

行政院及所屬各機關出國報告

(出國類別：參加國際會議)

出席「2014年APEC第2次標準及符合性次級委員會(SCSC)系列會議」報告

服務機關： 食品藥物管理署

出國人員： 職 稱： 科員

姓 名： 范瑋倫

出國地點： 中國大陸北京

出國期間： 103年8月8日至103年8月13日

報告日期： 103年8月26日

## 摘 要

2014 年亞太經濟合作(Asia Pacific Economic Cooperation, APEC) 第 2 次標準及符合性次級委員會 (Sub-Committee on Standards and Conformance, SCSC) 系列會議於 8 月 7 日至 12 日於中國大陸北京召開,計有十九個經濟體代表與應邀進行報告之相關專門組織等共 56 人參與大會。

本屆會議主要議程包括 APEC 近期活動報告、貿易便捷化、國際標準調合、良好作業規範 (Good Regulatory Practice, GRP)、技術相關基礎建設發展、食品安全、電子電機開路者倡議、域性專門組織 (Specialist Regional Bodies, SRB) 近況報告等,另韓國配合本次會議,在同一地點舉辦「培育下個世代的標準專業人才研討會」,探討相關專業人才在標準領域的角色、工作內容及所需之專業能力等。

本次出席會議報告有下列 2 點建議：

- 一、以台灣整體角度而言,APEC 與 WTO 同為我國政府活躍的兩大舞台,尤其 APEC 是第一個能擱置國家及主權議題、整合亞太背景各異的經濟體之多邊論壇,更是台灣公、私部門與亞太各政經領袖交流之平台。在 APEC 架構之下,本署主要參與為生命科學創新論壇 (LSIF) 及標準及符合性次級委員會 (SCSC),就本次所參與之 SCSC 大會而言,建議可由通盤性了解到長期參與、培養與各經濟體間友好關係,未來可視 SCSC 大會整體發展,逐漸朝向主動發言、參與其他經濟體提案、爭取合作案等方向,分階段、有策略、有目標的經營,深化我國影響力。
- 二、本次韓國於 APEC 資助下所進行的「啟發新世代標準專業人才發展」研討會,透過分析產業及對領袖級人物的訪談,描繪出新世代標準相關專業人才所需的專業教育、資格、可能發展途徑及職業生涯藍圖,對年輕世代提出具體建議,該研究雖以「標準相關人才」為主軸,但整體研究具有共通性,其模式可供本署發展培育國際事務等相關人才計畫參考。

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附件（會議資料）：

- 一、2014年第二次標準及符合性次級委員會（SCSC）大會議程
- 二、2014年3月25至26日舉行之WTO/SPS會議情形
- 三、2014年6月18至19日瓦舉行之WTO/TBT會議情形
- 四、2014年9月12日食品安全法規合作之高階政府及業界對話、9月13日出口證明及農藥MRL特別討論會資料
- 五、動物用藥殘留檢測能力調查計畫執行情形
- 六、合作夥伴培訓中心執行「實驗室能力建構」先導計畫之情形（食品）
- 七、「啟發新世代標準專業人才發展」研究成果
- 八、智利：「了解APEC各經濟體更新之食品安全法規及標準」提案
- 九、馬來西亞：「醫療實驗室外部品管能力建構計畫」提案

## 壹、會議基本資料

一、會議時間：2014年8月7-12日，共計6日。

二、會議主席：韓建平 中國國家質量監督檢驗檢疫總局  
國際合作司副司長

三、與會人員：

本屆2014年亞太經濟合作會議由中國主辦，第2次標準及符合性次級委員（Sub-Committee on Standards and Conformance, SCSC）大會暨相關會議於北京舉行，參與本次會議之經濟體包括中華臺北、中國、香港、日本、韓國、印尼、汶萊、菲律賓、新加坡、泰國、澳洲、紐西蘭、巴布亞新幾內亞、智利、秘魯、墨西哥、美國、加拿大和俄羅斯計十九個經濟體代表與應邀進行報告之專門組織共56人參加。

相關會議我方由經濟部標準檢驗局吳啟瑞技士、衛生福利部食品藥物管理署范瑋倫科員、內政部建築研究所劉青峰副研究員等代表出席，渠等參與之會議詳列如下：

(一) 8月7-8日：

1. 會議名稱：SCSC—利用建築資訊模型提升建築效能。
2. 出席人員：內政部建築研究所劉青峰副研究員、經濟部標準檢驗局吳啟瑞技士。

(二) 8月9-10日：

1. 會議名稱：SCSC—啟發下世代標準專業人才發展。
2. 出席人員：經濟部標準檢驗局吳啟瑞技士、衛福部食品藥物管理署范瑋倫科員。

(三) 8月11-12日：

1. 會議名稱：2014年標準及符合性次級委員會（SCSC）第二次大會。
2. 出席人員：經濟部標準檢驗局王鴻儒技正、吳啟瑞技士、侯經綸技士；衛福部食品藥物管理署范瑋倫科員、闕言容研究佐理員。

## 貳、前言與目的

亞太經濟合作 (Asia-Pacific Economic Cooperation, APEC) 會議，是由澳大利亞前總理霍克 (Robert Hawke) 於 1980 年倡議成立之亞太地區經濟體間諮商論壇，以貿易暨投資自由化、便捷化及經濟暨技術合作為三大支柱。創始會員有 12 個，目前已增加至 21 個，包含澳大利亞、汶萊、加拿大、智利、中國、香港、印尼、日本、韓國、馬來西亞、墨西哥、紐西蘭、巴布亞紐幾內亞、秘魯、菲律賓、俄羅斯、新加坡、中華臺北、泰國、美國及越南，各國均以「經濟體」身分參與。另尚有「東南亞國家協會」(Association of Southeast Asian Nations, ASEAN)、「太平洋經濟合作理事會」(Pacific Economic Cooperation Council, PECC) 及「太平洋島國論壇」(Pacific Islands Forum, PIF) 3 個國際組織為其觀察員。

APEC 目前共有 4 個層級：最高層為 APEC 經濟領袖會議，其次為部長級年會及專業部長會議、企業諮詢委員會，而後為資深官員會議 (Senior Officials' Meeting, SOM)，其下有貿易暨投資委員會 (Committee on Trade and Investment, CTI) 等各委員會、工作小組、及 SOM 特別任務小組。標準及符合性次級委員會 (SCSC) 建立於 1994 年，係屬 CTI 項下之次級委員會，旨在促進亞太地區各標準的調和，以減少各經濟體間因標準不同而導致之貿易障礙，達到 APEC 促進貿易暨投資自由化、便捷化的目標。

食品議題為 SCSC 項下之重要議題，亦涉本署所轄。為執行 2006 年 APEC 領袖會議所提出之食品安全合作倡議，SCSC 大會於 2007 年設立食品安全合作論壇 (Food Safety Cooperation Forum, FSCF)，用以強化區域性食品安全管理並建構合作網路，透過促進區域內食品標準與法規透明化、加速各會員體食品標準與國際標準整合，以達到促進食品貿易便捷化的最終目標。

涉本署議題除食品之外，提升實驗室檢驗能力亦屬 SCSC 討論範圍。就參與本次會議經驗而言，馬來西亞原擬提出醫療實驗室外部品質管控能力建構計畫 (新案)，惟本次會議馬國代表未予出席，各會員僅能就書面了解得知，該案目標在於促進醫療相關實驗室的檢驗品質。

## 參、104 年 SCSC 第 2 次大會會議紀要

會議主要根據 2014/SOM3/SCSC/001 (附件一) 之議程，就近期活動、貿易便捷化、國際標準調合、良好作業規範 (GRP)、技術相關基礎建設發展、食品安全、電子電機開路者倡議、區域性專門組織 (SRB) 最新進展等進行報告及討論：

### 一、貿易便捷化：

本項計有四項報告案，包含越南報告貿易便捷化共同行動方案 (Collective Action Plan, CAP) 進度、印尼通知各會員體訂定 1 項新技術法規及 7 項新標準、中國報告在 2014 年 3 月 25 至 26 日於日內瓦舉行之 WTO/SPS 會議情形及結論(附件二)、日本報告 2014 年 6 月 18 至 19 日舉行之 WTO/TBT 會議情形及結論(附件三)等。

### 二、國際標準調合：

日本簡報第六階段自願性行動計畫 (Voluntary Action Plan, VAP)，就各會員 (含中華臺北等共 13 個經濟體) 所提供之資料，分析其電子電機、LED 等領域之技術性法規數量，以及直接採用國際標準等情形，並提出 2015 年新 VAP 問卷格式。各經濟體對該計畫評論如下：

- (一) 新加坡：認為未來 VAP 調查應有備註欄，以便解釋技術法規與國際標準不同之理由；澳洲對此表示贊同。
- (二) 美國：要求在新的 VAP 格式中，加註其技術性法規所採用之符合性評鑑標準，必須記錄，避免會員體為了配合 VAP 計畫，而有誤用國際標準的情形。
- (三) 菲律賓、中國、韓國等，均對日本在 VAP 計畫的努力表示感謝，但菲律賓提醒日本，菲國提供之成果未顯現於報告內。
- (四) 汶萊：承諾接續辦理 2015 年 VAP 計畫。
- (五) 主席：表示對 VAP 表示肯定，希望藉由此計畫，調和各經濟體之國家標準與國際標準。



### 三、良好作業規範 ( Good Regulatory Practice, GRP ) :

GRP 屬 APEC 共通性議題，各級論壇近年來均大力推動。原 GRP 係 2011 年 APEC 經濟領袖宣言提出「強化落實良好法規作業實務」倡議，旨在促使各經濟體進行自我檢視法規制度，減少不良法規對經濟發展的影響、改善貿易與投資環境、促進區域內進經濟成長。本次 SCSC 會議各經濟體針對 GRP 之發言如下：

- (一) 澳洲：澳洲國內已建立 GRP 系統，未來推動 GRP 仍會列為該國優先事項，澳洲政府將持續減少對企業非必要的管制，以提升該國競爭力及效能。
- (二) 印尼：表示曾於 2003 頒布並強制執行國家標準化指導綱要，並於 2011 年進一步修訂；現階段印尼經濟合作部正著手訂定民意徵詢指導綱要。
- (三) 美國：簡介美國計畫於 SOM 層級提出的倡議，標題為「APEC 行動方案：如何透過網路向公眾徵詢對新法規草案的意見」。
- (四) 加拿大、澳洲及中國均對於美國之提案表示肯定。美國進一步表示，此倡議內容廣泛，重點在法規而非標準之發展，因此 SCSC 並非適切之提案平台，美國會將此倡議提升至 SOM 層級討論。
- (五) 主席：鼓勵 SCSC 各會員參與美國之倡議。

### 四、技術相關基礎建設之發展：

各會員國若有與標準相關之基礎建設新進展，均可在此簡報供其他會員參考，本案報告會員有中國及印尼。

- (一) 中國：簡報 2013-2020 中國大陸量測發展計畫，中國希望在 2020 年之前，建立一套更完整的量測系統及技術，以配合其在經濟上及社會上的快速發展。
- (二) 印尼：報告截至 2014 年 6 月止，印尼國家認證委員會 ( Komite Akreditasi Nasional, KAN ) 認證通過之實驗室及驗證機構數目，包含 828 家檢測實驗室、37 家醫療實驗室、6 家 HACCP 驗證機構、8 家有機食品驗證機構、7 家食品安全

監督系統驗證機構等。

- (三) 主席：標準、計量、符合性評鑑都是重要的基礎建設，期許未來各會員間能多進行相關合作。

## 五、食品安全：

食品安全為 SCSC 重要議題之一，SCSC 之下設有食品安全合作論壇 (Food Safety Cooperation Forum, FSCF)，為常設性論壇。2006 年 APEC 提出食品安全倡議 (Food Safety Cooperation Initiative)，2007 年經 APEC 各級會議討論，確認於 SCSC 下設立 FSCF，成為 APEC 成員間磋商食品安全合作之重要平台，2009 年 FSCF 下再設立合作夥伴培訓中心 (Partnership Training Institute Network, PTIN)，提供公私部門及學界食品相關訓練課程；2010 年起，FSCF 將提升實驗室檢測量能列為優先議題。本次會議各經濟體針對食品安全之發言如下：

### (一) 中國：

1. 報告 FSCF 近期將在北京舉辦之 2 項會議，包括 9 月 12 日將舉行的「食品安全法規合作之高階政府及業界對話」會議及 9 月 13 日的出口證明及農藥 MRL 特別討論會 (附件四)。
2. 簡報自 2012 年 12 月起，動物用藥殘留檢測能力調查計畫執行情形；現行有 14 個經濟體共計 30 家實驗室加入該計畫，結果將於 2014 年 9 月公布。該計畫目的在於了解並促進 APEC 各經濟體，檢驗動物用藥殘留能力、提升其檢驗報告品質，藉以增進相關產品在經濟體間之流通 (附件五)。

(二) 美國：報告該國於食品安全合作論壇 (FSCF) 下設之合作夥伴培訓中心 (Partnership Training Institute Network, PTIN)，執行「實驗室能力建構」先導計畫之情形。智利及中國選為計畫試辦地，目前已舉辦多場訓練活動，範圍涵蓋動物用藥殘留、微生物、黴菌毒素及農藥殘留等 (附件六)。

(三) 韓國：原擬報告 2014 年 5 月合作夥伴培訓中心 (PTIN) 於首爾舉辦之「增進食品查驗能力研討會」情形，惟當日韓國代表未於會中進行報告，亦未提供簡報檔。



- (四) 加拿大：口頭說明 2014 年 5 月 5 日至 8 日於溫哥華舉行之食品過敏原管理研討會成果。該會議係就各國食品過敏原管理規範及管理計畫進行討論，並朝各國管理法規調和方向推動，以期減低業者遵循不同國家法令之負擔。
- (五) 紐西蘭：提議食品安全合作論壇 (FSCF) 與糧食安全政策夥伴關係機制 (Policy Partnership on Food Security, PPFS) 間成果及資訊互享。中國表達支持並進一步提議，FSCF 可將 2014 年 9 月 10-13 日會議成果提供給 PPFS，做為同年 9 月 14-19 日「APEC 糧食安全部長會議」參考資料。
- (六) 主席：後續中國將代表 SCSC 主席，出面與 PPFS 主席溝通，並請 APEC 秘書處協助處理 FSCF 及 PPFS 資訊共享事宜。

#### 六、電子電機相互承認協議 (EEMRA) 開路者倡議：

由於會員間存在差異性及經濟多元性，某些計畫難以讓所有會員在同一時間執行，APEC 開路者倡議 (Pathfinder Initiatives) 應運而生。開路者倡議之概念是讓有能力、有意願的會員體先行，並與未執行之會員分享經驗，這種模式促進了議題的可實現性，並且更容易達成共識，APEC 自 2002 年起通過多項開路者倡議。

SCSC 項下之電氣電子相互承認協議 (Electrical and Electronic Equipment Mutual Recognition Agreement, EEMRA) 即為一項開路者倡議，印尼為本 (19) 屆 EEMRA 聯合法規諮詢委員會 (Joint Regulatory Advisory Committee, JRAC) 主席。本次會議印尼報告 2014 年 8 月 10 日於北京召開之 JRAC 會議內容，包含各會員體參與情形、下屆主席及 2015 年會議召開日期等。

#### 七、標準及符合性教育：

- (一) 韓國：韓國報告 APEC 資助執行之「啟發新世代標準專業人才發展」研究成果，該研究以問卷調查及訪談方式，收集共 28 家公司、35 個標準相關組織、21 位標準界領袖人物的成功經驗，整理就業市場需求、成功人士案例等，具體描繪出新世代標準相關專業人才所需的專業教育、資格、可能發展途徑及職業生涯藍圖，對年輕世代提出建議，以培養未來標

準界領袖人才為目標。另，韓國希望各會員能提供國內培養準備標準相關人才的資訊，以供進行後續計畫參考(附件七)。

- (二) 俄羅斯：簡報該國在關稅聯盟之下 如何對內部人員進行技術性法規教育訓練，以確保符合該國符合相關法規的要求。
- (三) 澳洲：介紹澳洲標準的青年領袖計畫，澳洲表計畫係為因應該國的技術專業人員出現高齡化現象，以培養高素質的中青年專業人士參與標準的發展為目標。
- (四) 中國：報告中國近期標準相關教育活動，並通知會員體中國職業分類 (National Occupational Classification, NOC) 曾經過編修，標準相關工程技術人員的職務描述和定義已修正。
- (五) 印尼：通知會員體印尼泗水 (Surabaya) 大學已在 2014 年 6 月開辦供應鏈及物流碩士課程；另印尼宣告布勞爪哇 (Brawijaya) 大學及泗水大學工業工程學系，分別從 2014 年 8 月開始及 2015 起將標準化課程列為必修。
- (六) 中華臺北：分享我國近期標準化教育活動的進展。2013 年辦理 2 梯次研習 (含標準化與智慧財產、國際標準編寫原則與指引課程)、2014 年辦理 1 梯次標準化人才培訓課程 (含參與國際標準化組織指引、國際暨區域標準編寫原則及標準制定、談判與共識凝聚技巧三門課程)。
- (七) 新加坡：分享新加坡的標準人才培育情形。新加坡標準、生產力與創新局 (Standards, Productivity and Innovation Board Singapore, SPRING) 刻正發展國家標準教育計畫，以培養標準人才、提升品質及標準、促進商業量能為目標，同時增進該國求職及在職人士之競爭力。
- (八) 主席：鼓勵各經濟體將標準教育相關的經驗和資訊提供給韓國參考，以利進行更進一步的研究。

#### 八、與企業互動：

- (一) 美國：簡報「酒類法規論壇：良好法規作業行動計畫」進展，除了表示將於 2014 年 9 月在中國北京召開會議，亦說明計畫目標及行動方案。

- (二) 澳洲：強調 APEC 區域中酒類貿易不斷增加，並提供世界葡萄酒貿易小組 (World Wine Trade Group, WWTG) 最新活動。
- (三) 中國：中國是全世界最大的葡萄酒消費經濟體，2014 年 9 月酒品規範論壇 (APEC Wine Regulatory Forum, WRF) 中，中國亦將以酒類進口大國的角度，兼具深度及廣度的介紹國內酒業發展情形。
- (四) 主席：強調 SCSC 是各經濟體和產業間的合作平台，未來希望大家共同努力，促進業界的參與度。

#### 九、區域性專門組織 (SRBs) 近況報告：

各個與標準相關組織受邀提出相關工作之更新報告。

- (一) 亞太實驗室認證聯盟 (Asia-Pacific Laboratory Accreditation Cooperation, APLAC)：  
報告現行 7 家能力試驗執行機構 (Proficiency Testing Providers, PTP) 間之相互承認協議 (Mutual Recognition Agreement, MRA) 已經生效，於 2014 年 7 月在加拿大渥太華辦理的教育訓練也圓滿成功。
- (二) 亞太法定計量論壇 (Asia-Pacific Legal Metrology Forum, APLMF)：  
預告 APLMF 將在印尼及巴布亞新幾內亞新辦訓練課程，並將參考各經濟體的需求撰寫相關指引。另外 APLMF 在德國中央聯邦技術院 (Physikalisch-Technische Bundesanstalt, PTB) 贊助之下，將與亞太計量組織 (APMP) 共同合作進行相關之銜接性計畫。
- (三) 太平洋認證合作組織 (Pacific Accreditation Cooperation, PAC)：  
報告食品安全管理系統 (Food Security Monitoring System, FSMS) 及溫室氣體確證及查證 (Greenhouse Gas, GHG) 兩項相互認證協議已於 2014 年 6 月生效，累計共有 15 個經濟體簽署；而資訊安全管理系統 (Information Security Management System, ISMS) 目前簽簽署會員為日本，效期

為 12 個月。PAC 同時表示，國內外能源管理系統 (Energy Management System, ENMS) 標準認證的計畫，將是下個相互認證協議執行目標。

(四) 亞太度量衡計畫 (Asia Pacific Metrology Programme, APMP):

更新近期發展，包括新主席和新成員變化、2013 年重要活動及 2014 年的重要工作計畫及事件。

(五) 亞太標準與合格評定常設委員會 (Pacific Area Standards Congress, PASC):

表示依據 PASC 近期會議討論內容，未來將強化與國際貿易標準例如與 WTO 間之連結、深化 ISO 技術管理委員會 (ISO/TMB)、國際電工委員會標準管理局 (IEC/SMB) 及國際電聯電信標準化部門 (ITU-T/TSAG) 間合作以避免重覆驗證等。

(六) 印尼：APLAC 及 PAC 的目標是在於推動各經濟體的標準互認以促進貿易，但現行各經濟體仍有許多非共同的標準造成潛在的貿易障礙；爰此，印尼促請 SRB 大力推動 APLAC 及 PAC 所推動之相互認證協議，以消弭貿易障礙。

(七) 主席：強調在 SCSC 與 SRBs 合作無間，中國以 SCSC 主席的身份鼓勵各會員體與 SRBs 合作、共同爭取 APEC 資金贊助進行研究。

十、其它提案及報告：

本項係供 SCSC 會員報告未被納入議程的報告案或進行中的計畫、新提案等。

(一) 未納入議程的報告案或進行之計畫 (共四案):

美國簡報 8 月 7 日至 8 日舉行之提升建築效能研討會、印尼報告 CTI 在 2014 年 4 月 13 日所舉辦「人員驗證多邊相互承認準備計畫」、日本報告「能源管理系統 ISO 50001 多邊相互承認協議準備計畫」、中國報告「節能產品測量及檢定之標準調和與技術能力提升計畫」。

(二) 新提案：

1. 菲律賓：簡報「第 8 屆良好法規作業 (GRP) 研討會」提案，菲國表示該案與 2011、2013 年 APEC 經濟領袖會議通過之加強 GRP 方向相符，希望爭取 APEC 基金。
2. 智利：共有 2 份新提案
  - (1) 「執行抗藥性菌株控制策略研究計畫」提案：擬就動物、環境及食品之微生物抗藥性舉辦研討會，以作為各經濟體建立微生物抗藥性監測系統之基礎。
  - (2) 「了解 APEC 各經濟體更新之食品安全法規及標準」提案：本計畫擬由智利食品安全局 (Food Safety Agency of Chile, ACHIPIA) 主導，目的在了解各經濟體食品安全法規修正之近況及修法內容，達到促進食品安全及國際貿易之目的 (附件八)。
3. 馬來西亞：提案「醫療實驗室外部品管能力建構計畫」：透過比較的方式，評估不同實驗室的檢測能力及品質，建立多一道外部品質管控標準，藉此提升實驗室檢驗品管能力 (馬國代表未出席故未予簡報，書面資料如附件九)。

(三) 主席：希望各經濟體能多支持這些提案、給予正面回應，並感謝所有提案經濟體的努力。主席同時表示綠能是未來 APEC 發展的一大主軸，鼓勵會員朝向綠能議題思考。

十一、下次會議預告：

2015 年 APEC 主辦國為菲律賓，下次 SCSC 委員會例會將在 SOM1 期間召開，地點在菲律賓潘帕嘉克拉克區 (Pampanga Clark)。



## 肆、心得與建議

- 一、未來對於 SCSC 大會暨相關會議，包含涉本署所轄之食品安全合作論壇 (FSCF)、食品安全事件網絡研討會 (FSIN) 等，建議可由現在段派員通盤了解大會議題及運作模式，到長期參與、逐漸培養與各經濟體間友好關係默契。未來可在 APEC 架構之下，視 SCSC 大會整體發展，朝向主動發言、參與其他經濟體提案、爭取合作案等方向進行，策略性經營，以深化我國影響力。
- 二、對於參與 APEC 會議，除了解會議本身議題、參加活動外，亦可加強與國際友人，尤其是各會員體與本署相關領域之代表（如各國 FDA 或食品、藥政主管機關）之互動，將相關資料建檔並保持聯繫，未來若需進行雙邊合作時可有助洽商，使參與國際會議發揮加值效益。
- 三、本次韓國於 APEC 資助下所進行的「啟發新世代標準專業人才發展」研討會，透過產業分析及領袖級人物的訪談，描繪出新世代標準相關專業人才所需的專業素養、資格、可能發展途徑及職業生涯藍圖，對年輕世代提出具體建議，會中邀請官、產、學界之領袖級人物與年輕世代分享心路歷程，對年青世代的確是很大的鼓舞。該研究雖以「標準相關人才」為題，但整體研究不論是生涯藍圖或是經驗分享，在育才議題上都具有共通性及參考價值，實可作為本署發展培育人才計畫時之借鏡。

伍、補充事項（會議合影）：

圖一、SCSC 與會代表合影



圖二、中華臺北代表（左起：標檢局、食藥署），與 SCSC 下屆主席 Ann Claire（右二）及菲律賓貿易與工業部代表（右一）合影



圖三、本署代表（左一）與泰國食品藥物管理局代表（中）及泰國國家農業商品及食品標準局代表（右）合影



圖四、本署代表（左一）與韓國「啟發新世代標準專業人才發展」計畫主持人崔博士（中）及標檢局代表（右一）等合影



SCSC  
會議資料  
參考資料

大會議程



**Asia-Pacific  
Economic Cooperation**

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**2014/SOM3/SCSC/001**  
Agenda Item: 2

## **Draft Agenda**

Purpose: Consideration  
Submitted by: SCSC Chair



**Second Sub-Committee on Standards and  
Conformance Meeting  
Beijing, China  
11-12 August 2014**



APEC Sub-Committee on Standards and Conformance  
2<sup>nd</sup> Meeting  
Beijing, China  
11-12 August 2014

Draft Agenda

1. Opening 9:00-9:15 主席開場 (宣讀全部議程)

SCSC Chair to make opening remarks, and review 2014 priorities.

2. Adoption of the Agenda 9:15~ 確認議程 (請 all member 檢視)

SCSC members to comment on the Agenda and propose changes if any.

3. Business Arrangements 9:20~ 秘書處報告

SCSC Chair to inform participants of the meeting program and other administrative arrangements if any.

APEC Secretariat to brief on overall APEC developments. 9:25~9:30.

CTI Chair to discuss CTI Priorities 9:50~9

9:30~9:30. ETPC (No. 33)

4. SCSC Work Program for 2014 and Related Issues

4.1. Trade Facilitation

(No. 4) 9:35~ Vietnam to report on the update of SCSC Collective Action Plan in Trade Facilitation (CAP).

No. 6 9:40 Japan to report on developments within the WTO TBT Committee.

(No. 8) 10:05 ~ 10:20 China to report on the developments within the WTO SPS Committee.

4.2. Alignment with International Standards and Active Participation in International Standardization

Japan to brief on the further activity on the VAP Alignment work.

11:10~ (8) 4.3. Good Regulatory Practice Australia

Members are invited to update on good regulatory practices.

11:15~ 4.4. Technical Infrastructure Development

Members are invited to update on technical infrastructure development.

11:25~ (7) 4.5. Food and Product Safety

China to update the APEC FSCF developments and report on CTI 33/13A Towards A Better Regulatory Environment: APEC Food Safety Cooperation Forum Special Session and APEC High-Level Regulation-Industry Food Safety Dialogue on Regulatory Cooperation of Food Safety.

11:40~ (9) China to report on M CTI 03/12A Veterinary Drug Multi-residues in Chicken Proficiency Testing Program.



11:40 ~

59 United States to report on progress of Laboratory Capacity building Activity under **M CTI 03/12A** Building Convergence in Food Safety Standards and Regulatory Systems - with test pilots in Chile and China.

Cancel! X Korea to report on APEC FSCF PTIN Workshop on Improved Food Inspection Capacity Building Based on Risk Analysis (An Element of **M CTI 03/12A**, Building Convergence in Food Safety Standards and Regulatory Systems).

11:55. #5 slide. Canada to report on **CTI 34/13A** Enhancing Standards, Conformity Assessment, Technical Regulations and Promoting Regulatory Cooperation in **Food Allergen Management**.

12:00 = Korea 報告. 8/9-10. 會議 結局  
5. Pathfinder Initiatives

**EEMRA Pathfinder Initiative**

JRAC Chair (Indonesia) to report on the 19<sup>th</sup> Joint Regulatory Advisory Committee (JRAC) on Electrical and Electronic Equipment held on 10 August 2014.

**6. Standards and Conformance Education**

> Korea to report on **CTI 07/13T** Workshop on Standards Professional Development held on 9 August.

- Russia to present "Personnel training in the field of technical regulation in the Customs Union".
- Members are invited to update on recent progress in standards education activities in their economies.

**7. Interaction with Business**

P>140 ~ United States to report on progress of **M CTI 01/13A** Wine Regulatory Forum: Good Regulatory Practices Action Plan, and upcoming Wine Regulatory Forum September 11-12 to be held in Beijing, China.

P>145 ~ Australia to present an update on the activities of the World Wine Trade Group (WWTG)

SCSC members to report on plans to increase business engagement in SCSC activities in 2014.

**8. SRBs Report**

P>170 ~ SRB Forum Chair to provide progress report on SRB activities, including Work Plan for Technical Infrastructure Development.

Report on relevant activities from each of the SRBs:

- Asia-Pacific Laboratory Accreditation cooperation (APLAC) 亞太實驗室認證合作
- Asia-Pacific Legal Metrology Forum (APLMF) 亞太法規計量論壇
- Asia-Pacific Metrology Programme (APMP) 亞太計量計畫
- Pacific Accreditation Cooperation (PAC) 太平洋認證組織
- Pacific Area Standards Congress (PASC) 太平洋標準大會

**9. SCSC Projects**

SCSC members to report on progress of new and on-going projects not reported elsewhere on the agenda.

- P15:10 - United States to report on the 10<sup>th</sup> APEC Conference on Standards and Conformance (joint event of **M CTI 02/12A** and **CTI 27/13A**) held on 7-8 August, and other activities related to **M CTI 02/12A** and **CTI 27/13A**.
- P15:20 - Indonesia to report on **CTI 04/13T** Multilateral Recognition Arrangement (MLA) Readiness Project in Person Certification.
- P15:30 - Japan to report on **CTI 25/13A** Multilateral Recognition Arrangement (MLA) Readiness Project in Energy Management System, ISO 50001.
- P15:50 - China to present on **CTI 13/14A** Harmonizing Standards and Enhancing Technical Capacity in Measurement and Verification of Energy Savings.

**SCSC members to present new concept notes submitted for Session2, 2014**

- P16:20 - Philippines to present on Concept Note for 8th GRP Conference
- Chile to present on Concept Note for Coordinated Research Initiative for the Implementations of Antimicrobial Resistance Control Strategies
- Chile to present on a Concept Note for Facilitating trade through updates on food safety regulatory standards of APEC economies
- Malaysia to present on a Concept Note for Medical External Quality Assurance (EQA) Capacity Building Programme

↓  
Days

**10. Adoption of the SCSC 2 Summary Conclusion**

A10:30

**11. Next Meeting**

P 1:45

Philippines to inform the arrangement of the SCSC 1 meeting in 2015.

**12. Meeting Documents**

SCSC members to consider the public release of documents.

**13. Other Business**

**Adjournment**

2014.3.25-26

WTO/SPS



**Asia-Pacific  
Economic Cooperation**

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**2014/SOM3/SCSC/028**

Agenda Item: 4.1

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## **A Summary Report on Latest Activities of WTO/SPS Committee**

Purpose: Information  
Submitted by: China



**Second Sub-Committee on Standards and  
Conformance Meeting  
Beijing, China  
11-12 August 2014**



APEC  
CHINA 2014

## A Summary Report on Latest Activities of WTO/SPS Committee

APEC SCSC II

August 11-12, 2014 Beijing, China



### 59th WTO/SPS Committee Meeting

- SPS Committee (the Committee on Sanitary and Phytosanitary Measures )
- 25-26 March, 2014
- Geneva

## Items Discussed

- Information from Members
- Specific Trade Concerns
- Pest or Disease Status
- Technical Assistance and Cooperation
- Review of the Operation and Implementation of the SPS Agreement

## Information from Members

- United States—Final Bovine Spongiform Encephalopathy (BSE) Comprehensive Rule brings US regulations in line with OIE criteria for classifying regions as negligible, controlled and undetermined risk for BSE.
- United States – passed the Safe Food for Canadians Act (SFCA) provides a basis for consistent regulatory requirements and inspection approaches across all fields; the SPS National Notification Authority (NNA) and Enquiry Point (NEP) would be managed directly by Foreign Affairs Trade and Development Canada of April 2014
- Japan - lifted a ban on imports of fresh fruits from Argentina, Australia, Chile, Italy and Turkey, following agreements with these trading partners on certain conditions to prevent the introduction of fruit flies and codling moth into its territory.



## Specific Trade Concern(1)

**New Concerns** (7 out of 9 concerns in red were withdrawn following bilateral meetings; 7/9 items are APEC economies-related)

		Raised by
1	EU protective measures on products of animal origin	China
2	Korea's requirements of BSE-free certification on compound feed	China
3	Indonesia's import restrictions on commercial feathers and down	Chinese Taipei's
4	EU requirements on imports of raw milk and dairy products	Ecuador
5	US limits of procymidone in onions	China
6	Brazil's pest risk assessment for bananas	Ecuador
7	Australia's fumigation requirements on wooden furniture	China
8	Russia's measures on live pigs and pork products due to African swine fever	European Union
9	US imports of meat from Brazil	Nicaragua

## Specific Trade Concern(2)

**Issues previously raised** by

(6 out of 10 issues are APEC economies related)

10	Brazil's risk assessment for shrimp - Concerns of	Ecuador
11	China's import restrictions in response to the nuclear power plant accident	Japan
12	Russia's import restrictions on confectionary products	Ukraine
13	Application and modification of the European Union Regulation on Novel Foods	Peru
14	Korea's strengthened import restrictions on food and feeds with regard to radionuclides	Japan
15	European Union temperature treatment requirements for imports of processed meat products	Russia
16	India's import conditions for pork and pork products	European Union
17	Turkey's requirements for importation of sheep meat	Australia
18	Import restrictions due to BSE	European Union
19	European Union phytosanitary measures on citrus black spot	South Africa

## Operation of Transparency provisions

- **Concerns of the United States**– the European Union planned to publish a road map outlining different options and a preliminary impact assessment in its process to assess, classify and regulate endocrine disruptors.
- **The European Union** drew Members' attention to two proposals on animal cloning. The first proposed directive prohibited animal cloning for farming purposes and the placing on the EU market of animal and embryo clones; The second proposed directive prohibited the placing of food obtained from animal clones on the EU market

## Pest and Disease Free Area

Area	Pest and Disease Free information
Australia	Information on freedom from highly pathogenic avian influenza
South Africa	Information on foot and mouth disease (FMD) status
Paraguay	Information on foot and mouth disease status
Honduras	Information on declaration of a pest free area
Guatemala	Response to query raised by Senegal regarding areas free of Mediterranean fruit fly

## Technical Assistance and Cooperation

- The Secretariat provided information that identified all SPS-specific technical assistance activities undertaken by the WTO Secretariat from 1 September 1994 to 31 December 2013. The total number of SPS-specific TA activities was 288, with an overall participation of more than 11,000 persons since 1994.
- Since Jan of 2014, technical assistance on the SPS Agreement had been provided through the following activities: (a) seven national seminars held in Azerbaijan, China, Costa Rica, Guinea, Haiti, Lao People's Democratic Republic and Zimbabwe; (b) SPS training workshops held in Mexico and Japan; as well as (c) a Regional SPS Workshop in the United Arab Emirates.

## Review of the Operation and Implementation of the SPS Agreement

The Chairperson reported that at the informal meeting regarding fourth review held on 24 March 2014, the following issues and proposals had been discussed for consideration:

- Canada had presented its proposal on a catalogue of available instruments for the management of SPS issues
- The E.U. proposed that the recommended procedures be reviewed to ensure that the information provided be clear, complete, reliable and timely despite of growing number of notifications.
- US proposed workshop on risk analysis.
- According to the agreed Review process, The chairperson required members to provide comments or suggestions on the background document prepared by the which would provide the basis the Fourth Review

## Monitoring of the use of international standards

The Chairperson reported on the informal meeting on SPS-related private standards held 24 March 2014.

- the electronic working group (e-WG) with China and New Zealand as "co-stewards" submitted a proposed compromise text on a working definition of an SPS-related private standard for consideration at the meeting.
- Unfortunately, despite the Chairperson's urging Members to show flexibility and fulfill this long standing action, **no consensus had emerged** on the working definition tabled by the co-stewards.
- This issue will remain on the agenda

## Dates of Next Meeting

- **15-16 November 2014**
- Geneva

**Thank you for your attention!**



2014.6.18-19  
WTO-TBT



**Asia-Pacific  
Economic Cooperation**

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**2014/SOM3/SCSC/006**  
Agenda Item: 4.1

## **Report on the Developments Within the WTO / Technical Barriers to Trade Committee**

Purpose: Information  
Submitted by: Japan



**Second Sub-Committee on Standards and  
Conformance Meeting  
Beijing, China  
11-12 August 2014**

# **Report on the developments within the WTO/TBT Committee**

## **-Agenda Item 4(1)-**

August, 2014

APEC 2014 SCSC 2<sup>nd</sup> meeting in Beijing (China)  
Ministry of Economy, Trade and Industry (METI)  
Japan

# Agenda of the Presentation



経済産業省  
Ministry of Economy, Trade and Industry

1. Specific Trade Concerns raised at the TBT formal meeting on 18-19 June, 2014
2. Other Agenda at the formal meeting
3. Informal Sessions on 17 June 2014
4. Future schedule of the TBT Meetings

# 1. Specific Trade Concerns

## 1. New issues

	Specific Trade Concern	Notification Number(s) / Designation of the measure	Member(s) raising
1	China - Safety Requirement for Lithium Ion Cells and Batteries used in Portable Electronic Equipment	G/TBT/N/CHN/1016	Japan
2	Russian Federation - Measure affecting import of Ukrainian dairy products	-	Ukraine
3	Thailand - Draft Notification of the Alcoholic Beverages Control, Re. Rules, Procedure and condition for Labels of Alcoholic Beverages, issued under BE	G/TBT/N/THA/437	Canada European Union Mexico
4	China - Regulations for the Supervision and Administration of Medical Devices (Order No. 650 of the State Council)	G/TBT/N/CHN/1022 G/TBT/N/CHN/1023 G/TBT/N/CHN/1024 G/TBT/N/CHN/1025 G/TBT/N/CHN/1026 G/TBT/N/CHN/1029	Canada European Union
5	Brazil - Higher Risk Medical Devices Good Manufacturing Practices (GMP) Certification	-	India
6			
7	United States - Formaldehyde: Third-Party Certification Framework for the Formaldehyde Standards for Composite Wood Products	G/TBT/N/USA/828 G/TBT/N/USA/828/Add.1 G/TBT/N/USA/828/Add.2	Indonesia
8	European Union - Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers establishes the general principles, requirements and responsibilities governing food information, and in particular food labelling	G/TBT/N/EU/143	Indonesia
9			
10	Colombia - Draft Ministry of Commerce, Industry and Tourism Decree Restructuring the National Quality Subsystem and amending Decree No. 2269 of 1993	G/TBT/N/COL/201	Mexico
11	Ecuador - Draft Technical Regulation of the Ecuadorian Standardization Institute (PRTE INEN) No. 189: Labelling of alcoholic beverages	G/TBT/N/ECU/243	United States
12	European Union - Proposal for a Directive of the European Parliament and of the Council amending Directive 96/53/EC of 25 July 1996 laying down for certain road vehicles circulating within the Community the maximum authorised dimensions in national and international traffic and the maximum authorised weights in international traffic (COM(2013) 195 final)	G/TBT/N/EU/109	United States
13	Kingdom of Saudi Arabia - Certificate of Conformity (not notified) and GSO marking requirements for toys	-	United States
14	Indonesia - Regulation of Minister of Trade No. 10/M-DAG/PER/1/2014 concerning Amendment of Regulation of Minister of Trade No. 67/M-DAG/PER/11/2013 concerning Affixed Mandatory Label in Indonesian Language for Goods	G/TBT/N/IDN/85	United States

14 items are newly raised.



# 1. Specific Trade Concerns

## 2. Previously raised issues (1)

	Specific Trade Concern	Notification number / brief description of measure	Member(s) raising	WTO ID
15	European Union - Regulation on the Registration, Evaluation and Authorization of Chemicals (REACH)	G/TBT/N/EU/73	China United States	88
16	India - Pneumatic tyres and tubes for automotive vehicles	G/TBT/N/IND/20 G/TBT/N/IND/20/Add.1 G/TBT/N/IND/40 G/TBT/N/IND/40/Rev.1	Japan Republic of Korea European Union	133
17	India - New Telecommunications related Rules (Department of Telecommunications, No. 842-725/2005-VAS/Vol.III (3 December 2009); No. 10-15/2009-AS-II/193 (18 March 2010); and Nos. 10-15/2009-AS-III/Vol.II/(Pt.)/(25-29) (28 July 2010); Department of Telecommunications, No. 10-15/2009-AS-III/Vol.II/(Pt.)/(30) (28 July 2010) and accompanying template, 'Security and Business Continuity Agreement')		Canada European Union United States	274
18	China - Requirements for information security products including, inter alia, the Office of State Commercial Cryptography Administration (OSCCA) 1999 Regulation on commercial encryption products and its on-going revision and the Multi-Level Protection Scheme (MLPS)		European Union	294
19	China - Provisions for the Administration of Cosmetics Application, Acceptance, Cosmetics Label Instructions Regulations and Guidance for the Cosmetics Label Instructions	G/TBT/N/CHN/821 G/TBT/N/CHN/937	Japan Republic of Korea Canada European Union	296
20	Russian Federation - Draft on Technical Regulation of Alcohol Drinks Safety (published on 24 October)	G/TBT/N/RUS/2	European Union Mexico	332
21	Korea - Regulation on Registration and Evaluation of Chemical Material	G/TBT/N/KOR/305	United States	305
22				
23	Indonesia - Technical Guidelines for the Implementation of the Adoption and Supervision of Indonesian National Standards for Obligatory Toy Safety	G/TBT/N/IDN/64	European Union United States	328
24	European Union - Draft Implementing Regulations amending Regulation (EC) No. 607/2009 laying down detailed rules for the application of Council Regulation (EC) No. 479/2008 as regards protected designations of origin and geographical indications, traditional terms, labelling and presentation of certain wine sector products	No. G/TBT/N/EEC/264 G/TBT/N/EEC/264, Add.1	Argentina United States	345
25	India - Electronics and Information Technology Goods (Requirements for Compulsory Registration) Order, 2012	G/TBT/N/IND/44 G/TBT/N/IND/44/Add.1 G/TBT/N/IND/44/Add.2 G/TBT/N/IND/44/Add.3	Japan Republic of Korea European Union United States	367
26	Ecuador - Resolution establishing the "General conformity assessment framework for Ecuador" and the "Handbook of procedures to be observed prior to all stages of the customs clearance, marketing and market surveillance of manufactured, imported and marketed goods subject to Ecuadorian technical regulations"	G/TBT/N/ECU/44 G/TBT/N/ECU/44/Add.1 G/TBT/N/ECU/44/Add.2 G/TBT/N/ECU/44/Add.3	European Union United States	398

35 items are previously raised issues



# 1. Specific Trade Concerns

## 2. Previously raised issues (2)

	Specific Trade Concern	Modification number/level description of measure	Measure(s)/country	IMS ID
27				
28	Thailand - Draft Thai Industrial Standard for Ceramic Tiles (TIS 2508-2555)		European Union	401
29	Russian Federation - Measure affecting the import of Ukrainian confectionary products	-	Ukraine	399
30	Ecuador - Resolution No. 116 of the Foreign Trade Committee of Ecuador of 19 November 2013 and Technical Regulation of the Ecuadorian Standardization Institute RTE INEN 022 on the labelling of processed and packaged food products	G/TBT/N/EU/19/Add3 G/TBT/N/EU/19/Add5 G/TBT/N/EU/19/Add6 G/TBT/N/EU/19/Add8	Costa Rica European Union Mexico United States	411
31				
32	India - Food Safety and Standards Regulation - Food labelling requirements	-	European Union	298
33				
34	Chile - Proposed amendment to the Food Health Regulations, Supreme Decree No. 977/96	G/TBT/N/CHL/219 G/TBT/N/CHL/219/Add.1 G/TBT/N/CHL/221	Canada Mexico	370
35	Peru - Act to Promote Healthy Eating Among Children and Adolescents	-	Canada Mexico	363
36	Indonesia - Ministry of Health Regulation 30/2013 on the inclusion of sugar, salt and fat content information, as well as health messages on the label of processed foods	G/TBT/N/IDN/84	Canada European Union	389
37	European Union - Revised Proposal for the Categorization of Compounds as Endocrine Disruptors of 19 February 2013 by DG Environment	-	Mexico United States	393
38	China - China Food and Drug Administration (CFDA) EMC Enforcement Notice for medical devices of 19 December 2012	-	European Union United States	387

The red colored items are withdrawn

# 1. Specific Trade Concerns

## 2. Previously raised issues (3)

	Specific Trade Concern	Notification number / brief description of measure	Member list raising	IMS ID
39	Peru – Implementing Regulations of 14 November 2012 for Moratorium on Planting Genetically Engineered Crops		United States	392
40	Ecuador - Resolution No. SENAE-DGN-2013-0300-RE relating to post entry - control of imported alcoholic beverages		Canada Mexico	394
41	China - China Food and Drug Administration (CFDA) Notice 191 of 16 - December 2013 - Free Sales Certificate for Imported Cosmetics		Canada European Union United States	415
42	Ecuador - Ministry of Public Health Executive Decree (Agreement) No. 00004522 amending the Sanitary Regulations for the Labelling of Processed Foods for Human Consumption		Canada Mexico	416
43	France - Recycling Triman Mark: Draft Decree on a common set of symbols informing the consumer about recyclable products subject to a system of extended producer responsibility associated with waste sorting instructions	G/TBT/N/FRA/153	Canada United States	420
44	Russian Federation - Safety of products for children and adolescents	G/TBT/N/RUS/29	European Union	418
45	India - Labelling Regulations for Canola Oil	-	Canada	413
46	Egypt - Bottled water	G/TBT/N/EGY/32 G/TBT/N/EGY/32	Canada Mexico	409
47	Italy - Testing requirement on import of steel cutlery products	-	Turkey	421
48	India - Drugs and Cosmetics Rules 2007	-	India	395
49		G/TBT/N/IND/33	European Union	167

49 items are raised in total.

7 items are withdrawn due to e.g. the result of bilateral meeting.



# 1. Specific Trade Concerns

WTO/TBT committee		6/16 (Mon)	6/17 (Tue)	6/18 (Wed)	6/19 (Thu)
morning	<p>10:00-13:00@Room W Thematic Session</p>	<p>10:00-13:00 WTO/TBT formal session</p>	<p>10:00-13:00 WTO/TBT formal session</p>	<p>10:00-13:00 WTO/TBT formal session</p>	
lunch	<p>13:00- Lunch Time Training Event: TBT NSS@</p>				
afternoon	<p>16:00-@Room D Informal session GRP: Voluntary Mechanisms and Related Principles</p>	<p>15:00-18:00@Room W Thematic Session</p>	<p>15:00-18:00 WTO/TBT formal session</p>	<p>15:00-18:00 WTO/TBT formal session</p>	

Bilateral meetings are held in the margin of TBT informal and formal meetings. They are used effectively, which consequently reduce the STC.

## 2. Other Agenda

### Exchange of Experiences

- (i) **Transparent;**  
    **Coherent Use of Notification Formats**
- (ii) **Good Regulatory Practice**

### Technical Cooperation Activities

**by ISO, IEC, Secretariat**

### Updating by Observers

**by ISO, IEC, UN-ECE**

## 2. Coherent Use of Notification Formats

Type	Description
New Notification	<p>Members should use a new notification to notify the draft text of a proposed technical regulation or conformity assessment procedure (hereafter referred to as the "notified measure"). If the notified measure is associated with a previously notified measure (e.g. amending or supplementing an adopted measure, or replacing a withdrawn or revoked measure), the symbol(s) of the associated notified measure(s) should be indicated in Box 8 of the new notification.</p>
Addendum	<p>Members should use an addendum to notify additional information related to a notification or the text of a notified measure, including if:</p> <ul style="list-style-type: none"> <li>• The comment period has been changed (e.g. extended or re-opened);</li> <li>• The notified measure is adopted, published, or enters into force, especially in cases where relevant dates have not been provided in the original notification or have been changed. Members are encouraged to indicate how the final text of the measure can be obtained, including website address;</li> <li>• The notified measure is withdrawn or revoked, if replaced with a new measure, where possible, the symbol of the corresponding new notification should be indicated;</li> <li>• The content or scope of a notified measure is partially changed or amended. In this case, Members should consider opening a new comment period;</li> <li>• Interpretive guidance is issued; and</li> <li>• Any other useful and relevant additional information directly related to a notification or notified measure has been made available that does not qualify as a corrigenda, revision or supplement.</li> </ul>
Corrigenda	<p>Members should use a corrigendum to correct minor administrative or clerical errors (which do not entail any changes to the meaning of the content) in:</p> <ul style="list-style-type: none"> <li>• a notification or subsequent related addendum or revision; and</li> <li>• the text of the notified measure.</li> </ul>
Revision	<p>Members should use a revision to indicate that the notified measure has been substantially re-drafted prior to adoption or entry into force. A revision replaces the original notification. A revision should normally open a new comment period.</p>
Supplement	<p>Members should use a supplement to notify the availability of unofficial translations of notified measures.</p>

Coherent use of notification formats is adopted in the June WTO/TBT committee



## 2. Notification Format

### New notification

### Addenda

- to notify additional information

### Corrigenda


- to correct minor administrative or clerical errors

### Revision

- to indicate that the notified measure has been substantially re-drafted

### Supplement

- to notify the availability of unofficial translations of notified measures

 WORLD TRADE ORGANIZATION		C/WT/IN/	
Committee on Technical Barriers to Trade		Date	
Doc. No.:		Page 1/1	
NOTIFICATION			
The following notification is being circulated in accordance with Article 20.6.			
1.	Notifying Member:	If applicable, name of local government involved (Articles 2.2 and 7.2):	
2.	Agency responsible:	Agency telephone and fax numbers, e-mail and web-site names and address. The notification shall be accompanied by comments regarding the notification shall be indicated if different from above:	
3.	Notifier under Article 20.6 ( ) ; A.0.1 ( ) ; A.0.2 ( ) ; S.7.1 ( ) ; other:		
4.	Products covered (HS or CCCN where applicable, otherwise national tariff heading):	ICS numbers may be provided in addition, where applicable:	
5.	Title, number of pages and language(s) of the notified document.		
6.	Description of content:		
7.	Objective and rationale, including the nature of urgent problems where applicable:		
8.	Relevant documents:		
9.	Proposed date of adoption: Proposed date of entry into force: }		
10.	Final date for comments:		
11.	Texts available from: National enquiry point(s) or address, telephone and fax numbers, e-mail and web-site addresses, if available of the other body:		



## **3. Thematic Sessions**

**Thematic Session is held as a follow up of the Sixth Triennial Review of the Operation and Implementation of the TBT Agreement**

### **Main themes of the Thematic Sessions on 17 June 2014**

- Functioning of enquiry point  
by Ukraine, Kenya and United States
- Transparency in Standard-Setting  
by Egypt
- Regional experiences  
by Kingdom of Saudi Arabia and Peru
- Developments in Online tools  
by EU and Kenya

## 4. Future schedule of the TBT Meetings

### Next TBT meetings

- 4th November: Thematic Session (Topic(s) to be decided)
- 5th-6th November: TBT committee

### TBT Meetings in the future

- March, 2015
- June, 2015
- Discussion for 7<sup>th</sup> Triennial review will start from the fall of 2014, and 7<sup>th</sup> Triennial review will be finalized on fall of 2015

**Thank you for your attention !**

食品會議報告

- 2014.9.12  
食安法規高階對話

- 2014.9.13  
出口證明與農葯MRL



Asia-Pacific  
Economic Cooperation

2014/SOM3/SCSC/035

Agenda Item: 4.5

食品安全論壇

**APEC FSCF Developments and Report on CTI  
33/13A Towards A Better Regulatory Environment:  
APEC Food Safety Cooperation Forum Special  
Session and APEC High-Level Regulation-Industry  
Food Safety Dialogue on Regulatory Cooperation of  
Food Safety**


Purpose: Information  
Submitted by: China

Food Safety / Food security




**Second Sub-Committee on Standards and  
Conformance Meeting  
Beijing, China  
11-12 August 2014**





APEC  
Asia-Pacific  
Economic Cooperation



APEC  
CHINA 2014

## Update on APEC FSCF Developments & Project Progress

*CTI 33 2013A: Towards A Better Regulatory Environment: APEC Food Safety  
Cooperation Forum Special Session and APEC High-Level Regulator-Industry  
Food Safety Dialogue on Regulatory Cooperation of Food Safety*

APEC/SCSC II  
August 11-12, 2014 Beijing, China

## Background of Food Safety Cooperation Forum

- ◆ FSCF was established in 2007 under SCSC to strengthen food safety capacity building activities and improve information sharing, with the goals to assist MEs : building robust food safety systems, to accelerating progress towards harmonization of food standards with international standards, and to improving public health and facilitating trade in the region.
- ◆ Co-chaired by Australia and China. Participants include senior officials of each APEC member economy's food safety regulatory agency, with other trade and economic representatives in attendance, as appropriate.
- ◆ The FSCF meet every two years to make recommendations to the SCSC, based on agreed priorities, in its consideration of funding proposals.
- ◆ FSCF PTIN was established in 2008 to engage the private sector and academia to bring additional expertise, resources, and commitment towards fulfilling the critical food safety capacity building needs and goals identified in FSCF.



## Recent Progress

- ◆ In 2013, APEC FSCF developed an Action Plan, which was endorsed at its 4th meeting to implement the APEC Regulatory Cooperation Plan. The aim of the action plan is to promote alignment to relevant international standards wherever possible consistent with WTO obligations based on science and duly justified. The projects are developed under the Action Plan in order to put into action to achieve effective and efficient regulatory cooperation to meet the goal.

## Upcoming Events in September

Date	Activities	Place
September 10-11	APEC FSCF PTIN Proficiency Testing Workshop	Beijing, China
September 11-12	APEC Wine Regulator Forum	
September 12	APEC High-Level Regulator-Industry Food Safety Dialogue	
September 13	FSCF Special Session	

### CTI33 2013A

- ◆ Leading Economies: China, Australia and US;  
Co-sponsored by: Chile, Thailand, the Philippines
- ◆ Including 2 events:
  1. *APEC High-Level Regulator-Industry Food Safety Dialogue*
  2. *APEC Food Safety Cooperation Forum Special Session*
- ◆ September 11-12, Beijing

項目目標

### Objectives

- ◆ **The Dialogue** aims to establish a platform to improve communication between government agencies and industries and try to find out how to deal with the complex situation and challenges emerging in the food safety area, and secure a safe and sufficient food supply in the region together.
- ◆ **The APEC FSCF Special Session** provides an opportunity for economies to transfer skills, knowledge, technical expertise and best practice between officials on the regulatory issues of food safety in the two pilot areas, export certificates and pesticide maximum residue limits, to implement the APEC FSCF Action Plan and APEC Regulatory Cooperation Plan.

## Prospective Deliverables

- ◆ The APEC High-Level Regulator-Industry Food Safety Dialogue will sign a Beijing Statement to guide the future work of FSCF and its PTIN.
- ◆ The APEC FSCF Special Session
  - a Report of concrete, practical outcomes to reducing regulatory barriers based on two pilot projects: export certificates and pesticide MRLs.
  - Recommendations on ways for FSCF to support MEs to overcome the identified challenges.

## Nominations

Activity	Nomination Number	Economy Number	NMP	APEC Funded Number
Dialogue	78 (45) Government (33) Industry	16	14 WTO, World Bank, industry (FIA, Danone)	5 Speakers & 15 Active Participants  funded by APEC
Special Session	69	15		

## Contacts

- **Project Overseer:** Dr. LIN Wei ([linwei@aqsiq.gov.cn](mailto:linwei@aqsiq.gov.cn))
- Questions about the nomination process, agenda and additional information about the activities can be directed to Dr. YANG Binbin ([yangbh@aqsiq.gov.cn](mailto:yangbh@aqsiq.gov.cn)) and Dr. Liu Hanxia ([liuhanxia\\_cn@163.com](mailto:liuhanxia_cn@163.com)) and Ms. Zhang Rong ([zhangrong@aqsiq.gov.cn](mailto:zhangrong@aqsiq.gov.cn)).

Thank you and  
warmly welcome to join  
the activities of APEC FSCF!



动物用藥殘留  
檢測能力調查計畫

執行情形

(2012/12 ~ 2014/9)  
<預計>



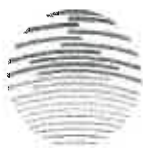
**Asia-Pacific  
Economic Cooperation**

2014/SOM3/SCSC/029

Agenda Item: 4.5

**The Proficiency Testing of Determination of  
Veterinary Drug Multi-Residues in Animal Origin  
Products (M CTI 02/12A)**

Purpose: Information  
Submitted by: China



**APEC**  
CHINA 2014

**Second Sub-Committee on Standards and  
Conformance Meeting  
Beijing, China  
11-12 August 2014**





## The Proficiency Testing of Determination of Veterinary Drug Multi- Residues in Animal Origin Products

M CTI 02/12A

2014 APEC SCSC 2  
August 2014, Beijing China  
AQSIQ China

### Overview

- ◆ This sub-project is under the Multi Year Project, entitled *Building Convergence in Food Safety Standards and Regulatory Systems* (CTI 03 12A) funded by APEC Technical Assistance and Training Facility (TATF)
- ◆ APEC funding: 124,000 ; China co-funding 137,928 USD.
- ◆ This project responds to the newly revised and agreed Food Safety Capacity Building Priority Areas 2011-2015 of APEC Food Safety Cooperation Forum (FSCF).

## Overview

- ◆ The project organized inter-laboratory proficiency testing in 2013 and will hold the workshop to review project outputs in 2014 in China.
- ◆ This project is carried out by Chinese Academy of Inspection and Quarantine (under AQSIQ) with great assistance from FSANZ, NMIA, SRBs, US FDA, USDA and ASEAN.

## Objective

- ◆ This project is an inter-laboratory proficiency testing (PT) program, to determine veterinary drug multi-residues in animal origin products, which is important to develop laboratory capabilities within APEC economies, to improve the acceptability of test results so as to facilitate animal origin products trade among APEC economies.

## Timetable

Timelines	Activities	Key Deliverables
Dec. 2012 – July 2013	1.1 Expert Working Group Establishment	List of Member
	1.2 Develop and confirm PT scheme	Confirmed PT scheme
	1.3 Laboratories Recruitment	List of Participant Laboratories
May- Oct. 2013	2.1 Testing Items Preparation	Prepared Items; Homogeneity and Stability of Items; Assigned Value and Acceptable Range
Nov. 2013 – Feb. 2014	2.2 Testing Items Distribution and Analysis	Testing Result

## Timetable

Timelines	Activities	Key Deliverables
Dec. 2013 – March 2014	2.3 Results collection and Data Analysis	Data form
April – August 2014	3.1 Data Analysis	Draft Interim Report and final report
September 10-11, 2014	3.2 Workshop in China	PT Report; Improvement Proposal
Sep.-Oct. 2014	3.3 Evaluation and Completion	final Report

## Progress

- ◆ The project carried out proficiency testing on 6 veterinary drug
- ◆ 30 labs from 14 economies have participated in the PT Program.
- ◆ Two vacuum freeze dried chicken samples have been shipped to participants in the end of November 2013.
- ◆ 24 results reports have been received.
- ◆ Interim Report has been approved by participants.
- ◆ Invitation letter and nomination form have send out in June.
- ◆ 49 nomination have been received so far, and more nomination are expected by 12 Aug.

## Progress

Economy	Nominees
Australia	2
Brunei Darussalam	3
Canada	1
Chile	3
China	15
Indonesia	2
Malaysia	2
Mexico	2
Papua New Guinea	2
Peru	2
Russia	1
Thailand	7
The United States	4
Viet Nam	2
Lao PDR	1
Total	49

## Future Activities

- ◆ The workshop on the PT program will be held on 10-11 September, 2014 in Beijing. The PT report will be shared and the proposal on improving PT performance are expected.
- ◆ Speakers' Nomination are expected for the topic below.
  - Share experience in the APEC PT program
  - Share experience for veterinary drug multi-residues analysis
  - Role of Proficiency Testing on Lab Capacity Building
  - Progress of Proficiency Testing Provider Accreditation
  - Experience share on Proficiency Testing Organization

Thank you!

Dr. Liu Hanxia

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PTIN (食品) 合作夥伴培訓中心

「實驗室能力建構」先導計畫

執行情形



**Asia-Pacific  
Economic Cooperation**

2014/SOM3/SCSC/027

Agenda Item: 4.5

## Report on the Partnership Training Institute Network: Laboratory Competency Strengthening Initiative

Purpose: Information  
Submitted by: United States



**Second Sub-Committee on Standards and  
Conformance Meeting  
Beijing, China  
11-12 August 2014**

Report to the SCSC on the Partnership Training  
Institute Network (PTIN):  
**Laboratory Competency  
Strengthening Initiative**

U.S. Department of Agriculture  
August 2014



**APEC FSCF PTIN Laboratory Competency Strengthening Initiative:**  
**Building Comprehensive Laboratory Capacity**

**Guiding Principles**

- **Objective: To facilitate trade through the strengthening of food safety laboratory practices.**
- **Cooperative effort between government regulators, academia, and industry.**
- **Emphasis on “hands-on” activities**



**APEC FSCF PTIN Laboratory Competency Strengthening Initiative:**  
**Building Comprehensive Laboratory Capacity**

**Past FSCF Laboratory Capacity Building Efforts  
2010-2012**

**2010:** The FSCF identifies laboratory capacity as a priority area.

**2011:** Workshop in Thailand on the global context of food safety

**2012:** Workshops in Peru, Malaysia, and Vietnam

**APEC FSCF PTIN Laboratory Competency Strengthening Initiative:**  
**Building Comprehensive Laboratory Capacity**

**How to Prioritize Food Safety Laboratory Capacity  
Building Needs in the APEC Region?**

2013

- Given the diversity within the APEC member economies, a “one size fits all” approach will not work.



**APEC FSCF PTIN Laboratory Competency Strengthening Initiative:  
Building Comprehensive Laboratory Capacity**

**Roadmap to Prioritize Needs**

- Guide process of implementing **comprehensive food safety laboratory system**
- Hybrid: self-evaluation, decision-tree, guideline, resource library.
- **Case-by-case** basis
- Pilot Projects in Chile and China

**APEC FSCF PTIN Laboratory Competency Strengthening Initiative:  
Building Comprehensive Laboratory Capacity**

**Chile Pilot Project**

- **Priority Areas Identified Included:**
  - Bridge the gap of information imbalance regarding rapid techniques in microbiology;
  - Expert advice on the measurement of veterinary drug residues in fish, seafood, meat and poultry;
  - Expert advice on the USDA and FDA-recommended methods for the detection of **Salmonella** and viruses in fish, seafood and poultry;
  - Guidance on the requirements for verification and validation of laboratory methods
- **Training and Webinars:**
  - Webinars on the latest technologies for detecting pathogens
  - Webinars on verification and validation of analytical methods
  - In-lab trainings on detecting veterinary drugs in livestock and seafood, and identifying **salmonella and campylobacter**.

**APEC FSCF PTIN Laboratory Competency Strengthening Initiative:**  
**Building Comprehensive Laboratory Capacity**

**China Pilot Project**

- **Academic to Academic Partnership**
  - University of Maryland JIFSAN
  - Qingdao Agricultural University (QAU)
- **JIFSAN and QAU Identified the Following Priority Areas at the Local Level:**
  - Understanding and implementing a foreign supplier verification program
  - Accreditation of third party auditors
  - Multilateral acceptance of laboratory methods and testing techniques
  - Accredited contract lab outside of the U.S.
- **Follow-up Activities**
  - A survey of needs was conducted in the Shandong Province
    - Advanced laboratory management systems
    - Food safety risk analysis
    - Symposium on laboratory capacity building planned for September (in Qingdao)

**APEC FSCF PTIN Laboratory Competency Strengthening Initiative:**  
**Building Comprehensive Laboratory Capacity**

**Needs Prioritization Workshop**

**Participants from:** Australia, Chile, China, Chinese Taipei, Indonesia, Japan, Malaysia, Mexico, Papua New Guinea, Peru, Philippines, Russia, Thailand, U.S., Vietnam.

→ list of participants

**Demonstrations Provided on:** Microbiological Detection Techniques, Validation and Verification of Methods, Chromatography and Mass Spectrometry in Food Safety.

**Round Table Discussions on:** Capacity Building Needs and Process of Prioritization.



**Workshop Outcomes:**

- Important additions were made to the "roadmap"
- Participants identified priority areas for future work
- Criteria for prioritization were defined for the development of a software-assisted prioritization tool.



**APEC FSCF PTIN Laboratory Competency Strengthening Initiative:**

**Building Comprehensive Laboratory Capacity**

**Project Outcomes (and status)**

- **Multi-Criteria Decision Analysis Tool (Roadmap) for Prioritizing Capacity Building Needs in APEC Food Safety Laboratory Systems**
  - Based on priority areas identified in the Regional Workshop, a software-assisted multi-criteria decision tool was developed. The tool was completed and is being evaluated by Chile.
- **In-laboratory training for Chilean and Chinese participants**
  - Training in veterinary drug residues (Chile) completed
  - Training in *Salmonella* and *Campylobacter* (Chile) completed
  - Webinars on new methods for food microbiology (available on PTIN website)
  - Training on mycotoxins detection and quantitation (Papua New Guinea, Vietnam) completed
  - Training on pesticide residue analysis (China) completed

**APEC FSCF PTIN Laboratory Competency Strengthening Initiative:**

**Building Comprehensive Laboratory Capacity**

**Project Outcomes (and status) -Continued**

- **Follow-up training on veterinary drug residues** 动物用兽药残留检测
  - In Chile led by "trainers" from APEC training and the University of Chile April 2014
- **Follow up training on methods validation in microbiology**
  - Follow up training in microbiological methods validation was done in Chile, led by the author of the APEC webinar (DeAnn Benesh, 3M)
- **A resource library of training tools available online to address priority areas identified in the Regional Workshop is being compiled**
  - Over 100 tools have been identified so far. Completion expected in September 2014
  - This survey will also be incorporated in the "Online Resources Library" for the GFSP's Expert Working Group on Laboratory Capacity Building.

**For further information, please contact:**

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**Ben Rau:** 202.690.2744, [ben.rau@fas.usda.gov](mailto:ben.rau@fas.usda.gov)







**Asia-Pacific  
Economic Cooperation**

韓國

「啓發新世代標準人才發展」

研究

8/9.10. 會議紀錄

2014/SOM3/SCSC/037

Agenda Item: 6


## **Progress Report for CTI 07/2013T - Inspiring Next Generation of Standards Professional Development**


Purpose: Information

Submitted by: Korea



**Second Sub-Committee on Standards and  
Conformance Meeting  
Beijing, China  
11-12 August 2014**

 Asia-Pacific  
Economic Cooperation

 APEC

2014 SCSC 2 in Beijing, China


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**APEC Project: Inspiring Next Generation of  
Standards Professional Development**  
**- Who are Standards Professionals? How many of them?**

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11-12 August 2014  
Beijing Hotel, Beijing, China

**Republic of Korea**  
**(Project Editor: Donggeun Choi, KSA)**

 Asia-Pacific  
Economic Cooperation


 APEC

Table of contents

- 1. Project Overview and Tentative Definition
- 2. Project Survey and Interview Summary
- 3. Conference Summary Report
- 4. Conference Recommendations (Priority)
- Annex A. Definition and Classification
- Annex B. Survey/Interview Questions
- Annex C. Conference Program

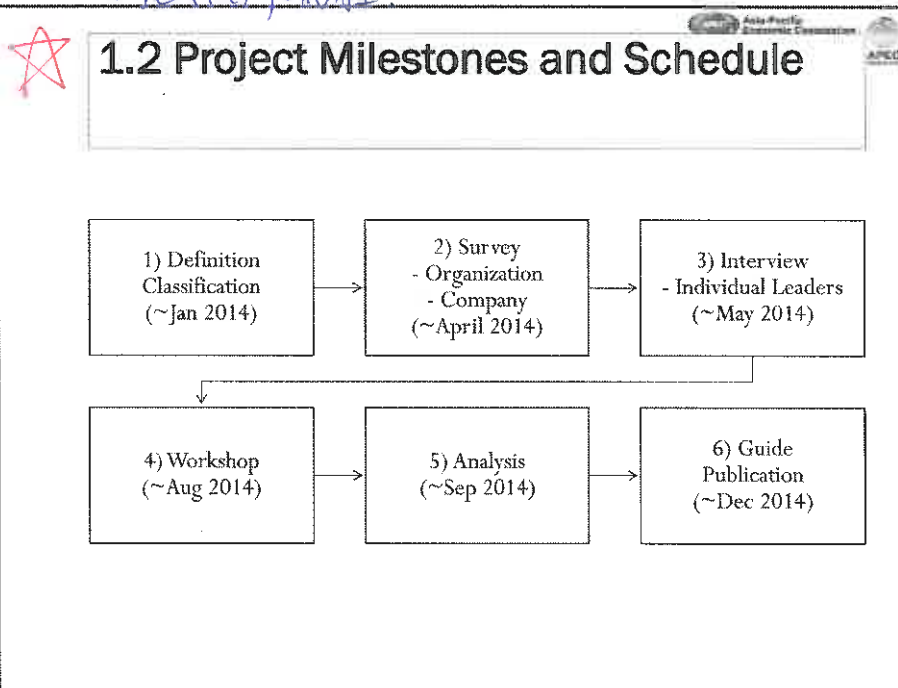


## 1.1 Project Objectives



- To define the concept of 'Standards Professionals'
- To identify competence requirements for standards professionals
  - Knowledge, Skill-set, Attitude, Training/ Education, Materials, Personnel Certificate
- To identify the gaps between current workforce status and preference/expectations
- To develop actionable recommendations on how best to fill the gaps, and propose collaborative action plan in 2015-2020 in the region

訓畫執行流程



### 1.3 Definition and Classification - Who is a Standards Professional?

- Because there is *no universally used or accepted definition of standards professional yet*,
  - this project provides a preliminary definition of standards professional for the purpose of this survey.
- **Standards professionals are those people who have job or business activities in the areas of standardization, conformity assessment, and metrology.**
  - Professional vs. Amateur (job, business, money-making, etc)
  - Usually, these professional activities require certain level of knowledge, skills, experiences as well as education.
  - These standards related activities may be their full (primary) or partial (secondary) duty in terms of priority or time allocation.
  - The responsibilities of standards professional may include the following tasks, but not limited to.

### 1.4 Definition and Classification - Tasks of Professionals

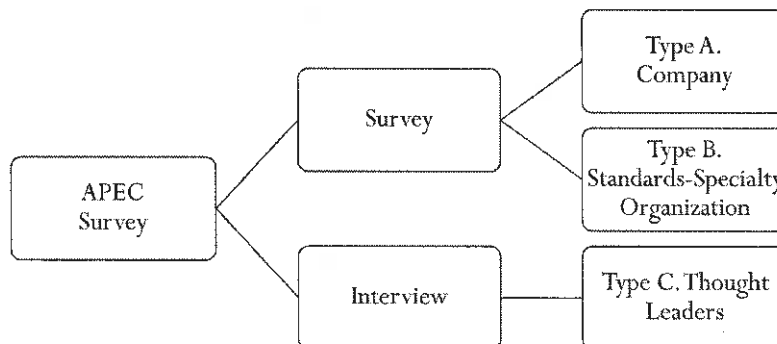
ST.00 Standardization	[ST.01] Standardization Planning and Evaluation
	[ST.02] Development
	[ST.03] Dissemination
	[ST.04] Others
CA.00 Conformity Assessment	[CA.0x] Conformity Planning and Evaluation
	[CA.01] Testing
	[CA.02] Inspection
	[CA.03] Certification
	[CA.04] Accreditation
[CA.05] Others	
ME.00 Standardization	[ME.0x] Metrology Planning and Evaluation
	[ME.01] Scientific Metrology
	[ME.02] Industrial Metrology
	[ME.03] Legal Metrology
	[ME.04] Others

\*Red color: considering survey responses

## 1.5 Definition and Classification - Candidate Titles to consider

Classification	Candidate Title(s)
[ST.01] ST Planning and Evaluation	Standardization Strategist (Manager)
[ST.02] Development	[Company] Standards Engineer (Developer) [Special Org.] Standardization Secretariat
[ST.03] Dissemination	[Company] Standards Information Manager [Special Org.] Standards Marketer/Promoter
[ST.04] Others	-
[CA.0x] CA Planning and Evaluation	CA Strategist/Manager (Compliance Manager)
[CA.01] Testing	Testing Technician (Engineer)
[CA.02] Inspection	Inspection Technician/Engineer, Inspector
[CA.03] Certification	[Company] Certification Manager [Special Org.] Certification Auditor
[CA.04] Accreditation	[Company] Accreditation Engineer/Manager [Special Org.] Accreditation Assessor
[CA.05] Others	-
[ME.0x] ME Planning and Evaluation	Metrologist (Metrology Specialist)
[ME.01] Scientific Metrology	Measurement Engineer (Scientist)
[ME.02] Industrial Metrology	Calibration Technician(Engineer/Manager) [Special Org.] Ref. Mat. Producer
[ME.03] Legal Metrology	Legal Metrology Specialist
[ME.04] Others	Standards Ref. Data Specialist

## 2.1 APEC Survey and Interview - Three Types



## 2.2 Survey Responses

Economy	A:Companies	B:SpecOrgs.	C:Leaders
Australia	--	1 (ST 1)	--
Canada		1 (CA 1)	
China	1 (EE)	1 (ST 1)	2 (Wang, Song)
China, Hong Kong	--	4 (Gov 2, CA/ME 2)	--
Indonesia	2 (construction)	2 (Gov NMI)	4 (Sunarya, Suprato, Hanafiah, Lambaga)
Japan	6 (ICT/EE)	7 (Gov, NMI, ST, CA4)	3 (Fujisawa, Ichikawa, Ezaki)
Korea	8 (EE 3, Serv 1, Oil 1, Steel/Auto 2, Construction 1)	5 (ST, CA 4)	2 (Kim, Kim) (+ 3 YP)
Malaysia	2 (chem 1, steel 1)	1 (ME 1)	1 (Lee)
Peru	0	1 (1 incomplete)	1 (Uria)
Philippines	2 (Auto, Steel)	3 (mixture)	1 (Navarette)
Singapore	2 (EE)	--	--
Taipei, Chinese	5 (energy, food..)	6 (NMI 1, mix 5)	
Vietnam	--	2 (Gov 2)	1 (Bang)
USA	-	1	3 (Arnold, Cendrowska, Puskar)
Others	-		2 (Steel, De Vries)
합계	28	35	20

## 2.3 Some observations

- Providing Visibility of Standards Professional, and their tasks
- Visibility/Estimation of Job Market and Basis for Job Analysis
  - Companies (22/28 responses, 15K/383K employees)
    - ST: 3.5% , CA: 7.7%, ME: 2.6%(10:zero)
      - Average: avoiding the imparity of big companies (big employees)
    - Specialty Orgs (35 responses, 5K/9K employees)
  - Gap Analysis and Needs Identification (as is – to be)
  - Leaders view and comments
    - Growing job market, more recognition needed, diverse views
  - Overall Comments
    - SCSC joint efforts: best practices, next generation program
    - Competence requirements, Personnel certification



### 3.1 Conference Design

#### Face to face in-depth discussion about

- Reviewing definition/classification of standards professionals
- Job market and job(tasks) analysis
- Identifying needs and discussing recommendations

#### Speakers from

- Education Institutions (Panel 1-1)
- SCSC representatives (survey collection) (Panel 1-2)
- Companies (Panel 2)
- Standards Specialty Organizations (Panel 3)
- Open enlightening discussion and Wrap Up (Panel 4)

Participation: 51 signed participants from 15 Economies

### 3.2 EDU- Prof. MS SONG (CJLU) - University Graduates Survey

- All CJLU students study one of the four subjects : QM, Standardization, Metrology Mgt, Conformity Assessment
  - During 1996-2013, 1680 (80%) out of 2100 students majored in QM/ST are now standards professionals
    - Companies 60%, Standards Bodies 28%, Gov. 12%
- Career Paths
  - 10+ years experienced: 5% management positions
  - Career paths: Staff for Mgt Std // Quality / Certification  
→ Top Manager // Senior Standards Experts
- Challenge
  - Lack of teachers: Training of Teachers
  - Top decision makers in universities: Lack of recognition -- no job market

### 3.3 EDU – Prof BG KANG (KU) - SME manager survey

- In 2012, 248 Korean SME middle managers responded
- Job Demands
  - QA, standardization strategy, Testing/Inspection/Certification, Standards & Patents/R&D linkage..
- Positions of Standards Professionals
  - Currently limited to operation level, but needs to expand up to strategic level
    - Suggesting the concept of **Chief Standardization Officer (CSO)**
      - CIO use grew up from operational level up to strategic level
      - Top management understanding standards as strategic asset

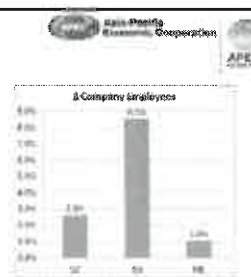


### 3.4 SCSC 1 – Indonesia (Nurlathifah)

- Company jobs from Indonesia
  - A (1031) - ST: 38/1031, CA: 35/1031, ME: 33/1031
  - B (252) - ST: 11/252, CA: 20/252, ME: 2/252
  - Mostly Sci/Eng majored, 20% graduate degree & females
  - Both companies highly require (80%) education and personnel certification programs
- Recommendations
  - Importance of career development to top management level
  - Information system of standards (MIS to Standards information)
  - Establishment of std-prof qualification scheme in the region
  - Establishment of personnel certification scheme

### 3.5 SCSC 2 – Korea (Choi)

- Company Jobs from Korea
  - 5~20% (ST: 0.3~9.5%) of total employees
  - Internal education/certification for ST is limited compared to that of CA, ME
- Recommendations
  - Career path for standards professional should be moved up to top management to attract young generation
  - Joint programs (mutually recognized) – education /training, qualification scheme, personnel certifications
    - Different tasks, different stage (staff to managers) to be considered



### 3.6 SCSC 3 - Philippines (CREDO-CABOCHAN)

- Company jobs
  - TMPC (1500): ST 300, CA 300, ME 50
  - UGC (190): n/a
- Recommendations
  - Providing opportunities to develop global knowledge and skills, build cross-cultural capabilities and develop leadership competencies through international experiences
  - Offering related courses in Universities
  - Supporting career development for relevant trainings and mentoring/coaching from senior employees
  - Harmonizing quality infrastructure and professional networking
  - Enhancement of personal certification and mutual recognition

### 3.7 Panel 2 (Companies) - Employee characteristics

Class	Haier (Dr. SHA)	Panasonic (Kajiya)	Samsung.E (Park)	WKB (WIDYANTORO)	AVIC (GENG)
Employees	70,000	300,000	R&D: 55K	1,031	500,000
- ST	-0.3%	-0.3%	- 0.6%(full)	- 3.7%	-0.12+0.27
- CA	-0.1%	- 0.1%	- NA	- 3.4%	-8.8%
- ME	-NA	- NA	- NA	- 2.9%	-N/A
Training		Mentoring	Some tasks		

### 3.8 Panel 2 (Companies) - Recommendations to APEC SCSC

- APEC young generation program (Haier) 青年人才培訓.
- APEC award system for companies, org., and individual for best practices (Panasonic)
- APEC standards professional bank (Panasonic) 人力庫.
- APEC good practices (Samsung)
- APEC standards professional development for company development (WKB)
- APEC's attention to the jobs (occupation) of standardization will strengthen the regional competitiveness (AVIC)

### 3.9. Panel 3 (Std. Specialty Org) - Employee characteristics

Class	SA (Fisher)	ASTM (LIU)	IEC (CHEW)	UL (O'NEILL)	NMIJ (Kuroiwa)	SST (Mohamed)
Employees	100	195	100	10,175	461	135
- ST	-80%	- 74%	- 90%	- 1%(full)	-(<10%)	-NA
- CA	-NA	- 21%	- NA	- 70%	-NA	-NA
- ME	-NA	- NA	-NA	- NA	-100%	-100%
Tasks (vs. companies)	SD Mgt. (process manager /tech. experts)	SD Mgt. (process manager /tech. experts)	SD Mgt. (process manager /tech. experts)	CA (judge/designer)	ME	ME
Know.	*Project/Process management *Communication/Language *Tech/industry understanding			CA: more technical, CBS	Scientist/ Researcher	70% Technician
EE/Sci	ST: mixed	ST:mixed	ST:EE Eng	40~50%	90~60%	70%
Training				UL univ.		

### 3.10 Panel 3 (Std. Specialty Org) - Recommendations to APEC

- Promote APEC best practices (SA)
- Promote participation based programs (ASTM)
- Exchange on Best Practices (IEC)
  - Engagement of young generation to IECYP programs
- Invest in People. Develop 21<sup>st</sup> experts and leaders (UL)
- Promote joint activities of different stakeholders (NMIJ)
- Promote joint activities to improve awareness level standards and standards professionals (SST)



## 3.11 Day 2

### - Definitions and Tasks

- Modification
  - Added: Planning/Evaluation for (CA01) Conf. Ass. and (ME01) Metrology
  - Added: (ST01) ST surveillance (ST03) ST maintenance
- Scope of Standards Professionals
  - In this project, standards professionals involves standardization (standards development), conformity assessment, and metrology
    - We also note that some experts consider standards professional is 'documentary standards experts' while standardization professional is involving conformity and metrology (language tone)
  - Metrology professionals, in particular, scientific metrology experts have a very different characteristics compared to standardization and conformity assessment
- Relationship between Standards/Conformity vs. Quality
  - Agreed that standards and conformity are core foundation for quality infrastructure, but also other important objectives including technology innovation, safety and environment protection, sustainability, etc

## 3.12 Day 2 - Competency requirements & qualification framework

- In general, project survey responses and speaker's recommendations indicates high level of interest in competency requirements and qualification scheme
- Pros
  - Providing guidance to individuals and companies, and policy makers
  - Raising awareness and organizing professional networking/associations
  - Mobility of skilled experts in the region (mutual recognition)
  - UL's career path and training program is a good reference for CA
    - Technician - Evaluator – Senior Evaluator - Primary designated engineer – Chief engineer (systematic program)
- Cons
  - Standards professional needs lifelong learning, and developing sector specific and stage-relevant certificate is challenging
  - Like driver license, the qualification could be useful as an entrance exam but not guarantee point Panasonic: negative, driver's license violates rules
  - Should not function as cost factor for SMEs

### 3.13. Day 2 – Career paths/models & Best practices

- Good way to show career paths/models of thought leaders from Large/SMEs, special organizations, governments, and females
  - Individual: Female leaders, SME executives
  - Companies: Manufacturing, Food, Service
  - Org.: Gov, Private, SDO, CA, AB, NMI

### 4. Conference recommendations

#### - Priority for next step

1. Developing Career Path/Model Best Practices (Case Studies)
  - both those of individuals or within a company or organization to show career vision (including female leaders, SMEs)
2. Developing Competency Requirements (Blueprint)
  - the development of a guide that outlines the baseline core competencies, skills and attributes that are required to support the next generation of standards and conformance professionals
3. Developing a Qualification Scheme or Personnel certification
  - Some pros and cons, more discussion in SCSC Plenary meeting needed
  - ASEAN – mobility of skill leader/experts
4. More actively exchanging information on next generation and discussing joint activities: students, internship, young professional, participation program

↓  
海州建議給政府



Thank you for your attention!



Annex A. Definition and Classification  
Annex B. Project Survey/Interview  
Annex C. Conference program



Annex. A  
Definition and Classification  
of Standards Professional

## A.1 Definition and Classification - References/Terminology

- **Note 1:** Standards-specialty organizations are specialized organizations mainly dedicated for standardization, conformity assessment, and metrology.
  - These include national standards bodies (NSBs, usually the members of ISO or IEC), standards developing organizations (SDOs), testing laboratories, certifications bodies (CBs), accreditation bodies (ABs), national metrology institutes (NMIs).
  - The organizations can be governmental, public, or private (either non-for profit or for-profit). Governmental regulatory agencies may be considered as a specialty organization in a sense that they set and enforce mandatory standards (technical regulations).
- **Note 2:** These terms used here are defined in following references:
  - ISO/IEC Guide 2 (Standards, Standardization)
  - WTO/TBT Agreement (Standards, Regulations, Conformity Assessment)
  - BIPM website (Scientific/ Industrial/ Legal Metrology)
- **Note 3:** Please note that, as this project will have completed, the definition will be updated based on the input of APEC SCSC members through this survey and discussion of upcoming project workshop in 2014.

## A.2 Definition and Classification - Tasks of Standardization Professional (1)

[ST.01] <b>Planning and Evaluation</b>	(Standards-specialty organizations) Strategy/policy setting and legislation Cooperation/coordination with SDOs Performance/achievement evaluation Standardization needs & trend analysis
	(Companies) Strategy/plan setting, standardization and patenting strategy Cooperation with NSB/SDO and forum/consortium Performance/achievement evaluation Standardization needs & trend analysis
[ST.02] <b>Development</b>	(Standards-specialty organizations) Committee secretariat (Standards development processing) Development (by staff) Development (by technical committees) Development (by accredited/cooperative SDOs)
	(Companies) Development (company standards) Development (participation in external SDO's activities)

<b>A.3 Definition and Classification</b> - Tasks of Standardization Professional (2)	
<b>[ST.03]</b> <b>Dissemination</b>	(Standards-specialty organizations) Copyediting & publication; Sales & marketing Information services Consultancy and training
	(Companies) Standards information management - copyediting, publication, distribution of standards Training for standards application
<b>[ST.04]</b> <b>Others</b>	(Standards-specialty organizations) TBT inquiry related issues, link of standards-regulation
	(Companies) TBT, Regulation analysis and reaction (domestic, foreign)

<b>A.4 Definition and Classification</b> - Tasks of CA Professional (1)	
<b>[CA.01]</b> <b>Testing</b>	(Standards-specialty organizations) Testing service development & operation Establishment of management system for testing laboratory (ISO/IEC 17025); Testing method development; Proficiency testing; Testing
	(Companies) Testing procedure development Testing for materials & product, Testing for new product development
<b>[CA.02]</b> <b>Inspection</b>	(Standards-specialty organizations) Inspection service development & operation Establishment of management system for inspection body ISO/IEC 17020); Inspection criteria & method development; Inspection
	(Companies) Inspection procedure development Receiving inspection for materials In-process inspection; Final inspection for product



## A.5 Definition and Classification - Tasks of CA Professional (2)

<b>[CA.03] Certification</b>	(Standards-specialty organizations) Certification scheme development & operation Establishment of management system for certification body (ISO /IEC 17065, 17021); Certification criteria & method development Certification audit/assessment
	(Companies) Acquisition & maintenance of certification for product, service, or management system
<b>[CA.04] Accreditation</b>	(Standards-specialty organizations) Accreditation scheme development & operation Establishment of management system for accreditation body (ISO /IEC 17011) Accreditation criteria & method development Accreditation assessment
	(Companies) Accreditation related tasks
<b>[CA.05] Others</b>	(Standards-specialty organizations) any other tasks
	(Companies) any other tasks

## A.6 Definition and Classification - Tasks of Metrology Professional (1)


<b>[ME.01] Scientific Metrology</b>	(Standards-specialty organizations) Establishment & dissemination of national measurement standards Research & development of measurement standards International Key comparison
	(Companies) Application of measurement standards
<b>[ME.02] Industrial Metrology</b>	(Standards-specialty organizations) Calibration service development & operation Management system for calibration laboratory (ISO/IEC 17025) Calibration procedure development; Calibration; Reference material production Management system for reference material producer (ISO Guide 34) Reference material certification (ISO Guide 35)
	(Companies) Establishment of management system for calibration laboratory (ISO/IEC 17025) Calibration procedure development; Calibration; Application of reference materials

## A.7 Definition and Classification - Tasks of Metrology Professional (2)

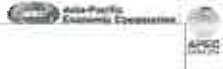
<b>[ME.03] Legal Metrology</b>	(Standards-specialty organizations) Policy and Legislation for legal metrology Type approval, verification and periodical inspection for measuring instruments; Net weight certification for pre-packaged food
	(Companies) Compliance with laws/acts on legal metrology
<b>[ME.04] Others</b>	(Standards-specialty organizations) Development Standard reference data (SRD)
	(Companies) Application of standard reference data (SRD)

## A.8 Definition and Classification - Your comments

- Welcome your comments to improve this interim definition and classification
- Within the survey questionnaire, there is a question for your input



Annex. B  
Survey/Interview Questions



**B1. Type A: Company &  
Type B: Standards-Specialty Org.**

- Survey Scope
  - Type A: Large or SME, Manufacturing/R&D/Service..
  - Type B: NSB, NMI, SDO, Labs, CB, AB.... (Gov, Pub, Private)
- Survey Target Number of Responses
  - A few responses for each Type A and Type B
  - Prefer diverse/different types of responding orgs/companies
- In Korea we are contacting...
  - Type A: NMI, two major testing labs
  - Type B: 3~4 Big Companies (multi sectors), 1~2 SME/Venture

## B.2 Type A (Company) & Type B (Spe Org) - Survey Structure

### 1 Org/Company Overview

- 1.1 Employees and Budget of whole company
- 1.2 Number of Employees in Standards-related Tasks
- 1.3 Number of Senior Executives in Standards-specialty positions

### 2 Job Analysis and Profiling

- 2.1 Jobs for Standardization
  - 2.1.1 Standardization – Current Status Profiling
  - 2.1.2 Standardization – Requirement Profiling
  - 2.1.3 Standardization – Sample Requirements (Advertisements)
  - 2.1.4 Standardization – Training Program: Status and Needs
  - 2.1.5 Standardization – Personnel Certification: Status and Needs
- 2.2 Jobs for Conformity Assessment
- 2.3 Jobs for Metrology

### 3. Overall Recommendations to APEC SCSC


- 3.1 Comments on Definition/Classification of Standards Professional
- 3.2 Career Path and Vision for Standards Professional
- 3.3 Recommendations for APEC SCSC Members

## B,3 Type C: Individual (Thought Leaders)

- Survey Scope
  - Thought leaders: Senior Executive level (Top 1~5 %)
  - Role model for Career Development: For young generation who (will) work in standards community, perhaps his/her career could be a best practice
- Survey Target Number of Responses: A few
- Length: 1200 words ~ 2500 words (1~2 pages)
  - Usage: The interview will be incorporated in the final report as a special column
- In Korea we are contacting...
  - A president of major test lab (30 years in public sector)
  - Senior Vice President (Samsung, R&D)
  - Vice President (LG, Quality and Conformity)
  - CTO (a Venture Company)

## B.4 Type C (Individual) - Survey Structure

- Would you please **describe your career path** -- when and how you started your career, and have developed it throughout your professional life by far?
- What do you think are the **most important event(s) or experiences(s)** in your professional career as standards professional?
- ~~What kind of standards professionals did you hire or will hire. What kind of knowledge, skills, experiences, or attitudes do you expect from them.~~
- How do you see conceptually professional development or practically **job market for standards professionals**? Can you share your vision or prediction on standards professionals with next generation or current experts working in standards-related tasks?
- Finally, please share your **suggestions or recommendations** to inspire standards professional development, to APEC Member Economies, their organizations or companies, in terms of regional or international cooperation.



## Annex. C Conference Program



## C.1 Conference – Opening & Panel 1

**9:00am - 9:30am INTRODUCTION with CONFERENCE CO-CHAIRS**

Mr. Donggeun CHOI  
Project Editor, APEC SCSC Standards Professional Development  
Chief Researcher, Korean Standards Association, Republic of Korea

Ms. Chunjing DLI  
Director for International Cooperation, Certification and Accreditation Administration of China (CNCA),  
China

**9:30am - 10:50am PANEL 1 – MODERATOR**

Mrs. Metrawinda TINJUS, Head of Center for education and promotion of standardization, BSN, Indonesia

### SPEAKERS

#### 1-1 <Education Institutions>

Prof. Byung-Goo KANG, Dean and Professor, Korea University, Korea

Prof. Mingshun SONG, Vice President and Professor, China Jiliang University, China

#### 1-2 <SCSC Members>

Mrs. NURLATHIEAH, Head of Sub Division for Profession Development of Standardization, BSN, Indonesia

Mr. Donggeun CHOI, Chief Researcher, Standards Policy Research Center, KSA, Korea

Ms. Atty. ANN CLAIRE CREDO-CABOCHAN, Director-in-Charge, Bureau of Philippine Standards (BPS),  
Philippines

## C.2 Panel 2 – S.P in Companies 11:20am - 1:00pm

### MODERATOR

Mr. Steven TAN, Group Director of Quality & Standards, SPRING, Singapore

### SPEAKERS

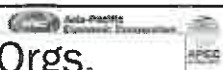
Dr. Jiming SHA, Director for International Standards, Haier Group, China  
(ICT/EE industry)

Mr. Toshiyuki KAJIYA, Senior Counselor to International Standardization, Product  
Safety and Quality Administration Center, Panasonic Corporation, as well as a  
Japanese member of IEC/CAB member (ICT/EE industry)

Ms. Jiseon PARK, Head of Standards Team, Samsung Research Center in Beijing,  
Samsung Electronics, Korea (ICT/EE industry)

Mr. Sila Agung WIDYANTORO, Business Development Manager,  
Wijaya Karya Beton Plc, Indonesia (construction/chemical Industry)

Ms. Jinfeng GENG, Senior Engineer and also Senior Business Manager, Aviation  
Industry Corporation of China (AVIC), China (aviation/defense industry)



## C.3 Panel 3 – S.P in Specialty Orgs. 2:30am - 4:00pm

**MODERATOR**

Mrs. Patrica HARRIS, International Standards Specialist, NIST,  
USA

**SPEAKERS**

Mr. Damian FISHER, Senior International Development Manager, Standards Australia,  
Australia (Standards Development Organization)

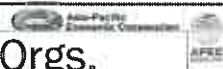
Mr. Fei LIU, Chief Representative, ASTM International China Office  
(Standards Development Organization)

Mr. Dennis CHEW, Regional Director, IEC Asia-Pacific Regional Centre  
(Standards Development Organization)

Ms. Eve O'Neill, Program Manager, Asia Pacific and Emerging Markets  
Certification Programs Office, UL (Conformity Organization)

Dr. Takayoshi KUROIWA, Manager, Reference Materials Office/Metrology Management,  
National Metrology Institute of Japan (NMIJ), AIST, Japan (Metrology Organization)

Mr. Wan Abdul Malik WAN MOHAMED, Operations Manager, Technical Department,  
SIRIM Standards Technology Sdn Bhd, Malaysia (Metrology Organization)



## C.4 Panel 4 – S.P in Specialty Orgs. 4:00am - 5:20pm

**MODERATOR 4**

Conference Co-Chairs (Ms. Chunjing DU & Mr. Donggeun CHOI)

**COCOMMENTERS (invited)**

Three Panel Moderators

(Mr. Steven TAN, Mrs. Metrawinda TUNUS, Mrs. Patrica HARRIS)

The SRB Forum Chair (Mr. Michael FRASER)

The SCSC Chair (Mr. Jianping HAN)

**COMMENTERS (voluntary basis from the floor)**

Three to Five conference participants, both from public and private  
sectors, will be invited on-site for comments and ideas

**C.5 August 10<sup>th</sup> - Day 2 Program**  
**- Close door session Speakers/Moderators**

**9:00am - 9:10am      OPENING**

**9:10am - 12:00am      REVIEWING THE DISCUSSION OF  
FIVE MAIN ISSUES**

- 1) Definition and classification of 'standards professionals'
- 2) Practical tasks and roles of standards professionals in companies and organizations
- 3) Competency requirements, education programs, and qualification framework for standards professionals
- 4) Career paths/models or best practices for standards
- 5) Recommendations and priorities to APEC Members

**12:00am - 1:30pm      LUNCH**



**Asia-Pacific  
Economic Cooperation**

智利  
(新案)

了解APEC各會員國更新之  
食品法規及標準。

2014/SOM3/SCSC/022

Agenda Item: 9

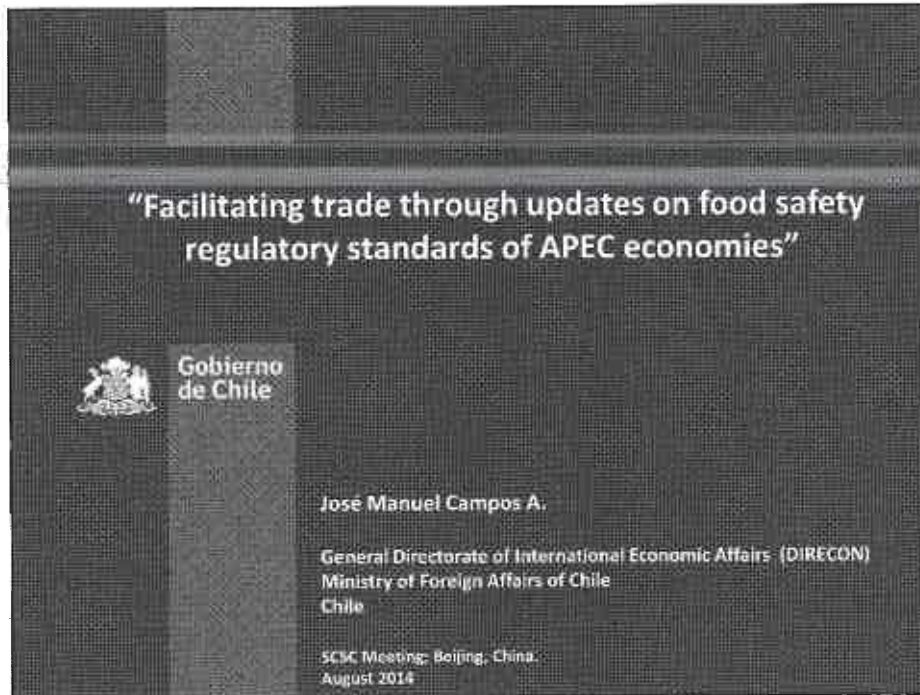
## **Concept Note – Facilitating Trade Through Updates on Food Safety Regulatory Standards of APEC Economies**

Purpose: Information

Submitted by: Chile



**Second Sub-Committee on Standards and  
Conformance Meeting  
Beijing, China  
11-12 August 2014**



## Relevance

- » Many APEC member economies have experienced modifications on their food safety regulatory standards, management system, and responsibilities.
- » In the light of this dynamic context and according to the 21<sup>st</sup> APEC Economic Leaders' Declaration, it is crucial to comprehensively understand the updates on food safety regulations of APEC economies in order to achieve the Bogor Goals of free and open trade and investment by 2020.
- » APEC Leaders agreed on the need to develop a more robust approach to strengthening food safety standards and practices in the region.
- » The relevance of this project has a close relation on what it is expected to do under the Sub Committee on Standard and Conformance (SCSC) and the Food Safety Cooperation Forum (FSCF)





## Objectives

- » Enhance understanding of the updates on food safety regulatory standards of the APEC economies with the most transformative changes.
- » Develop recommendations/best practice on how APEC economies should align their food safety standards and conformity assessment for mutual recognition of products and services to improve their food safety standards, facilitate trade and promote economic integration of the region.
- » Share the manner in which APEC economies are dealing with emerging food safety challenges, in order to identify the similarities and differences on this matter in the region.

### Co-sponsoring economies: 8

United States, Canada, New Zealand, Indonesia, Mexico, Peru, Australia, Thailand.

## Methodology

- » Three day workshop in during the second semester of 2015 in Santiago, Chile.
- » Stakeholders: Government officials, academia experts, export associations, government policy makers and risk managers, and consumers associations.
- » The outcome of this workshop will consist in obtaining detailed data of all APEC economies on their modifications in food safety regulations and a better understanding of the similarities and differences on food safety challenges in the region.

**Total amount being sought from APEC (USD):** 174,000

**Project Overseer Information and Declaration:**

**Name:** Michel Leporati.

**Title:** Executive Secretary of the Chilean Food Quality and Safety Agency (ACHIPIA).

**Organization:** Chilean Food Quality and Safety Agency (ACHIPIA), Ministry of Agriculture, Government of Chile.

**THANKS**

JCAMPOS@DIRECON.GOB.CL

Michel.leporati@achipia.gob.cl



**Asia-Pacific  
Economic Cooperation**

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**2014/SOM3/SCSC/023**

Agenda Item: 9

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## **Concept Note – Medical External Quality Assurance Capacity Building Programme**

Purpose: Information  
Submitted by: Malaysia



**Second Sub-Committee on Standards and  
Conformance Meeting  
Beijing, China  
11-12 August 2014**

## APEC Concept Note

*Please submit through APEC Secretariat Program Director. Concept Notes of more than 3 pages (including title page) or incomplete submissions will not be considered.*

<b>Project Title:</b>	Medical External Quality Assurance (EQA) Capacity Building Programme
<b>Fund Source (Select one):</b> <input type="checkbox"/> Operational Account <input type="checkbox"/> TILF Special Account <input checked="" type="checkbox"/> APEC Support Fund <b>For ASF:</b> As per Guidebook Ch. 3, list <b>ASF Sub-fund</b> if appropriate for this project.	
<b>APEC forum:</b>	Committee on Trade and Investment / Sub-Committee on Standards and Conformance
<b>Proposing APEC economy:</b>	Malaysia
<b>Co-sponsoring APEC economies:</b>	Philippines; Indonesia; Thailand, Hong Kong, China; Singapore
<b>Expected start date:</b>	May 2015
<b>Expected completion date:</b>	November 2015
<b>Project summary:</b>  Describe the project in under <u>150 words</u> . Your summary should include the project topic, planned activities, timing and location:  <i>(Summary must be no longer than the box provided. Cover sheet must fit on one page)</i>	<p>Medical External Quality Assurance (EQA) is a mandatory requirement in complying to international standard (ISO 15189) for medical testing to fulfil regulatory requirements of an economy. In ensuring competency of EQA providers, it is a requirement for them to comply with international standards of ISO/IEC 17043. Unfortunately, it is known that accredited EQA programmes or EQA providers complying with international standard are still scarce in numbers yet to accredited to ISO/IEC 17043 especially in developing economies. At present most EQA programmes in developing economies in APEC region are supplied by specific international providers only.</p> <p>A three (3) days' workshop will be held in Malaysia in October 2015 with aims to:</p> <ol style="list-style-type: none"> <li>a) Share best practices on Medical External Quality Assurance among APEC economies;</li> <li>b) Create awareness on the importance of EQA;</li> <li>c) Increase number of competent EQA provider in APEC region; and</li> <li>d) Strengthen networking and technical cooperation among stakeholders in EQA.</li> </ol>
<b>Total cost of proposal:</b> <i>(APEC funding + self-funding):</i> <b>= USD 128, 030</b>  <i>(USD 118, 030 + USD 10, 000)</i>	<p><b>Total amount being sought from APEC (USD):</b> 118,030</p> <p><b>By category:</b> Travel: 93,030      Labor costs:          Hosting: 24,000      Publication &amp; distribution: 1,000      Other:</p> <p><i>(See Guidebook on APEC Projects, Ch. 9 to ensure all proposed costs are allowable.)</i></p>

**Project Overseer Information and Declaration:**

**Name:** Mrs. Fariza Wan Abdullah

**Title:** Senior Principal Assistant Director

**Organization:** Department of Standards Malaysia

**Postal address:** Accreditation Division, Department of Standards Malaysia, Level 1, Block 2300, Century Square, Jalan Usahawan, 63000 Cyberjaya, Selangor, MALAYSIA

**Tel:** +603 8319 1317

**E-mail:** fariza@jasm.gov.my

As Project Overseer and on behalf of the above said Organization, I declare that this submission was prepared in accordance with the **Guidebook on APEC Projects** and any ensuing project will comply with said Guidebook. Failure to do so may result in the BMC denying or revoking funding and/or project approval. I understand that any funds approved are granted on the basis of the information in the document's budget table, in the case of any inconsistencies within the document.

Fariza Wan Abdullah  
*Name of Project Overseer*  
**Date:** 21<sup>st</sup> July 2014

## Project Synopsis

1. **Relevance – Benefits to region:** What problem does the project seek to address? What is the relevance of the project? Does it have sustained benefits to more than one economy?

Medical testing laboratories are essential to patient care and therefore have to be available to meet the needs of all patient and the clinical personnel responsible for the care of those patients. In most APEC economies medical testing laboratories are required to comply to international standards of ISO 15189 - Medical Laboratories - Requirements for Quality and Competence. In complying to ISO 15189, a medical testing laboratory must participate in External Quality Assurance (EQA) programmes. This is to ensure the competency of the laboratory in carrying out the testing work and producing credible test result.

Unfortunately, accredited EQA programmes or EQA providers complying to international standard are still scarce in numbers yet to accredited to ISO/IEC 17043 especially in developing economies. At present most EQA programmes in developing economies in APEC region are supplied by specific international providers only due to limited capacity and capability of local providers. This involved high participation cost to medical testing laboratories and result in limited participation and non-compliance to the requirements of international standards

There are many laboratories in the region which need to bare a very high cost to subscribe and participate in the EQA programme organised in developed countries. Statistic in 2010, shows that one country need to spend about USD 1.6 million to participate such programme for only several laboratories. Therefore, it is more appropriate if the allocation spent could be reduced and used to enhance the national EQA Programme.

The workshop is aimed to initiate efforts to build up capacity and capability of EQA providers especially in developing economies in APEC region. This project will benefit EQA providers where it can increase their readiness to establish and run its own EQA programmes.

**Relevance – Rank:** Which Rank in the annual *APEC Funding Criteria* does this project fall under? Briefly explain why. Is it also linked to other Ranks? If so, briefly explain which/how.

This is a rank 1 project that specifically and significantly contributes to promoting regional economic integration focusing on improving standards, conformity assessment, technical regulations and regulatory cooperation.

2. **Objectives:** Describe the 2-3 key objectives of the project. (e.g. ensure workshop participants will be able to...; to create a framework...; to develop recommendations...; to build support...; to revise strategies...; to create an action plan;...to increase knowledge in; to build capacity in... etc.)

The overall goal of this project aims to:

- a) Share best practices on Medical External Quality Assurance among APEC economies;
- b) Create awareness on the importance of EQA;
- c) Increase number of competent EQA provider in APEC region; and
- d) Strengthen networking and technical cooperation among stakeholders in EQA.

3. **Alignment – APEC:** Describe specific APEC priorities, goals, strategies, workplans and statements that the project supports, and explain how the project will contribute to their achievement.

This project implements the **Leaders' Declaration 2013** on promoting sustainable healthcare systems that deliver universal health coverage by engaging in capacity building efforts and effective regional and global partnerships across the public and private sectors with the aim of strengthening public health systems.

In addition, this project reflects the **2013 statement by the third APEC High Level Meeting on Health and the Economy** which mentioned the importance of ensuring the integrity of the health system through access to medical products and health services meeting safety, quality and efficacy standards as well as ensuring ethical collaborations in the medical innovation development process and health care stakeholders.



**Alignment – Forum:** Briefly explain how the project is aligned with your forum’s work plan / strategic plan.

This project is also aligned with the **APEC Ministers’ Statement 2011** on convergence on regulatory approval procedures for medical products by 2020, which will allow patients more timely access to innovations. This project put into practice actions to reduce the social and economic burden of disease, as adopted measures to ensure transparency and stakeholder consultation in the process of regulatory and policy reform in the health and life sciences sectors. Furthermore, the project overall goal of mutual recognition towards testing results will facilitate the import and export of services and expand regional economic integration.

**4. Methodology:** How do you plan to implement the project? In this section, briefly address the following:

- **Workplan:** Project timelines, dates of key activities and deliverable outputs.

May – July 2015	-Submit letter of undertaking -Establish working committee to focus on detailed agenda, invitation, documentation and other matters -Confirmation of event details
August – September 2015	-Ground arrangement (logistics and documentation) -Invitation to participating economies and speakers -Submit monitoring report to APEC Secretariat
October 2015	-To organise the workshop in Malaysia
November 2015	-Submission of completion report to APEC secretariat

- **Beneficiaries:** The proposed selection criteria for participants, beneficiary profiles (e.g. workshop participants, end users, policy makers, researchers/analysts, gender) and how they will be engaged.

The beneficiaries of the projects are government official formulating policies relating to EQA, the accreditation bodies, EQA Providers and also the technical experts. The project overseer would also extend the invitation to the APEC Life Sciences Innovation Forum (LSIF) to strengthen this project. APEC funding will be made available for the invited speakers and APEC traveling eligible economies. This is the first APEC project focusing on Medical External Quality Assurance. Previous work in APEC Sub-Committee on Standards Conformance was focused on other field such as food safety, seafood toxicity and veterinary drug residues.

- **Evaluation:** Potential indicators developed to measure progress, project outcomes and impacts/successes. Where possible provide indicators which could assess impacts on women.

The workshop’s short term indicator;

- To identify potential Proficiency Testing (EQA) provider / facilities (or to enhance the capability of existing PT providers) for medical testing; and
- To increase no. of expertise in APEC economies.

Long Term indicator:

- To develop/establish PT design (protocol, costing, schedule etc)
- To launch the PT (EQA) for medical testing laboratories in APEC economies to participate and provide reporting.

- **Linkages:** Information on other APEC and non-APEC stakeholders and how they will be engaged. If and how this proposal builds on (but does not duplicate) the work of other projects. How will this activity promote cross fora collaboration?

EQA provider and technical expert from selected APEC economies which are able to share best practices in the practical operation to ensure the competency of the laboratory in carrying out the testing and producing credible test result. Participants from member economies will also be expected to share their EQA implementation. Active participants will include government officials from APEC economies, EQA provider from public and private sector, accreditation bodies, and technical experts. The workshop’s presentations and training materials will be made available in printed copy and on the APEC’s website for all participants and future reference and guidance. A report of the workshop will also be presented during SCSC meetings.

馬來西亞(新案)

醫療實驗室外部品質能力建構  
計畫



**Asia-Pacific  
Economic Cooperation**

2014/SOM3/SCSC/024

Agenda Item: 9

## **Concept Note – Medical External Quality Assurance Capacity Building Programme (Presentation)**

Purpose: Information  
Submitted by: Malaysia



**Second Sub-Committee on Standards and  
Conformance Meeting  
Beijing, China  
11-12 August 2014**

**Proposal for :**  
**Medical External Quality**  
**Assurance (EQQA) Capacity**  
**Building Programme**

## Definition :

- PT/EQA\* is the determination of the calibration or testing performance of a laboratory or the testing performance of an inspection body by means of interlaboratory comparison
- PT/EQA supplements laboratories' own internal quality control procedures by providing an additional external audit of their testing capability.....
- APLAC Evaluator PT/EQA = **Beauty Contests**

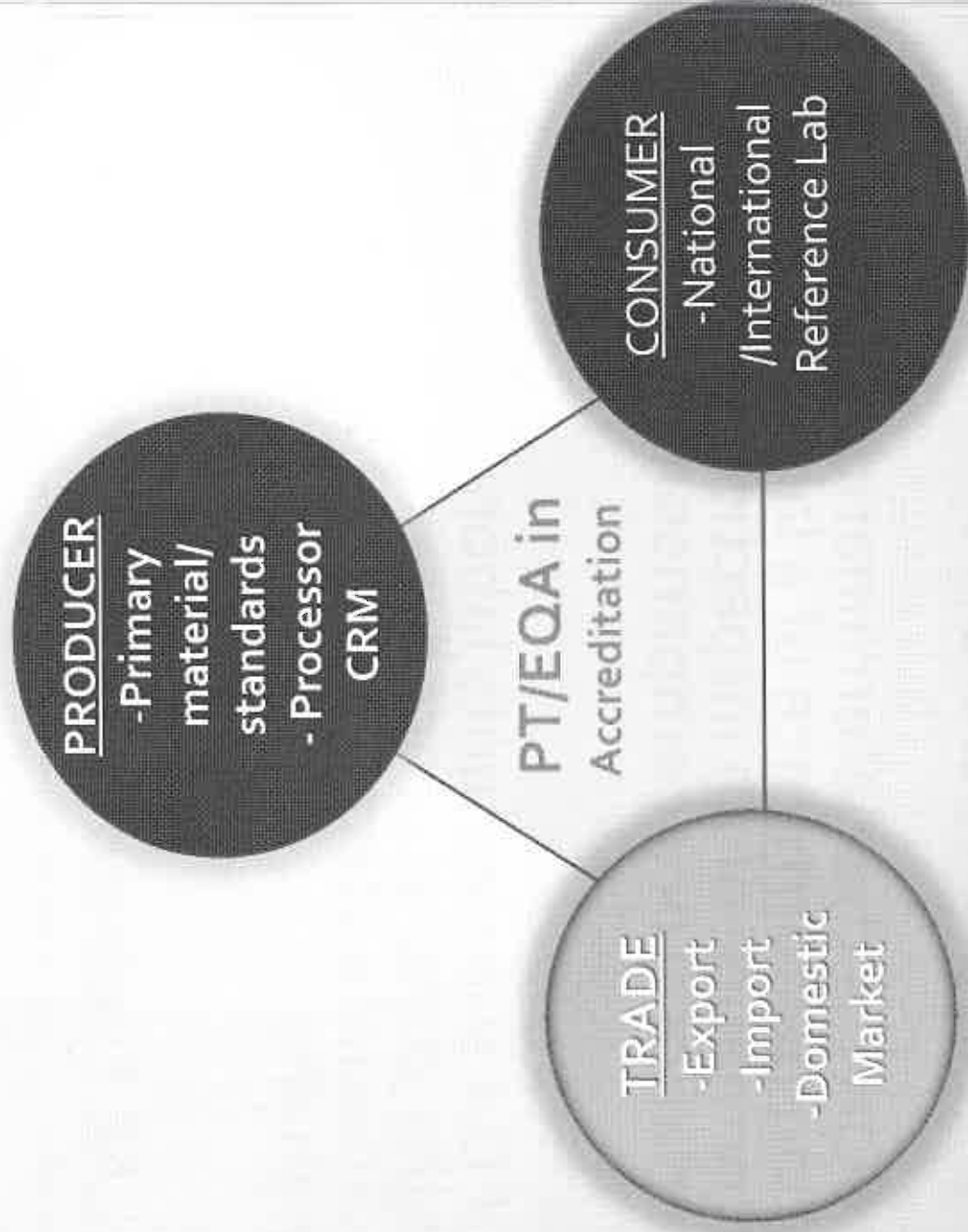
*Note\**

*PT= Proficiency Testing*

*EQA = External Quality Assurance*



# Role of PT/EQA in Accreditation





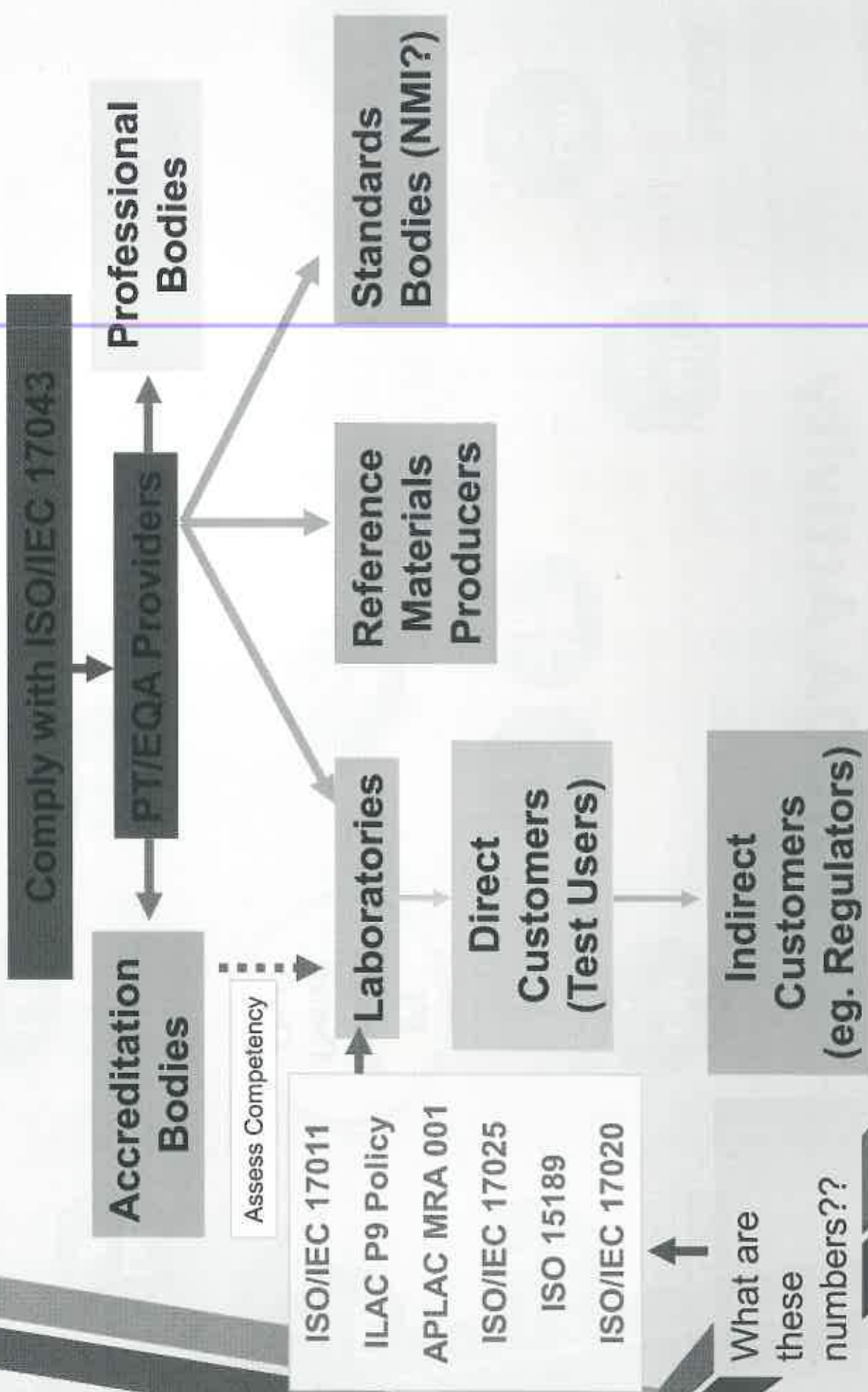
## **Benefits of PT/EQA vs Beauty Contests**

- **Confirming competent performance vs Beauty**
- **Identifying testing measurement vs Identified criteria**
- **Comparing methods/instrument vs clothing**
- **Improving performance vs appearance**
- **Educating staff vs training/courses**
- **Finally : Instilling & ensuring confidence of staff, management and external users of laboratory services**

## Technical Benefits of PT/EQA

- Comparing operator capabilities
- Generating reference materials
- Determining method precision and accuracy
- Satisfying regulators and accreditation bodies
- Providing laboratories with additional risk management element

# Who are the stakeholders in PT/EQA?



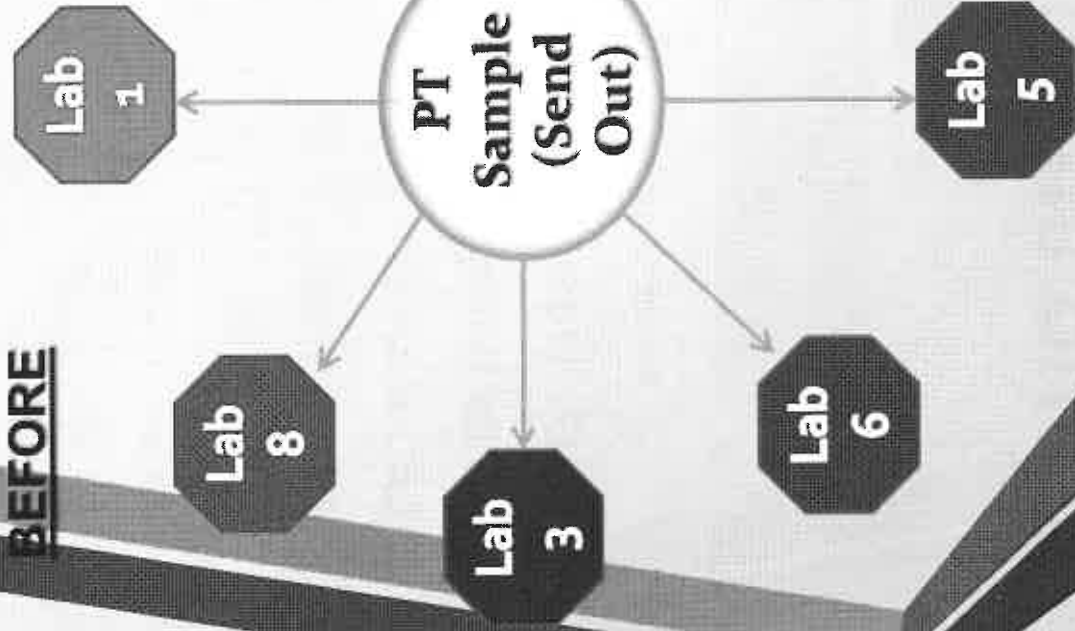
- ISO/IEC 17011
- ILAC P9 Policy
- APLAC MRA 001
- ISO/IEC 17025
- ISO 15189
- ISO/IEC 17020

What are these numbers??

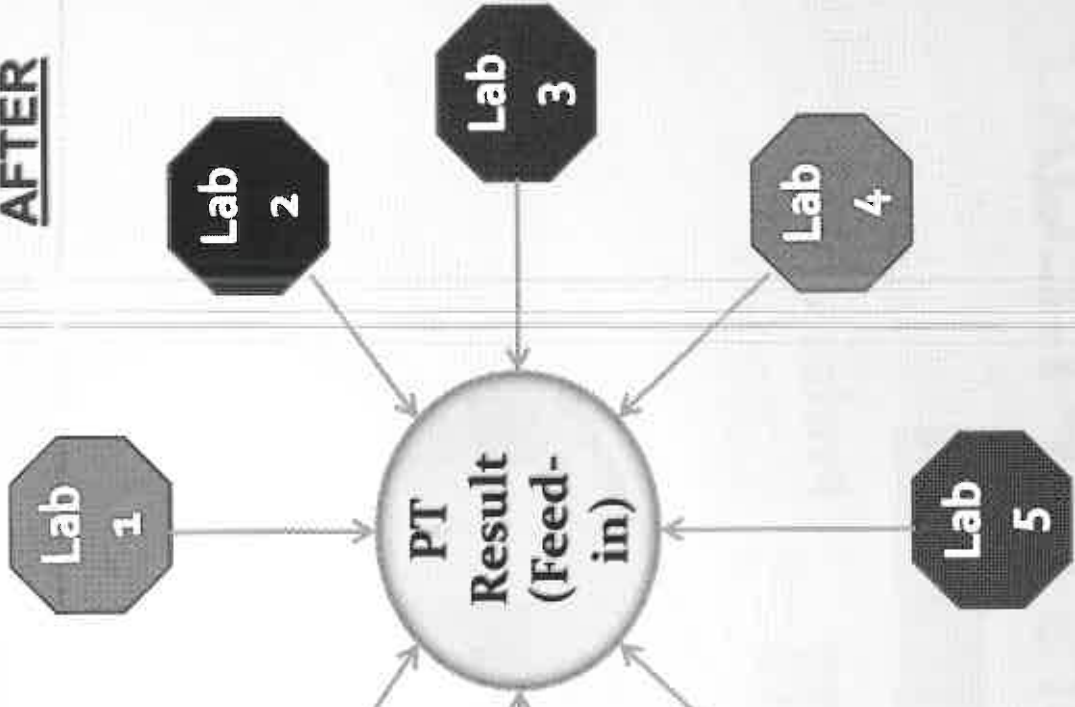


# PT/EQA Activity

BEFORE



AFTER



# International Requirements

1. ISO/IEC 17011 Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies
  2. ILAC P9 ILAC Policy for Participation in National and International Proficiency Testing Activities
  3. APLAC MR001 Procedures for establishing and maintaining mutual recognition agreements between laboratory accreditation bodies
  4. ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories
- 
1. ISO 15189 – Medical Laboratories – Requirements for Quality and Competence  
ISO/IEC 17043 -.....



# Issues of PT/EQA Programme

- no specific human resources/personnel
- budget to initiate/establish programme
- limited number of CRM\* analyte
- data analysis (software)
- result format
- morphology exercise (experts)
- logistic
- marketing
- Limited Accreditation Body accredits EQA Provider

Note\*: CRM-Certified reference material

As a result..... seek APEC for Assistant ....

To Organised :

Medical Testing

External Quality Assurance (EQA) Capacity  
Building Programme

in Malaysia

October 2015

# Details of the workshop:

- Date : October 2015
- Venue : Malaysia
- Speakers : Australia, US and Thailand (TBC)
- Tentative programme :
  - Understanding ISO/IEC 17043 elements
  - Knowledge Sharing by accredited EQA Providers
  - Discussion –establishing EQA Provider
- Participants :
  - 20 funded participants from 10 APEC developing economies
  - 10 local participants (potential EQA provider)



# Initiatives/Methodology

May – July 2015	<ul style="list-style-type: none"><li>- Submit letter undertaking</li><li>- Establish working committee to focus on detailed agenda, invitation, documentation and other matters</li><li>- Confirmation of event details</li></ul>
August- September 2015	<ul style="list-style-type: none"><li>- Ground arrangement (logistics and documentation)</li><li>- Invitation to participating economies and speakers</li><li>- Submit monitoring report to APEC Secretariat</li></ul>
October 2015	<ul style="list-style-type: none"><li>- To organise the workshop in Malaysia</li></ul>
November 2015	<ul style="list-style-type: none"><li>- Submission of completion report to APEC secretariat</li></ul>

## **Workshop aims to :**

- 1. Share best practices on Medical External Quality Assurance among APEC economies;**
- 2. Create awareness on the importance of EQA;**
- 3. Increase number of competent EQA provider in APEC region; and**
- 4. Strengthen networking and technical cooperation among stakeholders in EQA.**



# Outcome of workshop:

- By organising this program, targeted participants are to enhance valuable data and information which:
  - allows mechanism for comparison of performance and results among different test sites;
  - able to detect warning for systematic problems associated the test method or equipment used or its operations
  - target better objective evidence credible and reliable testing quality; and
  - indicates areas that need improvement and time efficiency.
- EQA helps to assure customers, such as physicians, patients, and health authorities, that the laboratory will produce reliable results with a safer and efficient cost

Thank you!!!