出國報告(出國類別：開會)

出席 2024 年 APEC「農業生物技術高階政策對話 (HLPDAB)」系列會議

服務機關：農業部
衛生福利部食品藥物管理署
姓名職稱：黃代理科長明雅
江科長仟琦
派赴國家：秘魯
出國期間：113 年 8 月 12 日至 8 月 19 日
報告日期：113 年 11 月 7 日

摘要

APEC 農業生物技術高階政策對話(HLPDAB) 系列會議於本(113)年 8 月 14 日至 17 日在祕魯特魯希略舉辦，14 日由美國主辦之「透過 APEC 監管合作推進農業生物技術研習會」，目的係深化討論農業生物技術監管合作政策方法；15 日至 16 日由秘魯舉辦之「APEC 農業生物技術在糧食安全與氣候變遷中扮演之角色研習會」及 HLPDAB 年會會議，則有助了解農業生物技術之潛在優勢、及該技術在解決糧食問題及氣候變遷之研究成果；17 日則為 ATCWG-OFWG-PPFS-HLPDAB 聯合會議。本次出席之經濟體有澳洲、加拿大、智利、印尼、日本、韓國、馬來西亞、墨西哥、秘魯、菲律賓、俄羅斯、泰國、美國、越南及我方共 14 個經濟體 40 人與會，我國由主管基因改造(GM)食品原料查驗登記之衛生福利部食品藥物管理署江仟琦科長，及主管農業生物技術發展之農業部農業科技司黃明雅代理科長出席。透過與 APEC 各經濟體執行規劃農業生物技術法規政策之監管單位人員交流，了解農業生物技術相關產品監管架構及法規進展，有助於提升我國在該領域之施政品質。

目次

出席 2024 年 APEC「農業生物技術高階政策對話(HLPDAB)」系列會議

壹、目的

農業生物科技高階政策對話(High Level Policy Dialogue on Agricultural Biotechnology, HLPDAB) 於 2001 年 APEC 年度部長會議之認可與支持下，第一次農業生物技術高階政策對話於 2002 年召開，後續每年皆於 APEC 資深官員會議期間辦理 HLPDAB 會議，是 APEC 架構下針對農業生技應用資訊交流之重要政策論壇。本會議關切農業生物科技之透明與科學基礎之途徑發展，並經常針對農業生物技術應用相關議題進行討論，亦與 ATCWG 保持密切合作關係，我國主政單位為農業部及衛生福利部，並由農業部擔任連絡窗口。

繼 2023 年美國主辦 APEC 會議後，本(2024)年 APEC 主辦經濟體為秘魯。本年 HLPDAB 會議呼應 APEC 會議主題「賦權、包容、成長」(Empower. Include. Grow.)」，並以三項領域「貿易及投資促進包容且互連成長」(Trade and investment for inclusive and interconnected growth)、「創新及數位化推動正式及全球經濟轉型」(Innovation and digitalization to promote transition to the formal and global economy)，及「永續成長達韌性發展」(Sustainable growth for resilient development)為優先規劃系列會議。

貳、行程及工作內容

時　間	行 程	內　容
8 月 12 日(一) 8 月 13 日(二)	啟程	由臺北出發前往秘魯特魯希略
8 月 14 日(三)	特魯希略	出席透過 APEC 監管合作推進農業生物技術工作坊
8 月 15 日(四) 8 月 16 日(五)上午	特魯希略	出席 APEC 農業生物技術在糧食安全與氣候變遷中扮演之角色工作坊
8 月 16 日(五)下午	特魯希略	出席農業生物技術高階政策對話會議(HLPDAB)
8 月 17 日(六)	特魯希略	出席 ATCWG-OFWG-PPFS-HLPDAB 聯合會議
8 月 18 日(日) 8 月 19 日(一)	返　程	抵達臺北

參、會議過程

一、透過 APEC 監管合作推進農業生物技術工作坊

由美國農業部(簡稱 USDA)指導，美國農業與食品系統研究所(簡稱 AFSI, Agriculture and Food Systems Institute)主辦為期一天之工作坊，重點內容如下：

（一）GM 作物田間試驗評估數據之可轉移性(Data Transportability：Exemption of Corn, Cotton, and Possibly Soybean from Domestic Confined Field Trials)

由日本農林水產省(簡稱 MAFF)食品安全及消費者事務局 Oda Masayuki 報告。他表示日本已導入數據可轉移性(簡稱 DT, Data Transportability)於 GM 玉米、棉花之田間試驗上，並已提案將 DT 用於 GM 大豆，因為該三項作物占日本批准品系總數的 80%。DT 審查制度詳細說明如下：

1. 日本 GM 植物審查制度

日本對於 GM 植物之管理，只要在食品安全、動物飼料安全及生物多樣性三面向無不利影響，即被批准用於進口、分銷、加工等一般用途。自 2004 年以來，已有超過 200 個 GM 品系被審查並批准，包含玉米 98 項、棉花 38 項及黃豆 30 項，主要特徵以抗蟲、耐殺草劑為主。

生物風險評估委員會分設作物、昆蟲、水產生物、樹及微生物小組委員會，以作物小組委員會為例，專家組成包括：保育生物學、植物病理學、園藝學、植物生理學、雜草學、植物育種學、環境生物學、分子生態學、分子生物學、分子與細胞生物學、進化生態、進化生態等領域專家，就 GM 植物之環境風險評估項目包含：競爭優勢、有害物質、及親和性進行評估。在環境風險評估(簡稱 ERA)階段，如果 GM 植物在日本自然環境中的生長情況尚未有科學上的

明確認知，則應進行 GM 田間試驗(簡稱 CFT)，委員進行綜合審查批准田間試驗後，才會進到公眾評論，最後送到環境部及 MAFF 確認生物安全性。

2. 田間試驗之數據可轉移性(簡稱 DT)

DT 即是利用其他經濟體之田間試驗數據進行科學檢視 GM 植物在日本自然環境的生長情況。此方法可將節省之人力與物力，重新配置於 GM 植物審查，以精細進行 ERA，提升分析報告之品質。

以玉米、棉花為例，作物小組委員會在親和性審查方面，認為日本沒有可以與 GM 玉米或棉花雜交之野生近緣種；競爭優勢方面，GM 玉米或棉花無法在沒有人為栽培情況下存活或維持；此外，海外田間試驗中若未發現 GM 與 Non-GM 作物表現之顯著差異，那麼在日本的受限 CFT 中也不會認定有顯著差異。因此 GM 玉米從 2014 年 12 月起、GM 棉花從 2019 年 3 月起即採行 DT，只要滿足以下兩項要求，即無須再進行田間試驗：(1)導入基因的作用機制已充分被研究且清晰明確、(2)導入性狀對生物多樣性的影響未超出先前審查過的性狀範圍。日本 GM 玉米、棉花審查導入 DT 要求的轉基因範例如下，需經過 MAFF 與環境部加以確認。

【GM 玉米】

(1) 耐殺草劑：嘉磷塞(cp4 epsps, mEPSPS, mepsps)、固殺草(bar, pat)、烯氧烷酸酯 (aad-1、ft_t),、汰克草(dmo)。

(2) 抗蟲：抗鱗翅目 BT 蛋白類型：cry1Ab, cry1Ac, cry1A.105, cry1.B868, cry1Da, cry1F, cry2Ab2, vip3A；抗鞘翅目 BT 蛋白類型：cry3Aa2, cry3Bb1, ecry3.1Ab, mcry3A, cry34Ab1/cry35Ab1, ipd072Aa，及 RNA 干擾類型：RNA interference type：DvSnf7, DvSSJ1

(3) 其他：耐熱性 α-澱粉酶生產(amy797E)、抗旱性(cspB)、吐絲期穗位高(ATHB17)、高賴氨酸生產(cordapA)、產量增長(zmm28)。

【GM 棉花】

(1) 耐殺草劑：嘉磷塞(cp4 epsps, 2mepsps)、固殺草(bar, pat)、烯氧烷酸酯 (aad-12), 、汰克草(dmo)、4-羥基苯丙酮酸雙加氧酶(hppdPfW336-1Pa)。

(2) 抗蟲： 抗鱗翅目 BT 蛋白類型： cry1Ab、cry1Ac、cry1F、cry2Ab(cry2Ab2)、cry2Ae、vip3A；抗鞘翅目 BT 蛋白類型：cry51Aa2。

3. GM 玉米田間試驗數據可轉移性案例

自 2014 年 12 月以來，15 個轉殖系中已有 8 個採用 DT 而不用進行田間試驗。

案例一、美國提供 1 個 GM 玉米在 5 個州、8 塊田地之形態與生長特性、種子產量、豆莢脫落習性資料，並與 1 個非基因改造品種(non-GM)、4 個商業品種進行比較。

案例二、美國提供 1 個 GM 玉米在 1 個設施之低溫耐受性(在早期生長階段)、有害物質產生資料，並與 1 個非基因改造品種(non-GM)、4 或 6 個商業品種進行比較。

案例三、美國提供 1 個 GM 玉米在 1 塊田地之越冬能力、花粉肥力、大小、種子休眠與發芽率資料，並與 1 個非基因改造品種(non-GM)、1 個無越冬能力之商業品種進行比較。

（二）動物生物技術指引草案(The Philippines' Experience： Drafting the Guidelines on Animal Biotechnology)：

由菲律賓農業部卡拉寶中心(Philippine Carabao Center, Department of Agriculture Philippines)Dr. Claro N. Mingala 報告，菲律賓是除了美國及加拿大外，第三個開始針對動物進行管理的國家

，據悉係因美國倡議促使菲國開始進行草案制定。該指引草案目的為基因改造動物與利用現代生物技術衍生動物產品之研發、處理與使用、跨境轉移、釋放到環境與管理規則條例，適用範圍包括當地動物、寵物、漁業及水產等，但不包括蚊子。

菲國一直是 GM 作物研發重要國家，惟近年 GM 作物受到挑戰，對黃金大米的安全性提出質疑。2024 年 4 月 25 日上訴庭以科學觀點矛盾極可能嚴重影響人體健康與環境為由，判決撤銷監管當局 2021 年發出的黃金大米可作商業生產的生物安全許可證，亦撤銷轉基因 BT 茄子的生物安全許可證。

指引草案內容包括序言、第 1 條總則、第 2 條生物安全決策、第 3 條管理框架、第 4 條基於受監管物品分類之生物安全評估政策指南及第 5 條附則。相關條文內容介紹如下：

4. 第 1 條總則第 1 節適用範圍：包括基因改造漁業與其他水產資源、基因改造家畜與用於動物飼養或獸醫目的之生物產品及源自現代生物技術應用之農業與漁業生物防治生物劑。(本指引草案範圍不包括未含新穎性基因遺傳材料組合之基因編輯產品。)
5. 第 2 條生物安全決策第 3 節生物安全決策指導方針：包括社會經濟、道德與文化考慮、預防措施標準、資訊訪問、透明化及公眾參與、環境與健康風險評估、風險評估。
6. 第 3 條管理框架第四節政府機構角色：菲律賓相關政府機關簡述如下：

(1) 農業部(簡稱 DA, Department of Agriculture)：領導解決與經濟農業生產力與糧食安全相關生物安全問題、評估與監測受監管物品。
(2) 衛生部(簡稱 DOH, Department of Health)：制定評估現代生物科技對健康影響指引及檢討結果。在評估與監測源自或含有轉基因生物加工食品方面發揮領導作用。

(3) 科技部(簡稱 DOST, Department of Science and Technology)：領導確保在採用生物安全政策與做出生物安全決策時利用與應用最佳科學，在評估與監測受管制物品之封閉使用方面發揮領導作用。

(4) 環境與天然資源部(簡稱 DENR, Department of Environment and Natural Resources)：確保進行適用環境評估，並確定潛在影響；在評估與監測生物修復、遺傳資源改良與野生動物遺傳資源方面發揮領導作用。

(5) 內政及地方政府(簡稱 DILG, Department of the Interior and Local Government)：執行部門。

7. 第 3 條第 5 節設立生物安全委員會(簡稱 BC, Biosafety Committees)：科學技術部(DOST)、農業部(DA)、環境與自然資源部(DENR)與衛生部(DOH)應各自設立一個生物安全委員會或相應機構，由擁有必要科學或技術知識之成員組成，以便根據各部門之職責對申請進行評估。

8. 第 3 條第 6 節組成聯合評估小組(簡稱 JAG, Joint Assessment Group)：由農業部畜牧局(簡稱 BAI, Bureau of Animal Industry)或漁業與水產資源局(簡稱 BFAR, Bureau of Fisheries and Aquatic Resources)依據生物安全許可證之申請，負責成立委員會並主持，並由相關部門生物安全委員會代表或人員組成，並進行安全評估。

9. 第 3 條第 7 節及第 8 節畜牧局(BAI)及漁業及水產資源局(BFAR)生物技術辦公室：畜牧局及漁業與水產資源局應各設立一個生物技術辦公室，負責接受、分類與處理本指引下之許可申請。生物技術辦公室應向其各自機構所設立聯合評估小組提供技術與行政支持。

10. 第 3 條第 9 節機構生物安全委員會(簡稱 IBC, Institutional Biosafety Committee)：申請許可之公司或機構應設立一個由至少五名成員組成 IBC。該委員會成員名單須經科學技術部生物安全委員會(針對封

閉使用)或農業部生物安全委員會(針對有限釋放)批准。

11. 第 3 條第 10 節外部技術專家(簡稱 ETE, External Technical Experts)：科學技術部(DOST)、農業部(DA)、環境與自然資源部(DENR)與衛生部(DOH)可各自指派一名外部專家作為其生物安全委員會顧問，參與聯合評估小組工作。

12. 第 4 條基於受監管物品分類之生物安全評估政策指南：

(1) 針對封閉使用受監管物品之商業使用政策：

食品、飼料或加工(水產物種以外之動物)：BAI	工業用生物反應器：BAI
食品、飼料或加工(水產物種) ：BFAR	寵物(除水產物種以外之動物)：BAI
異種轉殖：BAI	觀賞水生物種：BFAR
醫療或製藥用生物反應器(生物製藥)：BAI	其他可能用途：BAI 或 BFAR

(2) 針對釋放至環境受監管物品之商業使用政策：

食品、飼料或加工(水產物種以外之動物)	食品、飼料或加工(水產物種)
用於農業目的之生物控制	其他可能用途
動物疾病控制	-

(3) 綜合整理表格如下：

		使用		
		封閉使用	有限釋放	一般釋放
階段	研發	DOST-BC (第 11 節)	BA 或 BFAR (第 12 節)	-
	商品化	BAI 或 BFAR (第 13 節)	-	BAI 或 BFAR(第 14 節)

13. 第 5 條附則第 25 節上訴：對決定不滿之申請人有權於十五天內向農業部長提出上訴。
14. 第 5 條附則第 27 節補救措施：在違反與生物安全相關法律、規章與規定情況下，應採取以下補救措施：(1)行政補救措施(2)刑事責任(3)民事責任(4)國際法。

該指引草案最近進展：根據反繁文縟節法(ARTA, Anti-Red Tape Act) 審查對該指引草案之初步影響聲明，該指引屬重大規範，因此需要進行全面之政策影響評估(RIA, regulatory impact assessment)。為遵守 RIA 要求，將進行另一系列公共諮詢，並瞭解除直接規範以外之其他可能政策選項，藉以確保實施最適合政策選項。

菲律賓目前所面臨之挑戰，依據 2024 年 4 月 18 日馬尼拉上訴法院裁定如下：

1. 停止抗蟲害基因改造 Bt 茄子與含維生素 A 前驅物 β-胡蘿蔔素之 GM 黃金米相關商業繁殖及活動，並撤銷生物安全許可，直至證明其安全性並符合所有法律要求。
2. 提交具體機制，用於監控所有進行活動，以及所有強化風險評估程序措施。
3. 在確立符合要求之前，禁止任何涉及封閉使用、田間試驗、直接作為食品或飼料使用、加工、商業繁殖與進口 GM 生物體申請。

（三）農業生物技術合作：阿根廷與巴西簽署合作備忘錄(Cooperation on Agricultural Biotechnology： MOU Between Argentina and Brazil)

由阿根廷經濟部生物經濟秘書處(Secretariat of Bioeconomy, Ministry of Economy Argentina) Mr. Facundo Simeone 報告，簽署目標包括：

1. 同步評估及授權 GM 生物技術產品(植物、微生物及動物)，並確認

源自新興育種技術(New breeding technology, NBT)產品之監管狀態。

2. 降低監管成本及時間(評估流程開始時之代理成本)。
3. 現在與未來可減少及/或消除非同步性之 GMO 授權。
4. 促進地方與區域發展、創新與技術，可鼓勵區域產品之創新與行銷。
5. 透過同步法規與經驗，加強機構監管與決策團隊之間現有合作關係。
6. GM 生物與 NBT 經驗與良好之監管實踐，鞏固出口市場之戰略聯盟。

目前阿根廷與巴西已通過 GM 植物產品分別為 74 及 126 品項、基改微生物產品分別為 5 及 36 品項，以及 GM 動物/昆蟲產品分別為 0 及 4 品項，期望藉由合作備忘錄減少及/或消除非同步性之 GMO 授權。

阿根廷與巴西 GM 生物技術產品共同評估之申請流程：申請商可透過阿根廷與巴西網站之「join entry」申請入口或電子郵件信箱(abre.bio@magyp.gob.ar)提交申請文件，巴西由國家技術生物安全委員會(CTNBio, National Technical Commission on Biosafety)，阿根廷由國家農業生物技術諮議委員會(CONABIA, National Advisory Commission for Agricultural Biotechnology)及農牧產品品質暨衛生檢驗局(SENASA, National Service of Agri-Food Health and Quality)，兩經濟體協調評估工作計畫，藉由同步會議聯合評估，並聯合決策，在目的國設立法律代表，最後授權核可。目前兩國已共同評估降低酵素性褐變之基因編輯馬鈴薯(Solanum tuberosum L.)轉殖品系 M08001、Novozymes 公司申請之基因編輯啤酒酵母(Saccharomyces cerevisiae) SCY010 菌株及 SEMPRE AGTECH 公司申請之 SEMPRE

生物投入可噴灑生物殺蟲劑。

2022 年阿根廷與巴西簽署生物安全協議，2023 年內部化協議法規更新，2024 年開始聯合受理申請及進行評估與商業授權，2025 年目標為消除商業授權中所有不同步問題。邁向同步之路包括：未有非同步或減少可能不同步情形、擁有區域產品上市、確保阿根廷與巴西產品之生物安全、將該地區定位至世界市場、促進生物技術產品之生產、使用及消費。

阿根廷、巴西、巴拉圭及烏拉圭於 2024 年 6 月 12 日簽署生物安全協議，拉丁美洲所生產之 GM 作物出口量逐年增加，分析拉丁美洲所生產之 GM 作物占此類產品全球總貿易比例，其中黃豆、玉米及小麥約占 49%、33%及 21%，主要五大外銷國為中國(33.7%、30,762 百萬美元)，其次為越南(5.4%、4,904 百萬美元)、印度(4.6%、4,207 百萬美元)、荷蘭(3.9%、3,544 百萬美元)及西班牙(3.6%、3,254 百萬美元)。2025 年目標為進行第一次聯合受理申請及進行評估與商業授權。

（四）監管合作對創新的重要性(The Importance of Regulatory Cooperation for Innovation)

由加拿大薩斯喀徹溫大學(University of Saskatchewan) 農業食品創新講席教授 Stuart Smyth 博士進行報告，他與研究團隊創建 SAIFood 網站(https：//saifood.ca/)，目標是向公眾提供關於當前農業與基因組學研究之綜合概述，並促進農業食品創新開放對話與研究。

他認為法規會扼殺創新，舉例美國 2012 年監管費用相較 1980 年增加將近 4 兆美金，排擠進行研發創新的費用。且自從 1994 年，全球 72 個國家為 GM 作物進行超過 4400 次風險評估試驗，沒有任何風險評估顯示 GM 品種之風險與 Non-GM 品種有差異或更危險

，且如今全球已有科學上的共識。他認為所有農作物與食品生產都存在風險，零風險概念是由社會環境發展而來，並非正確觀念，而是在商品生產、運輸與食品生產中，對有害物質設有閾值進行層層把關。

他認為各國對於GM植物監管法規的不一致性與長時間的延遲，會抑制公共與私人投資動力，惟有增加科學證據與知識，甫能改善監管決策的一致性、及時及可重複性，進而對農業生物技術創新進行有效投資。此類監管障礙，使 GM 作物效益僅發揮其潛力之三分之一。

他舉聯合國糧農組織(FAO)1995 年至 2019 年間之統計數值為例，美國農作物產量成長 38%、加拿大成長 28%，而歐盟只成長 7%。1995 年，歐盟占全球農業研發(R&D)投資的 33%，相當於每年約 22.5 億美元，惟至 2014 年投資比例下降至 7.7%，約減少了超過 300 億美元研發資金，並使數以千計科研人員與研究生離開歐盟到其他地方進行研究工作。他認為開發一個新的 GM 作物品種成本約為 1.5 億美元，而這些資金將流向最有效監管體系地區，為該區域帶來數百個高薪工作，並帶來可觀的經濟活動與 GDP 增長。

他亦指出創新對貿易之重要性，產品與生產創新有助提高產量，並增加貿易與國內生產總值(GDP)增長，而區域合作提升監管效率後，更可驅動研發投資，是促進經濟增長之關鍵因素。如今全球面對極端氣候，農業需要許多創新產品與技術，例如 1960 年以來全球糧食產量增長了 390%，而所使用的土地只增加了 10%，此減緩對土地的壓力；又如美國伊利諾伊大學開發一新型大豆品種，可儲存更多的碳並同時提升 33%產量。

（五）政策方法文件概述：目的與目標、內容及入口網站(Overview of the Policy Approaches Document： Purpose and Objectives,

Content, and Web Portal)

由美國農業與食品系統研究所(AFSI) Dr. Andrew Roberts 與 Dr. Karen Hokanson 介紹。Dr. Andrew 認為 APEC HLPDAB 小組本身就是監管合作平臺，透過會議及工作坊供經濟體交換農業生物技術相關政策，惟相關討論較不容易轉化為實際行動，因此 2023 年於西雅圖 APEC HLPDAB 會議提出一份政策方法文件(Policy Approaches Document, PAD)大綱，並獲得多數經濟體認同後，AFSI 即以 PAD 大綱為草本規劃一份正式文件草稿，提出了包含與 APEC 經濟體進行諮詢之實施流程，並共同開發一個隨文件發布之網站平臺 (https：//biotechpolicyportal.org/)，俾供更多人查詢參考。

該網站平臺提供案例研究資訊可隨時進行增加或更新，靈活資料庫內容，AFSI 認為此方式會比 PDF 檔更容易引用。該網站可下載 PAD 文件、查詢監管合作方法及資源與案例研究資料庫，並可直接連結至相關網站，以了解更多訊息。PAD 網站是一個資訊來源，以確保人們能輕鬆了解各經濟體於 HLPDAB 研討會上討論內容，PAD 亦為各經濟體間或與相關利害關係者之溝通工具，更提供監管合作之基礎。

AFSI 於 2024 年上半年已就 PAD 草案進行諮詢，包括：5 月 6 日資訊共享、5 月 29 日對數據要求進行對齊、標準化申請/檔案模板，以及協調風險評估方法、6 月 18 日相互認可風險評估。PAD 草案內容包括：1.持續對於監管合作保持高度興趣，並認識到任何實際努力都將面臨挑戰。2.需要工具與資源來促進合作。3.每次活動中都要求對於未有經驗經濟體進行能力建構，以確保任何監管合作成功之關鍵因素。4.各經濟體認為在 APEC 框架下進行討論具有價值。PAD 內容架構說明如下：

第一節、提供工具與資源

幫助 APEC 成員經濟體制定、採用與實施政策及最佳實踐，以減少對農業生物技術產品之監管負擔。

第二節、利益

監管合作對監管機構、開發者、農業貿易商、農民與生產者及消費者皆有利益，總體利益包括：(1)提高效率，節省時間與成本。(2)減少由於貿易中斷引起經濟損害之無效率。從過去兩年舉辦的研討會期間收集的反饋表明，APEC 成員經濟體對於監管合作所帶來的效益持積極態度。

第三節、監管合作方法

(1) 資訊分享：包括機構發布之監管資訊、生物技術相關監管數據庫、資料共享/資料可轉移性、資訊共享與能力建構。其中資料可轉移性近期受到關注，其概念系將符合數據收集標準的方法所設計的監管研究所產生的數據，特別是將 GM 植物與其常規品種進行比較的數據，在一個司法管轄區提交以進行監管決策後，可以用於另一個司法管轄區的風險/安全評估。數據在風險/安全評估中的轉移已在多個經濟體中有效地提高了監管效率，並消除了重複工作。

(2) 政策一致性：

- 高階政策一致性：技術政策一致性所必需、APEC 成員經濟體之間已經一定程度政策一致性。
- 技術政策一致性：為實現高階政策所設置機制，包括行政程序、科學/技術程序：評估進行指導、進行風險/安全評估所需資訊(數據)類型、數據接受標準或測試指導原則、申請或數據提交之標準化模板。
- 政策簡化一致性：隨著監管體系成熟，經驗積累使得政策可被簡化，改採更快速或更簡便方法，使監管系統更有效率與效能。在某些

情況下，即使複雜政策未對齊，各經濟體仍可以考慮在特定情況下對簡化程序進行對齊。例如厄瓜多憲法不允許種植 GM 作物，但在拉丁美洲的監管合作下，該國頒布一項法令，將某些基因編輯產品排除在與 GM 生物相關監管外，類似於其他經濟體。

- 國際政策一致性：當成員經濟體的政策與既定與公認的國際政策(Codex、OECD、Cartagena Protocol、OIE 等)保持一致時，經濟體之間的政策對齊變得更加簡單。

(3) 風險/安全評估合作，合作類型如下：

- 安全評估審查：一個機構將安全評估結果與另一個機構分享，以進行同行評審與評論。
- 平行安全評估：兩個或多個機構獨立完成對同一申請之安全評估，但以協調方式進行。
- 共享安全評估：一個主導機構完成安全評估，然後與合作機構分享，以便進行同行評審與協作最終確定。
- 聯合安全評估：兩個或多個機構共享資源，以完成單一安全評估。

分析四種風險/安全評估合作類型，依安全評估審查、平行安全評估、共享安全評估及聯合安全評估之順序，其複雜度愈高，其好處及挑戰亦愈大。相關好處及挑戰如下：

好處	挑戰
減少監管負擔並提高效率	法律問題、立法框架
改善授權之同步性	機構間操作差異
促進機構間共同能力建構與加強合作關係	物流與實際挑戰
支持創新之監管環境	初期對資源之需求
增強公眾對監管決策信心	承諾程度

第四節、資源與案例研究

案例研究資料庫之內容包括：名稱、描述、合作夥伴、地區(亞洲太平洋區、北美或全球)、機制(資訊共享、政策一致性、風險/

安全評估合作)、合作類別(協議、論壇或政策)、關鍵字搜尋。

1. 最新之案例研究：

(1) 資訊共享：全球低度殘留(Low Lever Presence, LLP)倡議、經濟合作暨發展組織(OECD)。

(2) 政策一致性：國際食品法典(CODEX Alimentarius)、越南對進口之直接使用產品快速監管批准。

(3) 風險/安全評估合作：阿根廷-巴西對於基因編輯性狀之相互認可合作備忘錄、加拿大衛生部與澳洲紐西蘭食品安全標準局(FSANZ)GM 食品安全評估方法共享倡議、南美洲南方共同市場針對 GM 產品最低殘留之協議 MERCOSUR/GMC/RES. Nº 23/19(減少貿易中斷)。

2. 資源資料庫之內容包括：名稱、描述、來源、來源地區(亞洲、北美、南美或全球)、資源類型(線上課程、會議紀要、指導方針、聲明、網站、工作文件)、來源類型(政府間組織 IGO、非政府組織 NGO)、關鍵字搜尋。

第五節、未來方向：將依據本次工作坊討論成果，納入 PAD 內容。

二、APEC 農業生物技術在糧食安全與氣候變遷中扮演之角色工作坊，由秘魯主辦，為期一天半之工作坊。

（一）農業生物技術促進永續農業與健康環境

1. 農業生物技術促進糧食與氣候安全

由越南農業與農村發展部 Nguyen Thi Thanh Thuy 博士主持此節，USDA 首席經濟學家辦公室及蟲害管理辦公室 Jennifer Rowland 博士進行分享。

她認為生物技術創新，有助氣候韌性、糧食安全、土壤健康、肥料取代、食品創新，並引用 ISAAA 2019 年統計，目前已有 14

種GM產品分布於29個國家,美國為最大宗,占全球種植面積37.6%，全球約 19.5 億人或 26% 世界人口受益於生物技術。她認為生物技術係為解決傳統育種耗時選種問題，並以抗蟲茄子、抗殺草劑玉米、非褐化蘋果、高儲架壽命番茄、耐熱牛等為例，證實生物技術減少用藥、抗藥性以及農民暴露農藥之風險，並有助經濟動植物提升氣候調適韌性。

她表示早期生物技術雖可提供有用性狀但較缺乏準確度，除須從其他物種導入相關基因外，尚需幾個世代回交才能獲得較為穩定之最終產品。直到重要基因組序列陸續被解碼後(水稻 2002 年、大豆 2008 年、玉米 2009 年、小麥 2018 年)，再搭配全基因組定序、基因編輯工具後，才得以透過修改小部分序列造成性狀大大改變。她也強調，仍有部分物種需透過轉殖基因的方式進行編輯，且有時基因編輯程度差異大，因此當與其他經濟體在談問基因編輯產品時，需要更精準地講述，才不易造成溝通落差。

- HB4®小麥攜帶來自向日葵之抗旱基因 Hahb4，於 2019 年在阿根廷首次研發，有助旱季生長增加 20%產量及 7%碳封存，目前已在至少十個國家獲批用於食品與飼料市場。阿根廷與巴西還批准其作為商業化栽培品種。
- 非洲科學家研發 Bt 抗蟲豇豆，具有高產、低損失特性，有助減少減少殺蟲劑，奈及利亞已准許其種植並作為食品及飼料使用。
- CoverCress 綠肥油菜有助管理土壤健康減少氣候影響，改良過程不僅透過傳統育種提升產量與成熟度，並運用基因編輯技術改良其油脂與蛋白質成分，理想地成為生物能源的原料，用於製造可替代的可持續航空燃料(SAF)、再生柴油、生物柴油及其他增值副產品。在美國農業部國家食品與農業研究所

(USDA-NIFA)資助及公私協力投資下，CoverCress 保存的遺傳資源與農業管理實踐進步顯著，預計使田間生產短期內超過1,680 公斤/公頃(1,500 磅/英畝)。穀物三分之二轉化為燃料與化學品油脂，三分一做為飼料、工業應用及潛在植物蛋白產品之粕料。除為生產者與農業企業帶來收入外，種植 CoverCress 還能提供一系列生態系統服務，其中最顯著的是減少土壤養分流失與降低土壤侵蝕以保護水質。

她亦關注環境釋放 GM/基因編輯微生物，於生物管理及生物刺激扮演之角色，她認為微生物源之植物生物刺激素，可取代化學肥料施用之原因，並非提供植物生長營養源，而是有助調節植物生理作用，增強植物吸收與利用養分的能力，或利於植物生長發育，目前相關管理規範少部份國家已制定/實施，美國與其他大部分國家一樣刻正進行草案撰擬。

此外，她認為微生物亦能產生創新食品，例如利用微生物產生之凝乳酶可用來製造起司，該酵素原係由反芻動物腸道中的微生物所生產，現在 90-99%凝乳酶來自於 GM 酵母菌，並列舉運用酵素製造此類創新食品公司包括：Impossible、BASF、Bayer、Dupont、Abbott、perfect Day、Ginkgo Bioworks、Zymergen、Novozymes、TurtleTree、Zero Cow Factory、Nourish Ingredients、DaisyLab、EdenBrew 等，全球酵素相關食品及飲料市場估計有 23 億美元。

並以美國植物園特展「耕耘：變遷世界中的食物種植」，說明以 GM 作物為基底之產品可再生，並逐漸取代不可再生資源。此外亦有助展望更多新興研究主題，包括：增加農產品營養成分、增加固氮作用減少肥料使用、生物法合成香草醛、減少食品浪費等面項已有許多貢獻。

她認為基因轉殖方法僅限於玉米、大豆及棉花等作物，而基因

編輯技術可操作的物種較廣，農、漁、畜都可使用，相關試驗研究將對環境做出貢獻。她補充，過去相關專利都掌握在大型國際種苗公司，而基因編輯專利需經 Corteva 公司授權使用，目前有許多新創公司想開發新型基因編輯工具迴避專利，但未來專利授權使用是否擴及種苗上仍備受挑戰，針對基因編輯專利問題已針對各處農民進行說明，並會幫助發展商了解相關法規。

目前基因編輯是否被歸類為 GMOs 仍有部分國家各執己見，惟全球對於 GM 的管理規範定義也逐漸在改變，從前 GM 與傳統育種之管理法規涇渭分明，然而基因編輯產品被歸類的分界線是浮動的，大部分可視為傳統育種，小部分則需 GM 進行管理。

最後，她認為要為農業生物技術創造有利環境，可於以下面項著手：

- 防止或消除農業生物技術產品在國際使用與貿易障礙
- 促進農業生物技術於全球接受範圍，以支持 APEC 目標。
- 提升各經濟體於科學決策能力及參與國際貿易能力。
- 支持與農業生物技術相關全球對話與外交，以提高認知、建立關係並促進決策制定。

（二）以生物技術獲得可保障糧食安全及因應氣候變遷之作物

本節由國際農業生物技術應用服務組織(ISAAA) Mahaletchumy Arujanan 博士主持，並由國際農業研究諮商組織(CGIAR)中 3 個重要的合作夥伴成員進行分享。

1. 稻米研究中心(IRRI)之基因編輯研究

由該中心基因轉殖實驗室支援科學家 Erwin Arcillas 進行分享。他表示全球仍有 29%人口較難取得安全營養食物以供正常生長所需，有 14 億人口處於中度飢餓、860 萬人處於研究飢餓狀態。而亞太地區則有 9.1%人口其取得的食物無法提供足夠的能量與健康，並

推估 2030 年時仍有 6.8%人口無法提供足夠的能量與健康。傳統水稻育種經過 5-7 個回交世代，花費 7-10 年獲取新品種；誘變育種透過選種與回交，也要 6-7 年，轉殖育種將外源基因導入，也要花費 4-6 年時間，而基因編輯水稻僅需要 2-3 年即可獲得改良性狀品種。他認為水稻相當適合進行基因編輯，原因如下：

- 基因組較小，只有 430Mb。
- 農桿菌及基因槍等轉殖技術已被完整建立。
- 高轉殖效率，部分品種甚至高達 100%。
- 全球重要經濟作物。
- 遺傳資源已被研究得很透徹。
- 已有 13 個稻屬的基因組序列可供研究。

另介紹許多運用 SDN1 類型基因編輯技術改善性狀案例，包括：編輯 OsNAS2 基因啟動子,提升水稻鋅與鐵濃度;另編輯 elF4G 基因使其突變，提升水稻 Tungro 病毒抗性；編輯 SWEET11、SWEET13、SWEET14 基因的啟動子，能廣效對抗白葉枯病；編輯目標基因的 Exon1 區域，可增加稻穀長、寬及千粒種；先導編輯另一個目標基因，能廣效對抗真菌性病原菌。

最後，他認為基因編輯可應對水稻產業之挑戰，在氣候變化中能直接加強亞太地區糧食與營養安全。透過基因編輯，水稻可以發展的性狀尚有：1.增加整米率：增加稻穀碾磨後保持其長度 75%比例；2.增加對病蟲抗性：水稻螟蟲、褐飛蝨、瘤野螟、癭蚊、黃斑駁病毒(*RYMV*)、白葉枯病、紋枯病及稻熱病；3.增加非生物逆境抗性：淹水及鹽害；4.水稻雜交特徵：改善組合、表現較佳的遠緣雜交及無融核生殖；5.直播水稻需改善的特性：厭氧發酵及收穫指數等，都是未來值得持續投入研究的課題。

2. 國際玉米及小麥研究所(CIMMYT)之基因編輯研究

由該所遺傳資源計畫 Mohan Murall Achary 博士進行分享。他介紹自然天擇、人為育種到分子生物等育種技術演進，以及新一代生物技術 CRISPR 如何透過 T-DNA 在細胞核內生成並完成序列編輯，分離後即可選出完成編輯但沒有外源 T-DNA 之世代。並引用全球基因編輯法規網(https://crispr-gene-editing-regs-tracker.geneticliteracyproject.org/)資料，揭露全球基因編輯作物法規管理現況及各國基因編輯產品上市進程。

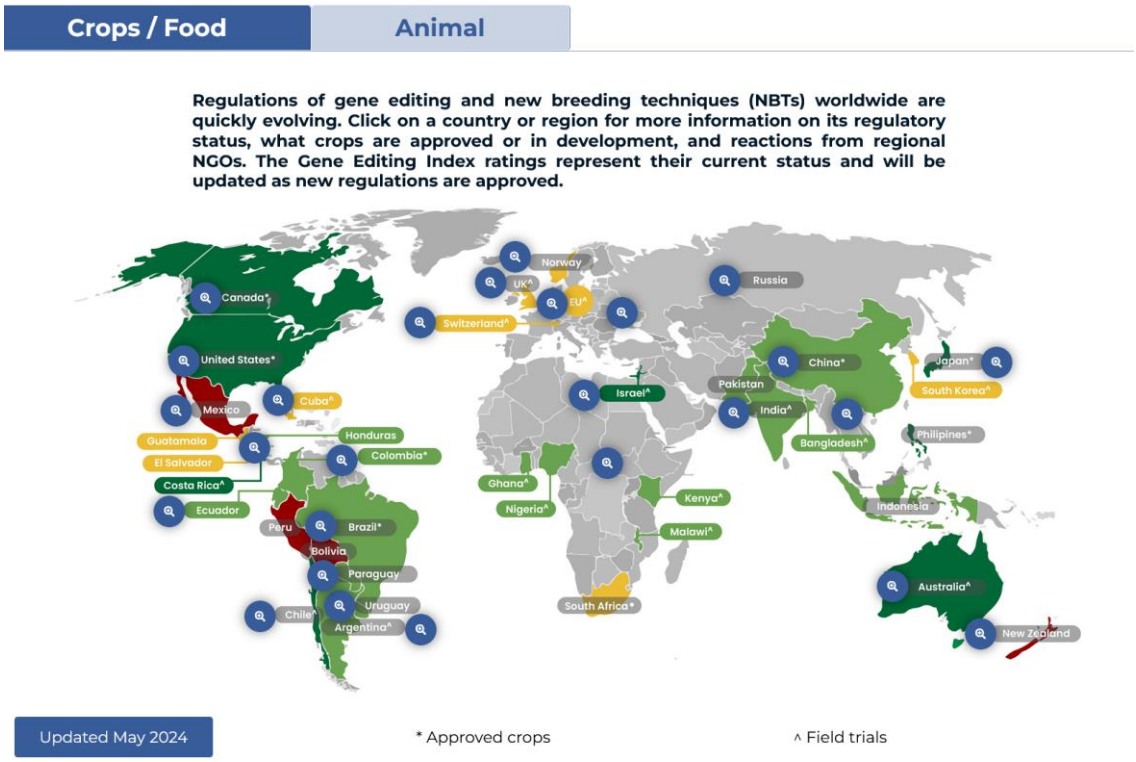


圖 1. 全球基因編輯法規網呈現各國對於基因編輯作物監管態度。

由於部分作物往往面臨轉殖率不佳問題，因此他分享載體帶入型態調節基因可克服基因型依賴性，以改善培植體轉殖及再生率之案例，包括觀賞植物使用 WUS/BBM 與 GRFGIF 基因、小麥使用 TaWOXS 基因、單子葉植物使用 Baby boom 及 Wuschel 基因，或是使用 GRF-GIF 鑲嵌蛋白加以改善。

CIMMYT 與基因編輯相關研究專案說明如下：

- 玉米致死性壞疽(MLN)抗性研究

  由比爾蓋茲基金會、肯亞農業與畜牧業研究組織、美國農業部及 Corteva 所支持。玉米致死性壞疽(MLN)於非洲好發的區域相當廣泛，有 4 成農民每年損失 50 萬公噸，非洲損失總價約 1.87 億美元。而寄生草 (Striga) 抗性產生的隱匿伸展內酯 (strigolactone)與 MLN 病毒共感染，會壓垮植物抗性機制並加劇產量損失，因此該中心正在研究調節寄生草產生隱匿伸展內酯之機制，以提升玉米抗性。

- 減少黃麴毒素花生研究(2023-2025)

  由比爾蓋茲基金會及 Corteva 所支持。因非洲有 25-83%花生在生產或採後作業時受到黃麴毒素汙染，使東非有將近 4 成人口得到肝癌。該研究目前處於初期研究狀態，目前已蒐集到奈及利亞的優良花生自交系。

- 減少珍珠栗酸敗增加倉儲壽命研究(2022-2024)

  由比爾蓋茲基金會及 Corteva 所支持。珍珠栗為營養無麩質的優質穀類，由於脂質含量高(5-7%)，油脂中多元不飽和脂肪酸占 62-66%，造成珍珠栗磨粉後容易有酸敗問題使其無法被廣泛使用，非洲多處都有種植，產量僅次印度。該研究擬運用基因編輯方式阻斷多元不飽和脂肪酸生核成路徑。

- 編輯 Lr67 基因發展小麥銹病品種

  由英國外交部、澳洲國際研究中心(ACIAR)、澳洲海外援助計畫、加拿大農業及農業食品部所支持 CGIAR，進而獲得相關經費挹注。目前已針對 Fielder、Reedling 及 Kachu 三個小麥品種，進行 150 個獨立的 events，植株維持在 GM 隔離溫室中。

最後，他表示 CRISPR-Cas 技術因其簡單性、精準性、廣泛接

受度，無外源基因展現無限潛力，並且證實可應用於各種作物，此外有助將遺傳多樣性引入栽培品種，有助加速新品種開發並可更快速應對糧食安全問題。許多國家已免除對 SDN1 及 SDN2 基因編輯作物之管理，他認為符合生技產業需求，也符合消費者期望。期待未來能將更為精進之 CRISPR-Cas 技術，搭配形態調控因子，以整合擴大基因編輯技術在植物育種平臺上之應用，實現了各種作物系統的精確基因改造。

3. 國際馬鈴薯中心(簡稱 CIP)之基因編輯研究，由肯亞的 Erick Magembe 博士進行分享。

CIP 位於秘魯利馬的研究機構，致力於透過馬鈴薯、甘藷、其他塊根作物與塊莖作物之科學研究及相關活動，在發展中國家持續減少貧困與實現糧食安全。該中心基因編輯的研究尚在起步階段，由於該物種基因體的複雜性增加編輯難度，目前初步研究說明如下：

抗馬鈴薯 Y 屬病毒品種，很難透過傳統育種方式獲得，透過編輯 elF-4E 基因家族的 7 個基因，使相關蛋白能阻斷病毒感染途徑。此外，該中心 2017 至 2021 年間也陸續用基因編輯技術進行抗晚疫病、根部磷肥的運輸、防止褐化、耐鹽品系等試驗，已獲取實驗室階段性成果，相關研究可為減少損失、提升產量、減少食物浪費及儲架壽命等做出貢獻。

抗馬鈴薯晚疫病 GM 品種推廣，該計畫係由美國海外援助計畫、肯亞農業與畜牧業研究組織、非洲農業技術基金會愛達荷大學、密西根大學等機構所支持，CIP 與孟加拉、印尼、肯亞及奈及利亞等國合作，轉殖 3 個抗性基因至農民較能接受之馬鈴薯品種，大幅提升當地馬鈴薯品種對於晚疫病之抗性，並大規模進行商業推廣，

目標希望肯亞與奈及利亞農民能接受並種植，以全面提升該國對抗馬鈴薯晚疫病能力。

（三）以基因編輯動物促進糧食安全之進展與前景

1. 全球動物生物技術現狀及食品安全觀點-APEC 糧食安全政策夥伴案例研究，由新加坡理工大學(Singapore Institute of Technology, SIT) Matthew Tan 博士分享。

動物生物技術(特別是基因編輯技術)目前全球快速進步及採用，由於研究重點、監管環境及公眾接受度不同，不同國家以不同速度接受動物生物技術，簡要介紹如下：

1. 美國：目前在動物生物技術創新方面處於領先地位，發展趨勢為領先創新、監管格局及農業應用。
2. 歐盟：相較於美國，歐盟對基因編輯技術規定較為嚴格，發展趨勢為嚴格規定、公眾認知及研究與應用。
3. 亞洲：中國、日本等國對動物生物技術進行大量投資，發展趨勢為投資與研究、關鍵國家投資及重點領域。。
4. 非洲：重點通常是透過投高牲畜之產量及抗病性，以解決糧食安全問題，發展趨勢為新興倡議、關注糧食安全、挑戰與機會。

目前面臨人口增長、氣候變化及資源限制等全球挑戰，動物生物技術與糧食安全息息相關，糧食安全關鍵觀點包括：提高產量、抗病能力、環境永續、經濟影響及道德社會考量，說明如下：

1. 提高產量：基因編輯技術可有效提高牲畜產量。
2. 抗病能力：隨著動物疾病發病率增加，藉由基因編輯技術可開發具抗病性牲畜，以提供解決方案。
3. 環境永續：基因編輯技術之動物，可實踐農業之永續發展。
4. 經濟影響：動物生物技術之經濟效益包括降低生產成本及提高市場競爭力。

5. 道德社會考量：必須解決動物福祉及遺傳多樣性等道德問題，以獲得公眾信任及接受。

目前挑戰與未來方向有技術監管挑戰、未來之研究領域、國際合作之角色及重要性,針對目前水產品生物技術案例分享-馬來西亞 GK AQUA 公司生產巨型淡水蝦(Giant Freshwater Prawns)，傳統養殖技術培養下，通常雌蝦與雄蝦比例約為 7：3，且雌蝦約重 60 克，雄蝦重 170 克，其價格亦不同。傳統養殖技術不僅高成本，另有垂直疾病傳染、依賴低品質之野生品種，而造成產量逐年降低，利用生物技術培養出單一雄性巨型淡水蝦，與傳統養殖技術相比，可使巨型淡水蝦尺寸大 3 倍、價格提高(原每公斤 5 美元變 15 美元)、生長期縮短(原需養殖 9 個月，現只要 4 個月)、可於單日收穫及產量提升 300%。整個供應鏈包括親蝦研究、親蝦增殖、孵化期、幼苗期、蝦類養殖及銷售至消費者。

利用線上調查問卷請現場與會者參與，問題如下：

1. 在您的經濟體目前是否已應用動物生物技術於糧食安全：與會者回復為 35%已應用、57%尚未應用及 8%不確定。
2. 是否於應用水產品生物技術遇到法規疑義：與會者回復為 42%有遇到、11%未有疑義及 47%不確定。
3. 從糧食安全角度來看，公部門於水產品生物技術應該發揮多大作用：與會者回復為 65%公部門應支持、20%公部門應領導及 15%公部門應制定法規。
4. 應用生物技術通常價格昂貴，小農夫如何從應用生物技術獲益：答案包括政府補貼、私部門支持、農場整合、改善法規及市場接受度等。
5. 您認為您的經濟體會有興趣啟動單一雄性巨型淡水蝦專案嗎：與會者回復為 70%有興趣、4%未有興趣及 26%不確定。

2. 加拿大新穎性食品管理，由加拿大農業及農業食品部 Kathryn Forrestery 資深貿易政策分析員報告 (未有簡報，僅口頭報告)。

加拿大 GM 食品或基因編輯食品須符合加拿大衛生部(Health Canada)依據食品藥物法規第 28 章第 B 部分(Division 28, Part B of the Food and Drug Regulations)之新穎性食品法規(Novel Food Regulations)，於 2006 年制定之新穎性食品安全評估指導方針(Guidelines for the Safety Assessment of Novel Foods)，為提高審查法規之透明度、可預測性與清晰度，於 2022 年針對指導方針新增兩個附錄指引：附錄一為植物育種產品新穎性解釋指引(Guidance on the Novelty Interpretation of Products of Plant Breeding)，附錄二為轉基因食品上市前評估指引(Guidance on the Pre-Market Assessment of Foods Derived from Retransformants)。GM 食品或基因編輯食品經加拿大衛生部(Health Canada)依上述安全評估指導方針審查確認後可上市，未強制要求 GM 食品需特別標示，惟若有安全考量(含過敏原)或食品成分、營養成分改變時，應自動標示，且標示內容必須清楚、真實，不致誤導消費者。

此外，針對環境釋放及飼料部分，加拿大食品檢驗署(Canadian Food Inspection Agency, CFIA)在 2023 年修正新穎性狀植物之環境釋放指引(Guidance for Environmental Release of Plants with Novel Traits)，加拿大食品檢驗署動物飼料計畫(CFIA Animal Feed Program)於 2024 年訂定植物源成分是否需要飼料上市前評估指引(Guidance on how to determine when a plant-derived ingredient requires a feed pre-market assessment)。

利用線上調查問卷請現場與會者參與，問題如下：

1. 在您的經濟體目前對於基因編輯農作物之發展階段：與會者回復為 44%早期研究階段、34%已商品化上市階段、13%法規允許階段、6%田間試驗階段及 3%尚在發展仍在討論。
2. 基因編輯技術如何加速農作物育種：答案包括耐乾旱、提升營養素、精準育種、縮短時間提升效率等。
3. 您的經濟體在基因編輯農作物之發展所遇到之挑戰為何：答案包括法規、資金、IP 議題、消費者溝通、預防措施原則等。
4. 您認為基因編輯農作物之哪項優先性狀是關鍵因素：答案包括增加氣候韌性、昆蟲抗性、在惡劣氣候下可增加產量、具有經濟價值或需求、食品永續性等。
5. 您認為使用基因編輯農作物可受益者為何：與會者回復為 40%全球糧食安全、35%農夫、20%消費者及 5%環境。
6. 您認為基因編輯農作物之主要潛在關注為何：與會者回復為 95%消費者接受度及 5%生態影響。

（四）糧食安全為前提微生物生物技術之進展與展望

1. 農業微生物生物技術觀點 (Perspectives on Microbial Biotechnology)，由由美國農業部(USDA) Dr. Jennifer Rowland 分享。

利用基因工程微生物生產相關產品大概可分為利用 1.發酵作用(1)以純化食品或飼料成分或作為加工助劑(未來挑戰為食品或飼料中是否可含活基因工程或編輯微生物)。(2)生物燃料或其他生物製造。2.以活基因工程或編輯微生物進行之環境釋放：生物肥料/生物刺激素、生物修復。

常用之基因工程微生物像是大腸桿菌(*E.coli*)、酵母菌(*Saccharomyces cerevisiae*)、乳酸菌(Bacillius subtilis)、麴菌(*Aspergillus oryzae*)、木黴菌(*Trichoderma spp*)等，或是從動物、植物或其他微生物分離之 rDNA。利用基因工程微生物進行發酵步驟

，包括培養微生物、發酵、分離及純化，其優點為可以增加產量、純度、風味、品質、穩定性、環境永續發展及經濟效益。利用基因工程微生物生產相關產品如下：

- 酵素：例如： 凝乳酶 chymosin 用來製造起司；蛋白酶 protease 用來作為嬰兒配方食品、肉品萃取或蛋白質補充劑；植酸酶 phytase 用來製造動物飼料等) 。
- 食品添加物：玉米糖膠 Xanthan Gum 作為黏稠劑、香茨蘭醛Vanillin 作為香料等。
- 調味或著色：甜菊醣苷Steviol Glycosides 作為甜味劑、大豆血紅蛋白 soy leghemoglobin 添加到植物肉，可增加顏色及香氣等。
- 維生素類：維生素 A、Riboflavin/維生素 B2、維生素 D、維生素 E)作為營養添加劑或抗氧化劑等。

在 2023 年 APEC HLPDAB 系列會議青年學者與新創事業研討會，泰國朱拉隆功大學生物技術與基因工程研究所之 Dr. Panaya Kotchaplai 研究員報告利用基因工程 E. coli 從農業廢棄物降解木質素，並轉換生產香茨蘭醛，此研究將低價值之農業廢棄物轉換提高其價值。

各國對於 GM 微生物管理法規考量，包括評估所生產成分之安全性，部分國家要求標示，像是天然香料與人工香料標示(香草 vanilla 及香茨蘭醛 vanillin)；許多國家要求終產品須不含轉殖基因，部分國家要求實施新穎性實驗(血紅蛋白 hemoglobin 為傳統性食品原料，而以基因工程酵母菌生產之大豆血紅蛋白 soy leghemoglobin 較新穎性)。

以活體 GM 或基因編輯微生物進行之環境釋放：生物肥料/生物刺激素、生物修復。利用活體 GM 或基因編輯微生物進行生物修復，可回復被重油汙染的土地及海洋，Jeniffer 博士認為基因編輯微

生物可彌補 GM 微生物外源基因汙染的缺點，然而至今生物修復未能實踐最大的阻礙是目前沒有足夠發酵量能足以供應大面積海岸處理需求，因為量體愈大，發酵條件就需要愈精準掌控，目前尚未掌握相關技術。

活體 GM 或基因編輯微生物發展步驟如下，利用基因工程大腸桿菌直接進行步驟四土壤微宇宙實驗，則可省略步驟一至三。

步驟一：先分離原有微生物(約 3~5 天)。

步驟二:將原有微生物與 E. coli 與分解代謝載體作用(約 20 分鐘) 。

步驟三：於平板進行培養(約 48~72 小時)。

步驟四：執行土壤微宇宙實驗(約 30 天)。

步驟五：最後進行田間試驗(約 1~5 年)。

各國對於基因工程微生物進行之環境釋放管理法規考量，包括環境安全(考量生物多樣性變化)、卡塔赫納法、如在食品產品存在持久性，則需進行食品安全評估。

利用線上調查問卷請現場與會者參與，問題如下：

1. 經濟體是否有使用基因工程微生物：大部分國家答覆已有使用。
2. 舉例說明基因工程微生物之產物：答案包括起司、酵素、凝乳酶、蛋白酶、優格、維生素等。
3. 在您的經濟體所使用之基因工程微生物產物：大部分國家答覆基因工程微生物所生產之純化產物。
4. 在您的經濟體所投資研究或開發之基因工程微生物產物：答案包括基因工程微生物所生產之純化產物、以基因工程微生物之環境釋放等。
5. 您經濟體會因為基因工程微生物產物使用目的不同而有不同管控方式：63%與會代表回覆是的。
6. 請描述您的經濟體如何管控基因工程微生物及其產物：答案包括個案審查、針對其不同用途(食品、飼料及環境)有不同管

理單位、加工食品不能使用、尚未有管控法規等。

7. 基因工程微生物及其產物之優點為何：答案包括穩定性、增加產量、提升生產速度、減少碳足跡等。
8. 您的經濟體為何需要基因工程微生物：答案包括農產品生產、食品、更便宜藥品、新生物農藥/生物刺激素等。
9. 您的經濟體採用基因工程微生物會遇到什麼困難：消費者接受度、進入市場前通知、適當法規、環境釋放及其法規等。

（五）糧食安全與氣候變遷前提下監管體系之各方面發展與調適

1. 哥倫比亞對農業生物技術的調適：由 Agro-Bio María Andrea Uscátegui 博士進行分享。

該組織是一家非營利協會，成立於 2000 年，針對安第斯地區國家，提供真實、及時、科學且有道德依據的農業生物技術資訊，並與對 GM 作物教育、推廣、研究、開發、生產與行銷感興趣之組織攜手合作，使每個公民都有知情權、享受生物技術好處並自行決定是否接受它。

哥倫比亞自 2000 年至今，已有 7 種 GM 作物核准種植，其中最有名為 2009 年獲准種植之藍色 GM 玫瑰。2002 年配合卡達荷娜條約進行立法，2005 年進行各部門間的管理架構協調，2020 年完備了商業種植的監管計畫。2005 年成立的生物安全技術委員會，由哥國農業部、環境部與衛福部組成，其任務包含 1.審查風險文件 2.要求增加或補充資訊 3.審查潛在風險之預防及管理措施 4.向主管機關推薦授權簽發，從受理申請到核發上市需要 3-5 年時間。她以在哥倫比亞種植了 15 年的 GM 玉米與棉花為例，認為生物技術使農民與環境都收到正面影響，包括：產量提升、農民用較少成本且較容易管理農田、總計獲得了超過 3 億美元利潤，農作物獲得更多保護但農藥減量 19%，環境影響減少了 26%。她補充，該國仍有部允許種植 GM 作物的地區，需有 500 公尺隔離帶。

然而她同持對於是否能持續按照過去方式生產糧食感到懷疑，認為不應拒絕像基因編輯這樣可以為我們帶來永續且環境友善方式的工具與做法，使我們獲得更多、更好的食物，使我們雖面臨各種挑戰能能持續保障糧食安全體系。

最後她認為，世今仍有非科學的錯誤資訊在流通，仍相信 GM 生物與基因編輯產品對健康及環境有負面影響，並將許多觀點混為一談。她認為應該要從教育推廣改變消費者觀念做起，以成功案例宣揚生物技術好處，強調它可帶來的永續性，並用簡單的語言進行基因編輯議題溝通即可；透過問卷了解消費者意象，並積極回饋聽眾留言以保持良善互動；邀請長期關注此類議題的科學家、農民及意見領袖擔任宣傳大使，提高相關倡議的可信度。

三、農業生物技術高階政策對話會議(HLPDAB)

本次會議出席之經濟體有本次會議出席之經濟體有澳洲、加拿大、智利、印尼、日本、韓國、馬來西亞、墨西哥、秘魯、菲律賓、俄羅斯、泰國、美國、越南及我方共 14 個經濟體 40 人與會。本次會議過程及討論要點臚列如下(附件 4)：

（一）由大會主席秘魯 Dr. Dina Gutiérrez Reynoso 及副主席韓國 Dr. Tae Hun Ryu 致歡迎詞，並由主席請各經濟體代表團成員自我介紹。

（二）接著由秘魯 Institute of Agricultural innovation of Peru (INIA)代表說明，繼 2008 及 2016 年之 後，今年為秘魯第三次主辦 APEC 會議，此舉係秘魯國家政策之一，藉以強化亞太地區關 係，並揭示今年主題為「賦權、包容、成長」(Empower, Include, Grow)。

（三）事務性報告：由 2023 年主辦方美國報告年度成果，及秘魯報告 2024 年相關活動摘要。由秘魯說明 2022 至 2024 年 HLPDAB 策略計畫(附件 5)及 2025 至 2027 年 HLPDAB 策略計畫(附件 6)。

（四）接著由各國報告最近一年之農業生技議題/政策或與 HLPDAB 相關

之計畫，提出書面及口頭報告之經濟體包括澳洲、加拿大、日本、韓國、菲律賓、泰國、美國、越南及我方，另俄羅斯及印尼以口頭補充。

我方發言要點：面對日益嚴峻的環境挑戰，我國致力將傳統農業轉型至企業化結構並進行產業創新，透過農業生物技術策略投資，推動觀賞魚、動物疫苗及生物技術檢測等領域發展，以及基因組學與分子生物學於育種之相關應用。近年著重運用 AI 技術與基因編輯等新興技術來節省農業勞力及增強農業韌性。我方舉辦了一系列基因編輯研討會與座談會，從學術界、產業界與消費者逐步推進溝通，以評估大眾對於此類農業與漁業創新技術之意見，後續將科普教育方式讓公眾更了解農業生物技術對於生物安全與糧食安全等議題扮演之角色。

（五）APEC 秘書處更新 HLPDAB 計畫，並進行事務性宣達。

（六）主席說明 ATCWG-OFWG-PPFS-HLPDAB 聯合會議之 HLPDAB 相關活動摘要

（七）主席簡單進行結語後，由下次副主席即 2025 年主辦方韓國歡迎各經濟體赴韓國出席會議。

四、ATCWG-OFWG-PPFS-HLPDAB 聯合會議

由秘魯 Dr. Dina Gutiérrez Reynoso 代表總結 HLPDAB 2024 辦理情形，並對準「2040 太子城願景」、「奧特亞羅瓦行動計畫(Aotearoa Plan of Action)」及「2030 年糧食安全路徑圖」及其行動計畫，揭示 2025-2027 策略計畫，將強化相關機制定出三大目標。

(一) APEC 各經濟體間農業生物資訊交換：

包括植物、動物、微生物及面對氣候變遷及糧食安全的各項技術，核准 HLPDAB 2026 年至 2029 年新職權範圍 (ToR)，並拜訪研究機構，使利害關係人與政策決策者了解最新技術及產品發展。

(二)促進透明且具科學根據的管理規範

持續鼓勵透過政策對話及工作坊，分享如何建立透明、可預測、具科學根據、及適當的風險管控機制，藉以支持對 APEC 經濟體有益處的農業生物技術的發展、應用及貿易。一旦各地政策及管理規範因相關諮詢交流找出最佳實踐，政策對話會議及工作坊將該案例納入議題。定期提供相關素材，以提升 APEC 各經濟體對於農業生物技術的接受度及貿易。

(三)加速管理各經濟體規範的差異性

透過制定因應全球挑戰之農業生物技術方案，加速管理各經濟體規範的差異性，並提高 APEC 各經濟體就這些議題之進行有效溝通的能力。包括：

1.分享可增強糧食與飼料生產系統之農業生物技術產品；

2.就 GM 產品低度殘留(LLP)、非同步批准、不同農業生產系統共存、以及風險與科學交流等議題進行合作及資訊共享；

3.分享各經濟體農業生物技術監管政策、框架與指南間之一致性、相似性與差異性資訊；

4. 制定一套共享原則，加強農業生物技術產品評估與批准監管協調。

肆、心得與建議

一、 有關農業生物技術監管合作部分，如阿根廷-巴西已簽署合作備忘錄、加拿大衛生部與澳洲紐西蘭食品安全標準局 GM 食品安全評估方法共享倡議，藉以加快 GM 食品核准速度，並減少安全評估審查負擔，我國可思考是否有機會與其他經濟體監管合作方式及內容。

二、 黃金米由菲律賓國際稻米研究所研發，係為改善開發中國家兒童維生素 A 不足，而綠色和平組織等環保團體持續反對該等 GM 作物。本次會議講者提及 2024 年 4 月菲律賓馬尼拉上訴法院裁定撤銷抗蟲害基因改造 Bt 茄子與黃金米之生物安全許可案，值得持續關注後續。

三、 本次會議深刻體會到各經濟基改管理法規差異原因，除了來自各國的法系不同，領土大小及地理環境亦影響法規制定走向。例如哥倫比亞領土較大、印尼有許多小島組成，該國有條件將基改種植田地進行隔離；而我國領土較小、人口密集，隔離帶容易造成破口，因此我國對於基改種植態度較為謹慎。

四、 基因編輯仍是本次會議關注議題，包括：SDN2 類型最多造成幾個鹼基改變可免除監管、基因編輯專利權是否能於種苗中主張、基因編輯是否與有機農業共存等，各個經濟體皆未獲共識，值得持續關注後續。

五、 我方與會代表私下關切韓國、越南及馬來西亞基因編輯立法進度 (皆尚未立法)，另向泰國表達對其最新公告基因編輯指引之興趣，更向日本、加拿大、菲律賓等國了解該國基因編輯管理制度。

六、 我方與會代表連續兩年參與 HLPDAB 實體會議，與泰國、菲律賓及韓國代表團較為熟識且有較多互動，因人脈網絡之穩定性，有助我國取得其他經濟體在農業生物技術之最新進度及政策草案，提升我國在該領域之施政品質。本次會議菲律賓代表團為 8 人，泰國、越南、美國及日本代表團各 3 人，爰建議往後出席成員至少有 1 位固定成員，如主辦國與我國鄰近，甚至可以多爭取出席機會，以維繫並拓展人脈網絡。

七、 我方與會代表從印尼代表團獲知美國於 HLPDAB 工作坊及會議前，邀請印尼、馬來西亞、越南、加拿大、秘魯代表，於 8 月 12 日在利馬進行農業生物技術政策座談，惟我方未獲邀請，可能係因美國為推動 PAD 草案欲獲其他經濟體支持，而我國由於 GM 管理法規較為保守，故未獲邀請，建議持續觀察 PAD 草案後續發展。

八、 建議推薦我國基因編輯已有顯著成果之學者擔任講者，期提升我國農業生物技術成果能見度。

伍、照片紀錄

一、透過 APEC 監管合作推進農業生物技術工作坊

AFSI 執行長 Dr. Andrew Roberts(右一)與日本講者 Mr. Masayuki Oda (左一)、加拿大講者 Dr. Stuart Smyth(左二)及菲律賓講者 Dr. Claro N. Mingala(左三)專題討論

透過 APEC 監管合作推進農業生物技術工作坊之各經濟體與會代表團體照

二、APEC 農業生物技術在糧食安全與氣候變遷中扮演之角色工作坊

新加坡講者 Dr. Matthew Tan 專題演講動物生物技術現狀與糧食安全展望

印度講者 Dr. Mohan Murali Achary(右一)專題演講基因編輯玉米，主持人為 ISAAA 之 Dr. Mahaletchumy Arujanan(右二)、以及肯亞講者 Dr. Erick Magembe(左二)及菲律賓講者 Dr. Erwin Arcillas(左一)

APEC 農業生物技術在糧食安全與氣候變遷中扮演之角色工作坊各經濟體與會代表團體照

我國與會代表與國際農業生物技術應用服務組織(ISAAA) Dr. Mahaletchumy Arujanan 合影

三、農業生物技術高階政策對話會議(HLPDAB)

APEC 農業生物技術高階政策對話(HLPDAB)會議會場

2024 年 APEC 農業生物技術高階政策對話(HLPDAB)會議之主席秘魯 Dr. Dina Gutiérrez Reynoso (右二)、副主席韓國 Dr. Tae Hun Ryu (右一)

APEC 農業生物技術高階政策對話(HLPDAB)會議我國及泰國與會代表

2024 年 APEC 農業生物技術高階政策對話(HLPDAB)會議各經濟體與會代表團體照

四、ATCWG-OFWG-PPFS-HLPDAB 聯合會議

PPFS 主席 Mr. Christian Alejandro Garay Torres 致詞

HLPDAB 主席 Dr. Dina Gutiérrez Reynoso 於聯合會議報告 HLPDAB 事項

陸、附件

附件 1、透過 APEC 監管合作推進農業生物技術工作坊議程

附件 2、AFSI 之 Policy Approaches Document 草案

附件 3、農業生物技術在糧食安全與氣候變遷中扮演之角色工作坊議程

附件 4、農業生物技術高階政策對話會議(HLPDAB)議程

附件 5、2022 至 2024 年 HLPDAB 策略計畫

附件 6、2025 至 2027 年 HLPDAB 策略計畫

附件 7、ATCWG-OFWG-PPFS-HLPDAB 聯合會議議程

WORKSHOP | HIGH LEVEL POLICY DIALOGUE ON AGRICULTURAL BIOTECHNOLOGY

Moving Forward on Agricultural Biotechnology through Continuing Efforts on Regulatory Cooperation in APEC

Trujillo, Peru | August 14, 2024 | 08:30-17:00 (PET/UTC-5)

APEC economies continue to work together towards reducing resource costs, increasing efficiencies in regulatory processes, and lowering barriers to innovation and trade. To continue the discussions on furthering regulatory cooperation for the development, use, and trade of products of agricultural biotechnology, the Agriculture & Food Systems Institute will implement a full-day workshop on August 14, 2024 in Trujillo, Peru, prior to the Asia-Pacific Economic Cooperation High Level Policy Dialogue on Agricultural Biotechnology (APEC HLPDAB) plenary meeting. This event is supported by the United States Department of Agriculture Foreign Agricultural Services (USDA FAS) New Technologies and Production Methods Division.

On July 30-31, 2023 in Seattle, at the Workshop on Reducing Redundancies and Facilitating Efficiencies – Regulatory and Policy Solutions for Oversight of Agricultural Biotechnologies, participants from APEC member economies explored potential mechanisms for alignment for the oversight of agricultural biotechnologies and the feasibility of developing a "Policy Approaches Document." The outline for this document was presented at the 2023 APEC HLPDAB plenary meeting. To develop a draft of the Policy Approaches Document, AFSI conducted the following consultative meetings in 2024 to gather input from APEC member economies, with the aim of ensuring the document is fit for purpose and represents policy approaches that have real opportunities for practical uptake:

- **Session 1**: Information Sharing (May 6, 2024)
- **Session 2**: Aligning Data Requirements, Standardizing Application/Dossier Templates, and Harmonizing Risk Assessment Methodologies (May 29, 2024)
- **Session 3**: Mutual Recognition of Risk Assessments (June 18, 2024)

The input gathered thus far has been integrated into a draft of the "Policy Approaches Document," which will be presented at this workshop. A companion online portal showcasing case studies of successful approaches to regulatory cooperation will be introduced, and a session will be dedicated to allowing attendees to browse the website and provide feedback. The workshop will also include interactive breakout sessions using a case study approach to facilitate in-depth discussions among APEC member economies on practical and feasible approaches to strengthening regulatory cooperation, which can promote the safe use and adoption of agricultural biotechnologies.

Agenda

Time	Presentation/Activity	Presenter/Lead
	Session 1: Introduction and Context Setting	
08:30	*Welcome Remarks*	*Dr. Jennifer Rowland* Biotechnology Coordinator United States Department of Agriculture (USDA) USA
08:40	*Overview of the Agenda*	*Dr. Andrew Roberts* Chief Executive Officer Agriculture & Food Systems Institute (AFSI) USA
08:45	*Data Transportability: Exemption of Corn, Cotton, and Possibly Soybean from Domestic Confined Field Trials (CFTs) in Japan*	*Mr. Masayuki Oda* Plant Products Safety Division, Food Safety and Consumer Affairs Bureau, Ministry of Agriculture, Forestry and Fisheries Japan
09:05	*Development of the Guideline on Animal Biotechnology in the Philippines*	*Dr. Claro N. Mingala* Scientist IV Philippine Carabao Center, Department of Agriculture Philippines
09:25	*Cooperation on Agricultural Biotechnology: MOU Between Argentina and Brazil*	*Mr. Facundo Simeone (virtual)* Technical Specialist Secretariat of Bioeconomy, Ministry of Economy Argentina
09:45	*The Importance of Regulatory Cooperation for Innovation*	*Dr. Stuart Smyth* Professor and Agri-Food Innovation & Sustainability Enhancement Chair University of Saskatchewan Canada
10:05	*Panel Discussion and Q&A: Regulatory Cooperation - Working Together to Benefit Agricultural Biotechnology and Trade*	*Dr. Andrew Roberts* *Speakers and Organizers*
10:30	*Tea Break*	
	Session 2: Policy Approaches Document	
10:45	*Overview of the Policy Approaches Document: Purpose and Objectives, Content, and Web Portal*	*Dr. Andrew Roberts* *Dr. Karen Hokanson* Senior Manager–Scientific Programs Agriculture & Food Systems Institute (AFSI) USA

Time	Presentation/Activity	Presenter/Lead
11:30	*Q&A and Feedback*	*All Participants*
12:00	*Lunch Break*	
Session 3: Moving Forward with the Policy Approaches Document		
13:00	*Breakout Goups: Case Studies*	*Dr. Bhavneet Bajaj* SeniorManager–Scientific Programs Agriculture & Food Systems Institute (AFSI) USA *Dr. Andrew Roberts* *Dr. Karen Hokanson*
15:30	*Q&A*	*All Participants*
15:50	*Tea Break*	
Discussion and Wrap-up		
16:00	*Discussion on Policy Approaches Document and Feedback on the Document*	*Dr. Karen Hokanson*
16:45	*Post-Event Survey*	*All Participants*
16:55	*Concluding Remarks*	*Dr. Jennifer Rowland*

Post-Event Survey

We would like to gather your feedback on how well the event was organized and how it helped build capacity for you. The post-event survey may be found by scanning the QR code or accessing the URL to the right. If you require a certificate of attendance, please complete the survey with your name as you would like it to appear.

https://forms.gle/fsYsRwPdUAvCFvXF9

SESSION 3: Interactive Breakout Sessions on Moving Forward with the Policy Approaches Document

This session will be conducted in an interactive breakout format in small groups. All participants attending the workshop will be divided into groups of 6-8 people to discuss the presented case scenarios. Each scenario details an example of a type of regulatory cooperation that has been covered in the Policy Approaches Document and for the sake of discussion, is followed by a set of 4-6 questions. The goal of the session is for participants to discuss the presented case scenario and explore potential avenues/mechanisms for regulatory agencies from APEC economies to collaborate with each other, or the feasibility for the same, and address the given issue within the current policy framework of their economy.

All scenarios presented are hypothetical and have been put together to foster improved understanding of the commonalities in biotechnology regulations among the APEC economies. The discussions are intended to enable economies to envision practical mechanisms to align their approach in regulating products of agricultural biotechnology and move forward together in the interest of reducing barriers to trade of such products. For each scenario, consider a practical and feasible approach that your economy may (in collaboration with one or more other economies) be able to implement to address the issue.

CASE SCENARIO I: LOW-LEVEL PRESENCE

Consider the case of a GM insect-resistant corn event, which is approved in Economy A for food use, feed use, and cultivation but not approved in Economy B. Said event was found in a shipment of grain imported for food use in Economy B. In the scenario that Economy B does not have an official policy for low-level presence of unapproved GM events:

A. What in your view could potentially be done to resolve the situation so that the trade flow is not affected between the two economies?

B. Considering a practical approach to fulfilling the grain needs of Economy B and considering the approval of said event in Economy A, would it be beneficial to explore a temporary solution to the issue in terms of accepting the safety assessment from Economy A?

C. The food safety assessment framework in both Economies A and B is based on the Codex Plant Guideline. Keeping this in view, what value do you think an independent safety assessment, if done by Economy B, would add to the current conclusion by Economy A?

D. If your economy were in such a situation, what solution(s) would you be willing to consider in the interest of supporting international trade?

E. Of the solutions that you are willing to consider, do you think any of them are feasible under the current policy framework in your economy?

F. What can be done at the level of APEC to better enable your economy to resolve this situation?

CASE SCENARIO II: DATA TRANSPORTABILITY

Consider the case of a nutritionally enhanced GM banana event that has been approved in 4 economies for food use and cultivation. The product developer has now applied for approval for food use in 3 additional APEC economies, including your own.

A. What elements of previous safety assessments conducted by the 4 economies would you consider for your own review?

B. If 4 Codex-compliant economies have approved the GM banana event, how likely is it that your economy would require additional data for safety evaluation?

C. If the product developer puts forth an application for cultivation of the GM banana in these 3 APEC economies, would you consider porting agronomic and composition data for the event from one of the economies where the event is already being cultivated? Why or why not?

D. Considering the natural variability of compositional components in plant varieties, is it likely that porting data from another geography may be appropriate for the compositional assessment? Why or why not?

E. What can be done at the level of APEC to better enable your economy to make use of prior assessment data from other economies?

CASE SCENARIO III: JOINT REVIEW OF A GM EVENT INTENDED TO BE EXPORTED AS A HIGHLY REFINED PRODUCT FOR FOOD USE

An application for a drought-tolerant GM sugarcane event has been sent to 3 APEC economies by the product developer for consideration. The developer intends to market the sugar derived from this event to these 3 economies.

A. Would you be willing to consider working with the other 2 economies to review the said event?

B. Given that the timeline for the review process is similar among the 3 economies, are there challenges that you foresee in undertaking a joint review with the regulatory agencies from other economies? List those challenges and think about how these can be addressed with support from other APEC economies.

C. In case you do consider collaborating with another economy to undertake a joint review, what will the likely next steps be?

D. What might be done at the level of APEC to better enable your economy to collaborate in undertaking a joint review?

CASE SCENARIO IV: DRAFTING OF DOMESTIC GUIDELINES – LEVERAGING THE EXPERIENCE OF OTHER APEC ECONOMIES

You are drafting a new guideline for risk assessment of GM plants for your economy.

A. List the key elements for drafting such a guideline.

B. Considering the information available to you from other economies, international standard setting bodies, and other resources, develop a plan to draft the guideline within the policy framework of your economy.

C. If you are a regulator and wanted to collaborate with regulators from other economies who have drafted and finalized a GM plant guideline, what are the considerations that you would consider when moving forward with such a collaboration?

D. How do you envision leveraging the experience of other economies in reducing duplicative efforts around regulating products of agricultural biotechnology?

E. What can be done at the level of APEC to better enable your economy to make use of the experience of other economies?

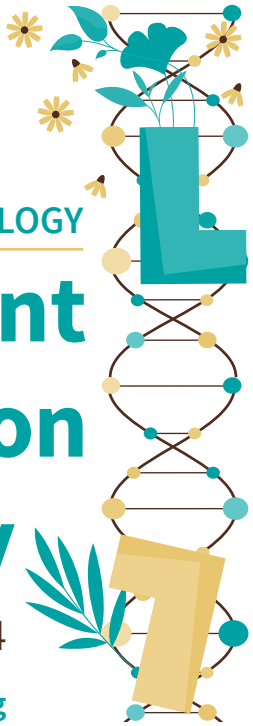
APEC PERU 2024

USDA

Agriculture & Food Systems Institute

APEC | HIGH LEVEL POLICY DIALOGUE ON AGRICULTURAL BIOTECHNOLOGY

Policy Approaches Document for Regulatory Cooperation on Agricultural Biotechnology



Working Draft | Presented in Trujillo, Peru on August 14, 2024

Find the most up-to-date version of this "living" document at **biotechpolicyportal.org**

I. INTRODUCTION

[Pending]

II. POTENTIAL BENEFITS OF GREATER COOPERATION AND ALIGNMENT OF AGRICULTURAL BIOTECHNOLOGY POLICIES AND REGULATIONS IN APEC ECONOMIES

Regulatory cooperation and alignment provide an opportunity for APEC member economies to realize a variety of potential benefits, based both on general principles and benefits of cooperation, as well as on the results of specific benefits of cooperation related to agricultural biotechnology. These benefits can be immediate, short and long term, and may accrue substantially over time. It is important to consider the benefits and the lasting potential for benefit over time because regulatory cooperation also comes with a cost. Typically, these costs are in the form of making changes or adaptations to existing regulatory frameworks and may include both a human resource cost (for example staff time for development and finalization of regulatory changes) as well as a political cost (the time and attention of policy makers and officials necessary to make changes to regulatory mechanisms).

While the benefits of regulatory cooperation are generally well recognized, efforts to achieve practical harmonization are often stymied by the simple truth that the costs (in the form of effort) for regulatory cooperation are immediate, while the benefits are more often accrued over time. For example, the OECD reports that the financial benefits from regulatory cooperation around chemicals regulation result in savings of over €317 Million /year based on quantifiable savings to the chemicals industry. Comparatively, the budget for OECD's harmonization work, estimated at under €9 Million/year is clearly well justified. However, the budget for these harmonization efforts is also an easily identifiable "cost" to the governments funding OECD. As a result, despite the obvious success of these programs, investments in OECD are frequently the subject of discussion for budget cuts and efforts to reduce spending. Importantly, none of the benefits included in OECD's analysis incorporate estimates of the benefits accrued to other stakeholders. For example, the availability of safe chemical alternatives and the distribution of uniform safety information have real benefits for the health and economic well-being of farmers and consumers, but these can be difficult to quantify.

This reality has been reflected in multiple rounds of engagement at the APEC HLPDAB, where participants frequently identified "political will" as a barrier to practical implementation of regulatory cooperation. It is therefore useful to explore the expected breadth and depth of benefits over time in order to allow APEC economies to make rational decisions about the types and extent of regulatory cooperation efforts they might engage in.

The benefits of greater cooperation and alignment of agricultural biotechnology policies and regulations can be categorized in any number of ways. Here we will briefly explore the generally recognized benefits of regulatory cooperation, which primarily accrue to governments and regulators as well as to developers who are applicants to regulatory systems. Then we will take a brief look at how regulatory cooperation can provide additional, and often unrecognized benefits to governments (including regulators and policymakers), developers, consumers, traders and other participants in the supply chain, and farmers (and other agricultural producers).

II. A. General Benefits of Regulatory Cooperation

Regulatory cooperation provides generally recognized benefits essentially through improvements in efficiency. This means savings in cost, and in time. Feedback collected through dialogue at the APEC HLPDAB workshops and the regulatory consultations that have informed this publication identified "efficiency" and "cost savings" as the two most frequently identified benefits by APEC economy participants. The theory behind this is quite simple, if economies are operating in a harmonized way, then the duplication of effort by both applicants and regulators is reduced.

It's important to note that this is true even for relatively passive methods of regulatory cooperation. For example, alignment of data requirements can allow applicants to assemble a single data package that can be used in multiple jurisdictions. Similarly, regulators benefit from aligned data requirements because they are likely to see uniformly prepared applications organized around those aligned requirements, reducing the time needed to review and likely also time required to explain requirements to applicants, ask for revisions or corrections to deficiencies and other administrative measures related to helping applicants understand data requirements. Applicants may additionally save time and money by having to conduct fewer tests if requirements are aligned.

In addition to improving efficiency, a significant benefit of regulatory cooperation comes from reduced inefficiencies and vulnerabilities associated with trade disruptions that can cause economic harm. Disparate and asynchronous approvals can complicate trade, and reduce efficiency of commodity production by requiring efforts to segregate or restrict the movement of agricultural products to jurisdictions where authorizations are in place. This works against the efficiencies inherent in commodity trade that provide economic advantage to producers, traders and consumers and economies as a whole. Regulatory cooperation makes synchronous approvals more likely, reduces the likelihood of trade disruption and can decrease the severity and duration of trade disruptions by allowing for swift review and decision-making for products and commodities that have been subject to review in another economy.

Benefits to Regulators

As discussed above, the benefit most often considered for regulators is a savings of time and effort. Depending on the type of regulatory cooperation and the administration of the regulations, this can include reducing the time spent analyzing an individual application or even removing the need to review an application that has already been reviewed somewhere else. More commonly, regulatory cooperation leads to more standardized applications that have predictable data presented in a predictable way, which facilitates review. This doesn't provide a complete picture, however. In part because time savings must be balanced against time dedicated to regulatory cooperation. While most cooperative efforts take less effort than reviewing dossiers, there is still a time commitment necessary to achieve and often maintain functional regulatory cooperation. As evidenced in the OECD experience with chemical regulations, the cost of those efforts are small compared to the accrued savings, but it is still important for economies hoping to benefit from regulatory cooperation to understand that some amount of effort will be required to develop the cooperation and maintain it.

There are also intangible benefits that regulators accrue through cooperative efforts. These are benefits that may be difficult to quantify but are no less real. Primary among these is increasing the amount of knowledge, experience and expertise regulators have access to through engagement with regulators from other economies and the value of enhanced understanding that emerges from technical discussions and negotiations around the regulatory cooperation. For example, the OECD publication "Considerations for Collaborative Work on Safety Assessments of Foods and Feeds Derived from rDNA Plants"(OECD, 2023) identifies "mutual capacity building and learning," as a benefit, highlighting the "opportunity for sharing knowledge between agencies and enhancing professional development of staff using actual submissions," as well as the opportunity for regulators with less experience to learn from more experienced colleagues. In the example of regulatory cooperation involving Health Canada and FSANZ provided in the same document, regulators from those economies highlighted that, despite a high level of existing capacity for safety assessment, their collaboration has provided an opportunity for continued learning. While these benefits are difficult to value monetarily, they can result in increased confidence in regulators and regulatory decisions.

Benefits to Developers

Benefits to developers are often the easiest to quantify because many are direct, in the form of reduced costs for duplicative testing and reduced time and resources spent to assemble applications. However, developers also benefit from regulatory cooperation through a reduction in decision times and improved predictability of regulatory decision-making when regulatory cooperation provides for more harmonized processes. These benefits also make investments in research and development less risky and encourage innovation and the development of new products which can in turn provide benefits to farmers and consumers.

We often think about the benefits to developers in the context of multinational companies, because these are the developers typically submitting multiple applications across many regions and economies. Benefits of regulatory cooperation can also be realized by small developers, startups and public sector researchers who have developed agricultural biotechnology products that they plan to release only in their local economy or a small subset of economies that have a shared need. Most directly, the improved regulatory clarity and predictability that results from regulatory cooperation can reduce

uncertainty and speed up approvals for their applications. However, regulatory cooperation also helps by expanding the pool of knowledge and applications that can be referenced and that may be relevant to their own application.

For example, imagine an economy that has only issued a few decisions related to agricultural biotechnology products. It may be difficult for new or novice developers hoping to release a product in that economy to understand how to prepare and submit an application. If regulatory cooperation efforts have aligned elements of the technical and regulatory framework with other economies, then the local developer can also reference applications that have been submitted to those other economies with some confidence that their submission will be subject to a similar review.

Benefits to Agricultural Traders

In the modern context, agriculture is intertwined with an elaborate global trade network that works to move agricultural products from where they are grown to where they are needed. This supply chain involves local and international organizations, government and private tenderers and procurement, and can be affected by import/export policies, sanitary and phytosanitary regulations and other financial risks associated with commodity and agricultural markets. The value of agricultural trade is growing, rising from around $300 Billion USD in 2000 to more than $1.6 Trillion in 2022[1]. It can also be heavily impacted by regulations for agricultural biotechnology. Regulatory cooperation can reduce the financial risks and uncertainties associated with asynchronous regulatory approvals as well reduce the costs associated with product segregation.

In addition to the immediate economic advantages provided by regulatory cooperation, predictable and harmonized approaches to agricultural biotechnology can also improve the ability of traders to respond to other disruptions and shocks. If production is disrupted in one economy, then it is much easier to find alternative sources of supply if economies have implemented measures to align regulatory requirements through regulatory cooperation. This also allows producers to more predictably respond to global market demand.

Benefits to Farmers and Agricultural Producers

Regulatory cooperation leads to benefits for farmers and other agricultural producers by reducing disruptions in the supply of seed and feed products that they depend on as well as cost reductions that can be passed on through the reduction in the burden on developers and trade organizations. However, there are also more specific benefits to regulatory cooperation on agricultural biotechnology that can be seen by looking at the experiences in economies where farmers have access to these technologies. A meta-analysis of published reports by Areal et al. demonstrated that the products of agricultural biotechnology produced meaningful economic gains when compared to conventional products and that these gains were most evident in developing economies (AREAL et al., 2013). With the understanding that products are beneficial, the opportunity to enhance the speed and predictability of regulatory processes through regulatory cooperation will then allow broader and faster access to these benefits from farmers and producers.

Benefits to Consumers

Ultimately, economic benefits of regulatory cooperation for developers, agricultural producers and traders will also translate into economic benefits for consumers. This is typically seen in reduced prices but consumers can also benefit from increased availability and diversity of agricultural products and the resilience of markets to price and production shocks. When regulatory cooperation encourages investment in research and development consumers may also benefit from the availability of new products that match their needs or tastes as well as the improved environmental and health impacts. For example, the use of agricultural biotechnology in North America has been associated with increased use of low and no-till agricultural systems that reduce erosion and agricultural run-off. This decreases the environmental impacts of nitrogen and fertilizer pollution as the water runs into lakes rivers and ponds and can provide public benefits.

II. B. Relevance to APEC economies and the HLPDAB

Regulatory cooperation is an investment. Regulatory agencies and economies invest time and effort into cooperation in order to see a return on that investment in the form of future savings in time and effort, as well as the intangible benefits described above. In order to help decision-makers and officials make informed decisions about how to allocate time and resources to cooperative efforts, it is necessary to provide them with evidence that those benefits will be realized and that they represent a good return on the invested effort.

The good news for APEC and the HLPDAB is that all of the available evidence suggests that the return on investment for regulatory cooperation is very high. The OECD's analysis of annual savings from cooperative efforts around chemical regulation show a 30 fold annual return in the form of cost savings that can be reasonably accounted. This does not include any attempt to capture the value of more intangible benefits and those that accrue more indirectly to stakeholder groups within the OECD economies.

[1] https://www.wto.org/english/tratop_e/agric_e/ag_imp_exp_charts_e.htm

Feedback collected during the preparation of this document, and during workshops conducted over the last two years indicates that there is appreciation among APEC member economies for the benefits that can be achieved as a result of regulatory cooperation. With that consensus, the task becomes determining which mechanisms and levels of effort are most appropriate for APEC and individual economies to engage in.

III. APPROACHES TO GREATER COOPERATION AND ALIGNMENT OF AGRICULTURAL BIOTECHNOLOGY POLICIES AND REGULATIONS IN APEC ECONOMIES: POTENTIAL MECHANISMS OF REGULATORY COOPERATION

There are many different approaches representing a range of usefulness and complexity that economies can use to enhance regulatory cooperation and alignment. This section explores some different options for economies to consider. Key approaches to regulatory cooperation are considered in three categories: 1) information sharing, 2) policy alignment, and 3) collaboration on risk/safety assessments. The details, merits and inherent challenges of each of these different approaches are considered here. The relevance of each approach and perceived opportunities for APEC and the HLPDAB, based on input from the member economies through a series or webinar consultations in May/June 2024, are also described for each of these broader approaches.

III. A. Information Sharing

Information sharing is the most easily implemented and commonly employed approach to regulatory cooperation. It is simply the provision of relevant information by organizations or agencies between member economies, accomplished through general broadcasting of information or more targeted direct communication, either of which can be tailored to different situations to accomplish specific goals. Broadcasting may be general for 'public communication' with no specific audience in mind or it can be more limited to a select group. Information can also be shared directly by an individual or organization specifically to another individual or organization, not intended for sharing outside the targeted audience. In the case of direct communication, there is often the expectation of a response. Some different types of information sharing are described below. It should be noted that while information sharing can be an effective approach to regulatory cooperation, it will also occur implicitly as part of other more advanced approaches that are discussed in the sections on policy alignment and risk/safety assessment collaboration.

Agency Postings of Regulatory Information

Most regulatory authorities will make information publicly available for stakeholders through an agency website and/or by posting in national registers or other federal listings. Information shared will typically include policies, guidelines, and decisions, with more or less detail determined by the needs of the agency.

Biotechnology Regulatory-Related Databases

There are a number of databases that contain policies, risk/safety assessments, authorizations, and dossiers. For example:

The Biosafety Clearing-House (BCH) of the Convention on Biological Diversity is an online platform for exchanging information on Living Modified Organisms (LMOs) and a key tool for implementation of the Cartagena Protocol on Biosafety

The Food and Agriculture Organization (FAO) has multiple databases and platforms related to biotechnology, including:

- FAO-BioDeC is a database that collects, organizes, and shares information on crop biotechnology products and techniques used or being developed in developing economies.
- FAO Biotechnology Forum is a platform that provides access to information and a neutral space for stakeholders to exchange views on agricultural biotechnologies in developing economies.
- FAO GM Foods Platform is a publicly accessible central database that contains information on recombinant-DNA plants authorized in accordance with the Codex Plant Guideline.

The International Service for Acquisition of Agri-biotech Applications (ISAAA) hosts the GM Crop Approvals database that includes all available information on biotech/GM crops that have been approved for food and feed use and/or cultivation globally.

The Organization for Economic Cooperation and Development (OECD) has several databases related to biotechnology, including:

- BioTrack Product Database allows stakeholders to share information about products from modern biotechnology and other products with novel traits that have been approved for commercial use in at least one member economy.
- Emerging Technology Indicators is a database that combines measures of the number of companies active in biotechnology, R&D expenditure, and inventions.

Data Sharing/Data Transportability

Member economies can establish standardized mechanisms for the sharing of regulatory data, and this can be a particularly effective form of regulatory cooperation. The concept of 'data transportability' has gained interest among the regulatory and product developer communities in recent years. The concept is centered around the notion that data from well-designed regulatory studies following accepted methods for data collection, especially for comparison of GM plants to their conventional counterparts, submitted for a regulatory decision in one jurisdiction can be used for risk/safety assessment in another jurisdiction. Transportation of data for risk/safety assessments has been used effectively in multiple economies to increase regulatory efficiency and eliminate redundancy.

Information Sharing and Capacity Building

Regulatory coordination in the form of information sharing can also be accomplished by APEC member economies through arranged capacity building, when member economies with more experience are willing to provide information on policies, processes and decisions taken to economies with less experience through consultations, seminars, workshops, study tours, internships, and other methods.

Information Sharing - APEC Opportunities and Challenges

A webinar consultation on information sharing held on May 6, 2024 was attended by 16 participants from eight member economies – Australia, Canada, Indonesia, Japan, Peru, Philippines, USA, and Vietnam. A discussion with participants during this webinar provided some important insights regarding the value of and capacity for information sharing among member economies as a form of regulatory cooperation.

Key points from the consultation on information sharing as an approach to regulatory cooperation:

- Among APEC member economies, those that have made decisions on cultivation and/or food and feed use of GMOs do typically publish decisions in a national register and/or announce decisions on an agency website, and some share decisions with international bodies such as FAO and the CBD.
- Member economies are more likely to provide information to the CBD Biosafety Clearing House (BCH), and fewer to the FAO GM Foods Platform. Member economies are less likely to provide information to specific databases such as the ISAAA GM Crop Approval Database and the OECD Biotrack Database. While some APEC member economies do utilize some or all of these databases as information resources for decision-making, others are not familiar with any of these databases as a resource.
- Technical capacity, resources and policy constraints (whether too strict or lacking) are potential barriers for information sharing and confidential information and public perception also raise significant concerns. APEC member economies would benefit from a dedicated online resource serving as a directory to the available databases and information resources, and/or a repository for existing regulations, guidelines, products approved, risk/safety assessments and decision documents (ideally with translation of documents into English).
- There are also opportunities for more direct communication between member economies, whether between two economies or between or within groups of economies with similar needs based on the status of their regulatory systems and level of experience. Member economies could benefit from sharing experiences of functional systems and processes for regulation of biotechnology, risk/safety assessments and decision-making.
- Economies with experience handling certain issues, for example the handling of confidential information identified as a potential barrier for information sharing in general, could work with other economies to develop a system for providing confidential information to each other. Because concerns about public perception are a potential barrier to sharing information with the public, member economies might benefit from best practices for communicating with the public and public engagement for about regulation and regulatory decisions.
- Any number of case studies relevant for the HLPDAB and lessons learned, based on member economies experience around specific products with global impact, could serve as a catalyst for information sharing, ranging from best practices for assessing and managing risk/safety and regulatory approvals to best practices for public communication and managing public perceptions.

III. B. Policy Alignment

Alignment of policies and procedures is in itself an approach to regulatory cooperation and it can be necessary and important step toward achieving other forms of regulatory cooperation, in particular for efforts to harmonize risk/safety assessments among member economies, as discussed in the next section on collaboration on risk/safety assessments. Depending on the reason for cooperating, policy alignment can be pursued at different levels. High level policy alignment and lower-level technical policy alignment are discussed here.

High Level Policy Alignment

High level policy alignment may be the easiest to achieve. Most economies will have established a similar high-level policy for biotechnology, along the lines of 'to realize the potential benefits pf biotechnology while ensuring safety for humans and the environment, organisms derived using modern biotechnology are subject to risk/safety assessment

prior to introduction to the market'. This is also consistent with the international obligations for economies that are party to the Cartagena Protocol on Biosafety under the Convention on Biotechnology. However, if economies will strive to achieve policy alignment at a lower level, such as technical policies or policies to streamline regulatory cooperation, it is essential to acknowledge alignment of higher-level policies first. The existence of the APEC High Level Policy Dialogue on Agricultural Biotechnology suggests there is already at least some degree of high-level policy alignment within APEC economies.

Technical Policy Alignment

At another level, technical policies are the 'mechanisms' put in place to accomplish higher level policies. Technical policies may refer to administrative procedures or scientific technical procedures such as those for risk/safety assessment. Administrative procedures include defined timelines for issuing decisions or defined steps and required committees for reviewing applications. Alignment of administrative procedures may not be necessary for regulatory cooperation although it will always be important to carefully consider similarities and acknowledge differences in administrative procedures before economies embark on efforts to align technical policies for risk/safety assessments.

Technical policies related to risk/safety assessment include methodologies or ways to conduct risk/safety assessments and scientific or technical requirements for generating information or evidence in support of an assessment. Most experienced regulatory systems will have established 'tools' for risk/safety assessment that can be used as a basis for comparison and a catalyst for alignment among economies, such as guidance on the conduct of assessments, agreements on the types of information (data) needed to inform risk/safety assessments, criteria for data acceptance or guidelines for testing, or standardized templates for application or data submission. Alignment of risk/safety assessment policies may be the most impactful approach to regulatory cooperation, but also bring significant challenges, as discussed in more detail in the section on risk/safety assessment collaboration.

Alignment of Streamlined Policies

As biotechnology regulatory systems mature, experience makes it possible to streamline or modify policies in ways that employ faster or simpler methods to make the systems more efficient and effective. Policies may be streamlined for assessment and decision making, for example, in the cases of products that have been subject to earlier reviews or products that have other risk/safety mitigating properties. Simplified procedures represent another opportunity for policy alignment among member economies. In some cases, economies can consider alignment of a simplified procedure for certain cases even when there is not alignment of the more complex policies in each economy.

A good example of regulatory cooperation through the alignment of streamlined policies is the declaration on new breeding techniques signed in 2017 by the Ministers of Agriculture from Argentina, Brazil, Chile, Paraguay, and Uruguay, specifically with the goal to exclude certain gene edited products from strict regulation by adopting common streamlined policies (Turnbull et al. 2021). Among the economies in Latin America, Colombia, Honduras, and Ecuador have also drafted legislation for this purpose. In the case of Ecuador, the constitution does not allow cultivation of GM crops unless the president deems it to be in the interest of the nation, but the Ecuadorian government implemented a decree in 2019 excluding certain gene edited products from regulations associated with GMOs, similar to other economies.

International Policy Alignment

When member economies policies are aligned with established and accepted international policies, the alignment of policies between member economies becomes much more straightforward. Several international forums provide guidance and information that support consistent policies and assessments. Some of these are listed below:

- Codex Alimentarius
- OECD Working Party on Safety of Novel Foods and Feeds
- OECD Working Party on Harmonisation of Regulatory Oversight in Biotechnology
- International Plant Protection Convention
- World Organization for Animal Health
- Cartagena Protocol Annex III

APEC member economies may also work toward aligned policies and approaches through participation in international capacity building programs. For example, the Food and Agriculture Organization (FAO) conducts biosafety capacity building as part of its efforts to improve food security and agricultural practices globally. There are also a number of capacity building programs associated with the implementation of the Cartagena Protocol on Biosafety, including those supported by the United Nations Environmental Programme (UNEP) and Global Environment Fund (GEF). Capacity building programs exist to provide support for policy development, risk assessment training, development of biosafety guidelines, and some to foster regional cooperation specifically.

Policy Alignment - APEC Opportunities and Challenges

A webinar consultation on consistent policies and procedures held on May 29, 2024 was attended by 14 participants from eight member economies – Australia, Canada, Indonesia, Japan, Peru, Philippines, USA, and Vietnam. A discussion with

participants during this webinar provided some important insights regarding the value of and capacity for alignment of policies and procedures among member economies as a form of regulatory cooperation.

Key points from the consultation on consistent policies and procedures as an approach to regulatory cooperation:

- Member economies acknowledge the value of consistent policies for cooperation and harmonization. They also see capacity and political issues as the challenges that will prevent more economies from exploring efforts to achieve consistent policies and assessments.
- International standards are seen as useful tools for overcoming these challenges and important for working towards alignment of policies and assessments for agbiotech. Most APEC member economies have at least a little experience with information and guidance from international forums and have at least taken these into consideration in their policy development.
- Codex Alimentarius is the most noted example, as is the work of the OECD Working Party on Safety of Novel Foods and Feeds and the OECD Working Party on Harmonization of Regulatory Oversight in Biotechnology. Member economies may be less familiar the information from the International Plant Protection Convention and the World Organization for Animal Health or information on risk/safety assessment found in Annex III of the Cartagena Protocol on Biosafety, and these may be less useful in efforts to align policies.
- Member economies see the value in alignment on food and feed safety as well as environmental risk/safety assessments, and they acknowledge that this may be easier to accomplish for food and feed safety largely because there are accepted international guidance for these from CODEX and from OECD.
- Economies recognize that there are some worthy examples of harmonization of approaches to food and feeds safety assessment between economies, including most notably the adoption of common guidelines in Mercosur and the process for joint food safety assessments developed by FSANZ and Health Canada, and see value in learning from these and other examples of policy alignment.
- To pursue policy alignment, APEC member economies might have more success by identifying a subset of economies, grouped according to come criteria such as regional similarities or common language, or with similar systems in place for cultivation and food and feed or at a similar stage of advancement of the technology.
- Member economies also acknowledged the importance of trust and taking into consideration existing relationships and past experience with policy alignment, other than biosafety policies, among economies.

III. C. Collaboration on Risk/Safety Assessments

Possibly the most challenging approach to regulatory coordination for APEC economies to consider is collaboration on risk/safety assessments. There are a number of different ways to collaborate on risk/safety assessments, as described in this section: safety assessment review; parallel safety assessment; shared safety assessment; joint safety assessment. These options and the benefits and challenges of each are also described in the OECD document on considerations for collaborative work on safety assessments of food and feeds derived from rDNA plants (OECD 2021).

Benefits and Challenges of Collaboration on Risk/Safety Assessment

Some of the benefits and challenges that can be associated with collaboration on risk/safety assessment are described below. The benefits of these generally increase as the complexity at multiple levels also increase (Figure 1). As APEC member economies evaluate the feasibility of pursuing collaborations on risk assessment, they will want to consider how these different benefits and challenges factor into the process depending on the type of collaboration being considered.

Benefits of collaboration on risk/safety assessment:

- Efficiency gains in the assessment process
- Potential to reduce regulatory burden
- Improved synchronization of authorizations
- Mutual capacity building and learning
- Stronger working relationships among between economies
- Provides a regulatory environment that supports innovation
- Increased public confidence in regulatory decisions

Challenges of collaboration of risk/safety assessment:

- Legal issues, legislative frameworks
- Operational differences between agencies
- Logistical and practical challenges
- Initial demand on resources
- Level of commitment
- Level of experience and expertise

Safety Assessment Review

Inter-agency peer review as a way to collaborate on risk/safety assessment is plainly a matter of agencies from different member economies having an arrangement in place to share safety assessments with each other for review. It is an example of sharing information through direct communication, as described earlier in this document. Although sharing safety assessments for review is also part of other types of risk/safety assessment collaboration, it can be in itself a form of collaboration. As part of the agreement, the reviewing agency may be expected to share comments or a critique of the assessment. Member economies may enter into such an arrangement in the interest of providing some assurance that the review and the review process are credible and acceptable according to pre-determined standards. Sharing safety assessments for review can also be a particularly useful tool for capacity building when more advanced member economies agree to share safety assessments with less experienced economies. In cases where economies choose to accept the review of another agency for their own decision-making, as described in the section on technical policy alignment.

Following a review of a safety assessment, an economy may also choose to consider the safety assessment, all or in part, for their own decision making of a given biotech product, as a simplified procedure to risk/safety assessment. In these cases, the economy accepting the review of another will have to coordinate closely with the assessing economy to understand the technical policies for safety assessment and ensure alignment of the process with their own. For this process to work, the reviewing economy will establish clear criteria based on the expectation for an assessment that must be met for the economy to accept the assessment for a decision. The review process then becomes a matter of reviewing the assessment against the established criteria.

Parallel Safety Assessment

This type of collaboration on risk/safety assessment is a pre-determined process by which two or more member economies complete their own safety assessment, but they do this in a coordinated fashion according to a mutually agreed timeline. It is similar to inter-agency peer review, but requires considerably more commitment from the member economies involved because there would be a timeline in place and regularly scheduled inter-agency discussions to complete the review within a prescribed period of time. More time would be required by the member economies to compare and contrast their established approaches to risk/safety assessment before agreeing to this type of collaboration. This arrangement would also require cooperation of a product developer willing to submit an application simultaneously to both economies.

Shared Safety Assessment

Shared safety assessments are assessments developed together by two or more economies, where one economy takes the lead on drafting the risk/safety assessment and this draft is shared with another member economy for their review. The collaborating agencies then work jointly to finalize the assessment, and this final safety assessment is used independently by the agencies in their decision-making process. As with the parallel safety assessment, this type of collaboration requires a time investment up front to compare each economies approach and requires an agreement with the product developer.

Joint Safety Assessment

The joint safety assessment combines the elements of all previously described ways to collaborate on risk/safety assessments. In this type of collaboration, two or more economies conduct an assessment simultaneously with each agency taking the lead on specific elements of the assessment. Once the draft is completed it is reviewed and finalized by all economies involved and the final assessment independently by the agencies in their decision -making processes. This approach requires the most commitment from each of the collaborating economies, as all economies involved must contribute expertise and follow a close timeline, in order to finalize the assessment.

Collaboration on Risk/safety Assessment - APEC Opportunities and Challenges

A webinar consultation on sharing risk/safety assessments and procedures held on June 17, 2024 was attended by 12 participants from five member economies – Canada, Indonesia, Japan, Peru, and Philippines. A discussion with participants during this webinar provided some interesting insights regarding the value of and capacity for sharing risk/safety assessments and product approvals among member economies as a form of regulatory cooperation.

Key points from the consultation on sharing risk/safety assessments and procedures as an approach to regulatory cooperation:

- Although it seems likely that APEC member economies would benefit from collaborative risk/safety assessment, most do not have experience working with other economies in this way. Member economies see the usefulness of collaborating to carry out risk/safety assessment of an agricultural product, but they do not see clearly how this can be accomplished. A few member economies have experience working with other economies toward collaborative risk/safety assessment of agricultural biotechnologies, but most have very little or none at all.
- Member economies see a clear benefit from pursuing some sort of collaboration on risk/safety assessment for reducing regulatory burden and increased efficiency with regards to time, but may not necessarily see the potential benefit of resource savings or reducing trade barriers.

- Although there is likely to be some resource savings for the regulatory community mainly in terms of the cost of people's time, it is worth considering what might be even more opportunity presented to the product developers to save resources that might be associated with collaborative risk/safety assessments, and how that will benefit the economy.
- Some APEC member economies understand the potential benefit of synchronization of approvals and the benefit of this particularly to facilitate movement of biotech products between economies, but most have not fully considered the important economic benefits associated with the reduction in trade barriers that is a likely benefit of many of collaboration on risk/safety assessment.
- Regardless, member economies will need to weigh the benefits of pursuing such an approach against the challenges for establishing a working collaboration.
- Among the challenges member economies see, the greatest is reconciling differences between the economies. This includes differences in legislation and procedures, protection goals and other priorities, and differences in information and data requirements, as well as environmental and cultural differences that could factor into the risk/safety assessment process.
- The time and resources required to engage in collaboration on risk/safety assessment is also seen as a significant challenge.
- At a more nationalistic level, perceptions about maintaining sovereignty could present challenges. For collaborative risk/safety assessments to work, it will be important to clearly distinguish the shared process of risk/safety assessment from the independent process of decision-making ensure sovereignty is retained.
- APEC member economies that choose to embark on a collaborative risk/safety assessment will need guidance on how to initiate a collaboration. The first steps include understanding the options for collaboration (as described in this document), and identifying key economies for collaboration by comparing systems, identifying similarities and differences and determining how these might factor into efforts to collaborate on risk/safety assessment.
- Collaboration on risk/safety assessment is only possible if there is a shared commitment by the economies involved to pursue the collaboration. In addition, willingness of product developers to pursue collaborative risk/safety assessment should be taken into consideration.
- Another perceived benefit of cooperation on risk/safety assessment is the opportunity this presents for learning and building capacity. Economies with less experience could learn about risk/safety assessment from economies with more experience. While this is true, this is not a primary goal of collaboration on risk/safety assessment.
- Collaboration on risk/safety assessment is much more likely to be successful among economies that have a similar level of experience. There is an element of capacity building that comes with but is not the purpose for collaboration on risk/safety assessment between member economies. Capacity building for risk/safety assessment is a form of regulatory cooperation worth pursuing among member economies as described in section III. A. on "information sharing."

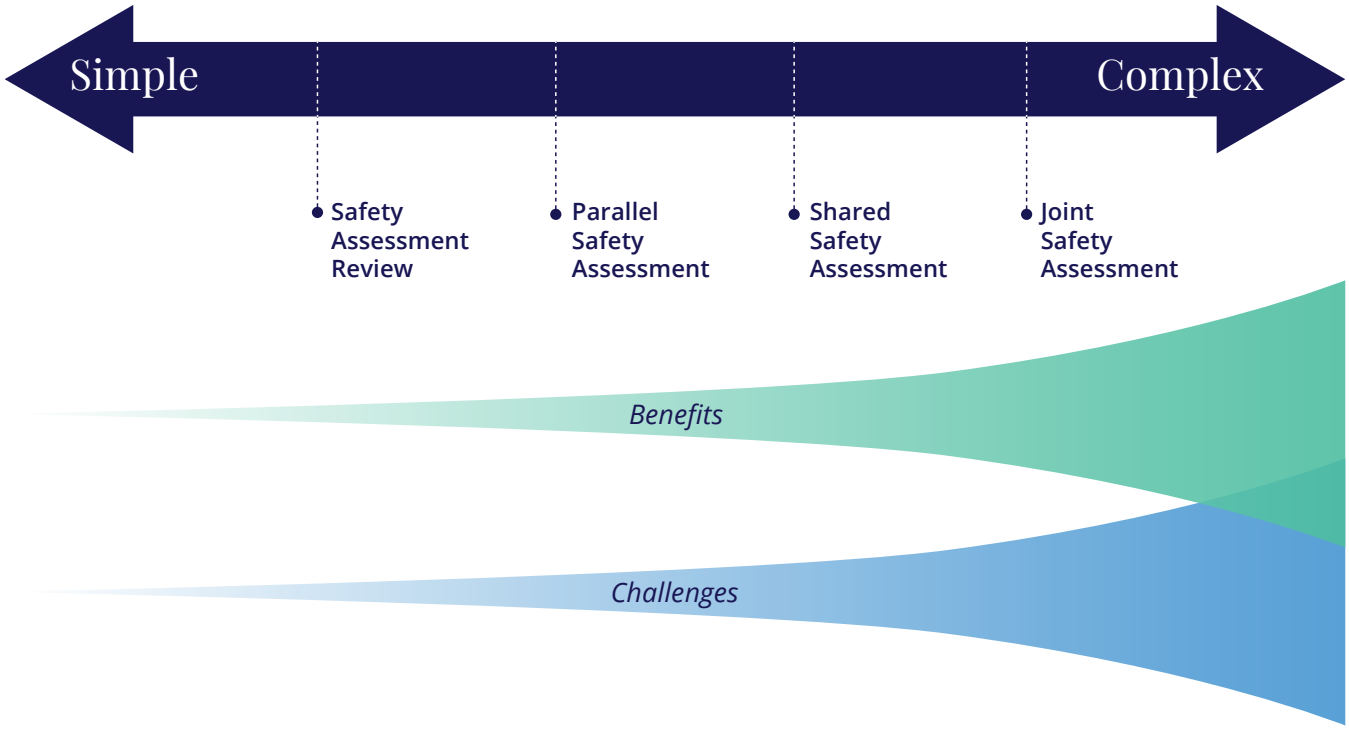


Figure 1: Benefits vs. Challenges of Different Ways to Collaborate on Risk Assessment as an Approach to Regulatory Cooperation among APEC Member Economies.

IV. CASE STUDIES – BEST PRACTICES AND LESSONS LEARNED

The following case studies on biotechnology regulatory cooperation and alignment provide real world examples of how the above approaches have been put into practice in other economies and the methods by which they have enhanced regulatory cooperation.

- Information Sharing
  - Global Low Level Presence Initiative
- Alignment of Regulatory Policies, Disclosures and Assessments
  - Vietnam's expedited regulatory approval of imported products for direct use
- Sharing Risk/Safety Assessment and Regulatory Approval Resources
  - Health Canada – Australia/New Zealand (FSANZ)
  - Argentina-Brazil (MOU on mutual recognition of genome-edited traits)
  - Mercosur Resolution MERCOSUR/GMC/RES. Nº 23/19 (LLP Agreement – reduce trade disruptions)
  - Paraguay (recognition of risk/safety assessments completed in other economies)
- Case Studies from Non-Ag Biotech Sectors
  - Medical device industry
  - MRL harmonization initiatives
  - WHO/ Biosafety Risk/safety Assessment (sharing templates)

V. FUTURE DIRECTION

- Review of objectives
- Summary of regulatory cooperation and alignment options
- Opportunities for agricultural biotechnology regulatory cooperation and alignment in APEC

APEC High-Level Policy Dialogue on Agricultural Biotechnology (HLPDAB)

Workshop: "Role of Agricultural Biotechnology in Food Security and Climate Change"
Trujillo, Peru
Los Conquistadores Convention Center
August 15, 2024: 8:30-17:00 (GMT -5)

Workshop Agenda

Schedule	Time	Agenda
Opening Session		
08:30-09:00	30 min	Registration and Accreditation
09:00-09:20	20 min	Welcome to Participants Opening Remarks of the Workshop by HLPDAB Chair, Dr. Dina Gutierrez, (INIA) Peru
Session 1: Agricultural Biotechnology for Sustainable Agriculture and Healthy Environment		

09:20-10:40	80 min	• Introduction to the Session 1 by Dr. Nguyen Thi Thanh Thuy, (MARD) Vietnam (10 min)
		  ○ Agricultural Biotechnology for Food and Climate Security by Dr. Jennifer Rowland, (USDA) United States of America (30 min)
		  ○ Panel Discussion 1
		  Moderator: Dr. Nguyen Thi Thanh Thuy, (MARD) Vietnam (30 min)
		• Closing Session 1 (10 min)

10:40-11:00	20 min	Coffee Break
Session 2: Agricultural Biotechnology Used to Obtain Crops with Important Characteristics for Food Security and Climate Change		

11:00-13:00	120 min	• Introduction to the Session 2 by Dr. Mahaletchumy Arujanan, (ISAAA) Malaysia (10 min)
		  ○ Genome Editing in Rice by Dr. Erwin Arcillas, (IRRI) The Philippines (20 min)
		  ○ Genome Editing in Maize by Dr. Mohan Murali Achary, (CIMMYT), India (20 min)
		  ○ Genome Editing in Potato by Dr. Erick Magembe, (CIP) Kenya (20 min)
		• Panel Discussion 1
		  Moderator: Dr. Mahaletchumy Arujanan (ISAAA) Malaysia (50 min)

13:00-14:00	60 min	Lunch

Schedule	Time	Agenda
13:00-14:00	60 min	Lunch
14:00-15:00	60 min	● Introduction to the Session 2 by Dr. Mahaletchumy Arujanan, (ISAAA) Malaysia (10 min) ○ Canada Novel Food Regulation by Kathryn Forrestery, Canada (40 min) ● Closing Session 2 (10 min)

Schedule	Time	Agenda
Session 3: Advances and Perspectives on the Use of Genome-Edited Animals for Food Security.		
15:00-16:00	60 min	● Introduction to the Session 3 by Dr. Mahaletchumy Arujanan, (ISAAA) Malaysia (10 min) ○ The current state of animal biotech globally and the perspectives on Food Security - An APEC PPFS case study by Dr. Matthew Tan, (SIT) Singapore (50 min)
16:00-16:30	30 min	Coffee Break
16:30-16:40	10 min	Closing Session 3 (10 min)
16:40-17:00	20 min	Closing Remarks of Day 1 by HLPDAB Coordinator, Ms. Aura Garcia, (INIA) Peru

APEC High-Level Policy Dialogue on Agricultural Biotechnology (HLPDAB)
Workshop: "Role of Agricultural Biotechnology in Food Security and Climate Change"
Trujillo, Peru
Los Conquistadores Convention Center
August 16, 2024: 8:30-12:00 (GMT -5)

Workshop Agenda

Schedule	Time	Agenda
Opening Session		
08:30-09:00	30 min	Registration and Accreditation
09:00-09:10	10 min	Welcome to Participants Opening Remarks of the Workshop by HLPDAB Coordinator, Ms. Aura Garcia, (INIA) Peru
Session 4: Advances and Perspectives on the Microbial Biotechnology for Agriculture in the Context of Food Security		
09:10-10:10	60 min	● Introduction to Session 4 by Dr. Jennifer Rowland, (USDA) United States of America (15 min) ○ Perspectives on Microbial Biotechnology for Agriculture by Dr. Jennifer Rowland, (USDA) United States of America (40 min) ● Closing Session 4 (5 min)
10:10-10:20	10 min	Coffee Break
Session 5: Aspects of Regulatory Systems for Its Development and Adoption in the Context of Food Security and Climate Change		
10:20-11:30	70 min	● Introduction to Session 5 (10 min) ○ Adoption of Agricultural Biotechnology in Colombia by Dr. María Andrea Uscátegui, (Agro-Bio) Colombia (25 min) ○ Panel discussion Moderator: Dr. Sergio Feingold, (INTA) Argentina (25 min) ● Closing Session (10 min)
Closing Remarks		
11:30-12:00	30 min	Closing Remarks of Day 2 by HLPDAB Chair, Dr. Dina Gutierrez, (INIA) Peru
		Lunch

23rd APEC High Level Policy Dialogue on Agricultural Biotechnology Meeting (HLPDAB)

Trujillo, Peru
Los Conquistadores Convention Center
Room España
August 16, 2024: 14:00-17:30 (GMT-5)
Meeting Agenda

TIME	AGENDA
14:00-14:30	Registration
14:30-14:50	**Session 1: Opening Session** • Welcome Remarks by HLPDAB Chair, Dr. Dina Gutiérrez Reynoso • Welcome Remarks by HLPDAB Deputy Chair, Dr. Tae Hun Ryu • Opening Remarks by the Head of the Institute of Agricultural Innovation (INIA), Mr. Jorge Juan Ganoza Roncal • Brief introductions by heads of delegations *(Member economies' heads of delegations to introduce themselves by providing names and organization in APEC alphabetical order)* • Adoption of the agenda by HLPDAB Chair
14:50-15:35	**Session 2: Progress of HLPDAB** • Outcome Report of HLPDAB 2023, by HLPDAB Chair 2023, Dr. Jennifer Rowland • Outcomes of HLPDAB Strategic Plan (2022-2024), by HLPDAB Chair • APEC economies are invited to share comments or feedback *(Please limit your intervention to 2 minutes).*
15:35-16:20	**Session 3: HLPDAB Strategic Plan and Workplans** • Presentation of HPLDAB Work Plan 2024, by HLPDAB Coordinator, Ms. Aura García • APEC economies are invited to share comments or feedback *(Please limit your intervention to 2 minutes).* • Presentation of HLPDAB Strategic Plan (2025-2027) by Coordinator HLPDAB, Ms. Aura García • APEC economies are invited to share comments or feedback *(Please limit your intervention to 2 minutes.* • Endorsement of HLPDAB Work Plan 2024 and Strategic Plan (2025-2027), by HLPDAB Chair
16:20-16:30	Break
16:30-17:00	**Session 4: HLPDAB Economy Progress and Updates** • Heads of delegations are invited to make an update on domestic agriculture biotechnology policies and initiatives (*Please limit your intervention to* 2 minutes)
17:00-17:20	**Session 5: Other Matters** • Updates on HLPDAB projects and initiatives going forward, by APEC Secretariat • Summary of HLPDAB's participation at the Joint Meeting of ATCWG, OFWG, and PPFS by the HLPDAB chair

	• HLPDAB 2025 Meeting by HLPDAB Deputy Chair.
17:20-17:30	**Session 5: Closing Session**
	• Summary of meeting discussions, final deliberations, and adoption of summary reports by HLPDAB Chair • Closing remarks by HLPDAB Chair

APEC High-Level Policy Dialogue on Agricultural Biotechnology (HLPDAB)

Work Plan for 2024

I. Introduction

The important role of the High-Level Policy Dialogue in Agricultural Biotechnology (HLPDAB) was recognized by APEC Senior Officials in 2001. The HLPDAB 2024 will focus on the APEC 2024 priority of "Sustainable Growth for Resilient Development." This aligns with the third economic driver of the Putrajaya Vision 2040: "Strong, Balanced, Secure, Sustainable, and Inclusive Growth," and the Aotearoa Plan of Action, by promoting agricultural sustainability and innovation and implementing the Food Security Roadmap Towards 2030. The meeting will aim to coordinate efforts to make our agri-food systems more resilient, productive, innovative, and sustainable, ensuring lasting food security, food safety, and improved nutrition, as well as promoting agricultural and food trade.

The proposed activities will be conducted under the framework of the HLPDAB Strategic Plan (2022-2024), which focuses on three priority areas:

1. **Strengthen mechanisms for information exchange**: Continue sharing experiences with agricultural biotechnologies among economies to achieve food security, environmental sustainability, and economic prosperity.
2. **Promote transparent, science-based regulations**: Continuously advocate for risk-proportionate and effective regulatory systems to support the development, application, and trade of innovative agricultural biotechnologies for the benefit of APEC member economies.
3. **Facilitate the management of regulatory differences**: Work towards developing solutions to global challenges in innovative agricultural biotechnologies, including trade-related issues, and improve the ability of APEC economies to communicate effectively about these issues.

II. HLPDAB Activities

2.1 Annual HLPDAB Meeting

HLPDAB will hold its annual Plenary Meeting (HLPDAB 23) on 16 August in Trujillo, Peru, during APEC Food Security Week. The meeting aims to continue with the mandate of exchanging information, promoting capacity building, fostering transparent, science-based, and effective regulatory systems, encouraging investment, and strengthening public confidence in biotechnology. The ultimate objective is to promote food security and sustainable growth for resilient development, by the HLPDAB Strategic Plan (2022-2024), as well as to endorse the new HLPDAB Strategic Plan for 2025-2027.

The annual meeting will continue to build relationships among APEC members while exchanging information about the responsible use, development, and adoption of innovative agricultural biotechnologies. Emphasis will be placed on providing APEC Economy Members with an overview of the role that agricultural biotechnology can play in addressing climate change and food security. In addition, we will analyze the uses of this technology in plants, animals, and microorganisms.

2.2 HLPDAB 2024 Workshops

Virtual workshops	Date
AGRICULTURAL BIOTECHNOLOGY SEMINAR SERIES -2024 (HLPDAB 02 2023S) These virtual seminars are performed with the support of the USDA from the United States, with technical support provided by the ASFI to four economic members (Peru, Vietnam, Indonesia)	
Virtual seminars I: Genome Editing: Opportunities for Adoption in Addressing Climate Change and Food Security Lead by Peru	June 4, 2024
Virtual seminars II: The Role of Plant Breeding Innovations in Crop Improvement: Status and Prospects. Lead by Viet Nam	June 25, 2024
Virtual seminars III: Title to be confirmed Lead by Indonesia	TBD
In-person workshops	**Date**
Workshop on Moving Forward on Agricultural Biotechnology Through Continuing Efforts on Regulatory Cooperation in APEC (HLPDAB 01 2024S) Lead by USA	August, 2024
Workshop Role of Agricultural Biotechnology in Food Security and Climate Change. Lead by Peru	August, 2024

2.2 HLPDAB 2024

Expected Outcomes/ Deliverables for 2024

N°	Expected outcomes	Deadline
1	Continue to encourage APEC economies to share resources and exchange experiences about the use of agricultural biotechnology as a technology for facing climate change and as a tool for food security.	Ongoing
2	Support the development, application, and adoption of agricultural biotechnology as an innovative tool used in plants, animals, and microorganisms.	Ongoing
3	Continue to promote transparent and science-based regulations to further develop agricultural biotechnology and innovation in the context of global trade	Ongoing
4	Promote capacity building in regulatory systems and the use of agricultural biotechnology among APEC Economic Members.	Ongoing
5	Share and endorse the HLPDAB Annual Plan 2024 among APEC Economic Members.	July, 2024
	Share and endorsed the HLPDAB Strategic Plan 2025-2027 among APEC Economic Members.	July, 2024
6	Prepare HLPDAB inputs for the APEC Ministerial Meeting on Food Security 2024.	Ongoing
7	To develop and hold the 23rd HLPDAB Plenary Meeting.	16 Aug, 2024

III. ASSESSMENT OF STRATEGIC PLAN (2022-2024)

The HLPDAB Strategic Plan has a term of three years. The last Strategic Plan started in 2022 and concludes at the end of this year, 2024. An evaluation of the projects and activities undertaken under the Strategic Plan will be presented.

IV.ENDORSEMENT OF STRATEGIC PLAN (2025-2027)

The presentation of the new HLPDAB Strategic Plan for the period 2025 to 2027 will take place. The assessment of HLPDAB projects and activities will ensure alignment with Strategic Plan priorities, including the Putrajaya Vision 2040, the APEC Food Security Roadmap Towards 2030 and its Implementation Plan, the La Serena Roadmap for Women, and Inclusive Growth.

V. ENDOSERMENT BY HLDPDAB GROUP

Additionally, we will review the Alignment Policy Approaches Document (PAD) outlined in Seattle 2023 and updated during the virtual discussion groups (member economies only) held in 2024.

APEC High-Level Policy Dialogue on Agricultural Biotechnology (HLPDAB)
Strategic Plan (2025-2027).

RATIONALE:

The High Level Policy Dialogue On Agricultural Biotechnology (The Policy Dialogue) reports directly to the APEC Senior Officials. Accordingly, the Policy Dialogue needs Senior Official approval of the Strategic Plan. Senior Officials have previously approved six Strategic Plans for [2004-2006,2007-2009,2010-2012,2013-2015,2016-2018, 2019-2021, and 2022-2024]. This new Strategic Plan 2025-2027 is submitted to Senior Officials for their review and approval.

The Policy Dialogue has noted its achievements against the goals outlined in the 2022-2024 Strategic Plan. The 2025-2027 Strategic Plan seeks to strengthen mechanisms for information exchange, promote transparent, science-based regulations, and facilitate the management of regulatory differences, to align with the Putrajaya Vision 2040 and the Aotearoa Plan of Action, as well as with the Food Security Roadmap Towards 2023 and its Implementation Plan.

Following the guidance of the Putrajaya Vision 2040 to foster “an open, dynamic, resilient and peaceful Asia-Pacific community by 2040, for the prosperity of all our people and the future generations” as well as the implementation plan of the Putrajaya Vision, Aotearoa Plan of Action, to “ ensure lasting food security, food safety and improved nutrition for all, as well as reducing food waste and loss in the region by promoting agricultural and food trade, agricultural sustainability and innovation, and implementing the Food Security Roadmap Towards 2030”, policymakers use the Policy Dialogue to promote the development of science-based regulatory frameworks, share information on innovative agriculture technologies, encourage investments and strengthen public confidence in biotechnology, to increase agricultural productivity and protect the environment, facilitate trade, and enhance food security.

BACKGROUND:

In 2001, APEC Senior Officials affirmed the benefits of biotechnology and called for the establishment of a High-Level Policy Dialogue on Agricultural Biotechnology. The purpose of the Policy Dialogue is for policymakers in APEC’s 21-member economies to exchange information and promote public policy development to support the responsible use and informed adoption of agricultural biotechnology as one tool to increase agricultural productivity, protect the environment, facilitate trade, and promote food security. The Policy Dialogue is a forum for APEC member economies to discuss issues of common interest regarding agricultural biotechnology, including the safe introduction of biotechnology products and public acceptance of these products.

Objective 1. Strengthen the mechanisms for maintaining the continuous exchange of information and experiences among the member economies of the APEC region regarding agricultural biotechnology, especially in the context of climate change and food security.

Activities/Deliverables

a. Update the contact list of focal points on the APEC Agricultural Biotechnology (Coordinator: APEC Secretariat). A contact list is available according to the information provided for the APEC Economic member.
b. Regular update of the APEC Agricultural Biotechnology Website. (Coordinator: APEC Secretariat). These updates should include events, news, and contact information.
c. Annual Meeting held at either APEC Food Ministerial or a Senior Officials Meeting to include Workshops and concept papers. Continue building relationships among APEC Policy Dialogue members while exchanging information regarding the responsible use, development, and adoption of Agricultural Biotechnology. This information exchange will include the use of this technology for plants, animals, and microorganisms, technology to face the challenges of food security and climate change. (Coordinator: Host APEC Economic Member)
d. The Policy Dialogue will coordinate and share updates on workstreams with other APEC sub-fora (such as PPFS, ATCWG, and OFWG) to share information and avoid duplication of work.
e. Endorsement of new Terms of Reference (ToR) of the Policy Dialogue for the period from 2026 to 2029.
f. Conduct Technology Missions (visits to facilities and research institutions, including virtual engagements) to enable stakeholders and policymakers to better understand upcoming technologies and products in development. By enhancing knowledge about future innovations, these missions provide the necessary information to implement policies that best ensure the safe use of agricultural biotechnological products.

Objective 2: Consistently encourage the establishment of transparent, predictable, science-based, and risk-appropriate regulatory systems. These systems should support the development, application, and trade of innovative agricultural biotechnologies to benefit APEC member economies.

a. Enhance understanding, best practices, and confidence in the regulatory frameworks for Agricultural Biotechnology across APEC economies by sharing knowledge and experiences at Policy Dialogue meetings and workshops. (Coordinators: APEC Member Economies, Sponsoring Economies, and Host Economy)

b. Leverage best practices and international forum work to better align domestic policies and regulatory frameworks for Agricultural Biotechnology among APEC economies. When suitable, include sessions at Policy Dialogue meetings or workshops on current work, findings, or sharing platforms from other international forums or APEC member economies. (Coordinator: Host Economy)

c. Periodically remind APEC member economies about available resources on approved Agricultural Biotechnology products and science-based regulatory policies and frameworks that aid in their acceptance and trade. (Coordinators: APEC Member Economies, APEC Secretariat)

Objective 3: Facilitate the management of regulatory differences by striving to develop solutions to global challenges related to innovative agricultural biotechnologies—including trade-related

issues—and improve the ability of APEC economies to communicate effectively about these issues.

Activities/Deliverables:

a. Share information on production methods and products developed using Agricultural Biotechnology that can enhance the resilience of food and feed production systems to environmental challenges. Utilize relevant Policy Dialogue resources for information sharing. (Coordinator: Member Economies)

b. Promote collaboration and information sharing among member economies to address common challenges such as low-level presence, asynchronous approvals, coexistence of different agricultural production systems, and risk and science communication. APEC members may share their experiences, including participation in other international forums, at Policy Dialogue meetings and workshops. (Coordinator: Member Economies).

c. Share information on the alignment, similarities, and differences between APEC member economies' regulatory policies, frameworks, and guidelines for Agricultural Biotechnology. (Coordinator: Member Economies).

d. Collaboratively develop a shared set of principles for participating economies to enhance regulatory alignment in evaluating and approving products of Agricultural Biotechnology. (Coordinator: Member Economies)

APEC Joint Meeting of PPFS, OFWG, ATCWG and HLPDAB

August 17, 2024
Costa del Sol Wyndham Trujillo Golf Hotel, Room Moche
Trujillo, Peru

AGENDA	
14:00 - 14:30	**Registration** ● Arrival and registration of Delegates, APEC Observers, and Guests.
14:30 - 14:50	**I. Opening Session (20 min)** • Welcome and Opening Remarks: ○ Mr. Christian Alejandro Garay Torres – Vice-Minister of Agrarian Development Policies and Supervision, Peru / PPFS Chair ○ Ms. Monica Rojas Noack – OFWG Lead Shepherd, Chile ○ Dr. Su-San Chang – ATCWG Lead Shepherd, Chinese Taipei ○ Ms. Dina Lina Gutierrez Reynoso – HLPDAB Chair, Peru
14:50 - 15:10	**II. Introduction by Heads of Delegations and Invited Guests (20 min)** ● Head of each delegation will give self-introduction for 1 min each (in APEC alphabetical order) ● Host Economy to announce PPFS meeting arrangements
15:10 - 15:15	**III. Adoption of the meeting agenda (5 min)** ● PPFS Chair invites members to adopt the agenda
15:15 - 16:05	**IV. Update on PPFS, OFWG, ATCWG and HLPDAB activities (3 minutes each intervention)** ● Update of PPFS activities (PPFS Chair) ● Update of OFWG activities (OFWG Lead Shepherd) ● Update of ATCWG activities (ATCWG Lead Shepherd) ● Update of HLPDAB activities (HLPDAB Chair) *Economies will be invited to provide insights on the importance of improving collaboration and synergies between the four sub fora, including potential initiatives. (20-minutes discussion)*
16:05 - 16:25	**Coffee Break**
16:25 - 16:50	**V. Presentation of the Principles for Preventing and Reducing Food Loss and Waste in the Asia-Pacific Region** ● Presentation by Mr. José Luis Alarcón Tello, Ministry of Agrarian Development and Irrigation, Peru ● Q&A: Members are invited to provide their comments during a 15-minute discussion
16:50 - 16:55	**VI. Update on the APEC 9th Food Security Ministerial Meeting (FSMM)** ● PPFS Chair to brief on the preparations of the FSMM and on the proposed statement
16:55 - 17:00	**VII. Closing Session** ● PPFS Chair to provide closing remarks