出國報告（出國類別：其他）

出席「世界貿易組織/技術性貿易障礙(WTO/TBT)委員會第 72 次會議」報告

服務機關：經濟部標準檢驗局

姓名職稱：洪專門委員權修、侯技士建綸

派赴國家：瑞士日內瓦

出國期間：106 年 6 月 11 日至 17 日

報告日期：106 年 7 月 26 日

摘　要

WTO/TBT 委員會於本(106)年 6 月 13 日至 15 日舉行主題性研討會及第 72 次例行會議。本次主題性研討會主題為「風險評估」，經區分為產品及網路安全 2 大次主題方式進行，我國推派本局第三組侯技士建綸擔任講師分享本局「前市場檢驗風險評估」經驗，獲哈薩克代表會後向我索取簡報資料，表示有興趣學習本局作法。第 72 次正式會議，主要就「特定貿易關切事項（STC）」、「會員經驗交換」、「技術合作活動」及「觀察員組織活動更新」等議程進行討論。本次會議中，會員共提出新增及既有計 56 項 STC 案，其中歐盟對我國行政院農業委員會「有機農業法」草案持續提出特定貿易關切。

值得注意的是，本次會議新列入共 9 項特定貿易關切事項中，即有 4 項係關於中國大陸發布之網路安全（cybersecurity）相關規定草案，受到歐盟、美國及日本等國關切。該等草案擬規範包括網路產品及服務安全、密碼（加密保護或安全憑證）、車聯網（Internet of vehicles）安全防護以及民航網路資訊安全等領域。另外，中國大陸及美國並於風險評估主題研討會中，分別簡報有關工業控制系統之網路安全風險以及網路安全之風險管理現況。網路安全領域逐漸成為各國關切之新興議題，並以技術性貿易障礙議題呈現，值得後續持續觀察其發展趨勢。

本次出席會議觀察及建議如下：(1) 主動研提 TBT 主要關切議題，積極參與經驗分享；(2)積極運用 TBT 委員會及雙邊諮商機制，維護我國廠商對外貿易利益；(3)加強教育宣導 TBT 協定之功能，鼓勵並協助業者提出關切意見；(4)掌握國際關切議題重點，深入研究分析妥善因應。

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附件

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4. JOB/TBT/234：2018 年召開 TBT 委員會預定時程表
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6. JOB/TBT/233：第 72 次 TBT 委員會正式會議議程
7. 特定貿易關切一覽表
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9. G/TBT/N/TPKM/225：我國「有機農業法」草案通知文件
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11. RD/TBT/224、225、226：2017 年 WTO、IEC、CODEX 技術協助活動
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壹、 前　言

世界貿易組織(WTO)技術性貿易障礙委員會(簡稱 TBT 委員會)於每年3、6 及 11 月定期召開例行會議，本(106)年 6 月 13 至 15 日召開第 72 次例會，並於會前(6 月 13 日)召開主題性研討會，我國由本局第五組洪專門委員權修、第三組侯技士建綸及我常駐世界貿易組織代表團洪秘書敬庭出席。本次會議由 3 月會議選出之新任主席智利籍 Mr. Jose Manuel Campos 主持，會議安排如下：

(一) 106 年 6 月 13 日召開「風險評估」主題性研討會，並接續討論明（107）年召開 TBT 委員會及第 8 次三年總檢討之預定時程。

(二) 106 年 6 月 14 至 15 日召開 TBT 委員會第 72 次正式會議。

貳、 106 年 6 月 13 日風險評估主題性研討會紀要

TBT 委員會依據 104 年 11 月完成之 TBT 協定第 7 次三年總檢討建議，接續於委員會例行會議辦理主題性研討會，並取得會員同意於本年 6 月 13 日辦理風險評估主題性研討會（議程如附件 1）。

「風險評估」主題性研討會係由我國於去（105）年 11 月召開之 TBT 委員會第 70 次例會提案，續經 2 次非正式會議討論及本年 3 月第 71 次 TBT 例會通過後辦理。本次研討會共有來自歐盟、印尼、美國（2 人）、中國大陸及我國 6 名講師逾 150 人參加，會議主持人則由新任主席 Mr. Jose Manuel Campos（智利籍）擔任。各國講師大多介紹該國風險評估在法規作業之角色，以及特定類別產品之風險評估方式。

我國由本局侯技士建綸簡報本局風險評估制度，並以我國列檢電動車電池案例作為經驗分享。研討會主持人於總結時說明風險評估與 TBT 委員會各項工作息息相關，並建議 TBT 委員會應繼續探討此議題。會後，哈薩克代表親自向侯技士致意，表示簡報內容對於該國法規主管機關進行風險評估實務作業極有幫助，並索取簡報電子檔。

▲「風險評估」主題性研討會辦理情形。（圖中左一為本局侯技士建綸、左二為美國代表 Mr. Denial Reese、左四為智利籍會議主持人 Mr. Jose Manuel Campos；右一為印尼代表 Mr. I Nyoman Supriyatna、右二為歐盟代表 Mr. Pablo Neira。圖片來源：WTO 官方網站，來源網址：https://www.wto.org/english/news_e/news17_e/tbt_20jun17_e.htm）

茲摘要主題研討會各國講師簡報重點如下（簡報資料如附件 2）：

(一)「歐盟之風險評估及符合性評鑑程序的選定」（Risk Assessment and the Choice of Conformity Assessment Procedures in the EU）：

本題目由歐盟代表 Mr. Pablo Neira 主講，渠解釋風險評估在歐盟法規程序上之運用。歐盟風險評估之基本準則係依比例原則及預防性原則，歐盟執委會基於高規格保護健康、安全、環境及消費者保護之目的，依據「歐盟運作條約」（Treaty on the Functioning of the European Union）第 114（3）條提出法案。然歐盟條約中並未提供任何有關如何執行風險評估之指引，而歐盟執委會訴訟案件 T-70/99 中，美國生物製藥公司 Alpharma 建議執行風險評估兩項要點為：（1） 判定何種程度的風險為不可接受，並涵蓋政策決定於其中；（2） 以科學評估風險性。根據該案件，該科學的風險評估必須使主管機關能夠：（1） 確定是否情況已超出社會可接受的風險程度；（2） 得以選擇何種適當且必要的措施以避免風險實際發生。有關歐盟之衝擊影響評估（impact assessment），將於執委會提出可能具有重大經濟、環境或社會影響之規定時執行，其包含以下

幾項評估：(1) 議題為何以及為何該議題發生問題；(2) 為何歐盟應涉入；(3) 欲達成之目標；(4) 達成目標之多種方法；(5) 經濟、社會及環境衝擊以及受影響的對象；(6) 比較不同方法之效用及效率（效益及成本)；(7) 如何規劃後續之監測及評估。有關符合性評鑑程序部分，歐盟決議第 768/2008 號列出依風險等級及安全需求選擇程序之準則。該等準則包含產業型態及規模、產品科技複雜度、製程類型及重要性、產品類型之適合性、涉及的風險性質、符合性評鑑程序就風險之類型和程度的相對性。總結歐盟經驗顯示：(1) 在確保合理兼顧前市場及後市場管制措施時，應可達成相當的保護程度；(2) 運用良好法規作業（good regulatory practices)及工具，以決定管制之必要性及符合性評鑑程序；(3) 任何類型的符合性評鑑程序皆需要適當程度的後市場監督措施；(4) 法規目標應能有效分配私部門及公部門資源。

(二)「前市場風險管理機制」(Risk Management in Pre-Market Inspection)：

本題目由本局侯技士建綸代表主講，解釋在商品檢驗法之檢驗制度下本局如何執行風險評估。商品檢驗法管理有四大類商品：消費性商品、電機類商品、機械類商品及電子類商品。本局執行前市場檢驗、邊境管制措施以及市場監督作業。依商品風險性適用不同檢驗方式：逐批檢驗、型式認可逐批檢驗、監視查驗、驗證登錄及符合性聲明，其中逐批檢驗適用於高風險商品、符合性聲明則是用於低風險商品，而對於中風險商品，製造商則可有多種選項。在本局商品安全架構下，風險評估涉及於下列階段：(1) 管制及訂定標準；(2) 前市場管制；(3) 邊境管制措施；(4) 市場監督；(5) 罰則。在管制階段，本局訂有商品實施檢驗及廢止作業程序，其中：(1) 零階評估表決定是否新產品應實施檢驗；(2) 一階評估表決定應施檢驗商品之檢驗方式。零階評估表方面，潛在風險因子係由本局專家團隊判定，並運用層級分析法（analytic hierarchy process）以比較問卷調查（comparative survey）方法來決定各風險

因子之權重；另執行額外問卷調查以得出風險評估分數是否高於管制門檻分數，以決定是否該商品應實施檢驗。簡報以電動機車充電器為例，介紹該風險評估程序如何執行。由經驗觀察得當不同社會議題之演進，對於風險因子而有不同看法，因而影響風險評估之結果。因此，判定出風險之重要因子並納入評估當中係為關鍵。

(三)「印尼電機電子類商品之風險評估（Risk Assessment for Electrical and Electronic Product in Indonesia）：

本題目由印尼代表 Mr. I Nyoman Supriyatna 主講，描述印尼電機電子類商品之風險評估機制。渠解釋印尼工業部 2009 年第 86 號法規建立印尼國家標準實施程序。個別法規草案應依下列分析程序，包括：（1） 效益及風險分析；（2） 製造商及符合性評鑑機構是否具能力執行；（3） 決定符合性評鑑程序及工廠檢查作業；（4） 決定市場監督作業，並當印尼工業部發布管制措施，該草案將會通知 WTO。目前印尼工業部就國內外製造業者共實施 14 項電機電子商品強制性標準及檢驗規定。印尼對於不同電機電子商品分配風險評估分數，風險等級由中風險至高風險。渠指出會員對於同項商品具不同之評估風險，而部分會員認定電機電子類商品為低風險等級商品。因此，印尼建議委員會探求對於高風險及低風險商品之國際定義。

(四)「美國食品藥品監督管理局訂定技術性法規之風險評估及市場監督經驗」（FDA's Experience with Risk Evaluation and Marketplace Monitoring in Developing Technical Regulations）：

本題目由美國代表 Mr. Denial Reese 主講，渠指出美國食品藥品監督管理局（FDA）之任務為保護公眾健康以避免受各類風險影響，涵蓋食品安全（SPS）與營養政策以及標示規定（TBT）。美國 FDA 積極協助消費者維持健康飲食以及防止肥胖，包含經由食品標示規定以引領改進食品之成份。各類科學根據指出心血管疾病與攝取反式脂肪之關聯性，因此美國 FDA 於 2003 年強制規定反式脂肪之標示，並且於 2015 年廢止部份氫化油（partially hydrogenated oils）

之「一般認定是安全」(Generally recognized as safe, GRAS)聲明。渠說明大部分食品的納含量仍舊偏高,即使業界已有努力,並且納含量與高血壓和中風具關連性。美國 FDA 已發布「自願性鈉含量降低目標指引」草案,目前正評估考量收到的評論意見。為確保消費者具備資訊以做出健康的選擇,依政策優先目標,美國 FDA 更新食品包裝營養標示(Nutrition Facts Label)以達成:(1) 強調卡路里數值;(2) 較實際反映份量(serving sizes)標示;(3) 除總含糖量外聲明添加糖(added sugars)含量;(4) 每包裝之卡路里及營養成份標示。

(五)**「工業控制系統之資訊安全風險分析」(Information Security Risk Analysis of Industrial Control System):**

本題目由中國大陸代表 Dr. XIAO Junfang 主講,渠強調工業控制系統(ICS)之網路安全風險嚴重性及其增長,尤其該系統係廣泛運用於能源、電力、飲水,以及關鍵製造及通訊基礎設施。ICS 面臨多數資訊安全之漏洞,並且因駭客能夠簡單辨識 ICS 並可經由線上開源社群之分享資訊,運用其安全漏洞,使得發動 ICS 網路攻擊之難度逐漸降低。目前影響 ICS 網路安全的事故案件有上升的趨勢,渠亦舉國際上一些重要能源、電力及通訊基礎設施之攻擊事件為案例說明。另外,勒索軟體的威脅亦也逐漸形成風險。因此,在互聯頻繁的世界中,傳統資訊科技安全架構已未能充分確保 ICS 的安全,不僅因 ICS 之高性能的需求,更尤其係具有關鍵基礎建設停機之重大風險性。業界通常低估 ICS 之安全需求,並且對於安全危害性不夠重視。國家工業信息安全發展研究中心(隸屬中國大陸工業及信息化部)因而執行 ICS 之風險評估、模擬測試、威脅監測以及技術研究,並且尋求與其他會員在標準發展領域的合作以及資訊和技術交流。

(六)**「美國國家標準技術研究所之網路安全架構發展」(The United States Cybersecurity Framework Developed by the National Institute of Standards and Technoloy):**

本題目由美國代表 Mr. Timothy Wineland 主講，渠簡介美國國家標準技術研究所（NIST）與私部門、技術專家及公部門合作發展之網路安全架構。該網路安全架構源於 2013 年之行政命令，後續於 2014 年制定「網路安全強化法案」（Cybersecurity Enhancement Act）。該網路安全架構係協助各類型組織建立降低網路安全風險方案的一套自願性及彈性的工具，並著重於 16 項關鍵基礎建設部門，亦認知網路安全係一共同責任，並非由政府或企業單獨能夠解決的議題。因網路安全議題之專家、智庫以及技術專家主要來自於受網路安全威脅影響之企業部門內，爰該網路安全架構係在與業界緊密的合作下推動與設計。該架構係以遞迴模式建構，並執行廣泛的利害關係人協商，多達 3,000 名業界、學界及政府的專家參與其發展過程，其並非特定標準清單或法規要求，而是一套動態納入業界使用標準的文件，並強調運用國際標準。該架構協助組織判定其與合作夥伴、廠商及供應商之依賴程度，並使得組織能夠於業界或部門中溝通及協調網路風險管理，其目的在於找出網路安全風險管理之最佳方案，並轉化為能夠廣泛於業界應用之一般性準則，其網路安全風險管理包含 5 項功能，包含判定、偵測、防護、回應及復原。渠進一步解釋該網路安全架構非屬法規制度，而是一套標準化語言及基準以供主管機關表達任何必要的管制需求，在自願性的運作之下，處理法規訂定耗時而未能跟上技術及威脅的問題，使得該自願性指引及私部門專家能夠更迅速回應科技上所面臨之挑戰與變化。

有關明（107）年召開 TBT 委員會及第 8 次三年總檢討預定時程（詳附件 4 及附件 5）部分，美國代表發言認為明年 6 月需討論完畢所有會員提交之實質建議，恐議程有所緊迫；歐盟代表亦發言支持美國之意見。WTO 秘書處則表示第 8 次三年總檢討之預定時程（詳附件 5）當中，已預定本年 11 月 7 日至 9 日召開之 TBT 委員會中討論會員之實質建議，並預定於明年 3 月間及 6 月間再次討論，建請會員提早送交建議案，避免在接近截止日前（明年 6 月 1 日）提送，俾會議順利討論與進行。

參、 106 年 6 月 14 日至 15 日 TBT 委員會正式會議紀要

一、 會議主要根據 JOB/TBT/233（詳附件 6）之議程進行，主要聚焦討論特定貿易關切議題，經加拿大撤銷對歐盟化學品(REACH)(第 10 案)、韓國撤銷對中國大陸嬰兒及成長奶粉配方註冊 (第 35 案)、墨西哥撤銷對哥倫比亞玩具及其零組件測試需求(第 49 案)及美國撤銷對多明尼加進口鋼筋檢驗 (第 56 案)之關切案；另歐盟新增阿拉伯聯合大公國電子產品案，加拿大新增美國乳酪標準案及奶油標示案，本次計有 56 件特定貿易關切議題（新關切 9 件，延續關切 47 件，請參考附件 6）。

我國於本項議程「有機農業法」草案遭歐盟持續提出貿易關切：另中國大陸網路安全相關法規遭大量關切(第 1、2、5、6、14 及 50 案計 6 案，範圍涵蓋車聯網、民航網路、銀行及保險等所謂重要基礎設施)，詳細內容說明如下。至其他貿易關切案，則依據產品重要性及雙邊貿易量，於附件 7 摘要說明 18 件關切案（資通訊／電機／電子產品 3 件、化學品／玩具 6 件、醫療器材／化粧品／藥品／農產品 6 件、及其他 3 件)之討論情形。

(一) 我國「有機農業法」草案(G/TBT/N/TPKM/225, 225/Add.1-2)（附件 9）

我國行政院農業委員會農糧署於 2015 年 12 月 8 日提出「有機農業法」草案通知文件，2016 年 2 月 2 日通知會員延長評論期至 2016 年 3 月 31 日，並於 2016 年 3 月 15 日提供法規草案英譯本。通知文件發出之後，我國收到歐盟、印度、澳洲及美國之評論意見，關切重點包含(1)建議明確規定實施範圍（如食品、飼料、加工產品、生產資材）及生產階段（如：初級、加工、配送、零售）；(2)草案第 37 條規定於 1 年內建立同等性協定過於倉促，建議延長時限或於 1 年內要求各國開啟與臺灣有機同等性討論，但不限於 1 年內完成協議簽署；(3)建議對禁用物質設定容許量（符合食品法典規範之環境殘留物容許標準），採以 MRL 為容許量（基因改造物質除外），以免禁用物質殘留原因超出有機農產品經營業者可控制範圍。

歐盟於 2016 年 6 月 TBT 委員會正式會議開始對我國提出特定貿易關切，本次會議持續提出 STC，除感謝近期雙邊會議外，重申前述第 2 項關切，請我考量對於單向採認同等性國家同歐盟一樣提供 5 年之緩衝期，另請我提出實施辦法供評論及希望瞭解最新進展。

我國回應感謝歐盟的意見，說明「有機農業法」草案目前尚在行政院審查，有關歐盟希望延長與我國完成簽定雙邊有機同等性相互承認協議或協定之 1 年過渡期，將併同與其他會員意見謹慎考量；我國歡迎有興趣的會員與我國展開有機同等性雙邊討論或協商，使得有機農產品可以在法規生效後立即受惠。有關於產品及生產階段範圍，草案第 3 條有載明其定義；該草案係為基本架構性條文，未來實施管理辦法將待法規草案通過後提出供評論。此外我國已經且將持續與歐盟就此議題進行密切雙邊溝通討論，特別我主管機關農委會農糧署已在最近 6 月間與歐盟雙邊會談中提供許多詳細具體資料。（我國回應說明如附件 10）

(二) 中國大陸網路安全相關法規

本次會議 1/3 以上新 STC 關切網路安全議題，在美、加、歐、日等主要關切該等措施具有許多不確定法律概念(如何謂關鍵基礎設施之範圍)、對 ICT 產品造成貿易障礙、歧視外商企業及科技，並可能造成商業機密及科技資訊不必要的揭露；反之陸方則表示相關措施目的關係國家安全議題及保護消費者隱私，合乎 WTO 不歧視規範，並認為該等措施非屬 TBT 議題。相關關切及回應事項彙整如下：

編號	產品/措施	關切重點	關切會員	回應重點
1	網路產品和服務安全審查辦法	1.定義產品範圍 2.定義所謂安全及可控制的服務及產品“secure and controllable services and products” 3.不可藉防範網路攻擊及保護消費者個資而歧視外國產品及服務	歐盟 美國 日本 加拿大 澳洲	1.保護國家安全 2.非針對特定會員也非歧視外國產品 3.因保護網路產品安全而增加消費者信心
2	密碼法修正	1.依國際慣例及標準、非歧視原則 2.不要求製造商提供機敏及受保護資訊，如密碼金鑰或程式原始碼	歐盟 日本 美國 加拿大	1.對改進網路安全具重要性 2.對各會員國意見會列入考量
5	車聯網網路安全防護指南	1.歧視外國科技及廠商、造成不必要貿易障礙、限制資訊需在地化要求 2.部分條文未清楚定義、範圍不明確 3.要求通知 WTO 並提供緩衝期 6 個月以上	美國	1.保護消費者隱私及促進公平競爭 2.由獨力工業組織所發展，係屬自願性

6	民航網路資訊安全管理規定	1.對民航 ICT 設備要求“安全及可控制”，可能被解讀為需採購國產 ICT 產品 2.因可能會限制使用最先進科技，爰請中國大陸暫緩實施	美國 歐盟 加拿大	請相關會員國再具體說明關切事項，俾帶回供主管機關研議
14	1.資訊安全產品 2.銀行資訊科技設備安全法規 3.保險之資通訊科技規定	1.依國際慣例及標準、非歧視原則 2.要求相關修正情形要通知 WTO 3.釐清公安部現行多層保護計劃 (Ministry of Public Security's existing Multi-Level Protection Scheme, MLPS)與網絡安全法關係	歐盟 加拿大 日本 美國 澳洲	1.將秉持公平及公開原則，聽取各會員國意見 2.網絡安全法為基本法，MLPS 將轉型，相關銀行、保險等系統都要符合該法
50	網絡安全法	1.對“安全及可控制”定義不明確，可能被解讀為需採購國產品 2.其國家資訊安全標準技術委員會(National Information Security Standardization Technical Committee, TC 260)發展之相關標準是否會被法規引用為強制性，是否通知 WTO 提供 60-90 天評論期及至少 6 個月以上緩衝期	美國 歐盟 日本 加拿大 澳洲	1.說明法規主要規範設備安全、網路操作安全、網路資料安全及網路資訊安全 2.安全及可控制指(1)不得違法收集使用者資料；(2)不得違法控制使用者設備；(3)不得藉由使用者信賴獲取獨占非法利益，如無正當理由撤銷安全技術支援而迫使使用者升級產品或服務

反之中國大陸關切其資訊安全產品廠商無法獲歐盟會員國 CC(Common Criteria)評估及認可機構接受其申請取得 CC 證書，及參與 CC 相關的標準化組織。(STC 第 27 案)

歐盟回應歐盟或其會員國沒有規定進入市場須強制符合加密標準或符合性評鑑程序，因此不屬於 TBT 協定規範範圍，至於個別公司為確保在其系統或網路間安全傳送資訊，可自行要求符合其需求的資安設備，屬個別商業行為，中國大陸關切的 CC 證書是自願性，且已有中國大陸廠商拿到評估保證等級(Evaluation Assurance Level, EAL)4 證書。

二、協定之履行與管理

有關會員國依據TBT 協定第15.2 條提出入會履行協定之行政措施一次性通知已彙整於 G/TBT/39/Rev.1。自 1995 年迄今已有 138 個會員至少提出 1 次聲明，鼓勵尚未進行通知之會員儘速辦理是項通知。有

關會員查詢單位之資料可於 TBT 資訊管理系統(TBT IMS)線上取得。

三、經驗交換

有關 6 月 13 日召開之「風險評估」主題性研討會,主席 Mr. Jose Manuel Campos 總結認為風險評估係一個具多種面向的主題，並與 TBT 委員會的事務有不同層面之關聯性。使用風險評估協助符合性評鑑程序之選擇與設計為討論的重點之一。因此，研討會的簡報點出了商品風險等級及其符合性評鑑程序對應的重要性。參與簡報之會員亦分享評估風險的不同方式，包含定性與定量的方法評量風險等級。令人關注的則是會員進一步提出探索產品風險等級（由低風險至高風險）之國際性定義。另外，此研討會亦有會員分享如何應用風險評估指出如食品標示及網路安全等相關政策難題。主席表示相信風險評估議題係 TBT 委員會應持續反映並緊密連結於委員會的工作中。

三、技術合作活動

秘書處提供之 2017 年 TBT 技術協助活動，包括 TBT 特定之區域性、國家級及在日內瓦舉辦之研討會，另提供 E-Learning 線上課程給會員國政府官員參與，詳見附件 RD/TBT/225。

國際電工技術委員會（IEC）代表分享其 2017 年在葡萄牙舉辦的鄉村電氣聯盟(Alliance for Rural Electrification, ARE)能源投資論壇,其目標是在 2030 年前把電帶給大家，詳見附件 RD/TBT/224；另有國際度量衡局（BIPM）及國際法定計量組織（OIML）代表分享其 2017 年技術合作活動。

四、觀察員活動報告及資料更新

世界衛生組織（WHO）及國際食品法典委員會（Codex Alimentarius Commission, CAC）報告近期食品標示(營養標示、原產地標示等)、嬰兒配方、食品添加物活動,另聯合國糧農組織(FAO)、WHO 及 CODEX 於 2016/1/1 成立為期 12 年的基金以支持會員國發展食品安全（詳如附件 G/TBT/GEN/222 及 223）。

聯合國歐洲經濟委員會（UNECE）報告其第 6 工作小組發展關於技術法規、標準政策及有關品質基礎建設、符合性評估及市場監督的良好規範；聯合國工業發展組織（UNIDO）則於 2016 年底出版“國家品質政策發展指南”建立國家度量衡、標準化、認證及符合性評估基礎建

設以促進國際貿易（詳如附件 G/TBT/GEN/224 及 225）。

目前計有 24 個國際政府間組織已成為觀察員，另有 5 個要求成為觀察員待通過之最新名單已彙整於 G/TBT/GEN/2/Rev.12。

五、下次會議日期

有關下次會議議程安排，訂於 2017 年 11 月 8-9 日召開本年度 TBT 委員會第 3 次例會，並於會前 11 月 7 日舉辦主題性研討會。

肆、 檢討與建議

一、 主動研提 TBT 主要關切議題，積極參與經驗分享

本次風險評估主題研討會係由我主動於第 70 次會期中提出，並指派本局第三組技術專家侯技士建綸擔任講師分享本局「前市場檢驗風險評估」經驗。觀諸本次研討會因分為 2 大次主題（商品安全風險及網路安全風險），致簡報後發言問題多偏向新興之網路安全議題，另歐盟、美國等不得已臨時由貿易代表人員(DG Trade、USTR)代原訂專業部門講師(DG ENTR、國土安全部)主講產品及網路安全議題，也會影響簡報效果，惟本局用心準備會議資料及由專家講授則獲與會人員支持，其中哈薩克代表會後更向我索取簡報資料，表示有興趣學習本局作法。

二、 積極運用 TBT 委員會及雙邊諮商機制，維護我國廠商對外貿易利益

TBT 委員會例會，已成為進行特定貿易關切(STC)最主要之場域，各會員國透過 TBT 協定條文攻防，希望能結合有共同利益之會員一起發言，藉由群體力量迫使關切的措施能夠放寬或修改，減少其廠商對外貿易障礙。由於時間有限，在一輪發言表達關切及回應意見後，如有必要釐清相關細節，可再輔以雙邊諮商，以獲取所需的進一步說明及資料。

我國為世界前 20 大貿易國，並在 WTO 享有正式會員資格，應多利用 WTO 場域進行特定貿易關切及雙邊諮商，爭取貿易夥伴國檢討改善不合理規定、簡化符合性評鑑程序，以及提供充足之法規調適期，以降低我廠商產品出口成本、節省時間及有充分時間適應出口國規定。

三、 加強教育宣導 TBT 協定之功能，鼓勵並協助業者提出關切意見

由於 TBT 議題涵蓋各主管機關，為協助產業界掌握各國主管機關之相

關技術性法規動態，及早採取因應措施，透明化議題一直是 WTO 關切重點，從 2014 年建置公開的 TBT 資訊管理系統(TBT IMS)到新建置的 ePing (TBT 部分)，提供使用者可利用網站篩選器訂閱指定類別(產品、國家)之通知文件及討論區，方便彙整國內意見。

為此，我國已申請 TBT 國家級研討會並獲同意於今(106)年 9 月在台舉辦,藉參加會議期間與預訂講師 Mr. Erik Wijkstrom 參事討論會議安排事宜，以法規及實務課程，期與我公私部門均能充分交流互動，宣導 TBT 查詢單位的功能及服務內容,並瞭解業界可能的需求,形成有效運作的機制，確實為保障我國業者權益發聲。

四、 掌握國際關切議題重點，深入研究分析妥善因應

TBT 協定第 2.2 條載明各國技術性法規可在合法目的及不造成不必要之貿易障礙間取得平衡，近年來阻止他國有樣學樣的著名案例為菸品素面包裝案,在進入爭端解決機制後,我國「菸害防治法」修正草案，亦經印尼表達希望等待相關案例裁決結果後再來檢討的關切意見。

本次會議有一值得觀察網路安全議題，除於風險評估主題研討會區分以網路安全為主題之簡報外，另有為數頗多中國大陸網路安全相關法規遭美、歐、日等國關切及陸方認為該等措施非屬 TBT 議題之兩極意見。本議題本局已整理各會員國關切內容，函請我國全國工業總會及電機電子工業同業公會協助蒐集相關業者意見；未來有必要持續關切本議題發展，尋求相關主管機關分析因應，必要時亦可在大會發言表示關心及想參與收集各多資訊意見。

附件 1

RESTRICTED

JOB/TBT/232/Rev.1

12 June 2017

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Committee on Technical Barriers to Trade

THEMATIC SESSION ON RISK ASSESSMENT

13 JUNE 2017, 10:00

Programme

Revision

At the Seventh Triennial Review, Members agreed to continue to hold thematic sessions in conjunction with regular meetings of the Committee.[1] Members agreed to dedicate the 13 June 2017 thematic session to the topic of risk assessment. In the interest of giving sufficient opportunity for interaction, speakers are invited to make succinct presentations. The moderator will give opportunity for questions and interventions from the floor.

This thematic session will be moderated by: **Mr. José Manuel Campos (Chile)**

a. **EU:** *Risk Assessment and the choice of conformity assessment procedures in the EU* (Ms Nike Boennen) (JOB/TBT/226)

b. **Chinese Taipei:** *Risk Management in Pre-Market Inspection* (Mr. Chien-Lun HOU) (JOB/TBT/228)

c. **Indonesia:** *Implementation of Risk Assessment in Indonesia* (Mr. I Nyoman Supriyatna, Deputy Chief of National Standardization Agency of Indonesia) (JOB/TBT/229)

d. **United States:** *FDA Experiences in Appraising Risk for the Rulemaking Process, and in the Evaluation of Health Claims* (Mr. Daniel Reese, International Policy Analyst, US Food and Drug Administration) (JOB/TBT/230)

e. **China:** *Security risks of network products, information and communication technology and industrial control system* (Dr. XIAO Junfang, Electronic Technology Information Research Institute, Ministry of Industry and Information) (JOB/TBT/227)

f. **United States:** *The United States promotes a risk-based approach to enhance the security and resilience of critical infrastructure and to maintain a cyber environment that encourages efficiency, innovation, and economic prosperity while promoting safety, security, business confidentiality, privacy, and civil liberties. Together with the private sector, the United States Government developed the Cybersecurity Framework to help manage cybersecurity-related risk.* (Mr. Timothy Wineland, Deputy Assistant USTR for China Affairs) (JOB/TBT/231)

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[1] G/TBT/37, para. 8.3.

附件 2

RESTRICTED

RD/TBT/220*

12 June 2017

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WORLD TRADE ORGANIZATION
ORGANISATION MONDIALE DU COMMERCE
ORGANIZACIÓN MUNDIAL DEL COMERCIO

Committee on Technical Barriers to Trade Original: English/anglais/inglés

UNOFFICIAL ROOM DOCUMENT[1]

THEMATIC SESSION ON RISK ASSESSMENT

INFORMATION SECURITY RISK ANALYSIS OF INDUSTRIAL CONTROL SYSTEM

Dr. XIAO Junfang (China)

Comité des obstacles techniques au commerce

DOCUMENT DE SÉANCE NON OFFICIEL[1]

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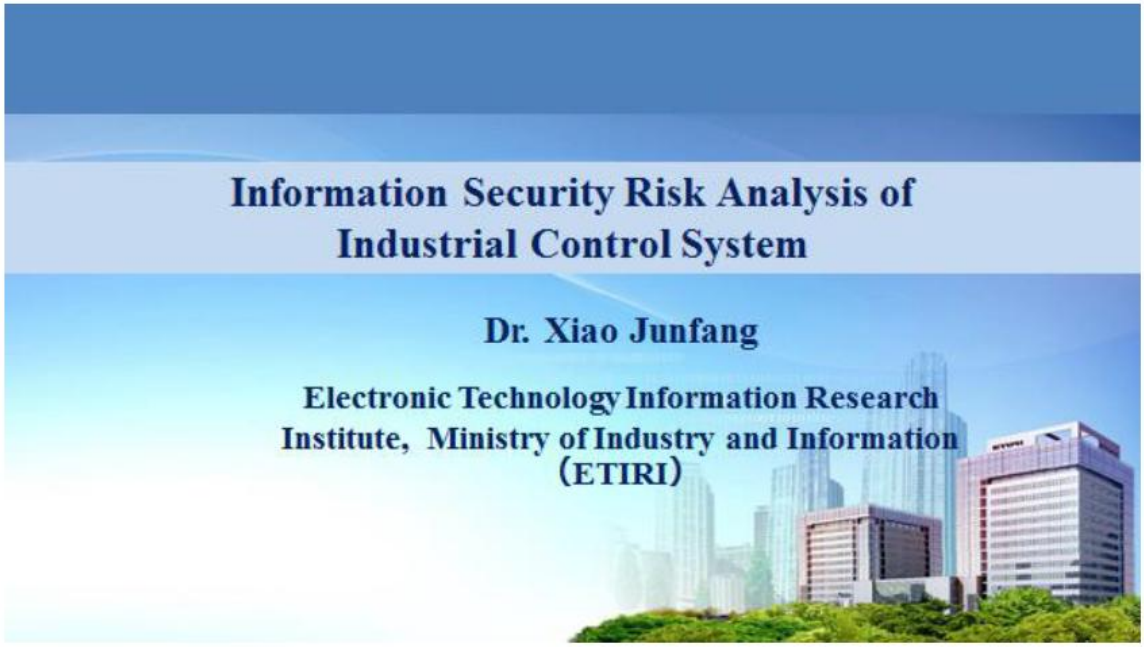


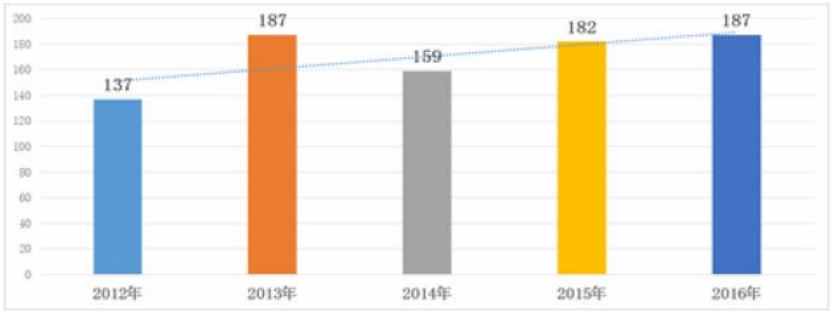
- Information Security Situation of Industrial Control Systems
- Information Security Risks of Industrial Control Systems
- Suggestion of Strengthening the Security of Industrial Control Systems

ETIRI

Information Security Situation of Industrial Control Systems

ETIRI

1. The number of vulnerabilities remains high, and the attack difficulty is decreasing



Source from ICS-CERT

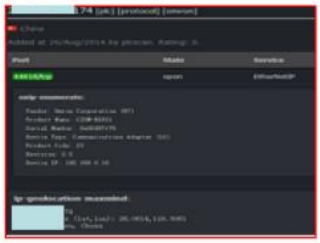
ETIRI

1. The number of vulnerabilities remains high, and the attack difficulty is decreasing

Hackers can find industrial control systems with the following three ways at least:

1. Search through google and other web search engines.

2. Search through host search engine such as Shodan.



3. Match the network fingerprint characteristics on private protocol and port for industrial control communication through online monitoring platform.

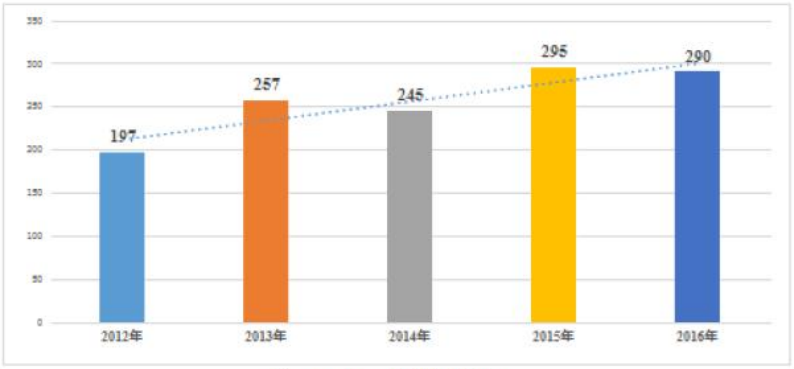
ETIRI

1. The number of vulnerabilities remains high, and the attack difficulty is decreasing

github
SOCIAL CODING

ETIRI

2. Industrial Control System Information Security incidents are frequent, and the scope of influence is wide



Source from ICS-CERT

ETIRI

2. Industrial Control System Information Security incidents are frequent, and the scope of influence is wide

In 2010, the virus Stuxnet attacked the Bushehr Nuclear Power Plant in Iran

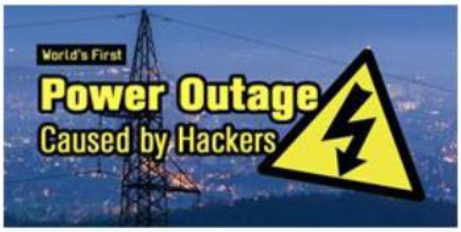
In 2011, the virus Duqu attacked the energy industries in the Middle East and Europe.

In 2012, the energy industry in the Middle East was infected with the virus Flame.

In 2014, the energy industry in Europe and America was infected with the malware Havex.

ETIRI

2. Industrial Control System Information Security incidents are frequent, and the scope of influence is wide



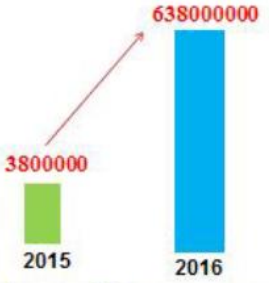
Ukrainian power grid blackout by "blackenergy"

half of the US Internet down by DDoS attack

ETIRI

3. The ransomware attack against industrial control system is worth paying attention

The number of recorded ransomware families largely **increased by 748%.**



The number of traceable ransomware attacks

ETIRI

3. The ransomware attack against industrial control system is worth paying attention

In 2016, the subway system in San Francisco was attacked by blackmail software.

In 2017, a global large-scale "Wannacry" infection incident occurred.

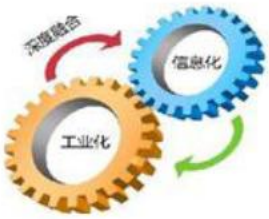
In the future, ransomware attacks are very likely to influence the industrial control system.

ETIRI

Information Security Risks of Industrial Control Systems

ETIRI

1. The connection of ICS to Internet has become prevalent, and the traditional information security threats continue to penetrate into ICS



ETIRI

2. The traditional information security protection mode is difficult to protect the ICS security effectively

- characteristic of IT security: Confidentiality, integrity, availability
- IT security protection mode is no longer applicable

ETIRI

3.The security protection means of industrial control system are required to meet the system's characteristics of high availability and real-time performance

The industrial control systems in petroleum refining, power and other sectors with automatic process should run continuously for **7*24 hours.**

ETIRI

4. Enterprises' consciousness of industrial control system security is weak and their management and protection capabilities are not enough

Weak consciousness

Lack of Management mechanism

ETIRI


Suggestion of Strengthening the Security of Industrial Control Systems
We do
Risks Assessment
Simulation Test
Threat Monitoring
Technical Research
We hope
Standard development
Technical exchanges
Information sharing
Fight against cybercrime
ETIRI


THANK YOU
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WORLD TRADE ORGANIZATION
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RD/TBT/222*

12 June 2017

Page: 1/17

Committee on Technical Barriers to Trade

UNOFFICIAL ROOM DOCUMENT[1]

THEMATIC SESSION ON RISK ASSESSMENT

RISK ASSESSMENT AND THE CHOICE OF CONFORMITY ASSESSMENT PROCEDURES IN THE EU

Nike Bönnen (European Union)

Comité des obstacles techniques au commerce

DOCUMENT DE SÉANCE NON OFFICIEL[1]

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Outline

- Legal Basis for Risk Assessment in the EU regulatory process
- Risk assessment as part of Impact Assessment
- Example of Risk Assessment for industrial products covered by New Legislative Framework

Basis for EU legislation

- Precautionary principle
- Proportionality

Article 114(3) of the Treaty on the Functioning of the European Union (TFEU)

"The Commission, in its proposals [...] concerning health, safety, environmental protection and consumer protection will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective"

Article 2(2) of the WTO Agreement on Technical Barriers to Trade (TBT)

"[...] Technical regulations shall not be more trade restrictive than necessary to fulfil a legitimate objective, taking account of the risks that non-fulfilment would create. Such legitimate objectives are, *inter alia*: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment. In assessing such risks, relevant elements of consideration are, *inter alia*: available scientific and technical information, related processing technology or intended end-uses of products"

Article 5.1.2 of the WTO TBT Agreement – Conformity Assessment

"[...] conformity assessment procedures shall not be more strict or be applied more strictly than is necessary to give the importing Member adequate confidence that products conform with the applicable technical regulations or standards, taking account of the risks non-conformity would create"

How to conduct risk assessment?

- **Article 114(3) TFEU – no guidance**
- **Case T-70/99-Alpharma** (judgment of the Court of First Instance of 11.9.2002 – on use of antibiotics as additives in feedingstuffs):

Case T-70/99-Alpharma

- This case confirms **the need to conduct a risk assessment when regulating risks**
- "Risk assessment includes for [...] Community institutions, a twofold task [...] :
  1. **determining what level of risk is deemed unacceptable and,**
  2. **conducting a scientific assessment of the risk"**

Alpharma, paras 175, 176:

"If it is not to adopt arbitrary measures which cannot in any circumstances be rendered legitimate by the precautionary principle, the competent public authority must ensure that any measures that it takes, even preventive measures, are based on as thorough a scientific risk assessment as possible"

Cont'd

" The scientific risk assessment must enable the competent authority to ascertain, on the basis of the best available scientific data [...] whether matters have gone beyond the level of risk that it deems acceptable for society [...] "

Cont'd

A scientific risk assessment must also enable the competent authority to decide in relation to risk management, which measures appear to be appropriate and necessary to prevent the risk from materialising [...]

Examples:

- Regulatory authorities: categorization or classification (examples machinery, medical devices)
- Manufacturer: risk assessment and technical documentation
- Market Surveillance officers – Articles 19 and 20 of Regulation 765/2008 - accident reporting

Impact Assessment–Drafting Legislation

COMMISSION STAFF WORKING DOCUMENT Better Regulation Guidelines COM (2015) 215 final - Impact Assessment Guidelines

- **gathering and analysing evidence to support policy making**
- **informed decision-making**
- respecting the principles of subsidiarity and proportionality
- **What? - Commission initiatives that are likely to have significant economic, environmental or social impacts** (thus both legislative and non-legislative initiatives as well as delegated acts and implementing measures)

Questions an Impact Assessment Should Answer

- *What is the problem and why is it a **problem**?*
- *Why should the EU act?*
- *What should be achieved?*
- *What are the various **options** to achieve the objectives?*
- *What are their economic, social and environmental **impacts** and who will be affected?*
- *How do the different options **compare** in terms of their effectiveness and efficiency (benefits and costs)?*
- *How will monitoring and subsequent retrospective evaluation be organised?*

Impact Assessment

- Risk assessment and Risk management are part of IA
- Public consultation - 12-week internet-based public consultation - complemented by other approaches and tools in order to engage all relevant stakeholders and to target potential information gaps

Drafting Legislation

When preparing legislative proposals, the Commission may rely on the opinion delivered by relevant:

- Scientific committees managed by DG Sante on:
  - **Consumer Products (SCCP)**
  - **Emerging and Newly Identified Health Risks (SCENIHR)**
  - **Health and Environmental Risks (SCHER)**
- Specialised agencies (e.g. EFSA (food), ECHA (chemicals), EMEA (pharmaceuticals))
- Other scientific expertise (e.g. studies by independent experts)

Drafting Legislation - Cont'd

According to the scientific expertise received, the European Commission decides:

- whether action is needed or not
- if yes, the appropriate tool (Regulation, Directive, Decision, Communication, Guidelines, etc…) in order to deal and mitigate the risk

Drafting Legislation – Cont'd

The decision whether or not a product represents a serious risk shall be based on an appropriate risk assessment which takes account of the nature of the hazard and the likelihood of its occurrence.

Risk assessment in the context of legislation covered by NLF-New Approach

Successful example of task sharing between:

- regulatory authority
- standardisers
- manufacturers
- market surveillance authorities

Decision (EC) No. 768/2008

- Modernises conformity assessment modules
- Choice of **clear**, **transparent** and **coherent** conformity assessment procedures, restricting the possible variants
- Ensure **uniformity in the assessment** of conformity assessment bodies
- Ensure a **uniform high level of performance** of notified bodies throughout the EU

Conformity Assessment

- **Menu of modules**, enabling the legislator to choose a procedure from the least to the most stringent, in **proportion to the level of risk involved and the level of safety required**
- ISO/CASCO Toolbox
- Procedures divided into **8 different modules** (from manufacturer's declaration to full quality assurance certification)
- Range of options set in Directives
- All procedures give equivalent results: **presumption of conformity**

Criteria for the choice of the relevant conformity assessment procedure

General considerations:

- Proportionate and effective
  - economic infrastructure of the given sector (e.g. type and size of companies, complexity of product technology)
  - type and importance of production

Criteria set in Decision 768/2008:

- Appropriate to the type of product
- Nature of risk involved and correlation of the procedure to the type and degree of risk
- When 3rd party involvement is mandatory - manufacturer must be given the choice between quality assurance and product certification modules

Example on choice of SDoC
Restriction of Hazardous Substances

- the Impact assessment considered the risk involved with products
- then the benefits of SDoC vs. 3rd party assessment were considered in terms of mitigating the risks presented by the products in question, and the cost of each option
- the lightest possible conformity assessment procedure was chosen to reduce costs for manufacturers: SDoC

Example – on choice of 3rd party CA
Annex IV Machinery

- distinction between machinery as a whole and machines which present more serious hazards (Annex IV machinery when harmonised standards are not used)
- for the first category only conformity assessment with internal inspection applies;
- for the more **hazardous machines** - either adequacy in respect of harmonised standards, EC type-examination of the machine, or full quality assurance
- simplified procedure for machinery which presents no inherent risk to safety and health

RISK ASSESSMENT REQUIREMENTS ADDRESSED TO THE MANUFACTURER

Sectoral legislation covers the typical hazards/risks potentially present in relevant products by means of "essential requirements" aiming to ensure protection of health, safety, environment, etc...

- It is the obligation of manufacturers to establish the compliance of their products with relevant requirements of sectoral legislation (conformity assessment)

RISK ASSESSMENT REQUIREMENTS ADDRESSED TO THE MANUFACTURER Con't

OBLIGATIONS AFTER PLACING ON THE MARKET:

Decision No. 768/2008

"Where deemed appropriate with regard to the risks presented by a product, manufacturers shall, ... carry out **sample testing** of marketed products, **investigate, and, if necessary, keep a register of complaints** of non-conforming products and product **recalls** and shall **keep distributors informed** of any such monitoring"

Obligations to carry out corrective measures and to inform competent authorities.

RISK ASSESSMENT BY COMPETENT AUTHORITIES

Regulation (EC) No. 765/2008

Market surveillance authorities shall perform appropriate checks of products on the market on an **adequate scale** by means of documentary, physical and laboratory checks. They shall take account of the **established principles of risk assessment,** complaints and other information.

RISK ASSESSMENT BY COMPETENT AUTHORITIES – CONT'D

The decision whether or not a product represents a serious risk shall be based on an appropriate risk assessment which takes account of **the nature of the hazard** and the **likelihood of its occurrence**.

In this context market surveillance authorities need to take account of the risk assessment inherent in harmonised standards.

CONCLUSIONS

- EU experience shows that it is possible to attain a **high level of health, safety, environmental protection** whilst ensuring a **fair balance between pre-market and post-market controls**
- **Use Good Regulatory Practice principles and tools** (=> regulatory impact assessments) not only to determine the **need for regulation** but also in the **choice of conformity assessment procedures**
- Any type of conformity assessment procedure requires an **adequate level of post-market surveillance**
- Aim at an **efficient allocation of (private and public) resources** based on risk assessment and risk management considerations

More information

- Better Regulation and Impact Assessment:
  - http://ec.europa.eu/smart-regulation/index_en.htm
  - http://ec.europa.eu/smart-regulation/impact/index_en.htm
- Your Voice in Europe:
  - http://ec.europa.eu/yourvoice
- DG GROW – Free Movement of Goods:
  - http://ec.europa.eu/growth/single-market/goods/index_en.htm

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RD/TBT/227*

15 June 2017

Page: 1/10

Committee on Technical Barriers to Trade Original: English/anglais/inglés

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RISK MANAGEMENT IN PRE-MARKET INSPECTION

Chien-Lun HOU (Chinese Taipei)

Comité des obstacles techniques au commerce

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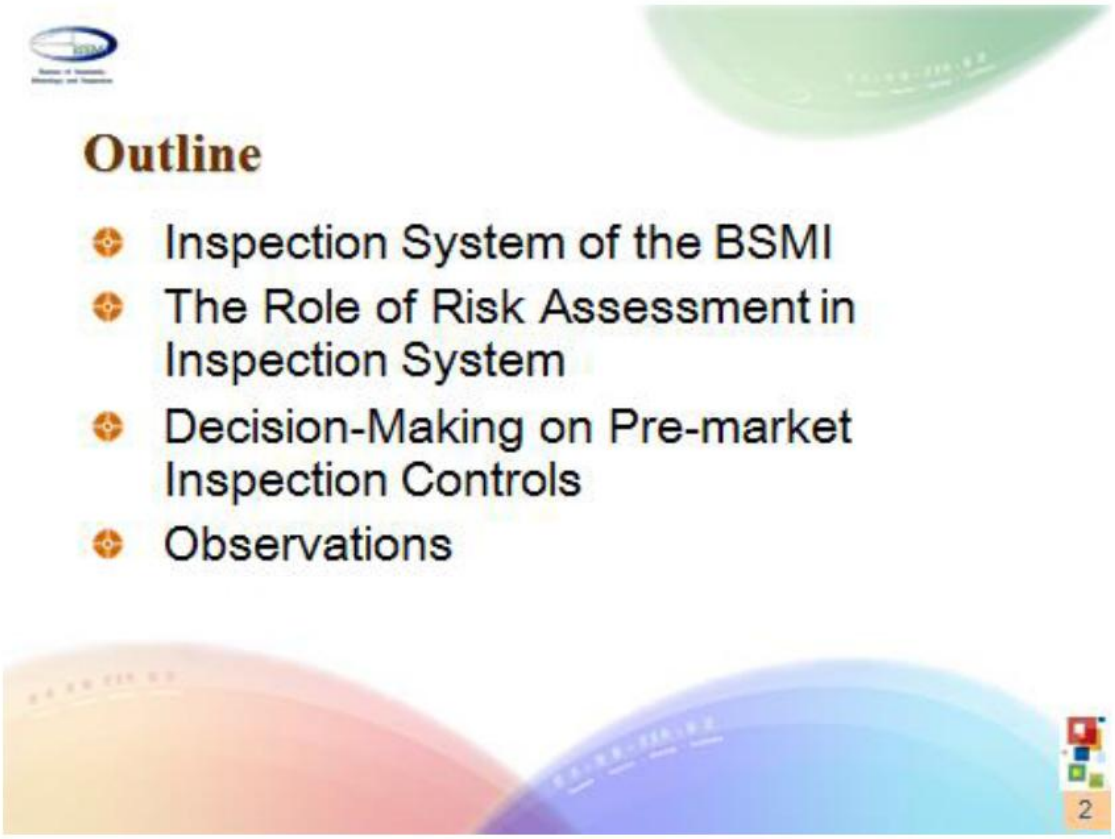
Risk Management in
Pre-Market Inspection
Chien-Lun HOU
Bureau of Standards, Metrology & Inspection, M.O.E.A.
13th June 2017
2017 WTO/TBT Thematic Session


Outline
Inspection System of the BSMI
The Role of Risk Assessment in Inspection System
Decision-Making on Pre-market Inspection Controls
Observations
2

Inspection System of the BSMI

- Basic law: The Commodity Inspection Act
- Scope:
  - consumer products
  - mechanical products
  - electrical products
  - electronic products
- Pre-market inspection: third-party testing/certification

  Conformity assessment procedures
  - Batch-by-Batch Inspection (BBI)
  - Monitoring Inspection (MI)
  - Registration of Product Certification (RPC)
  - Declaration of Conformity (DoC)
- Border and Customs Checks
- Market Surveillance

3

Conformity Assessment Procedures

High Risk

Low Risk

Inspection Scheme	Characteristics	Regulated Products
Batch-by-Batch Inspection (BBI)	• Applicable to **high-risk** commodities • Suitable for manufactured or imported customized products of SMEs • Per batch per certificate	Valves for high pressure gas cylinder, Baby walkers, Household pressure cooking pots, etc.
Type Approval Batch Inspection (TABI)	• Simplified BBI • Applicable to **medium-risk** commodities • With simplified procedures compared to BBI • Per batch per certificate • Some double-track with RPC	Household appliances, Handheld electric tools, Portable stoves, Fire-retardant paints, etc.
Monitoring Inspection (MI)	• Applicable to **medium-risk** commodities • With simplified procedures compared to BBI • Per batch per certificate • Some double-track with RPC	Toys, Cement, Gasoline, Diesel fuel, Butane, Tires, etc.
Registration of Product Certification (RPC)	• Applicable to **medium-risk** commodities • With type testing, quality management, or factory inspection requirements • Certificate is valid for 3 years, renewable	Household appliances, Loudspeakers, Laptops, Computers, Tablets, etc.
Declaration of Conformity (DoC)	• Applicable to **low-risk** commodities • Testing by designated laboratories is required, no needs for acquiring approval	Cash registers, USB drive, Hard-disks, CD-players, etc.

4

The Role of Risk Assessment in Inspection System

Risk Assessment at Different Stages of Product Safety Framework*

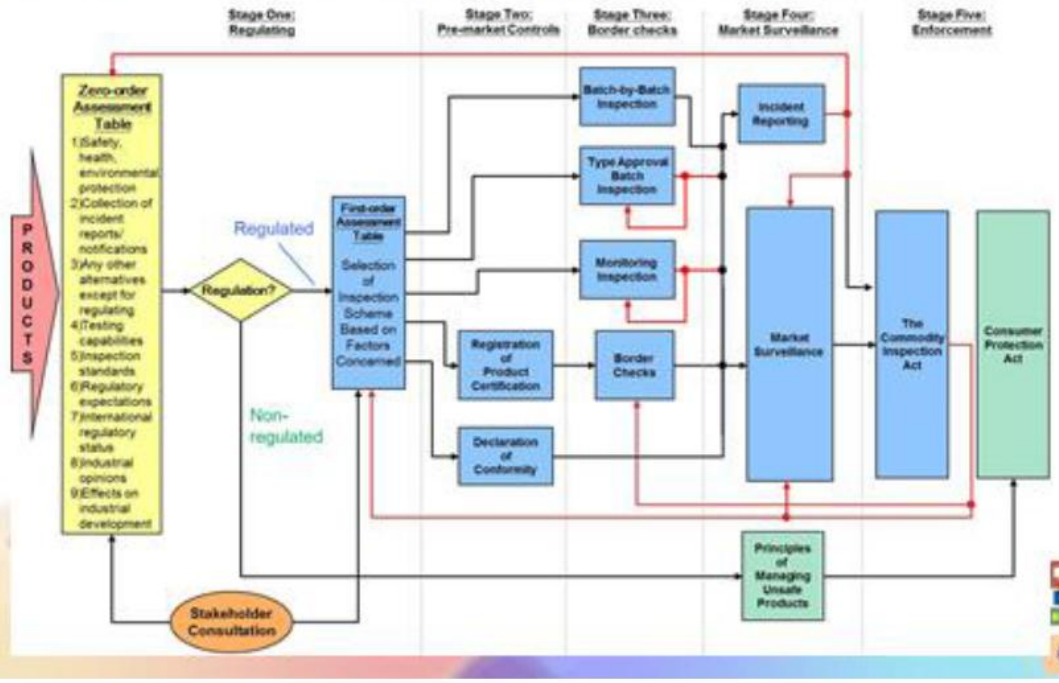
- Stage One – Legislating, Regulating and Setting Standards**
- Stage Two – Pre-market Controls
- Stage Three – Border and Customs Checks
- Stage Four – Market Surveillance**
- Stage Five – Enforcement**

* Reference: *Report on International Consumer Product Safety Risk Assessment Practices*, DSTI/CP/CPS(2015)13/FINAL, 20 September 2016, OECD

** Setting Standards, Stages Four and Five are not covered in this presentation

5

Risk Assessment in BSMI Product Safety Framework



6

Decision-Making on BSMI Pre-market Inspection Control

Stage One: Legislating, Regulating and Setting standards

- The criteria for identification of risks of hazard … the assessment procedure, analysis and application, as well as guidelines for other matters shall be prescribed by the competent authority. (Article 6 of the Commodity Inspection Act)
- Procedures of Implementing and Rescinding of Technical Regulations (Internal procedure)
  - Zero-order Assessment Table
    - To assist us in making decisions on whether a new product should be regulated
  - First-order Assessment Table
    - To assist us in making decision on what conformity assessment procedure should be selected for a regulated product
  - Case study: electric scooter chargers (pages 10-13)

7

Stage One: Legislating, Regulating and Setting standards

- Zero-order Assessment Table
  - Potential risk factors were identified by consultation with a group of experts from the BSMI.
  - **Analytic Hierarchy Process (AHP)** was used to give the weight of each risk factor(*) by conducting a comparative survey.
  - An additional survey was conducted to use the weighted Zero-order Assessment Table on non-regulated products to find out the distribution of scores and the threshold value for making decisions on whether a regulation is needed.
    - Threshold value = 44 (95% confidence interval)
      - Score > 44 : regulation is required
      - Score < 44 : regulation is not required

*The sum of weights on all risk factors is 100; the greater the risk, the greater the weight.

8

Stage One: Legislating, Regulating and Setting standards

- First-order Assessment Table
  - Potential risk factors were identified by consultation with a group of experts from the BSMI.
  - A questionnaire was established based on the risk factors with weights, determined by using qualitative analysis in accordance with AS/NZS 4360.
  - A survey was performed based on the questionnaire to establish discriminant function, by using Discriminant Analysis, for each conformity assessment procedure. Benchmarks were drawn from a number of regulated products from different categories.

9

Stage One: Legislating, Regulating and Setting standards

- Case study: electric scooter chargers
  - Background
    - Statistics show that there are more than 13.6 millions of scooters (motorbikes) registered in 2016, that is 91.5 scooters for every 100 people holding licenses.
    - Sound development of electric scooter industry is identified as prioritized environmental policy, which promotes the production and use of eco-friendly scooters.
  - Assessment of risks
    - Zero-order and First-order assessment tables were used, as a reference, in the process of determining whether regulating electric scooter chargers is necessary and the appropriate conformity assessment procedure.
    - Electric scooter chargers were regulated in 2013, and the conformity assessment procedure is RPC.

10

Stage One: Legislating, Regulating and Setting standards

Zero-order Assessment Table: electric scooter chargers

Item	Factor	Option	Descriptions of Factor / Weight on each Option		Selection of Option	Score
1	Concerns of safety, health, environmental protection	1	Seriously detrimental to safety, health, environmental protection	32.4	2	9.7
		2	Potential detrimental to safety and health	9.7		
		3	Potential detrimental to environmental protection	6.3		
		4	None	2.2		
2	Incident(s) happened in domestic/foreign market	1	Multiple incidents have been happening	18.9	2	6.1
		2	Incidents happened but as single events	6.1		
		3	None	2.3		
3	Any other measures except for regulation	1	None	9.9	1	9.9
		2	Existing voluntary certification, but it's been doubted	8.3		
		3	Existing safety liability insurance	2.3		
		4	Existing trusted voluntary certification	0		
4	Inspection capabilities of public or private units	1	Sufficient inspection capabilities of public and private units	9.6	1	9.6
		2	Only public units have inspection capabilities	6.1		
		3	Only private units have inspection capabilities	4.3		
		4	Insufficient inspection capabilities, but domestic witness test is adoptable	2.4		
		5	Insufficient inspection capabilities, but foreign witness test is adoptable	1.8		
		6	Insufficient inspection capabilities but could be developed	1.7		
		7	Insufficient inspection capabilities and couldn't be developed	0.7		

11

Item	Factor	Option	Descriptions of Factor and Weight on each Option		Selection of Option	Score
5	Availabilities of inspection standards	1	Existing national standards	9.3	1	9.3
		2	Existing inspection specifications developed by other domestic authorities	7.5		
		3	Existing international or regional standards (e.g., IEC, ISO, ITU, CODEX, EN)	6.3		
		4	Existing foreign national standards (e.g., BS, DIN, JIS)	3.7		
		5	Existing inspection specifications developed by foreign authorities	3.1		
		6	Existing standards developed by foreign standard setting bodies (e.g., UL, ASTM)	2.3		
		7	Existing local/foreign industrial specifications or tentative standards	2.0		
		8	None	0.8		
6	Regulatory expectations	1	Suggestion by consumers' protection organizations	7.2	3	6.6
		2	Public suggestions	6.9		
		3	Suggestion by the other authorities	6.6		
		4	Suggestion by representatives of public opinion	6.5		
		5	Suggestion by the media	4.5		
		6	None	2.1		
7	International regulatory status	1	Existing technical regulations	6.6	1	6.6
		2	Existing voluntary measures	2.1		
		3	None	0.8		
8	Industrial opinions	1	Few or no objections received	3.5	1	3.5
		2	Many objections received	1.2		
9	Effects on industrial development	1	Minor or no impacts	3.6	1	3.6
		2	Major impacts	0.7		
				Total score:		62.9

Total score: 62.9 > Threshold 44 ↓ Regulated

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Stage One: Legislating, Regulating and Setting standards

First-order Assessment Table: electric scooter chargers

Item	Factor	Option	Descriptions of Factor	Selection of Option
1	Concerns of safety, health, environmental protection	1	With no concerns to safety, health, environmental protection	3
		2	Potential detrimental to health and environmental protection	
		3	Potential detrimental to safety and health	
		4	Seriously detrimental to safety and health	
2	Incident(s) happened in domestic/foreign market	1	None	2
		2	Incidents happened but as single events	
		3	Multiple incidents have been happening	
3	Duration of testing	1	Over 10 days	2
		2	5-10 days	
		3	Less than 5 days	
4	Sales volume of single product type	1	Many sales	2
		2	Few sales	
5	Reliability of product technology	1	High reliability	1
		2	Low reliability	
Result of Assessment: • Batch-by-Batch inspection: 48.6 % • **Registration of Product Certification: 51.1 %** • Declaration of Conformity: 0.4 %				

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Stage Two: Pre-market Controls

The Relationship between Risks and CAPs

June 2017

	Inspection Scheme	Regulated products subject to each Inspection Scheme			
		Consumer products	Mechanical products	Electrical products	Electronic products
High Risk ↑	BBI	4% (33/843)	**22% (20/92)**	0% (0/189)	4% (5/121)
	TABI*	**27% (231/843)**	**55% (51/92)**	**98% (186/189)**	**63% (76/121)**
	MI*	**45% (377/843)**	0% (0/92)	0% (0/189)	0% (0/121)
	RPC*	**50% (425/843)**	**89% (82/92)**	**100% (189/189)**	**64% (78/121)**
Low Risk ↓	DoC	1% (11/843)	0% (0/92)	0% (0/189)	**31% (38/121)**

*Both MI/TABI and RPC are often made available to a single regulated product and the applicant may choose either one based on its needs.

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Stage Three: Border and Customs Checks

Border Checks and Sampling Frequencies

	Inspection scheme	Sampling frequency per batch of products	Inspection measures on the border
High Risk	BBI	1	• Sampling inspection
	TABI	0.33, 0.2, 0.1, or 0.05	• Sampling inspection on reduced frequencies(*); or • Random check and verification of conformity to type; or • Document examination
	MI	0.5, 0.2, or 0.1	• Sampling inspection on reduced frequencies(*), or • Document examination
Low Risk	RPC	• Randomly-selected batch verification: **0.003-0.005** • Enhanced randomly-selected batch verification: **0.03-0.05** • Batch-by-batch verification: **1**	• Sampling on random frequencies(**) to check the conformity to the appearance, type/model, marking and labelling
	DoC	0	• None

*Sampling frequency may be adjusted depending on inspection results.
**Sampling frequency may be adjusted depending on results of examination, market surveillance, incident reports, or non-compliant records, etc.

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Observations

- The evolution of the inspection system is a slow progress which dynamically seeks for a stable state that meets the expectations of different societies. Thus, different approaches of risk management are taken in different societies.
- The role of risk assessment in regulatory decision-making processes might be reduced due to pressures from the media, consumer groups, or legislators when incidents occur. However, risk assessment could play an important role to achieve regulatory objectives proactively to mitigate potential risks of hazard of a non-regulated product.
- Results of risk assessment may change overtime due to different perceptions of risk factors when different social issues evolve. It is crucial to identify and scrutinize the key factors that contribute to the risks, and to incorporate those factors into the assessment.

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附件 3

WORLD TRADE ORGANIZATION

G/TBT/GEN/226

19 June 2017

(17-3252)

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Committee on Technical Barriers to Trade

THEMATIC SESSION ON RISK ASSESSMENT[1]

MODERATOR'S REPORT[2]

This Report was delivered by the Moderator of this Thematic Session of the WTO TBT Committee at the meeting of 14-15 June 2017.

At the Seventh Triennial Review, Members agreed to continue to hold thematic sessions in conjunction with regular meetings of the Committee[3], and agreed to dedicate the 13 June 2017 thematic session to the topic of risk assessment. The presentations summarized below will be made available through the WTO website.[4]

1. **Mr. Pablo Neira** (European Union) explained how risk assessment features in the EU's regulatory process. The basic principles underpinning risk assessment are proportionality and the precautionary principle, and the Commission takes as a base a high level of protection of health, safety, environmental and consumer protection when proposing legislation, as per Art.114(3) of the Treaty on the Functioning of the European Union. While the EU Treaty did not provide any guidance on how to conduct risk assessment, the Case T-70/99- Alpharma suggested two elements for conducting risk assessments: (i) determining what level of risk is deemed unacceptable, which entailed a political decision; and (ii) scientific assessment of the risk. According to this case, the scientific risk assessment must enable the competent authority: (i) to ascertain whether matters have gone beyond the level of risk that it deems acceptable for society; and (ii) to decide which measures appear to be appropriate and necessary to prevent the risk from materializing. With respect to impact assessments in the EU, they are carried out for Commission initiatives that are likely to have significant economic, environmental or social impacts and should answer a number of questions: (i) what is the problem and why is it a problem?; (ii) why should the EU act?; (iii) what should be achieved?; (iv) what are the various options to achieve the objectives?; (v) what are their economic, social and environmental impacts and who will be affected?; (vi) how do the different options compare in terms of their effectiveness and efficiency (benefits and costs)?; and (vii) how will monitoring and subsequent retrospective evaluation be organised? With respect to conformity assessment procedures, he explained that Decision 768/2008 sets out criteria for selecting procedures in proportion to the level of risk and safety required. These criteria include the type and size of companies, the complexity of product technology, the type and importance of production, the appropriateness for the type of product, and the nature of risk involved and correlation of the procedure to the type and degree of risk. To conclude, he noted that the EU experience showed that: (i) it is possible to attain a high level of protection while ensuring a fair balance between pre-market and post-market controls; (ii) the use of good regulatory practices and tools allowed to determine both the need for regulation and the choice of conformity assessment procedures; (iii) any type of conformity assessment procedure requires an adequate level of post-market surveillance; and (iv) the aim should be an efficient allocation of both private and public resources.[5]

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[1] The list of speakers is contained in JOB/TBT/232/Rev.1.
[2] Mr. José Manuel Campos (Chile). This Report is provided on the Moderator's own responsibility.
[3] G/TBT/37, para. 8.3.
[4] https://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm
[5] The full presentation is contained in document RD/TBT/222.

2. **Mr. Chien-Lun Hou** (Chinese Taipei) explained that the Commodity Inspection Act set out how risk assessments feature in the inspection system of the Bureau of Standards, Metrology and Inspection (BSMI). The Act applies to four categories of products: consumer, electrical, mechanical and electronic. BSMI carries out pre-market inspections, border and customs checks and market surveillance. Different conformity assessment procedures are used depending on the risk of the product: batch-by-batch inspection; type approval batch inspection; monitoring inspection; registration of product certification; and declaration of conformity. While batch-by-batch inspection is used for products of high risk, declaration of conformity is used for products of low risk. For medium risk products, the manufacturer has the choice of different alternatives. Under the BSMI Product Safety Framework, risk assessment involves a number of different stages: (i) regulating and setting standards; (ii) pre-market controls; (iii) border and customs checks; (iv) market surveillance; and (v) enforcement. In the regulating stage, BSMI has an internal procedure for implementing and rescinding technical regulations: (i) the zero-order assessment table for deciding whether a new product should be regulated; and (ii) the first order assessment table for deciding the conformity assessment procedure that should be selected for a regulated product. In the zero-order Assessment Table, potential risk factors are identified by consultation with a BSMI group of experts and an analytic hierarchy process is used to weight each risk factor through a comparative survey. An additional survey is conducted to determine whether a regulation scores above a certain threshold, which indicates that the regulation is required. As an example, he shared how this process was carried out for electric scooter chargers, which were designated as a regulated product subject to registration of product certification. He observed that the results of risk assessment may change overtime due to different perceptions of risk factors when different social issues evolve, and that it is therefore crucial to identify the key factors that contribute to risks and to incorporate them into the assessment.[6]

3. **Mr. I Nyoman Supriyatna** (Indonesia) described risk assessment of electrical and electronic products in Indonesia. He explained that Ministry of Industry Regulation No. 86 of 2009 established the Procedure for the Implementation of Indonesia National Standards. Each proposal had to follow several steps of analysis, including: (i) a benefits and risk analysis; (ii) the readiness of producers and conformity assessment bodies to comply; (iii) the determination of the conformity assessment scheme and factory surveillance; and (iv) the determination of the market surveillance scheme. Once the Ministry issues the Regulation's Concept, the draft is then notified to the WTO. Currently, there are 14 standards and regulations from Ministry of Industry on electrical and electronic products that are mandatory for both domestic and foreign producers. Indonesia has assigned risk assessment scores to a number of different electrical and electronic products, ranging from medium to high. He noted that other Members sometimes assess the risk of the same products differently; and that some Members view electrical and electronic products as low risk. In this respect, Indonesia suggested that the Committee explore an internationally accepted definition on high and low-risk products.[7]

4. **Mr. Daniel Reese** (United States) stated that the Food and Drug Administration (FDA) has the mission of protecting public health from various risks, covering both food safety (SPS) and nutrition policy and labelling (TBT). The FDA actively assists consumers in maintaining healthy dietary practices and combating obesity, including through food labelling requirements which may lead to the reformulation of food products. There was ample scientific evidence about the association between the risk of coronary heart disease and trans fats consumption, and FDA therefore mandated trans fats labelling in 2003; and, in 2015 the agency revoked the "generally recognized as safe" (GRAS) status of partially hydrogenated oils. He said that overall sodium content of the food supply remains high, despite industry efforts and that sodium is associated with hypertension and strokes. The FDA issued a Draft Voluntary Guidance on Sodium Reduction Targets, and is currently considering comments received on the draft targets. In line with its strategic priority of ensuring that consumers have information to make healthy choices, the FDA updated the Nutrition Facts Label in order to: (i) emphasize the number of calories; (ii) more realistically reflect the current serving sizes; (iii) require the declaration of added sugars in addition to total sugars; and (iv) require calories and nutrients to be declared for single serving packages.[8]

[6] The full presentation is contained in document RD/TBT/227.
[7] The full presentation is contained in document RD/TBT/228.
[8] The full presentation is contained in document RD/TBT/221.

5. **Dr. Xiao Junfang** (China) highlighted the serious and growing cybersecurity risks of industrial control systems (ICS), which are widely used in the key information infrastructure such as energy, electricity, water, key manufacturing and communication infrastructure. ICS face a high number of information security vulnerabilities, and it is becoming less difficult to launch cyber-attacks on ICS, since hackers can easily identify ICS and exploit vulnerabilities in them with information shared through online open source communities. There is an upward trend in cybersecurity incidents affecting ICS, and she gave several examples of attacks on critical energy, electrical and communications infrastructure worldwide. In addition, ransomware attacks against ICS were an emerging risk. Against this backdrop, she explained that the traditional IT security paradigm was not sufficient to ensure the security of ICS in an increasingly interconnected world, especially given the high performance requirements of ICS and the major risks posed by shutdown of critical infrastructure. Enterprises often underestimate ICS security needs, and are not doing enough to address security hazards. The Electronic Technology Information Research Institute (of the Ministry of Industry and Information) was therefore engaged in risk assessment for ICS, simulation testing, threat monitoring and technical research, and also sought to increase cooperation with other Members in the areas of standards development, and information and technical exchange.[9]

6. **Mr. Timothy Wineland** (United States) presented the United States Cybersecurity Framework, developed by the National Institute of Standards and Technology (NIST), in collaboration with the private sector, technology experts and government agencies. The Cybersecurity Framework originated from a 2013 Executive Order, and was later enacted in the 2014 "Cyber Security Enhancement Act". The Cybersecurity Framework is a voluntary and flexible tool to help organizations of all types to develop plans for reducing cyber security risks, with particular focus on 16 critical infrastructure sectors. The Cybersecurity Framework recognizes that cyber security is a shared responsibility that neither government nor business can address alone. The expertise and knowledge-base of how to address cyber security lies within businesses impacted by cyber security threats, as well as technology experts, and therefore the framework is driven and designed in close collaboration with industry. The framework was developed in an iterative fashion, and was subject to extensive stakeholder consultation, with more than 3,000 experts from industry, academia and government participating in its development. The framework is not a particular set of standards or regulatory requirements, but rather a living document that incorporates effective standards that are being applied by industry, with an emphasis on the use of international standards. The framework helps organizations identify dependencies with partners, vendors, suppliers, and it allows organizations to communicate and coordinate cyber risk management within an industry or sector. The intent behind the framework is to identify best practices for cyber security risk management, and transform these into common practices that are widely applicable across industry sectors. The framework includes five functions in cyber security risk management: identification; detection; protection; response; and recovery. He explained that the Cybersecurity Framework is not a regulatory regime, but instead provides regulators with a standardized language and foundation for expressing any necessary regulation. The voluntary nature of the framework, as opposed to a regulatory regime, is intended to address the fact that regulations take time to prepare and may not be able to keep up with technology and threats, and that voluntary guidance and private sector expertise can more quickly respond to challenges and changes in technology.

7. On a personal note, the **Moderator** observed that risk assessment was a multi-faceted topic, with relevance to different aspects of the work of the TBT Committee. The use of risk assessment in support of the choice and design of conformity assessment procedures was one theme that emerged from discussions. In this respect, presentations highlighted the importance of aligning conformity assessment procedures with the nature and level of risk posed by products. Members shared examples of different ways to assess such risks, including quantitative and qualitative approaches to scoring the level of risk. One interesting suggestion was that Members further explore international definitions of the level of risk of products, from low to high risk. The session also usefully shared experiences on how Members applied risk assessment to specific policy challenges, such as with respect to food labelling and cybersecurity. I believe that risk assessment is a topic that the Committee should continue to reflect upon, given its close link to our work.

[9] The full presentation is contained in document RD/TBT/220.

附件 4

WORLD TRADE ORGANIZATION

RESTRICTED

JOB/TBT/234

19 June 2017

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Committee on Technical Barriers to Trade

TBT COMMITTEE MEETING DATES 2018

NOTE BY THE SECRETARIAT[1]

The following are the tentative dates for the meetings of the Committee on Technical Barriers to Trade scheduled in 2018.

20 March 2018**:** Informal meeting (Thematic Sessions)
21-22 March 2018: TBT Committee meeting

19 June 2018: Informal meeting (Thematic Sessions)
20-21 June 2018: TBT Committee meeting

13 November 2018: Informal meeting (Thematic Sessions)
14-15 November 2018: TBT Committee meeting

附件 5

WORLD TRADE ORGANIZATION

RESTRICTED

JOB/TBT/235

19 June 2017

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Committee on Technical Barriers to Trade

EIGHTH TRIENNIAL REVIEW OF THE TBT AGREEMENT

PROVISIONAL TIMELINE[1]

In light of the mandate in Article 15.4[2], the Committee is scheduled to complete its Eighth Triennial Review of the Operation and Implementation of the TBT Agreement at its last meeting in 2018. As with previous Triennial Reviews[3], the review process will be driven by substantive proposals from Members. Members are invited to begin submitting proposals in advance of the November 2017 meeting. Proposals will be discussed on a rolling basis at the meetings subsequent to submission.

a. **7-9 November 2017**: TBT Committee meeting (discussion of substantive proposals)
b. End-February 2018: circulation by Secretariat of overview of proposals received
c. **20-22 March 2018**: TBT Committee meeting (discussion of substantive proposals)
d. 1 June 2018: deadline for the submission of substantive proposals by Members
e. **19-21 June 2018**: TBT Committee meeting (discussion of substantive proposals)
f. July 2018: circulation by Secretariat of first draft report of the Review
g. End-August 2018: submission of written comments from Members on the first draft
h. End-September 2018: circulation of second draft report of the Triennial Review
i. **13-15 November 2018**: TBT Committee meeting (adoption of the Eighth Triennial Review)

附件 6

RESTRICTED

JOB/TBT/233

6 June 2017

(17-2992) Page: 1/9

Committee on Technical Barriers to Trade

14-15 JUNE 2017 TBT COMMITTEE MEETING

ANNOTATED DRAFT AGENDA[1]

The Committee on Technical Barriers to Trade (hereafter "the Committee") will hold its next regular meeting on 14-15 June 2017, starting at 10:00. The regular meeting will be preceded by a Thematic Session on Risk Assessment on 13 June.[2] Also on 13 June (in the afternoon) there will be an informal meeting to hold preliminary discussions on the approaches and timelines for the 8th Triennial Review which is due to be completed in November 2018.

Members' attention is drawn to the fact that no paper copies of documents will be provided at the meeting. Relevant documents for the meeting are available at "Documents for meetings" on the WTO website. The minutes of the last meeting of the Committee are contained in G/TBT/M/71.

The following are the proposed items for the agenda:

1 ADOPTION OF THE AGENDA

The agenda is contained in WTO/AIR/TBT/8 issued on 16 May 2017. Delegations are invited to indicate any items they may wish to raise under "Other Business" (Item 6).

2 ELECTION OF THE CHAIRMAN

The Committee will be invited to elect the Chairman of the Committee for 2017.

3 IMPLEMENTATION AND ADMINISTRATION OF THE AGREEMENT

(A) Statements from Members under Article 15.2

The latest list of statements submitted under Article 15.2 of the TBT Agreement is annexed to the Annual Review of the Implementation and Operation of the TBT Agreement contained in document G/TBT/39/Rev.1. In total, since 1995, 138 Members have submitted at least one Statement on Implementation under Article 15.2. Information about Members enquiry points is available online at the TBT Information Management System (TBT IMS) http://tbtims.wto.org/.

(B) Specific Trade Concerns

- **New and Previously raised concerns (Listed in Annex)**

  The Annex to this document contains a list of specific trade concerns which Members have communicated their intention to raise at the current meeting.

- **Reported Resolutions**

  Members are invited to update the Committee on any resolutions of specific trade concerns raised at previous meetings.

[1] This document has been prepared under the Secretariat's own responsibility and is without prejudice to the positions of Members or to their rights and obligations under the WTO.

[2] The draft programme was circulated on 2 June in JOB/TBT/232.

(C) Exchange of Experiences

Risk Assessment

The moderator will provide a brief report to the Committee on the Thematic Session on Risk Assessment held on 13 June.

Other decisions and recommendations adopted by the Committee

Members are invited to discuss any other matter relevant to the decisions and recommendations adopted by the Committee (G/TBT/1/Rev.13).

Thematic Sessions in November 2017

The Chairman will invite Members to discuss topics for November.

(D) Other Matters

Delegations wishing to raise any other matter relevant to the implementation and administration of the Agreement are invited to do so under this sub-item.

Eighth Triennial Review

The Chairman will update the Committee on the preliminary discussion on approaches and timelines for the 8th Triennial Review.

4 TECHNICAL COOPERATION ACTIVITIES

Members and Observers are invited to provide any general information on their technical assistance activities.

5 UPDATING BY OBSERVERS

Under this agenda item, Observers are invited to update the Committee on other relevant work. A list of observer organizations and international intergovernmental organizations whose requests for observer status are pending is contained in G/TBT/GEN/2/Rev.12.

6 OTHER BUSINESS

Any issues raised by Members under Item 1 will be addressed here.

7 DATE OF NEXT MEETING

The next regular meeting of the Committee is scheduled for 8-9 November 2017. It will be preceded by thematic sessions on 7 November.

附件 7

編號	遭關切會員	產品/措施	通知文件編號/措施簡介	關切會員	IMS ID
1	中國大陸	網路產品和服務安全審查辦法		歐盟 美國 日本	
2	中國大陸	密碼法修正		歐盟 日本 美國	
3	歐盟	活性物質嘧菌酯	G/TBT/N/EU/437	巴西	
4	中國大陸	輕型汽車污染物排放限值及測量方法	G/TBT/N/CHN/930/ Rev.1	日本	
5	中國大陸	車聯網網路安全防護指南		美國	
6	中國大陸	民航網路資訊安全管理規定		美國	
7	歐盟	二氧化鈦		美國	
8	阿曼、巴林、科威特、卡達、沙烏地阿拉伯阿拉伯聯合大公國葉門	動物產品驗證要求	G/TBT/N/OMN/198 G/SPS/N/BHR/164 G/SPS/N/QAT/22/Add.3 G/SPS/N/OMN/44/Rev.1/ Add.1 G/SPS/N/SAU/14/Add.2	美國	
9	尼泊爾	酒精飲料		美國	
~~10~~	~~歐盟~~	~~化學品(REACH)~~		~~加拿大~~	~~88~~
11	印度	汽車充氣輪胎	G/TBT/N/IND/20 G/TBT/N/IND/40	歐盟 韓國	133
12	中國大陸	化粧品管理	G/TBT/N/CHN/821 G/TBT/N/CHN/937	歐盟 日本	296
13	印度	新通訊產品規則(Department of Telecommunications, No. 842-725/2005-VAS/Vol.III (3 December 2009); No. 10-15/2009-AS-III/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")		歐盟 美國	274
14	中國大陸	資訊安全產品 銀行資訊科技設備安全法規保險之資通訊科技規定	G/TBT/N/CHN/1172	歐盟 加拿大 日本 美國	294 457 489

編號	遭關切會員	產品/措施	通知文件編號/措施簡介	關切會員	IMS ID
15	俄羅斯	酒精飲料	G/TBT/RUS/2	歐盟 美國 烏克蘭	332
16	韓國	化學物質註冊及評估法規	G/TBT/N/KOR/305 G/TBT/N/KOR/305/Add.1 G/TBT/N/KOR/478 G/TBT/N/KOR/547 G/TBT/N/KOR/592 G/TBT/N/KOR/700	美國	305
17	印尼	強制性玩具安全規定	G/TBT/N/IDN/64 G/TBT/N/IDN/64/Add.1-2	歐盟 美國	328
18	歐盟	酒精產品	G/TBT/N/EU/246 G/TBT/N/EU/246/Add.1	阿根廷 美國	345
19	印度	電子及資訊產品強制性登錄	G/TBT/N/IND/44 G/TBT/N/IND/44/Add.1-5 G/TBT/N/IND/47 G/TBT/N/IND/47/Add.1 G/TBT/N/IND/47/Add.1/ Corr.1	美國 歐盟 韓國	367
20	歐盟	環境荷爾蒙	G/TBT/N/EU/383 G/TBT/N/EU/383/Add.1 G/TBT/N/EU/384 G/TBT/N/EU/384/Add.1 G/TBT/N/EU/166 G/TBT/N/EU/166/Add.1	阿根廷 加拿大 美國	393
21	祕魯	青少年食品	G/TBT/N/PER/59 G/TBT/N/PER/89 G/TBT/N/PER/89/Corr.1	墨西哥 美國	383
22	厄瓜多	食品標示	G/TBT/N/ECU/19 G/TBT/N/ECU/19/Add.1-10	墨西哥	411
23	俄羅斯	兒童及青少年產品	G/TBT/N/RUS/29	歐盟 美國	418
24	泰國	酒精飲料標示	G/TBT/N/THA/437 G/TBT/N/THA/437/Add.1 G/TBT/N/THA/221/Add.1	美國	427
25	中國大陸	醫療器材監督與管理	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	歐盟 韓國	428
26	沙烏地阿拉伯、阿曼、巴林、科威特、卡達、阿拉伯聯合大公國、葉門	能量飲料	G/TBT/N/ARE/262 G/TBT/N/QAT/389 G/TBT/N/SAU/669 G/TBT/N/SAU/789 G/TBT/N/ARE/299 G/TBT/N/BHR/426 G/TBT/N/KWT/309 G/TBT/N/OMN/23 G/TBT/N/QAT/423 G/TBT/N/SAU/910	美國	442

編號	遭關切會員	產品/措施	通知文件編號/措施簡介	關切會員	IMS ID
			G/TBT/N/YEM/29 G/TBT/N/ARE/301 G/TBT/N/BHR/428 G/TBT/N/KWT/311 G/TBT/N/OMN/240 G/TBT/N/QAT/425 G/TBT/N/SAU/912 G/TBT/N/YEM/31		
27	歐盟	資訊科技安全評估驗證		中國大陸	448
28	中國大陸	化粧品標示管理辦法（AMCL）	G/TBT/N/CHN/1064	日本 歐盟	456
29	中國大陸	藥品及醫療器材註冊費用		韓國	466
30	巴西	葡萄酒及其衍生產品品質要求	G/TBT/N/BRA/613 G/TBT/N/BRA/675	歐盟 美國	470
31	巴西	玩具驗證	G/TBT/N/BRA/612 G/TBT/N/BRA/612/Add.1	歐盟	478
32	中國大陸	商用炭		澳洲	477
33	印度	不鏽鋼產品		歐盟	486
34	印度	酒精飲料	G/TBT/N/IND/51	歐盟	494
35	中國大陸	嬰兒奶粉	G/TBT/N/CHN/1165	歐盟 美國 韓國	493
36	印尼	清真產品		美國 歐盟	502
37	泰國	嬰兒食品	G/TBT/N/THA/471 G/TBT/N/THA/471/Rev.1	美國	503
38	俄羅斯	水泥	G/TBT/N/RUS/48 G/TBT/N/RUS/49	歐盟 墨西哥 烏克蘭	497
39	埃及	製造商登錄系統	G/TBT/N/EGY/114	土耳其 歐盟 美國	505
40	肯亞 烏干達 坦桑尼亞 盧安達 烏隆地	酒精飲料	G/TBT/N/KEN/472-477 G/TBT/N/KEN/479 G/TBT/N/KEN/482-483 G/TBT/N/KEN/556-561 G/TBT/N/KEN/563-565 G/TBT/N/KEN/567 G/TBT/N/UGA/434-435 G/TBT/N/UGA/437-441	歐盟 美國	510 519
41	歐盟	農產品品質系統	G/TBT/N/EU/139 G/TBT/N/EU/149/Add.1	美國	512
42	我國	有機農產品	G/TBT/N/TPKM/225 G/TBT/N/TPKM/225Add.1-2	歐盟	511
43	中國大陸	傢俱	G/TBT/N/CHN/1094 G/TBT/N/CHN/1095 G/TBT/N/CHN/1096	歐盟	509

編號	遭關切會員	產品/措施	通知文件編號/措施簡介	關切會員	IMS ID
44	韓國	菸酒	G/TBT/N/KOR/664 G/TBT/N/KOR/664/Add.1	歐盟 日本 美國	518
45	哈薩克、俄羅斯、吉爾吉斯	關稅同盟玩具安全技術法規第2號修正案	G/TBT/N/KAZ/7 G/TBT/N/RUS/73 G/TBT/N/KGZ/48	歐盟 美國 烏克蘭	514
46	愛爾蘭	酒精	G/TBT/N/IRL/2	墨西哥	516
47	俄羅斯	醫療器材	G/TBT/N/RUS/51 G/TBT/N/RUS/52 G/TBT/N/RUS/53 G/TBT/N/RUS/55	歐盟 美國 烏克蘭	520
48	俄羅斯	藥品	G/TBT/N/RUS/54 G/TBT/N/RUS/58 G/TBT/N/RUS/63	歐盟 美國	521
~~49~~	~~哥倫比亞~~	~~玩具及其零配件測試要求~~	~~G/TBT/N/COL/109~~ ~~G/TBT/N/COL/109/Add.3~~	~~墨西哥~~	~~479~~
50	中國大陸	網絡安全法		歐盟 日本 美國	526
51	中國大陸	新能源車管理規定	G/TBT/N/CHN/1187 G/TBT/N/CHN/1188	歐盟 日本 美國	527
52	義大利	用於製備義大利麵穀物來源的原產地標示要求		墨西哥 加拿大	530
53	歐盟	有機產品及標示		巴西	524
54	歐盟	無線電設備指令		中國大陸 美國	525
55	韓國	家用化學品和殺生物劑	G/TBT/N/KOR/684 G/TBT/N/KOR/547 G/TBT/N/KOR/702	美國	529
56	多明尼加	鋼筋		美國	528

附件 8

資通訊/電機/電子產品：

1. 印度新通訊產品規則

   歐盟、美國、日本及加拿大持續關切(1)採用逐批測試特別是對中小企業造成過度負擔，建議採用型式試驗；(2)要求使用國際標準，如CC評估標準或3G夥伴計劃標準；(3)接受境外試驗室如CCRA(共同準則承認協議, Common Criteria Recognition Agreement)會員認可或簽署ILAC MRA認證試驗室的測試報告；(4)甚至建議採SdoC檢驗方式；(5)通知確切實施日期，俾特別是外國廠商有足夠時間因應調整。

   印度說明通訊網路如電力、交通、國防等同屬重要基礎建設，本項規定已採國際標準如IT設備採ISO/IEC 15408、資安系統採ISO 27000系列、通訊設備採3GPP及3GPP2安全等國際標準；新增國家安全規定如後門等易遭惡意程式攻擊測試項目，經和國土事務部(Ministry of Home Affairs)、國家安全、通訊服務提供者等相關部門諮商，且國產和進口一體適用，無差別待遇，已延後至2018年4月1日實施，並於通訊部門網站提供通知及相關資訊供廠商因應調整。

2. 印度電子及資訊科技產品強制性登錄(G/TBT/N/IND/44, IND/44/Add.1-5, IND/47, IND/47/Add.1, IND/47/Add.1/Corr.1)

   美國、歐盟、韓國及加拿大持續關切(1)產品測試僅能由印度標準局(Bureau of Indian Standards, BIS)認可之印度實驗室進行，印度實驗室能量不足，已嚴重影響註冊申請案之進度，強力要求印度政府認可國外實驗室提供測試服務，特別是直接認可國際認證論壇(IAF)或國際實驗室認證合作(ILAC)相互承認協議簽署認證機構所認證之實驗室；(2)印度政府要求之測試標準與IEC標準相同，應擴大接受IECEE CB測試報告，避免重複測試；(3)簡化註冊程序且延長現有測試報告效期90日；(4)如要擴大產品登錄範圍，應通知WTO供評論，避免不確定性；(5)對於要銷售給中大型企業組裝而非直接給消費者之產品，應列入免驗。

   印度回應有關接受IECEE CB測試報告部分，經和IECEE討論結果，並沒有違反其規定；簡化註冊程序部分已持續改進，BIS已訂定案件辦理時間表並公布在其網站，於BIS Act 2016實施後也可以接受無紙化電子申辦文件等；另其他關切問題已轉請主管機關考量及回應。

3. 歐盟無線電設備指令(G/TBT/N/EU/93)

   中國大陸、美國及韓國關切歐盟2014/53/EU指令，又稱RED(Radio Equipment Directive)，以取代1999/5/EC, R&TTE，影響包括行動電話、基地台、WLANs、平板電腦、筆電、藍牙/WiFi、影音等廣泛產品(1)緩

衝期將屆(2016年6月12日至2017年6月12日)，該指令仍有很多模糊不清之處，很多標準及指引仍未公布；(2)部分標準變動太快，惟因缺乏指引，致驗證機構無法有效處理；(3)部分歐盟會員國尚未把該指令轉換為其國家法規；(4)如前述問題無法儘快處理，應延長緩衝期。
歐盟回應產品指令僅規範無線電設備需符合的基本要求，不會規定技術細節，調和標準係自願性表示符合指令要求，已由ETSI (European Telecommunications Standards Institute) 及 CENELEC (European Committee for Electrotechnical Standardization)發展中；另該指令第17(2)條提供廠商可採SdoC方式宣告符合規定。

化學品／玩具：

4. 韓國化學物質註冊及評估法規(G/TBT/N/KOR/305, 305/Add.1, 478, 547, 592)
美國持續關切(1)法規制訂透明化不夠，有毒物質清單增減應通知WTO接受評論；(2)指導文件沒有英文翻譯，導致資訊混淆；(3)業者機密資訊揭露的風險；(4)鼓勵採取以風險評估方法，以確保能達到保護消費者的目標，避免不必要的貿易障礙。
韓國回應本法規修正只改變登錄方法，且同為歐盟2018年5月所採用，並無增加登錄化學物質的負擔；另為減少業者負擔，已免除供研發用需登錄規定，及導入小數量新物質通知系統，取代現有登錄系統。

5. 印尼強制性玩具安全規定(G/TBT/N/IDN/64)
歐盟、美國及日本持續關切承認國外試驗報告於2016年4月底寬限期過後(1) 促請印尼政府直接認可已簽署ILAC MRA認證機構認證之國外試驗室；(2)允許印尼符驗證構與國外試驗室進行委託測試之合作，承認其測試報告；(3)進口玩具與國產玩具取樣方法不同，違反國民待遇(進口每批抽樣，國產每6個月抽樣)；(3)要求印尼玩具檢測標準與國際標準調和。
印尼回應會員國提供的意見仍在評估中，採用的標準皆與國際標準調和，與印尼政府簽署相互承認協議互惠之國家的認可試驗室測試報告可被接受。

6. 巴西玩具驗證(G/TBT/N/BRA/612)
歐盟、加拿大及美國持續關切(1)每個系列產品的每家工廠都要接受稽核，增加不必要的複雜性及費用，建議採用供應商符合性聲明制度或由ILAC認證機構認證的實驗室進行取樣工作；(2)產品追溯系統要求每一型式的產品都要登錄，對於廠商的負擔過重，建議改為製造商或進口商登錄即可，並允許製造商或進口商選擇適當的方法建立其內部追溯制度；(3)對於不被觸及的元件可以免除特定物質遷移的化性試驗，希望提供指

南供業者參考。
巴西回應針對該法規草案所收到的評論意見已列入評估考量，將會準備指南供業者參考。

7. 中國大陸木製家具中揮發性有機物質(TVOC)遷移限量(G/TBT/N/CHN/1094-1096)
歐盟關切檢驗標準與國際準有差異的問題(1)需要增加額外特定測試，某些特定測試既複雜又貴；(2)質疑某些特定測試的關聯性，如TVOC同時測得有害及無害物質總和，及該測試的可複製性；(3)哪些是自願性，哪些是強制性標準。
中國大陸表示有關詳細技術性資料已以書面回應，其標準係以相關國際標準為基礎，包括ISO 16000系列，強調有差異部分旨在模擬產品實際使用狀況，故測試結果可以更為科學且為TBT協議所允許，中國大陸已準備好隨就技術層面與歐盟討論。

8. 哈薩克、俄羅斯、吉爾吉斯關稅同盟玩具安全技術法規第2號修正案(G/TBT/N/KAZ/7, G/TBT/N/RUS/73, G/TBT/N/KGZ/48)
歐盟、美國及烏克蘭雖表贊同該歐亞經濟聯盟(Eurasian Economic Union, EAEU)保護兒童的目標，惟其措施為全球獨創(1)設立一專家委員會評估每1個玩具是否符合才上市規定流於主觀、缺乏科學證據；(2)不知如何化為符合性評估程序以產出證書；(3)建議採用ISO之兒童年齡分級國際標準；(4)請釐清要管制的標的及提出更新進展。
哈薩克當場提示2張投影片(如下)回應其市場已充斥各項暴力玩具，於安全之外影響兒童產生攻擊、恐懼行為，該措施係由合格的專家評估特定玩具對兒童心智發展的影響，對保護兒童至關重要，俄羅斯表同意並表示已將收到之意見之回應公布於其歐亞經濟委員會(Eurasian Economic Commission, EEC)網站，會將相關意見納入考量。


9. 韓國家用化學品和殺生物劑(G/TBT/N/KOR/684, 547, 702)
美國持續關切(1)是否全面禁止產品含卡松防腐劑(CMIT/MIT)，如有其他管理方式，現有產品是否須標示含殺生物劑、有毒等字樣；(2)環境部

(Ministry of Environment, MOE) 的通知是CMIT及MIT個別的CAS編號(化學摘要服務社Chemical Abstracts Service)，而非歐盟及美國等國際通用可接受的CMIT及MIT混合劑(3比1混合比率) CAS編號，請韓國釐清；(3)鼓勵韓國採風險管理方式以避免不必要貿易障礙。

韓國回應禁用的是18種含CMIT/MIT的噴霧劑及空氣清新劑；至於新標示規定係2016年12月30日公告18個月後，並無適用現有市場存貨，且可選擇有毒或該物質功能及其比例標示；採CMIT及MIT個別CAS編號係因CMIT及MIT可有各種不同混合劑；該國已有相當多的傷亡案例，故須加以列管。

醫療器材／化粧品／藥品／農產品：

10. 中國大陸化粧品管理（G/TBT/N/CN/821, 937）

歐盟及日本持續關切(1)有關中國大陸擬採高風險產品須前市場註冊及使用一般原料者僅須通報主管機關之差別管理方式，請問其具體方案及時程為何；(2)請提供「化粧品衛生監督條例」(Regulations concerning Hygiene Supervision over Cosmetics)修正內容及請通知WTO供評論；(3)現行「化粧品新原料申報與審評指南」(Guidance for Application and Evaluation of New Cosmetic Ingredients)之審查速度太慢、安全評估需求及資訊揭露問題。

中國大陸回應本措施自2011年通知以來已對有困難企業提供特別訓練及指引，並已投注極大能量辦理新原料核准，經與3輪公共諮商後已出版化粧品原料目錄。

11. 中國大陸醫療器材監督與管理法規（G/TBT/N/CN/1022-1026, 1029）

歐盟、韓國及加拿大仍關切(1)有關第二類(中風險)或第三類(高風險)之醫療器材需事先在原產地進行臨床試驗並於進口時需先登錄；(2)相關EMC標準大多採用IEC國際標準，希望接受相關國際認證機已核發之實驗室測試報告，避免額外費用之支出及醫療器材上市之延遲；(3)希望提供廠商3年之過渡期及發行相關程序指南。

中國大陸表示相關回應可參考前幾次會議紀錄，即接續2014年8月公布第一批後，進一步於2016年9月公布第二批免於進行臨床試驗之醫療器材目錄共359個產品，其中第二類醫療器材267個、第三類醫療器材92個。實施優先審批的醫療器材主要有2種情況：一是診斷或治療罕見疾病、惡性腫瘤、老年人或兒童特有和多發疾病具有明顯臨床優勢或目前尚無有效診斷或治療手段的醫療器材，或臨床急需且尚無同品種產品獲准註冊的醫療器材；二是列入國家科技重大專項或國家重點研發計劃的醫療器材。

12.中國大陸化粧品標示管理辦法（AMCL）（G/TBT/N/CHN/1064）

歐盟、日本及紐西蘭重申關切(1)能以標籤方式陳現進口國所規定資訊以符合國際慣例；(2)太多額外之標示規定，其中需要標示製造商（負責廠商）之名稱與地址，另委託（分包）製造企業亦要同時標示，建議僅標示最終法律責任之廠商名稱即可；(3)經功效評價驗證機構出具測試報告證明不應放置於官方指定的網站公開接受監督，因涉及廠商知識產權，且檢測驗證機構不應限於中國大陸境內；(4)另進口產品是否持續要求動物試驗及國產進口有別。

中國大陸表示本標示辦法尚在草案階段尚未實施，會遵循國際慣例考量各會員國意見併同前揭衛生管理辦法檢討修正。

13.中國大陸藥品及醫療器材註冊費用

韓國、加拿大、澳洲持續關切(1)中國大陸藥品及醫療器材註冊費用不透明；(2)進口產品未區隔註冊費及工廠檢查臨場（on-site）費用；(3)本國企業適用較低之「省級價格」有歧視之嫌；(4)該費用如何計算應公告周知等。

中國大陸回應有關徵收本項費用係國際普遍作法，該費用係以成本計算，會因申請人所在地所產生之聯繫、運輸及其他成本而有不同，且規費不屬TBT協定第5.6條之技術規範，因此無需通知及在此討論。

14.印尼清真產品保證法

美國、歐盟、巴西及澳洲繼續關切(1)只要清真產品有標示，則非清真產品強制標示是否有必要性；(2)非清真產品未來能否持續進口印尼；(3)相關規定散見在各法規，且實施辦法應通知WTO接受評論及有適當的緩衝期；(4)提供該國清真產品保證機構(Badan Penyelenggara Jaminan Produk Halal, BPJPH)資料及國外機構認可問題等。

印尼回應本法將在2019年後實施，並無禁止非清真產品販售，只有該產品是產自動物或由動物組成才需標示，實施辦法預計今(2017)年底完成草案討論，將適時提出通知文件。

15.歐盟農產品及食品品質系統(G/TBT/N/EU/139及G/TBT/N/EU/139/Add.1)

丹麥向歐盟提出保護danbo及havarti乳酪地理標示保護的申請，美國表示Codex已針對該2用語制定生產標準：50年為danbo、30年為havarti，供各國遵循，詢問歐盟未來通過該申請案後(1)是否禁止依據Codex標準而使用該等名稱之乳酪的進口，(2)歐盟是否會尋求國際協定，禁止其他市場販售符合Codex標準使用該等名稱乳酪的販售，(3)歐盟是否考慮對貿易影響較小之措施，如加註Danish，允許符合Codex標準之乳酪仍可使用該等名稱於歐盟市場販售。

歐盟回應該向申請尚未完成審查，目前無其他說明，建議於與貿易有關之智慧財產權協定(trade-related aspects of intellectual property rights, TRIPS)會議討論。

其他：

16.印度汽車充氣輪胎(G/TBT/N/IND/20、40)

歐盟、韓國及日本關切(1)印度標準機構(Indian Standards Institute, ISI)標籤費用過高；(2)強制性驗證時間太冗長；(3)要求境外工廠支付銀行擔保費造成歧視；(4)以生產量為基礎進行測試對部分業者造成測試頻率過高。

印度回應相關關切事項都不是新的，均已於前幾次會議作過回應，即ISI非營利機構，標籤費用涵蓋其合理成本；測試頻率已從5,000個輪胎抽1個放寬為30,000個抽1；另銀行擔保則是為確保外國企業與ISI的驗證契約能夠履行不致追償無門。

17.印度不銹鋼產品(品質管制)令,2015(G/TBT/N/IND/50)

歐盟已於2015年10月23日提出書面評論意見，重申就BIS強制性驗證要求、重複測試及費用提出關切，甚至對不販售給最終消費者而無衛生風險之中間產品也要檢驗，要求以ISO 9001驗證取代工廠檢查。

印度回應工廠檢查及臨場測試是BIS符合性評鑑制度的一環，而且ISO 9001是品質管理系統，與產品驗證制度不同，因此無法取代，另外費用包括維持驗證所需年度市場監督費，並無不合理。

18.中國大陸新能源車管理規定(G/TBT/N/CHN/1187、1188)

歐盟、日本及美國持續關切(1)由於新能源車銷售牽涉到價格、便利性、基礎設施普及性、補貼及其他獎勵等複雜條件，對於補貼是否國產進口車有別；(2)有關能源消耗借貸系統管理，信用可以在2016到2020年間自由交易，信用的移轉不應僅限同一中國大陸股東的合資或子公司，也應包括同一外國股東的合資公司；(3)對於小量生產汽車未達節能標準課徵高額燃料稅將阻礙其進口；(4)有關測試部分，是否須在中國大陸境內設R&D中心、測試能量是否足夠、是否採用國際標準；(4)應有足夠的緩衝期及如未達目標應有其他替代方案。

中國大陸回應該措施對其節能及環保至關重要，同時在新能源車大量湧進時也要為新科技帶來的新風險進行因應；新能源車製造商須確保其設計能力而非設設R&D中心在中國大陸境內，符合TBT協定非歧視國民待遇原則。

附件 9

WORLD TRADE ORGANIZATION

G/TBT/N/TPKM/225

8 December 2015

(15-6478)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	**Notifying Member:** THE SEPARATE CUSTOMS TERRITORY OF TAIWAN, PENGHU, KINMEN AND MATSU **If applicable, name of local government involved (Article 3.2 and 7.2):**
2.	**Agency responsible:** Agriculture and Food Agency (AFA) Council of Agriculture 8,Kuang-Hua Road Chung-Hsing New Village Nantou, 54044 Taiwan Tel: (886-49) 2332-380 ext 2429 Fax: (886-49) 234-1092 E-mail: hsiuhui@mail.afa.gov.tw **Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above**:
3.	**Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [X], 5.7.1 [ ], other:**
4.	**Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Organic agricultural products. Agriculture (ICS: 65)
5.	**Title, number of pages and language(s) of the notified document:** Draft of the Organic Agriculture Act (9 pages, in Chinese)
6.	**Description of content:** To maintain the ecological balance, enhance the quality of organic agricultural products, improve the public health and protect consumer rights, the AFA intends to promulgate "The Organic Agriculture Act" (hereinafter "the Act"). The Act will come into effect one year after adopted by Taiwan Legislative Yuan, and the AFA will propose implementing measures based on the Act. Organic agriculture is an important part of the sustainable circulation system of the

	nature and also the key production method for providing safe source of food. For this reason many countries in the world deem organic agriculture as a national green industry policy and provide support and management through legislation. Currently the management of Taiwan's organic agriculture relies on the provisions related to production of agricultural products and the certification management regulations. Although Taiwan stipulates explicit regulations governing the requirements for organic production process, certification management, and the penalties for organic agricultural product inspections, Taiwan is also facing challenges for changes in the environment of domestic agricultural production, rigorous requirements for quality from organic consumers, and discretions over the product trade regulations for international organic equivalence. The Act is drafted with 41 articles to promote the sustainable development of Taiwan's organic agriculture and improve the quality of organic agricultural products, in order to maintain national health, take consideration of the interest and rights of producers and consumers, and achieve the objectives in organic ecology of environment, farmers' organic production, and the organic live of consumers.
7.	**Objective and rationale, including the nature of urgent problems where applicable: Protection of the environment; Prevention of deceptive practices and consumer protection**
8.	**Relevant documents: –**
9.	**Proposed date of adoption: To be determined** **Proposed date of entry into force: One year after the legislative adoption and announcement**
10.	**Final date for comments: 60 days from notification**
11.	**Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:** **TPKM – WTO/TBT Enquiry Point** **Bureau of Standards, Metrology and Inspection** **Ministry of Economic Affairs** **No.4, Sec. 1, Jinan Rd.** **Zhongzheng Dist., Taipei City 100, Taiwan** **Tel: (886-2) 33435191** **Fax: (886-2) 23431804** **E-mail: tbtenq@bsmi.gov.tw** **http://www.afa.gov.tw/organicAgriculture.aspx?CatID=809** **https://members.wto.org/crnattachments/2015/TBT/CHT/15_4844_00_x.pdf**

附件 10

Thank you, Chair

We appreciate the continued interest from the EU on the Draft Organic Agriculture Act.

The draft is still under review by the Executive Yuan and will undergo legislative processes for adoption after the final review. The comment of the EU on extending the one-year period for concluding equivalence agreements for organic agriculture products will be taken into account along with comments from other WTO members and domestic stakeholders. We welcome consultations on new bilateral equivalence agreements even before the measure is adopted and will spare no efforts to work with Members on facilitating conclusion of such agreements.

Regarding the clarity of product coverage and process stage coverage, Article 3 provides their definitions. I would like to bring it to the EU's attention that the Organic Agriculture Act is the primary law, and once the Act is adopted, the implementing regulations, which will be based on the current practices, will be announced for commenting.

In addition, we have been engaging in bilateral discussions with the EU over the past months. At the most recent bilateral meeting in June, our regulator, the Agriculture and Food Agency, provided more detailed information. We will continue working closely with the EU to explore solutions that would address the EU's concerns.

Thank you