	1999	2000	2001	2002	2003
Patent rights	0	2	1	7	1
	0	1,036	5,000	39,200	550
Model utility rights	1	0	0	0	1
	6	0	0	0	960
Design rights	32	15	14	13	12
	109,707	13,289	74,445	41,693	42,641
Trademark rights	1,719	1,478	2,727	6,859	7,332
	786,035	484,731	239,879	611,100	591,061
Copyright & related rights	55	108	76	108	80
	100,263	602,830	690,654	318,751	136,094
Total	1,794	1,589	2,812	6,978	7,412
	993,565	1,099,001	1,009,958	992,908	771,306

Note: The first line shows number of cases, the second shows number of items

Source: 2003 Record of import suspension of alleged infringing goods (issued by Ministry of Finance)

<http://www.customs.go.jp/mizugawa/chiteki/index.htm> (in Japanese)

Statistics on arrests for IPR infringement

Year	1998	1999	2000	2001	2002
Number of arrests	153	153	193	173	246
Network related cases	19	24	36	43	51
Number of persons arrested	304	322	431	340	435
Number of companies charged	24	62	26	36	39

(Unit: cases)

Year	1998	1999	2000	2001	2002	
Imitation brand products	89	94	125	110	178	
Pirate Copies	Video / DVD	28	11	16	19	17
	Computer software	17	13	34	31	22
	Music CD/Tape	4	4	0	1	3
Character goods	0	8	1	0	0	
Others	15	23	17	12	26	
Total	153	153	193	173	246	

Resource: IPR infringement crimes in past 5 years (issued by National Police Agency)

<http://www.npa.go.jp/safetylife/seikan4/ipr.htm> (in Japanese)

**Korea**

<p><b>(Reference)</b> <b>Latest records of IPR related enforcement</b></p>	<p>(Please describe latest record with numbers in IPR related enforcement.)</p> <ul style="list-style-type: none"><li>- Korea conducts nationwide, year-round anti-counterfeiting measures.</li><li>- The number of IPR offenses detected and penalized in 2003 stood at 40,249, including 16,869 cases of Sound Record, Video Products &amp; Game Software Act violation and 8,542 cases of Trademark Act violation. A total of 967 IPR-related offenders were prosecuted under detention.</li><li>- In particular, the prosecution carried out intensive enforcement activities between April and June, 2004, in conjunction with the SITs at the MIC and the Ministry of Culture and Tourism. During this period, a total of 11,397 offenders were booked on IPR-related charges and among them, 269 were indicted with detention.</li></ul>
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## Malaysia

### 1. Total case on Optical Disc Factories and confiscation value (1 January 2001~ 31 August 2004)

Year	2001	2002	2003	2004	Total
Number of Cases	5	21	13	8	47
Confiscation Value RM (Million)	13.5	20.939	27.257611	13.011503	74.708114

### 2. Cases by unlicensed factories (1 January 2001 ~ 31 August 2004)

Year	2001	2002	2003	2004	Total
Number of Cases	3	2	9	5	19
Production Channel (lines)	7	7	14	7	35
Value confiscation RM (Million)	9.5	5.715	29.79	13.0	58.005

### Unlicensed Optical Disc Factory (16 March 2001 – 31 August 2004)

Number of Cases	Confiscated Replication Machinery (Units)	Confiscation Value RM (Million)
19	35	58.005

### 4. Licensed Optical Disc Factory (16 March 2001 – 31 August 2004)

Number of cases for Forensic Test Processing	Number of cases for Court Trial	Number of settled cases	License Not Renew (Factory)	Number of Factories Involved
8	4	2	4	14

**5. Optical Disc Factory Inspections and Case (1 January 2004 – 31 August 2004)**

Inspection (Factory)	Surveillance (Factory)	Total number of factories	Total number of cases
216	5	221	5

**6. Manufacturing Optical Disc and Original Label (January 2004 – 31 August 2004)**

Format Type	Total Replication Machine	Maximum Capacity (Million)	Total Manufacturing Optical Disc for Local Market	Total Manufacturing Optical Disc for Oversea Market	Total Polycarbonate Usage (Kg)	Total Purchased Original Label (Piece)
CD/ VCD	76	380	94,000,119	3,464,972	926,383.72	28,026,698
DVD	16	80	4,418,356	0	49,211.00	
CD-R/ DVD-R	193	965	64,071,323	311,042,375	12,181,519.78	

**7. Cases and Value of Counterfeit Goods on IPR (1 January 1998 ~ 31 May 2004)**

YEAR	TOTAL	
	CASES	VALUE (RM)
1998	483	4,670,578.12
1999	1,092	13,513,303.30
2000	1,645	23,646,452.40
2001	1,954	10,767,739.35
2002	3,171	19,341,891.82
2003	6,084	23,711,020.53
2004	605	39,536,259.80
TOTAL	15,034	135,187,245.32

Source provided by the Enforcement Division, Ministry of Domestic Trade and Consumer Affairs, Malaysia.

## Mexico

### 1. Statistics on piracy and counterfeiting seized goods<sup>1</sup>

Year	Total
1999	4,841,231
2000	1,909,498
2001	11,304,544
2002	24,473,113
2003	49,124,060
January 1, 2004 – September 30, 2004	69,647,231

### 2. Arrest statistics on piracy and counterfeiting cases<sup>2</sup>

Year	Total
1999	N/A
2000	N/A
2001	200
2002	312
2003	512
January 1, 2004 – September 30, 2004	198

### 3. Statistics on import suspension of alleged infringing goods<sup>3</sup>

1 Source: Federal Attorney General's Office, webpage [www.pgr.gob.mx](http://www.pgr.gob.mx).

2 Source: Federal Attorney General's Office, webpage [www.pgr.gob.mx](http://www.pgr.gob.mx).

Year	Boarding measures	Seized Goods	Economic Value
1999	NA	N/A	N/A
2000	NA	N/A	N/A
2001	NA	N/A	N/A
2002	17	11,150,180 (CD-ROMS)	8,502,230 (Mexican Pesos)
2003	2	N/A	N/A
January 1, 2004 – September 30, 2004	14	321,032	2,291,306 (Mexican Pesos)

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3 This information are IMPI's statistics provided by said Institute with regard to Article 199BIS of the Industrial Property Law (provisional measures) and to Article 148 of the Customs Law.

**The Philippines**

**Apprehensions, Cases Filed and Conviction Statistics on Piracy and Counterfeiting Cases**

YEAR	TYPE	TOTAL
1998	Apprehensions	579
	Cases Filed	101
	Conviction Cases	no data
1999	Apprehensions	514
	Cases Filed	258
	Conviction Cases	no data
2000	Apprehensions	816
	Cases Filed	679
	Conviction Cases	no data
2001	Apprehensions	633
	Cases Filed	415
	Conviction Cases	no data
2002	Apprehensions	1,031
	Cases Filed	582
	Conviction Cases	no data
2003	Apprehensions	1,012
	Cases Filed	113
	Conviction Cases	2
January to June 2004	Apprehensions	192
	Cases Filed	525
	Decided Cases	4



**Statistics on Import Suspension of Alleged Infringing Goods - Bureau of Customs (BOC)**

YEAR	TOTAL
1998	6
1999	29
2000	4
2001	11
2002	10
2003	8
January to June '04	4
	72

**Chinese Taipei**

**1. Arrest, Prosecution and Conviction Statistics on Piracy and Counterfeiting Cases**

Year	Type	Patent rights (including Utility model rights)	Design rights	Trademark rights	Copyrights	Others	Total
1999	arrest case	519		1151	3343		5013
	prosecution case	109		515	1421		2045
	Number of persons convicted	25		329	397		751
2000	arrest case	492		1664	4774		6930
	prosecution case	60		765	2409		3234
	Number of persons convicted	32		550	835		1417
2001	arrest case	483		1241	4381		6105
	prosecution case	49		598	2363		3010
	Number of persons convicted	19		636	1494		2149
2002	arrest case	452		1478	3678		5608
	prosecution case	46		704	1909		2659
	Number of persons convicted	21		513	1152		1686
2003	arrest case	607		2783	3120		6510
	prosecution case	2		1374	1473		2849
	Number of persons convicted	6		1076	1316		2398

**2. Statistics on import suspension of alleged infringing goods**

Year	Type	Patent rights(including Utility model rights)	Design rights	Trademark rights	Copyrights	Others	Total
1999							
2000							
2001							
2002							
2003	number of cases			68	20		88
	number of objects			261100	20719		281819

## The United States of America

### 1. Prosecution and Conviction Statistics on U.S. Federal Piracy and Counterfeiting Cases<sup>4</sup>

	Trademark rights	Copyrights	Others <sup>5</sup>
1998 prosecutions	99	7	40
1998 convictions	87	5	19
1999 prosecutions	106	28	27
1999 convictions	74	26	7
2000 prosecutions	103	43	16
2000 convictions	44	23	9
2001 prosecutions	76	36	30
2001 convictions	51	24	17
2002 prosecutions	79	73	22
2002 convictions	61	47	13

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<sup>4</sup>Derived from the U.S. Attorney General Annual Reports to Congress, available at [http://www.usdoj.gov/05publications/05\\_1.html](http://www.usdoj.gov/05publications/05_1.html). Although derived from official reports, these statistics are inaccurate and may substantially understate the actual number of prosecutions and convictions in several ways. First, the methodology by which the U.S. Department of Justice has collected this information has been discovered to be flawed insofar as it undercounts the actual number of intellectual property cases and, as a result, is currently undergoing a process of revision. Second, discrepancies may result from the carry-over of cases initiated during the previous years. Third, these statistics reflect only federal cases and do not reflect the significant number of intellectual property prosecutions undertaken in each of the fifty United States.

<sup>5</sup>Statistics for “others” reflect prosecutions under Title 18 U.S.C. §§ 2318 and 2319A only, and do not reflect other types of intellectual property cases such as theft of trade secrets or satellite signal theft.

**2. United States Statistics on import suspension of alleged infringing goods\***

Year(example)	Patent rights(including Utility model rights)**	Design rights***	Trademark rights	Copyrights	Others	Total
1999	Not Available	***	2141	1550		3691
2000	Not Available	***	2142	1102		3244
2001	147	***	2618	968		3733
2002	128	***	3940	1853		5921
2003	193	***	5200	1300		6693
<p>* CBP tracks "Seizures" and "Exclusions" but not "detentions." "Detentions" are technically "import suspensions" but may not always become a seizure or exclusion.</p>						
<p>** CBP does not track actions taken against patent violations electronically. Statistics under this category emanate from available paper records, estimates, or a combination thereof. Further, actions under this category relate to "Exclusions" carried out under Exclusion Orders issued by the International Trade Commission and while relating predominantly to patents, may also relate to Exclusion Orders covering trademark or trade dress issues.</p>						
<p>*** CBP does not separately track actions concerning "design rights". Such violations are typically considered as "design trademark" violations and are accounted for under "Trademarks."</p>						

**Vietnam**

**1. Arrest Statistics on Piracy and Counterfeiting Cases**

Year	Total
1999	211
2000	253
2001	247
2002	355
2003	163

**Part II. Progress report on The Comprehensive Strategy on IPR in APEC related activities**

<b>Activity Name</b>	<b>IP Toolkit</b>
<b>Lead Economy</b>	Australia
<b>Categories in table on the Comprehensive Strategy</b>	✓ Promotion of information exchange/sharing between APEC economies
	✓ IPR training for enforcement personnel
	✓ Provision of information to rights holders
	✓ Information provision and education for the general public
<b>Activity objective</b>	The Toolkit was proposed in 2002 as a framework for IPEG related enforcement activities emphasising training, guides/publications & public education and awareness. As an initial contribution, Australia proposed 3 projects. No other economy has yet made any contributions to this framework.
<b>Activity progress</b>	Australia's contributions to date are: <u>Training workshop on IPR Enforcement and Border Control.</u> Workshop was held in Hong Kong in May 2004. <u>Database on IPR enforcement activities for the IPEG web site.</u> The database was completed in 2003. Waiting for economies to populate the database with information. <u>Guide on Digital Rights Management</u> Guide was finalised and distributed in 2003 for economies to adopt as relevant.
<b>Activity Schedule</b>	Ongoing requirement for economies to update the enforcement database Other economies to propose new projects that would fit within the Toolkit framework.



<b>Activity Name</b>	<b>Survey on the Laws and Regulations, and Border Enforcement of IPRs</b>
<b>Lead Economy</b>	The Philippines
<b>Categories in table on the Comprehensive Strategy</b>	Promotion of information exchange/sharing between APEC economies
	IPR training for enforcement personnel
	Provision of information to IP holders
	Provision of information and education to the general public
<b>Activity objective</b>	The survey aims to gather data and information on the laws and regulations and enforcement practices to control cross-border movement of counterfeit/pirated products among APEC economies to be used in formulating action plan that would lower counterfeiting/piracy activity in the region.
<b>Activity progress</b>	<p>The Philippines (IPOPPhil) has received inputs from ten (10) out of the twenty (20) respondent Member Economies. The Member Economies who have submitted their inputs are: Australia, Hong Kong, Japan, Korea, Mexico, New Zealand, Chinese Taipei, Thailand, USA and Vietnam. Recently, Singapore requested a copy of the survey questionnaire.</p> <p>The IPOPPhil has been in constant communication with the IPEG Chair/Secretariat requesting them to post a reminder to member economies that have not yet submitted their response. The latest reminder to the rest of the Member Economies to submit their inputs was sent to IPEG Chair on 28 June 2004. Moreover, the IPOPPhil has already prepared a matrix of answers that were submitted by the member economies, which are ready for analysis.</p>
<b>Activity Schedule</b>	The analysis of the response submitted by the Member Economies will start as soon as all them have submitted their inputs. It is foreseen that projects directed at strengthening or enhancement of enforcement practices will be identified for implementation.

<b>Activity Name</b>	<b>Illustrative Practice</b>
<b>Lead Economy</b>	Japan
<b>Categories in table on the Comprehensive Strategy</b>	○ Promotion of information exchange/sharing between APEC economies
	IPR training for enforcement personnel
	Provision of information to rights holders
	Information provision and education for the general public
<b>Activity objective</b>	The Illustrative Practice was submitted as a starter to establish common enforcement guidelines among APEC economies. The objective of Illustrative Practice is to contribute as a reference when each economy considers its own practice of enforcement.
<b>Activity progress</b>	Japan has conducted a survey on the legislative amendments of APEC economies to follow-up on the Illustrative Practice and we got responses from Hong Kong, the Philippines, and Vietnam. The Philippines and Vietnam informed of the specific legislative changes after the proposal of the Illustrative Practice.
<b>Activity Schedule</b>	The result of the follow-up is to be reported at the IPEG Meeting XIX.

### IPR Service Center Progress Report

Economy	Progress	Schedule
Australia	IP Australia is modifying an existing web portal to co-brand as the IPR Service Centre <a href="http://www.ipaccess.gov.au">www.ipaccess.gov.au</a>	Modification to be completed during the 2004-05 year
Brunei Darussalam		
Canada		
Chile		
People's Republic of China		
Hong Kong, China	Hong Kong, China will use the Intellectual Property Department's website ( <a href="http://www.info.gov.hk/ipd">www.info.gov.hk/ipd</a> ) as its IPR Service Center. A link has been created via the APEC IPEG website (IPR Service Centers corner) w.e.f. August 2004	
Indonesia		
Japan	Website is launched on November 9 <sup>th</sup> 2004 <a href="http://www.meti.go.jp/policy/ipr/index.html">http://www.meti.go.jp/policy/ipr/index.html</a> (Japanese) <a href="http://www.meti.go.jp/policy/ipr/eng/index.html">http://www.meti.go.jp/policy/ipr/eng/index.html</a> (English)	Established
Republic of Korea	Established Website name : Intellectual Property Protection Center URL : <a href="http://www.kipo.go.kr/ippc">www.kipo.go.kr/ippc</a>	Korea plans to revamp this site continuously to meet with the APEC IPR Service Center manual.
Malaysia	The Intellectual Property Corporation of Malaysia (IPCM), is currently providing services similar to an IPR Service Center. The IPCM web site is developed to give information on IP related laws and regulations for public access. Information available online through <a href="http://www.mipc.gov.my">www.mipc.gov.my</a> .	
Mexico	Under preparation for establishment	
New Zealand	<a href="http://www.med.govt.nz/buslit/int_prop.html">http://www.med.govt.nz/buslit/int_prop.html</a>	Established
Papua New Guinea		
Peru		
Philippines		
Russia		
Singapore	Core functions of an IPR Service Center are provided by the Intellectual Property Office of Singapore (IPOS). Information on IPR and application forms can be obtained from IPOS and/or found on IPOS' website: <a href="http://www.ipos.gov.sg">www.ipos.gov.sg</a> .	In operation.
Chinese Taipei	Under preparation for the establishment	
Thailand	IP Promotion and Development Division, Department of Intellectual Property. Information available online through	Arranged

	<a href="http://www.ipthailand.org">http://www.ipthailand.org</a>	
United States	reviewing examples and under preparation to establish center	
Viet Nam	Under preparation for the establishment Website: <a href="http://www.noip.gov.vn">www.noip.gov.vn</a>	

# KEY APEC DOCUMENTS 2004

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## ADDITIONAL DOCUMENTS

Policy/Strategy papers referred to in Leaders' and Ministerial Statements

*Implementing the e-APEC Strategy - Progress and Recommendations for Further Actions: Overview Report*

Can be downloaded from:

[http://www.apec.org/apec/publications/all\\_publications/others.html](http://www.apec.org/apec/publications/all_publications/others.html)

## **LEADERS' AGENDA TO IMPLEMENT STRUCTURAL REFORM (LAISR)**

**Santiago, Chile  
November 2004**

The APEC Leaders reaffirm their sustained political commitment made in Bangkok 2003 to promote structural reform and their determination to demonstrate leadership to strengthen implementation of structural reform in the APEC region. They recognize the value of well-executed structural reform, underpinned by institutional capacity building, for achieving sustainable economic growth and supporting APEC's goal of trade and investment liberalization.

The APEC Leaders fully recognize that structural reform improves the functioning of market in order to sustainably enhance living standards and realize the economic potential of the APEC region by raising our economic efficiency and increasing our competitiveness. They stress the importance of structural reform, which provides a crosscutting perspective and potential for greater synergy across APEC's traditional approach to APEC's wide-ranging economic development agenda.

With a view to advancing structural reform initiatives in APEC, the APEC Leaders commit to addressing the following agenda by priority.

- Focus APEC's structural reform related work on the following as possible priority areas based on its ability to add value and to build on its existing work: regulatory reform , strengthening economic legal infrastructure, competition policy, corporate governance and public sector management.
- Identify an institutional mechanism to address structural reform as a major APEC priority, in consultation with the relevant APEC fora and the Finance Ministers' Process, in order to promote APEC's structural reform related activities in a more enhanced and effective manner.
- Stimulate policy-oriented discussions on structural reform with a view to providing further clear guidance on APEC's work.
- Foster understanding of the benefits of structural reform among APEC economies through better reporting process and sharing of good practices.
- Promote further capacity building, including for regulators.
- Strengthen cooperation and collaboration, where appropriate, with relevant international fora, notably the OECD, to deepen and expand structural reform related activities and measures.

For continued structural reform in each APEC economy, the APEC Leaders acknowledge the relevance to:

- Accelerate domestic efforts and enhance communication with business on priority areas to be identified by each member economy.
- Develop pioneering policies/measures with a view to encouraging the initiation of reforms and promoting domestic regulatory reform.
- Enhance transparency to realize the predictable business environment through reversing those actions that perpetuate corruption.

## REPORT TO THE 16<sup>TH</sup> APEC MINISTERIAL MEETING ON PREPARATION FOR MID-TERM STOCKTAKE OF THE BOGOR GOALS

### I. Backgrounds

1. In Shanghai, October 2001, Leaders reaffirmed their strong commitment to achieve free and open trade and investment in the Asia Pacific region. With this vision, APEC Leaders further agreed to conduct a mid-term stocktaking in 2005. In 2003, Ministers agreed that completion of preparations for this mid-term stocktake should be agreed on by the 16th Ministerial Meeting (AMM) 2004. In 2004, at SOM III, based on a proposal made by Korea, Senior Officials agreed on modalities of the stocktake as follows.

### II. Agreed modalities

#### (a) General Principle

2. Mid-term stocktake should be a forward-looking exercise to highlight what APEC has achieved so far and show APEC's way forward. This Stocktake is an opportunity for APEC to express its strong political will to make its utmost efforts to accomplish free and open trade and investment in the Asia-Pacific region.

#### (b) Basic Elements on the Modalities

3. This exercise will be undertaken by SOM within the following agreed scope and timelines, and the final results will be delivered to Ministers and to Leaders in 2005.

##### Steering APEC Fora

- Having developed the modality of the mid-term stocktake, SOM will play a leading role in conducting the whole stocktaking process.

##### Scope of Stocktaking

- The scope of the mid-term stocktake will include both what APEC as a whole has achieved and also what individual member economy has contributed to the progress towards the Bogor Goals since 1994.

##### Timelines

Timeline	Tasks
2004 CSOM	<ul style="list-style-type: none"> <li>• SOM to report the AMM on the preparation for the stocktake</li> </ul>
2005 SOM I	<ul style="list-style-type: none"> <li>• Economies to submit their assessment reports</li> <li>• Requested stakeholders (ABAC, PECC, ASC) and APEC fora (CTI, ESC, EC) to submit their reports</li> <li>• The PO economies to propose the details of a symposium on stocktake for SOM's approval</li> </ul>
2005 SOM I ~ SOM II	<ul style="list-style-type: none"> <li>• SOM chair to host a symposium on midterm stocktake</li> </ul>
2005 SOM II	<ul style="list-style-type: none"> <li>• SOM to establish SOM steering group for drafting final report</li> <li>• SOM to report MRT the progress of stocktake</li> </ul>
2005 SOM III	<ul style="list-style-type: none"> <li>• SOM steering group to present the first draft of the final report to SOM for comments</li> </ul>
2005 CSOM	<ul style="list-style-type: none"> <li>• SOM steering group to present the second/final draft to SOM for approval</li> <li>• SOM submit the final report to AMM and AELM</li> </ul>

### **III. Progress in the preparation**

4. Having agreed upon the specific timelines and methodology, at SOM II in 2004 SOM further agreed to ask member economies and APEC stakeholders to get actively involved in the preparation for mid-term stocktake:

- For the assessment of each economy's contribution towards the Bogor Goals, each member economy will submit its own evaluation report up to five (5) pages by SOM I in 2005;
- For the assessment of APEC's overall achievement, related stakeholders of APEC such as ABAC, PECC and ASC as well as APEC fora such as CTI, ESC and EC will submit their respective evaluation reports up to twenty (20) pages by SOM I in 2005;
- In preparation for the above-mentioned reports, contributions from ECOTECH activities should be duly reflected.

5. SOM intersessionally approved the proposal of establishing a project team utilizing the TILF fund of \$69,950. Project overseer economies – Korea and co-sponsor economies, Australia, China, Japan, and Viet Nam – were asked to select experts who would undertake the project. Under SOM's direction, the project team will carry out the following tasks;

- Assist member economies to maintain consistency in their reports;
- Collect and compile the reports from member economies, related stakeholders, APEC fora and IAP Peer Review reports;
- Make an analysis of all the reports mentioned above;
- Prepare a discussion paper for mid-term stocktake symposium (see below);
- Make a summary of mid-term stocktake symposium.

### **IV. Future tasks to be completed**

6. The following are the list of tasks to be carried out by Senior Officials before and the 17th AMM in 2005.

- At 16th AMM in 2004, SOM will make a report on the preparation of the stocktake.
- At SOM I in 2005, SOM will approve the details of the symposium on midterm stocktake.
- At SOM II in 2005, a symposium will be held among SOM leaders, representatives from ABAC, PECC and ASC, Chairs and Lead Shepherds of APEC fora and internationally renowned APEC experts. The symposium to be organized by Korea and other co-sponsor economies will focus on a framework and elements to be reflected on the final report of mid-term stocktake to AMM and AELM in 2005.
- At SOM II in 2005, SOM will establish a SOM steering group whose main task is drafting a final report to AMM and AELM. The steering group will be chaired by SOM Chair and split into several sub-groups which are supposed to draft each designated section of the final report.
- At MRT in 2005, SOM will make a report on the progress made to date.
- At SOM III in 2005, the steering group will present the first draft of the final report and SOM will make comments on it. The SOM steering group will keep revising the final report reflecting comments from member economies and submit the final version to CSOM in 2005.

### **V. Composition of the Project Team**

7. At CSOM, the project team composed of five (5) experts nominated by overseer economies was approved and mandated to undertake the afore-stated tasks under the supervision of SOM. Those experts are:

#### **Project Team Coordinator**

- **Dr. Sangkyom Kim, Executive Director, Korean National Center for APEC Studies, Korea Institute for International Economic Policy (KIEP), Korea**

#### **Project Team Members**



- **Ms. Jane Drake-Brockman, Managing Director, Trade and Environment Solutions, Australia;**
- **Dr. Sheng Bin, Senior Research Staff and Professor, Institute of Economics and APEC Study Center, Nankai University, China;**
- **Dr Hikari Ishido, Research Fellow, Institute of Developing Economics, Japan; and**
- **Ms. Phan Thanh Ha, Deputy Director and Researcher, The Central Institute for Economic Management, Vietnam.**

#### **VI. Recommendation for Ministers**

8. It is recommended that Ministers note the progress of the preparation for the Midterm Stocktake, endorse work plans that Senior Officials put forward to Ministers and state in their Joint Statement that:

“Ministers commended Senior Officials for their work on the preparation for the Mid-term Stocktake of the overall progress towards the Bogor Goals, and endorsed the recommendation on the work program. Ministers instructed Senior Officials to provide a preliminary progress report to the APEC Meeting of Ministers Responsible for Trade in 2005 and bring the final results of the Mid-term Stocktake to the 17th APEC Ministerial Meeting (AMM) so that Ministers may report to Leaders on the final outcomes. They underscored that the result should comprise an assessment on APEC’s progress towards the Bogor Goals based on members’ evaluation, inputs from fora, and stakeholders such as ABAC, ASCC, PECC, and include Senior Officials’ policy recommendations for future activities that need to be taken to achieve the Bogor Goals.”

## **SANTIAGO COMMITMENT TO FIGHT CORRUPTION AND ENSURE TRANSPARENCY**

Santiago, Chile  
21 November 2004

The APEC Leaders commit to fight corruption and promote transparency.

Corruption is a complex economic, political and social problem with destructive repercussions in every sphere of our societies. Corruption threatens democracy and economic growth, the integrity of our institutions and our social values. As the World Bank has noted, the direct costs of bribery alone to national economies is over one trillion dollars each year.

Corruption is found in both the public and private sectors. A comprehensive approach is required.

Good governance, transparent legal regimes and systems to fight corruption are vital elements to nurture and sustain economic development, growth, and prosperity.

The APEC Leaders highlight the important role of the United Nations Convention against Corruption as the first legally binding global instrument specifically targeted to fight the scourge of corruption.

Accordingly, to fight corruption and ensure transparency, the APEC Leaders decided on a course within the framework of the principles and provisions of the United Nations Convention against Corruption.

APEC Leaders agreed to:

- Encourage each other to deny safe haven to officials and individuals guilty of public corruption, those who corrupt them, and their assets;
- Promote regional cooperation on extradition, mutual legal assistance and the recovery and return of proceeds of corruption.
- Work toward implementation of punitive and preventive anticorruption policies and practices consistent with the UN Convention Against Corruption, including those policies and practices necessary for the proper and effective management of public affairs and public property;
- Intensify our individual and joint actions to fight corruption and ensure transparency, including cooperation with other multilateral and regional intergovernmental institutions and exchange of information on implementation of domestic anti-corruption commitments;
- Develop innovative training, targeted- capacity building and results-oriented technical assistance to fight corruption and ensure transparency; and
- Implement the APEC Transparency Standards, a key to both the fight against corruption and progress on the WTO Doha Development Agenda.

They applaud the APEC Business Advisory Council (ABAC) and the leaders of the Asia Pacific corporate community for committing themselves to operate their business affairs with the highest level of integrity and to implement effective anticorruption measures in their businesses, wherever they operate.

By working together, Leaders are confident that APEC can make a difference to fight corruption and ensure transparency, and can cut the cost of corruption to our economies and create a culture of integrity and shared prosperity.

## **SANTIAGO AGENDA ON ENTREPRENEURSHIP**

**Santiago, Chile  
6–7 October 2004**

### **1. APEC ENTREPRENEURSHIP PROMOTION POLICY**

The quality of the businesses and the strength of the entrepreneurial capability are key factors in the productivity of an economy. The number and quality of people with entrepreneurial skills are key to maximize the efficient use of capital, labour and natural resources of an economy.

Consequently, in order to increase productivity and competitiveness, firms require first- class business management as well as value-added generating and innovative projects that can provide them with the necessary competitive edge.

Encouraging an entrepreneurial culture and business start-ups, have become central policy goals for the development of small and medium-sized enterprises. Several Asian-Pacific economies are undergoing a critical shift in terms of business development policies. These policies include the development of new businesses and the promotion of a new way of thinking that values entrepreneurship. This is evidenced by the numerous programmes launched in recent years by public and private institutions for the development of new enterprises and the promotion of an entrepreneurial spirit –both at national and local levels.

The various entrepreneurship promotion policies of the APEC economies are aimed at promoting the development of innovative, value-added generating firms. The emphases placed on entrepreneurship promotion differ according to the priorities of each member economy.

### **2. PURPOSE OF APEC'S ENTREPRENEURSHIP PROMOTION ACTIVITIES**

Entrepreneurship promotion is aimed at increasing an economy's competitiveness through: a) strengthening and broadening the business base; b) promoting innovation; and, c) increasing the number of well-established, successful, value-added generating enterprises.

### **3. CRITERIA FOR THE INTERVENTION**

#### **3.1. Justifying Public Interventions**

Entrepreneurship promotion policies in APEC economies respond to the need to correct market failures that prevent the optimal allocation of productive resources.

In addition to market failures, there are other reasons justifying public intervention in the economy, among others: unequal income distribution; economic instability; disadvantage based on ethnicity; imbalance between rural and urban development; and gender inequity. The priority accorded to these objectives will vary between economies.

#### **3.2. Market Failure and Barriers to Entrepreneurship Development**

In this context, market failure refers to, among other things, lack of competition, the existence of public good, externalities, incomplete markets and information asymmetries.

Entrepreneurship promotion policies and actions seek to mitigate such market failures in order to encourage the development of the private sector's entrepreneurial drive. Such barriers often stem from:

- a) Information asymmetries.
- b) Inadequate human capital.

- c) Poor access to funding.
- d) Low levels of innovation skills.
- e) Excessive government bureaucracy.
- f) Market entrance and exit transaction costs.

#### **4. INTERVENTION STRATEGY AND SCOPE**

Government intervention seeks to solve or mitigate market failures that limit entrepreneurial development. The aim of these policies is to have entrepreneurship as one of the main drivers of economic development.

The institutions and regulatory frameworks of each of the APEC economies should be consistent with entrepreneurship promotion. Regulations should be facilitators rather than barriers to business activity. The specific regulations will vary according to the economy's particular features and conditions.

A key issue of entrepreneurship promotion strategies is the development of comprehensive networks that support entrepreneurship. These networks must cover all steps of entrepreneurs' training and business development. They should involve public-private cooperation and link the efforts of the many stakeholders involved in business development processes.

Another critical aspect of entrepreneurship promotion strategies is the social positioning of the entrepreneurial activity. Entrepreneurs should be esteemed by society for their contribution to employment generation, improvements in local quality of life and innovations with which they enrich society. Citizens should be encouraged to create new ventures.

Several cross-cutting areas of work are available to promote entrepreneurship in APEC economies:

- a) Extend the social and gender base for the generation of dynamic businesspersons.
- b) Increase the number and quality of business opportunities.
- c) Disseminate positive role models to create an entrepreneurial vocation.
- d) Provide potential entrepreneurs with work experience.
- e) Encourage the development of entrepreneurial networks.
- f) Promote local entrepreneurial development.
- g) Leverage the transforming power of new knowledge-intensive businesses.
- h) Create entrepreneurial enabling conditions.
- i) Take a holistic approach based on the combination of efforts among the different governmental agencies, with the private sector playing a key role.
- j) Understand entrepreneurial development as a long-term economic and social investment.

Public policies for entrepreneurship promotion may be focused on the following areas: Developing Human Capital, Access to Funding, Removing Barriers to new Business Creation, and Innovation and Technology.

##### **4.1. Developing Human Capital**

Human capital development aims at creating a culture of entrepreneurship through the training of students from different disciplines and at different educational levels as well as workers and business people. It includes:

- a) Promotion of an entrepreneurial culture.
- b) Promotion of entrepreneurial vocation and skills through the education system and fostering of a closer relationship between academia and the labour market.
- c) Development of frameworks to facilitate and reinforce early entrepreneurship training.
- d) Entrepreneurship education and training plans at national and local levels.

- e) Development of education centers to promote entrepreneurship abilities among students.
- f) Teacher training to deliver education projects focused on entrepreneurship.
- g) Fostering program contents to promote entrepreneurship skills, responsible decision-making, systemic problem analysis, creativity, self-management and responsibility among the students of all educational levels.
- h) Development of training programs and consulting services designed for start-ups.

#### **4.2. Access to Funding**

The objectives for improving the access to funding for entrepreneurial efforts include the implementation of mechanisms and networks for entrepreneurs to access financial resources to carry out their projects. Also:

- a) Public grants to support the access to financial markets should be limited in time, to avoid companies becoming dependent on permanent state support for businesses.
- b) Good banking practices in terms of regulation and rules for the financial market.
- c) Government assistance for transaction costs rather than for prices or interest rates.
- d) Coordination of guarantees between private financial institutions and micro and small businesses.
- e) Promotion of specialization in the financial institution sector and creation of specialized providers for funding emerging companies.
- f) Development of Capital Networks – Seed Capital and Venture Capital.

#### **4.3. Removing Barriers for New Business Creation**

The removal of barriers for business development seeks to eliminate those issues that prevent the adequate development of the entrepreneurial activity. Such actions, however, should not lead to market distortions. They could include:

- a) Support for the incorporation of companies.
- b) Facilitation of the exit of failed enterprises.
- c) Speeding-up government and municipal decision-making.
- d) Eliminate barriers to market access.
- e) Enhance communication between entrepreneurs and regulatory authorities about new regulatory burden.

#### **4.4. Innovation and Technology**

Technology innovation, development and adaptation are key factors for the achievement of competitive-edge, value-added business initiatives. Special emphasis must be provided to the development of knowledge networks and project development and implementation skills. Amongst other things:

- a) Development of knowledge-based networks by strengthening the links between universities and firms.
- b) Technology adaptation and development, specifically in niches with high potential or emerging industries.
- c) Generation and strengthening of business incubators to help increase the numbers of innovative and/or competitive edge enterprises.
- d) Promotion of world-class intellectual and industrial property protection.
- e) Fostering of technological business networking.

## STATEMENT TO IMPLEMENT APEC POLICIES ON TRADE AND THE DIGITAL ECONOMY

Los Cabos, Mexico  
27 October 2002

Bangkok, Thailand  
21 October 2003

Santiago, Chile  
21 November 2004

In Brunei in 2000, APEC Economic Leaders agreed to “continue to work toward pro-competitive and market based policy frameworks for liberalization in trade in telecommunications and IT services,” and in 2001 in Shanghai to develop trade policy targets for the new economy.

The exponential growth in Internet connectivity and use of electronic commerce as a channel for international business require the development of trade policies that promote a networked world. The trade agreements and rules we develop now will affect the world economy of the coming decades.

APEC Economies, as an important part of the world community, need to make constructive efforts to liberalize the trading environment with effective trade rules for the digital economy where products and services can be exchanged using electronic networks free of tariffs and other barriers.

Accordingly, APEC economies agree to support implementation on a pathfinder basis of the following objectives, taking into account the general principles in the Osaka Action Agenda.<sup>1</sup>

### **General Objectives**

1. The digital economy should continue to flourish in a liberal and open trade environment, which will lead to greater development of e-commerce and economic growth.
2. Market access and national treatment commitments across a broad range of relevant goods and services sectors will promote trade in products and services using electronic networks.
3. Where legitimate policy objectives require domestic regulations that affect trade in products and services using electronic networks, such regulations should be transparent, non-discriminatory and least restrictive on trade, taking Economies' international commitments into account.
4. In light of the importance of liberalization in digital trade, Economies support a long term moratorium on customs duties on electronic transmissions.
5. Economies support demand-driven capacity building projects that promote trade and the digital economy, with a view to ensuring that developing Economies benefit fully from the new economy.

### **Specific Objectives**

6. APEC Economies agree to take a collective leadership role in the WTO negotiations to pursue market openness in areas related to trade in the digital economy, including encouraging other WTO Members to pursue the same degree of openness that APEC Economies support in the following areas relevant to the digital economy:

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1 For non-WTO Members, implementation of paragraphs 7, 8, 9, 10, 11, 15 and 16 should not be viewed as reflecting the on-going process of accession to the WTO.

## **Services**

7. Pursuant to the Shanghai Accord, APEC Economies identified and exchanged information on the following services related to electronic commerce: telecommunications and value added services, subscription video services (including via cable or satellite and excluding broadcasting), computer and related services, advertising, distribution (including products distributed electronically), express delivery, and video rental/leasing (including online rentals).

For services it identifies as critical to electronic commerce, each Economy will:

- (a) reduce progressively or eliminate limitations on the number of suppliers permitted to supply such services;
  - (b) reduce progressively or eliminate limitations on ownership and control that:
    - (i) prevent significant foreign investment in the supply of telecommunications services; and
    - (ii) prevent majority ownership or control of suppliers of other services; and
  - (c) otherwise accord market access and national treatment with a minimum of exceptions.
8. Each Economy will make offers in the WTO services negotiations on the services it identifies as critical to electronic commerce, recognizing that there are on-going WTO discussions on these issues.
  9. Recognizing the need to implement pro-competitive regulatory reform in the telecommunications sector, Economies will adopt and implement as soon as possible the WTO Basic Telecommunications Reference Paper.
  10. Any Economy that is not currently a WTO Member is, in its negotiations to accede to the WTO, encouraged to offer meaningful commitments for as many services critical to electronic commerce as possible, and agree to adopt and implement the WTO Basic Telecommunications Reference Paper.

## **Intellectual Property**

11. In light of the importance of protecting intellectual property rights to promote trade in the digital economy, Economies will fully implement and enforce the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights.
12. Economies will ratify and fully implement the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty as soon as possible. If an Economy is a non-Member of WIPO, it will implement the provisions of these treaties as soon as possible. For any Economy in the process of reviewing accession or implementation, it will commit to completing that review as soon as possible.
13. Economies will ensure through adequate oversight mechanisms that their government entities use only legal software or other content.
14. Economies will to the largest extent possible ensure that the internet and e-commerce does not facilitate trade in infringing and counterfeit goods, and will put into place appropriate regulatory and enforcement systems aimed at curtailing these activities.

## **Tariffs**

15. Economies will become participants in the Information Technology Agreement, and present their schedule of commitments to the WTO ITA Committee, as soon as possible. Any Economy that is not currently a WTO Member will, in its negotiations to accede to the WTO,

consider becoming a participant in the Information Technology Agreement.

16. Economies will work toward eliminating tariffs on additional information technology products at the broadest level possible.
17. Economies will submit their annual tariff and trade data to the WTO Integrated Data Base. For any Economy that is not a WTO Member, it will submit equivalent data to the APEC tariff database as soon as possible.

#### **Future Work**

18. Recognizing the dynamic nature of the digital economy and the on-going need to ensure that our trade policies create incentives for creativity, growth and development, officials will:
  - (a) review Economies' progress in meeting the objectives set forth in this Statement and report to the 2003 Ministerial Meeting; and,
  - (b) pursue on an annual basis the process developed in the Shanghai Accord of exchanging information and setting trade policy targets in areas important for ensuring the free flow of trade and investment in the digital economy and report annually at the Ministerial Meeting.

#### **List of participant economies**

1. Australia
2. Brunei Darussalam
3. Canada
4. Chile (according to the understanding in Attachment 1).
5. People's Republic of China
6. Hong Kong, China
7. Indonesia
8. Japan
9. Korea
10. Malaysia
11. Mexico
12. New Zealand
13. Papua New Guinea
14. Peru
15. The Philippines
16. Singapore
17. Chinese Taipei
18. Thailand
19. United States
20. Viet Nam



Chile agreed to become a participating economy in the Leaders' Statement to Implement APEC Policies on Trade and the Digital Economy, on the basis of the following understanding of the requirements of this pathfinder statement:

- The commitment in paragraph 14 of the Statement to put into place appropriate regulatory and enforcement systems aimed at curtailing trade in infringing and counterfeit goods using e-commerce and internet does not require a participant to put into place a judicial system for the enforcement of intellectual property rights that are separate and distinct from its general judicial system to enforce its laws;
- No commitment in this Statement regarding implementation of the WIPO Copyright Treaty of the WIPO Performances and Phonograms Treaty can be enforced through any dispute settlement mechanism;
- The commitment in paragraph 15 of the Statement regarding participation as soon as possible in the Information Technology Agreement is understood to take account of the need for Chile to change its across the board flat tariff policy on this matter, in order for ITA participation to become a possibility.

# KEY APEC DOCUMENTS 2004

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## ADDITIONAL DOCUMENTS

CTI, EC and ESC Annual Reports:

- [2004 APEC Committee on Trade and Investment: Annual Report to Ministers](#)

[http://www.apec.org/apec/publications/all\\_publications/committee\\_on\\_trade.html](http://www.apec.org/apec/publications/all_publications/committee_on_trade.html)

- [2004 APEC Senior Officials Report on Economic and Technical Cooperation](#)

[http://www.apec.org/apec/publications/all\\_publications/ecotech\\_sub-committee.html](http://www.apec.org/apec/publications/all_publications/ecotech_sub-committee.html)

- [APEC Economic Committee Publications](#)

- *2004 APEC Economic Outlook*
- Realising Innovation and Human Capital Potential in APEC, 2004
- Trade Facilitation and Trade Liberalisation: From Shanghai to Bogor, 2004

[http://www.apec.org/apec/publications/all\\_publications/economic\\_committee.html](http://www.apec.org/apec/publications/all_publications/economic_committee.html)

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## **SENIOR OFFICIALS' REPORT TO MINISTERS**

**Santiago, Chile  
17–18 November 2004**

### **Executive Summary**

#### **SENIOR OFFICIALS' REPORT TO MINISTERS**

The First, Second, Third and Concluding Senior Officials' Meetings for the Sixteenth APEC Ministerial Meeting were convened on 2-3 March 2004 (Santiago, Chile), 1-2 June 2004 (Pucón, Chile), and 3-4 October 2004 (Santiago, Chile), respectively.

This report contains a list of information and decision points that arise from those meetings. At the Concluding Senior Officials' Meeting on 14-15 November 2004, Senior Officials agreed to submit them to APEC Ministers.

#### **Recommendations**

1. Ministers to take note of the SOM Report to Ministers; and
2. Ministers to endorse the recommendations contained herein.

## SENIOR OFFICIALS' REPORT TO MINISTERS

The First, Second and Third Senior Officials' Meetings in preparation for the Sixteenth APEC Ministerial Meeting were convened on 2-3 March 2004 (Santiago, Chile), 1-2 June 2004 (Pucón, Chile), and 3-4 October 2004 (Santiago, Chile), respectively. At the Concluding Senior Officials' Meeting on 14-15 November 2004, Senior Officials agreed to submit to APEC Ministers the following list of information and decision points:

### 1. Strengthening the Multilateral Trading System

#### INFORMATION POINTS:

- **Highlight** the importance of APEC's contribution to the July Package, especially in launching the negotiations on Trade Facilitation.
- **Recognize** the importance of reaching an ambitious outcome in the WTO negotiations, whilst considering flexibility.
- **Highlight** the relevance of special and differential treatment and cooperation regarding WTO negotiations and activities.
- **Welcome** the workshop on WTO Capacity Building Best Practices held in Santiago in the margins of SOM I 2004, and its outcomes aimed at identifying best practices in multi-stakeholder consultations and in intra-government coordination; developing the process of evaluation of past practices.
- **Welcome** the implementation of WTO capacity building projects in 2004.
- **Welcome** Japan's contribution to advancing Trade Facilitation in the WTO by sponsoring two important capacity building initiatives: the APEC Seminar on WTO Trade Facilitation held in Bangkok, and the APEC/WTO Roundtable in Geneva on the benefits of a Trade Facilitation Agreement with WTO disciplines.

#### DECISION POINTS:

- **Instruct** their WTO officials to intensify their work in Geneva with a view toward achieving progress in all areas of the DDA in 2005.
- **Call** for further enhancing of WTO Capacity building efforts to support WTO activities and negotiations, by increasing the capacity of developing economies to participate in negotiating DDA.
- **Agree** on the importance of agricultural reform, including the abolition of all forms of agricultural export subsidies and unjustifiable export prohibitions and restrictions at an early date, as well as of improved market access for goods and services, and the clarification and improvement of WTO rules.
- **Call** for completion of the work to identify automotive and chemical non-tariff measures.
- **Call** to support efforts in the accession of the Russian Federation and Viet Nam.
- **Call** for identification of additional areas in which APEC can make a strong contribution to a successful completion of the DDA.

### 2. Regional Trade Agreements (RTAs) and Free Trade Agreements (FTAs)

#### INFORMATION POINTS:

- **Take note** of the outcomes and policy recommendations of the Second SOM Policy Dialogue on RTAs/FTAs held on 30 May 2004 in Pucon.
- **Welcome** the substantial progress that has been achieved to maximize the contribution of RTAs/FTAs to achieving the Bogor Goals and advancing the WTO process, including an APEC policy response, concrete measures to enhance transparency and targeted capacity building.
- **Welcome** the inclusion of links to official information on APEC economies' RTAs/FTAs on the APEC Secretariat's website.
- **Welcome** the proposals to deliver RTA/FTA capacity building activities for APEC member economies in 2005.

- **Take note** of the concerns expressed by the business community about the potential costs for business arising from the growing number of RTAs/FTAs.
- **Welcome** Korea's proposal to convene the 3rd SOM Policy Dialogue on RTAs/FTAs in the margins of SOM II in 2005.

**DECISION POINTS:**

- **Endorse** the "*APEC Best Practices for RTAs/FTAs*" and highlight its importance as a meaningful reference to ensure that RTAs/FTAs contribute to high standard agreements in our region that contribute to achieving the Bogor Goals.
- **Instruct** officials to use these Best Practices as a helpful reference for any capacity building activities with regard to RTAs/FTAs.
- **Instruct** member economies to use these Best Practices as a reference for the current negotiations to clarify and improve existing WTO rules on RTAs, and practices relating to RTAs.
- **Endorse** the template for a new IAP reporting template for economies to use in reporting on their RTAs/FTAs beginning in 2005.
- **Instruct** Senior Officials to study the feasibility of developing an APEC RTAs/FTAs Database for the use of business, policy makers and other stakeholders.

### **3. Trade and Investment Liberalization and Facilitation**

#### **3.1 Committee on Trade and Investment**

##### **DECISION POINTS:**

- **Endorse** the 2004 Committee on Trade and Investment Annual Report to Ministers and its recommendations.

#### **3.2 APEC Transparency Standards**

##### **INFORMATION POINTS:**

- **Welcome** economies progress to implement the APEC Leaders' Transparency Standards according to the "Transparency by 2005 Strategy".
- **Note** that a SOM-led roundtable involving member economies and relevant stakeholders in the wider community is being planned for 2005 to discuss economies' implementation of the Leaders' Transparency Standards into their domestic legal regimes.

##### **DECISION POINTS:**

- **Endorse** the Transparency Standards on Government Procurement and recommend that Leaders in Santiago incorporate these into the Leaders' Statement to Implement APEC Transparency Standards
- **Approve** revisions to the IAP to reflect the Leaders' General Transparency Standards in the new Transparency IAP template, and the Leaders' area-specific Transparency Standards in revisions to the existing IAP templates.
- **Welcome** the steps taken by ABAC to identify issues regarding economies' implementation of the Transparency Standards, and **instruct** officials to continue working with ABAC and the wider business community to identify a concrete list of issues for which economies would develop in APEC to address an action plan for consideration at the June 2005 MRT.

#### **3.3 Pathfinder Initiatives**

##### **INFORMATION POINTS:**

- **Welcome** the adoption of a strategy by Senior Officials to improve the effectiveness and implementation of Pathfinder Initiatives.
- **Welcome** the decisions by Australia, Canada and China to join the Leaders' Digital Economy Pathfinder Statement; Chinese Taipei to join the pathfinder initiatives on Electronic Sanitary and Phyto-sanitary (SPS) Certificates, Electronic Certificates of Origin (ECO) and the Sectoral Food MRA; Russia to join the Revised Kyoto Convention on the Simplification and Harmonization of Customs Procedures pathfinder; and Malaysia to participate in Part II of the Electrical and Electronic Equipment MRA pathfinder.
- **Note** the work undertaken to advance a survey on Enforcing Best Practices of member economies for combating Optical Disc Piracy.
- **Note** the work undertaken to update the digital economy reporting template to report economies' progress to implement Leaders' objectives on e-commerce, services critical to e-commerce, intellectual property and tariffs.
- **Note** the discussion on the proposal to amend the Leaders' Digital Economy Pathfinder Statement to make APEC's long-term moratorium on customs duties on electronic transmissions permanent.

##### **DECISION POINTS:**

- **Endorse**, in the context of the Trade and the Digital Economy Pathfinder, a list of information technology (IT)<sup>1</sup> products on which tariffs could be eliminated for forwarding to the WTO for consideration as part of a balanced outcome, and **welcome** Mexico's<sup>2</sup> list of IT products for unilateral tariff elimination.

### **3.4 Anti-Corruption and Transparency**

#### **INFORMATION POINTS:**

- **Commend** the success of the first APEC Anti-Corruption Experts' Meeting held in Santiago on 25-26 September 2004.
- **Welcome** the establishment of an Experts' Task Force in 2005.

#### **DECISION POINTS:**

- **Recognize** the importance of fighting corruption in the APEC region as one of the most serious threats to good governance and the proper development of rule of law and economic systems within our region, and globally.
- **Agree** that APEC's commitment and leadership on anticorruption is indispensable in strengthening the integrity of enforcement and the core foundations of our collective values in society including the areas of economic development, growth, and prosperity.
- **Agree** to approve the "*Santiago Commitment to Fight Corruption and Ensure Transparency*" and the "*APEC Course of Action on Fighting Corruption and Ensuring Transparency*" for endorsement by Leaders.
- **Call** for the launch of the APEC Anti-Corruption and Transparency Initiative with concrete actions to be undertaken in 2005.
- **Agree** to develop the Terms of Reference by SOM I 2005 in order for the Experts' Task Force to meet starting in 2005.
- **Call** for the development of demand-driven training and capacity building to assist developing economies to implement the *APEC Course of Action on Fighting Corruption and Ensuring Transparency*.
- **Encourage** effective and results-oriented synergies and partnerships with other multilateral and regional organizations, particularly on donor coordination on training, capacity building and exchanges of technical expertise.

### **3.5 Trade and Investment Facilitation**

#### **INFORMATION POINTS:**

- **Welcome** the report on *APEC Trade Facilitation Action Plan – A Mid-term Assessment* prepared by an external expert, and **direct** officials to intensify efforts to deepen the implementation of the Action Plan by drawing up a road map outlining concrete actions and target dates to meet the APEC trade facilitation objectives by 2006.
- **Note** the various studies seeking to measure trade facilitation and welcome the completion of the *Study on the Mutual Advancement of APEC's Trade Facilitation and Secure Trade Goals post September 11* and the *Study on Assessment of Effectiveness in Implementing Trade Facilitation Actions*.
- **Welcome** the steady progress on the Time Release Survey as one of the proxies for measurement.

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<sup>1</sup> One economy is still undergoing technical and Cabinet consultations on the feasibility of joining this initiative under the Pathfinder.

<sup>2</sup> Mexico expressed that it is not a participating economy in the agreed list of IT products that will be forwarded to the WTO for consideration and possible tariff elimination. Mexico presented a list of IT goods for unilateral tariff elimination that shall be maintained within the APEC context and not to be sent as a recommendation to WTO.

- **Welcome** the successful conclusion of the Expanded Dialogue on Trade Facilitation and the results of the mid-term review of the implementation of the APEC Trade Facilitation Action Plan.
- **Welcome** the proposal to hold a High Level IPR Symposium in China next year.
- **Welcome** the Food Safety initiative.

#### **DECISION POINTS:**

- **Endorse** the recommendations emanating from the Expanded Dialogue on Trade Facilitation in three areas: deepening and better monitoring the implementation of the Trade Facilitation Action Plan; better interaction with business; and advancing trade facilitation negotiation in the WTO and **instruct** officials to report to the June 2005 MRT on ways to take them forward.
- **Endorse** the IPR Policy Progress Mapping and the follow up report on the Comprehensive Strategy on IPR in APEC.
- **Encourage** the establishment of IPR Service Centers in all member economies as soon as practicable.
- **Encourage** economies to hold training seminars on intellectual property enforcement, based on the guidelines set out in the comprehensive Strategy. In this context, we welcome China's proposal to host a High Level Conference on IPR Protection and Enforcement in 2005.

### **3.6 Intellectual Property**

#### **INFORMATION POINTS:**

- **Welcome** SOM's recommendation to elevate the work on IPR in 2005, including building on the comprehensive strategy
- **Welcome** the establishment of IPR Service Centers by seven member economies

#### **DECISION POINTS**

- **Endorse** taking concrete actions in 2005 to reduce piracy and trade in counterfeit goods, address online piracy issues, and increase cooperation and capacity building in 2005.
- **Endorse** the work on IPR Policy Progress Mapping and the implementation of the Comprehensive Strategy on IPR in APEC.
- **Encourage** the establishment of IPR Service Centers in all member economies as soon as possible.

### **3.7 Individual Action Plans (IAPs)**

#### **INFORMATION POINTS:**

- **Welcome** the successful IAP Peer Review Sessions of Chile, China, Peru, Singapore, Chinese Taipei and United States.
- **Welcome** the revised IAP Peer Review Guidelines.
- **Take note** of the progress to complete the IAP Peer Reviews of Brunei Darussalam, Indonesia, Malaysia, Papua New Guinea, Philippines, Russia and Viet Nam, at SOM I, 2005, to complete the first cycle of IAP Peer Reviews as agreed.

#### **DECISION POINTS:**

- **Endorse** the Senior Officials' Summary Report on 2004 IAP Improvements.
- **Approve** all 2004 IAPs for public release.

### **3.8 Collective Action Plans (CAPs)**

#### **INFORMATION POINTS:**

- **Welcome** the progress made on the implementation of collective action plans.

#### **DECISION POINTS:**



- **Instruct** Senior Officials to keep reviewing and progressively improving the CAPs to ensure that they produce tangible benefits to the business community and meet the Bogor Goals.

#### **4. Strengthening the Functioning of Markets**

##### **INFORMATION POINTS:**

- **Welcome** the work of the Strengthening Economic Legal Infrastructure (SELI) Coordinating Group, particularly the compilation of reports on SELI submitted by 12 member economies as a follow-up of the inclusion of a new chapter on SELI in the Osaka Action Agenda.
- **Welcome** the successful completion of two seminars focusing on enforcement in corporate governance and competition policy which were held in Malaysia and Pucón, Chile, on 22-23 April, and 26 May 2004, respectively.
- **Welcome** the launching of the report on “The Enforcement of Business Regulation and Commercial Laws in the APEC Region” at the MRT in June 2004.
- **Welcome** the successful completion of the third and fourth APEC Training Program on Competition Policy in Kuala Lumpur, Malaysia, and Ho Chi Minh, Viet Nam, on 1-3 March and 3-5 August 2004, respectively, as well as the up-coming fifth training session scheduled to be held in Yogyakarta, Indonesia, on 6-8 December 2004.
- **Welcome** the presentation by SELI of the “Study on Debt Collection Litigation Arbitration in APEC Economies” delivered at the ABAC/PECC Conference on Developing Bond Markets in APEC as a measure to enhance communication with business.
- **Welcome** Japan’s Capacity Building Program for the Implementation of the Accounting System scheduled to be finalized in 2005.
- **Welcome** the SELI Coordinating Group’s participation in a session on strengthening economic legal infrastructure at the APEC High-Level Conference on Structural Reform held in September 2004.
- **Welcome** the up coming Symposium on Legal Instruments and Mechanisms Relating to International Financing and Dispute Settlement, to be held at the APEC Secretariat, in Singapore on 14-16 December 2004.

##### **DECISION POINTS:**

- **Endorse** the compilation of the Report on Strengthening Economic Legal Infrastructure which consists of an executive summary and 12 member economies’ reports as the group’s deliverable this year.
- **Endorse** the report for public release on the APEC website.

## **5. Other Expansion of Trade and Investment Initiatives**

### **5.1 Industry Dialogues**

#### **INFORMATION POINT:**

- **Welcome** the cross-cutting work of the Automotive and Chemical Dialogues on: standards, trade facilitation, non-tariff measures, support for the WTO and security.

#### **DECISION POINT:**

- **Endorse** efforts by multiple fora and by the Chemical Dialogue to engage substantively with the European Commission on EU REACH, which, unchanged, may negatively affect numerous sectors across the APEC region.

### **5.2 Dialogue on Non-Ferrous Metals**

#### **INFORMATION POINTS:**

- **Welcome** the launch of the APEC Dialogue on Non-Ferrous Metals.

#### **DECISION POINTS:**

- **Encourage** economies to participate in the first meeting of APEC Dialogue on Non-Ferrous Metals to take place in May 2005 in Korea.

### **5.3 Life Sciences Innovation Forum (LSIF)**

#### **INFORMATION POINTS:**

- **Welcome** the second *APEC Life Sciences Innovation Forum* held in Penang, Malaysia, in September 2004
- **Welcome** the completion of the Life Sciences Strategic Plan.
- **Recognize** that the implementation of the basic principles of the Strategic Plan should be instrumental to improving health and well-being by promoting global trade and investment, economic and technical cooperation and government-business sector collaboration in this field.

#### **DECISION POINTS:**

- **Endorse** the principles and concepts of the Strategic Plan as a best practices guideline for the region to follow individually and collectively in the life sciences sector to improve the health and well-being of citizens while supporting economic development goals.
- **Encourage** members to consider the best practices in the Life Sciences Innovation Plan in domestic life sciences policy discussions.

#### **5.4 Structural Reform**

##### **INFORMATION POINTS:**

- **Take note** of the progress in Structural Reform-related activities, particularly in the areas of competition policy and deregulation, corporate governance and corporate restructuring, strengthening economic legal infrastructure, and work related to Structural Reform carried out by the Economic Committee, the Finance Ministers' Process and the Social Safety Net Capacity Building Network.
- **Welcome** the outcomes of the APEC High-Level Conference on Structural Reform held in Tokyo, Japan, on 8-9 September 2004, which exchanged views and information on policy measures and discussed future APEC initiatives on structural reform related issues.
- **Welcome** the "*Leaders' Agenda to Implement Structural Reform*" (LAISR) as a deliverable for 2004.

##### **DECISION POINTS:**

- **Encourage** all member economies and relevant APEC fora to continue their efforts to implement further structural reform initiatives.
- **Agree** to submit the "*Leaders Agenda to Implement Structural Reform*" (LAISR) for adoption by Leaders at AELM.
- **Endorse** the Senior Officials' decision that the Economic Committee should be the responsible entity to coordinate the work on Structural Reform.

#### **5.5 Preparation of the Mid-Term Stock-Take**

##### **INFORMATION POINTS:**

- **Welcome** the "Work Plan for the Mid-term Stock-take of the Bogor Goals.
- **Take note** of the report from SOM on the Preparations for the Mid-term Stock-take of the Bogor Goals.

##### **DECISION POINTS:**

- **Approve** the Work Plan for the Mid-term Stock-take of the Bogor Goals.
- **Instruct** Senior Officials to provide a preliminary progress report to the APEC Meeting of Ministers Responsible for Trade in 2005 and bring the final results of the Mid-term Stocktake to the 17<sup>th</sup> APEC Ministerial Meeting for reporting to Leaders.

## **6. Enhancing Human Security**

### **6.1 Counter Terrorism Task Force**

#### **INFORMATION POINTS:**

- **Acknowledge** the work of the CTTF to implement the 2003 Bangkok Leaders's counter-terrorism commitments.
- **Take note** of the key outcomes of the 2nd Secure Trade in the Asia-Pacific Region (STAR) Conference held in Viña del Mar, Chile, on 5-6 March 2004.
- **Welcome** the 3<sup>rd</sup> Conference on Secure Trade in the Asia Region (STAR) to be held in March 2005 in Korea.
- **Take note** of the feasibility of an automated Regional Movement Alert List (RMAL) System and the trials of a pilot RMAL in 2005.
- **Welcome** the appointment of Philippines as new Chair and Chile as new Vice-Chair of the CTTF for the next two years.

#### **DECISION POINTS:**

- **Endorse** the counter-terrorism deliverables for consideration by Leaders.
- **Encourage** economies to continue to update the Counter-terrorism Action Plans (CTAPS) and identify counter-terrorism capacity building needs.
- **Encourage**, where appropriate, cooperation between APEC and international financial institutions and other international organizations with common goals, including UNSC Counter-Terrorism Committee, the International Civil Aviation Organization (ICAO), the International Maritime Organization (IMO), the G8 Counter Terrorism Action Group, the World Customs Organization and the Organisation of American States.

### **6.2 APEC Response to Infectious Diseases**

#### **INFORMATION POINTS:**

- **Acknowledge** the progress made by the Health Task Force on infectious diseases.
- **Welcome** the proposal on Fighting Against AIDS in APEC.

#### **DECISION POINTS:**

- **Endorse** the proposal on Fighting Against AIDS in APEC and **agree** to submit it to Leaders for endorsement.
- **Restate** the importance of fighting against infectious diseases in APEC.
- **Instruct** Senior Officials to supervise the Health Task Force to work on infectious diseases related issues and report the progress to the next Ministerial Meeting in 2005.

## **7. Economic and Technical Cooperation (ECOTECH)**

### **INFORMATION POINTS:**

- **Acknowledge** the contribution by the SOM Committee on ECOTECH to the reform efforts in APEC through independent assessments of working groups and the revised project evaluation frameworks.
- **Welcome** the independent assessment of the ECOTECH activities of the Fisheries Working Group.
- **Welcome** the development of a Quality Assessment Framework as a first step to foster good quality project proposals.
- **Acknowledge** the need to revitalize APEC's work on sustainable development which involves cross-cutting issues undertaken by various working groups.
- **Welcome** the initiative by the SOM Committee on Economic and Technical Cooperation to play a coordinating role on issues related to sustainable development.
- **Welcome** the results achieved to date by ABAC and several APEC Fora to foster capacities in English and other languages and look forward to specific actions aimed at achieving the full potential of this communication vehicle and promoting entrepreneurship, mutual understanding and increased opportunities in a digitalized region.
- **Welcome** the collaboration between the APEC Secretariat and the World Bank's Global Development Learning Network (GDLN) and look forward to concrete outcomes from the Second APEC/IFIs Roundtable Dialogue on ECOTECH to be held in Korea in 2005.

### **DECISION POINTS:**

- **Endorse** the *2004 Senior Officials' Report on Economic and Technical Cooperation* and its recommendations.
- **Encourage** independent assessments of other working groups to ensure that their work is responsive to APEC's current priorities and contributes to the Bogor Goals.
- **Approve** the Quality Assessment Framework developed by the ESC to foster good quality project proposals and to replace the existing ECOTECH Weightings Matrix.
- **Endorse** a proposal to hold a High-Level Meeting on Sustainable Development in 2005-6.
- **Instruct** the SOM Committee on Economic and Technical Cooperation to oversee the work to be developed through the Education Network from the Human Resources Development Working Group, so as to establish a Strategic Action Plan for English and other languages in the APEC Region, with the support of all relevant fora, aimed at creating competitive human capital, and to report progress in 2005.
- **Encourage** economies and APEC fora to continue to engage IFIs in the ECOTECH and capacity building work of APEC and to develop relationships with other suitable organisations and the business sector in the year ahead.

### **7.1 APEC Food System (AFS)**

#### **INFORMATION POINTS:**

- **Take note** of the progress report compiled by the APEC Secretariat on the implementation of the AFS by six APEC fora, CTI, ATCWG, FWG, HRDWG, SME, TPT, and member economies that submitted information in the AFS Chapter of their IAPS.

#### **DECISION POINTS:**

- **Encourage** member economies to fulfill their commitment to implement the AFS.

### **7.2 High-Level Policy Dialogue on Agricultural Biotechnology**

#### **INFORMATION POINTS:**

- **Take note** of the outcomes and policy recommendations of the Third High-Level Policy Dialogue on Agricultural Biotechnology that was held on 1 March 2004 in Santiago, Chile.
- **Welcome** the progress made by the Steering Committee to set future directions and agenda and to organize capacity building activities.
- **Welcome** Korea's offer to host a 4th APEC High Level Policy Dialogue on Agricultural Biotechnology in Korea in 2005 in the margins of SOM I.

**DECISION POINTS:**

- **Endorse** the 2004-2006 Work Plan of the APEC High Level Policy Dialogue on Agricultural Biotechnology.
- **Call** for the Policy Dialogue to continue to advance discussions in the areas of policy and information exchange, intellectual property rights and technology transfer, economic and human resource investment, and agricultural biotechnology public policy development, based on sound science.

**7.3 Addressing the Social Dimension of Globalization**

**INFORMATION POINTS:**

- **Take note** of the annual workplan of the Human Resources Development Working Group (HRDWG) and the collaboration with the Social Safety Net Capacity Building Network (SSNCBN) on the issue of workforce retraining. Welcome the undertaking of the HRDWG to conduct a comprehensive in-house review of the Working Group and the offer of Thailand to host the 27<sup>th</sup> HRDWG meeting in 2005.
- **Endorse** the work of the APEC Education Foundation (AEF) and the APEC Cyber Education Cooperation Consortium (ACEC) in cyber education and ICT capacity building. Take note of the AEF's work program for 2004 and encourage economies and stakeholders to actively participate in the work of the Foundation.
- **Welcome** the endorsement by APEC Education Ministers on the usage of ICT in education and the learning of English and other foreign languages at the school level.
- **Recognize** the work of SSNCBN on the need to address the social dimension of globalization and the importance of developing social safety nets to minimize the costs of structural change and the collaboration between SSNCBN and HRDWG on the issue of workforce retraining.
- **Welcome** the successful completion of the 2004 APEC International Youth Camp held in Chinese Taipei from 1-6 August 2004 with the theme of "Youth Entrepreneur" and the offer of Korea to host the next International Youth Camp in 2005.

## **8. APEC Reform**

### **INFORMATION POINTS:**

- **Welcome** the package of reforms agreed by Senior Officials for immediate implementation.
- **Welcome** the agreement by Senior Officials to further work next year on the list of additional issues already discussed in 2004.
- **Note** the efforts made by fora to evaluate and reform their own processes.

### **DECISION POINTS:**

- **Endorse** the proposed APEC Support Fund (ASF) as a means of broadening APEC's capacity building funding base.
- **Instruct** senior officials to work on the operational modality of ASF and report next year on progress.



## **9. SOM Database on the Implementation of APEC Commitments**

### **INFORMATION POINTS:**

- **Take note** of the work done on the development of the SOM Database to manage the APEC process.

### **DECISION POINTS:**

- **Instruct** senior officials and fora to support the database by making timely and relevant input to this useful working tool once it is fully operational.

## **10. Electronic Commerce**

### **DECISION POINTS:**

- **Endorse** the APEC Privacy Framework and the Future Work Agenda on International Implementation of the APEC Privacy Framework.
- **Endorse** APEC's Strategies and Actions Towards a Cross-Border Paperless Trading Environment and its recommendations and timelines.

## **11. Telecommunications and Information**

### **INFORMATION POINTS:**

- **Welcome** the holding of the 2<sup>nd</sup> High Level Symposium on e-Government in Mexico in October 2004 and call for further work on e-Government.
- **Take note** of the experience and good practices that the Telecommunications and Information Working Group (TEL) has performed regarding Cyber Security and Cyber Crime within the scope of the Counterterrorism Task Force.
- **Acknowledge** the three fruitful broadband workshops and work in progress on broadband activities and encourage the TEL to continue working on the broadband principles drafting exercise.
- **Acknowledge** that the TEL needs to explore New Generation Networks from many aspects, including its relation to the needs and expectations of developing economies and end users; emerging technical and financial considerations; a variety of technology platforms; and potential implications for trade and investment.

## **12. e-APEC Strategy**

### **INFORMATION POINTS:**

- **Welcome** the *“Implementing the e-APEC Strategy – progress and recommendations for further action”* report’s findings and its policy recommendations.
- **Take note** of the progress made in implementing the e-APEC Strategy and the work that remains to be done.
- **Welcome** the e-commerce fair held in Yantai, China, 1 June 2004.

### **DECISION POINTS:**

- **Agree to enhance** APEC’s future work on the digital economy.
- **Restate** their commitment to the Brunei Goals on internet access.
- **Instruct** Senior Officials to study the *“Implementing the e-APEC Strategy – progress and recommendations for further action”* report’s recommendations and to report back to the Meeting of Ministers Responsible for Trade in 2005.

### **13. Energy Security and Accessible Energy Supply**

#### **INFORMATION POINTS:**

- **Take note** of the impact of current high oil prices on the economies of APEC and emphasize that access to adequate, reliable and affordable energy is fundamental to achieving the region's economic, social and environmental objectives.
- **Acknowledge** the achievements of the APEC Energy Security Initiative and support the outcomes of the APEC Energy Ministers meeting in June this year, including their call for adequate supply to help stabilise the oil market, and efforts to enhance energy security by preparing for energy supply disruptions, facilitating energy investment, using energy more efficiently, expanding energy choices and capitalising on technological innovation.
- **Welcome** the "Comprehensive Action Initiative Recognising the Need for Strengthening the APEC Energy Security Initiative".

#### **DECISION POINTS:**

- **Endorse** APEC Energy Ministers' Decisions made at their sixth meeting held in Manila in June 2004.
- **Approve** the Energy Working Group's (EWG) *Comprehensive Action Initiative recognising the need for strengthening the APEC Energy Security Initiative – energy security, sustainable development and common prosperity*, and recommend it to the 16<sup>th</sup> AELM for endorsement.

#### **14. Sustainable Development of APEC Mining Industry**

##### **DECISION POINTS:**

- **Applaud** the first APEC Meeting of Ministers Responsible for Mining held in Antofagasta, Chile on June 16-17, 2004.
- **Endorse** the Statement issued by the said Ministerial Meeting, and
- **Recommend** it to the 16<sup>th</sup> AELM for endorsement.

## **15. Economic Committee**

### **INFORMATION POINTS:**

- **Take note** of the progress report on the research projects under the Economic Committee's (EC) 2004 Work Program.
- **Take note** that SOM III requested the EC Chair to come up with a set of proposals for the EC's new Terms of Establishment for consideration at SOM I in 2005.

### **DECISION POINTS:**

- **Reaffirm** the request to the EC Chair given at SOM III.
- **Endorse** the following reports for release, to be shared with other APEC fora and disseminated to media and other APEC target audiences:
  - (1) *2004 APEC Economic Outlook*, which includes the structural chapter on the *FTAs/RTAs in the APEC Region*;
  - (2) *Realizing Innovation and Human Capital Potential in APEC*, incorporating two research papers on the Knowledge Based Economy.
  - (3) *Trade Facilitation and Trade Liberalization: From Shanghai to Bogor*, a compendium of two research papers on TILF.

## **16. Framework of the Integration of Women in APEC**

### **INFORMATION POINTS:**

- **Welcome** the importance of the role of the Gender Focal Point Network in the implementation of the Framework for the Integration of Women in APEC.
- **Take note** of the need to reinforce gender integration in APEC through joint studies, research and collaborative projects among APEC Fora to strengthen the participation of women in commerce and trade within the APEC region.
- **Welcome** the continued participation of the Women Leaders Network (WLN) in the APEC process and commend its commitment towards the advancement of women and gender issues throughout APEC.



## **17. SMEs and Micro-enterprises – Opportunities for Entrepreneurial Growth**

### **INFORMATION POINTS:**

- **Welcome** the “Santiago Agenda on Entrepreneurship” adopted at the Eleventh APEC Ministerial meeting.
- **Welcome** the “APEC SME Coordination framework”
- **Commend** the progress made by the micro enterprises sub group in strengthening its role in the APEC process.
- **Welcome** the convening of the 7<sup>th</sup> APEC SME Business Networking Promotion Forum and the APEC Meeting for Cooperation among SME Policy-Implementing Agencies.

### **DECISION POINTS:**

- **Support** the theme for APEC SMEs in 2005 on “Promoting Innovation of SMEs” which recognizes that innovation is a practical response to the fast-changing international business environment.
- **Endorse** the “*Santiago Agenda on Entrepreneurship*” to underline the importance of the APEC process in developing and supporting the requisite policy environment for the emergence of Micro and Small and Medium enterprises within the region and to enhance the linkage between the entrepreneurial process, job creation and income generation for the wider APEC population.
- **Encourage** economies to invite appropriate micro enterprises agencies and experts to be APEC Micro Enterprises Sub Group focal points.
- **Instruct** the APEC fora to coordinate with the SMEWG on activities that will benefit SMEs according to the APEC SME Coordination Framework.

## **18. Sectoral Ministerial Meetings in 2004**

### **INFORMATION POINTS:**

- **Welcome** the outcomes of the Sectoral Ministerial Meetings held in 2004:
  - The 4<sup>th</sup> APEC Meeting of Science Ministers, Christchurch, New Zealand, 10–12 March, 2004;
  - The APEC Education Ministerial Meeting, Santiago, Chile, 29–30 April, 2004;
  - The VI APEC Energy Ministers Meeting, Makati City, Philippines, 10 June, 2004;
  - The First Meeting of APEC Ministers Responsible for Mining, Antofagasta, Chile, 16-17 June, 2004;
  - The 4<sup>th</sup> APEC Transportation Ministers' Meeting, Bali, Indonesia, 27–29 July, 2004;
  - The 11<sup>th</sup> APEC Finance Ministers Meeting, Santiago, Chile, 2–3 September, 2004;
  - The 11<sup>th</sup> Small and Medium Enterprise Ministerial Meeting, Santiago, Chile, 6–7 October, 2004; and
  - The 3<sup>rd</sup> APEC Tourism Ministerial Meeting, Punta Arenas, Patagonia, Chile, 13–14 October 2004.

## 19. APEC Business Advisory Council Proposal (ABAC)

### Interaction with the Business Community

#### INFORMATION POINTS:

**Take note** of ABAC's recommendations, contained in the 2004 ABAC Report to Economic Leaders "Coping with the Challenges of Globalization".

**Welcome** ABAC's critical feedback and business perspective as well as its recommendations in key areas including:

*Achieving concrete results for the WTO Doha Development Agenda (DDA);  
Reinvigorating APEC's trade and investment liberalization and facilitation agenda;  
Coping with new challenges for trade and investment;  
Strengthening financial systems in the APEC region;  
Capacity building to face the challenges of globalization; and  
Enhancing the effectiveness of APEC.*

- **Take note** of the concerns expressed by the business community regarding the critical importance of advancing the DDA negotiations in the WTO, over the proliferation of RTAs/FTAs, and the need to reinvigorate APEC's TILF agenda.
- **Take note** of ABAC's proposals on a joint scoping study for a Trans Pacific Business Agenda (TPBA) and a feasibility and scoping study for a prospective Free Trade Area of the Asia Pacific (FTAAP).  
**Commend** ABAC leadership in promoting closer collaboration between business and APEC officials and processes.

#### DECISION POINTS:

- **Reaffirm** APEC's commitments to its TILF goals.
- **Endorse** the proposed language to enhance and reinvigorate APEC's TILF agenda.  
**Instruct** officials to continue to work closely with ABAC and the business community on issues raised, and to examine ways to better communicate APEC's accomplishments to the business community.
- **Instruct** officials to ensure that ABAC recommendations are conveyed to, and considered by APEC fora.
- **Endorse** the Santiago Initiative to expand trade in APEC for transmission to Leaders.

## **20. APEC 2005 Budget**

### **Budget and Management Committee**

#### **INFORMATION POINTS:**

- **Take note** that SOM has instructed the APEC Secretariat to conduct by 30 January 2005, a thorough analysis of administrative expenditure.

#### **DECISION POINTS:**

- **Approve** APEC budget and members contributions for 2005 (Administrative Account of US\$ 3,098,200; Operational Account capped at US\$2,000,000 and with 2005 projects that were approved by BMC at its meeting in August 2004; TILF Special Account with affordable level of expenditure at US\$5,000,000 and with 2005 projects that were approved by BMC at its meeting in August 2004; and Members' Contributions unchanged at US\$3,338,000.
- **Instruct** Senior Officials, working with the Budget and Management Committee, to develop by SOM III in 2005 a sustainable financial strategy for APEC for the coming years, taking into account developments in APEC Reform, the approved taskings of the APEC Secretariat from SOM, measures to enhance efficiencies in the operation of the APEC Secretariat, improved evaluation strategies for APEC-funded projects, the possibility of new funding sources and the affordability of Members' contributions to APEC.

## 21. Future Hosts of APEC

### INFORMATION POINTS:

- **Welcome** the announcement that Peru will offer to host APEC in 2008, and Singapore in 2009.

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# KEY APEC DOCUMENTS 2004

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## ADDITIONAL DOCUMENTS

### Other Reports:

APEC Business Advisory Council: Report to APEC  
Economic Leaders 2004

*Bridging the Pacific: Coping with the Challenges of  
Globalization*

Can be downloaded from:

[http://www.apec.org/apec/publications/all\\_publications/apec\\_business\\_advisory.html](http://www.apec.org/apec/publications/all_publications/apec_business_advisory.html)