出國報告(出國類別：開會)

出席 WTO 技術性貿易障礙委員會第 78 次例會及相關會議

服務機關：經濟部標準檢驗局
姓名職稱： 查秘書全淑、魏技士立宇
出國地區： 瑞士日內瓦
出國期間： **108** 年 **6** 月 **16** 日至 **23** 日
報告日期： **108** 年 **7** 月 **17** 日

摘　　要

世界貿易組織（WTO）技術性貿易障礙（TBT）委員會於本（108）年 6 月 18 至 21 日舉行非正式會議、透明化主題性研討會暨第 9 屆資訊交換特別會議，以及第 78 次正式會議。本次會議我國於透明化主題性研討會暨第9屆資訊交換特別會議中簡報我國TBT查詢單位運作經驗、於 TBT 委員會正式會議中就歐盟對我「有機農業促進法」所提出之特定貿易關切提供回應說明，並於會議期間與美國及韓國進行雙邊會談。

6 月 18 日上午為非正式會議，討論符合性評鑑程序指導文件之內容，會中除歐盟提出討論文件外，美國亦表達提出討論文件之意願，並鼓勵 WTO 會員踴躍分享經驗。美國在與我國雙邊會談時，特別提及我國對符合性評鑑程序的討論多有貢獻，期待我國能夠分享看法。

6 月 18 日下午至 19 日辦理透明化主題性研討會暨第 9 屆資訊交換特別會議，該會議每三年召開一次，供 WTO 會員之 TBT 查詢單位進行經驗交流，以提高 TBT 查詢單位的運作效益，WTO 會員於會中分享 TBT 查詢單位與國內其他主管機關或貿易官員協調合作之作法、透過 WTO 秘書處發展之通知文件警示系統增進會員間橫向及國內縱向溝通之成果、與其他 WTO 會員推動透明化技術合作之成果、業者與政府部門的合作機制，以及政府處理非關稅障礙整體性的策略等。

6 月 20 至 21 日召開第 78 次正式會議，主要就特定貿易關切事項（STC）進行討論。本次會議中，會員共提出新增及既有計 65 項 STC 案，其中歐盟對我國行政院農業委員會「有機農業促進法」提出特定貿易關切。美國及印尼也於會議期間與我國進行雙邊會談，議題涵蓋我國特殊配方食品、西藥專利連結、塑膠微粒限制使用及化粧品標示規定。

藉由出席本次會議，我國主動要求與韓國雙邊會談，瞭解韓國 TBT 查詢單位之運作，特別是與業者的互動機制。綜合會員分享的經驗，本報告提出 3 項建議：(1)建置我國技術性貿易障礙處理機制，(2)推廣 WTO 建置之通知文件預警系統 ePing，(3)推動與 WTO 會員透明化技術合作，希望能夠以更有效的方法協助國內業者解決所遭遇的技術性貿易障礙。

目　　錄

附件：

1. TBT 委員會第 78 次會議議程（JOB/TBT/319）
2. 歐盟符合性評鑑程序指導文件討論文件（JOB/TBT/322）
3. 透明化主題性研討會暨第 9 屆資訊交換特別會議議程（JOB/TBT/273/Rev.3）
4. 我國「TBT 查詢單位運作實務經驗」簡報
5. 歐盟對我「有機農業促進法」提出特定貿易關切之發言資料
6. 我國回應歐盟對我「有機農業促進法」提出特定貿易關切之發言資料
7. 2019 年 6 月 TBT 委員會會議重要貿易關切案件彙整表

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（108）年 6 月 18 至 21 日召開第 78 次例會及相關會議（例會議程如附件 1），我國由經濟部標準檢驗局第五組查秘書全淑及魏技士立宇出席。除研討會中的分組討論時段外，會議皆由 TBT 委員會新任主席韓國駐 WTO 代表團 Sung-Hwa JANG 主持，相關會議如下：

- 108 年 6 月 18 日上午：非正式會議（討論符合性評鑑程序指導文件）。
- 108 年 6 月 18 日下午至 19 日：「透明化主題性研討會暨第 9 屆資訊交換特別會議」。
- 108 年 6 月 20 至 21 日：「TBT 委員會」第 78 次正式會議。

貳、 108 年 6 月 18 日上午 TBT 委員會非正式會議紀要

依據 TBT 委員會於 2018 年完成之第 8 次三年總檢討報告，TBT 委員會同意展開草擬符合性評鑑程序指導文件的工作，這份指導文件主要目的在協助法規主管機關選用及設計適當且符合比例原則的符合性評鑑程序（用以證明產品符合特定規定的流程，例如我國驗證登錄制度、逐批檢驗制度）。歐盟於 6 月 14 日提出討論文件（JOB/TBT/322，附件 2），建議前述指導文件內容應包含(1)通用性的原則及良好作業，(2)風險評估及其他可以辨識產品風險程度的因素，(3)符合性評鑑程序的種類及要件，及(4)利用市場監督支持符合性評鑑程序的有效實施。

針對歐盟提出的討論文件，美國表示該國訂有 3 項法規，要求聯邦政府在訂定符合性評鑑程序時遵循。未來 2 周，美國也會以該國經驗為例提出有關指導文件內容的建議，並將同時就歐盟討論文件中的內容提供回饋意見，也歡迎其他會員分享經驗（美國在與我國雙邊會談時，特別提及我國對符合性評鑑程序的討論多有貢獻，期待我國能夠分享看法），盼於下次 TBT 委員會會議能有更熱烈的討論。智利則表示指導文件應為自願性質，且各國有其特別的制度與需求，對於產品風險的評估結果也因國而異，沒有一體適用的標準。加拿大認為指導文件的發展需要多年的努力，建議能夠平衡納入已存在並有效運作的機制，如國際認證論壇（IAF）或國際實驗室認證合作（ILAC）的相互承認協議。

參、 108 年 6 月 18-19 日「透明化主題性研討會暨第 9 屆資訊交換特別會議」紀要

WTO 秘書處安排一天半的會議探討透明化的各個面向（議程詳附件 3），包含查詢單位的運作、對於會員通知措施的追蹤與回應、評論意見的傳遞及回復、措施同時通知 TBT 及 SPS 委員會之作法、TBT 查詢單位間之合作等，其中，秘書處首次安排分組討論，讓會員就(1)通知文件的品質、(2)與業者的連結及(3)查詢單位間的溝通 3 個主題，聚焦於遭遇的問題並交換彼此的經驗與想法。

一天半的會議中一共有 22 位講師（來自 13 個 WTO 會員），以及聯合國貿易暨發展會議（UNCTAD）與國際貿易中心（ITC）各 1 位講師進行簡報，為歷次相同性質會議中規模最大。我國簡報「TBT 查詢單位運作實務經驗」（詳附件 4），分享所接獲國內外查詢案件之常見問題態樣、處理程序及回復時效，同時促請會員查詢單位遵循 TBT 委員會的決定，在接獲查詢時回復確認，並於 5 個工作日內答覆。此外，我國也建議會員 TBT 查詢單位在答覆查詢時一併提供相關文件，方能提高答覆內容的可信度，也方便收到答覆的業者更全面地瞭解相關規定。另一項建議則是請會員分享查詢其他會員法規資訊的方法，可以有效提高查詢單位的運作效率。

綜合會中所有簡報的內容可以觀察到，會員 TBT 查詢單位的功能大同小異，開發中國家普遍認為最大的挑戰在如何增強與業界的連結，特別是協助業者分析其他會員擬採行的技術性法規可能造成的影響，並進一步提出評論意見。針對 TBT 查詢單位的功能、角色及國內機制的運作，因美國及澳洲的說明較為深入，彙整說明如下：

一、 TBT 查詢單位間增加溝通可以有效避免遭遇特定貿易關切：有不少特定貿易關切的產生是因為資訊不透明，TBT 查詢單位如果可以有效追蹤接獲之問題的回應進度並釐清疑慮，將可避免會員提出特定貿易關切。

二、 建議多加利用 WTO 秘書處發展之通知文件警示系統（e-Ping, http://www.epingalert.org/en#）：e-Ping 系統提供訂閱功能，讓使用者可以透過指定的篩選條件接收 TBT 及 SPS 通知文件，及早掌握出口國法規的變動，並在草案階段提供評論意見。e-Ping 同時也提供論壇功能，讓各會員的 TBT 及 SPS 查詢單位間可以彼此分享資訊，以及與國內業者互動。

三、 透明化技術合作：美國分別與巴西、阿根廷簽署「法規一致性及民間部門實質參與合作意向備忘錄」（Memorandum of Intent on Joint Cooperation on Regulatory Coherence and Meaningful Engagement with the Private Sector），協助合作夥伴將良好法規作業納入制度性運作。透過備忘錄所架構的合作對話，雙方就公眾諮詢、電子化法規作業及評論意見納入考量的方式在技術層面充分交換意見，在巴西及阿根廷政府領導階層推動法規改革政治信念的支持下，合作頗具成效。

四、 確立業者公會與政府部門的合作機制：美國對於會員提出的通知文件，從資訊傳遞、通知措施研析到評論意見的提出，各個環節的分工明確，銜接緊密。TBT 查詢單位主要負責資訊的傳遞（通知文件及書面評論意見）、預警系統（NotifyUS，訂閱人數約 3,000 人）的維護、回復來自其他會員的信件及提供國內業者出口產品所需的資訊及指導。其他會員通知的措施則由商務部、美國貿易代表署（USTR）及公會合作評估對國內產業的影響，最後決定是否提出評論意見。商務部人員有各自負責的產業領域，並與對應的公會保持密切聯繫。以個人照護產品協會（Personal Care Products Council，簡稱 PCPC）為例，該協會致力於推動全球化粧品法規的一致性、倡導化粧品法規的良好作業，並協助會員瞭解新的法規。PCPC 與商務部、USTR 及食品藥品監督管理局（FDA）都建有對話平台，在接獲會員通知文件後，對於有重大貿易影響的措施會在每次 TBT 委員會議前與政府討論是否有未解決的貿易關切。

五、 非關稅障礙的處理需要政府部門整體性的策略：澳洲政府回應產業的要求，將非關稅障礙的處理列為優先業務，並發展非關稅障礙行動計畫（Non-tariff Action Plan），期與業界合作共同解決不合理的貿易障礙。為此，澳洲政府建立了非關稅障礙入口網站（https://tradebarriers.dfat.gov.au/），便利業者通報非關稅障礙，並讓第一線的政府部門（貿易官員、法規主管機關技術專家、駐外單位等）可以及時掌握資訊提供協助。澳洲政府也將成立貿易障礙協調團隊，個案管理貿易障礙案件，並定期向業界報告處理進度。由於非關稅障礙通常較為隱密，政府部門需與業界合作確認障礙的本質、評估可能的處理方式，並討論採取行動的利弊風險，才能提高成功的機率。政府與業界的溝通及意見回饋須即時、透明並完整。

圖 1－澳洲政府建置之非關稅障礙入口網（https://tradebarriers.dfat.gov.au/）

除了會員分享經驗外，國際貿易中心（ITC）也報告了其與聯合國貿易暨發展會議（UNCTAD）及 WTO 合作建置之 Global Trade Helpdesk 資料庫，將分散的貿易資訊匯流集中，讓微中小型企業可以利用單一窗口取得所有貿易資訊。Helpdesk 主要包含市場

進入要求、進出口程序導航、貿易機會及政策總覽等 4 大主題，各主題未來將包含的資料(部分內容尚未實裝)如下表：

主題	資訊態樣
市場進入要求	關稅、關稅配額、貿易救濟、稅費、原產地、非關稅措施、WTO 會員通知文件、自願性永續標準、國際標準等
貿易程序	進出口程序、驗證、註冊或登錄、許可、授權、通關、費用等
企業機會	企業名錄、政府名錄、市場消息、貿易活動、公共標案等
政策綜覽	市場價格、貿易統計、自由貿易協定、出口潛在評估等

表 1－Global Trade Helpdesk 資料庫主要內容分類

Helpdesk beta version 於第 11 屆 WTO 部長會議啟動，目前資料仍持續增補中。

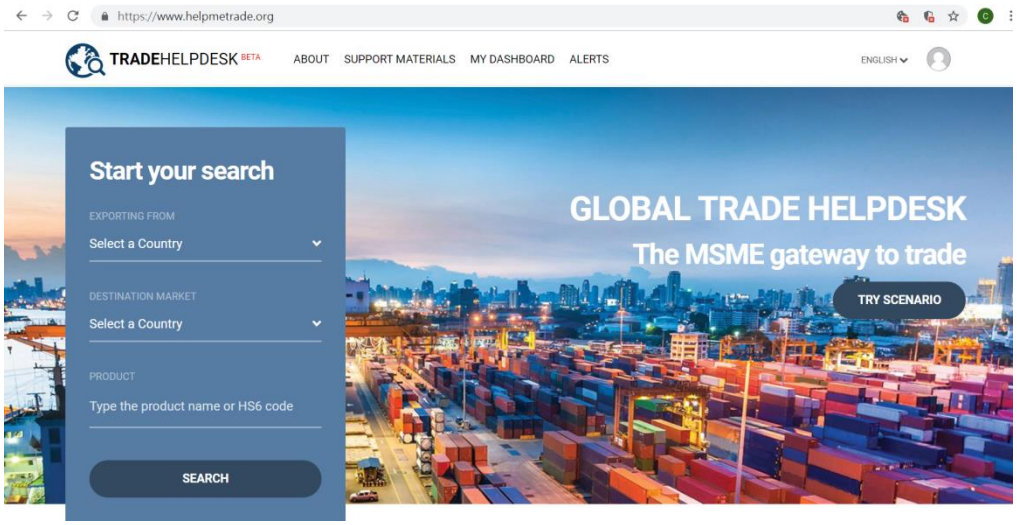

圖 2－Global Trade Helpdesk 網站首頁

肆、 雙邊會談紀要

108 年 6 月 19 日分別與韓國、印尼及美國進行雙邊會談。會談情形如下：

一、 瞭解韓國 TBT 查詢單位之運作，特別是與業者的互動機制

韓國 TBT 查詢單位設於科技標準局（Korean Agency for Technology and Standards，簡稱 KATS）技術性貿易障礙組的 WTO 科。韓國對於技術性貿易障礙的處理主要由 KATS

負責與主導，從資訊的蒐集、分析、建立策略到採取行動有一套完整的作業流程，且各涉及單位的分工明確。說明如下：

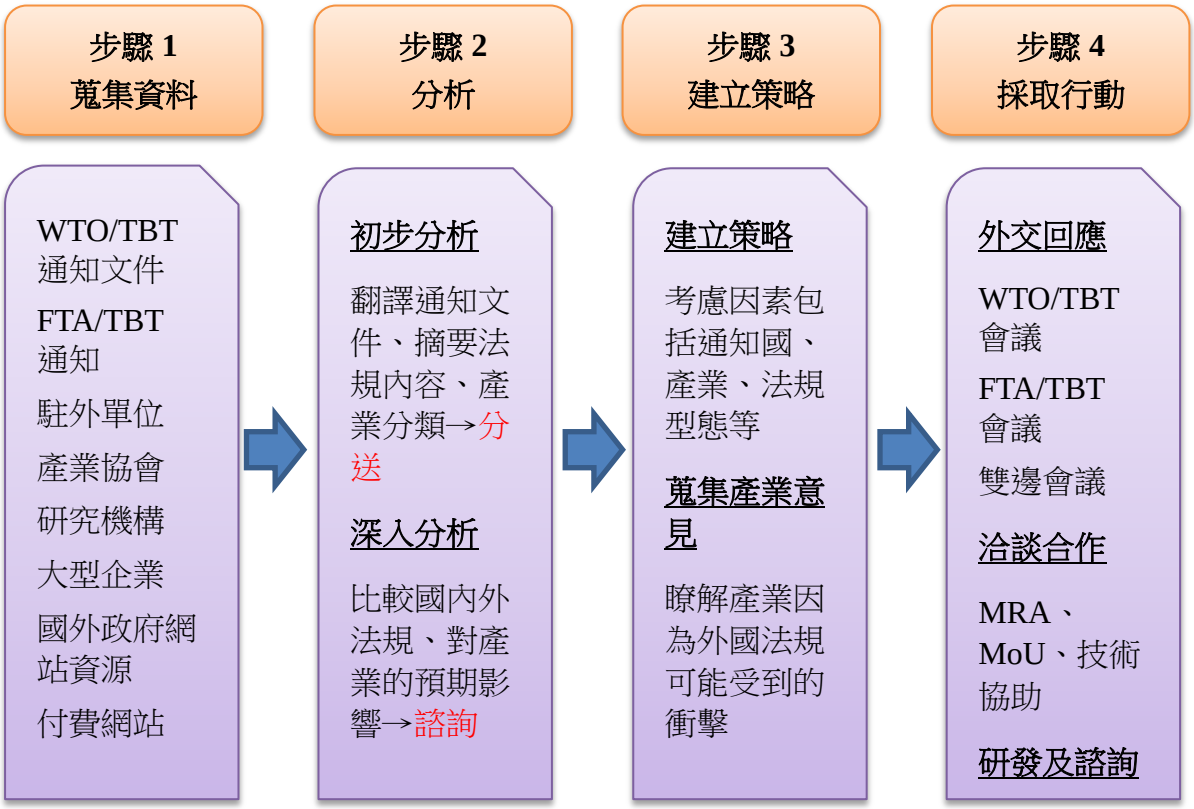

圖 3－韓國 KATS 處理技術性貿易障礙機制(翻譯自韓國簡報資料)

蒐集資料：除了 WTO/TBT 通知文件外，KATS 從許多來源蒐集外國技術性法規，其中特別一提的是，KATS 加入一個專門協助企業符合法規的付費網站會員（https://www.complianceandrisks.com），要求法人實驗室或驗證機構（韓國測試研究院 KTR、韓國符合性實驗室 KCL 及韓國測試驗證機構 KTC）指派專人就各自負責的領域每日檢視付費網站上的資訊，並比對 TBT 通知文件，如果遇到沒有通知的法規，KATS 會要求該國提出通知。此外，資訊來源還包含大型跨國性的檢測機構網站，如 SGS、TUV 等。

分析：KATS 會初步篩選重要的法規草案（無論有無 TBT 通知）交給簽約的法人實驗室或驗證機構（即 KTR、KCL 及 KTC）進行技術分析，並就業界反映的關切協助回應。在這個階段，部門別負責的產業公會（電氣電子產品為韓國電子協會 KEA，機械及金屬產品為韓國營建設備製造商協會 KOCEMA，化學民生用品為韓國專業化學工業協會 KSCIA）在收到 TBT 通知文件時，也會同步轉發該領與的相關公會，並蒐集會員意見。

建立策略：韓國工業技術院 KIIET 及韓國國際經濟政策院 KIEP 協助 KATS 檢視 TBT 通知文件所涉措施之妥適性及是否違反國際協定或國際標準，並就政府可以採取的策略提供建議。

採取行動：由 KATS 評估適當的雙邊及/或多邊管道採取行動解決障礙，手段包括：(1)向措施實施會員提出評論意見、(2)要求雙邊會談、(3)於 WTO/TBT 委員會提出特定貿易關切、(4)推動相關合作、(5)支援產業所需的研發等。

在整個合作機制下，KATS 也透過至少每月一次與業者或公會的座談中，將辦理情形告知業者，直接溝通問題並即時調整策略。KATS 同時也建置 KNOWTBT 網站（www.knowtbt.kr，訂閱人數高達 8,837，平均每月造訪人數為 25,000），將蒐集到的所有資訊都上傳網站，供業者利用。對於中小企業，資訊翻譯為韓文有其重要性，而 KATS 更免費提供法規資訊、測試及驗證的技術諮詢。由於國內重視的程度提高，政府編列的經費及投入的人力皆逐年增加。

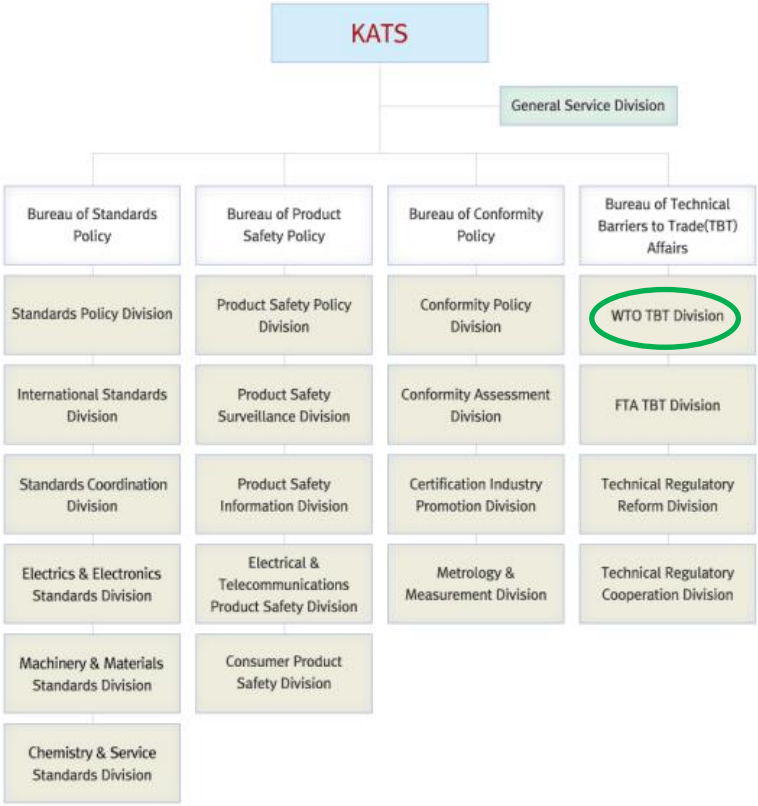

圖 4－韓國 KATS 組織架構圖

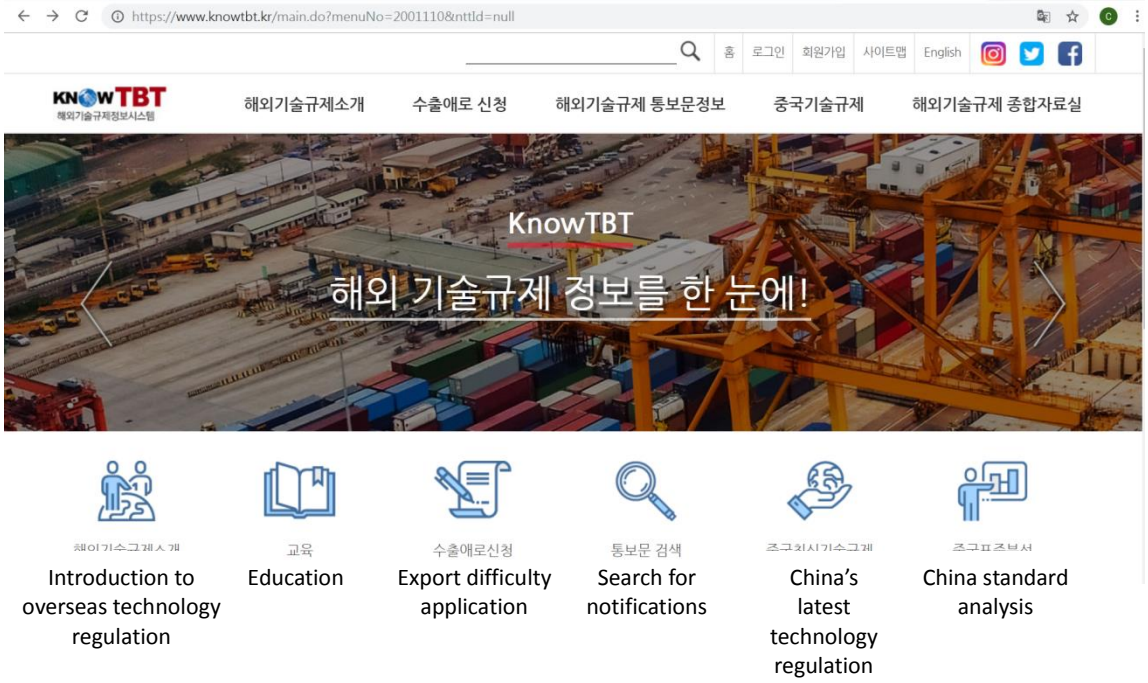

圖 5－韓國技術性貿易障礙知識庫 KNOWTBT 網頁（韓文網頁，英文補充為 google 翻譯結果）

二、 與印尼之雙邊會談

措施：外包裝容器標籤或仿單標示規定（G/TBT/N/TPKM/355/Add.1）及國內分裝或改裝者之輸入化粧品應標示詞語（G/TBT/N/TPKM/356/Add.1）

印尼曾於 108 年 3 月 19 日電郵就「外包裝容器標籤或仿單標示規定」草案詢問我國化粧品應標示資訊是否接受貼標、掛牌或其他型態方式附加在產品上，而非直接印刷。我國於 4 月 1 日透過 TBT 查詢單位將國內主政機關衛生福利部食品藥物管理署之回復提供印尼。惟印尼於會議期間仍要求與我雙邊會談，盼釐清化粧品包裝是否允許非永久性之標示方式，以及我國規定是否符合 ISO 22715:2006 有關化粧品包裝及標示之內容一致。經依據食藥署提供之回應說明向印尼解釋，印尼盼我國提供書面資料，同時請我國一併釐清標示之文字尺寸可否小於 1.2 毫米（如 1.1 毫米）及可能之後果。

三、 與美國之雙邊會談

措施：「食品與相關產品查驗登記及許可證管理辦法」（G/TBT/N/TPKM/341/Rev.1）、「西藥專利連結施行辦法草案」（G/TBT/N/TPKM/337/Rev.1）、「限制含塑膠微粒之化粧品與個人清潔用品製造、輸入及販賣」修正草案（G/TBT/N/TPKM/375/Rev.1）

美國於 6 月 12 日提供擬與我國會談之內容，經依據食藥署及環保署提供之資料向美方說明，美方意見如下：

(一)「食品與相關產品查驗登記及許可證管理辦法」：美方感謝我方對於申請程序所需文件提供彈性，但強調我國為全球唯一要求檢附「無人種差異」資料之國家，盼我方提供科學證據證明此要求之必要性。

(二)「西藥專利連結施行辦法草案」：美方認為食藥署現行草案極好，促請我方儘速通過，倘未來法規草案決定不納入生物相似藥或有重大修正，請我方再次通知，以利會員評論。

(三)「限制含塑膠微粒之化粧品與個人清潔用品製造、輸入及販賣」修正草案：美國感謝我方說明，惟盼我方能進一步提供「合成蠟」之定義，美方認為合成蠟種類繁多，部分合成蠟應具可分解性，而毋須禁止。

伍、 108 年 6 月 20 日至 21 日 TBT 委員會正式會議紀要

本次正式會議議程詳附件 1，會議時間大多在處理特定貿易關切，其他較重要的議題則為第 8 次三年總檢討後續執行及觀察員報告等，以下分別說明之。

一、 特定貿易關切

本次計有 65 件特定貿易關切案（新關切 12 件，延續關切 53 件）。我國「有機農業促進法」自 2016 年 6 月起即遭遇歐盟持續關切，歐盟本次亦對有機農業促進法提出特定貿易關切（歐盟發言請詳附件 5），主要仍重申其既有立場（延長過渡期、擴大對歐盟之單方有機同等性承認、盼釐清實施細節等），其中特別強調希望我方建置資訊工具以利歐盟利害關係人瞭解進口程序，並要求農糧署儘速認可歐盟控制機構（Control Body）。我方則回應相關實施細節皆已通知 WTO 會員（我方發言請詳附件 6）。

前述特定貿易關切以食品飲料標示、醫療器材及藥品相關措施佔多數，網路安全相關規定（主要為中國大陸之措施）亦持續受到美國、歐盟、日本等已開發會員關切，而歐盟對於化學物質分類的調整則引起中南美洲眾多以農業出口為主的開發中會員抨擊。本報告特別篩選了 38 件特定貿易關切案件，重點說明會員關切意見及被關切會員之回應（詳附件 7，完整的特定貿易關切案件清單請見附件 1）。篩選的標準為(1)新關切案件、(2)多個 WTO 會員關切（關切會員超過 5 個）、(3)新南向國家措施、(4)重要貿易地區（中國大陸）、(5)我國曾關切案件，及(6)我國重要產品。這些選出的特定貿易關切涵蓋的產品類別如下表所示：

產品類別	被關切會員—特定貿易關切案件名稱
食品	中國大陸—進口食品隨附證書管理辦法草案 沙烏地阿拉伯－部分食品糖份添加上限 印尼－清真產品保證法 歐盟－食品「不含棕櫚油」標示
醫材、藥品	歐盟－醫療器材及體外診斷醫療器材法規 中國大陸－醫療器械監督管理條例修正草案 中國大陸－藥品及醫療器材註冊費用
化粧品	中國大陸—「化粧品註冊和備案檢驗管理辦法」草案 印度－2018 化粧品規則草案 中國大陸－化粧品監督管理條例草案及化粧品註冊和備案檢驗管理辦法
化學物質分類、農業	歐盟－不再重新核准殺蟲劑活性物質「四氯異苯腈（Chlorothalonil）」的使用 歐盟－農藥殘留容許量過渡期及國際協商 歐盟－以風險為基礎的植物保護產品及進口容許量的設定 歐盟－不再重新核准活性物質啶氧菌酯（picoxystrobin）
玩具	印度－2019 玩具（品質）命令草案 印度－進口玩具法規修正 印尼－有關強制性玩具安全印尼國家標準之採納及實施技術指導文件
酒類	歐盟－酒精性飲料的定義、描述、呈現及標示；其他食品標示及呈現所使用的酒精性飲料名稱；保護酒精性飲料的地理標示；酒類飲料中乙醇及農業來源蒸餾酒的使用 烏拉圭－進口產品分析—國家葡萄生產及酒類製造院決定—實施日期延至 2019 年 5 月 1 日之—酒中之外加水 愛爾蘭－公共衛生（酒精）法案 2015
家電、電子產品	歐盟－不同產品生態設計法規（草案及已通過） 歐盟－電子顯示器生態設計法規草案 印度－電子及資訊科技商品強制性登錄命令
資訊、網路安全(可連網裝置)	中國大陸－保險機構信息化監管規定草案 中國大陸－加密法草案 中國大陸－資安產品要求，包含 1999 商用密碼管理條例與其更新版及多層保護架構(Multi-Level Protection Scheme, MLPS) 中國大陸－國家互聯網信息辦公室關於「網路安全審查辦法」草案 中國大陸－網路安全法 越南－網路安全措施 印度－新通訊相關規定及附隨的「安全及商業延續協議」範本

紙類	歐盟－「中間紙類產品環境足跡類別規則」草案（Product Environment Footprint Category Rule, PEFCR）
無人機	歐盟－「無人機系統及第三國無人機操作人員解釋文件」草案
汽車	越南－汽車製造、組裝及進口之企業要求及汽車保固與維修服務
其他 (受影響產品不明或範圍極大)	歐盟－物質及混合物分類、標示及包裝（CLP）法規草案附件 6－二氧化鈦（TiO_2）及鈷 中國大陸－固體廢棄物禁止進口目錄 韓國－「包裝回收分類法規」草案 歐盟－再生能源指令（2009/28/EC）修正 印度－陰香（樟科植物）濕度含量（SPS 措施）

針對本次會議的特定貿易關切有 4 點觀察：

(一) 化學物質的停止核准使用及重新分類對貿易的影響必須納入對下游產品的影響

本次會議歐盟不再核准活性物質「四氯異苯腈（Chlorothalonil）」及「啶氧菌酯（Picoxystrobin）」使用於殺蟲劑，以及重新將二氧化鈦（TiO_2）與鈷改分為第 2 類化學物質，引起為數眾多的會員關切，最主要的原因都是對下游產品的貿易將造成直接影響。依據會員關切的理由，「四氯異苯腈」及「啶氧菌酯」在全球多數國家都核准使用，更是農民普遍用於控制果樹及穀類作物病蟲害的活性物質，而二氧化鈦（TiO_2）與鈷改分類亦同樣可能對下游產品的生產造成限制，因此我國未來評估其他 WTO 會員法規對我產業影響時，應該將其對下游產品之影響一併納入考量。

(二) 網路安全相關法規多半沒有通知

中國大陸一系列有關網路安全的法規包括 2015 年的保險機構信息化監管規定草案、2017 年的網路安全法、加密法、網路安全審查辦法草案等，但中國大陸僅就保險機構信息化監管規定草案提出 TBT 通知文件，其他法規均未提出通知文件；而越南 2017 年的網路安全措施同樣遭遇會員質疑，也沒有提出通知文件。這些規定除了直接要求資訊安全產品應符合特定標準，而直接與 TBT 協定相關，其餘有關加密要求、保險機構系統驗證、個人資訊和重要數據之出境安全評估等，與 TBT 協定的關係似較薄弱，可能是會員未進行通知的一部份原因。

(三) WTO 會員對於只允許境內測試的關切數量上升

印尼的清真產品保證法及強制性玩具安全國家標準；印度的化粧品規則草案、玩具相關法規、電子和資訊科技商品強制性登錄及電報機測試與驗證；中國大陸的化粧品註冊和備案檢驗管理辦法及醫療器械監督管理條例修正草案，因為限定產品必須於進口會員境內的實驗室測試，外國測試報告必須透過相互承認協議之簽署（政府間或認證機構間）才能接受而遭到會員質疑。

二、 第 8 次三年總檢討後續執行

(一) 有關 TBT 委員會運作中針對特定貿易關切所作之建議（第 8.2b），即會員如希望提出特定貿易關切，應於 TBT 會議召開日期 20 日前通知秘書處及被關切會員，秘書處應於會前 15 日將會議詳細議程（包含會員通知之特定貿易關切案件資料）分送會員，經過試行 2 次會議後（3 月及 6 月會議），會員同意此作法將持續適用以後的會議。

(二) TBT 委員會預定於 11 月 12 日上下午分別辦理「符合性評鑑程序（國家品質基礎架構）」及「標準（法規引用標準之作法）」主題性研討會。目前已有國際度量衡局、印尼、中國大陸、歐盟、千里達及托巴哥及南非表示將派員分享國家品質基礎架構之國家經驗，澳洲及加拿大已表示將派員分享法規引用標準之經驗。會員預告分享的內容如下：

1. 符合性評鑑程序（國家品質基礎架構）：

i. 國際度量衡局—國際品質基礎架構共同的作法及近期發展。

ii. 印尼—使用認證作為接受符合性評鑑結果之基礎。

iii. 歐盟—認證在歐盟國家品質基礎建設的概論。

iv. 南非—南部非洲發展共同體之技術性法規同等性合作。

v. 中國大陸與千里達及托巴哥的講題尚待確認。

2. 標準（法規引用標準的作法）：

i. 加拿大—從貿易政策觀點探討引用標準的概念。

ii. 澳洲—當被法規引用的標準修正時如何提升認知。

iii. 中國大陸及歐盟的講題尚待確認。

三、 觀察員組織活動報告

本次會議有聯合國歐洲經濟委員會（UNECE）、經濟合作發展組織（OECD）、國際度量衡局（BIPM）、國際法定度量衡組織（OIML）、國際標準化組織（ISO）、國際電工委員會（IEC）報告近期活動。此外，亦針對觀察員申請案邀請會員表示意見。重點摘要如下：

(一)ISO 簡報該組織與 IEC 共同修訂 ISO/IEC Guide 59「標準化良好作業」(Code of Good Practice for Standardization）之進度

ISO 說明 ISO/IEC Guide 59 係於 1994 年完成（在 TBT 協定簽署之前），由於年代久遠，且希望與 TBT 協定內容取得一致，經過檢討認為有必要予以更新，其目的並非要詮釋 TBT 協定附件 3 的條文，僅是提供良好標準制定作業。委員會草案(Committee Draft）已於 3 月 15 日展開諮詢程序，7 月底結束諮詢，預計於 2019 年 9 月公布。沒有 WTO 會員就本案提出進一步意見。

(二)觀察員申請案

土耳其發言支持伊斯蘭國家標準度量衡局（SMIIC）成為觀察員，獲得約旦附議，美國表示保留。主席裁示留待 11 月會議再討論。

四、 下次會議時間：第 79 次 TBT 委員會例會暫訂本年 11 月 13 至 14 日舉行，11 月 12 日將舉辦主題性研討會，而 11 月 15 日將舉辦 TBT40 周年紀念活動（自 GATT 東京回合談判起算）。

陸、 檢討與建議

一、 建置我國技術性貿易障礙處理機制

依聯合國貿易發展會議資料，TBT是非關稅貿易障礙中最常見也最昂貴的問題，惟此等問題常需政府與產業緊密合作才能發現、分析並採取適當的方法解決。美國、韓國及澳洲對於技術性貿易障礙的資料各自建置了系統化的運作機制，雖然切入點不同，但都兼顧資料的蒐集及與業者的連結。

美國分別由TBT查詢單位（美國國家標準技術研究院）與貿易部門（商務部及貿易代表署）分工合作，各自扮演不同的角色；韓國則由韓國科技標準局設立專責處理技術性貿

易障礙的部門（包含TBT查詢單位）統整相關工作；澳洲則從非關稅障礙角度著眼，將技術性貿易障礙納入，訂定行動計畫，讓政府部門及業界有共同的努力方向。

我業者絕大多數為中小型企業，對於遭遇之TBT問題缺乏足夠的認知與分析能力，而目前國內對於技術性貿易障礙的處理尚未有系統化的作法，從資訊的蒐集、分析到與業者的互動都呈現零星片段的型態，無法匯集成有效的行動策略，應參考美、澳、韓的作法評估可用的資源以建立合適的處理機制，以充分利用TBT會議平台與其他會員協商，協助解決貿易障礙。

二、 推廣WTO與其他國際組織合作建置之通知文件預警系統ePing

ePing系統主要整併TBT及SPS的通知文件，訂閱的用戶能夠設定條件輕鬆取得他國法規動態。這個系統於2016年10月建置，依據WTO秘書處統計，3年來訂閱人數成長迅速（2019年6月15日已接近7,000）。除了預警的功能，這個系統也提供論壇功能，讓會員TBT查詢單位可以彼此交流，也可以直接與國內業者溝通。

本局前因ePing網站無中文介面而未在國內大力推廣，隨著ePing功能逐漸完善及WTO會員的推廣與使用（例如傳遞評論意見），預估其重要性與日遽增，將成為WTO會員共同的使用工具，且目前已有建置非WTO官方語言介面之案例（越語），可以嘗試接洽WTO秘書處瞭解建置中文繁體網頁之可行性，並在國內推廣使用ePing網站，讓業者不會錯失可能的資訊。

三、 推動與WTO會員透明化技術合作

透明化不僅是TBT協定最重要的精髓，也是貨品貿易最基本的需求。它涵蓋許多制度面的議題，如良好法規作業的導入、公眾諮詢的方式、資訊工具的運用等。而跨國的透明化技術合作亦有助於雙方法規制度的交流與學習。美國簡報其與巴西、阿根廷在透明化領域的合作成效，建議可接洽美國進一步瞭解其具體的合作內容，我國亦可思考與貿易夥伴推動類似合作。

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Committee on Technical Barriers to Trade

20-21 JUNE 2019 TBT COMMITTEE MEETING

ANNOTATED DRAFT AGENDA[1]

The Committee on Technical Barriers to Trade (hereafter "the Committee") will hold its next regular meeting on 20-21 June, starting at 10:00. The regular meeting will be preceded by a dedicated informal meeting on Guidelines on Conformity Assessment Procedures starting at 10:00 on 18 June, and the Thematic Session on Transparency starting at 15:00 on 18 June and continuing on 19 June. The latest programme for the thematic session is contained in document G/TBT/GEN/264. 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/77.

The following are the proposed items for the TBT Committee agenda:

1 ADOPTION OF THE AGENDA

The agenda is contained in WTO/AIR/TBT/14 issued on 20 May 2019. Delegations are invited to indicate any items they may wish to raise under "Other Business" (Item 6).

2 ELECTION OF THE CHAIRPERSON

3 IMPLEMENTATION AND ADMINISTRATION OF THE AGREEMENT

(A) Statements from Members under Article 15.2

Since 1995, 142 Members have submitted at least one Statement on Implementation under Article 15.2. Information about Members' enquiry points is available on the TBT Information Management System (TBT IMS).

(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 Progress

Members are invited to update the Committee on any resolutions or positive developments related to specific trade concerns raised at previous meetings.

(C) Exchange of Experiences

- (i) Guidelines on Conformity Assessment Procedures

The Chairperson will provide an update on the informal meeting on Guidelines on Conformity Assessment Procedures (G/TBT/41, para. 4.17(b)), held on 18 June.

[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.

- **(ii) Transparency**

  The Chairperson will provide a report on the Thematic Session on Transparency, held on 18-19 June.

(D) Follow-up on Committee Decisions and Recommendations

Delegations wishing to raise any matter relevant to the follow up on the Eighth Triennial Review (G/TBT/41), or any other previous Committee decisions and recommendations (G/TBT/1/Rev.13), are invited to do so under this sub-item.

(E) 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.

4 TECHNICAL COOPERATION ACTIVITIES

Under this agenda item, Members 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 relevant work, including on technical cooperation. A list of organizations whose requests for observer status are pending is contained in G/TBT/GEN/2/Rev.14, circulated on 19 February 2018. A room document containing the requests is contained in RD/TBT/1/Rev.6, circulated on 3 November 2017.

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 13-14 November 2019. It will be preceded by an informal meeting on 12 November.

ANNEX

New Specific Trade Concerns

	Specific Trade Concern	Notification symbol	Brief description of measure	Proposed/Final Measure	Member(s) raising
1	China - Regulation on Cosmetic Inspection in Registration and Filing	G/TBT/N/CHN/1311		Proposed	Japan Korea
2	European Union - Explanatory memorandum of unmanned aircraft systems and third-country operators of unmanned aircraft			Proposed	China
3	India - Notification of 2018 draft cosmetic rules, amending provisions of the India Drug and Cosmetics Act of 1940			Proposed	United States
4	India - Toys (Quality Control) Order, 2019			Proposed	United States
5	Republic of Korea - Package Recycle Classification Regulation			Proposed	United States
6	Kingdom of Saudi Arabia - Added Sugar Upper Limit in Some Food Products	G/TBT/N/SAU/1108		Proposed	United States
7	Uruguay - Analysis of Imported Products - Resolution of the Board of the National Grape-Growing and Wine Production Institute (INAVI) of 14 February 2019. Resolution of the Board of INAVI postponing implementation until 1 May 2019) - exogenous water in wine	G/TBT/N/URY/27/Rev.1		Proposed	United States Chile

	Specific Trade Concern	Notification symbol	Brief description of measure	Proposed/Final Measure	Member(s) raising
8	European Union - Product Environmental Footprint Category Rules (PEFCR)		The European Commission is developing a Product Environmental Footprint (PEF) Category Rule (CR) for intermediate paper products	Proposed	Indonesia
9	European Union - Concerns on regulations with regard to eco-design requirements for various products in EU.		The concerns will be on the regulations with regard to eco-design requirements for several products in the EU, which include data storage products, household washing machines and household washer-dryers, household dishwashers, light sources and separate control gears, and energy labelling of light sources. Some are proposed drafts and some have been implemented.	Proposed and Final	China
10	European Union - Regulation of the European Parliament and of the Council on the definition, description, presentation, labelling of spirit drinks, the use of the names of spirit drinks in the presentation and labelling of other foodstuffs, the protection of geographical indications of spirit drinks, the use of ethyl alcohol and distillates of agricultural origin in alcoholic beverages, which repeals Regulation (EC) No. 110/2008	G/TBT/N/EU/432/Rev.1	This regulation entered into force in April 2019.	Final	Guyana

	Specific Trade Concern	Notification symbol	Brief description of measure	Proposed/Final Measure	Member(s) raising
11	European Union - Medical Device Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR)	G/TBT/N/EU/71/Add.1 G/TBT/N/EU/72/Add.1		Final	United States
12	India - Moisture content for Cassia Vera (Cinnamomum Burmani)	G/SPS/N/IND/69	Since early 2019 Indonesia is no longer able to export Cassia Vera to India, even though it is in compliance with the maximum moisture content of Cassia as set in the regulation.	Final	Indonesia

Previously raised Specific Trade Concerns

	Specific Trade Concern	Notification symbol	Brief description of measure	Proposed/Final Measure	Member(s) raising
13	Indonesia - Technical Guidelines for the Implementation of the Adoption and Supervision of Indonesian National Standards for Obligatory Toy Safety (ID 328)	G/TBT/N/IDN/64 G/TBT/N/IDN/64/Add.1 G/TBT/N/IDN/64/Add.2 G/TBT/N/IDN/64/Add.3		Proposed	United States European Union
14	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 (ID 345)	G/TBT/N/EEC/264 G/TBT/N/EEC/264/Add.1		Proposed	United States

	Specific Trade Concern	Notification symbol	Brief description of measure	Proposed/Final Measure	Member(s) raising
15	European Union - Quality Schemes for Agricultural Products and Foodstuffs (ID 512)	G/TBT/N/EU/139 G/TBT/N/EU/139/Add.1 G/TBT/N/EU/593	Quality Schemes for Agricultural Products and Foodstuffs. Geographical Indications for Cheese: Havarti and Danbo (Denmark applications)	Proposed	United States
16	European Union - Chlorothalonil (pesticide active substance) (ID 579)	G/TBT/N/EU/625	Non-renewal of approval of active substance chlorothalonil	Proposed	United States Colombia
17	European Union - Transitional periods for MRLs and international consultations (ID 580)			Proposed	United States
18	China - Cosmetics Supervision and Administration Regulation (Draft) (ID 576)	G/TBT/N/CHN/1310 G/TBT/N/CHN/1311	Cosmetic Supervision and Administration Regulations (CSAR)/ Measures for the Registration and Filing of Cosmetics	Proposed	Japan United States Korea
19	Uruguay - Labelling of Packaged Food (ID 578)	G/TBT/N/URY/25 G/TBT/N/URY/26		Proposed	United States

	Specific Trade Concern	Notification symbol	Brief description of measure	Proposed/Final Measure	Member(s) raising
20	European Union - Draft Commission Regulation laying down eco-design requirements for electronic displays pursuant to Directive 2009/125/EC of the European Parliament and of the Council, amending Commission Regulation (EC) No 1275/2008 and repealing Commission Regulation (EC) 642/2009 (and its accompanying annexes)" (ID 575)	G/TBT/N/EU/609 G/TBT/N/EU/610	EU proposed eco-design regulation for Electronic Displays	Proposed	United States China
21	Republic of Korea - Warning statement and graphic health warnings on alcoholic beverages (ID 577) (ID 577)	G/TBT/N/KOR/817		Proposed	United States
22	China - Regulations for the Supervision and Administration of Medical Devices (Order No. 650 of the State Council) (ID 428)	G/TBT/N/CHN/1313		Proposed	Korea
23	China - Insurance Regulatory Commission (CIRC) Information and Communication Technology Regulation (ID 489)	G/TBT/N/CHN/1172		Proposed	European Union
24	Ireland - Public Health (Alcohol) Bill 2015 (ID 516)	G/TBT/N/IRL/2		Proposed	United States
25	China - Draft revised Encryption Law of the People's Republic of China by the Office of State Commercial Cryptography Administration (OSCCA) (ID 534)			Proposed	Japan European Union
26	European Union — Regulation (EC) No 1272/2008 (CLP Regulation) (ID 539)	G/TBT/N/EU/629	Titanium dioxide and Cobalt: Regulation (EC) No. 1272/2008 (CLP Regulation), Annex VI, Part 2	Proposed	Russia United States

	Specific Trade Concern	Notification symbol	Brief description of measure	Proposed/Final Measure	Member(s) raising
27	Brazil - Draft Technical Resolution n° 51, 7 April 2017 on labelling of beverages, wine, and grape derivatives (ID 557)			Proposed	European Union
28	Israel - Addendum to the Pharmacist Regulations (Cosmetics 5778-2018) (ID 552)	G/TBT/N/ISR/709/Add.2		Proposed	Korea
29	European Union - Regulation of the European Parliament and of the Council laying down rules and procedures for compliance with and enforcement of Union harmonization legislation on products and amending relevant regulations (ID 565)			Proposed	China
30	Dominican Republic - Regulation on Cosmetic and Hygiene Products (ID 569)			Proposed	Mexico
31	Chile - Regulations on the classification, labelling and notification of chemical substances and mixtures (ID 570)			Proposed	Mexico
32	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) (ID 294)			Proposed/Final[1]	Japan European Union
33	Indonesia - Halal Product Assurance Law No. 33 of 2014 (ID 502)			Proposed/Final[2]	United States European Union

[1] The EU has indicated that this measure is proposed. Japan has indicated that this measure is final.
[2] The US has indicated that this measure is proposed. The EU has indicated that this measure is final.

	Specific Trade Concern	Notification symbol	Brief description of measure	Proposed/Final Measure	Member(s) raising
34	China - Cybersecurity Administration of China- Draft implementing measures for the Cybersecurity Review of Network Products and Services (CAC) (ID 533)			Proposed/Final[3]	Japan European Union
35	European Union - Amendments to the Directive 2009/28/EC, Renewable Energy Directive (ID 553).			Proposed/Final[4]	Malaysia Colombia Indonesia
36	Kingdom of Saudi Arabia - Technical Regulation for plastic products OXO - biodegradable (ID 583)	G/TBT/N/SAU/947		Final	United States European Union
37	India - New Telecommunications related Rules (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") (ID 274)			Final	United States European Union
38	Russian Federation - Draft Technical Regulation on Alcohol Drinks Safety (published on 24 October 2011) (ID 332)	G/TBT/N/RUS/2		Final	European Union

[3] The EU has indicated that this measure is proposed. Japan has indicated that this measure is final.
[4] Colombia has indicated that this measure is proposed. Malaysia and Indonesia have indicated that this measure is final.

	Specific Trade Concern	Notification symbol	Brief description of measure	Proposed/Final Measure	Member(s) raising
39	India - Electronics and Information Technology Goods (Requirements for Compulsory Registration) Order, 2012 (ID 367)	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 G/TBT/N/IND/44/Add.6 G/TBT/N/IND/47 G/TBT/N/IND/58		Final	United States
40	European Union - Hazard-based approach to plant protection products and setting of import tolerances (ID 393)	G/TBT/N/EU/383 G/TBT/N/EU/384 G/SPS/N/EU/166	Revised Proposal for the Categorization of Compounds as Endocrine Disruptors of 19 February 2013 by DG Environment	Final	United States Canada
41	India - The Stainless Steel Products (Quality Control) Order, 2015 (ID 486)	G/TBT/N/IND/50		Final	European Union
42	China - Registration Fees for Drugs and Medical Device Products (ID 466)			Final	Korea
43	China - Interim Measures for Quality Management of Commercial Coal (ID 477)			Final	Australia
44	India - Draft Food Safety and Standards (Alcoholic Beverages Standards) Regulations, 2015 (ID 494)	G/TBT/N/IND/51		Final	European Union
45	China - Formula Registration Regulation for Infant and Follow-up Formula (ID 493)			Final	United States
46	Russian Federation - Rules of cement certification (ID 497)	G/TBT/N/RUS/48 G/TBT/N/RUS/49		Final	European Union

	Specific Trade Concern	Notification symbol	Brief description of measure	Proposed/Final Measure	Member(s) raising
47	Egypt - Manufacturer Registration System (Decree No. 43/2016 and Decree No. 992/2015) (ID 505)	G/TBT/N/EGY/114 G/TBT/N/EGY/115	Registration of importers: Decree No. 43/2016 and Ministerial Decree No. 991/2015	Final	European Union
48	The Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu - Draft of the Organic Agriculture Act (ID 511)	G/TBT/N/TPKM/225 G/TBT/N/TPKM/225/Add.1 G/TBT/N/TPKM/225/Add.2		Final	European Union
49	China - National Standards on Limits of Volatile Organic Compounds for Furniture (ID 509)	G/TBT/N/CHN/1094 G/TBT/N/CHN/1095 G/TBT/N/CHN/1096		Final	European Union
50	China - Cybersecurity Law (ID 526)			Final	Japan European Union United States Korea
51	European Union - Organic production and labelling - Maté (erva-mate) (ID 524)		Regulations EC 834/2007 and EU 2018/848	Final	Brazil
52	China - Draft revised Encryption Law of the People's Republic of China by the Office of State Commercial Cryptography Administration (OSCCA) (ID 534)			Final	United States
53	European Union - Regulation (EC) No 1107/2009 - non-renewal of approval of the active substance picoxystrobin (ID 535)	G/TBT/N/EU/437		Final	Brazil
54	China - Certification requirements for processed foods (ID 547)			Final	United States

	Specific Trade Concern	Notification symbol	Brief description of measure	Proposed/Final Measure	Member(s) raising
55	Viet Nam - Decree 116/2017/ND-CP on business requirements for manufacturing, assembly and imports of automobiles, automobiles warranty and maintenance services (ID 549)	G/TBT/N/VNM/116	Decree on the regulation on conditions for automobiles manufacturing, assembling importing and automotive warranty & maintenance services	Final	United States European Union Thailand
56	Viet Nam - Cybersecurity Measures (ID 544)			Final	Japan United States
57	China - Catalogue of Solid Wastes Forbidden to Import into China (ID 545)			Final	United States Australia New Zealand
58	India - Amended regulation on toy imports (ID 546)			Final	China
59	European Union - Application of Regulation No. 1169/2011 and Regulation (EC) No. 1924/2006 as regards the labelling of food products, in not prohibiting or examining the use of "palm oil free" labels (ID 555)			Final	Colombia Indonesia
60	Thailand - Certificate of Analysis for the import of alcoholic beverages (ID 556)	G/TBT/N/THA/524	New certification requirements under the Thai Ministry of Finance's Ministerial Notification on Importation of Spirits into the Kingdom of Thailand (B.E 2560)	Final	European Union

	Specific Trade Concern	Notification symbol	Brief description of measure	Proposed/Final Measure	Member(s) raising
61	India - Testing and Certification of telegraph (The Indian telegraph (Amendment) Rules, 2017) (ID 558)	G/TBT/N/IND/66		Final	United States Korea
62	United States - TSA Certification on security screening equipment) (ID 559)			Final	China
63	Russian Federation - Federal law No 487-FZ, providing a framework for comprehensive use of special labelling and traceability of goods and Decision No. 792-r specifying the goods to which labelling will apply and the dates of introduction of the mandatory labelling (ID 567)			Final	European Union
64	Brazil - Technical Regulation 14, 8 February 2018, to set the additional official identity, quality standards for wine and derivatives of grape and wine products as well as the requirements to be acquainted and Technical Regulation No. 48, 31 August 2018 published in the Official Gazette on 10 September 2018 (ID 568)			Final	European Union New Zealand
65	Egypt - Halal requirements for Poultry Parts and Offal (ID 571)			Final	United States

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Committee on Technical Barriers to Trade Original: English

PRACTICAL GUIDELINES TO SUPPORT REGULATORS IN THE CHOICE AND DESIGN OF APPROPRIATE AND PROPORTIONATE CONFORMITY ASSESSMENT PROCEDURES

Submission from the European Union

The following communication, dated 14 June 2019, is being circulated at the request of the delegation of the European Union.

1.1. The European Union welcomes the recommendation of the Eighth Triennial Review adopted on 15 November 2018[1] under Article 15.4 of the Agreement on Technical Barriers to Trade (TBT Agreement), whereby the TBT Committee agreed to initiate work on developing non-prescriptive practical guidelines to support regulators in the choice and design of appropriate and proportionate conformity assessment procedures (the "Guidelines").

1.2. Annex 1 to the TBT Agreement defines conformity assessment procedures as any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled. They include, inter alia, procedures for sampling, testing and inspection; evaluation, verification and assurance of conformity; registration, accreditation and approval as well as their combinations.

1.3. In accordance with the Eighth Triennial Review, the Guidelines should include, but not be limited to, the following areas:

i. Criteria related to risk assessment and other relevant factors, including for identification of lower and higher risk products;

ii. The range of approaches to conformity assessment available to regulators within different regulatory frameworks;

iii. Elements of conformity assessment that regulators can use in designing appropriate procedures;

iv. Legal and administrative frameworks that enable regulators to confidently rely on a particular conformity assessment regime.

1.4. This submission intends to identify and develop some initial key guidance principles and best practices for regulators to set up appropriate and proportionate conformity assessment procedures of products in their domestic systems. These guidance principles and best practices should also serve as trade-facilitating tools, enhance trust between different regulatory systems and contribute to facilitating the acceptance of results of conformity assessment. For that purpose, this submission refers to some of the approaches contained in the TBT Committee's "indicative list of approaches to facilitate acceptance of the results of conformity assessment"[2].

1.5. The European Union proposes to consider in the future work of the TBT Committee on the Guidelines the elements on conformity assessment presented in Section 1 of this submission.

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[1] G/TBT/41.
[2] G/TBT/1/Rev.13.

These elements proved useful in the creation and efficient functioning of the EU internal market for goods.

1.6. Section 2 of this submission further develops some of these elements and provides information on specific regulatory features of the EU system on conformity assessment, including an overview of the EU conformity assessment procedures and the main EU approaches to accept results of conformity assessment[3].

1.7. This submission also takes stock of the main outcomes of prior discussions on conformity assessment held in the TBT Committee in the past, including the latest thematic session on risk assessment and market surveillance held in March 2019.

1 PROPOSED OBJECTIVES AND PRINCIPLES AND UNDERLYING CRITERIA OF THE GUIDELINES

1.1 GENERAL REMARKS

1.8. The European Union considers that the Guidelines' objectives should be to list a **baseline of common guidance principles and best practices** to be considered by regulators when setting up domestic mandatory conformity assessment procedures of products. This would contribute to reducing technical barriers to trade and to preventing the emergence of new ones.

1.9. The Guidelines should be without prejudice to specific regulatory requirements on conformity assessment that Members may require in their domestic systems for the fulfilment of legitimate public interest objectives, and which are not in contradiction with the proposed guidance principles and best practices.

In this regard, the European Union proposes the following general underlying principles to be considered in the Guidelines:

- *Members should be strongly encouraged to make best use of **relevant international standards** when adopting regulatory approaches on conformity assessment.*

  The Guidelines should refer to, and take stock of the existing international guides, recommendations and standards related to conformity assessment developed by ISO/IEC, in particular the ISO Committee on Conformity Assessment ("CASCO") toolbox, given their wide support and use.

  This is important as the use of relevant international standards, guides and

[3] The relevant EU regulatory framework on conformity assessment includes:

(i) **Regulation (EC) 765/2008** of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products (OJ L 218/30, of 13.8.2008). Regulation (EC) 765/2008 sets down the general principles and rules governing the EU regulatory systems on accreditation and marker surveillance.

(ii) **Decision 768/2008/EC** of 9 July 2008 on a common framework for the marketing of products (OJ L 218/82, of 13.8.2008). Decision 768/2008 provides for a general horizontal framework for EU sectoral harmonisation legislation. It lays down common principles and reference provisions on conformity assessment intended to apply across all EU sectoral harmonisation legislation. It also provides for a horizontal menu of conformity assessment procedures (modules) to be used in EU sectoral harmonisation legislation.

(iii) Commission Notice "The "**Blue Guide**" on the implementation of EU product rules 2016" (OJ C 272/1, of 26.7.2016). The Blue Guide is a guidance document intended to better understand the EU product rules and ensure their uniform and coherent application across different sectors and throughout the EU single market.
On the basis of these horizontal rules and provisions, EU sectoral harmonisation legislation provides for specific rules on conformity assessment applicable to the particular sectors subject to their scope of application. These provisions and rules can be further developed and interpreted by the case-law of the EU Courts of Justice. They are also complemented by the following general rules on product safety and liability:

(iv) **Directive 2001/95/EC** of 3 December 2001 on general product safety (OJ L 11/4, of 15.1.2002).

(v) **Directive 85/374/EEC** of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (OJ L 210/29/29, of 7.8.1985).

recommendations gives a common understanding of how conformity assessment should be performed with respect to the functioning of the different activities carried out (e.g. testing, calibration, inspection or certification) and of the possible range of conformity assessment procedures. The use of relevant international standards is also an essential prerequisite for developing mechanisms to facilitate the acceptance of conformity assessment results generated by conformity assessment bodies in different jurisdictions. This facilitates global trade and reduces burdens and costs for industries.

- *Members should also ensure the **transparency, coherence, predictability and legal certainty** in the definition and implementation of conformity assessment procedures. **Internal coordination** structures and appropriate **consultation** mechanisms should be envisaged and effectively implemented among all relevant actors intervening in domestic decision-making processes for the set-up of conformity assessment procedures.*

1.2 CRITERIA RELATED TO RISK ASSESSMENT AND OTHER RELEVANT FACTORS, INCLUDING FOR IDENTIFICATION OF LOWER AND HIGHER RISK PRODUCTS

1.10. Article 5.1.2 of the TBT Agreement provides that conformity assessment procedures shall not be stricter or applied more strictly than is necessary to give the importing Member adequate confidence that products conform to the applicable technical regulations or standards, taking account of the risks non-conformity would create.

1.11. By referring in particular to the need to take into account the risks that non-conformity would create (that is, the risk of placing on the market a product non-compliant with essential requirements), the TBT Agreement incorporates the notion that risk assessment is a crucial element for Members in choosing and designing appropriate and proportionate conformity assessment procedures. This requires that conformity assessment procedures do not create unnecessary obstacles to trade whilst ensuring that risks are effectively addressed.

1.12. The European Union considers that the Guidelines should further develop these considerations with the aim of facilitating the selection of conformity assessment procedures correlated and proportionate to the nature and degree of the risks involved by the products at stake and the level of safety or protection of other relevant public interest required as based on a **risk assessment**[4].

In this context, the European Union proposes that the Guidelines include the following elements:

- *The risk assessment should include the identification, analysis and evaluation of the particular risk for the public interests at stake and should be undertaken in accordance with criteria inspired or based on existing relevant international guides, recommendations and standards (e.g. ISO 31000 series on risk management and risk assessment).*

- *For this purpose, regulators should ensure, whenever possible, that the choice of conformity assessment procedures is based on as thorough a scientific risk assessment as possible, account being taken of the particular circumstances of the case at issue. This risk assessment should enable regulators to ascertain, based on the best technical or scientific evidence, when available, whether the risk and/or its magnitude is acceptable or not. In doing so, regulators may rely on opinions of relevant scientific bodies, specialised agencies or other independent scientific expertise.*

- *The choice of conformity assessment procedures should consider other factors that might also influence the regulators' decision-making process, such as the economic infrastructure of the sector (e.g. type and size of companies), the complexity of product technology, the lifetime of a product, or the type and importance of production.*

- *Taking into account these overall factors aiming at providing a high level of confidence as*

[4] For further information on risk assessment in the European Union, reference is made to the EU presentation given at the thematic session of 13 June 2017, G/TBT/GEN/226; RD/TBT/222.

*regards the conformity of products, while avoiding the imposition of heavier procedures than necessary and minimising the burden on manufacturers to the extent possible, regulators should select the **least onerous and proportionate** procedure.*

- *In particular, the European Union considers that the Guidelines should include the following criteria for the selection of conformity assessment procedures*:

  *(a) the **nature of the risks** entailed by the product and the extent to which conformity assessment corresponds to the type and degree of risk;*

  *(b) whether the procedure concerned is appropriate to the **type of product**, including its complexity, nature, way of production (e.g. mass production based on a "specimen", small series production) and its intended use;*

  *(c) the need to avoid imposing procedures which would be **too burdensome** for the manufacturers in relation to the risks covered by the technical regulations concerned;*

  *(d) the **size and the structure of the manufacturers** in the sectors concerned; and*

  *(e) the **specificities of these sectors**.*

- *The carrying out of a risk assessment should also be embedded in domestic regulatory frameworks as a **good regulatory practice** to be considered by regulators, not only on the possible need for regulation, but also on the choice of adequate and proportionate conformity assessment procedures.*

1.3 RANGE OF APPROACHES TO CONFORMITY ASSESSMENT AND ELEMENTS OF CONFORMITY ASSESSMENT THAT REGULATORS CAN USE IN DESIGNING APPROPRIATE PROCEDURES

1.13. The successful accomplishment of conformity assessment procedures enables manufacturers to demonstrate and the competent authorities to ensure that products made available on the market conform to the essential requirements set by the legislation to protect the relevant public objectives.

1.14. In this regard, the European Union proposes that the Guidelines should provide elements on practical aspects of the implementation of the main regulatory approaches to conformity assessment available to regulators (i.e. first-party and third-party conformity assessments). These approaches should be based on **clear**, **transparent**, **non-discriminatory** and **coherent criteria**.

1.3.1 First-party conformity assessment (Supplier's Declaration of Conformity, "SDoC")

1.15. First-party conformity assessment (SDoC), whereby the manufacturer declares conformity on his/her sole responsibility as assurance of conformity to technical regulations, can facilitate market access for both domestic manufacturers and suppliers located in other countries without prejudice to the fulfilment of legitimate policy objectives. As indicated by the European Union in its submission of 9 March 2018[5], SDoC schemes are generally regarded as bringing advantages to businesses, increasing the offer of products available to consumers, and facilitating trade. From the manufacturers' perspective, the main advantages are considered to be: lowering costs of demonstrating compliance, giving more control over time and access to market, often shortening time-to-market, and giving the choice of testing bodies between third-party conformity assessment bodies and in-house testing bodies.

[5] G/TBT/W/462.

In this regard, the European Union proposes the following elements for the Guidelines:

- *The Guidelines should consider the use of SDoC as the **preferred option** by regulators for the conformity assessment of product categories presenting risks for the public interest that are generally considered to be **low** as based on a risk assessment.*

- *Regulators may need to take into account other factors besides the nature of risks, such as in particular the economic infrastructure of the sector and the production system, as well as ex post market surveillance and product liability regimes that complement the assumption of responsibility by manufacturers.*

The European Union considers that in order to facilitate the use of SDoC by manufacturers and its acceptance by regulators, the Guidelines should:

- *Include the requirement by the manufacturer to establish a **technical file** containing the relevant documentation on the conformity of the products and to make this file available to public authorities, so as to render the monitoring and control of SDoC more effective.*

- *In case **testing to support the SDoC** is undertaken by in-house bodies belonging to the manufacturers' organisation, provide for the conditions of **independence** as far as possible and **impartiality** of the activities of these bodies.*

1.3.2 Third-party conformity assessment

1.16. With respect to third-party conformity assessment procedures, the Guidelines should address a number of general horizontal elements to be considered in the set-up of these procedures in order to facilitate its compliance by manufacturers and ensure trust and reliability on the activities of conformity assessment bodies.

In particular, the European Union proposes, as elements for the Guidelines, that regulators should:

- *Offer manufacturers a choice of alternative third-party conformity assessment **procedures** to demonstrate compliance with technical requirements, where this choice is possible and ensures the same level of assurance of conformity.*

- *Where appropriate, provide for the possibility of carrying out the **conformity assessment procedure in two steps** (first the examination of conformity of the prototype/specimen against the relevant legal requirements, and then the determination of the conformity of the series products against the approved type), for instance, in cases of mass production based on a prototype/specimen.*

- *Promote and use **accreditation** as a preferred method of qualifying conformity assessment bodies and demonstrating their technical competence in accordance with relevant international standard (e.g. ISO/IEC 17011).*

  This requirement would be in line with Article 6.1.1 of the TBT Agreement, which specifies that accreditation, when operated according to relevant international standards, guides and recommendations, offers a mechanism which could promote confidence on the technical competence of conformity assessment bodies.

  The particular value of accreditation would also lie in the cases in which it provides an authoritative statement of the technical competence of bodies whose task is to ensure conformity with the applicable requirements.

- *Do not adopt regulatory measures that limit or reduce the **choice** among the conformity assessment bodies designated for a particular product or set of products in their territories.*

- *Ensure that conformity assessment bodies are **impartial** and **independent** of*

manufacturers, importers and other interested parties, including their clients, in the performance of their activities, and that there are ***no conflicts of interest*** *between accreditation bodies and conformity assessment bodies.*

The proposed requirement for **independence** should cover the whole organisation, including the board or directors, and also apply to bodies belonging to business associations or professional federations.

In order to guarantee their **impartiality**, conformity assessment bodies and their staff should be free from any commercial, financial and other pressure that might influence their judgment. The structure of the body should also safeguard its impartiality, especially if the body has activities other than those of a conformity assessment body.

- *Where conformity assessment bodies* ***use subcontractors*** *to perform testing or inspections in relation to conformity assessment, require subcontractors to meet the same requirements that the sub-contracting conformity assessment body should meet in order to perform the sub-contracted tests or inspections itself. The conformity assessment body should retain responsibility and control over the subcontracted activities, and sufficient oversight of the subcontracted activities should also be ensured.*

- *Ensure the* ***protection of confidential information and data*** *and avoid unnecessary burdens for economic operators, so that the technical documentation provided to conformity assessment bodies is limited to that which is required solely for the purpose of assessing conformity to the legislation.*

- *Ensure* ***transparency****, so that information on the bodies that regulators have designated to perform conformity assessment is made publicly available, including on the scope of activities of each body.*

  Transparency should also be advocated in particular in relation to the fees methodology applied for conformity assessment performed by specified government authorities. It should also be ensured that such fees are made publicly available and are limited to the approximate cost of the services provided.

- *Ensure the* ***coordination*** *and exchange of best practices among conformity assessment bodies, where appropriate, to guarantee the consistency of the assessments carried out by those bodies against the applicable requirements.*

The Guidelines should also provide for elements to facilitate the acceptance of third-party conformity assessment results from other jurisdictions. In particular, it is suggested that regulators should:

- *Make best use of and/or take into account* ***international agreements or arrangements*** *involving cooperation among* ***accreditation bodies*** *to contribute to reinforcing the acceptance of conformity assessment results. This should be without prejudice to requirements that regulators may impose on accreditation bodies and conformity assessment bodies for the acceptance of results of conformity assessment on the basis of* ***public policy interests*** *in accordance with their domestic rules on products.*

- *Encourage conformity assessment bodies to join relevant functioning* ***international agreements or arrangements for harmonisation and/or facilitation*** *of acceptance of conformity assessment results.*

1.4 MARKET SURVEILLANCE AS LEGAL AND ADMINISTRATIVE FRAMEWORK THAT COMPLEMENTS THE EFFECTIVE IMPLEMENTATION OF CONFORMITY ASSESSMENT

1.17. The Eighth Triennial Review highlighted the importance of market surveillance when referring to "*legal and administrative frameworks that enable regulators to confidently rely on a particular conformity assessment regime*" as an area of work in which the Guidelines should focus. This was further emphasized during the thematic session on this topic held in March 2019 in which market surveillance was singled out as a post-market control that effectively complements conformity assessment. Taking stock of these discussions, the following considerations are put forward by the European Union for the Guidelines.

1.4.1 The role of market surveillance

1.18. Market surveillance consists of monitoring products placed on the market to ensure that they comply with applicable requirements and taking remedial action when products do not comply. Market surveillance is crucial to the enforcement of product legislation. It contributes not only to protecting users against unsafe or otherwise non-compliant products, but also to shielding businesses from unfair competition by those who do not comply with or wilfully circumvent the rules.

1.4.2 Market surveillance and conformity assessment

1.19. In the overall scheme of product compliance assurance, pre- and post-market controls need to be considered as two sides of the same coin. Indeed, any type of conformity assessment procedure requires an adequate level of post-market surveillance. The aim should be to achieve a balance between pre-market and post-market controls responding to the risk to be managed and to the particular circumstances of the market.

1.20. The development of adequate quality infrastructure and market surveillance capacity is essential to enable regulators to choose more flexible conformity assessment procedures that facilitate trade, and therefore to support the implementation of the TBT Agreement. In particular, investment in market surveillance can support the choice of conformity assessment procedures based on first-party conformity assessment (SDoC) for categories of products presenting a lower risk.

1.4.3 Key pillars of market surveillance to be considered in the Guidelines

1.21. The European Union considers that the Guidelines should include the following principles:

General market surveillance principles

- *Considering the impossibility to check all products placed on the market, market surveillance systems should be **evidence-based and risk-focused**, in accordance with the general principles of risk assessment and risk management. Such risk-based approaches require adequate prioritisation, targeting based on sound data and evidence, as well as regular evaluation of results.*

- *Market surveillance activities should be exercised in accordance with the **principle of proportionality**, meaning that the frequency of inspections and the resources employed should be proportionate to the level of risk and that enforcement measures should take into account the expected level of non-compliance and its likely impact.*

- *Restrictive measures taken by market surveillance authorities, for instance to recall or withdraw a product from the market, should follow **principles of due process** in respect of the economic operators concerned. In particular, such measures should state the exact grounds on which they are based. They should be communicated to the affected economic operators, together with adequate information on the remedies available to them and on the time limits applicable for such remedies. The economic operator should have the opportunity to be heard prior to the formal adoption of the measures, unless urgent action needs to be taken (in which case the operator should be heard as soon as possible and the*

actions taken may be reviewed thereafter).

- *Market surveillance activities should rest on a **clear legal framework** building on the above principles and ensuring good governance. For example, it should be fundamental to maintain transparency in the designation and role of the authorities responsible for enforcing regulation in specific geographic areas or product sectors. **Adequate cooperation structures and processes** between the different authorities involved (including customs authorities) should be established, including for the exchange of information and for ensuring smooth and effective controls that do not create unnecessary delays.*

- *Regulators should ensure the **independence** of market surveillance functions from conformity assessment functions with a view to avoiding conflicts of interest; and ensure that there are **no conflicts of interest** between market surveillance authorities and the economic operators subject to control or supervision, in particular the manufacturer, the importer and the distributor.*

Market surveillance capacities and approaches

- *Market surveillance authorities should be entrusted with the **powers, resources and knowledge** necessary for the proper performance of their tasks. This includes not only professional skills and competences but also adequate testing facilities since compliance verification often requires specialised laboratory capacities. Market surveillance activities should rely on an **appropriate mix of pro-active and reactive investigations**. In addition, the approach should not be restricted to compliance controls and enforcement measures: public policies should also seek to **promote and support compliance** through adequate information or guidance to economic operators, and the use of other relevant instruments facilitating cooperation with stakeholders.*

- *In order to maximise the effectiveness of market surveillance, **priority should be given to requesting corrective action** from the operator(s) responsible for placing a non-compliant product on the market. Should this approach fail, or if urgent action is necessary, national authorities should of course be empowered to adopt adequate and proportionate restrictive measures.*

- ***Strategic planning** is key to ensuring the effectiveness of market surveillance policies. Strategies should take into account not only short-term risks but also medium- to long-term developments of the market.*

Market surveillance powers

- *Clear definition of powers should be established for effective functioning of market surveillance, which may be exercised directly by the market surveillance authorities, through other public authorities or by judicial means. **Critical powers** should include – but not be limited to – the right to carry-out inspections, request information and documents, take samples of products and adopt proportionate measures which are required when products present a risk or do not comply. These should be accompanied by **appropriate sanction mechanisms**, such as the ability to impose penalties to economic operators found to be in breach of the rules.*

- *In the context of increasing internationalisation of trade and of the rapid **development of e-commerce**, new challenges arise for public authorities in charge of market controls. This may require new types of powers, such as the ability for market surveillance authorities to buy products on-line under a cover identity, as well as cooperation with relevant actors in the e-commerce supply chain.*

2 CONFORMITY ASSESSMENT IN THE EUROPEAN UNION

2.1 OVERVIEW OF EU CONFORMITY ASSESSMENT PROCEDURES

2.1. The EU system on conformity assessment provides for a menu of conformity assessment procedures (the so-called "modules") which are pre-defined and regulated in a horizontal decision addressed to the EU legislators[6]. Out of this menu, each sector-specific harmonisation legislation must specify which one(s) of those procedures is or are applicable to the products which fall under its scope of application. This modular approach is based on the conformity assessment toolbox developed by ISO CASCO[7], and provides for a wide range of conformity assessment solutions from which the legislator can make a choice in relation to its specific regulatory needs. That ensures a coherent approach to the extent that the legislator cannot deviate from the specified conformity assessment procedures.

2.2. Conformity assessment procedures in the EU are grouped in two main categories which include:

a. First-party conformity assessment, whereby the manufacturer declares conformity on his/her sole responsibility as assurance of conformity to technical regulations. This is the preferred procedure for low to medium risk products, which are the vast majority of products covered by EU harmonisation legislation[8].

b. For products presenting a higher-risk to the relevant public policy objectives, the intervention of an independent third-party conformity assessment body is required, including cases where the assessment is performed by specified governmental bodies.

2.3. These two broad categories include sub-variants and combinations. They are without prejudice to other voluntary procedures that might also be used in non-regulated sectors or complementarily, such as second-party conformity assessment, whereby the purchaser/user of the products performs the conformity assessment for his needs of assurance that the products meet the applicable technical requirements. They are also without prejudice to the existence of specific systems of regulatory pre-market approvals, whereby the regulator itself may authorise the placing on the market of a particular product in certain sectors (e.g. pharmaceuticals).

2.4. The key regulatory features of each of these approaches are the following.

2.1.1 First-party conformity assessment

2.5. First-party conformity assessment (also called internal production control in the EU system) includes the performance of a safety assessment of the product by the manufacturer for both the design and production phases of a product.

2.6. In order to render the monitoring and control of this type of conformity assessment, manufacturers must establish a technical file containing the documentation that covers the design, manufacture and operational aspects of the product reflecting the results of an appropriate risk assessment, the standards followed and, if applicable, the test results obtained from a competent laboratory.

2.7. The manufacturer must also draw up and keep together with the file a copy of the declaration of conformity. The manufacturer must keep the file and the declaration of conformity for a specific period (10 years) in order to make them available to the competent authorities upon request.

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[6] Decision 768/2008 of 9 July 2008, on a common framework for the marketing of products, see footnote 3 above.

[7] In particular, European harmonised standards on conformity assessment developed by the European Standardisation Bodies are based on relevant ISO/IEC standards (i.e. ISO/IEC 17000 series). The list of harmonised standards on conformity assessment can be found at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:C:2017:298:FULL&from=EN.

[8] In the European Union, first-party conformity assessment applies in the fields of electrical equipment, machinery, toys, some medical devices, cosmetics, personal protective equipment, radio equipment, textiles, some equipment for explosives atmospheres, some construction products, and consumer products.

2.8. The manufacturer takes responsibility for placing the products on the market and must also take all necessary measures in order that the manufacturing process ensures compliance with the technical documentation and the relevant applicable legal requirements.

2.9. First-party conformity assessment may be supported by additional testing. In these cases, the manufacturer has the free choice of the testing laboratory: it can perform the relevant tests in-house if he possesses the adequate facilities, or make recourse to a third-party body.

2.10. Furthermore, in the cases where legislation allows conformity assessment to be performed with the involvement of an in-house body or test facility that forms a part of the manufacturer's organisation, it must be ensured that this facility, including its personnel, remains impartial and does not participate in the design, production, supply, installation, use or maintenance of the product it assesses. They must not engage in any activity that might conflict with their independence of judgment or integrity in relation to their assessment activities either.

2.1.2 Third-party conformity assessment

Conformity assessment procedures/modules

2.11. EU third-party conformity assessment modules include procedures such as type examination, quality assurance of the final product, quality assurance of the production process, product verification, unit verification, or combinations of these elements. In some cases the conformity assessment procedure can take place in two phases combining two modules: first, examination of a specimen or the design of the product (the so-called EU-type examination) and secondly, examination of the conformity of the manufactured products against the approved specimen. This is relevant for the cases of mass production based on a prototype/specimen representative of the production envisaged and where the product in question is of complex design, as it clearly reduces the burden of conformity assessment for manufacturers.

2.12. In many cases EU legislation also enables manufacturers to choose the type of conformity assessment procedure to follow (e.g. product verification or quality assurance), so as to allow them to have different alternatives equally acceptable and leading to the same results of assurance of conformity which take into account their manufacturing structures and production processes. This is of importance for small and medium sized companies that might not have full-fledged in-house capacities to apply more stringent conformity assessment procedures, such as full quality management systems of their manufacturing process.

2.13. As in the case of first-party conformity assessment, the manufacturer must also establish a technical file and keep it together with the declaration of conformity at the disposal of the competent authorities for a period of 10 years.

Notification process and accreditation

2.14. To carry out conformity assessment activities in the European Union, third-party conformity assessment bodies must be officially designated (notified) by the competent national authorities of the Member States in which they are established (notifying authorities). By means of the notification, Member States' notifying authorities take final responsibility for the technical competence, independence and impartiality of their notified bodies.

2.15. Through the notification, the notifying authority informs the European Commission and the other Member States that a conformity assessment body has been designated to carry out conformity assessment according to a specific EU harmonisation legislation. Through this process, the European Commission and other Member States must be given sufficient information to demonstrate the competence of the conformity assessment body to carry out their tasks.

2.16. For this purpose, Member States may rely on accreditation, which is the preferred instrument for evaluation of the technical competence and integrity of the conformity assessment bodies to be notified in the European Union.

2.17. Accreditation is an essential tool to ensure the professional competence and reliability of conformity assessment bodies. Accreditation of conformity assessment bodies is based on European harmonised standards that rely on relevant international standards. They define the general competence criteria for EU conformity assessment bodies, but additional competence criteria that are specific to the relevant sectorial legislation are also required where applicable.

2.18. Accreditation bodies in the European Union have to demonstrate that they are capable and competent to carry out accreditation and for that purpose they have to adhere to the European harmonised standard EN ISO/IEC 17011 that relies on relevant international standards. The main principles of accreditation in the European Union that accreditation bodies must also meet are:

i. Accreditation is to be operated as a public authority activity. For this reason, each Member State may appoint one single national accreditation body.

ii. The responsibilities and tasks of national accreditation bodies have to be clearly distinguished from those of other national authorities.

iii. There is no competition between national accreditation bodies.

iv. Accreditation is to be provided on a not-for-profit basis.

v. Accreditation bodies are only to be active on the territory of their own Member States as a general rule.

vi. Stakeholders' involvement is ensured in the accreditation bodies.

2.19. If accreditation is not used in the assessment of the technical competence of conformity assessment bodies, the notifying authority must base its evaluation in alternative documentary evidence necessary for the verification of this competence.

2.20. In terms of process, the notification of a notified body is sent by the notifying authority to the Commission and the other Member States through an electronic notification tool managed by the European Commission where a list of all notified bodies can be found[9]. The notification must include full details of the body, its conformity assessment activities, the conformity assessment procedures and products concerned for which it is competent, and the relevant attestation of competence.

2.21. The notification is published following a period allowed for objections by other Member States or the European Commission, and only where no such objections have been raised.

2.22. After the notification, there is a regular public monitoring by Member States' notifying authorities and the European Commission of the notified bodies which have been listed. For instance, notifications must be updated every 5 years. Also the notifying Member State in case of serious concerns that the notified body does not longer fulfil the applicable requirements, may suspend or withdraw the designation/notification.

2.23. The European Commission can also on its own initiative or upon a complaint request information and appropriate documented evidence to a notifying Member State if it considers that a notified body does no longer meet the appropriate criteria. If information is not provided, it might bring the case to the attention of the other Member States for discussion and ultimately request the notifying Member State to de-notify the conformity assessment body. In case this request is not carried out, the European Commission may ultimately open an infringement procedure against the notifying Member State before the European Court of Justice.

[9] This system is named the New Approach Notified and Designated Organisations (NANDO) Information System.

2.2 ACCEPTANCE OF RESULTS OF CONFORMITY ASSESSMENT BY THE EUROPEAN UNION

2.24. The European Union accepts results of conformity assessment produced in other jurisdictions in different ways and by means of different procedures that are in line with the TBT Committee's indicative list of approaches to facilitate results of conformity assessment.

2.25. As above mentioned[10], the European Union widely accepts the use of first-party conformity assessment (SDoC) in a wide range of sectors, which directly facilitate market access.

2.26. Another of the instruments to promote international trade of products by the European Union is the conclusion of mutual recognition agreements (MRAs) in accordance with Article 6.3 of the TBT Agreement. MRAs are government-to-government agreements for the purpose of mutual recognition of results of conformity assessment between the parties.

2.27. Further to the practice and experience of the European Union, MRAs may differ in terms of scope, regulatory aspects and levels of ambition:

a. *Traditional MRAs*: Traditional MRAs are designed so that conformity assessment bodies of one party certify products for access to the other party's market according to this second party's technical regulations. In other words, the second party accepts the mandatory test reports and/or certificates issued by laboratories and/or conformity assessment bodies of the first party. The conformity assessment bodies and/or laboratories are designated under the MRA for assessing conformity in the field(s) covered by the MRA, so that the products are evaluated in the country of production against the regulatory requirements of the country of destination. As pre-condition for a MRA the two regulatory systems of the parties are, as a rule, deemed to ensure a comparable level of protection regarding health, safety, environment or other public interests.

   MRAs may apply to one or more categories of products or sectors for which the regulations of at least one of the parties require third-party conformity assessment. They may also contain provisions on cooperation between the accreditation bodies of the parties with the aim of extending their scope to a broad range of categories of products.

   MRAs bring forward different benefits and advantages. Where a product intended for two markets may still have to be assessed twice (when technical requirements or standards are different), the assessment will be cheaper when carried out by the same body. The time to market is also reduced since contacts between the manufacturer and the single conformity assessment body, and a single assessment, speed up the process. MRAs can also pave the way towards bringing the systems of standardisation and certification by the parties closer to each other, and increase transparency of their regulatory systems.

b. *Enhanced-MRAS*: MRAs can provide for further regulatory convergence and equivalence of the legislation of the parties. In such cases, the conformity assessment bodies of one party is allowed to issue certificates according to its own legislation, which are deemed equivalent to those issued by the conformity assessment bodies of the other party. In these cases, the benefit is clear as the product is assessed only once.

   This can only be possible in case the parties have equally developed technical infrastructure (e.g. public or private institutions dealing with standards, accreditation, conformity assessment, market surveillance and consumer protection). Moreover, the parties must modify and align their legislation in the sectors covered by the agreement or, alternatively, have their respective legislations harmonised in accordance with and based on relevant international instruments and standards.

[10] See Section 2.1.1 above.

3 CONCLUSION

3.1. The European Union trusts that the initial elements on conformity assessment presented in this submission will positively contribute to the future work on the development of the Guidelines, and it looks forward to a fruitful exchange of views, experiences and practices with other Members on conformity assessment.

3.2. The European Union remains ready to provide further complementary explanations and contributions on this topic as the discussions and work on the Guidelines progress as a follow-up to the implementation of the Eighth Triennial Review.

歐盟有關符合性評鑑程序指導文件之討論文件（JOB/TBT/322）內容摘譯

一、 通用性的原則及良好作業：儘量使用國際標準作為符合性評鑑程序；符合性評鑑程序應透明化、維持一致性、可預測性及法規明確性。

二、 風險評估及其他可以辨識產品風險程度的因子：

1. 風險評估應包含 2 件事，辨識、分析及評估當時公共利益所面對的特定風險，並採用相關國際標準或建議的做法（如 ISO 31000 有關風險管理及風險評鑑的系列標準）。

2. 法規主管機關選用符合性評鑑程序應儘可能使用科學性的風險評估，讓法規機關可以依據最佳的技術或科學證據確認所面對的風險或其影響是否可接受，為此，可以仰賴科學機構、專業機構或獨立科學專業人員的意見。

3. 符合性評鑑程序的選擇應考量其他可能因素，如該產業領域的經濟架構（公司的種類及大小）、產品技術複雜度、產品生命週期或製程的種類及重要性。

4. 考量可以提供產品符合規定高度信心的所有因素，但應選擇最小負擔及符合比例原則的持續。

5. 選擇符合性程序的標準：產品的風險性質及符合性評鑑程序是否可以處理該風險型態與程度、符合性評鑑程序是否適合該產品類別（產品複雜度、特性、一個型式大量生產方式或系列生產、產品使用用途）、業者規模及產業架構、產業的規格等。

6. 風險評估的執行應納入法規制訂架構的良好法規作業中，作為是否需要制訂法規及選擇適當符合性評鑑程序的考量。

三、 符合性評鑑程序的種類及要件

1. 對於普遍評估對公眾利益造成低風險的產品類別應優先選用供應商符合性聲明：

   i. 法規主管機關可能考慮風險本身以外的其他因素，如產業的經濟結構及產製體系、市場監督、產品責任等可以補足製造商負擔責任的其他因素

   ii. 要求製造商準備證明產品符合性資料的技術文件，提供法規主管機關查閱，以便有效監督並控管 SDoC 的使用

   iii. 對於 SDoC 制度下使用製造商自己的機構測試產品者，應確保該測試機構運作的獨立性及公正性。

2. 如使用第三者符合性評鑑：

   i. 應提供第三者符合性評鑑程序的替代方案用來證明符合技術要求，並讓製造商可以自行選擇

   ii. 適當時，提供 2 步驟的符合性評鑑是程序，第一個步驟為檢查原型或樣本符合相關法規，第二個步驟為決定系列產品（如為大量生產者）符合核可的原型式

iii. 鼓勵使用認證作為符合性評鑑機構之資格要求，並證明其技術能力符合相關國際標準

iv. 勿採用可能就特定產品業者在其國內選擇指定符合性評鑑機構造成限制之措施

v. 符合性評鑑機構應公正獨立、且認證機構與符合性評鑑機構間無利益衝突

vi. 符合性評鑑機構將測試或檢查外包時，外包機構亦應符合相關規定，符合性評鑑機構對於外包的作業負完全責任

vii. 機敏資訊及數據的保護

viii. 法規主管機關指定可以執行符合性評鑑工作的機構資訊應公開(包含每個機構可以執行的範圍）

ix. 由特定政府部門執行之符合性評鑑作業的收費方法應透明且限於符合執行成本所需

x. 符合性評鑑機構間應彼此協調並交換良好作業，確保不同機構執行的符合性評鑑活動的一致性

3. 相互承認

i. 儘量使用認證機構間的國際協定或協議，促進符合性評鑑結果的接受，法規主管機關基於公共政策利益得依據國內法規要求符合性評鑑結果的接受有其他規定。

ii. 鼓勵符合性評鑑機構參與促進符合性評鑑結果接受的國際協定或協議

四、 市場監督在法規及行政架構中支持符合性評鑑的有效實施

1. 市場監督一般性原則

i. 市場監督制度應基於證據及風險（風險評鑑及風險管理），並有適當的優先順序及定期檢討結果

ii. 市場監督活動應符合比例原則，執行的頻率及資源的運用應適合風險的程度，執行方法要考量預期的不符合率及可能的影響

iii. 市場監督主管機關所採取的召回或下架措施應遵循適當程序，說明理由，並將理由告知受影響的業者，一併提供可採取的改善措施資訊，以及改善時間，讓業者有機會陳述意見

iv. 市場監督活動應有清楚的法律架構，執行市場監督機構的指定及角色應維持透明化，應建立不同市場監督間（含海關）適當的協調架構及作業，避免造成不必要的延誤

v. 法規主管機關應確保市場監督功能獨立於符合性評鑑功能之外，並避免與業者產生利益衝突

2. 市場監督的能力與方法

i. 市場監督機關應具備足夠的權力、資源及知識，包含專業技巧與能力，以及適當的測試設備，來證明產品符合規定。市場監督有被動及主動調查，不應限制在產品符合性的管制上，應該透過適當的資訊或指導文件協助業者符合規定

ii. 為強化市場監督效益，市場監督管制措施應優先要求業者改正措施，如無效或有緊急狀況，才採取其他限制性措施。

iii. 市場監督政策的效益必須有中長期的策略規劃

3. 市場監督的權力

i. 為有效發揮市場監督功能，應清楚定義市場監督的權力，如有權力執行工廠檢查、提供資訊、取樣及採取適當措施，此外應有適當的處罰機制，對於違法業者祭出罰則。

ii. 國際貿易活動增加及電子商務迅速發展，市場監督機關應賦予新的能力，如隱匿身份於網站上查訪、購買產品，並與電商業者合作。

RESTRICTED

JOB/TBT/273/Rev.3

14 May 2019

(19-3334) Page: 1/6

Committee on Technical Barriers to Trade

FOLLOW-UP TO THE EIGHTH TRIENNIAL REVIEW: AIDE-MEMOIRE

NOTE BY THE SECRETARIAT[1]

Revision

At the 14-15 November 2018 meeting, the Chairperson reported on discussions related to the organization of work in 2019. The Chairperson invited Members to provide ideas and proposals for speakers for all thematic sessions to be held in 2019. In addition, the Chairperson invited the Secretariat to prepare a running list to keep track of the proposals and ideas received from Members relating to work in 2019, including thematic sessions. This document is intended to serve as an aide-memoire of the ideas and proposals received to date; it is intended to facilitate Members' deliberations on the follow-up to the Eighth Triennial Review (G/TBT/41). It will be updated as appropriate.

1 GOOD REGULATORY PRACTICE

1.1 March 2019

1.1. The **Thematic Session** on *domestic committees, and other administrative mechanisms, that facilitate internal coordination on TBT*[2] took place on 5 March 2019.[3]

1.2 Other

1.2. **Future thematic sessions**:

a. Ecuador called for discussion of regulatory impact assessment to facilitate analysis of new regulations, and of experiences of Members in applying cost benefit analysis.[4]

2 CONFORMITY ASSESSMENT PROCEDURES

2.1 March 2019

2.1. The **Thematic session** on *risk assessment; post market controls (e.g. market surveillance) and other pre-market controls*[5] took place on 5 March 2019.[6]

[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] G/TBT/41, para. 8.2(a)(iv), and footnote 294.
[3] G/TBT/GEN/256, Moderator's report.
[4] G/TBT/M/76, para 4.7.
[5] G/TBT/41, para. 8.2(a)(iv), and footnote 295.
[6] G/TBT/GEN/257, Moderator's Report.

2.2 November 2019

2.2. **Thematic session** on *National Quality Infrastructure*[7]

a. Indonesia proposed a presentation: "Indonesia's experience on the use of Accreditation as a basis for conformity assessment acceptance", speaker to be confirmed.[8,9]

b. The European Union [10] proposed a presentation: "Overview of the system for accreditation in the EU as part of National Quality Infrastructure" (title to be confirmed), Mr. Andreas Steinhorst, Executive Secretary, European co-operation for Accreditation.[11,12]

c. Australia said the Australian Technical Infrastructure Alliance (ATIA) will require further time to consult and identify relevant case studies and specific potential speaker/s, and may possibly be able to present.[13]

d. The International Bureau of Weights and Measures (BIPM) suggested a presentation: "A common international approach to Quality Infrastructure – recent developments", Mr. Andy Henson, Director of International Liaison and Communication Department, BIPM.[14]

e. China expressed interest in participating in the session, the exact topic and speaker would be confirmed in due course.[15]

f. Trinidad and Tobago proposed a presentation: title to be confirmed, Ms. Joanne Beharry, Standards Officer III, Trinidad and Tobago Bureau of Standards.[16]

2.3 Other

2.3. **Future thematic sessions**

a. Brazil highlighted the recommendation for a thematic session on "case studies of practical examples of how Members arrive at the acceptance of conformity assessment results"[17] and said it was preparing a paper on this topic for upcoming discussions.[18]

b. South Africa suggested that the issue of "certificates of free sale" [19] be discussed, including: the cost to the exporting Member; how certificates of free sale fit within the TBT Agreement; application of a certificate of free sale requirement in conjunction with other technical regulations or conformity assessment procedures; the challenges in connection with complex value chains and products that are manufactured only for export and according to the requirements of the importing Member but not domestic requirements; the competent authority that issues such certificates and the possibility of issuing a certificate of free sale as an exporter's declaration of conformity; and, resource constraints that prevent Members (requiring certificates of free sale) from putting technical regulations and conformity assessment procedures in place domestically.[20]

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[7] G/TBT/41, para. 8.2(a)(iv), and footnote 298.
[8] G/TBT/M/76, para 4.4.
[9] JOB/TBT/278.
[10] G/TBT/M/76, para 4.4.
[11] JOB/TBT/281.
[12] Informal TBT Committee meeting, 8 February 2019.
[13] JOB/TBT/285.
[14] JOB/TBT/276.
[15] Informal TBT Committee meeting, 8 February 2019.
[16] JOB/TBT/302.
[17] G/TBT/41, para. 4.17(c.vi).
[18] G/TBT/M/76, para 4.4.
[19] G/TBT/41, para 4.17(c.iii).
[20] Informal TBT Committee meeting, 8 February 2019.

2.4. **Follow-up to Triennial Review Recommendations**

a. Development of guidelines to support regulators in the choice and design of conformity assessment procedures.[21]

i. The European Union said this recommendation was a priority for follow-up. The EU believed that the guidelines should at least contain elements of the four main areas identified in the Eighth Triennial Review report: criteria related to risk assessment; range of approaches to conformity assessment available to regulators; elements of conformity assessment that regulators can use in designing appropriate procedures; and, other legal and administrative frameworks that could enable regulators to rely on one or another conformity assessment procedure.[22] Working on this basis, the EU suggested the development of an initial outline, to bring forward ideas or elements under the four main areas of work, that could be complemented afterwards by subsequent written contributions on specific topics for discussions within the Committee. The EU invited other Members to bring forward their initial ideas and elements as to the main principles and criteria that should be contained in these Guidelines.[23] The EU intended to present an initial outline of relevant general principles ahead of the 18 June 2019 informal meeting, to facilitate the start of the discussions. In addition, the EU intended to draw out some general principles on market surveillance following the outcome of the March 2019 thematic session[24], and intended to build on the Indicative List of Approaches to Facilitate the Results of Conformity Assessment[25].[26]

ii. The United States said recommendations on conformity assessment producers were a priority for follow-up.[27] The US was preparing a submission along the lines of the mandate contained in the Eighth Triennial Review, which it anticipated circulating ahead of the June 2019 informal meeting.[28]

iii. China said recommendations on conformity assessment procedures were a priority for follow-up, and in particular discussion on mutual recognition of conformity assessment results.[29]

iv. New Zealand welcomed discussions on the guidelines for conformity assessment procedures and offered to share its experiences, possibly ahead of the June 2019 informal meeting, including materials to guide regulators and businesses on standards and conformity assessment.[30]

v. Canada said the Standards Council of Canada was working on a submission, likely to be provided ahead of the June 2019 informal meeting.[31]

[21] G/TBT/41, para. 4.17(b).
[22] G/TBT/41, para. 4.17(b).(i-iv).
[23] Informal TBT Committee meeting, 8 February 2019.
[24] G/TBT/GEN/257, Moderator's Report.
[25] See: Annex 1 of G/TBT/1/Rev.13.
[26] Informal TBT Committee meeting, 29 April 2019.
[27] Informal TBT Committee meeting, 8 February 2019.
[28] Informal TBT Committee meeting, 29 April 2019.
[29] Informal TBT Committee meeting, 8 February 2019.
[30] Informal TBT Committee meeting, 29 April 2019.
[31] Informal TBT Committee meeting, 29 April 2019.

3 TRANSPARENCY

3.1 June 2019

3.1. **Thematic Session on Transparency including the Ninth Special Meeting on Procedures for Information Exchange**[32,33]

a. The European Union proposed a presentation: "EU practice on the dissemination of comments and substantive replies on notified measures via online tools", by Ms. Patricia McGinley, EU WTO TBT Enquiry Point Coordinator, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, European Commission.[34,35,36]

b. Brazil proposed the following topics and presentations with respect to "Submission of notifications: measures that may relate to both the SPS and TBT Agreements"[37]:

   i. Introduction of relevant provisions and procedures by the Secretariat.

   ii. Members' experiences with incoming notifications / trade implications. Brazil proposed a presentation: title to be confirmed, Representative of the Department of Non-Tariff Negotiations of the Ministry of Agriculture.

   iii. Members' experiences in submitting notifications. Brazil proposed a presentation: title to be confirmed, Representative of Inmetro.

c. The United States[38] proposed five presentations[39]:

   i. "How Communication Between Enquiry Points Can Be Used to Reduce, Clarify and Resolve Specific Trade Concerns", MaryAnn Hogan, United States Enquiry Point, National Institute of Standards and Technology.

   ii. "Using a TBT Notification Alert System to Engage the Private Sector in Commenting on WTO Notifications: U.S. Experiences and Practices", MaryAnn Hogan, United States Enquiry Point, National Institute of Standards and Technology.

   iii. "How the United States evaluates and incorporates comments received in the rulemaking process", Ravi Bharwani, U.S. Food and Drug Administration.

   iv. "Notice & Comment and Cooperation on Other Transparency Best Practices: U.S. Experience on Cooperation in Commercial Dialogues and Other Initiatives", Sigrid Simpson, Senior International Trade Specialist, Good Regulatory Practices, U.S. Department of Commerce.

   v. "Experience Assisting with the Functioning of Enquiry Points in Africa via the Standards Alliance", Leslie McDermott, Director, International Development, American National Standards Institute.

[32] G/TBT/41, para. 8.2(a)(iv), and footnotes 296 and 297.
[33] On 19 March, a draft outline was circulated by the Secretariat in JOB/TBT/303.
[34] JOB/TBT/280.
[35] Informal TBT Committee meeting, 8 February 2019.
[36] Informal TBT Committee meeting, 29 April 2019.
[37] JOB/TBT/283.
[38] Informal TBT Committee meeting, 29 April 2019.
[39] JOB/TBT/305.

d. Australia proposed:

i. that the Secretariat provide a draft for Members' consideration of the proposal contained in the Eighth Triennial Review with respect to adopted final texts.[40]

ii. a topic for presentation[41]: "Increasing transparency and addressing Non-Tariff Barriers (NTBs): Australia's experience", speaker to be confirmed.[42]

e. China proposed a presentation[43]: "The Working Mechanisms of China on TBT Transparency", Mr. Yang Song, Director, National TBT/SPS Notification and Enquiry Center of the People's Republic of China.[44]

f. The Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu proposed a presentation: "Practical Experience of Processing Requests", Li-Yu Wei, Associate Technical Specialist, Bureau of Standards, Metrology and Inspection[45]

g. Uganda proposed a presentation": "Use of ePing by the Enquiry point to disseminate and coordinate review of draft SPS and TBT measures in Uganda", George Opiyo, Uganda National Bureau of Standards.[46]

3.2 Other

3.2. **Follow-up to Triennial Review Recommendations**

a. Switzerland expressed interest in the recommendations on improving the handling of comments[47], and would provide more specific suggestions in due course.[48]

b. China said recommendations on transparency were a priority for follow-up, in particular those relating to the submission of notifications.[49] During China's internal notifying procedure, it was sometimes difficult to establish whether a draft technical regulation or conformity assessment procedure may fall under TBT or SPS Agreements. China also faced challenges on identification of products including with respect to the use of ICS or HS Codes and product names where precise codes do not apply.[50]

4 STANDARDS

4.1 November 2019

4.1. **Thematic session** on *incorporating standards by reference in regulations*[51]

a. Canada proposed a presentation: "Incorporation of Standards by Reference in Canada: Considerations for Trade", Stephen Head, Manager, Strategic Policy and Sector Engagement, Standards Council of Canada.[52,53]

[40] JOB/TBT/304.
[41] Informal TBT Committee meeting, 29 April 2019.
[42] JOB/TBT/306.
[43] Informal TBT Committee meeting, 29 April 2019.
[44] JOB/TBT/307.
[45] JOB/TBT/308
[46] JOB/TBT/309.
[47] G/TBT/41, para. 6.19(f).
[48] Informal TBT Committee meeting, 8 February 2019.
[49] G/TBT/41, para. 6.19(d).
[50] Informal TBT Committee meeting, 8 February 2019.
[51] G/TBT/41, para. 8.2(a)(iv), and footnote 299.
[52] G/TBT/M/76, para 4.4.
[53] JOB/TBT/293.

b. Australia said Standards Australia could possibly present on the topic of Australia's experience with incorporating standards by reference in regulations. This could be followed by a discussion of how to increase awareness when standards referenced in regulations have been updated.[54]

c. China expressed interest in participating in the session, the topic and speaker would be confirmed in due course.[55]

d. The European Union expressed interest in participating in the sessions, to provide an overview of EU practice on incorporation of standards by reference in legislation.[56]

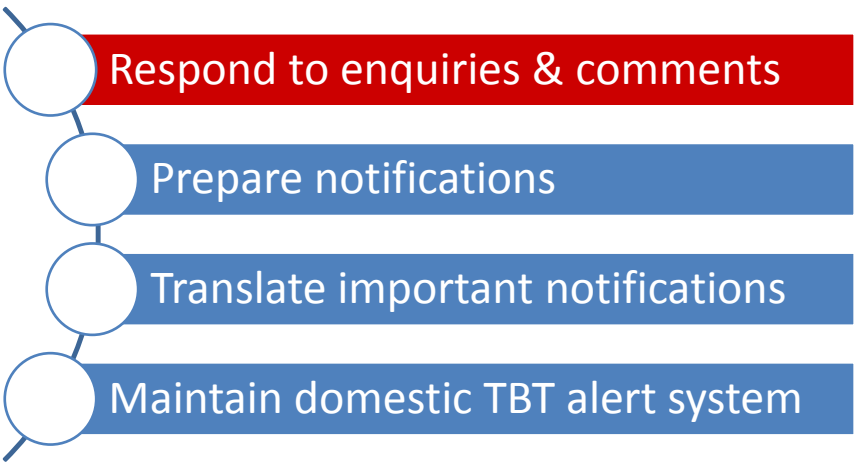
[54] JOB/TBT/286.
[55] Informal TBT Committee meeting, 8 February 2019.
[56] Informal TBT Committee meeting, 8 February 2019.

Practical Experience of Processing Requests

Li-yu Wei
TBT Enquiry Point
The Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu (Chinese Taipei)

1

The tasks of our Enquiry Point



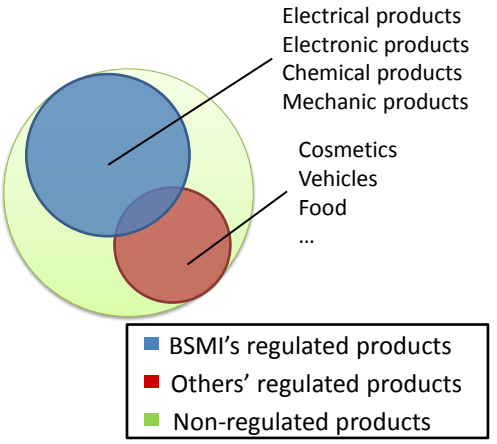
2

Where are we?

Ministry of Economic Affairs

Bureau of Standards, Metrology and Inspection (BSMI)

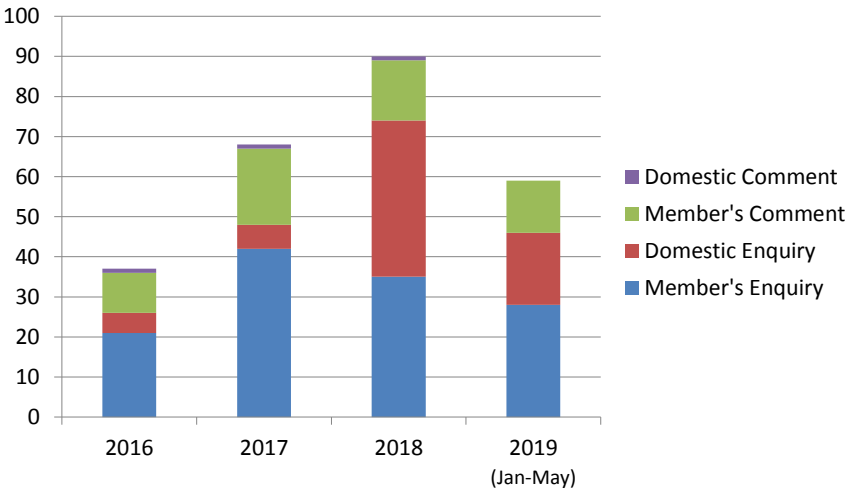
TBT Enquiry Point



Domestic TBT Meeting

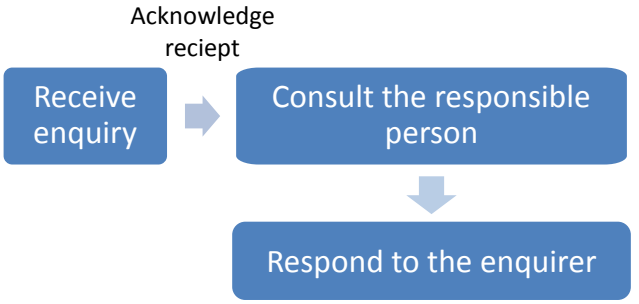
3

Usage of Enquiry Point is increasing!



4

Procedure of handling enquiries from international stakeholders

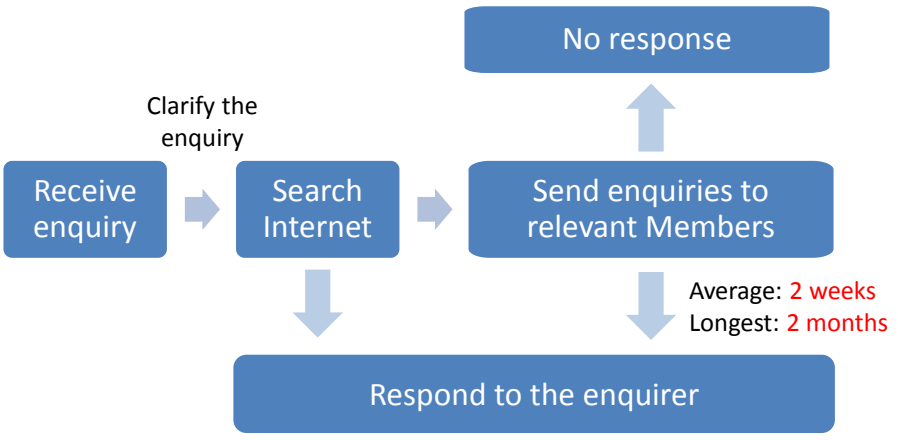


Note:
Our response usually contains:
(1) supporting documents; or
(2) links to official websites.

time needed:
< 5 days

5

Procedure of handling enquiries from domestic stakeholders



6

Difficulties in sending enquiries to Members

- No acknowledgement/response
- Time consuming
- Partial response
- Accuracy/correctness of the response

7

Suggestions (1)

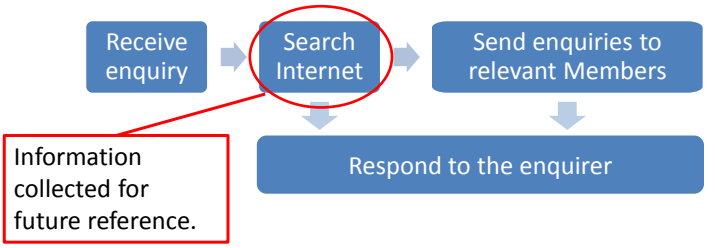
- To follow the decisions stated in Paragraph 5.7.2.1.1 of G/TBT/1/Rev.13
  - To acknowledge receipt of an enquiry
  - To process within 5 working days for requests for documentation

  (Chapter 3 of WTO TBT Enquiry Point Guide also contains similar texts)
- To provide supporting documents or official links

8

FAQ by domestic stakeholders

1. Is my product for export regulated?
2. What are the applicable standards?
3. Who can perform the CAPs?



9

Sharing what we have collected

Information on the access to websites of mandatory standards or technical regulation

The following table shows links to the official websites of some Members that contain the information on the scope of regulated E&E products and applicable standards. The links were collected, as of 31 May 2019, by Chinese Taipei's TBT Enquiry Point during its service to respond to enquiries received. They were provided to enquirers as the first step to answer questions instead of raising them directly to the TBT Enquiry Point of relevant Members. Requests were sent afterwards if the information was not available on the websites or if further clarification was needed.

No.	Members	Links	Access method/update time
1.	The Philippines	Bureau of Philippine Standards http://www.bps.dti.gov.ph/	Click "List of Products Under Mandatory Certification" at the bottom-right of the website. *last updated on 2 April 2019
2.	Viet Nam	Vietnam TBT Enquiry Point http://tbt.gov.vn/	DATA>>Group 2 – Products and Goods *last updated on 2 April 2019
3.	Indonesia	Baden Standardisasi Nasional http://www.bsn.go.id/	SNI>>Technical Regulation>>Technical Regulation (SNI Required) *last updated on 2 April 2019
4.	Thailand	Thai Industrial Standards Institute (TISI) https://www.tisi.go.th/home/en	Standards List>>List of Compulsory Standards *last updated on 2 April 2019

Total 13 Members

Main page of official website

10

Suggestion (2)

- To share Member's approaches to helping stakeholders access other Members' TBT information

Thank you for your attention!

Liyu Wei
Chinese Taipei TBT Enquiry Point
Bureau of Standards, Metrology and Inspection
Email: tbtenq@bsmi.gov.tw
Fax: 886-2-2343-1804

ORGANIC AGRICULTURE ACT

SEPARATE CUSTOMS TERRITORY OF TAIWAN, PENGHU, KINMEN AND MATSU –THE ORGANIC AGRICULTURE ACT

(G/TBT/N/TPKM/225, & ADD. 1-2)

Thank you, Chair.

The European Union would like to thank Chinese Taipei for its written communication and the bilateral dialogue on the reform of its regulation on organic products.

The new Organic Bill was promulgated on 30 May 2018. Chinese Taipei notified to the TBT Committee, on 7 January 2019 the draft implementing regulations of the new bill. The European Union submitted comments on the implementing regulations on 14 March 2019, to which Chinese Taipei replied on 22 March 2019.

We very much regret that the new Bill allows only for a transitional period of 2 years, after which the unilateral recognition of 16 Member States will expire. The European Union considers that the consequences for trade partners are disproportionate, and a more flexible transitional arrangement should be considered in the future.

The European Union's main concern is how the Organic Bill will be implemented. Given that the European Union is the second largest exporter of organic products to Chinese Taipei, this system needs to be effective and to avoid any trade disruptions which would also harm retailers and consumers from Chinese Taipei. In particular, the European Union requests Chinese Taipei to quickly set up a clear information tool to allow European operators and Control Bodies to familiarize with the new imports procedures as soon as possible.

Subsequently, the European Union calls for a rapid and swift recognition of the European Control Bodies by the competent authorities of Chinese Taipei.

The European Union would also request to effectively recognize the European standards for products coming from the European Union. This is currently not the case since, in practice, compliance with Chinese Taipei standards is still checked. This is causing tremendous problems for trade and, given the high level of European standards, Chinese Taipei can have full confidence that by respecting the European standards, products from the EU are safe. This recognition should extend to all 28

EU Member States because the EU is a single market with a single production standard.

Thank you, Chair.

附件 6

Statement by Chinese Taipei for STC no.48 "Draft Organic Agriculture Act" (ID 511)

Thank you, Chair.

We appreciate the continued concern by the EU for our Organic Agriculture Promotion Act. We notified all implementing regulations to the WTO, and all of them are adopted. For details of the adopted text, please see the addendums of notifications G/TBT/N/TPKM/346-348, 364-366, 370 and 371.

Without reiterating what was said at the previous meeting, we assure to the EU of our continued efforts to work closely with the EU on this matter. Thank you.

附件 7

2019 年 6 月 TBT 委員會會議重要貿易關切案件彙整表[註]

2019.07.11 彙整

特定貿易關切(STC)是 WTO 會員國間解決技術性貿易障礙（TBT）問題的重要途徑，TBT 問題通常來自進口國過於嚴格的產品規定(多與檢測驗證有關)，造成產品難以出口到該國。當業者遭遇TBT問題時，WTO會員國會在WTO的TBT委員會上向造成貿易障礙的國家提出STC，希望藉由 164 個 WTO 會員的同儕壓力讓造成貿易障礙的會員修正規定，或是提出更清楚的說明資料。

108 年第 2 次的 TBT 委員會會議已在 6 月 20-21 日召開，考慮到會對其他國家造成貿易障礙的法規也很有可能對我國業者造成不利影響，經濟部標準檢驗局共整理 38 項 STC（如下表，篩選的原因列於備註欄），包含食品、醫藥產品、化粧品、化學物質、玩具、家電電子產品等，針對每一項 STC，我們摘要其他會員關切或質疑的內容重點，如果您的產品出口到這些國家時也遭遇同樣問題，歡迎與我國 TBT 查詢單位聯絡(電郵信箱：tbtenq@bsmi.gov.tw)，以便提供進一步協助。

編號	遭關切會員	內容簡述	備註
食品			
1	中國大陸	案件名稱： 進口食品隨附證書管理辦法（草案） 會員關切意見： 1. 希望中國大陸說明草案的最新進展及實施細節。 2. 涵蓋範圍過大，盼能考慮產品風險有不同管制方式。 3. 未採用國際標準。 被關切會員回應立場： 中國大陸回應該辦法的目的並非限制貿易，而是確保食品安全，並藉由加強出口國家主管機關的責任改善追溯性。中國大陸向會員保證，法規在 10 月生效之後，即使會員不提供證書，亦不會影響現行貿易。中國大陸目前正向 Codex 提出制定有關低風險食品定義的指導文件。(但該文件極可能來不及在 10 月前完成)	特定貿易關切編號： IMS ID 547 通知文件編號： G/TBT/N/CHN/1209 列為重要案件原因： 我國曾經關切案件 提出關切會員： 美國、日本、瑞士、墨西哥
2	沙烏地阿拉伯	案件名稱： 部分食品糖份添加上限 會員關切意見： 沙烏地阿拉伯於本年 4 月 16 日通知涉及所有含糖食品	特定貿易關切編號： 暫無 通知文件編號： G/TBT/N/SAU/1108

[註]表格中的案件細節可至 WTO 建置之 TBT IMS 網站（http://tbtims.wto.org/），以特定貿易關切編號或通知文件編號進行搜尋。

編號	遭關切會員	內容簡述	備註
		（排除使用人工代糖之蘇打飲料及特定飲食需求之食品）之技術性法規，5 月 1 日再追加通知能量飲料及預包裝鮮果汁含糖上限。（會員表示因該法規草案影響範圍極大，包含冰淇淋、糖果、果凍等，應以提高消費者意識取代訂定強制性規定，且業者符合規定有困難） **被關切會員回應立場**： 沙烏地阿拉伯於 6 月 12 日發出追加通知，表示暫不實施該法規，將再檢討並願與會員雙邊諮商。	G/TBT/N/SAU/1108/Add.1 G/TBT/N/SAU/1108/Add.2 **列為重要案件原因**： 新關切案件 **提出關切會員**： 美國、瑞士、歐盟、俄羅斯
3	印尼	**案件名稱**： 清真產品保證法 **會員關切意見**： 1. 涵蓋範圍過廣，可能涵蓋食品、飲料、藥品、化學品、消費性產品、化粧品等。要求說明產品類別的實施期程（目前瞭解於 5-7 年內分階段實施，第 1 階段為食品及飲料）。 2. 非清真食品的販售不應受影響，且非清真產品要求額外標示為不必要的規定。 3. 盼確切實施日期是否為 2019 年 10 月 7 日。 4. 希望取得最終文本及指導文件。 **被關切會員回應立場**： 印尼表示實施法規仍在研擬中，未來將指定強制納入規範的產品，並提供過渡期。境外驗證機構必須取得認證(核發的認證機構須與 KAN 簽有相互承認協議)，或者有政府間的相互承認協議才能執行清真產品的驗證。產品的標示可以使用印尼政府認可的驗證機構所提供的 Halal 標籤，但產品必須先有 BPJPN 登錄號碼。非 Halal 產品仍可在適當標示後販售。	**特定貿易關切編號**： IMS ID 502 **通知文件編號**： 未通知 **列為重要案件原因**： 經濟部國際貿易局關注議題 **提出關切會員**： 美國、歐盟、巴西、紐西蘭、澳洲、加拿大
4	歐盟	**案件名稱**： 食品「不含棕櫚油」標示 **會員關切意見**： 1. 「不含棕櫚油」標示將誤導消費者，對含棕櫚油的食品產生健康或環境疑慮。允許食品出口業者在缺少科學證據下作此標示將造成不公平及不必要的貿易障礙。雖然是自願性標示，但自願性標示不應	**特定貿易關切編號**： IMS ID 555 **通知文件編號**： 未通知 **列為重要案件原因**： 多個 WTO 會員關切

編號	遭關切會員	內容簡述	備註
		造成混淆。國際標準（Codex Stan 1-1985）對此有一般性的原則。 2. 促請歐盟給予棕櫚油及其他蔬菜油（葵花籽、黃豆、芥花油）相同的待遇。 3. 詢問歐盟如何查核前述額外造成混淆的標示，歐盟主管機關如何保證標示「不含棕櫚油」食品的資訊是否正確。 **被關切會員回應立場：** 歐盟有關提供消費者食品資訊的法規並未要求任何型態的負面標示，但法規允許製造商在自願的基礎上提供產品未包含特定成分的資訊，前提是該資訊不得含混不清或誤導消費者。「不含棕櫚油」的標示並非法規所定義的營養宣稱，但可以被認為是所允許的營養宣稱的一部分內容。監督食品符合法規要求的責任在歐盟會員國。	**提出關切會員：** 印尼、哥倫比亞、哥斯大黎加、厄瓜多、瓜地馬拉、泰國、馬來西亞、宏都拉斯
醫療器材、藥品			
5	歐盟	**案件名稱：** 醫療器材及體外診斷醫療器材法規 **會員關切意見：** 1. 歐盟於 2017 年 4 月採納了 2 份與醫療器材相關的法規，其中醫療器材法規(Regulation 2017/745)於 2020 年 5 月生效，體外診斷醫療器材法規(Regulation 2017/746)於 2022 年 5 月生效。這兩份法規將分別取代舊的指令。 2. 會員關切醫療器材法規實施日期在即，認可驗證機構的數量不足執行新法規的要求，建議延長至 2024 年實施。 **被關切會員回應立場：** 歐盟表示法規將在 2020 年 5 月及 2022 年 5 月實施，今年年底前認可驗證機構數量應會達到 20 多家，並會製作指導文件供業者參閱。舊法的過渡期到 2024 年 5 月。	**特定貿易關切編號：** 暫無 **通知文件編號：** G/TBT/N/EU/71/Add.1 G/TBT/N/EU/72/Add.1 **列為重要案件原因：** 新關切案件 **提出關切會員：** 美國、加拿大
6	中國大陸	**案件名稱：** 醫療器械監督管理條例修正草案 **會員關切意見：** 1. 進口醫療器材的許可及註冊所需的測試僅能在中國大陸境內實驗室進行，要求中國大陸承認國外測	**特定貿易關切編號：** IMS ID 428 **通知文件編號：** G/TBT/N/CHN/1313 **列為重要案件原因：**

編號	遭關切會員	內容簡述	備註
		試報告。 2. 詢問醫療器材申請備案或註冊所要求的測試報告是否需要現場測試或者文件審查。 3. 詢問第19條要求的臨床試驗對象是否有資格限制。 4. 草案新增境外醫療器械上市許可證持有人的代理人未履行相關義務的罰則，對國內卻無，沒有國民待遇。 5. 要求足夠的過渡期。 **被關切會員回應立場：** 中國大陸回應已公布指導文件說明外國臨床試驗結果的接受作法，整個註冊程序已簡化：醫療器材分為3類，低風險產品的程序進一步簡化；某些產品免除臨床試驗，提供1年過渡期。2018年9月公布免除臨床試驗產品1248項清單，其中包含855項醫療器材及393項植入式醫療器材。	重要貿易地區 **提出關切會員：** 韓國
7	中國大陸	**案件名稱：** 藥品及醫療器材註冊費用 **會員關切意見：** 進口醫療器材註冊費用高於國內生產，雖然中國大陸說明進口產品費用包含工廠檢查，但工廠檢查並非強制性，直接納入計算不合理。 **被關切會員回應立場：** 中國大陸回應國際間收取註冊費乃常態，中國大陸收取人民幣624,000元已比其他會員低。	**特定貿易關切編號：** IMS ID 466 **通知文件編號：** 未通知 **列為重要案件原因：** 我國過去關切案件、重要貿易地區 **提出關切會員：** 韓國、澳洲
化粧品			
8	中國大陸	**案件名稱：** 「化粧品註冊和備案檢驗管理辦法」草案 **會員關切意見：** 第7條有關檢驗機構應具備獨立行政法人資格並取得檢驗檢測資質認定（CMA），資格僅限中國大陸境內機構（建議應開放國外機構申請）。 **被關切會員回應立場：** 中國大陸回復本案仍在草案階段，歡迎會員評論。	**特定貿易關切編號：** 暫無 **通知文件編號：** G/TBT/N/CHN/1311 **列為重要案件原因：** 新關切案件 **提出關切會員：** 日本、韓國、美國
9	印度	**案件名稱：**	**特定貿易關切編號：**

編號	遭關切會員	內容簡述	備註
		2018 化粧品規則草案 **會員關切意見**： 1. 「2018 化粧品規則」草案未通知，該草案修正印度 1940 藥品及化粧品法案與 1945 藥品及化粧品規則 *註：印度於 TBT 委員會後(6 月 21 日)提出通知文件，並提供 60 日評論期* 2. 測試僅能在印度境內實驗室進行（建議承認外國實驗室測試報告） 3. 草案未採用國際標準。 **被關切會員回應立場**： 草案已通知，並提供 60 日評論期。	暫無 **通知文件編號**： G/TBT/N/IND/101 **列為重要案件原因**： 新關切案件 **提出關切會員**： 美國、歐盟
10	中國大陸	**案件名稱**： 化粧品監督管理條例草案及化粧品註冊和備案檢驗管理辦法 **會員關切意見**： 1. 管理條例第 15 條規定化粧品的功效宣稱應當在指定的網站公開，可能涉及機密資訊的揭露。 2. 管理條例第 38 條要求進口化粧品加貼的中文標籤應當與原標籤一致，應重新考量，因原標籤的設計通常是為了符合原產國的規定，與進口國不同。 3. 新成分的申請程序需要進一步釐清。 4. 應接受業者自行測試的報告，提供足夠的過渡期，並告知實施日期。 **被關切會員回應立場**： 中國大陸表示相關實施規則正草擬中，歡迎會員的評論意見。	**特定貿易關切編號**： IMS ID 576 **通知文件編號**： G/TBT/N/CHN/1310 G/TBT/N/CHN/1311 **列為重要案件原因**： 重要貿易地區 **提出關切會員**： 日本、美國、韓國
化學物質分類、農業			
11	歐盟	**案件名稱**： 不再重新核准殺蟲劑活性物質「四氯異苯腈（Chlorothalonil）」的使用 **會員關切意見**： 1. 四氯異苯腈普遍被農民做為殺菌劑（如香蕉、咖啡、柑橘類水果、木瓜及西瓜、穀類作物）控制病蟲害，應以基於科學證據的風險評估決定限制量，並應符合國際標準。	**特定貿易關切編號**： IMS ID 579 **通知文件編號**： G/TBT/N/EU/625 **列為重要案件原因**： 多個 WTO 會員關切

編號	遭關切會員	內容簡述	備註
		2. 殺蟲劑的改變及尋找替代方案都需要時間，過渡期要足夠。 3. 歐盟停止核准四氯異苯腈的使用及後續農藥殘留容許量（MRLs）的調降已造成貿易問題。 4. 四氯異苯腈在全球 109 個國家核准使用，且 Codex 的 MRLs 值允許 70mg/kg。 5. 將四氯異苯腈由第 2 類改為第 1b 類的科學根據不足。 **被關切會員回應立場：** 歐盟表示由於四氯異苯腈代謝會污染地下水，目前無法證明代謝物的存在對人體健康不會造成不可接受的傷害。	**提出關切會員：** 美國、瓜地馬拉、巴西、巴拿馬、巴拉圭、加拿大、厄瓜多、哥斯大黎加、宏都拉斯
12	歐盟	**案件名稱：** 農藥殘留容許量過渡期及國際協商 **會員關切意見：** 1. 農產品要符合新規定的 MRLs 一般需要 36 個月，只提供 TBT 協定要求的 6 個月過渡期是不夠的。 2. 要求給予噻嗪酮（buprofezin）新的容許量更長的過渡期。 3. 歐盟修改不同化學物質使用於農業生產的容許量應與貿易夥伴協商，並採納 Codex 多邊架構的決定。 **被關切會員回應立場：** 歐盟表示 MRLs 的討論應在 SPS 委員會討論，且已履行兩個協定下的相關義務，所接獲的資訊及評論意見在做成決定前均已適度納入考量。	**特定貿易關切編號：** IMS ID 580 **通知文件編號：** 未通知 **列為重要案件原因：** 多個 WTO 會員關切 **提出關切會員：** 哥倫比亞、瓜地馬拉、美國、巴拉圭、巴西、厄瓜多、哥斯大黎加、巴拿馬
13	歐盟	**案件名稱：** 以風險為基礎的植物保護產品及進口容許量的設定 **會員關切意見：** 1. 歐盟採用的方式是以化學物質本身危害性（hazard-based），而非化學物質可能造成傷害的風險（risk-based）為基礎，造成許多活性成分已不再獲得歐盟核准使用。 2. 一但被歸類為「賀爾蒙干擾素」，相關食品及飼料必須符合 MRLs。請歐盟確認 MRLs 及進口容許值的訂定仍將以風險為基礎。	**特定貿易關切編號：** IMS ID 393 **通知文件編號：** G/TBT/N/EU/383 G/TBT/N/EU/384 G/SPS/N/EU/166 **列為重要案件原因：** 多個 WTO 會員關切

編號	遭關切會員	內容簡述	備註
		3. 要求歐盟採用 Codex 標準，避免造成不必要的貿易障礙。 **被關切會員回應立場**： 歐盟回應理解會員的關切主要是有關植物保護產品中歐盟認定賀爾蒙干擾素的科學基準，以及歐盟是否會對於其境內禁用的物質設立進口產品的容許值(參考 Regulation (EC) No 1107/2009)。歐盟在考量各方意見後決定採用 Regulation (EC) No 396/2005 規章中的程序，該程序包含歐盟會員國的風險評估及歐洲食品安全主管機構（EFSA）的科學意見，而進口容許值的核准是以個案方式進行。	**提出關切會員**： 加拿大、阿根廷、美國、巴拉圭、哥斯大黎加、巴西、印度、泰國、烏拉圭、哥倫比亞、瓜地馬拉、澳洲、巴拿馬
14	歐盟	**案件名稱**： 不再重新核准活性物質啶氧菌酯（picoxystrobin） **會員關切意見**： 1. 有 65 個國家允許使用啶氧菌酯，歐盟的決定並未基於科學證據、國際共識及專業機構對於該物質使用未構成毒性的意見。 2. 歐盟先於 TBT 委員會通知不再核准活性物質的使用，後續才在 SPS 委員會通知 MRLs 修訂的措施，而且只提供 6 個月過渡期，嚴重影響會員農產品的出口。 3. 對於此類跨領域的措施，歐盟應同時提出 TBT 及 SPS 通知。 **被關切會員回應立場**： 歐盟表示有關降低啶氧菌酯 MRLs 的措施草案已透過 SPS 通知文件告知第三國，在考量收到意見後，動植物食品飼料常設委員會決定同意草案，修正後的 MRLs 於 2019 年 1 月通過，將自 2019 年 8 月 13 日實施。進口容許值申請將以個案處理。	**特定貿易關切編號**： IMS ID 535 **通知文件編號**： G/TBT/N/EU/437 **列為重要案件原因**： 多個 WTO 會員關切 **提出關切會員**： 巴西、加拿大、巴拿馬、巴拉圭、哥倫比亞
玩具			
15	印度	**案件名稱**： 2019 玩具（品質）命令草案 **會員關切意見**： 1. 「2019 玩具（品質）命令」草案不接受國際實驗室認證合作機制下的測試報告，並指接受印度境內之測試數據（建議接受外國測試實驗室報告）	**特定貿易關切編號**： 暫無 **通知文件編號**： 未通知 **列為重要案件原因**：

編號	遭關切會員	內容簡述	備註
		2. 請印度儘速提出通知文件 **被關切會員回應立場：** 印度正與利害關係人協商中，完成後將提出通知。	新關切案件 重要產業 **提出關切會員：** 美國、歐盟、加拿大
16	印度	**案件名稱：** 進口玩具法規修正 **會員關切意見：** 1. 盼印度對國內外玩具採用同樣的測試要求。 2. 不應只接受 NABL 認證實驗室進行的玩具測試。 3. 印度不再利用國際標準測試玩具，也不接受 ILAC 認證實驗室測試的規定。建議將國際標準作為 BIS 標準之替代作法。 4. 外國實驗室申請 NABL 認證很困難。 **被關切會員回應立場：** 印度回應 IS9873 等同 ISO8127，IS15644 等同 IEC62115。NABL 認證申請案都已在處理中。	**特定貿易關切編號：** IMS ID 546 **通知文件編號：** G/TBT/N/IND/68 **列為重要案件原因：** 新南向國家 重要產業 **提出關切會員：** 中國大陸、美國、歐盟
17	印尼	**案件名稱：** 有關強制性玩具安全印尼國家標準之採納及實施技術指導文件 **會員關切意見：** 1. 感謝印尼的玩具驗證制度除了逐批檢驗外，在製造階段另外納入品質管理系統的替代選項。 2. 外國測試報告必須透過與 Komite Akreditasi National (KAN)簽署相互承認協議才能接受。促請印尼政府接受 ILAC 認證實驗室的測試報告。 3. 要求採用 SNI 7617:2013 版本的標準，因為該版本有關甲醛的測試與國際標準較為一致。 4. 請印尼儘速公布指導文件。 5. 國內產品測試頻率仍比進口產品享有優惠待遇。 **被關切會員回應立場：** 印尼表示玩具的檢驗制度有逐批檢驗及產品驗證 2 種。相關規定在 29/2018 號法規中，指導文件起草中。	**特定貿易關切編號：** IMS ID 328 **通知文件編號：** G/TBT/N/IDN/64 G/TBT/N/IDN/64/Add.1 G/TBT/N/IDN/64/Add.2 G/TBT/N/IDN/64/Add.3 **列為重要案件原因：** 新南向國家 玩具 **提出關切會員：** 美國、歐盟、日本、加拿大
酒類			
18	歐盟	**案件名稱：** 酒精性飲料的定義、描述、呈現及標示；其他食品標示及呈現所使用的酒精性飲料名稱；保護酒精性飲料的地理標示；酒類飲料中乙醇及農業來源蒸餾酒的使	**特定貿易關切編號：** 暫無 **通知文件編號：**

編號	遭關切會員	內容簡述	備註
		用 **會員關切意見**： 修正後的草案版本比之前2016年通知的版本酒精飲料的定義更為嚴格，並且就「農業」(agriculture)用詞設限，請歐盟說明其理由。 **被關切會員回應立場**： 歐盟回應，對於在蘭姆酒上使用 agriculture 這個字的限制是自 1989 年以來就有的，歐盟也未曾收到任何就本酒精性飲料修正草案的意見。	G/TBT/N/EU/432/Rev.1 **列為重要案件原因**： 新關切案件 **提出關切會員**： 蓋亞那
19	烏拉圭	**案件名稱**： 進口產品分析一國家葡萄生產及酒類製造院決定一實施日期延至 2019 年 5 月 1 日之一酒中之外加水 **會員關切意見**： 烏拉圭禁止外加水的酒進口，並要求所有酒類產品進口時提出該批產品未包含外加水之證明，造成貿易障礙。另烏拉圭納入規定的產品範圍不明確(特別是發酵時添加的水是否受規範)，希望烏拉圭採用國際標準(OIV)。 **被關切會員回應立場**： 烏拉圭表示如果是稀釋用的水排除在外，將繼續與會員溝通。	**特定貿易關切編號**： 暫無 **通知文件編號**： G/TBT/N/URY/27/Rev.1 **列為重要案件原因**： 新關切案件 **提出關切會員**： 美國、智利、澳洲、南非、紐西蘭
20	愛爾蘭	**案件名稱**： 公共衛生（酒精）法案 2015 **會員關切意見**： 1. 要求額外標示及上市銷售的規定，特別是在警語標示部分將酒精與致命性癌症做出直接連結(將使消費者對酒類有負面印象)。 2. 相關標示規定細節將於子法中列出，希望了解立法的程序及預計通知 WTO 的時程。 3. 盼釐清對於已經進入歐盟市場的產品，當輸往愛爾蘭時是否需要二次貼標。 **被關切會員回應立場**： 歐盟回應法案已於 2018 年 10 月 17 日通過，相關子法必須先通知歐盟，也會通知 WTO。3 年的過渡期將等待所有通知程序完成後才開始起算。	**特定貿易關切編號**： IMS ID 516 **通知文件編號**： G/TBT/N/IRL/2 **列為重要案件原因**： 多個 WTO 會員關切 **提出關切會員**： 阿根廷、美國、紐西蘭、墨西哥、澳洲、智利

編號	遭關切會員	內容簡述	備註
家電、電子產品			
21	歐盟	<u>案件名稱</u>： 不同產品生態設計法規（草案及已通過） <u>會員關切意見</u>： 1. 歐盟最近制訂一系列有關伺服器及家電產品之生態設計法規，盼釐清法規涵蓋的產品範圍，如沒有烘衣功能的洗衣機、沒有烘乾功能的洗碗機等是否包含在內。 2. 法規要求維修零組件必須於 15 天內提供，對於國外製造商不公平。 3. 有關燈源的測試要求與國際標準(IEC)不同。 4. 盼延長過渡期。 <u>被關切會員回應立場</u>： 歐盟回應本案已提供充足的評論期。	<u>特定貿易關切編號</u>： 暫無 <u>通知文件編號</u>： G/TBT/N/EU/615 G/TBT/N/EU/611 G/TBT/N/EU/606 G/TBT/N/EU/581 等 <u>列為重要案件原因</u>： 新關切案件 <u>提出關切會員</u>： 中國大陸
22	歐盟	<u>案件名稱</u>： 電子顯示器生態設計法規草案 <u>會員關切意見</u>： 1. 歐盟法規草案中禁止使用所有鹵素阻燃劑，並要求零組件送達時間，對貿易造成重大影響。 2. 最新草案內容與前一版有重大差異，應重新通知，並再次提供 60 日評論期。 3. 盼釐清工業用顯示器是否涵蓋在法規範圍內。 4. 業者無法符合新的 EMC 規定。 <u>被關切會員回應立場</u>： 歐盟答復阻燃劑的使用為部分限制，限制範圍從電視及電視顯示器延伸至電子顯示器，包含電腦顯示器。除了因應技術提昇而提高能效要求外，也新增循環經濟要求，包括耐久性、可維修性，及回收過程效率。	<u>特定貿易關切編號</u>： IMS ID 575 <u>通知文件編號</u>： G/TBT/N/EU/609 G/TBT/N/EU/610 <u>列為重要案件原因：</u> 重要產業 <u>提出關切會員</u>： 美國、中國大陸、日本
23	印度	<u>案件名稱</u>： 電子及資訊科技商品強制性登錄命令 <u>會員關切意見</u>： 1. 要求改善程序以縮短延誤的時間 2. 要求允許同一個廠牌的一件登錄案可以包含多個製造工廠 3. 目前測試須由印度標準局(BIS)認可實驗室執行才	<u>特定貿易關切編號</u>： IMS ID 367 <u>通知文件編號</u>： G/TBT/N/IND/44 G/TBT/N/IND/44/Add.1 G/TBT/N/IND/44/Add.2

編號	遭關切會員	內容簡述	備註
		能進行登錄，盼明確知道登錄的規定。 4. 目前印度只接受關鍵安全零組件的 IEC CB Scheme 測試報告或 ILAC 認證實驗室架構下的測試報告，應擴大接受範圍。 **被關切會員回應立場**： 印度回應登錄的申請已可於線上完成，整體流程已改善，外國測試報告需有相互承認協議始能接受。	G/TBT/N/IND/44/Add.3 G/TBT/N/IND/44/Add.6 **列為重要案件原因**： 新南向國家 重要產業 **提出關切會員**： 美國、加拿大、歐盟
資訊、網路安全(可連網裝置)			
24	中國大陸	**案件名稱**： 保險機構信息化監管規定草案 **會員關切意見**： 1. 在中國大陸資訊安全等級保護制度中，倘被歸類在第三級或以上之保護等級，將在事實上排除所有外國資通訊產品。 2. 要求釐清決定保護等級的原則。 3. 要求制定網路安全相關法規時應公開透明，且讓外商也能參與討論。 4. 中國大陸要求產品符合定義不清的要求(如安全可控的)，使得境內業者只敢採購中國大陸製品，造成實質歧視。 **被關切會員回應立場**： 中國大陸表示已遵守 WTO 規則，並且未歧視國外產品。	**特定貿易關切編號**： IMS ID 489 **通知文件編號**： G/TBT/N/CHN/1172 **列為重要案件原因**： 新興議題(網安&資安) **提出關切會員**： 歐盟、美國
25	中國大陸	**案件名稱**： 加密法草案 **會員關切意見**： 1. 盼釐清定義、審查要求、法規範圍。 2. 盼釐清加密法與網路安全法的關聯性。 3. 要求不妨礙外國產品進入中國大陸市場。 4. 要求中國大陸遵循國際標準。 5. 要求採用風險導向的做法。 **被關切會員回應立場**： 中國大陸表示立法將採用科學方法，並與利害關係人溝通，未來修法將朝降低行政許可數量的方向進行。	**特定貿易關切編號**： IMS ID 534 **通知文件編號**： 未通知 **列為重要案件原因**： 新興議題(網安&資安) **提出關切會員**： 日本、歐盟

編號	遭關切會員	內容簡述	備註
26	中國大陸	案件名稱： 資安產品要求，包含 1999 商用密碼管理條例與其更新版及多層保護架構(Multi-Level Protection Scheme, MLPS) 會員關切意見： 1. 盼釐清新的 MLPS 是否會取代舊的 MLPS。 2. 要求中國大陸將草案進行通知。 3. 在中國大陸資訊安全等級保護制度中，倘被歸類在第三級或以上之保護等級，將在事實上排除所有外國資通訊產品。 4. 要求制定網路安全相關法規時應公開透明，且讓外商也能參與討論。 5. 中國大陸要求產品符合定義不清的要求(如安全可控的)，使得境內業者只敢採購中國大陸製品，造成實質歧視。 被關切會員回應立場： 中國大陸表示本案仍在草擬階段，完成後將開放評論。	特定貿易關切編號： IMS ID 294 通知文件編號： 未通知 列為重要案件原因： 新興議題(網安&資安) 提出關切會員： 日本、歐盟、澳洲
27	中國大陸	案件名稱： 國家互聯網信息辦公室關於「網路安全審查辦法」草案 會員關切意見： 1. 要求中國大陸將草案通知 WTO，並供會員評論。 2. 會員認為草案內容的用字定義不清，且將影響大範圍產品。 3. 盼瞭解後市場監督的作法。 4. 要求不歧視外國產品。 被關切會員回應立場： 中國大陸表示相關審查機制早在 2017 年 5 月就已公布，中國大陸認為本草案對外國並無歧視。	特定貿易關切編號： IMS ID 533 通知文件編號： 未通知 列為重要案件原因： 新興議題(網安&資安) 提出關切會員： 日本、歐盟、加拿大
28	中國大陸	案件名稱： 網路安全法 會員關切意見： 1. 要求將法規內容通知 WTO，並提供適當過渡期。 2. 中國大陸網路安全法在 2017 年 6 月 1 日已經實施，但某些關鍵字彙的定義還不明確，例如關鍵資訊基礎建設、安全且可信任的產品等。	特定貿易關切編號： IMS ID 526 通知文件編號： 未通知 列為重要案件原因： 新興議題(網安&資

編號	遭關切會員	內容簡述	備註
		3. 中國大陸要求業者提供「相關資料」以證明產品的安全性及可控性，但這些相關資料可能導致程式原始碼被揭露。 4. 要求相關國家標準參考國際標準。 5. 事實上歧視國外業者。 6. 要求中國大陸提供指導文件，讓業者遵循。 **被關切會員回應立場**： 中國大陸表示網路安全法是一個基礎的法規框架，不會限制外國產品進口及資料的流通。	安) **提出關切會員**： 日本、歐盟、美國、韓國
29	越南	**案件名稱**： 網路安全措施 **會員關切意見**： 1. 越南應通知而未通知，促請越南連同子法（於 2018 年 11 月 2 日公布）一併通知。 2. 請明確定義「網路安全條件」及澄清企業是否必須在越南成立分公司或辦公室，以符合在地貯存資料的規定。 **被關切會員回應立場**： 越南回應網路安全法於 2018 年 6 月 12 日採納，其目的不僅在有效保護國家安全，也提供安全的網路空間讓外國企業可以安心做生意。該法第 10 條列出適用國家安全、關鍵資訊系統及應屬於國家之關鍵機敏資訊的條件。	**特定貿易關切編號**： IMS ID 544 **通知文件編號**： 未通知 **列為重要案件原因**： 新興議題(網安&資安) **提出關切會員**： 日本、美國、歐盟、加拿大、澳洲
30	印度	**案件名稱**： 新通訊相關規定及附隨的「安全及商業延續協議」範本 **會員關切意見**： 1. 法規將強制要求特定產品取得印度境內的測試報告及驗證，希望瞭解該要求的確切生效日期。 2. 希望確認適用的產品範圍是否將從通訊產品擴大到所有與印度通訊網路連接之產品。 3. 安全測試要求將可能影響到企業的專有資訊，如來源碼及智慧財產權。 4. 請印度遵守其在資安產品共同準則驗證證明相互承認協議（CCRA）的承諾，接受 CC 測試報告。 **被關切會員回應立場**： 印度回應 CC 測試報告並未考量國家安全，因此需要	**特定貿易關切編號**： IMS ID 274 **通知文件編號**： G/TBT/N/IND/66 **列為重要案件原因**： 新興議題(網安&資安) **提出關切會員**： 美國、歐盟、日本、加拿大

編號	遭關切會員	內容簡述	備註
		額外的測試（安全部分）。境內測試的要求因一體適用所有製造商，不應被認為是貿易障礙。測試實驗室須由經通訊工程中心（TEC）認可之認證機構進行認證，外國實驗室則透過 MRA 認可。實施日期延後至 2019 年 8 月。	
紙類			
31	歐盟	**案件名稱**： 「中間紙類產品環境足跡類別規則」草案（Product Environment Footprint Category Rule, PEFCR） **會員關切意見**： 歐盟針對中間紙類產品所研擬之環境足跡類別規則草案的環境衝擊要項中，未將熱帶地區的氣候條件納入考量，使得熱帶地區國家種植的樹木種類無法符合規則的要求，造成歧視。 **被關切會員回應立場**： 歐盟說明「環境足跡的計算」為自願性質，應不涉 TBT 協定。本措施是因應歐盟消費者對於大量出現的環保資訊所產生的困惑及不信任感。	**特定貿易關切編號**： 暫無 **通知文件編號**： 未通知 **列為重要案件原因**： 新關切案件 **提出關切會員**： 印尼
無人機			
32	歐盟	**案件名稱**： 「無人機系統及第三國無人機操作人員解釋文件」草案 **會員關切意見**： 1. 建議刪除對於燈光識別裝置不得與載人飛機的導航燈造成混淆的要求，因風險低的開放類無人機在大小、體積及飛行空域都與載人飛機本質上已有區別。 2. 要求放寬對於開放類無人機飛行/操作距離之限制。 3. 將實施日期延後至公告後的 2 年施行。 **被關切會員回應立場**： 歐盟表示已經考慮過中國大陸提供的意見，距離的限制是基於安全及隱私權理由，歐盟同意提供 3 年過渡期。	**特定貿易關切編號**： 暫無 **通知文件編號**： 未通知 **列為重要案件原因**： 新關切案件 **提出關切會員**： 中國大陸
汽車			
33	越南	**案件名稱**： 汽車製造、組裝及進口之企業要求及汽車保固與維修	**特定貿易關切編號**： IMS ID 549

編號	遭關切會員	內容簡述	備註
		服務 G/TBT/N/VNM/116 會員關切意見： 1. 要求進口汽車需逐批檢驗，國產汽車不需要，造成歧視。且進口程序需耗時 2 個月。 2. 要求同一生產系列的車輛免除逐批檢驗程序，並接受 VTA 證書。 3. 要求越南承認 UN 汽車零組件證書，而不要求境內測試。 被關切會員回應立場： 越南回應汽車產品因其對消費者及環境環境有高度風險，需要嚴格的檢驗，確保其符合品質規定。依據越南瞭解，進口商已經熟悉調適新的程序。費用亦合理。	通知文件編號： G/TBT/N/VNM/116 列為重要案件原因： 多個 WTO 會員關切 提出關切會員： 美國、歐盟、泰國、日本、俄羅斯
其他(受影響產品不明或範圍極大)			
34	歐盟	案件名稱： 物質及混合物分類、標示及包裝（CLP）法規草案附件 6－二氧化鈦（TiO_2）及鈷 會員關切意見： 1. 歐盟將 TiO_2 重新分類為致癌性是錯誤詮釋聯合國 GHS 的分類，目前並沒有證據顯示 TiO2 對人類健康有立即危害。 2. 將 TiO_2 改列第二類將對下游產品造成巨大範圍，如食品（添加物）、油漆、化粧品、塑膠、玩具等必須調整配方，或被迫標示為含有致癌物質。 3. 建議僅規範奈米 TiO_2 (<100 nm)，並限於吸入或液體的接觸方式。 4. 鈷重新分類將影響鎳、醫療器材及食物處理設備出口歐盟，如醫療器材的不銹鋼材質部分含有 2-3% 的鈷是無法移除的。 5. 要求歐盟檢視所收到的 400 多份意見並延後金屬限制鈷含量的要求。 被關切會員回應立場： 歐盟表示被分類在第 1 類的物質常會導致禁用，而第 2 類則不會有如此嚴重的後果。相關單位還會繼續就此議題進行討論。	特定貿易關切編號： IMS ID 539 通知文件編號： G/TBT/N/EU/629 列為重要案件原因： 多個 WTO 會員關切 提出關切會員： 俄羅斯、美國、日本、菲律賓、加拿大、紐西蘭、澳洲、墨西哥
35	中國大陸	案件名稱： 固體廢棄物禁止進口目錄	特定貿易關切編號： IMD ID 545

編號	遭關切會員	內容簡述	備註
		<u>會員關切意見</u>： 1. 中國大陸並未說明禁止進口可再利用之物質對其環境所造成影響，以及全面禁止廢棄物之做法如何達成目的。 2. 促請中國大陸修改措施以與現行回收貨品貿易的國際標準一致。 3. 中國大陸將可回收物質與廢棄物一併禁止，導致可回收物質無法進行回收，對環境保護有負面效果。 4. 中國大陸禁止廢棄物進口卻不見其處理國內廢棄物使用同一套標準。 5. 盼釐清釩渣（vanadium slag）為何列入禁止目錄。 <u>被關切會員回應立場</u>： 中國大陸表示每個國家應對其製造的廢棄物負起處理責任，中國大陸仍允許來自固體廢棄物的原料進口。	<u>通知文件編號</u>： G/TBT/N/CHN/1211-1212 G/TBT/N/CHN/1224-1234 <u>列為重要案件原因</u>： 重要貿易地區 <u>提出關切會員</u>： 美國、澳洲、紐西蘭、加拿大
36	韓國	<u>案件名稱</u>： 「包裝回收分類法規」草案 <u>會員關切意見</u>： 1. 本案未提出通知，亦未提供評論機會。 2. 韓國特殊的包裝要求與國際標準（如 ASTM）不同。 <u>被關切會員回應立場</u>： 韓國表示本案仍在草案階段，未來會進行通知，並提供評論機會及過渡期。	<u>特定貿易關切編號</u>： 暫無 <u>通知文件編號</u>： 未通知 <u>列為重要案件原因</u>： 新關切案件 <u>提出關切會員</u>： 美國、加拿大
37	歐盟	<u>案件名稱</u>： 再生能源指令（2009/28/EC）修正 <u>會員關切意見</u>： 1. 歐盟訂定生物燃料<u>間接土地使用變遷</u>造成氣體排放的標準，其驗證的要求不同於巴黎協定架構下協商的結果，且相關方法/程序尚不清楚，也未獲國際專家認可。 *註：間接土地變遷（indirect land use change, ILUC）造成的氣體排放指以農地取代草地、雨林等自然土地，導致溫室氣體無法被吸收，該效果視為額外的氣體排放* 2. 種植作物與砍伐森林的風險並無明確的連結關係，農業生產用地多，不一定威脅到森林。 3. 驗證基準直接影響棕櫚油，對其他蔬菜油製成的燃料卻沒有影響，不符合 TBT 協定第 2 條不歧視原則。	<u>特定貿易關切編號</u>： IMS ID 553 <u>通知文件編號</u>： 未通知 <u>列為重要案件原因</u>： 多個 WTO 會員關切 <u>提出關切會員</u>： 馬來西亞、哥倫比亞、印尼、哥斯大黎加、厄瓜多、泰國、瓜地馬拉

編號	遭關切會員	內容簡述	備註
		<u>被關切會員回應立場：</u> 歐盟回復修正後的指令全文已於 2018.12.21 公布，內容並未禁止特定生物燃料。該指令授權制訂之法案草案中包含 ILUC 判定的進一步資料。	
38	印度	<u>案件名稱：</u> 陰香（樟科植物）濕度含量(Cassia Vera, Cinnamomum Burmani) <u>會員關切意見</u>： 會員表示即使產品符合法規中的濕度規定（低於 12%），自 2019 年初起就無法出口陰香至印度。 <u>被關切會員回應立場</u>： 印度回應本措施在 2010 年已通知 WTO，並在 2011 年實施，目的係為了避免黃麴毒素。印度認為本議題不屬於 TBT 範疇而是貿易便捷化議題。	<u>特定貿易關切編號</u>： 暫無 <u>通知文件編號</u>： G/SPS/N/IND/69 <u>列為重要案件原因</u>： 新關切案件 <u>提出關切會員：</u> 印尼