出國報告（出國類別：開會）

出席 2023 年 APEC「農業生物技術高階政策對話 (HLPDAB)」系列會議

服務機關：行政院農業委員會
衛生福利部食品藥物管理署
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派赴國家：美國
出國期間：112 年 7 月 25 日至 8 月 3 日
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目錄

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壹、目的

為促進生物技術運用於農業發展，美國於 2001 年在上海亞太經濟合作(Asia Pacific Economic Cooperation, APEC)領袖會議倡議建立溝通機制，並於 2002 年成立農業生物科技高階政策對話(High Level Policy Dialogue on Agricultural Biotechnology, HLPDAB)。此後 APEC 主辦國均在資深官員會議期間舉行 HLPDAB 會議，我方每年均派員與會。近年受新冠肺炎疫情影響，2020 年馬來西亞、2021 年紐西蘭，以及 2022 年泰國主辦時，均以線上方式辦理。

本(2023)年 APEC 主辦經濟體美國之主題為「為各方創造具韌性且永續未來」(Creating a Resilient and Sustainable Future for All)，三大優先領域議題為「互連：建立具韌性及相互連結的區域以增進具廣泛基礎的經濟繁榮」(Interconnected: Building a resilient and interconnected region that advances broad-based economic prosperity)、「創新：為永續未來打造有助創新的環境」(Innovative: Enabling an innovative environment for a sustainable future)以及「包容：為各方樹立衡平且包容性的未來」(Inclusive: Affirming an equitable and inclusive future for all)，HLPDAB 係由美國農業部主辦，安排實地參訪戴維斯及聖路易斯之基因工程相關研究機構與公司，並召開系列工作坊及年會。

從 2002 年 HLPDAB 之首次會議，即開始討論基因改造生物與產品(GMO)之發展、管理及安全性評估議題，針對農業生物技術之應用以確保全球糧食安全、APEC 各經濟體對基改產品之發展立場與管理及法規調和，以及降低農業生技產品之貿易障礙等議題進行探討。2018 年起，討論內容開始加入介紹近年新興之基因編輯技術，並進一步探討相關法

規及政策。

我方多年來推動農業生物技術創新與成果產業化應用，成功帶動如觀賞魚、動物用疫苗及生技檢驗檢測等農業生技產業持續成長，2016 年進一步推動農業生物經濟相關產業發展，聚焦農業基因體科技平臺、動植物健康管理，並從農業副產品發掘功能性成分。近年來氣候異常事件頻繁且嚴重，而基因編輯技術有機會有效、精準調整重要性狀，爰我方持續關注新興育種技術改善品種對於氣候變遷韌性之效果，觀察新技術對產業造成之改變，並仔細研析國際對精準育種相關管理議題及技術進展，以及其衍生之食品管理議題，關注 APEC 各經濟體之發展，以妥適研訂國內相關科技發展策略與管理措施，以兼顧我國農業產業調適、生態環境保護、食品安全保障與國際貿易發展。本次會議由主管基因改造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行政院農業委員會科技處湯惟真科長出席（註：行政院農業委員會於 112 年 8 月 1 日改制為農業部，科技處改制為農業科技司）。

貳、行程及工作內容

時　　間	行 程	內　　容
7 月 25 日(二)	啟程	由臺北出發前往美國 (1)湯科長前往戴維斯 (2)江科長前往聖路易斯
7 月 26 日(三) 7 月 27 日(四)	(1)戴維斯 (2)聖路易斯	生技創新與農業生產力實地考察
7 月 28 日(五)	西雅圖	前往西雅圖
7 月 29 日(六)	西雅圖	出席青年學者與新創事業研討會
7 月 30 日(日) 7 月 31 日(一)	西雅圖	出席農業生物技術之有效監管與政策解決方案工作坊
8 月 1 日(二)	西雅圖	出席農業生物技術高階政策對話會議(HLPDAB)
8 月 2 日(三) 8 月 3 日(四)	返　程	抵達臺北

參、會議過程

一、生技創新與農業生產力實地考察

（一）戴維斯實地考察

由美國農業部(USDA)對外農業局(Foreign Agricultural Service, FAS)顧問(Science Advisor) Jennifer Rowland博士及加州大學戴維斯分校(UC Davis) Kent Bradford 教授領隊，計有加拿大1人、中國大陸2人、印尼3人、馬來西亞2人、祕魯1人、菲律賓2人、新加坡1人、泰國1人、越南2人及我國1人共10個經濟體16人參與。兩天行程包括實地參訪拜耳公司蔬菜研究發展基地、UC Davis植物科技系Diane Beckles教授實驗室及該系之植物轉殖設施(Plant Transformation Facility)，其餘則邀請該校專家及新創公司於該校之國際中心進行簡報（現場或線上）與交流。

1. 參訪跨國集團拜耳(Bayer)公司在加州 Woodland 之蔬菜研究發展基地（全程不可拍照、錄影、錄音）：

   該基地 1972 年設立，現為拜耳公司蔬菜品種、生產、作物營養、種子健康之研發核心，占地約 400 英畝（約 162 公頃），全職員工 180 人，主要進行抗病、抗逆境之蔬菜作物育種、遺傳、生產、品質之研發、種子健康，以及殺草劑與環境之交互作用等研究工作，但未在該基地進行基因工程(Genetic Engineering)含基因編輯之試驗研究。其研究之蔬菜作物包括茄科（番茄、甜椒、茄子）、葫蘆科（甜瓜、西瓜、胡瓜、南瓜）、根莖類（洋蔥、胡蘿蔔、韭蔥）、十字花科（青花菜、花椰菜、甘藍）、葉菜類（萵苣、菠菜、茴香）、甜玉米、豆類、秋葵等。

   拜耳公司表示，如何使用更少之土地及資源生產作物一直是為該公司於農業研發之總目標。以玉米為例，產量250公斤從1940年所需土地1,347平方公尺，進展到1980年400公頃、2000年297公頃、2019年167公頃，未來希望減少到120公頃即可生產

，手法包括使用雜交種子、基因改造，以及再生農業(Regenerative agricultural practice)，促進土地永續利用。近年也重視太陽能之利用，目前執行之太陽能計畫已經可以供應該基地 70%用電量，2030 年預計可達 100%。

另拜耳公司刻正推動〝Life Hub Network〞，與其他公司、研究人員、決策者、企業家等領先創新者合作驅動開放式之創新計畫，以因應氣候變遷下之糧食安全，並為各規模之合作夥伴提供專業知識與資源。例如拜耳公司投資 NuCicer 公司、加州大學戴維斯分校(UC Davis)合作利用遺傳多樣性資源，以野生鷹嘴豆與栽培種雜交選育出較栽培種蛋白質倍增之品種，已於 2023 年進行商業蛋白質原料生產。基因編輯部分，該公司則各方專家刻正執行約 200 件研究計畫，主要研究對象為玉米、小麥、大豆、油菜等，針對病害、產量、產油品質等目標進行育種；亦有計畫與 UC Davis 合作，進行土壤固氮微生物之基因編輯以減少稻作對於肥料之需求。

此外，拜耳公司之州與地方政府事務部門(State and Local Government Affairs)之副處長 James Curry 談到美國州政府層級對於 GMO 標示立法情況，起源於 2013 年美國多個城市在 5 月 25 日發起抗議孟山都公司事件(Get Monsanto Out of My Food)，2012 至 2014 年間，加州、華盛頓州、俄勒岡州陸續針對基因改造食品強制標示辦理公投，當時總體而言，反對票僅略多於贊成標示者（差距不到 1%）。事件發展到 2023 年統計，美國有 8 個州（含加州）針對食物權(Right to food)立法，其中緬因州、紐澤西州、波多黎各州立法標示 GMO，緬因州、紐約州、奧勒岡州針對基改鮭魚須標示，另目前緬因州針對基因編輯產品需要標示，拜耳公司研判未來趨勢應該會有更多州跟進。拜耳公司自收購孟山都公司

後，並不特別教育民眾改變對過去孟山都公司之印象，而多是致力於與各非政府組織合作，以降低民眾對於拜耳公司之疑慮。

會後實地走訪蔬菜種子健康實驗室，全美國拜耳公司之蔬菜種子均抽樣在此進行病原（針對已知病害，不含新興病害）檢測後才會外銷。該公司要從美國出口之種子均會經過該基地檢測後才外銷。田間部分則參觀導入智慧感測設備之番茄試驗田，主要感測溫度、濕度、蒸散量等變化以控制灌溉，並使用大疆無人機進行空拍性狀調查與病害防治。

2. 畜產動物基因工程相關成果介紹

(1) 動物科技系微生物學家 Matthias Hess 副教授說明，UC Davis 已建立牛隻瘤胃甲烷排放之體外量測系統，並尋找可有效降低甲烷排放量之解決方案。包括以咖啡、飲料、洋蔥、堅果之副產物作為飼料添加物減少甲烷排放之研究，其中咖啡與堅果效果好，但洋蔥反而增加排放量；另 UC Davis 聞名之創新研究，以海藻(Australian Macroalgae)作為飼料添加物之體外研究，證明可減少 90%之甲烷排放。Hess 實驗室獲得 TED 大會有限責任公司支持之經費，找尋海藻基因與甲烷生合成之關係，即將進一步利用 CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats)技術編輯牛腸道微生物基因，減少牛隻排放甲烷，未來規劃針對小牛進行口服治療，以便早期干預腸胃之微生物系統。

(2) 動物科技系 Elizabeth A. Maga 副教授說明，全球 2019 年 5 歲以下有 5.3 百萬個孩童死於腹瀉，溶菌酶(Lysozyme)可以分解細菌之細胞壁，而羊奶內所含溶菌酶的含量比牛奶多一倍，爰自 1999 年起發展基因轉殖羊，以生產表達大量表達人類溶菌酶之羊奶，目標改善人類健康。2004 年起已進入

到以豬隻做為動物模型，證實服用羊奶的豬隻其體內大腸桿菌含量顯著下降，並確認其免疫反應，以及評估基改食品之安全性。2021 年起進行臨床試驗，未來擬純化溶菌酶進行食品添加。

(3) Alba Veronica Ledesma 博士與碩士班學生 Austin Brown 介紹利用 CRISPR/Cas9 技術於動物育種之研究，如代理種公牛(Surrogate sire)系統之建立：創造無法產生自體之生殖細胞，但可量產其他優良性狀公牛之精原幹細胞。另介紹運用基因編輯綿羊進行抗牛白血病（用羊成本較低且速度較牛快）之研究。

3. 美國農業部 Dr. Jennifer Rowland 總結第 1 天安排之參訪及演講，係傳達創新生物技術之好處，包括育種資源節省、動物福利、人類健康促進、產量增加、疾病預防等。

簡要提到美國基於可靠科學基礎、實質等同之原則，1986 年由白宮發布之生物技術監管協調框架(Coordinated Framework for Regulation of Biotechnology)由農業部(USDA)、食品與藥物管理局(FDA)與環境保護局(EPA)共同管理，監管對象為生物技術產品(product base)而非生物技術(process base)。近年因應基因編輯技術等現代化之發展，於 2017 年更新版本，強調推動科技發展之同時繼續保護健康與環境之保護、確保公眾對於監管體系之信心、提高對於生技產品監管之透明度、協調性、可預測性與效率，並目標提高國際對於農業生技產品之接受度，推動生物經濟發展。

Dr. Rowland 說明美國生物技術發展 30 年來，監管體系應為 product base，但後來已往 process base 發展，相關法規也比以往複雜。另提到 USDA 於 2020 年 6 月 12 日發布之農業生物技術安全規則(USDA's secure rule to regulate agricultural biotechnology)可供

各國參考（附件 1，經查該規則於本年 8 月 4 日更新如附件 2）。

4. 作物基因工程相關成果介紹

(1) UC Davis 植物科技系 Diane Beckles 教授以生物技術作為維護糧食安全與主權之工具為題，介紹因應糧食安全，育種目標主要聚焦於抗逆境與病蟲害、減少採前與採後糧損、增進營養與儲架壽命。

另概略介紹 CRISPR-Cas9 之基因編輯技術，以及簡述優點包括：效率且便宜，意味著基因工程可以更普及，發展中的經濟體也較可以採用此工具進行育種；編輯的作物不具外來 DNA 且天然也會發生相關改變，研發與通過監管的時間約 4-7 年，在美國採取 CRISPR 編輯的作物不用視為 GMO 管理；也有很高的機率可以獲得創新性狀，且可以同時編輯多個基因，對於無性繁殖作物更有利，可以克服以往傳統育種無法達到的作用。但缺點包括：編輯結果可能無法預測，且需要進行多次嘗試才能達到所要的結果；CRISPR-Cas9 等基因編輯技術之智慧財產權複雜且不清楚；公眾對於基因編輯的看法與安全仍有所擔憂，但不太可能似反對 GMO 一樣激烈；而編輯過程中可能產生脫靶效應，特別在動物與人類細胞更容易發生。

會後參訪 Diane Beckles 教授實驗室，主要研究作物澱粉與蔗糖間轉化、長期儲存等相關基因，刻以 CRISPR-Cas9 技術進行番茄果實採後冷害與避免馬鈴薯變黑等採後處理相關研究。

(2) 參訪 UC Davis 之植物轉殖設施(Plant Transformation Facility)，係幫助該校研究人員、學生或合作企業將外源基因導入植物並進行組織培養與馴化，採收費機制，透過研究分工，讓

研究人員可更專注於基因編輯與轉殖成功後性狀之分析與研究。

(3) 生物科技系 Venkatesan Sundaresan 名譽教授介紹其利用基因編輯技術修改植物生殖機制，去除水稻減數分裂之能力，只進行有絲分裂，而可進行雜交稻的無性繁殖，避免優良性狀在 F1 子代被分離，保持水稻品種之雜交優勢。研究團隊已利用品質優良之商業F1雜交品種BRS-CIRAD 302進行改良，2022 年 12 月發表於 Nature 期刊。該項技術未來可以大幅簡化人工授粉等育種流程與成本，並且因雜交優勢之維持提高稻米產量與品質，可降低雜交品種的價格，農民亦可維持自行留種之習慣，有助於解決糧食供應問題。

(4) 化工系 Somen Nandi 兼任教授為全球健康分享組織(Global Healthshare Initiative)之常務董事兼總經理，該組織係 UC Davis 於 2010 年成立，已發展成 8 個國家 30 多個機構組成之全球網絡，整合公私部門提供貧窮地區之健康解決方案。Nandi 教授主要研究領域是以植物細胞作為生產重組蛋白之生物反應器，簡要介紹合成生物學(Synthetic Biology)係跨生物學、工程學與化學等多個領域，設計並建造新的生物學系統、生物體或生物分子，重新設計或重新組合生物體之 DNA、RNA 與蛋白質等生物分子，創造出具有獨特功能的生物體或產品，例如細胞培養肉。

(5) 由 NORFOLK Health Produce 公司 Jassica Loule 技術長線上介紹其基改高花青素紫色番茄。該公司為 NORFOLK Plant Sciences (NPS)之子公司，NPS 為英國生物科技研究機構 John Innes Center 及 The Sainsbury Laboratory 之衍生新創公司。NORFOLK Health Produce 總部位於美國加州戴維斯，

其任務係將 NPS 之創新研發成果推向市場，目標將推出一系列以創新技術開發之有益健康蔬果，而此次介紹之深紫色抗氧化番茄為其第一個產品。其發展自英國 East Anglia 大學兼 John Innes Center 研究主持人之 Cathie Martin 教授，將金魚草基因轉入番茄，花青素含量為一般番茄品種之兩倍，與黑莓與藍莓含量相當。

該公司認為現代消費者注重創新產品的選擇，而在美國發展市場，係根據美國民調機構 Pew Research Center 在 2018 年對於 GM 食品之民調，近 50%民眾認為 GM 食品對健康無害甚至更有益健康。該公司與 UC Davis 合作品種試驗，並於舊金山、聖路易斯、波士頓及北卡羅萊納州之羅里(Raleigh)上市推廣。其自 2007 年發展技術並申請專利後，經分析競爭優勢與消費者喜好性狀，在 2021 年始推出新品種經 2022 年 USDA 核准生產與 2023 年 FDA 核准上市，2023 年起著手與廚師合作走餐廳之通路，預計 2024 年起擴大商業規模往零售發展。

該紫色番茄目前售價每公斤約 17-18 美元，為一般品種之兩倍，而儲架壽命較一般品種長。經安排現場試吃，個人感覺外觀深紫色、圓形很吸引人，其風味不具酸味，在口中會殘留清甜味，果皮比玉女番茄厚但不具澀味，果肉具有彈性。

(6) 由 Pairwise 公司副總經理 Megan Thomas 線上介紹其旗下品牌 Conscious Greens 推出之基因編輯新品種芥菜，為美國第一個核准上市（2020 年）之基因編輯食物。該公司由哈佛大學與麻省理工學院於 2017 年創立，基於對於生菜沙拉之市場調查，48%消費者認為生菜種類的選擇性不足，該公司

專注於應用CRISPR基因編輯技術改善水果與蔬菜之口感與營養。除了本次介紹去除苦味之基因編輯芥菜（產品名為Purple Power Baby Greens Blend）等綠色蔬菜，該公司刻正開發無子漿果、無核櫻桃及其他產品。

該基因編輯芥菜透過品牌活動於西雅圖、灣區及奧斯汀等地推廣 6,000 多個消費者試吃，並獲得 3,000 名消費者完成線上調查，結果顯示超過 90%消費者接受此產品且具有購買意圖。該種綠色芥菜之葉脈為紫色，經安排現場試吃，在混有其他種類生菜之情形下，個人覺得吃起來還是具有苦味，但不具辛辣味。

5. UC Davis 研發成果商品化與產業化機制

(1) 植物科技系 Alan Bennett 名譽教授簡要介紹其 2004 年創建之農業公共智慧財產資源中心(Public Intellectual Property Resource for Agriculture, PIPRA)，成員包括美國 11 所大學，共同因應在農業研究上越來越複雜之品種權、專利權及材料移轉等問題，透過早期資訊交換，建立合作機制，提高資訊透明度並降低智慧財產權之交易成本，以促進公部門之農業生物技術創新成果可更快速商業化，避免因權利複雜無法突破而中斷研究或成果無法被利用，並推薦該中心 2007 年出版且公開下載之智財權管理手冊，協助研究人員認識智慧財產權在農業的重要性，進而策略性管理，以支援創新發展。

(2) 學校設有創新與技術產業化中心(Innovation and Technology Commercialization, ITC)，協助將研發成果轉化為產品與服務。由 Janine Elliott 主任介紹 UC David 目前有效且在管理的專利有 900 項，透過學校的新創催化資源(Venture Catalyst)提供概念驗證資金、育成空間、促成投資、建構產業生態系

網絡等協助，自 2013-2014 年起已有超過 100 間新創公司受到該校的基金協助成立並於市場立足。

(3) 植物科技系 Kent Bradford 名譽教授介紹其於 2010 年成立之種子聯盟(Seed Central)組織。UC Davis 校區附近約有 100 家種子或種子相關公司，旨在促進該校針對植物與種子相關農業生物技術之公私協力合作，透過研究合作與技術移轉，將相關科技更快速推向市場，吸引人才及新創公司來戴維斯形成聚落，並保持該地區於種子產業之世界領先地位。

(4) 農業及資源經濟系 Daniel Sumner 名譽教授說明因應氣候變遷糧食安全最佳解方仍是研究創新。能源、肥料與糧食三者價格關係密切，由先進國家投入研發的結果，證明科技研發可以穩定長期之糧食價格，但很難有立即性的成果，要投資很久才能看得出結果，投資 1 元研發經費，可有 10 元之效果。

（二）聖路易斯實地考察

由美國農業部(USDA)國際貿易專員(International trade specialist) Josh Noonan及密蘇里大學Nicholas Kalaitzandonakes教授領隊，計有菲律賓3人、泰國2人、智利2人、越南2人、印尼2人、韓國2人、日本1人、新加坡1人、秘魯1人及我國1人共10個經濟體17人參與。首先由Dr. Nicholas Kalaitzandonakes先為大家介紹聖路易斯實地考察行程目的及內容。由於基改作物從研發到上市約需要9至13年，生技公司可能前15年必須投入研發經費，但卻無收入，第16年起可能有些收入回饋，可能要到第21年才達收支平衡。兩天實地考察行程包括生物技術相關之拜耳作物科學公司(Bayer Crop Science)及本森・希爾公司(Benson Hill)、生物技術新創企業(startup company)包括CoverCress、Solis Agroscience和Plastomics，以及國際植物研

究中心唐納德・丹佛斯植物科學中心(Donald Danforth Plant Science Center)，最後考察農場(W. Stemme Farm)，了解農夫實際如何種植基因改造作物。

1. 參訪跨國集團拜耳(Bayer)公司在密蘇里州聖路易斯之拜耳作物科學公司(Bayer Crop Science)

(1) 一進入該公司，即看到牆面有該公司之宗旨：以科學讓生活更美好(Science for a better life)，並展示目前全球人口數字及可種植土地面積，並敘明聯合國預估 2050 年將達 97 億人口，其中 60 歲以上人口約 20%，藉此提醒全球人口數增加及糧食危機，且相呼應著該公司願景：人人健康、無人飢餓(Health for all, Hunger for none)，並專注創新及永續發展。

(2) 由該公司全球法規策略 (Global Regulatory Pipeline Strategy Manager) 經理 Christine Shyu 報告基因編輯政策及未來願景(Genome editing policies and future vision)，相較傳統育種，基因編輯技術可以更精準且有效率地修正特定基因，但目前各國基因編輯法規有些不同，但原則上針對基因編輯作物，需經過評估，才能判定是以基因改造作物管理，或是以傳統育種作物管理。目前在美國基因編輯產品包括 Calyxt 公司高油酸含量之大豆油，Corteva 公司提升糯質成分比例之玉米(waxy corn)等。

(3) 由該公司全球法規政策經理(Global Regulatory Policy Manager) Lieselot Bertho 報告應用生物技術開發產品上市(Bringing biotechnology-derived traits to the market)，由於利用生物技術開發基改作物，讓原本需要大面積栽種面積的農田，可以較小面積栽種基因作物，獲得相同產量。目前美國、加拿大、巴西、阿根廷及印度約栽種基改黃豆、玉米及棉花比例約為 92.5%。以拜耳公司為例，基改作物從研發到上

市約需 12-15 年，經費約 130 百萬美元。主要可分為四個步驟：第一步驟從天然植物體中鑑定所需之性狀（如抗蟲或耐旱性），第二步驟將所需性狀轉殖入植物，第三步驟測試新植物以確保對人類、動物及環境安全，每個新的基因改造種子都需要經過多年測試，以確保與非基改種子一樣安全。第四步驟為經過科學家和政府監管機構嚴格審查後，新基改種子始被允許提供給農民使用。各國基改安全性評估要求法規不同，以美國及加拿大對於類似品系可以簡化，日本針對混合型基改作物可簡化查驗登記。

(4) 由該公司國際抗蟲管理負責人(International Insect Resistance Management Lead) Samuel Martinelli 博士報告昆蟲抗性管理(Managing resistance of insect control traits)，說明蘇力菌(Bacillus thuringiensis, Bt) 蛋白質是細菌中所合成，鱗翅目或鞘翅目害蟲食入 Bt 蛋白，會造成消化道上皮細胞穿孔死亡，轉殖可表現蘇力菌蛋白質基因，開發出具有抗蟲特性之基改 Bt 作物。昆蟲抗性管理之關鍵步驟包括：外部專家學者參與、昆蟲抗性風險評估、監測田間調查，以了解昆蟲抗性情形、建構最佳管理實踐(best management practices, BMP)、持續教育訓練及推動 BMP。

(5) 實地走訪實驗室，該公司介紹種子組織取樣機(Seed chipper)，現場以玉米為示範，可快速取樣種子組織作分析，取樣組織可做基因分析和建立 DNA 圖譜。考察法規科學實驗室(Regulatory Science labs)，該公司針對基改作物進行蛋白質安全評估及昆蟲生物測定，並參訪溫室，摘要如下：

A.蛋白質安全評估(protein safety assessment)：包括確認基因改造作物之安全使用歷史(history of safety use, HOSU)、生

物資訊分析(bioinformatics analysis)之有毒物質及過敏原、世代穩定性(generational stability)、熱穩定性(heat stability)、消化率及毒性。

B. 昆蟲生物測定(insect bioassay)：包括確認基因改造作物對目標昆蟲(target insect)之劑量反應生物測定(dose response bioassay)、非目標昆蟲(non-target insect)及非目標益蟲(non-target beneficial insect)之限制劑量生物測定(limit dose bioassay)及劑量確認生物測定(dose confirmation bioassay)，並以上述實驗結果進行綜合報告。

C. 溫室(green house)：該公司具有可控制溫度、濕度、光度等條件之溫室，可惜參訪當日尚無進行基因改造作物之溫室試驗。

2. 參訪唐納德‧丹佛斯植物科學中心(Donald Danforth Plant Science Center)

由該中心研究副總裁(VP of Research) Toni Kutchan 博士簡介唐納德‧丹佛斯植物科學中心為世界最大非營利植物研究中心，由比爾‧丹佛斯(Bill Danforth)於 1998 年創立，並擔任該中心主席至 2013 年，該中心使命係期望透過植物科學增進人類福祉，其願景為飢餓者提供食物並改善人類健康，同時保護環境，並提升聖路易斯地區作為世界植物科學中心之地位。該中心營造一個以卓越、信任和相互依賴為特徵之環境，鼓勵每個人之貢獻和成就都能得到認可、讚賞與重視。該中心強調以開放心態來接受新想法，運用創造性方法來發現和解決問題，並鼓勵自由思考及接受建設性回饋。該中心亦強調多元化及包容性，歡迎不同文化及觀點的員工加入，並努力提供一個讓每個人都感到舒適並表現出色之環境。這點可由該中心大廳設計看出，採中井搭配斜長樓梯設計

，可以方便不同辦公區之員工互相走動及交流，並裝飾各國國旗，來象徵地球村之理念。該中心期許員工以負責及謹慎方式管理和使用環境資源，力求適度地減少環境足跡，同時透過研究為永續環境做出貢獻。

目前該中心共有 396 個員工，來自 20 個國家，分為 31 個科學團隊，執行 199 個計畫，目前和 9 個生物技術新創企業合作，每年營運預算約 40 百萬美金，來自政府、業界贊助經費約 250 百萬美金，對聖路易斯地區之年度經濟影響約 352 百萬美金，截至目前已有 1,718 篇科學期刊發表。

3. 參訪 CoverCress Inc.

CoverCress 公司成立於 2013 年，該公司具有獨立的研發實驗室，並與唐納德‧丹佛斯植物科學中心合作，租用其溫室來培養。該公司透過精密育種和基因編輯，將一種常見的冬季一年生芥菜，轉變成一種新型的輪作經濟作物（商品名為 CoverCress™），可適應美國中西部地區現有的玉米和大豆輪作方式，使農民能夠在兩個季節種植三種作物。且該作物可協助將碳儲存於土壤中，同時透過增加有機物含量以及有益於田間微生物群落，改善土壤健康。該作物建議選擇排水良好之田地，建議播種時間為 9 月初至 10 月初，播種深度小於 0.25 英吋或直接於土壤表面，播種量約每英畝 6 磅，種植後前 3 天提供充足的水分（約半英吋之降雨量）。該作物於早春時快速生長，故建議於早春時以每英畝 40~50 磅施以氮肥，收割時機為當 95%豆莢變成棕褐色，通常於 5 月 20 至 30 日之間。

4. 參訪本森‧希爾公司(Benson Hill) （除休息區可拍照，其餘全程不可拍照、錄影、錄音）

該公司成立於 2012 年，認為從植物到餐桌(from plant to plate)

更佳之食品系統，應賦予權力於種子生產者、農民、運送業者、食品加工廠、食品零售業者、餐飲業及消費者，透過目的、設計和使用，以確保提供更好之食品。該公司透過 CropOS®技術平台，結合資料科學(Data science)、植物科學(Plant science)及食品科學(Food science)為基礎，利用植物自然遺傳多樣性來開發商業化更營養、更美味、更實惠之食品原料。此外，以基因創新(Genetic innovation)、原型創造(Prototype creation)、平行田間與食品測試(Parallel field & food testing)、優化產品(Optimization product)及商業化產品(commercial product) ，進行基因編輯作物開發。該公司主要生產產品包括提高 20%蛋白質含量及低寡糖含量之基因編輯黃豆粉(Ultra-high protein soy flour)，由於寡糖會導致消化率差，所以其大豆通常含有低於 1%水蘇糖(stachyose)及 0.5%棉子糖(raffinose)。該公司亦生產高油酸低次亞麻油酸(high oleic, low linolenic, HOLL)大豆油，強調其油酸較市售其他產品高 75%，飽和脂肪含量降低 20%，適用於需要油脂烹調方法包括煎炸、烘烤、烘焙等，因其次亞麻油酸含量較低，可減少油脂氧化，並提高油品耐熱性及穩定性。該公司位於美國中部重要穀物集散中心之聖路易斯，除持續激勵農民合作夥伴種植高蛋白質密度大豆，並和鄰近之愛荷華州及印第安納州大豆加工廠合作，形成一個合作之環狀網絡。

5. 生物技術新創企業(startup company)經驗分享，邀請 Plastomics 公司之執行董事會主席(Executive Board Chair) Martha Schlicher 及首席技術官兼創始人(CTO and Founder) Jeff Staub、Agragene 公司之執行長(CEO) Bryan Witherbee、Solis Agrosciences 公司總裁之 Mary Fernandes，分享生物技術新創企業創業過程、經營情況及該公司所生產之基因技術作物。

(1) Plastomics 公司：該公司開發一種新穎基因工程技術之性狀傳遞平台技術(Plastomics' trait delivery platform)，將有益性狀插入植物細胞之葉綠體，而非細胞核。因植物細胞僅有一個細胞核，卻有數百個葉綠體，將性狀插入葉綠體，可大量拷貝及獲得高濃度之性狀，使得作物能更有效地抵禦昆蟲、疾病和雜草之侵害，減少作物損害，以來提高產量，並藉由代謝途徑來增強作物營養。使用該公司之技術，可精確地插入性狀，所生產之作物屬基因改造作物(GMO)，將為種子公司提供簡化產品開發時間、開發更有效產品和新市場機會之好處。該公司更希望此技術可以協助解決全球人口增長所需之糧食需求。

(2) Agragene 公司：該公司於 2017 年於加州聖地牙哥成立，2022 年遷移至密蘇里州聖路易斯。利用 CRISPR/Cas9 基因編輯技術開發生物防治平台，其專屬授權技術稱為精準引導昆蟲不育技術(Precision-Guided Sterile Insect Technology™)，可產生不育之雄性昆蟲，將其運送至田間後，可與雌性害蟲交配產生未受精之卵，而不會產生存活之後代。相較傳統技術使用輻射造成昆蟲不育，此技術提供一種更安全抑制害蟲繁殖之方法，且無須擔心傳統化學殺蟲劑之危害，為種植者創造更健康之環境，且能確保作物正常生長。利用此技術不僅安全有效及高經濟效益地防治作物害蟲，且保護蜜蜂及瓢蟲等有益昆蟲，有助於促進自然生態平衡。目前該公司對於斑點翅果蠅(Spotted Wing Drosophila, SWD)生物防治之綜合害蟲管理系統正於俄勒岡州進行田間試驗，期望未來發展為商標產品。

(3) Solis Agrosciences 公司：該公司由具多年業界經驗之農業和

生物技術研究人員及企業家創立，提供產品設計與研發服務，主要協助科學家及新創公司加速農業創新，以解決全球糧食及氣候挑戰，透過該公司協助及提供相關意見，使業者可快速設計、生產及分析其基因編輯或轉基因作物，以縮短產品開發時間，以該公司歷年經驗，許多情況下可由幾年縮短到幾個月。該公司主要提供服務包括轉殖植物（黃豆、玉米、米、馬鈴薯、油菜、番茄）、CRISPR 基因編輯植物、全植物、組織和細胞測試。

6. 參訪 W. Stemme Farm

W. Stemme Farm 位於美國密蘇里州聖路易斯，1869 年即開始營運，占地約 1200 英畝(約 485.6 公頃)，目前是第四代農民，主要種植基改黃豆及玉米，該農場為密蘇里州大豆協會(Missouri Soybean Association)會員，並通過密蘇里州農業部自 2015 年推動之農業管理保證計畫(agricultural stewardship assurance program, ASAP)，該農場原則上是一年種植黃豆，一年種植玉米。考量參訪當天天氣溫度攝氏達 30 多度，協辦單位密蘇里大學特貼心為考察團準備該校運動帽，以利考察團至農田實地參訪。農場主人為我們介紹可大面積噴射農藥或肥料之機器，還有收割機(harvester)，兩個機器都有 GPS 系統，使得噴灑農藥或收割更精確。農場主人提到種植 GM 作物，可減少雜草生長、減少農藥使用，並大幅提升產量。

二、青年學者與新創事業研討會

由 USDA 指導、美國農業與食品系統研究所（Agriculture and Food Systems Institute, AFSI，非政府組織，USDA 之智庫）主辦（附件 3），邀請各經濟體從事農業生物科技之青年學者，透過 4 分鐘快閃演講、壁報

展示與交流討論，分享近期最新之農業生物技術研發成果，引導其持續投入研發，或成為制訂基於科學之農業生物技術之倡議者。另藉由新創企業與談，探討如何找尋市場潛力、監管考慮因素，以及為農業生物技術找尋有利發展環境。

（一）研究與創新簡短演講上半場

1. 澳洲聯邦科技工業研究所(Commonwealth Scientific Industrial Research Organization，CSIRO)之 Dr. Christiana Gregg 研究員報告轉基因植物之固氮能力研究，透過轉殖固氮酶(nitrogenase)之基因到植物，使植物可以自行固氮，以減少植物對於氮肥之需求。目前 Dr. Gregg 已經於 CISRO 建立厭氧生化設施，評估固氮酶基因組成及功能，以研析固氮酶生合成途徑。
2. 加拿大卡爾加里大學(University of Calgary)之 Neil Hickerson 研究生報告利用 CRISPR 工具於低油酸品種 Canola 油菜之應用。「Canola」，是由「Canada oil, low acid」縮寫而來，指的是低酸度加拿大產之油菜籽油，雜質含量低，飽和脂肪含量極低，油酸（omega-9 脂肪酸）含量高，已被證明可以改善心血管健康，且發煙點相對較高。本研究已成功透過 CRISPR-Cas9 系統透過農桿菌編輯 Canola 油菜基因，目標將控制如莖的結構與生殖潛力，以提高油菜籽產量之最大程度並改善育種技術。
3. 我方國立臺灣大學農業化學系博士後研究員吳晉宇博士說明藉由多重編輯基因組以調控穀胱甘肽含量對於水稻缺水耐受性之研究結果。吳博士指導教授為洪傳揚教授，本次受邀發表其博士論文成果略以（附件 4）：穀胱甘肽 (glutathione, GSH) 由麩胺酸 (glutamate, Glu)、半胱胺酸 (cysteine, Cys) 與甘胺酸 (glycine, Gly) 所組成，具有調控氧化還原、訊息傳遞及解毒之功能。以外加 GSH 試驗可得知，GSH 濃度提升，水稻幼苗在缺水逆境之存

活率下降，且會抵銷植物荷爾蒙離層酸 (Abscisic acid, ABA) 所抑制之葉片蒸散效果。GSH 生合成關鍵基因 *OsGSH1-1* 之 T-DNA 突變體種子具有致死無法發芽之特性，無法獲得後代供試驗使用。開起啟動子區域多重編輯系則可獲得 GSH 顯著降低之個體，其幼苗之缺水逆境耐受性較 wildtype 佳；利用雌激素誘導 GSH 含量增加之轉殖株幼苗較不耐缺水逆境。可知外加處理 GSH 及誘導增加內生性 GSH 含量之水稻幼苗皆較不耐缺水逆境，而內生性 GSH 含量較低之水稻材料較耐缺水逆境。進一步根據 ABA 蒸散作用試驗結果可推測 GSH 降低水稻缺水逆境耐受性與 ABA 作用有關，後續詳細分子機制可再深入探討。吳博士內容準備充分且英文表達流暢，4 分鐘快閃演講時間內完成其研究成果重點之表達，時間掌握很好。

4. 智利新創公司 Meristem 之執行長(CEO) Dr. Bernardo Pollak 概略說明該公司研發服務能量。該公司 2020 年由 Dr. Pollak 投資成立，關注領域在於水果與環境、生產與消費相關之研究，目前聚焦在抗柑橘黃龍病、減少草莓採後損耗、及增進櫻桃營養及風味等，針對該等作物已建立其組織培養、基因編輯與再生等技術，以及轉基因平台。
5. 印尼國家研究與創新機構(National Research and Innovation Agency，依印尼語名稱簡稱 BRIN)之研究員 Dr. Rikno Harmoko 報告利用 RNA 干擾甘蔗嵌紋病毒鞘蛋白基因以誘發甘蔗抗病性之研究結果。
6. 日本獨立行政法人農業・食品產業技術總合研究機構(National Agriculture and food Research Organization, NARO)研究員 Dr. Tetsuya Yoshida 以菸草嵌紋病毒為例，說明其建立之基因編輯技術平台。

7. 韓國 Kangwon 大學助理教授 Dr. Hyeran Kim 報告其探索利用 CRISPR/Cas9 在十字花科白菜、茄科辣椒與甜椒、大豆與矮牽牛等植物中可進行精準之編輯，但對於難培養之物種中，基因編輯商業化之應用仍然是一個挑戰。
8. 美國 UC Davis 之博士後研究員 Dr. Alba Ledesma 報告利用 CRISPR/Cas9 基因編輯技術研究牛隻性別決定機制。

（二）研究與創新簡短演講下半場

1. 澳洲聯邦科技工業研究所(Commonwealth Scientific Industrial Research Organization，CSIRO)之 Dr. Xiaoqing Li 研究員視訊報告開發具有耐乾旱特性之基因改造小麥品種(Spica 及 Maringa)，並確認該品種根之數量性狀基因座(quantitative trait loci，QTLs)。
2. 加拿大卡爾加里大學(University of Calgary)之 Dr. Connor Hodgins 研究員報告利用 CRISPR/Cas9 基因編輯技術生產更美味之豌豆蛋白質，主要以基因編輯技術抑制豌豆中具有苦味之皂素(Saponins)生合成，研究結果兩豌豆突變品系可有效降低 99%皂素量。
3. 印尼加查馬達大學(Gadjah Mada University) 之 Dr. Widhi Dyah Sawitri 助理教授報告建立轉基因甘蔗之過敏性及毒性評估方法，包括分析胺基酸序列、測定熱穩定性、模擬胃液及腸液、大鼠中 IgE 含量。
4. 馬來西亞馬來亞大學(University of Malaya) 之 Ms. Dharane Kethiravan 研究生報告藉由核糖核酸干擾調控哈密瓜對抗胡瓜嵌紋病毒(Cucumber mosaic virus)，以避免因該病毒導致葉片出現黃斑、果實變色及生長不良等情形。
5. 菲律賓國際稻米研究所(International Rice Research Institute)之 Mr. Erwin Arcillas 助理研究員報告利用基因編輯技術生物強化稻米中鋅含量，以減緩亞太地區鋅缺乏情形。

6. 泰國朱拉隆功大學(Chulalongkorn University)生物技術與基因工程研究所之 Dr. Panaya Kotchaplai 研究員報告利用微生物技術及永續農業，包括增加營養素及改善植物耐受性以提高作物產量、土壤生物修復、農業廢棄物及副產品管理，並使用重組細胞從木質素衍生物生產香草醛。
7. 美國伊利諾州立大學(Illinois State University)之 Ms. Liza Gautam 研究學者報告利用 CRISPR 基因編輯技術開發出減少種皮纖維含量、低芥酸，以及提高種子含油量之 Pennycress (Thlaspi arvense) 突變株。
8. 越南農業基因所(Agricultural Genetics Institute)之 Dr. Nguyen Duy Phuong 分子病理部主任報告利用 CRISPR/Cas9 基因編輯技術於優良 TBR225 水稻品種，以提高對於細菌性葉枯病之抗性。

（三）壁報論文時間

由 15 位在場之青年學者於各自研究壁報論文前，向有興趣之與會者說明研究內容及研究結果，並針對與會者問題進行解答。我方臺灣大學農業化學系吳晉宇博士亦於壁報論文前進行說明及解答。

（四）專題演講

1. 美國伊利諾大學遺傳學教授 Dr. John Sedbrook 演講「農業生技創新領導世界改變-以 Pennycress 為例」：世界面臨資源匱乏、農地流失、農村工作機會減少、全球升溫等問題，生物技術可快速且高效解決複雜的問題。然後介紹其正在研究之一種十字花科冬季 1 年生雜草 Pennycress (*Thlaspi arvense*)，與油菜、阿拉伯芥近源，具有高耐寒性、生命週期短、高產量且種子含油量及蛋白質含量高，不具入侵性且易控制族群，雙倍體，且似阿拉伯芥容易使用農桿菌浸潤花朵(floral dip)即可進行轉殖。CoverCress Inc.公司(CCI)將 Pennycress 商業化栽培，通過育種與基因編輯，使其種子

變大且減少纖維素、增加含油量與蛋白質含量，將其轉變為一種新型輪作經濟作物，命名為 CoverCress™ ，其生命週期短，適合中西部與玉米及大豆輪作，使農民能夠在兩個季節種植三種作物，也可作為綠肥作物，有助於改善土壤並提供生態系統服務。該作物可作為生質燃料，有助於滿足世界對於生質能源不斷增加之需求，且所生產之粗粉具有高蛋白質與胺基酸，為理想之動物飼料來源，亦可生產食用油，並使農民在冬季時仍有額外之收益，為非常具有潛力之新興作物。

2. 蓋茲基金會(Bill and Melinda Gates Foundation)農業發展資深專員 Mr. Lawrence Kent 演講「農業生物技術在發展中國家的機會及蓋茲基金會的角色」：該資金會資金達 67 億美元，推動 41 項重要計劃。該基金會關注世界上最貧困地區的健康與發展議題，爰投入資金和資源支持農業生物技術研發，幫助提高作物產量、抗耐病性以及營養價值，協助農民在惡劣的環境條件下取得更好的收成，以助於糧食安全與農村發展，並減少飢餓問題。該基金會聚焦於非洲及亞洲，採用的方式多為資助當地的基金會，所以相關研究成果大多由當地基金會發布。有關提高產量部分，該基金會聚焦於以基因工程研究植物固氮、發展將 C4 光合作用導入稻米，以及樹薯澱粉含量之提高；抗耐病性部分則研究樹薯、香蕉之抗病性、玉米耐旱及抗蟲、豇豆抗蟲，並以基因編輯方式增加稻米對白葉枯病(blight)之抗性，以及玉米對於致死性壞疽病(Maize Lethal Necrosis)之抗性；營養價值增加部分則推廣黃金米、距高鐵質與鋅含量的米及樹薯。Mr. Kent 於提問交流時提到 GM 或 GE 作物於非洲及亞洲國家之推廣，光田間試驗就耗時多年，而談到說服農民種植 GMO 之困難度，表示農民對於種植 GMO 之獲利眼見為憑就會接受，而最難說服的則是政治人物及制定法規的人

。另外表示希望能支持更多青年學者的成果往產業化發展，並希望能支持更多小型新創公司發展。

（五）產業座談

1. 主題一、市場定位、特色目標、法規考量與未來展望

與談之新創公司包括美國 Pairwise（旗下品牌 Conscious Greens 推出基因編輯去除苦味芥菜）、日本 SanatechSeed Co., Ltd.（基因編輯高 GABA 番茄）、加拿大 Okanagn Specialty Fruits（不會褐化之轉殖蘋果），各自說明其產品之研發與上市過程。

三間公司均認為專業分工為成功關鍵，研究人員專心從事研究，而行銷由專業人員進行。美國 Pairwise 公司推廣 6,000 多個消費者試吃，並獲得 3,000 名消費者(shelf to shelf)完成線上調查，取得統計數據，加深銷售產品之信心。日本 SanatechSeed 公司由筑波大學教授 Hiroshi Ezura 身兼公司技術長，於 2021 年 9 月將高 GABA 番茄上市，透過日本農林水產省的早期諮詢機制，確認該產品不屬於基因改造類別（不含外源基因），初期推廣之方式是提供超過 4 千位民眾試種（是家庭園藝使用，非提供農民進行商業生產），增加民眾認同度，未來將著力於推廣食用市場。另加拿大 Okanagn 公司轉殖蘋果則花了很多年才通過美國 FDA 核准上市。

有關市場拓展，加拿大 Okanagn 公司之策略是認為通過美國 FDA 後，其他市場就很容易開展，歐盟國家部分，目前正在努力銷入義大利市場。美國 Pairwise 公司下一階段想銷亞洲，而歐盟部分則認為需再觀察 5 至 6 年。日本 SanatechSeed 公司雖然提供種苗供家庭園藝，但僅限於讓消費者認識該產品，未來種子種苗不會向消費者銷售。對於如何改變民眾對於產品接受度，日本 SanatechSeed 公司則表示未曾試圖也不需要改變民眾想法，那是非常困難且耗成本之工作，15%已經是預期可達到的最大市場占

有率，加拿大 Okanagn 公司亦表示不會去花時間改變民眾想法。

2. 主題二、促進農業生物技術發展環境：與談之新創公司包括加拿大 AquaBounty Canada, Inc.（轉殖鮭魚）、阿根廷 Bioceres Crop Solutions（抗旱之轉殖小麥）、美國 Corteva Agriscience（基改黃豆）、韓國 ToolGen, Inc.（基因編輯技術平臺提供）。加拿大 AquaBounty 公司認為建立可信任之法規政策環境很重要；阿根廷 Bioceres 公司認為應重視智慧財產權與社會溝通，並讓市場決定需要什麼產品；美國 Corteva 公司認為國家政策最重要，應鼓勵縮短可上市所花的時程、鼓勵創新，最終並要幫助生產者與消費者，並強調政策決定應根據科學基礎；韓國 ToolGen 公司表示，韓國農民與消費者都不歡迎 GMO，但研究人員很喜歡利用該等創新技術進行研發，認為應透過教育鼓勵更多人學習基因科技，另建議 APEC 針對市場准入規範應訂定統一之格式供各經濟體遵循。

三、農業生物技術之有效監管與政策解決方案工作坊

由 USDA 指導、美國農業與食品系統研究所(AFSI)主辦，為期兩天之工作坊（附件 5），邀請各非營利組織分享以科學為基礎之監管與政策解決方案，促進監管效率與資訊共享，其幫助簡化農業生物技術產品之核准程序並促進貿易（為尊重講者智慧財產權，主辦單位未提供講者簡報檔案及書面資料）。

（一）由美國農業與食品系統研究所(AFSI)之執行長 Dr. Andrew F. Roberts 報告成功監管合作之必要條件(Necessary Ingredients for Successful Regulatory Cooperation)。Dr. Andrew F. Roberts 曾於 2005 至 2009 年於美國農業部負責風險評估業務，2009 年 12 月起於 AFSI 服務，有 15 年以上生物科技之風險評估及能力建構經驗。首先介紹 AFSI 為獨立非營利之科學組織，主要任務為實現安

全和永續農產品、健康及環境系統，目前五大任務為生物安全能力建構、環境風險評估、永續營養安全、食品及飼料安全評估及永續農業之植物產品。監管合作之形式分為單邊/多邊、政策/技術。監管合作之關鍵條件包括如下：

1. 共同目標 (shared goals)：依據 Cartagena 生物安全議定書(Cartagena Protocol on Biosafety, CPB)，其目標係規範以現代生物技術獲得且可能對生物多樣性及永續利用造成不利影響，並對人類健康造成風險之改造活生物體(living modified organisms, LMOs)，其安全運移、過境、處理及利用，並特別著重跨境運移之問題。因此，共同目標係藉由農業生物技術促進人類福祉，且依該議定書強調生物安全，須保護人類健康和環境，免受現代生物技術產品導致之可能不利影響。
2. 共享技術能力(shared technical competence)：農業生物技術需藉由安全評估來確認，目前安全評估可依循 Cartagena 生物安全議定書、國際食品法典委員會(Codex Alimentarius)、國際植物保護公約(International Plant Protection Convention)。
3. 信任與關係(trust and relationships)：HLPDAB 第 1 次於 2002 年召開，迄今已運作 20 多年，這類會議主要在建立監管合作所需之信任與關係。
4. 對監管合作益處達成共識(shared understanding of benefits from regulatory cooperation)：APEC 會員經濟體可藉由 HLPDAB 會議，進行農業生物技術監管合作，可增加對農業生物技術之了解，降低政府管理及實施法規成本，共同研商解決氣候變遷、糧食供應及糧食安全等問題。

（二）印度科技部國家 GLP 合規監管機構 NGCMA (National GLP Compliance Monitoring Authority, Department of Science and

Technology, India)科學家 Dr. Ekto Kapoor，以預錄方式報告以藥品為例，印度如何利用 OECD 會員國之相互接受數據機制取得產業上之成功 (India’s Journey to the OECD Mutual Acceptance of Data and Towards Excellence)。印度號稱世界藥房(The Pharmacy of the World)，2021 年已是全球最大之學名藥生產國，出口值占全球 20%，人用與動物用疫苗每年有 201 百萬劑銷往世界 100 個經濟體，世界衛生組織有 70%疫苗來自印度，且農用化學品市場(agrochemicals)生產為世界第 4 名、第 13 大出口國，2022 年產值達 600 萬美元，低成本且安全為其優勢。

GLP（良好實驗室規範，Good Laboratory Practice）是一套確保非臨床實驗室研究品質與可靠性之準則，以確保實驗室研究之可重複性、準確性與完整性，屬 OECD（經濟合作暨發展組織，Organisation for Economic Cooperation and Development）之國際性指導文件，印度於 1991 年時導入，NGCMA 則是負責該國監督與確保實驗室在執行研究時遵循 GLP 準則之機構。過去印度製造商因國內非臨床資料不被國際信任，而耗費鉅資高程度依賴外國之測試機構(test facilities, TFs)產出非臨床測試資料，經導入 GLP 規範後由科技部科學技術司於 2002 年成立 NFCMA，以認證並監管印度國內之 TFs，使其產出之非臨床測試資料符合全球標準之需求。經過多年努力，於 2011 年成為第 3 個（前兩個為南非、新加坡）符合相互承認數據規範(Mutual Acceptance of Data, MAD)之新興國家，MAD 旨在確保不同國家間對於化學品安全評估所使用的測試數據和評估結果的互相承認，以避免重複進行相同的測試，減少不必要的動物實驗，以及商業界與政府在不同國家間因為不一致的評估要求而產生的成本和障礙。

講者說明多年來印度在 OECD 經營國際關係與擔任工作小組

成員，並爭取多次主辦或協辦 OECD 活動，多年努力下，印度有 56 間實驗室被驗證，提供超過 50 個經濟體 GLP 服務，增加超過 3 千個就業機會，接受超過 6 萬件之 GLP 委託試驗金額共高達 13 億美元，投資 GLP TFs 金額快速成長，2019 年已經比 2010 年多 2.5 倍，造就產業上翻轉性之成功，且為世界節省超過 9 千億美元之相關支出。

（三）由美國農業與食品系統研究所(AFSI)之 Bhavneet Bajaj 博士報告調合南亞地區基因改造食品原料安全評估方法(Towards a Harmonised Approach to Safety Assessment of Food Derived from Genetically Engineered Plants in South Asia)。Codex 已公布基因改造植物食品安全性評估指引(Guideline for the Conduct of Food Safety Assessment of Food-derived from Recombinant-DNA Plant)，可供各經濟體參考。AFSI 邀集印度食品安全標準管理局(Regulators from Food safety and Standards Authority of India, FSSAI)、孟加拉衛生部及農業部(Ministry of Health and Ministry of Agriculture, Bangladesh)、斯里蘭卡衛生部及農業部(Ministry of Health and Department of Agriculture, Sri Lanka)及不丹食品藥物管理機構(Regulators from Bhutan Food and Drug Authority)，於 2020 至 2021 年召開專家工作小組(expert working group)，比較及討論四個經濟體對基改食品原料之安全評估要求，共同調合基因改造食品原料安全評估之架構，以及制訂通用申請表格及風險評估摘要報告範本，並鼓勵主管機構平行審查申請案，以促進同步批准。

（四）主辦單位透過分組並進行 2 回合之換桌討論。我方代表接觸到之經濟體包括馬來西亞、菲律賓、澳洲、哥斯達黎加、智利、越南、印尼、新加坡等。第 1 回合討論各經濟體對於環境、糧食安全

與人類健康之高階目標(high-level protection goals)。我方代表簡要分享透過智慧農業推動減少能資源投入、淨零碳排及農藥減量之政策目標。討論結果歸納各經濟體之高階目標大同小異，最重要的是如何用更少的自然資源在氣候變遷下保有韌性，保障人與動物的糧食安全與食品安全、食物可及性(accessible)，以及可獲利性(profitable)，建議各經濟體要有共同之用語、協調共同標準供參考但尊重各國之法律與體制。

第 2 回合則分享各經濟體對於現代農業生物科技(modern biotechnology in agriculture)所遵循之行政程序，包括分享是以修改現有法規之方式進行規範，如美國、加拿大等，或是制定新法如澳洲、南韓，以及分屬多機關決策，或是單一機關或人員決策等方式。與我方代表同桌之智利、澳洲與我方較相似，依環境、食品、繁養殖、藥品、健康等各政府部門依權屬管理，且依修改現有法規方式進行規範，未訂定專法。而阿根廷則係由委員會，並依農、漁、畜分成工作小組，提供評估意見後總統辦公室決策，新加坡也是類似做法。菲律賓較為特別，對於基因改造訂定專法，決策方式由中央機關如農業部門、科技部門、健康部門、環境部門決策，但如果是作物，尚需經過地方政府同意田間試驗與種植，地方政府具有否決權，如經某地方政府否決，則可再尋求其他地區之地方政府同意，目前菲國已核准 129 件基因改造作物種植與食用，最大宗 64 件為玉米，大豆 24 件，棉花 16 件，該等案件中尚未有基因編輯作物。

第 3 回合則是利用在線互動投票與問答工具(menti.com)，針對主辦單位擬定之問題用手機進行投票，並利用文字雲收集關鍵字。擬定之問題如下，但因為並非每個經濟體只有一票，所以結果僅為各參與者個人角度之想法。問題包括：

1. 調查參與者認為要利用農業生物技術來守護的最重要目標是什麼：文字雲顯示為生物多樣性、人類健康、環境保護、食品安全、糧食安全等。
2. 所屬經濟體對於現代生物技術產品之決策為單一決策者或是多個，且是否根據風險/安全評估結果，以及是否有協調機構。
3. 所屬經濟體是否有核准基改植物種植、是否核准基改植物食用或飼料用。
4. 是否同意 APEC 各經濟體係以確保商業中引入之生物技術產品是安全的為共同目標、在監管農業生物技術產品之方式上有根本相似之處，以及是否認為 APEC 具監管合作之價值，另文字雲顯示 APEC 於監管合作方面之益處包括提升效率、增進調和、增進貿易、增進糧食安全、促進創新、減少成本等。另顯示 APEC 協調生物技術法規方面之障礙最主要的是政治，該障礙是否可透過各經濟體間之監管合作克服，與會者樂觀看待者略占多數。
5. 認為 APEC 在監管合作促進部分最大之貢獻依序為資料需求/風險評估指南之技術性確認、資訊共享、食品安全決策之相互認可、相互承認環境釋放決定、聯合審查。

（五）第 2 天首先由菲律賓食品藥物管理局 (Philippine Food and Drug Administration) 顧問 Flerida A. Carino 博士報告國際基因改造食品原料安全評估指引(International Guidance on Safety Assessment of Food Derived from rDNA Organisms)：有關重組 DNA 生物體來源食品之國際組織為國際食品法典委員會及 OECD，食品法典委員會由聯合國糧農組織和世界衛生組織(FAO/WHO)於 1963 年設立，主要負責保護消費者健康、確保食品公平貿易，以及協調國際食品標準，目前成員有 188 個經濟體及歐盟。Codex 針對基因改造食品已公布 1 個原則及 3 個指引（重組 DNA 植物、微生物

及動物)：

1. 現代生物技術食品之風險分析原則(CAC/GL 2003: Principles for the Risk Analysis of Foods Derived from Modern Biotechnology)。
2. 重組 DNA 植物食品安全評估指引(CAC/GL 45-2003: Guideline for the Conduct of Safety Assessment of Food Derived from Recombinant-DNA plants) 。
3. 使用重組 DNA 微生物製造食品安全評估指引(CAC/GL 46-2003: Guideline for the Conduct of Safety Assessment of Food produced Using Recombinant-DNA Micro-organisms)。
4. 重組 DNA 動物食品安全評估指引(CAC/GL 68-2008: Guideline for the Conduct of Safety Assessment of Food Derived from Recombinant-DNA animals)。

基因改造食品安全評估主要目的係藉由科學基礎，確保基因改造食品上市前之安全性。基因改造食品安全評估框架包括基因改造植物之描述、宿主植物及其食物用途、基因提供生物之描述、基因改造之描述、基因改造之特徵、安全性評估(代謝物之評估、毒性與致敏性評估、關鍵成分之組成分析、營養變異評估、食品加工評估及其他考量因素)。

(六)由澳洲基因技術監管機構(Office of the Gene Technology Regulator, OGTR)植物評估部門(Plant Evaluation Section)之處長 Dr. Kylie Tattersall 說明農業生物技術產品之環境風險評估要素(Elements of Environmental Risk Assessment of Products of Agrivultural Biotechnology)。OGTR 於 2000 年成立，是澳大利亞聯邦政府負責監管基因技術相關事項之機構，職責包括評估、監測與控制 GMO 之引入、處理與使用，以確保相關活動之風險得

到適當管理與監督且符合安全與環境保護之標準。

講者引言先說明了目前國際上對於 GMO 之監管方式存在著定義上的不同、監管範圍不同，以及觸發監管之動機(triggers)之不同：使用的技術(technology used)即 process-based、成果產出(outcome achieved)即 produce-based，與產品預期用途(intended product use)，以及 OGTR 參考國際組織眾多標準與程序訂定風險分析之相關術語與定義。環境風險評估(Environment Risk Assessment, ERA)在生物的部分，關注的是環境、物種與 GM 性狀之交互作用。GMO 評估構面包括風險來源、因果關係、對風險接受者的潛在傷害等，要評估的因子包括：

1. 尚未被基因改造之原生物體是否為雜草/有害生物/有害微生物。
2. 基因改造後是否增加其變成雜草/成為有害生物之潛力/具致病性。
3. 基改生物是否有毒/有害，或對於特定物種有毒/有害。
4. 基因改造是否造成選拔優勢。
5. 是否會在空間或時間上發生傳播。
6. 是否會發生基因轉移以及傷害。
7. 親本/GMO 可否被控制。

依據風險因子進行之風險管理範疇，係需針對已確定之特定風險，以有效果、高效率、實用，且與風險水準相稱之方式管理，維護環境的背景值(強調田間試驗的重要性)、需區隔風險或貿易目的，進行上市/釋出後進行監控。各經濟體的 ERA 有許多相同處，然而存在之差異在於法規與政策、基因改造生物之定義、觸發監管之動機、具體需要保護的對象、基改生物目的之相關活動、釋放之環境、需要提出之資料項目、如何管理風險等。

（七）由美國貿易代表署(Office of the United States Trade Representative, USTR)負責農業事務及商品政策組長 Robert Ahern 博士報告農業生物技術貿易：世界貿易組織 SPS 委員會觀點與最新進度(Trade in Agricultural Biotechnology: Perspectives and Updates from the World Trade Organization SPS Committee)，食品安全檢驗與動植物防疫檢疫措施協定(Agreement on the Application of Sanitary and Phytosanitary Measures, SPS 協定) 主要避免或減少因農產品及食品貿易而導致外來動植物疫病及蟲害入侵或擴散之機會，及防範食品或飼料中安全衛生潛在風險，以保護境內國民及動植物的生命或健康，並維護自然生態環境。SPS 委員會近期相關工作包括核可程序工作小組(Approval Procedures Working Group)、第 12 屆部長會議 SPS 工作方案(12th Ministerial Conference (MC12) SPS Work program)、第 13 屆部長會議(13th Ministerial Conference, MC13)和糧食安全等。SPS 建議核可程序包括促進討論(facilitate discussion)、科學基礎(Science-based)、即時核可(Timely approval)、透明化(Transparency)及國際標準(International standards)。

（八）由加拿大衛生部(Health Canada)高級科學計畫協調生物學家 Jordan Bean 視訊報告加拿大衛生部和澳洲紐西蘭食品安全標準局基改食品安全評估方法共享倡議之發展(Development of Health Canada-Food Standards Australia New Zealand (FSANZ) Safety Assessment Sharing Initiative) 加拿大衛生部和澳洲紐西蘭食品安全標準局自 2013 年至 2019 年分為下列五個階段：

1. 第一階段(2013 年)：比較兩個主管機關之法規內容(Compare the regulatory approaches taken by the two organization)：

(1) 審核時間：加拿大為 410 天；紐澳為 9 個月。

(2) 公眾通知時間點：加拿大於審查決定後；紐澳於整個審查階

段對外公開。

(3) 公眾諮詢：加拿大無公眾諮詢；紐澳於安全評估及建議決定階段會進行公眾諮詢。

(4) 安全評估報告公開在網路的方式：加拿大提供安全評估摘要；紐澳提供整份安全評估報告。

2. 第二階段（2013 至 2014 年）：比較安全評估流程之基準評估和建立信任(Benchmarking exercise to compare the safety assessment processes and build trust)：比較兩個主管機關所制定之安全評估法規，包括資料要求、評估方法、評估結論。

3. 第三階段（2014 年）：制定共同合作之方法(Formulating an approach for the collaborative work)：加拿大衛生部和澳洲紐西蘭食品安全標準局選擇以「共享安全評估」為共同合作模式。

4. 第四階段（2015 至 2017 年）：進一步建立信任(Further trust-building)：優先對於簡單之申請案進行同步安全評估。

5. 第五階段（2018 至 2019 年）：行政法規及溝通考量(Administrative legal, and communication considerations)：制定共享安全評估之實施過程的詳細內容、公眾溝通、指引文件、與兩個主管機關及相關機關之高級官員聯繫溝通等。

加拿大衛生部和澳洲紐西蘭食品安全標準局基改食品安全評估方法共享倡議內容為一個主管機關作為主要評估者對產品進行安全評估，另一個主管機關則作為次要評估者對評估報告進行同行評審，兩個主管機關可以獨立作出監管決策，且皆符合兩個主管機關各自法規標準。其共享倡議之目標係為改善審核效率，使兩個主管機關基因改造食品安全評估審核同步化。

（九）由巴拉圭亞松森(Asuncion)大學教授 Danilo Fernandez Rios 說明巴拉圭基改作物之相關規範(Regulation of Genetically Engineered

Crops in Paraguay)。巴拉圭政府於 1997 年開始組成生物安全委員會，2004 年核准第 1 個商業栽種之基改大豆，2008 年委員會擴大規模，2011 年核准第 2 案為基改棉花。過程中重視協作方式建構提升國家能力，且須培育訓練有素之科學家，於是透過下列方式：

1. 建構國際間與國內各相關部門之間對於生物安全風險評估與監管建立夥伴關係。
2. 執行能力建設計畫，項目包括：針對監管體系之關鍵要素與程序進行分析、轉基因植物衍生食品之安全評估、針對基改生物之環境風險評估(ERA)之問題制定發展有效技能、針對創新技術生物(novel technology organisms, NTOs)或基改性狀堆疊之生物(stacked event crops)之特殊考慮等。
3. 納入問題表述之方法，改善監管體系增進其決策之及時性。
4. 基於 ERA/FFSA(food/feed safety assessment)問題定義導向統一基改作物風險評估之概念工具則是關鍵。

依據上述努力，2015 年大幅修正所有的格式。現況已經過 20 年使用基改生物以來都是安全的，也發表許多對於生物技術安全之出版物，已經被其他機構重複調查已進行過之評估，且強化各機構間之溝通並參與國際論壇，並且有來自專業科學組織之支援。2020 年起依據前述成就簡化現有之監管程序，針對新興基改作物與已經被其他國家核准之基改作物採取不同之步驟，依類型審核需時 3 個月至 3 年不等，參考其他國家已核准的話決策速度就會很快，不但可減少核准過程中不合時宜之程序，亦有效降低核准之行政成本，這樣的過程更可鼓勵小型新創公司之投入，為農民獲得新技術提供便利性。

（十）由阿根廷農業畜牧業及漁業秘書處(Secretariat of agriculture, livestock & Fisheries, Argentina)生物經濟組組長 Dalia Lewi 博士報告以阿根廷觀點進行知識分享與促進監管合作(Knowledge Sharing and Enabling Regulatory Cooperation: Argentina's Perspective)。

阿根廷已於 1991 年設立國家農業生物技術諮議委員會(CONABIA: National Advisory Commission for Agricultural Biotechnology)，並於 2014 年成為聯合國糧農組織參考中心(FAO reference center)。阿根廷政府於 1996 年第一個通過核准為基改黃豆作物，2005 年評估第一個基改動物（牛），2015 年制定新興育種技術規範(New breeding technology, NBT)，截至 2023 年 7 月已核准 7 種基改作物共 69 品項，已評估利用新興育種技術產品 69 項。生物安全評估重點包括個案審查、科學技術準則、論文品質、熟悉性原則、食用歷史。阿根廷政府為當地研究人員和開發者提供法規建議、辦理相關教育訓練、提供相關儀器補助計畫，以推動農業生物技術發展。

（十一） 由泛美洲國際農業合作機構(Inter-American Institute for Cooperation on Agriculture, IICA)生物技術及生物安全國際專員 Pedro J. Rocha S.博士報告宏都拉斯-瓜地馬拉-薩爾瓦多協議(Honduras-Guatemala-EI Salvador Agreement)。

三國之關稅同盟協議為允許貨物和人員的自由流通，從 2007 年 12 月開始推動，達成協議為 2015 年 2 月 26 日（薩爾瓦自 2018 年 8 月 20 日加入協議）。惟當宏都拉斯種植基因改造玉米，另外兩國未種植基改作物，且瓜地馬拉為中美洲之核心，玉米為當地主要糧食作物，且三國皆是 Cartagena 生物安全議定書(Cartagena Protocol on Biosafety, CPB)締約國。因此推動監管合作(Regulatory cooperation)，泛美洲國際農業合作機構亦提供相關技術協助，於

2018 年制定農業及畜產業使用之基因改造生物體之生物安全技術規範，並於 2019 年三國部長級協議簽署。

（十二） 日本農林水產省(Ministry of Agriculture, Forestry and Fisheries, MAFF)轄下農林水產技術會議事務局(Agriculture, Forestry and Fisheries Research Council, AFFRC) 研究總務官內田幸雄說明日本基因編輯政策與研發(Genome Editing Policies, Research and Development in Japan)。

日本農業面臨地球暖化、大規模災害、生產者銳減、生產力下降、地力衰退等問題，且新冠肺炎造成衝擊及消費者習慣改變威脅糧食供應體系，日本於 2021 年 5 月發布「綠色糧食戰略」稱為 MIDORI（日文的意思為綠色），預計 2050 年農業要達到淨零、農藥用藥減少 50%、肥料用量減少 30%、增加生產力 30%之戰略目標，且有機耕作要達到增加為 1 百萬公頃，即日本 25%之農田。而 MAFF 依據 MIDOR 戰略訂定育種方向為發展有助於減少溫室氣體、抗病抗蟲及高肥料利用率之品種，並完備智慧育種基礎建設(smart breeding infrastructure)，例如預測最佳配對組合，以加速國家公私部門之育種工作。而發展可運用於智慧農業之新品種，為轉換成高生產力且可永續生產之系統所必須。

日本對於活體改造生物(Living Modified Organisms, LMOs)之監管依下列架構完成安全評估後核准散布、進口、種植 LMO：

1. 生物多樣性：由 MAFF 及環境省(Ministry of the Environment, MOE)依據日本卡塔赫納法(Cartagena Act)執行。
2. 食品安全：由厚生勞動省(Ministry of Health, Labor and Welfare, MHLW)依食品衛生法(Food Sanitation Law)辦理。
3. 飼料安全：由 MAFF 依據飼料安全法(Feed Safety Act)執行。

日本針對基因編輯則依據日本卡塔赫納法進行適用性認定：

1. 如果生物不具外源核酸，則非屬 LMO。
2. 如果生物具有外來核酸，而導入的核酸與複製產物未殘存於生物體，則非屬 LMO。
3. 如果生物具有外來核酸，而導入的核酸與複製產物會殘存於生物體，則屬 LMO。

所以如果非屬 LMO，則政府批准或安全檢視是不必要的，但 MAFF 鼓勵申請者提交資訊(Information Form)進行事前諮詢，以確認對於生物多樣性之影響。已提交資訊文件之清單可於 https://www.maff.go.jp/j/syouan/nouan/carta/tetuduki/nbt_tetuzuki.html#flow03上查詢到。本次演講特別提到利用基因編輯技術選育且已上市之較一般品種 GABA 含量高 4 至 5 倍之小果番茄，與可食率提高 20%以上之真鯛。高 GABA 小果番茄案是第 1 個提送資料進行事前諮詢之案例，其於 2020 年 10 月送審，2021 年 5 月已經可由超過 4 千位消費者免費索取種苗進行家庭園藝栽培，鮮果則於同年 9 月線上銷售，2022 年則開始銷售其加工品，並於 2023 年 3 月在一般商店銷售。而可食率增高之真鯛案於 2021 年 9 月送審，2021 年 12 月已可線上銷售生魚片，該技術則於 2021 年獲得 MAFF 開放創新獎。另日本刻致力於發展創新之育種技術，包括由 NARO 與 KANEKA 化學公司合作開發 iPB (in planta particle bombardment)方法，iPB 方法可解決 CRISPR/Cas9 需要利用癒傷組織培養與再生之限制，而可直接將外源基因透過粒子轟擊之作法導入胚胎，並應用於哈密瓜儲架壽命之延長；另 NARO 與千葉大學、東京工業大學合作開發大氣壓等離子體處理法(atmospheric pressure plasma treatment) 之新技術，通過短時間暴露於大氣壓等離子體中，將基因組編輯所需的酶引入植物細胞中。傳統的基因組編輯技術需要引入外源 DNA，但這項新技術不需要去除外源

DNA。因此，它被認為更加方便，適用於各種植物，有望成為品種改良的新工具。

各經濟體好奇農林水產省對於 LMO 監管態度之轉變。日本強調從未改變監管態度，亦未修改審查程序，而是依據科學理性定義技術或產品是否屬 LMO 範疇。有關民眾對於基因編輯產品接受度，日本則表示未試圖改變民眾想法，而是讓民眾有自行選擇之機會；而日本自高中教育即已納入 LMO 及基因編輯等創新農業科技內容，可能因此年輕人對於創新科技產品之接受度約達 80%。

（十三） 由美國國際作物永續發展協會(CropLife International) Abby Simmons 博士報告監管合作：類型、好處與挑戰(Regulatory Collaboration: Types, Benefits, and Challenges)：國際作物永續發展協會目的為推動農業創新，發展永續未來。該協會之願景為領導促進永續食品系統，其合作成員包括先正達公司(Syngenta)、富美實公司(FMC Corporation)、巴斯夫公司(BASF)、住友化學株式會社(Sumitomo Chemical)、拜耳公司(Bayer)及科迪華農業科技(Corteva agriscience)等企業。透過其合作成員，統計 2017 至 2022 年一個基因改造作物從研發、測試到法規核准後上市，平均時程約為 16.5 年，約需投入經費 115 百萬美金；相較 2008 至 2012 年平均時程約 13.1 年，投入經費 136 百萬美金，平均時程增加 26%，投入經費減少 21 百萬美金。進一步分析平均時程 16.5 年，分為基因改造作物研發、測試及法規審核三階段，其中以法規審核約 204.6 個月（占 51.1%）最多。該協會以科學為基礎，針對審查所需文件提供建議，並持續推動監管合作。

（十四） 美國北山集團(North Hill Group, NHG)之執行長 Jeffrey V. Nawn 說明其協助 HLPDAB 制定農業生物技術監管合作政策方法

文件之過程與概要(Outline of Policy Approaches Document for Regulatory Cooperation and Alignment on Agricultural Biotechnology)。NHG 專門從事食品與農業領域之監管、政府和消費者事務之顧問公司，目標係啟用新的農業技術，推動政策改善並確保市場准入，服務內容包括協助中小型公司幫助應對世界各地針對基因編輯與基改生物複雜之監管系統，幫助客戶與關鍵影響者建立關係、協助制訂政策並了解政策變化之影響，並協助全球市場開阿與市場准入策略，以增加農產品出口。前揭文件(PAD)於 2023 年 7 月 16 日定稿，內容包括：

1. 前言：各經濟體對於農業生物技術監管之不同需求，以及建立機制時可能會面臨資源限制、政治意願與法律基礎之挑戰，此文件目標係促進各經濟體間之對話與調和，協助聚焦以尋求面對該等挑戰之方式。
2. 各經濟體監管合作之潛在利益：包括增進資源利用效率、增加研發投資、增進糧食安全、建立公眾對於監管決策之高度信任等。
3. 加強各經濟體監管合作與能力建構之方法：包括各經濟體間之資訊共享，有一致性之要求、揭露與評估之方式，以及可透過第三國進行監管決定。
4. 分析可供學習之案例，例如加拿大與澳洲、紐西蘭間對於基改食品安全評估方法共享倡議之發展，阿根廷與巴西針對基因編輯產品簽署之互相採認備忘錄，以及南美洲南方共同市場(Mercosur) 成員包括阿根廷、巴西、巴拉圭、烏拉圭針對基因改造產品最低殘留(Low Lever Presence, LLP)之協議。
5. 未來供各經濟體討論並提供回饋，此份文件亦於本次 HLPDAB 正式會議中公開。

四、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加拿大、智利、中國大陸、印尼、日本、韓國、馬來西亞、紐西蘭(視訊)、巴布亞紐幾內亞、秘魯、菲律賓、新加坡、泰國、美國、越南及我方共 16 個經濟體 40 多人與會。本次會議過程及討論要點臚列如下（附件 6）：

（一）由大會主席美國 Jennifer Lappin 及副主席祕魯 Dr. Dina Lida 致歡迎詞，並由主席請各經濟體代表團成員自我介紹。

接著由美國副國務卿 Alexis Taylor 致詞，揭示 APEC 主辦經濟體美國之主題為「為各方創造具韌性且永續未來」(Creating a Resilient and Sustainable Future for All)，三大優先領域議題為「互連：建立具韌性及相互連結的區域以增進具廣泛基礎的經濟繁榮」(Interconnected: Building a resilient and interconnected region that advances broad-based economic prosperity)、「創新：為永續未來打造有助創新的環境」(Innovative: Enabling an innovative environment for a sustainable future)以及「包容：為各方樹立衡平且包容性的未來」(Inclusive: Affirming an equitable and inclusive future for all)。生物技術為糧食安全與氣候變遷之因應提供重要之貢獻，各經濟體利用生物技術作為工具亦有多項創新之產品，例如耐熱牛隻、高 GABA 番茄、無毒河豚等。2022 年美國總統拜登發布行政命令啟動國家生物技術與生物製造倡議(National Biotechnology and Biomanufacturing Initiative)，目的係強化美國本土之生物製造，以減少新藥、化學品及其他產品對其他國家之依賴。

Taylor 表示對於 2022 年 HLPDAB 主辦方泰國之肯定，以及本次美國花許多努力與資源於 HLPDAB 會前辦理實地考察、創新

技術展示與研討，以及工作坊等工作，盼各經濟體能有更密切之互動與激盪。最後 Taylor 環顧身邊主席、副主席，以及在座各經濟體代表團之女性成員，強調女性領導力之提升與性別平等。

（二）事務性報告：由 2022 年的主辦方泰國報告年度成果，及美國報告 2023 年相關活動摘要。接著由各國報告最近半年之農業生技議題/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、巴布亞紐幾內亞、韓國、紐西蘭、菲律賓、祕魯、泰國、美國、越南及我方，另印尼以口頭補充。

我方發言要點：面對更加頻繁且嚴重之氣候事件，我方致力於推動智慧農業及耐候品種選育加強對於氣候變遷之韌性，亦鼓勵研究人員運用創新育種技術克服傳統育種方法之侷限性。而我方重視該等技術對於產業及消費者之影響，密切關注監管制度之國際趨勢。近 8 個月內，我方已舉開 5 場專家會議，並刻正整合關鍵意見，以利後續制定貼近國際共識之關鍵政策內容並徵求公眾意見。

（三）討論農業生技對於氣候變遷減緩與調適之糧食安全與供應鏈韌性之促進。由菲律賓、美國及越南分別進行簡報；

1. 菲律賓已採取生物科技作物農業現代化，使用農田管理、精準農業及生物作物，以期達到每年栽種農田減少 25%N2O 排放之目標。已核准商業基因作物產品為 Golden Rice 及 Bt eggplant，2023 年 4 月已核准第一個基因編輯作物之抗褐變香蕉，可減少 25%CO2 排放及 60%廢棄量（附件 7）。
2. 美國說明透過 APEC 會議，藉由各會員國可共同討論因氣候變遷可採行之方式，美國已有基因改造牛隻、耐乾旱之基改作物及基因改造需低氮量之觀景植物等，持續發展基因編輯作物及畜產品，以確保糧食安全（附件 8）。

3. 越南應用生物技術於農業，並建立人力資源、投資設施、公私夥伴關係、持續促進農業生物技術國際合作等方式，以進行農業生物技術研究開發及應用，並確保糧食安全及農業永續（附件 9）。

印尼代表於簡報後提問如何說服國內人民接受基改產品，菲律賓分享經驗為邀請社經專家加入政策決定小組，並與國會、參議院定期研討。美國則建議可以分享農民在經濟上的成功。加拿大則說明政治層面對於很多國家而言，的確是重大挑戰，要思考如何糾正人民所接受的錯誤訊息。

（四）檢視前一天工作坊說明之農業生物技術監管合作政策方法文件 (Policy Approaches Document for Regulatory Cooperation and Alignment on Agricultural Biotechnology)。各經濟體未表示修正意見（附件 10）。

（五）APEC 秘書處更新 HLPDAB 計畫與下次議題，並進行事務性宣達。

（六）主席簡單進行結語後，由下次副主席即 2024 年主辦方祕魯 Dr. Dina 歡迎各經濟體赴祕魯出席會議。

肆、心得與建議

一、 美國農業部主辦本次 HLPDAB 會議，安排從農業生物技術之實驗室創新、研發成果商品化、上市前後之產業化及監管之國際合作等各環節，透過實地考察與產品體驗、專家報告、座談會及工作坊交流討論等方式，並負擔各經濟體之食宿與機票費用以鼓勵實地參與（側面了解日本、韓國及中國仍自行出資），應為 HLPDAB 舉辦有史以來規模最大、會議期間活動最多之一次。確實較以往之舉辦方式，更可深入且充分討論農業生物科技發展相關議題與近況，有助於各經濟體引入國際經驗，與國際接軌。且以參與實地考察者而言，會議過程長達 6 天，並利用 WhatsApp 通訊工具成立群組，各經濟體代表參與實地考察者仍可持續建立關係，做為後續交流合作之基礎。本次會議相關活動之資訊量非常大，惟經洽主辦方考量智慧財產權，未能分享各議題簡報檔案供參與者回國後參考研析，對於母語非屬英語系之參加者而言，雖已盡力理解但仍力有未逮，是較為可惜之處，但也顯示美國對於智慧財產權之尊重。

二、 相較於 2012 年曾參與之 HLPDAB 會議，當時 APEC 各經濟體因產業結構及科技發展程度差距頗大，對農業生物技術發展之政策方向不一，多由美國及加拿大等生技大國分享技術發展情形並主導議題。但本次參加會議，觀察日本、菲律賓、泰國、越南、阿根廷等經濟體，近年於創新農業生物技術研發或管理制度上均有重要突破，尤其 2013 年發展之基因編輯系統 CRISPR/Cas9 具簡易性、方便性與精確性，大幅降低基因工程之門檻，已被各經濟體廣泛應用，並具急起直追美、加等國進展之勢。

三、 另觀察工作坊與座談會之交流互動情形，與會代表均好奇且關注日本在基因編輯技術及監管法規之進展，因過去資料顯示日本對於 LMO 之監管態度偏近歐盟較屬嚴格，然接二連三之基因編輯產品

已被視為非屬日本卡塔赫納法適用範圍且成功上市。由日本農林水產省代表所回答強調從未改變監管態度而是依據科學理性定義技術或產品是否屬 LMO 範疇，感受到其基因編輯產品之上市，對於日本消費者而言之吸引力，係多了創新產品之選項，但對於農業研究機構而言，更加激勵農業創新科技之持續發展與商業化，並藉由公私協力投入於更多可能超越 CRISPR 之創新育種技術之基礎開發。該等變化及科技進展，建議我國可視為案例持續深入觀測與分析。

四、 本次系列會議，各專家學者分享之內容對於基因改造生物稱 GMO 或 LMO，GE 有時係基因工程之簡稱，有時係指基因編輯。由於該等用語涉及該等國家之法規，且定義範圍有所不同，爰本報告未能統一用語，僅能如實呈現報告者之原用語。亦有經濟體代表注意到此節，建議 HLPDAB 雖不須制定具強制力之國際規範，但仍可訂定與農業生物科技相關之統一用語與定義，以供各經濟體遵循，以利各經濟體以共同語言溝通。觀察主辦方美國，即 HLPDAB 成立之倡議方，表示 HLPDAB 定位為資訊交流之平台，且各經濟體已經有行之有年之用法，爰未擬進行相關用詞統一之工作。

五、 有關美國國內對於基因改造產品，經本次拜耳公司及 NORFOLK Health Produce 公司提及有關民調之簡報內容，始知美國對於基因改造知看法持正面或負面者，各占一半，且歷經 2013 年多起抗議孟山都公司及抗議 GMO 事件，不難理解美國政府 2019 年修法要求基改標示並自 2020 年 1 月開始逐步志願性實施，決定不採取許多企業及消費者熟悉之 GE 或 GMO 等詞彙標示，而是用生物工程(Bioengineered)或 BE，以涵蓋其他如選擇性育種或細胞培養等產品，可能係為避免引起人民之反彈，並更能全面覆蓋不同類型之生物工程技術。但無須標示 BE 成分及含量，推測可能僅是為提供消費

者進行購買之決策。雖然國情對於基因改造產品則似趨於嚴謹，但經由聽取美國新創公司之說明，國內有50%的人會支持基因改造產品即代表著有廣大之消費市場，爰對於基因改造及可能更被接受之基因編輯產品發展相當樂觀。

六、 有關貿易部分，加拿大-澳洲、宏都拉斯-瓜地馬拉-薩爾瓦多，已分別依其貿易需求，相互簽署基改生物或產品之同步審查協議，以加速貿易；菲律賓已核准商業栽培基因編輯香蕉，盼可與鄰近國家如日本、韓國、中國等形成區域間監管合作機制，建議我國貿易部門可密切注意相關貿易關係之變化。

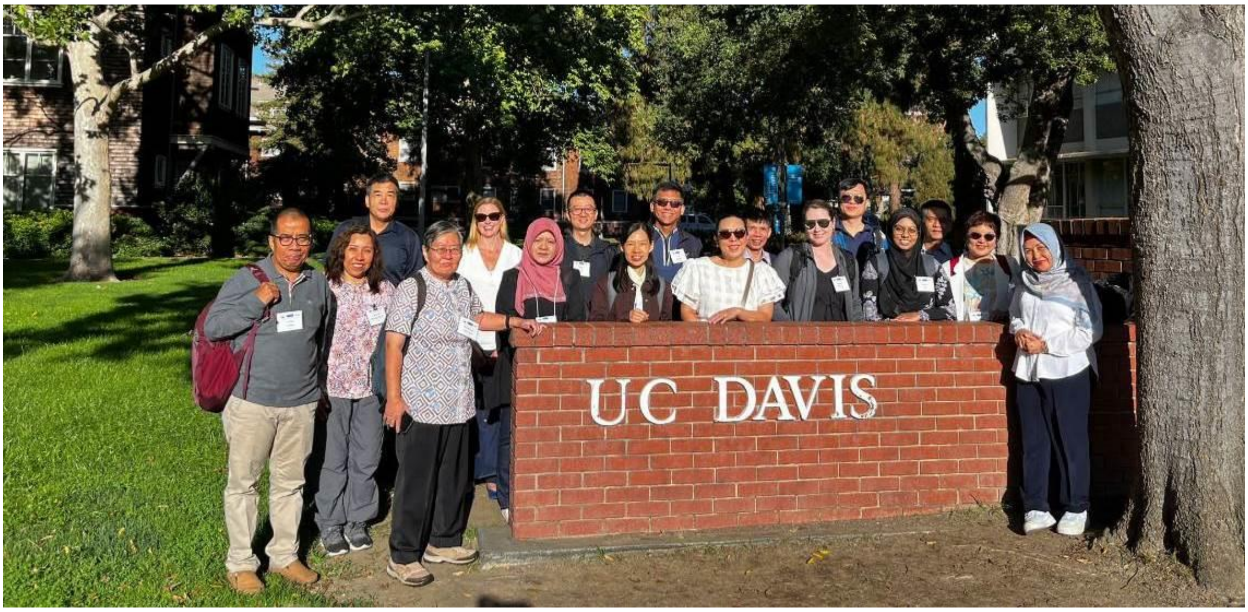
七、 藉由本次會議了解其他國家核准基因改造作物之情形，我國目前尚未允許栽種基因改造作物，已核准基因改造食品原料為黃豆、玉米、棉花、油菜與甜菜，持續與社會大眾進行風險溝通有其必要性。

八、 我國持續鼓勵研究人員運用基因編輯等創新生物技術改善相關品種對於氣候變遷之韌性，然亦須考量創新生物技術對於產業造成之衝擊，建議持續研析各國對於精準育種管理之相關議題，包括近期歐盟公眾諮詢結果，期能更貼近國際共識並將持續與公眾及利害關係人溝通，俾利我方對於創新生物技術發展適切之管理方式。

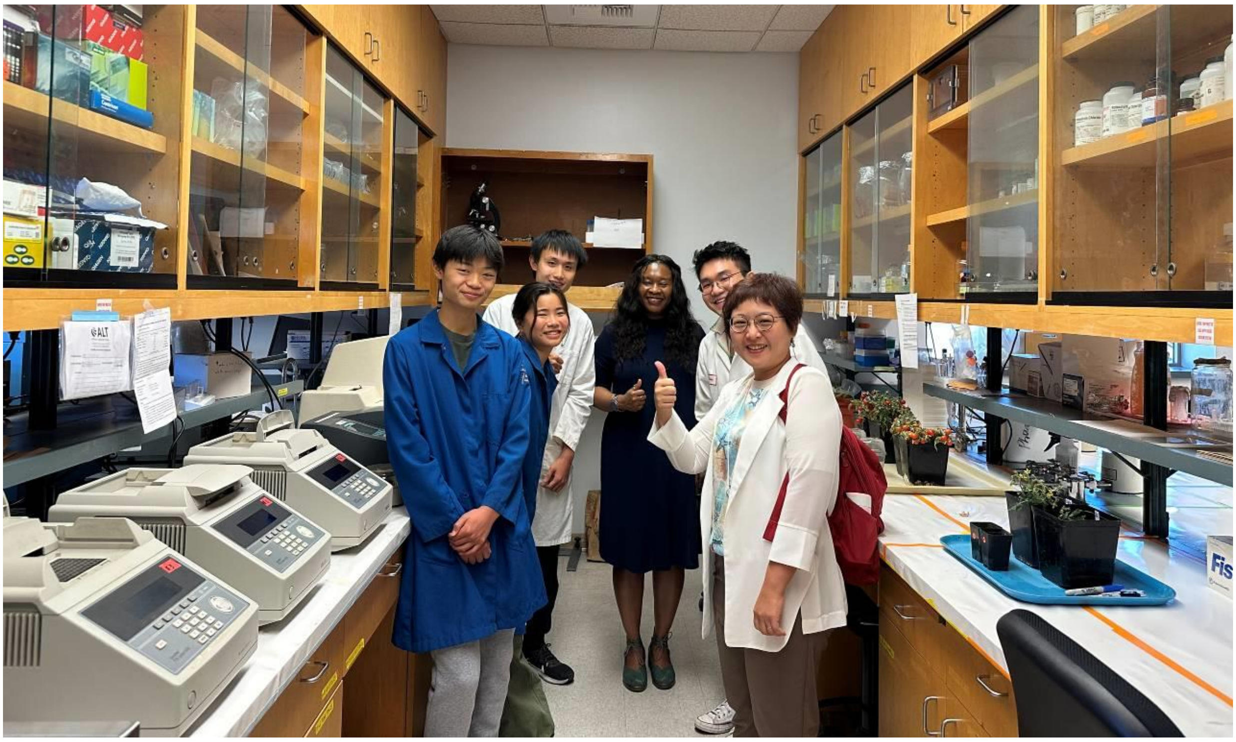
伍、照片紀錄

一、生技創新與農業生產力實地考察

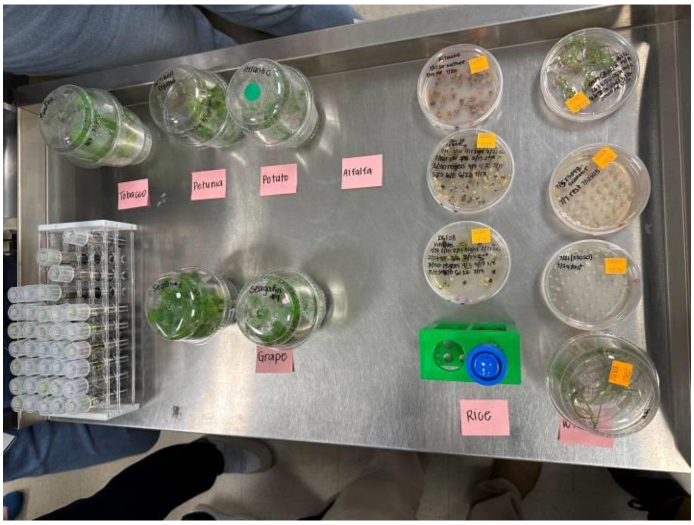
（一）戴維斯實地考察



UC Davis 實地考察之各國與會代表團體照

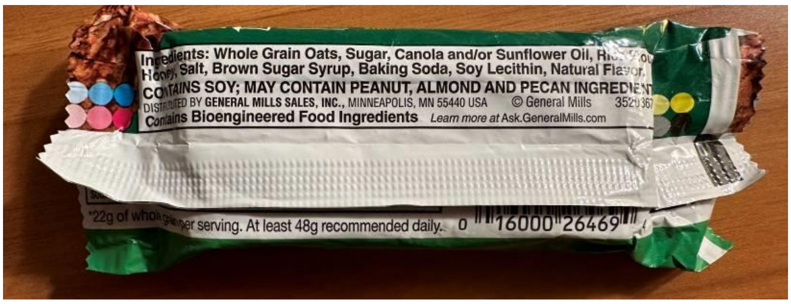


參訪 Diane Beckles 教授實驗室，著藍色實驗衣者為做專題之高中生



參訪 UC Davis 之植物轉殖設施(Plant Transformation Facility)，校方展示矮牽牛、馬鈴薯、苜蓿、稻米、葡萄、小麥、草莓等各種作物組織培養情形

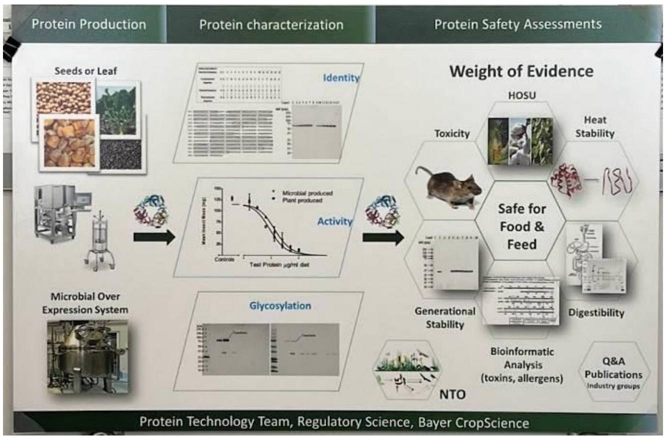
NORFOLK Health Produce 公司之基改高花青素紫色番茄，以及 Pairwise 公司之基因編輯芥菜

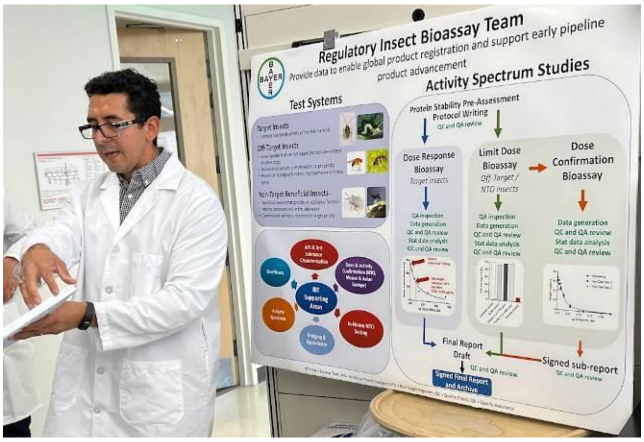


拜耳公司提供含有基改成份原料之穀物棒標示為'Contains Bioengineered Food Ingredients'

（二）聖路易斯實地考察

拜耳公司實驗室介紹種子組織取樣機

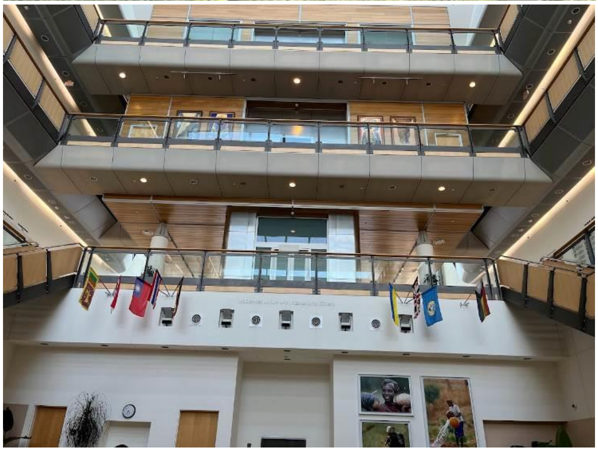




拜耳公司實驗室介紹蛋白質安全評估及昆蟲生物測定實驗

拜耳公司實地考察之各國與會代表團體照

本森·希爾公司實地考察之各國與會代表團體照



唐納德·丹佛斯植物科學中心

W. Stemme Farms 實地考察之各國與會代表於黃豆田前合影(左)及會議室(右)

W. Stemme Farms 農場主人介紹農藥噴灑機(左)及收割機(右)

二、青年學者與新創事業研討會

臺灣大學農業化學系博士後研究吳晉宇演講及壁報論文說明

15 位青年學者研究與創新簡短演講者合影(第二排右二為吳晉宇)

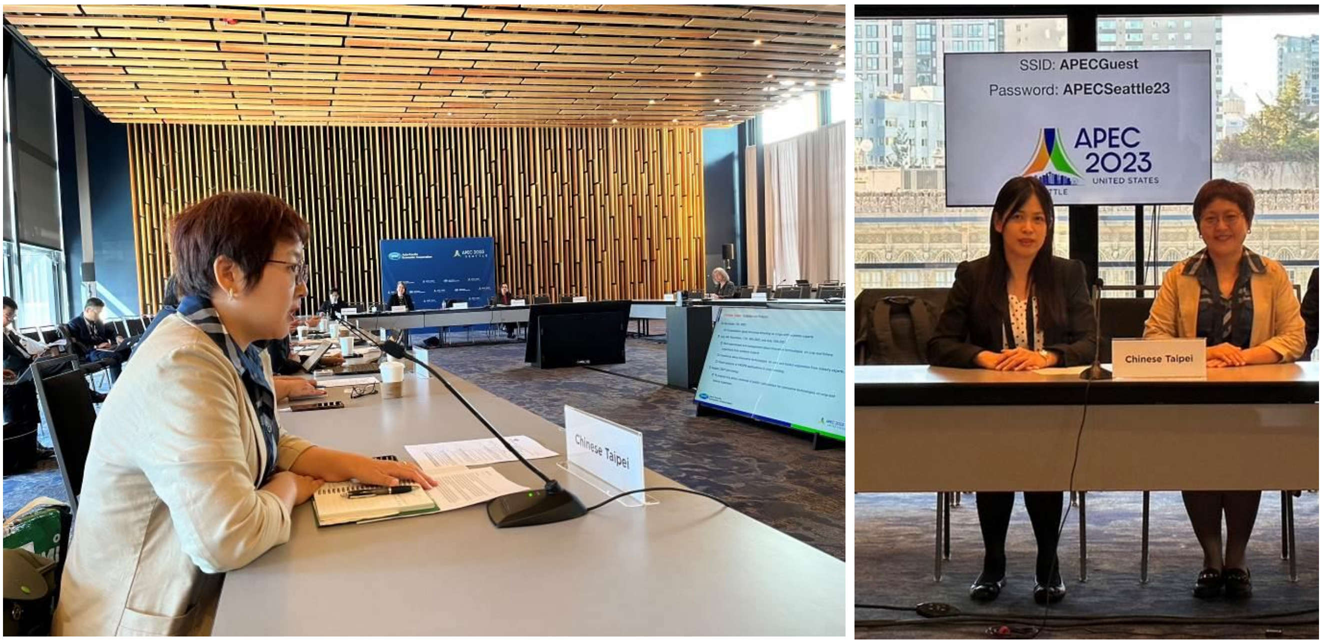
三、農業生物技術之有效監管與政策解決方案工作坊

我方代表參與工作坊分組討論情形，以及與 AFSI 之執行長 Andrew F. Roberts 合影(右下)

四、農業生物技術高階政策對話會議(HLPDAB)

2023 年 APEC 農業生物技術高階政策對話(HLPDAB)會議會場

2023 年 APEC 農業生物技術高階政策對話(HLPDAB)會議之主席美國 Jennifer Lappin(左一)、副主席祕魯 Dr. Dina Lida(左三)



2023 年 APEC 農業生物技術高階政策對話(HLPDAB)會議之我國與會代表發言

2023 年 APEC 農業生物技術高階政策對話(HLPDAB)會議各國與會代表團體照

陸、附件

附件 1、USDA 於 2020 年 6 月 12 日發布之農業生物技術安全規則(USDA's secure rule to regulate agricultural biotechnology)

附件 2、USDA 於 2023 年 8 月 4 日更新之農業生物技術安全規則(USDA's secure rule to regulate agricultural biotechnology)

附件 3、青年學者與新創事業研討會手冊

附件 4、國立臺灣大學農業化學系博士後研究員吳晉宇博士簡報內容

附件 5、農業生物技術之有效監管與政策解決方案工作坊議程

附件 6、農業生物技術高階政策對話會議(HLPDAB)議程

附件 7、菲律賓簡報內容 (Linking Agricultural Biotechnology, Climate Mitigation and Adaptation to the Advancement of Food Security and Supply Chain Resiliency)

附件 8、美國簡報內容 (Products and Approaches to Support Climate Mitigation and Adaptation and Food Security)

附件 9、越南簡報內容 (Linking Agricultural Biotechnology, Climate Mitigation and Adaptation to the Advancement of Food Security and Supply Chain Resiliency)

附件 10、APEC HLPDAB Policy Approaches Document Outline

Congressional Research Service
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IN FOCUS

June 12, 2020

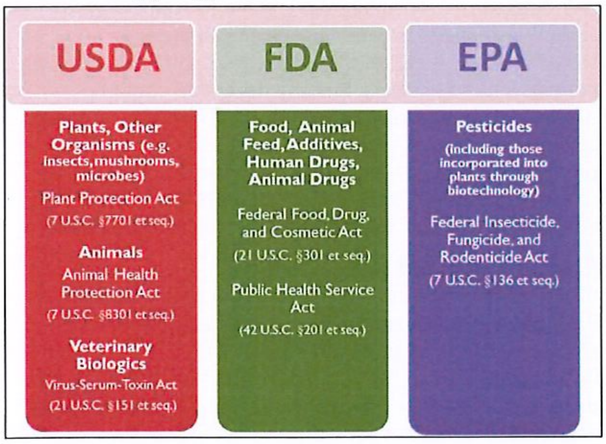
USDA's SECURE Rule to Regulate Agricultural Biotechnology

On May 18, 2020, the U.S. Department of Agriculture (USDA) published the final rule to revise its regulation of certain genetically engineered (GE) plants and other organisms (85 *Federal Register* 29790). USDA's Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient (SECURE) rule revises the regulations at Title 7, Section 340, of the *Code of Federal Regulations*. Phased implementation begins in June 2020, with full implementation by October 1, 2021.

The Coordinated Framework

USDA's SECURE rule is one component of the broader federal regulation of biotechnology products (e.g., GE plants, animals, and other organisms). The federal government's *Coordinated Framework for Regulation of Biotechnology* (the *Coordinated Framework*, 51 *Federal Register* 23302, June 26, 1986) outlines how USDA, the U.S. Food and Drug Administration (FDA), and the U.S. Environmental Protection Agency (EPA) apply existing statutes to regulate biotechnology products (**Figure 1**). A key principle of U.S. biotechnology policy is to regulate products according to their characteristics and unique features rather than the processes used to develop them.

Figure 1. Primary Legislative Authorities of Federal Biotechnology Regulation



Source: CRS.

Federal Regulation of Agricultural Biotechnology

Within the broader *Coordinated Framework*, USDA and EPA regulate the environmental release, transportation, and importation of GE agricultural products, including plants and other organisms (e.g., insects, mushrooms, microbes). FDA regulates GE material used in food products.

Within USDA, the Animal and Plant Health Inspection Service (APHIS) regulates new plants and other organisms according to their plant-pest and noxious weed risk under the Plant Protection Act (7 U.S.C. §7701 et seq.). *Plant-pest risk* refers to the potential for injury, damage, or disease in any plant or plant product resulting from introducing or disseminating a plant pest or potential to exacerbate a plant pest's impact. FDA regulates agricultural products for their safety for human and animal consumption, and EPA regulates plant pesticides, including those incorporated through genetic engineering. The APHIS regulations (7 C.F.R. §340) specify what organisms APHIS regulates (most *regulated articles* are plants), processes to determine whether they are regulated, and how APHIS regulates them.

USDA's Previous Regulations

Prior to USDA's SECURE rule, product developers could seek a USDA determination of whether a new organism met the definition of *regulated article* through the APHIS *Am I Regulated?* process. A **petition process** allowed individuals to request non-regulated status for an organism that met the definition. In this process, APHIS assessed the plant-pest risk of each new GE plant variety separately—irrespective of its similarity to GE varieties that APHIS had approved in the past. Regulated articles required either **permits** for their importation, interstate transportation, or environmental release or use of a **notification process** in lieu of permits when the plant was not considered a noxious weed and met other standards.

USDA's New Regulations

USDA states that the final SECURE rule is the first "significant" revision of the APHIS regulations since their creation in 1987. Unlike the prior rule, USDA's SECURE rule does not assess the risk of every new GE variety. It applies APHIS's current understanding of plant-pest risk to exempt broad categories of new plants from review:

> APHIS' evaluations to date have provided evidence that genetically engineering a plant with a plant pest as a vector, vector agent, or donor does not result in a GE plant that presents a plant pest risk. Further, genetic engineering techniques have been developed that do not employ plant pests ... yet may result in organisms that do pose a plant pest risk.

Major changes relate to exemptions, regulatory status review, and permitting, described in more detail below.

Exemption and Confirmation Process (§340.1)

USDA's SECURE rule exempts certain categories of modified plants (not other organisms) from the regulations because they could otherwise have been developed through conventional breeding. The rule identifies exemptions based on the type of GE modification. APHIS considers that such plants (e.g., certain genome-edited varieties) are "unlikely to pose an increased plant pest risk compared to conventionally bred plants." USDA's SECURE rule also exempts plants with a *plant-trait-mechanism of action combination* (i.e., combination of species, GE trait, and how the GE trait was introduced) that APHIS has previously deregulated or determined need not be regulated. Developers can request a written confirmation from APHIS that a plant is not subject to the regulations. Exemptions do not include non-plant organisms. The exemption and confirmation process takes effect on August 17, 2020. It replaces the prior *Am I Regulated?* process.

Regulatory Status Review (§340.4)

The regulatory status review (RSR) process replaces the prior petition process. Product developers may request a permit or an RSR for a new GE plant (not other organisms) that APHIS has not previously evaluated and determined to be non-regulated. Under the RSR process, APHIS evaluates whether the plant requires additional oversight based on its characteristics—its plant-pest risk—rather than the method used to develop it. If APHIS determines that the plant is not regulated, then later GE varieties using the same plant-trait-mechanism of action combination would not be regulated. If APHIS cannot determine that the plant does not pose a plant-pest risk, then it would require a permit. The RSR process is to be implemented for new GE corn, soybeans, cotton, potatoes, tomatoes, and alfalfa beginning April 5, 2021, and for all GE plants by October 1, 2021.

Permitting (§340.5)

USDA's SECURE regulations require a permit for the importation, interstate movement, or environmental release of any GE organism that may pose a plant-pest risk. These include plants that do not meet the exemption criteria or are determined to pose a plausible plant-pest risk through the RSR process, and other organisms. Developers may request a permit instead of an RSR, or they may request both. The RSR and permitting processes replace the former rule's notification process. The changes take effect April 5, 2021.

Stakeholder Reactions

Initial stakeholder reaction to USDA's final SECURE rule has been mixed. Some exporter and consumer groups criticized the new rule, while some producer groups supported it. In a May 14, 2020, statement, the National Feed and Grain Association stated that the rule "takes an overly broad approach that does not deliver adequate transparency and could contribute to future trade disruptions." On the same date, the Center for Science in the Public Interest stated that "a majority of genetically engineered and gene edited plants now will escape any oversight," and "government regulators and the public will have no idea what products will enter the market and whether those products appropriately qualified for an exemption from oversight."

Among supporters, the National Farm Bureau Federation stated that "the revised rule will encourage innovation of new plant breeding techniques while safeguarding our food supply." The National Corn Growers Association stated that the new rule provides "a modern framework to better address the innovations in and challenges facing modern agriculture."

Context for Regulatory Updates

USDA issued its SECURE rule in the midst of a broader debate about how the federal government should manage its roles, including those to protect consumers from risk and to support businesses and innovation. Some stakeholders have long called for updates to federal biotechnology regulations in light of scientific advances. *Genome editing*, which allows scientists to alter the characteristics of an organism through genetic changes in a more targeted way than previous biotechnology approaches permitted, was developed decades after the *Coordinated Framework* was designed. Some have argued that genome-edited products should not require the same regulatory scrutiny as products developed through less-specific techniques. Others have argued that products of all biotechnology may present new risks and should be strictly regulated.

The federal government revised the *Coordinated Framework* in 1992 and 2017. These updates did not involve changes to the underlying legislation and did not change the long-standing federal policy of evaluating risks and regulating products based on their characteristics rather than the processes used to develop them. The 2017 update states

> It is the characteristics of the biotechnology product, the environment into which it will be introduced, and the application of the product that determine its risk (or lack thereof).

Following the 2017 update, USDA addressed its position on the regulation of genome-edited plants in a March 28, 2018, statement, stating it did not—and did not plan to—"regulate plants that could otherwise have been developed through traditional breeding techniques as long as they are not plant pests or developed using plant pests."

The following year, the Trump Administration issued Executive Order (E.O.) 13874, *Modernizing the Regulatory Framework for Agricultural Biotechnology Products* (June 11, 2019). This E.O. called for USDA, FDA, and EPA to coordinate in modernizing the regulatory framework for agricultural plants and animals produced through biotechnology. It called for the agencies to review existing policies and regulations, identify those that could be streamlined in accordance with the E.O.'s policy guidance, begin to implement such changes, and exempt low-risk products from regulation "as appropriate." The SECURE rule meets this obligation for USDA. FDA and EPA have not yet revised their agricultural GE product regulations.

Congressional Interest

Congress may be interested in how any future changes to FDA and EPA regulation of GE plants align with the changes introduced through USDA's SECURE rule. As implementation of USDA's rule begins and potential updates of FDA and EPA regulations are made, Congress may consider whether the statutes underlying the *Coordinated Framework* continue to provide appropriate regulatory guidance or whether they require revision.

USDA's rule could also raise new concerns in international trade. Some have questioned whether certain U.S. trading partners would accept the revised regulatory requirements as sufficient to meet their own regulations for importing U.S. GE products. Congress may choose to monitor U.S. trading partner responses.

Genevieve K. Croft, Analyst in Agricultural Policy
Tadlock Cowan, Analyst in Natural Resources and Rural Development

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IN FOCUS

Updated August 4, 2023

USDA's SECURE Rule to Regulate Agricultural Biotechnology

In May 2020, citing 30 years of evidence, the U.S. Department of Agriculture (USDA) published a final rule to revise its regulation of certain genetically engineered (GE) plants and other organisms (85 *Federal Register* 29790). USDA's Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient (SECURE) rule revised the regulations at Title 7, Section 340, of the *Code of Federal Regulations* and further stated that new GE technologies, such as genome editing, do not engage with plant pests in any way. The rule was fully implemented in October 2021.

The Coordinated Framework

The federal government's 1986 *Coordinated Framework for Regulation of Biotechnology* (Coordinated Framework) governs how USDA, the U.S. Food and Drug Administration (FDA), and the U.S. Environmental Protection Agency (EPA) apply existing statutes to regulate biotechnology products.

A key principle of the Coordinated Framework is to regulate products according to their characteristics and unique features rather than the processes used to develop them (e.g., whether or not they were developed with biotechnology). The Coordinated Framework was updated in 1992 and 2017 to better guide the federal agencies and summarize the statutes under which they regulate biotechnology products.

Regulation of Agricultural Biotechnology

Within the broader Coordinated Framework, EPA regulates plant pesticides, including those developed through genetic engineering. FDA regulates agricultural products for their safety for human and animal consumption. USDA's primary engagement with the regulation of biotechnology-derived products has been through the Animal and Plant Health Inspection Service's (APHIS's) oversight of GE plants under the Plant Protection Act (PPA; 7 U.S.C. §§7701 et seq.). Under the PPA, APHIS regulates the importation, interstate movement, and environmental release (including field testing) of GE plants and organisms that may pose a plant-pest risk. *Plant-pest risk* is the potential for injury, damage, or disease in any plant or plant product resulting from introducing or disseminating a plant pest, or the potential to exacerbate a plant pest's impact.

APHIS's PPA regulations for GE organisms (7 C.F.R. §340) define regulated articles (i.e., the organisms subject to these PPA regulations; most are plants), processes to determine whether they are regulated, and how APHIS regulates them.

USDA's Previous Requirements

Prior to USDA's SECURE rule, product developers would seek a USDA determination of whether a new organism met the definition of a *regulated article* through the APHIS *Am I Regulated?* process. In this process, APHIS assessed the plant-pest risk of each new GE plant variety *separately*—irrespective of its similarity to GE varieties approved in the past. Regulated articles required either permits for their importation, interstate transportation, environmental release, or the use of a notification process when the plant was not considered a noxious weed and met other standards. Developers could go through a separate petition process to request nonregulated status for an organism that met the regulated article definition.

USDA's SECURE Rule

Unlike the prior requirements, USDA's SECURE rule does not assess the risk of *every* new GE variety and provides changes to the exemptions, regulatory status review, and permitting steps of the process, based on APHIS's current understanding of plant-pest risk (**Figure 1**). If exempted, developers can request a written confirmation from APHIS that a plant is not subject to the regulations (I). Plants that are not exempt must undergo a regulatory status review (II), which replaces the prior petition process. The review is followed by a new permitting process (III), which replaces the prior notification process.

Figure 1. The SECURE Rule Process

Source: CRS.

Exemptions and Confirmations (§340.1)

USDA's SECURE rule exempts certain categories of engineered plants (not other organisms) from the regulations because USDA deems that they could otherwise have been developed through conventional breeding. APHIS considers that such plants (e.g., certain genome-edited varieties) are "unlikely to pose an increased plant pest risk compared to conventionally bred plants." USDA's SECURE rule also exempts plants with a *plant-trait-mechanism of action combination* (i.e., a combination of species, GE trait, and how the GE trait was introduced) that APHIS has previously deregulated or determined need not be regulated. Under the revised rules, developers self-determine if their product meets the exempt status and can request written confirmation from APHIS that a plant is not subject to the regulations. The exemption and confirmation process took effect in August 2020.

Regulatory Status Review (§340.4)

The regulatory status review (RSR) process replaces the prior petition process. Product developers may request a permit or an RSR for a new GE plant that APHIS has not previously evaluated and determined to be nonregulated. Under the RSR process, APHIS evaluates whether the plant requires additional oversight based on its characteristics—

its plant-pest risk—rather than the method used to develop it. If APHIS determines that the plant is not regulated, then later GE varieties using the same plant-trait-mechanism of action combination also would not be regulated. If APHIS cannot determine that the plant does not pose a plant-pest risk, then it would require a permit. The RSR process took effect for all GE plants in October 2021.

Permitting (§340.5)

USDA's SECURE regulations require a permit for the importation, interstate movement, or environmental release of any GE organisms that may pose a plant-pest risk. These include plants and other organisms that do not meet the exemption criteria or are determined to pose a plausible plant-pest risk through the RSR process.

Developers may request a permit instead of an RSR, or they may request both. The RSR and permitting processes replace the former rule's notification process. The changes took effect in April 2021.

Reactions to the Changes

Initial stakeholder reaction to USDA's final SECURE rule has been mixed. Some exporter and consumer groups have criticized the rule, while some producer groups have supported it.

In a May 2020 statement, the National Feed and Grain Association stated that the rule "takes an overly broad approach that does not deliver adequate transparency and could contribute to future trade disruptions." The Center for Science in the Public Interest stated that "a majority of genetically engineered and gene-edited plants now will escape any oversight," and "government regulators and the public will have no idea what products will enter the market and whether those products appropriately qualified for an exemption from oversight." Among supporters, the National Farm Bureau Federation stated that "the revised rule will encourage innovation of new plant breeding techniques while safeguarding our food supply." The National Corn Growers Association stated that the new rule provides "a modern framework to better address the innovations in and challenges facing modern agriculture."

USDA states that the revised process has helped expedite the approval timing for new plants developed with biotechnology to about 41 days on average from submission, with small and medium-sized enterprises being the main clients. Although self-determination of exemptions provides flexibility in the approval process for developers, some have argued that it may provide less robust oversight of new GE and gene-edited varieties available in the market than the previous process.

In its five-year Strategic Plan for FY2023-FY2027, APHIS stated that one of its objectives is to ensure the safe development of agricultural biotechnology products using a science-based regulatory framework, including efficient permit review for GE organisms, clear communication of regulations to stakeholders, coordination with other agencies, and harmonization of regulatory oversight for biotechnology products.

Context for Regulatory Updates

USDA issued its SECURE rule amid a broader debate about how the federal government should manage its roles in the biotechnology context, including those to protect consumers from risk and support businesses and innovation.

Some stakeholders have long called for updates to federal biotechnology regulations in light of scientific advances. *Genome editing*, which allows scientists to alter the characteristics of an organism through genetic changes in a more targeted way than previous biotechnology approaches permitted, was developed decades after the Coordinated Framework was designed. Some assert that genome-edited products should not require the same regulatory scrutiny as products developed through less-targeted techniques. Others have argued that all biotechnology products may present new risks and should be strictly regulated.

In 2019, the Trump Administration issued Executive Order (E.O.) 13874, "Modernizing the Regulatory Framework for Agricultural Biotechnology Products" (June 2019). The order called for USDA, FDA, and EPA to coordinate in modernizing the regulatory framework for agricultural plants and animals produced through biotechnology. It also asked the agencies to review existing policies and regulations, identify those that could be streamlined in accordance with the E.O.'s policy guidance, begin to implement such changes, and exempt low-risk products from regulation "as appropriate."

In 2022, the Biden Administration issued E.O. 14081, "Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy," ordering the three agencies to further improve the clarity and efficiency of regulatory processes for biotechnology products and increase coordination and communication between federal regulatory agencies. FDA encourages developers of all new plant varieties to request premarket food safety consultations with the agency, which involves a discussion of the safety protocols and regulatory issues before the food is distributed in the market

In response to E.O. 14081, in May 2023, EPA announced changes to its regulations concerning genetically engineered plant-incorporated protectants (PIPs). These changes exempt certain PIPs from registration and tolerance requirements while implementing a notification process for transparency. EPA intends to consider additional exemptions and expand the list of categories not requiring EPA confirmation as biotechnology progresses. EPA's rule (88 C.F.R. §§34756 et seq.) went into effect in July 2023.

Congressional Interest

Congress may be interested in monitoring how USDA's revised regulatory requirements have affected the development and commercialization of GE and genome-edited products. Beyond that, Congress may consider monitoring how USDA, FDA, and EPA are assessing the effectiveness of the revised regulations, as underlined by the self-determination aspect of the exemption status of new GE and genome-edited products. Further, Congress may also oversee how well the three agencies are working together to harmonize the regulation of biotechnology products moving forward.

Eleni G. Bickell, Analyst in Agricultural Policy

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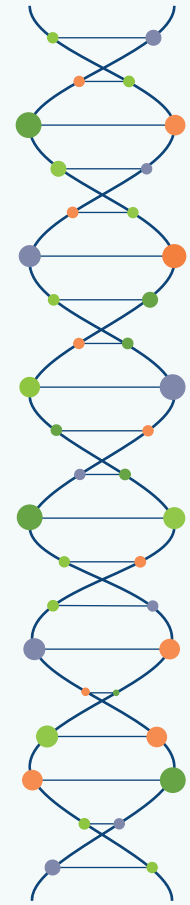

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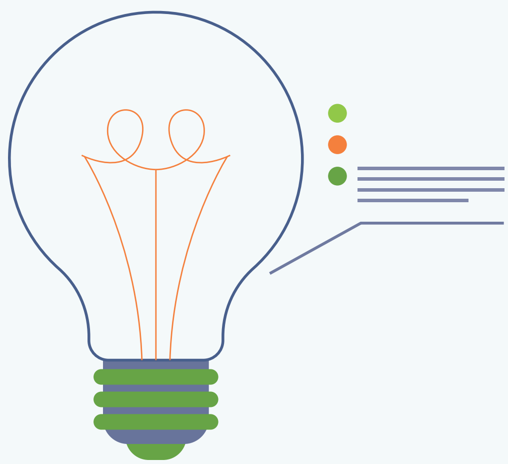
Early Career and Innovative Start-ups Symposium



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Declaration of Interests

Agriculture & Food Systems Institute (AFSI) speakers have no actual or potential conflict of interest in relation to the presentations given as part of the *Early Career and Innovative Start-Ups Symposium*. Invited speakers have been instructed to disclose financial interests related to the subject matter of their presentations. AFSI's activities related to this workshop are supported by a grant from the from the USDA FAS New Technologies and Production Methods Division.

Table of Contents

Overview

This one-day symposium shared new developments in agricultural biotechnologies and emphasized the role of youth in innovation. Through panel discussions, lightning talks, and a poster session, early career researchers presented on or learned of the impacts of policies on their work, empowering them as advocates for the development of trade- facilitating, science-based policies on agricultural biotechnology. In addition to highlighting early career researchers and start-ups from APEC member economies, this symposium provided an opportunity for researchers working in the field of agricultural biotechnology in the Asia Pacific region to exchange ideas. Industry representatives delivered presentations on enabling policy environments, current research and development, and career opportunities. As one of the activities on the margins of the High Level Policy Dialogue on Agricultural Biotechnology (HLPDAB) plenary, the symposium contributed to strengthening sustained information sharing related to agricultural biotechnologies between APEC member economies through highlighting innovations in the field.

Keynote Speaker

Lawrence Kent

Bill & Melinda Gates Foundation

For the past 16 years, Lawrence Kent has been serving as a Senior Program Officer on the Agricultural Development team at the Bill & Melinda Gates Foundation. He is based in Seattle but travels frequently to Africa and Asia to support grantees implementing programs to develop seed systems, build regulatory capacities, and test, deregulate, and deploy new crop varieties enhanced through both biotechnology and conventional breeding. Lawrence currently manages grants advancing transgenic disease-resistant cassava, insect-resistant cowpea, nutritionally enhanced rice, and drought-tolerant and insect-resistant maize hybrids. He also manages support for the HarvestPlus program, which has reached over 20 million farm families with seeds of crops bred to include elevated levels of iron, zinc, and pro-Vitamin A.

Prior to joining the Gates Foundation, Lawrence served as director of international programs at the Danforth Plant Science Center in St. Louis, Missouri (2002-2007), where he developed and supported programs leveraging biotechnology to produce nutritionally enhanced and virus-resistant cassava and disease-resistant sweetpotato with African partner institutions. He also led capacity-building programs on biosafety.

From 1990 until 2006, Lawrence worked on agricultural development and policy reform programs in Africa and Asia funded by USAID, the World Bank, UNDP, and the Asian Development Bank. He lived and worked for four years in Egypt, two years in Chad, one year in Burkina Faso, one year in Bulgaria, and conducted short-term consultancies in 25 countries, mainly in Africa.

An economist by training, Lawrence earned his master's degree at Princeton University in New Jersey after two years working as a Peace Corps Volunteer in West Africa (1985-87).

Agenda

Time	Presentation/Activity	Speaker/Facilitator
9:00 am	*Welcome and Introduction to the Symposium*	*Dr. Jennifer Rowland* Science Advisor New Technologies & Production Methods Division Foreign Agricultural Service U.S. Department of Agriculture The United States of America
9:05 am	*Opening Remarks*	*Ms. Sanah Baig* Deputy Under Secretary for Research, Education, and Economics U.S. Department of Agriculture The United States of America
9:15 am	**Session 1 – Research and Innovation Lightning Presentations** *8 Lightning Talks* Invited early career researchers will each give a 4-minute presentation to highlight their research and encourage further interaction during the poster session. *Moderator: Dr. Bhavneet Bajaj, Manager - Scientific Programs, Agriculture & Food Systems Institute, The United States of America*	
	Engineering Plants with Nitrogen Fixation Capabilities	*Dr. Christina Gregg* Research Scientist Commonwealth Scientific and Industrial Research Organisation Australia
	Implementation of CRISPR-Based Gene-Editing Tools in Brassica napus Canola	*Mr. Neil Hickerson* Graduate Student Researcher University of Calgary Canada
	Tuning Glutathione Content through Multiplex Genome Editing for Studying Dehydration Tolerance in Rice	*Dr. Chin-Yu Wu* Postdoctoral Research Fellow National Taiwan University Chinese Taipei
	Developing the Fruits for the Future: Precision Breeding in Fruit Crops	*Dr. Bernardo Pollak* Chief Executive Officer Meristem Chile

Time	Presentation/Activity	Speaker/Facilitator
	Induction of Resistance to Sugarcane Mosaic Virus by RNA Interference Targeting Viral Coat Protein in Sugarcane	*Dr. Rikno Harmoko* Research Scientist National Research and Innovation Agency Indonesia
	Use of Genetic Engineering to Develop Resistance to Biotic Stress in Plants	*Dr. Tetsuya Yoshida* Researcher Crop Disease Research Group Institute of Agrobiological Sciences, NARO Japan
	CRISPR Tools-Mediated Pepper Genome Editing	*Dr. Hyeran Kim* Assistant Professor Kangwon University The Republic of Korea
	Offspring Production of a SRY-knock in Bull	*Dr. Alba Ledesma* Post-Doctoral Researcher University of California, Davis The United States of America
9:55 am	*Agricultural Biotechnology Innovations Leading Change Around the Globe* *Q&A Opportunity*	*Dr. John Sedbrook* Professor of Genetics College of Arts and Sciences Illinois State University
10:30 am	*Coffee/Tea Break*	
11:00 am	**Session 2 – Research and Innovation Lightning Presentations** *8 Lightning Talks* Invited early career researchers will each give a 4-minute presentation to highlight their research and encourage further interaction during the poster session. *Moderator: Dr. Bhavneet Bajaj*	
	Developing Recombinant Wheat Cultivars with Drought Tolerance Traits	*Dr. Xiaoqing Li* Research Scientist Commonwealth Scientific and Industrial Research Organisation Australia
	Tastier Pea Protein Through CRISPR/Cas9 Gene-Editing	*Dr. Connor Hodgins* Researcher University of Calgary Canada
	Development of Allergenicity and Toxicity Assessment Methods for Evaluating Transgenic Sugarcane	*Dr. Widhi Dyah Sawitri* Assistant Professor Gadjah Mada University Indonesia

Time	Presentation/Activity	Speaker/Facilitator
	RNAi-Mediated Protection Against Cucumber Mosaic Virus (CMV) in Rockmelon (Cucumis melo L.)	*Ms. Dharane Kethiravan* Graduate Student Researcher University of Malaya Malaysia
	Biofortification of Rice Grains Through Genome Editing: Addressing Zinc Deficiency in Asia-Pacific Region	*Mr. Erwin Arcillas* Assistant Scientist International Rice Research Institute The Republic of the Philippines
	Microbial-Based Technology as an Alternative to Address Overflow of Agricultural Residues: Production of Vanillin from Lignin Derivatives Using the Recombinant Cell	*Dr. Panaya Kotchaplai* Researcher Institute of Biotechnology & Genetic Engineering Chulalongkorn University Thailand
	Improving Pennycress Seed Size and Glucosinolate Domestication Traits	*Ms. Liza Gautam* Research Scholar Illinois State University The United States of America
	Improved Bacterial Leaf Blight Disease Resistance in Major Elite TBR225 Rice Cultivar Using CRISPR/Cas9 System	*Dr. Nguyen Duy Phuong* Head of Molecular Pathology Department Agricultural Genetics Institute Viet Nam
11:40 am	**Poster Session** Early career researchers will present at a poster session, during which symposium participants can further engage with them about their research.	
12:40 pm	**Keynote Presentation** *Lunch Served* *Agricultural Biotechnology in the Developing World: Opportunities and the Role of the Gates Foundation*	*Mr. Lawrence Kent* Senior Program Officer Agricultural Development Bill & Melinda Gates Foundation The United States of America
	Panel Discussions	
1:50 pm	*Panel Discussion 1: Finding your Market, Traits and Targets, Regulatory Considerations, and Beyond* *Moderator: Dr. Jennifer Rowland*	*Mr. Dan Jenkins* Vice President of Regulatory and Government Affairs Pairwise The United States of America
		Mr. Shimpei Takeshita President Sanatech Seed Co., Ltd. Japan

Time	Presentation/Activity	Speaker/Facilitator
		Dr. M. Tahir Director of Research & Regulatory Affairs Okanagan Specialty Fruits Canada *Ms. Rebecca Catlett* Director of Marketing & Communication Okanagan Specialty Fruits Canada
3:20 pm	*Panel Discussion 2: Encouraging an Enabling Environment for Agricultural Biotechnology* *Moderator: Dr. Stuart Smyth, Associate Professor, University of Saskatchewan, Canada*	*Ms. Chantal March* Director of Quality & Regulatory Compliance AquaBounty Canada, Inc. Canada
		Mr. Martin Mariani Ventura Global Seeds & Traits Manager Bioceres Crop Solutions Argentina
		Mr. Paul Spencer Global Trade Policy Advocacy Leader External Affairs Corteva Agriscience™ The United States of America
		Dr. Chee Hark Harn Director, Seed R&BD Headquarters ToolGen, Inc. The Republic of Korea
4:20 pm	*Closing Remarks*	*Dr. Jennifer Rowland*
4:30 pm	*Early Career Researchers: Group Photo*	
4:45 pm	**Meet and Greet with Early Career Researchers** *Soft Drinks and Snacks Served*	
5:45 pm	*Symposium Ends for All*	

Early Career Researchers: Abstracts and Bios

Engineering Nitrogen-Fixing Plants: Reducing the Need for Nitrogen Fertilizer

Dr. Christina Gregg, Research Scientist, Commonwealth Scientific and Industrial Research Organisation, Australia

Currently, the nitrogen requirements of most crops are met by supplying synthetic nitrogen fertilizer. While nitrogen fertilizer is critical to agriculture and has been the main driver of the world's population expansion in the last century, it also comes with great economic and ecological costs. Here, we show our progress towards engineering plants that can fix nitrogen to reduce the need for nitrogen fertilizer.

About the Presenter

Christina Gregg is a biochemist and currently works on engineering plants with nitrogen fixation capabilities. She studied Chemistry at the University of Erlangen-Nuremberg, Germany, and completed her Ph.D. at the Humboldt-University of Berlin, where she worked on the biosynthesis pathway of enzymes containing metal clusters. Christina Gregg joined the Commonwealth Scientific and Industrial Research Organisation (CSIRO, Australia) as a Postdoctoral Fellow in 2017 and is now a Team Leader. She works on engineering plants that can fix their own nitrogen by directly transferring genes of nitrogenase, the enzyme that catalyzes biological nitrogen fixation, into plants. At CSIRO, Christina established an anaerobic biochemistry facility, and is currently focusing on assessing the function of individual nitrogenase components in order to build the complete nitrogenase biosynthetic pathway.

Implementation of CRISPR-Based Gene-Editing Tools in *Brassica napus* Canola

Mr. Neil Hickerson, Graduate Student Researcher, University of Calgary, Canada

Nearly 30 million tonnes of canola oil are produced globally each year, making canola among the top oil-seed crops worldwide. Canola has primarily been grown for its high-quality cooking oil. However, additional uses include industrial oil products for lubricants, adhesives, and biodiesel production, as well as a high-protein seed meal for plant-based protein products and animal feed stocks. Canola seeds feature a low-impurity oil with very low saturated fat content and high oleic acid (omega-9 fatty acid), which have been shown to improve cardiovascular health and contribute to its relatively high smoke point. Genetic transformation techniques have been in place for canola species since the mid-1990's and have been used to successfully create genetically modified (GM) canola varieties readily grown in North America. Targeted genome engineering via CRISPR-Cas systems provides a highly selective approach for molecular breeding of canola varieties and could potentially result in relaxed regulation of novel varieties compared to GM technologies among global trading partners. Owing to its unique genetic makeup, well-annotated genome, and genetic similarity to the model plant *Arabidopsis thaliana, Brassica napus* has been selected for extensive study and manipulation by gene-editing. We have been successful in the implementation of CRISPR-Cas9 gene editing systems via *Agrobacterium*-mediated genetic transformation of *B. napus* followed by subsequent segregation of transgenic material, resulting in stable, transgene-free, gene-edited plants. Gene knockouts have been the most reliable approach to achieving desired phenotypes by gene-editing, but additional variants and enzyme fusions also make it possible to achieve modified genes previously identified by chemical mutagen screens. Our work focuses on the manipulation of key regulatory pathways governing plant yield (e.g., stem architecture and reproductive potential) in order to maximize canola yield and improve breeding technologies. Continued expansion of the CRISPR-Cas9 toolset will allow for further optimizations to *in planta* editing efficiency and have made accessible nearly all annotated genes of the *Brassica napus* genome.

About the Presenter

Neil began his graduate studies in 2017, passing his Ph.D. candidacy exam in March 2020. This was immediately followed by a guest lecture series on CRISPR-Cas9 topics in plant biotechnology. His graduate research focused on the hormonal and post-translational regulation of seedling development, and he became involved in the design and implementation of the CRISPR-Cas9 system in the Samuel Lab for *Arabidopsis thaliana*, *Cicer arietinum* (chickpea), *Pisum sativum* (pea), *Glycine max* (soybean), and *Brassica napus* (canola) for the targeted mutation of various genes. This involves careful analysis of genomic DNA, gene expression, and precise selection of potential target positions within the gene of interest to reduce the risk of off-target effects and enable proper Cas9 function. Neil has expanded this work and applied it to several research projects within the Samuel Lab, with the goal of uncovering mechanisms for agricultural trait improvement focused on optimizing crop yield.

Tuning GSH Content by Multiplex Genome Editing Affects Drought Tolerance in Rice

Dr. Chin-Yu Wu, Postdoctoral Research Fellow, National Taiwan University, Chinese Taipei

Glutathione (GSH), a tripeptide, is involved in many physiological processes and plays a role in the response to stresses in plants. In addition to acting as a non-enzymatic antioxidant, GSH modulates physiological functions through S-glutathionylation or redox change in plant cells. Water stress is a major negative factor in agricultural production. Our recent study showed that exogenous GSH reduces dehydration tolerance in rice. To further investigate the role of GSH in dehydration tolerance, we studied the T-DNA insertion mutant of the key GSH synthesis gene, OsGSH1-1. Unfortunately, the loss of GSH1 caused a lethal phenotype. To obtain rice plants with varying levels of GSH, we performed multiplex genome editing on the promoter of the OsGSH1-1. Additionally, we generated rice plants with elevated GSH levels using an estrogen-inducible system. The genome-edited lines exhibited a decrease in GSH content by 27% - 49% compared to the WT, while GSH was increased by 20% in the estrogen-inducible line. The attenuation of GSH content resulted in a dehydration-tolerant phenotype compared to the WT. Conversely, elevated GSH increased sensitivity to dehydration stress in rice. These results demonstrate that GSH could act as a negative regulator for dehydration tolerance in rice.

About the Presenter

Chin-Yu Wu is a dedicated postdoctoral fellow in the field of crop functional genomics at National Taiwan University. His primary research revolves around the intricate interplay between two essential plant compounds, glutathione and abscisic acid (ABA), with a specific focus on rice. Chin-Yu's work delves into the fascinating realm of seed germination and the plant's response to dehydration stress. By investigating the interaction of glutathione and ABA in these processes, he aims to unlock crucial insights into the molecular mechanisms governing plant growth and adaptation to environmental challenges. With a passion for scientific discovery and a commitment to sustainable agriculture, Chin-Yu's research has the potential to pave the way for innovative strategies to enhance crop productivity and resilience in the face of changing climatic conditions. As a promising young scientist, Chin-Yu Wu's contributions to the field of crop functional genomics hold great promise for the future of agriculture and food security.

Developing the Fruits for the Future: Precision Breeding in Fruit Crops

Dr. Bernardo Pollak, Chief Executive Officer, Meristem, Chile

Meristem is a biotech startup that aims for the future. Our approach involves integrating innovative *in vitro* culture techniques, gene editing, and regeneration to develop a streamlined workflow for trait improvement in elite fruit cultivars. The experiment design for our *In vitro* Organogenesis Pipeline Platform involves strategies for experimentation and process optimization that allow testing a wide range of conditions with just two or three variables, facilitating the formulation of culture media. The use of this approach allows limiting the number of experiments and at the same time, obtaining enough data to carry out statistically powerful analyses. The culture media are prepared according to the experimental design, considering the tissue that we want to finally obtain–callus, shoots, or roots. Different organs are propagated *in vitro* (e.g., stem, leaves, roots), and they are used as a starting material for our transformation platform. The responses of each tissue are analyzed based on a wide range of variables, allowing us to determine the best *in vitro* condition for each desired process.

About the Presenter

Dr. Bernardo Pollak graduated in Biochemistry from the Pontifical Catholic University of Chile and earned a Ph.D. in Plant Sciences from the University of Cambridge, specializing in Plant Synthetic Biology. Subsequently, he conducted postdoctoral research at the J. Craig Venter Institute in La Jolla, California, where through a Moore Foundation grant, he developed foundational tools for diatom genetic engineering. He returned to Chile with the aim of developing technology in the fruit industry, and he founded Meristem, a biotech startup focused on developing novel fruit varieties using gene editing, in 2020.

Induction of Resistance to Sugarcane Mosaic Virus by RNA Interference Targeting Viral Coat Protein in Sugarcane

Dr. Rikno Harmoko, Research Scientist, National Research and Innovation Agency, Indonesia

RNA interference (RNAi) inhibits gene expression through RNA-mediated sequence-specific interactions and is considered an effective approach to control viral infection in plants. In this study, the *SCMVCp* gene encoding the coat protein (CP) was inserted into the pGreen0179 plasmid in both sense and antisense orientations. The 35SCaMV and ZmUbi promoters were selected to drive the transcription of the RNAi constructs, called HpSCMVCp-CaMV and HpSCMVCp-Ubi, respectively. Transgenic sugarcane expressing these constructs was generated through *Agrobacterium*-mediated transformation. Southern blotting revealed a single stable insertion of the DNA target in the genome of transgenic sugarcane lines. After artificial virus infection, lines that developed mosaic symptoms were classified as susceptible, whereas those that remained green without symptoms were classified as resistant at 42 days post-inoculation. Immunoblotting revealed CP expression at 37 kDa in susceptible and non-transgenic sugarcane, but not in resistant lines. RT-PCR analysis confirmed viral *Cp* and *Nib* gene expression in susceptible lines and their absence in resistant lines. We concluded that RNAi is effective for inducing resistance against SCMV and that the Ubi promoter is an effective promoter for producing transgenic sugarcane.

About the Presenter

Rikno Harmoko is a Researcher in the Research Center for Genetic Engineering, National Research and Innovation Agency, Indonesia. Previously, he was a researcher at the Indonesian Institute of Sciences (LIPI) for two years. He holds a bachelor's in agronomy from Jember University, Indonesia. Harmoko completed his master's and Ph.D. at Gyeongsang National University, Republic of Korea, where he also did the post-doctoral program for two years. He is very interested in molecular biology/biotechnology and has actively collaborated with researchers in plant science, particularly in plant stress response, plant hormone signaling, and glycobiology. Focusing his research on monocot crops, Dr. Harmoko develops sugarcane resistant to mosaic disease using molecular biology approaches such as RNA interference and genome editing. In rice, he investigates the contribution of the N-glycan structure of the protein to plant growth, phytohormone regulation, and stress response. Dr. Harmoko has published his research in several reputable journals in plant science.

Use of Genetic Engineering to Develop Resistance to Biotic Stress in Plants

Dr. Tetsuya Yoshida, Researcher, Crop Disease Research Group, Institute of Agrobiological Sciences, NARO, Japan

Crop production equivalent to feeding 800 million people is lost due to crop diseases. Disease resistance breeding is a powerful strategy for controlling plant diseases. Disease resistance can be developed by genetic engineering, such as gene editing. Knocking out a host factor involved in plant-pathogen interaction by conventional plant gene editing technology can confer disease resistance. However, this has some bottlenecks. For example, it is time- and labor-intensive, removing transgene by segregation is required, and the expression level of gene-editing components is not always high. Plant gene editing using virus vector is advantageous because it can be simple and easy, bypassing the use of transgene and have high expression level of gene editing components.

About the Presenter

Dr. Yoshida is a researcher at the Crop Disease Research Group, Division of Plant Molecular Regulation Research, Institute of Agrobiological Sciences at the National Agriculture and Food Research Organization (NARO) in Japan. He received his bachelor's degree and Ph.D. in agriculture from the University of Tokyo in 2013 and 2019, respectively. His research focuses on the interactions between plants and viruses and the development of strategies to control plant viruses. He has studied the molecular mechanisms underlying the replication of plant positive-sense RNA viruses, including viruses that cause significant crop loss, and the functions of host proteins that affect viral accumulation. He is also currently working on the development of plant gene editing technologies using virus vectors.

CRISPR Tools-Mediated Pepper Genome Editing

Dr. Hyeran Kim, Assistant Professor, Kangwon University, The Republic of Korea

Targeted crop improvement is critical for achieving global food security and improving human nutrition. Traditional breeding programs and modern molecular breeding techniques have increased crop yield and quality. However, conventional plant breeding procedures have been time and resource constrained. A newly improved crop takes a long time to reach the market, and genetic sources from wild species are not always available for crops of interest. CRISPR-Cas9, a distinguished tool in the field of genome editing, has gained prominence due to its remarkable speed, simplicity, and cost-effectiveness, surpassing previous methods like zinc finger nuclease (ZFN) and transcription activator-like effector nuclease (TALEN). The utilization of CRISPR tools has significantly accelerated fundamental and applied crop science research. Several genome-edited (GE) products, such as high oleic soybean, powdery mildew-resistant wheat, and brown-free mushrooms, have reached the global market, indicating their readiness for commercialization. We explored DNA-free genome editing techniques utilizing CRISPR-Cas9 ribonucleoprotein (RNP) and CRISPR-Cpf1 RNP for precise crop editing in *Brassicaceae*, *Solanaceae*, soybean, and other plant species. Despite the availability of cutting-edge genome editing tools for crops, the commercialization of precise editing applications in recalcitrant species for plant regeneration remains a challenge. Here, we present significant achievements, limitations, and recent advancements in the molecular breeding of pepper through precise genome editing.

About the Presenter

Hyeran Kim obtained a Ph.D. at the POSTECH in the Republic of Korea in 2007 and did a Postdoc at the MPIPZ in Cologne for four and half years. Her earlier work involved plant cellular protein trafficking and plant-microbe (fungal) interactions for seven years. She joined the Institute for Basic Science (IBS) to study Plant Genome Editing in 2014. Since September 2017, as an associate professor, she started her own group for various research interests; vesicle trafficking, environmental stresses, plant genome editing, and crop improvement. Recently, her group has been focusing on pepper genome editing.

Analysis of XX, SRY Positive Offspring of a SRY-knock in Bull

Dr. Alba Ledesma, Post-Doctoral Researcher, University of California–Davis, The United States of America

In mammals, the sex-determining region of the Y chromosome (SRY) expresses a protein in early embryogenesis that initiates male sexual differentiation and inhibits formation of the female gonad. Previously, a targeted knock-in of SRY:GFP into the safe-harbor H11 locus of chromosome 17 was accomplished using CRISPR-Cas9 genome editing in bovine zygotes to produce a XY bull calf, Cosmo (Fig. 1A). Sequencing revealed a compound heterozygote biallelic edit at the target location on chromosome 17, comprised of a complex 38 kb knock-in allele with seven concatenated copies of the SRY:GFP template and a single copy of the donor plasmid backbone on one chromosome (Fig. 1C), and a random 26 base pair insertion on the other (Owen et al., 2021). It was predicted that the offspring of this SRY knock-in bull would be 75% male (50% XY males, and 25% XX infertile phenotypic male individuals), and 25% fertile XX females (Fig. 2). Additionally, 50 % of blastocysts resulting from fertilization with Cosmo's semen would be expected to exhibit green fluorescence due to the inheritance of SRY:GFP on CHR17. The objective of this experiment was to test the hypothesis that inheritance of SRY on chromosome 17 by the offspring of Cosmo would result in XX infertile individuals with a male phenotype.

About the Presenter

Alba Ledesma is a postdoctoral researcher at the Laboratory of Alison Van Eenennaam at the University of California, Davis. Currently, she is investigating the application of stem cell technologies and genome editing in mammals. She obtained her D.V.M. from Central Buenos Aires University, an M.S. in Animal Science, and a Ph.D. in Agronomy Science from Mar del Plata National University Argentina, where she specialized in gametes collection, evaluation, cryopreservation, and embryo production. She received the Next Gen Leadership Award for Advances in Genome Biology and Technology in 2022. Dr. Ledesma's interests are aimed at the application of technology to increase livestock productivity and the promotion of activities for scientific awareness. In 2022, she organized the "Inspiring Women and Femmes in STEM Symposium."

Developing Recombinant Wheat Cultivars with Drought Tolerance Traits

Dr. Xiaoqing Li, Commonwealth Scientific and Industrial Research Organisation, Australia

Drought is a major constraint for agricultural production around the world, and with climate change, the severity of drought and its frequency will increase in many regions. Studies have shown that more than 40% of inter-annual wheat production variability is mainly due to heat waves and drought conditions throughout the world. Under drought, roots are the first organ exposed to the drying soil and the origin of the signals that coordinate the plant's response. Optimization of the root system is critical for developing crops that are better adapted to a drying climate. In this work, we used recombinant inbred lines (RILs) generated from two parental lines with contrasting root traits to phenotype for various root and shoot traits and to identify quantitative trait loci (QTLs) for key root traits. The results from this work provide opportunities to breed cultivars for particular environments, such as those susceptible to drought.

About the Presenter

Dr. Xiaoqing Li is an early career researcher. Her research experience ranges from plant molecular biology to plant physiology and morphology. She started her research career at China Agriculture University (CAU, China), where she studied the formation of cluster root in white lupin. Xiaoqing pursued her Ph.D. at Lancaster University in the United Kingdom to investigate plant root development and hormone signaling during soil drying. Her postdoctoral project in CSIRO Agriculture and Food (2016-2020) aimed to boost crop yields by delivering energy-efficient roots through phenotyping in the major crop, wheat. Xiaoqing then joined the Cotton Fibre Quality Team in CSIRO as a Research Scientist to develop novel cotton fibres through genetic engineering. Xiaoqing is now developing various capabilities, including gene editing technologies to support the Cotton Breeding Program, while also leading the development of Traceable Cotton Fibres. She received the Science and Innovation Awards for Young People in Agriculture, Fisheries, and Forestry in 2022.

Tastier Pea Protein Through CRISPR/Cas9 Gene-Editing

Dr. Connor Hodgins, Researcher, University of Calgary, Canada

Pea protein is a vital component of sustainable agriculture systems. The problem is that saponins cause bitter off-flavors in peas. Mutation of BAS can prevent their biosynthesis in peas. In our research, gRNAs 2, 3, and 4 were selected based on *in vitro* testing. The CaMV35S and AtU6-26 promoter were tested for gRNA expression. A multi-gRNA expression system was optimized in pea hairy roots, and two homozygous mutant lines were identified with a >99% reduction in saponin.

About the Presenter

Dr. Connor Hodgins is currently a post-doctoral fellow working on a collaborative project between the University of Calgary and a start-up company, AgGene. His Ph.D. training utilized CRISPR/Cas9 gene-editing to study the biosynthesis of specialized chemicals in lettuce and peas. Of particular interest to his current position was his development of novel traits in peas related to improved flavor. This was accomplished through the editing of a biosynthetic pathway in peas, which produced chemicals called saponins. Saponins are purified with pea protein and give it bitter and astringent off-flavors. The trait he developed in peas prevents them from producing saponins, thereby improving the flavor of the pea's protein. The skills he developed that allowed him to improve pea flavor are useful for almost any trait. His work at AgGene is based around utilizing these same skills to further develop improved pea varieties.

Development of Allergenicity and Toxicity Assessment Methods for Evaluating Transgenic Sugarcane

Dr. Widhi Dyah Sawitri, Assistant Professor, Gadjah Mada University, Indonesia

Sugarcane is considered an industrial crop that produces sugar. The number of transgenic sugarcane on the market is currently increasing. Therefore, investigation of the potential allergens and toxins in transgenic sugarcane is necessary since there is less information regarding food safety for human consumption. Bioinformatics and experimental analysis were used for the validation of the allergenic potential of transgenic sugarcane, such as analysis of amino acid sequences using the AllergenOnline software; *in vitro* assessment method using heat stability, simulated gastric fluid (SGF), simulated intestine fluid (SIF); and *in vivo* assessment method using ELISA analysis for IgE measurement in rats. An acute oral toxicity assay was performed by oral gavage of transgenic sugarcane juice in mice. In this study, we propose the development of a method for allergenicity and toxicity assessment in transgenic sugarcane.

About the Presenter

Dr. Widhi Dyah Sawitri is an Assistant Professor of Plant Genetic Engineering at the Department of Agronomy, Faculty of Agriculture, Universitas Gadjah Mada (UGM), Indonesia. Her research interests focus on agricultural biotechnology and the biochemical study of enzymes in plants, particularly sucrose phosphate synthase from C4 plants. Previously, she worked at the Center for Development of Advanced Science and Technology (CDAST), University of Jember for three years (2016-2019). At that time, she was involved in the development of genetically engineered sugarcane through overexpression of sucrose phosphate synthase and coat protein of sugarcane mosaic virus. In addition, her work on protein engineering through site-directed mutagenesis technique is undergoing research to support functional studies of certain enzymes.

RNAi-Mediated Protection Against Cucumber Mosaic Virus (CMV) in Rockmelon (*Cucumis melo* L.)

Ms. Dharane Kethiravan, Graduate Student Researcher, University of Malaya, Malaysia

Rockmelon is an important tropical fruit with a wide range of health benefits and high nutritional value. However, Cucumber Mosaic Virus (CMV), an aphid-transmitted virus, causes severe damage to its production. The existing control strategy to control viral infection using chemical insecticides are minimally effective and causes deleterious effects on the environment and human health. RNAi is a powerful biotechnological tool that can be used to combat viral infection in plants. RNAi can be triggered in plants by inserting dsRNA of viral genes into the plant genome or by exogenously applying dsRNA on the surface of the plants. In the current study, the protective effect using dsRNA of viral genes by exogenous application was tested in rockmelon. The effectiveness of RNAi protection was measured by the disease severity index (DSI) and compound enzyme-linked immunosorbent assay (Compound ELISA). Based on the DSI and ELISA, rockmelon treated with dsRNA to trigger RNAi in rockmelon showed a reduction in viral symptoms (4.31-fold lower) and titer (4.91-fold lower) compared to rockmelon plants that were not treated with dsRNA. These results indicate that exogenous treatment of dsRNA is an interesting approach as a biopesticide to combat the spread of CMV in rockmelon crops safely and effectively.

About the Presenter

Dharane Kethiravan graduated with a Bachelor of Science in Biology from the University of Malaysia Terengganu. She received an award for being the best student academically during her degree. With her knowledge and passion in biological sciences, she is pursuing a Ph.D. She is currently a Ph.D. candidate at CEBAR, University of Malaya, Malaysia. Her Ph.D. project is on protecting crops by using RNAi, a powerful biotechnology tool that can knockdown viral proteins to protect plants against virus infection. Her passion and interest is to make a meaningful contribution to addressing the global food demand while mitigating environmental risks.

Biofortification of Rice Grains Through Genome Editing: Addressing Zinc Deficiency in Asia-Pacific Region

Mr. Erwin Arcillas, Assistant Scientist, International Rice Research Institute, The Republic of the Philippines

Zinc deficiency has a high prevalence in the Asia-Pacific region, with the indicator of stunting in children under 5yo recorded at 77.2 million in 2018 (FAO, UNICEF, WFP, and WHO 2019). Diversification of diet, supplementation, and commercial food fortification are practiced but are inaccessible to marginalized populations. Traditional biofortification through breeding is limited by gene pool restrictions and linkage drag. Genome-editing using Site-directed Nucleases (SDN) is employed to exploit the rice nicotianamine synthase 2 (*OsNAS2*) gene, which encodes an enzyme responsible for synthesizing the zinc chelator nicotianamine. Promoter modification (SDN-1), promoter replacement (SDN-2), and targeted insertion (SDN-3) using CRISPR-Cas9, and TALENs are performed. Zinc concentrations in seeds of edited and non-edited plants are measured.

About the Presenter

Erwin Arcillas is a molecular plant biologist with a passion for translational crop research. He received his B.Sc. in Agriculture and M.Sc. in Genetics from the University of the Philippines Los Baños. His research focus is on the development of new rice varieties using plant biotechnology, with a particular interest in varieties that are more nutritious to alleviate micronutrient deficiencies. In addition to his research, Erwin is also passionate about graphic design. He enjoys designing posters and slide decks, as well as creating illustrations for book chapters, journal articles, and review articles. He believes that graphic design can help people understand complex scientific concepts in a clear and engaging manner.

Microbial-Based Technology: Their Roles in Sustainable Agriculture

Dr. Panaya Kotchaplai, Chulalongkorn University, Thailand

Microorganisms play many important roles in promoting sustainable agriculture. For example, plant growth-promoting microorganisms can enhance plant tolerance to stresses, ultimately increasing crop yield and quality. Certain microorganisms can produce allelochemicals, which reduce the need for agricultural chemicals and promote environmentally friendly practices. Some microorganisms aid in the degradation of contaminants and the restoration of degraded land, contributing to environmental conservation. One issue resulting from the increasing agro-industrial activities is the accumulation of lignocellulosic by-products and waste, which can have negative environmental consequences if not managed properly. To address this concern, researchers are exploring the biovalorization of lignocellulosic biomass. Lignin, a complex structure comprising heterogeneous aromatic compound, has been proposed as a renewable aromatic source for valuable compound production. Our study focused on the conversion of ferulic acid, an abundant lignin derivative, to vanillin, a highly demanded compound in the food and fragrance industries. In well-studied strains such as *Pseudomonas*, *Amycolatopsis* and *Streptomyces*, ferulic acid is typically converted to vanillin via the CoA-dependent pathway. However, in certain *Bacillus* and yeast strains, phenolic acid decarboxylase (encoded by *padC*) catalyzes the rapid conversion of ferulic acid to 4-vinylguaicol, a highly toxic compound. Interestingly, the decreasing 4-vinylguaiacol was found to be concurrent with the increasing amount of vanillin. We then explored *Bacillus* enzymes involved in vanillin production and found that CYP102A2, a *Bacillus* cytochrome P450, may be a potential enzyme. However, developing PadC-CYP102A cascade proved challenging due to low vanillin yield and cell stress caused by cytochrome P450 overexpression. Recently, aromatic dioxygenase (Ado) has been reported for its ability to catalyze the coenzyme-free oxidation of 4-vinylguaiacol to vanillin. Resting cells of *Escherichia coli* BL21(DE3) overexpressing *Bacillus* PadC and codon-optimized Ado demonstrated rapid conversion of ferulic acid to vanillin. This CoA-independent enzyme cascade presents an efficient biocatalyst for vanillin production and holds potential for further development as a cell-free system, making it a promising approach for lignin biovalorization

About the Presenter

Panaya Kotchaplai got a B.Sc. in Biochemistry and a Ph.D. in Environmental Management from Chulalongkorn University, Thailand. During her Ph.D., she focused on how bacteria respond and adapt to stressors, and how these adaptive changes affect their phenotypes and activity. Following her Ph.D., she took on a role as an industrial postdoctoral researcher at the Department of Biochemistry, Faculty of Science, Chulalongkorn University, where she developed an interest in the biovalorization of agro-industrial waste and byproducts. She focused on the development of a microbial biocatalyst for bioproduction of vanillin from lignin derivative(s). Currently, she is a researcher at the Institute of Biotechnology and Genetic Engineering, Chulalongkorn University, where she primarily focuses on harnessing microbial-based technology to promote a sustainable future. Her work involves developing biocatalysts to valorize agro-industrial residues, providing an alternative approach to agricultural waste management. Additionally, she also focuses on bioremediation and the restoration of degraded land.

Pennycress (*Thlaspi arvense*) Seed Size Mutants Affect Oil Accumulation Differently

Ms. Liza Gautam, Research Scholar, Illinois State University, The United States of America

Domesticated pennycress varieties (CoverCress™) have been developed having reduced seed coat fiber content, low erucic acid seed oil content, and which produce over 1,500 pounds of seed per acre, yielding 65 gallons of oil and 1,200 pounds of meal per acre. To improve this oilseed cash cover crop further, we are exploring ways to increase seed size and oil content. Three genes in which we have generated mutations are *DA1*, *DA1-RELATED* (*DAR1*), and *UBIQUITIN PROTEIN LIGASE3* (*UPL3*). In Arabidopsis, *DA1* and the functional homologue, *DAR1*, encode ubiquitin receptors thought to set final seed and organ size by restricting the period of cell proliferation in the seed integuments. UPL3 was shown in Arabidopsis to mediate proteasomal degradation of, among other targets, the transcription factor LEC2. LEC2 is known to activate expression of seed maturation and seed lipid accumulation genes. We found that pennycress *da1dar1* double mutants produced seeds that were 44 percent larger and 50 percent heavier than wild type; *upl3* mutant seeds were 17 percent larger and 16 percent heavier than wild type. Surprisingly, pennycress *upl3* mutant seeds had less oil per seed than wild type, even though the *upl3* mutant seeds were 17 percent larger. By contrast, *da1dar1* double mutant seeds had nearly 41 percent more oil per seed. Our results indicate that mutations in *DA1* and *DAR1* may be attractive targets for increasing seed size in conjunction with increasing seed oil content in domesticated pennycress and other Brassica oilseed crops.

About the Presenter

Liza Gautam is a Ph.D. candidate from Kathmandu, Nepal. Currently, she is working at Prof. John C. Sedbrook's laboratory in the Department of Biological Science at Illinois State University (ISU). She completed her Bachelor of Technology in Biotechnology from Kathmandu University (KU), Nepal, and her Master of Science in Biotechnology from the Norwegian University of Science and Technology (NTNU), Norway. After completing her master's degree, she worked as an Assistant Research Fellow in the Nepal Academy of Science and Technology (NAST), a leading research station and governmental organization in Nepal. As a molecular geneticist, Ms. Gautam is currently working on domesticating an oilseed cash cover crop-Pennycress (*Thlaspi arvense L.*). Her primary focus is implementing CRISPR-Cas9 genome editing technology to target multiple genes at different loci to increase seed size, reduce glucosinolate content, and increase drought tolerance in pennycress, and she would like to pursue a career in research and development.

Improved Bacterial Leaf Blight Disease Resistance in Major Elite TBR225 Rice Cultivar Using CRISPR/Cas9 System

Dr. Nguyen Duy Phuong, Head of Molecular Pathology Department, Agricultural Genetics Institute, Viet Nam

Bacterial leaf blight disease (BLB) caused by *Xanthomonas oryzae* pv. *oryzae* (*Xoo*) is a significant rice disease in Viet Nam. Most Vietnamese commercial rice varieties, including TBR225, are susceptible to BLB. The virulence of *Xoo* depends on the transcriptional activation of specific host disease-susceptibility (S) genes by transcription activator-like effectors (TALEs). TALEs bind to specific host nuclear gene promoter sequences termed Effector-Binding Elements (EBEs) and induce target gene expression to benefit the pathogen. Three S genes, *OsSWEET11*, *OsSWEET13*, and *OsSWEET14*, coding for transmembrane sugar exporter proteins are known to be targeted by several unrelated TALEs of all Xoo strains in nature. The clustered regularly interspaced short palindromic repeats/CRISPR-associated protein-9 nuclease (CRISPR/Cas9) system is a simple and efficient gene-editing tool developed in the past few years. This project focuses on improving the BLB resistance of the TBR225 cultivar through identifying and editing the transcriptional target of Vietnamese *Xoo* (VXO) in the TBR225 genome by using CRISPR/Cas9 tool.

About the Presenter

Dr. Nguyen Duy Phuong is a senior researcher at the Agricultural Genetics Institute in Viet Nam. He is also a visiting lecturer at the Viet Nam National University of Agriculture and University of Engineering and Technology, Viet Nam National University, Hanoi, Viet Nam. He completed a bachelor's, master's, and Ph.D. in Biochemistry at Hanoi University of Sciences – Viet Nam National University, Hanoi, Viet Nam. During his Ph.D., he did an internship and completed his doctoral thesis on identifying the transcription factor encoding the gene related to drought tolerance in rice at the International Centre for Genetic and Engineering Biotechnology, New Delhi, India. He has published over 50 publications in scientific journals of repute and three monographs. His current research looks at plant pathology, abiotic stress response, developing plant pathogen detection kits, and applying new technology in crop breeding.

APEC 2023 SEATTLE

HLPDAB: High Level Policy Dialogue on Agricultural Biotechnology

Early Career and Innovative Start-ups Symposium

Organized by the
Agriculture & Food Systems Institute

Seattle, USA
July 29, 2023

**This workshop is supported by a grant from the USDA FAS New Technologies and Production Methods Division.*

foodsystems.org

Innovation Symposium for Early Career Researchers
APEC, HLPDAB

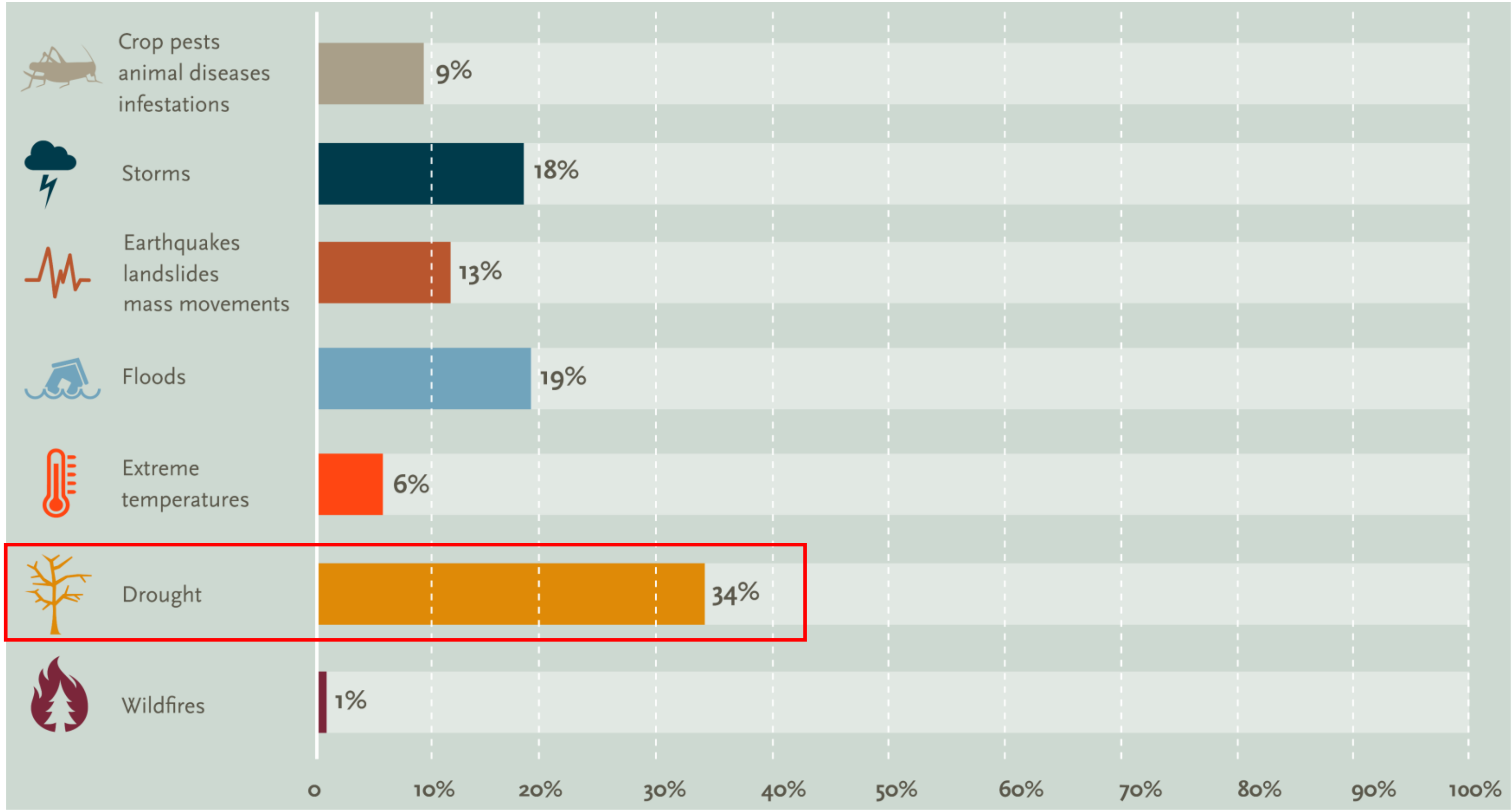
Tuning glutathione content through multiplex genome editing for studying dehydration tolerance in rice

Speaker: Dr. Chin-Yu Wu

Supervisor: Prof. Chwan-Yang Hong

Department of Agricultural Chemistry, NTU

Drought severely reduces crop production worldwide



(FAO, 2021)

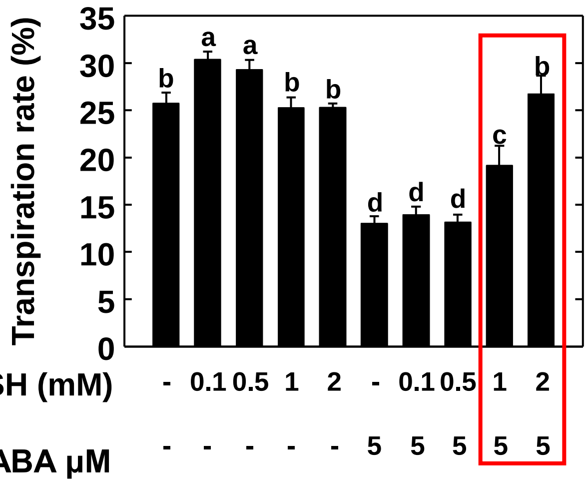
Exogenous GSH reduces dehydration tolerance in rice

(a) GSH decreases the dehydration tolerance of rice

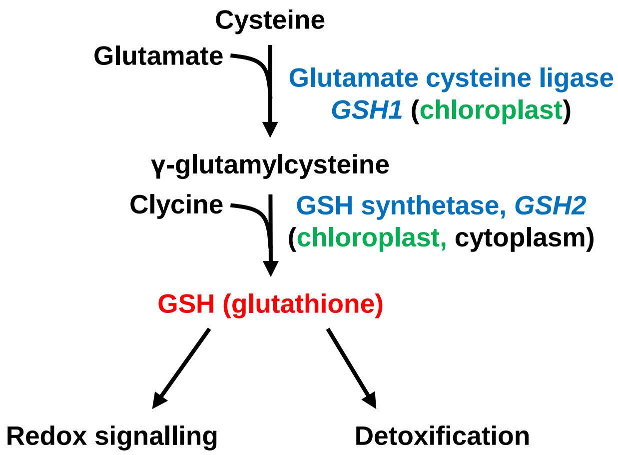
Survival rate	100%	100%	72%	44%	24%

GSH 0 mM	GSH 0.1 mM	GSH 0.5 mM	GSH 1 mM	GSH 2 mM

(b) GSH mitigates the ABA response in transpiration rate

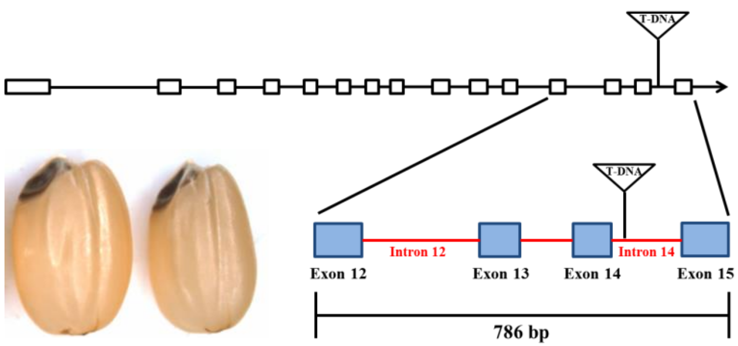


(c) *OsGSH1* is the key gene in biosynthesis of GSH

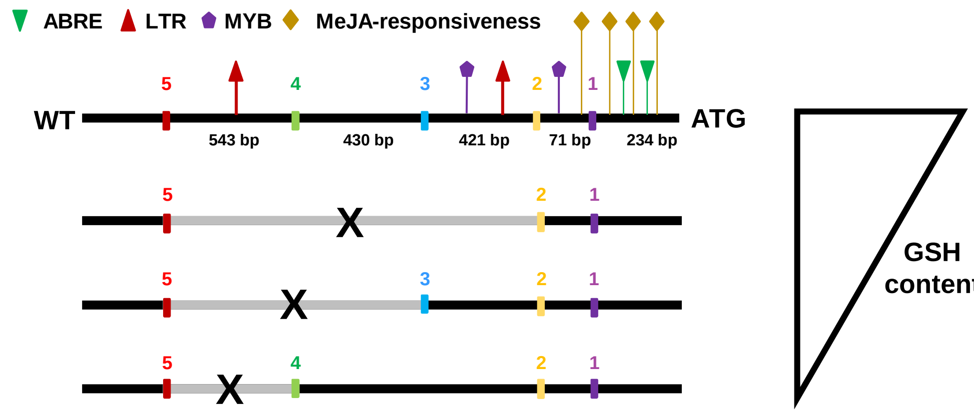


Strategies to manipulate GSH levels in rice

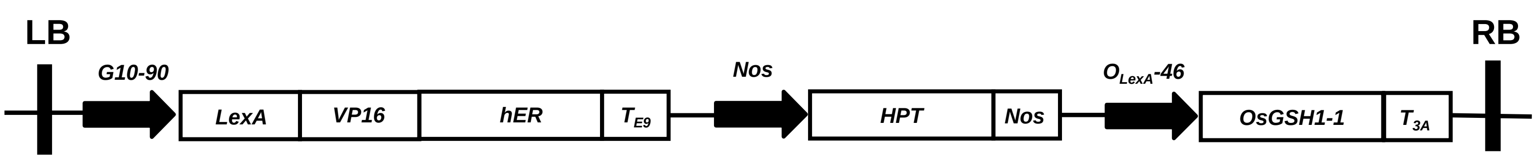
(a) The knock-out of *OsGSH1-1* causes a lethal phenotype in rice seeds



(b) *In vivo* multiplex genome editing on the promoter of *OsGSH1-1*

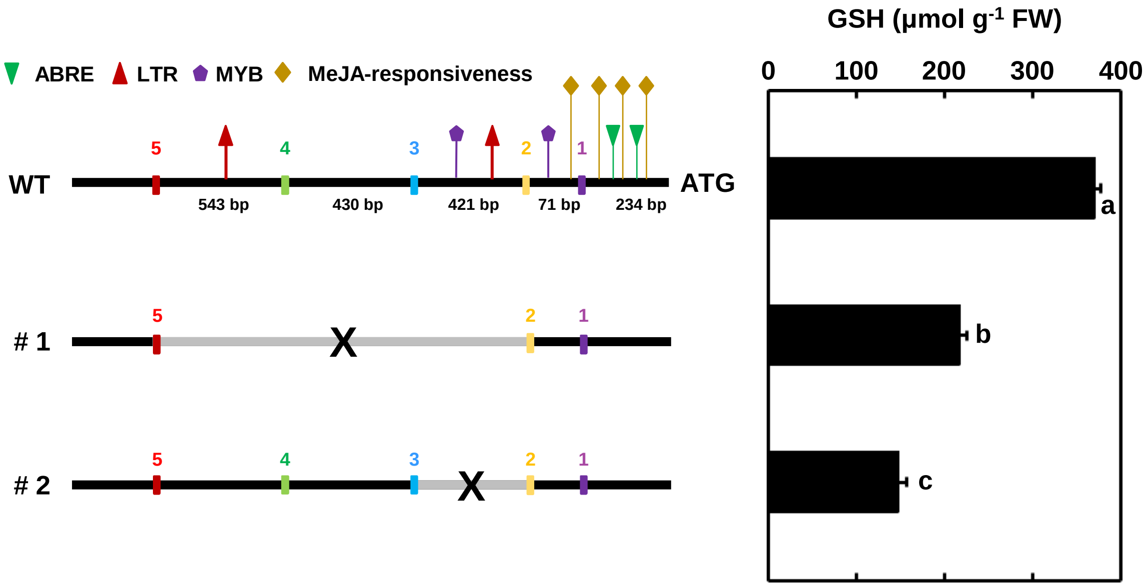


(c) Elevated GSH levels in rice using an estrogen-inducible system

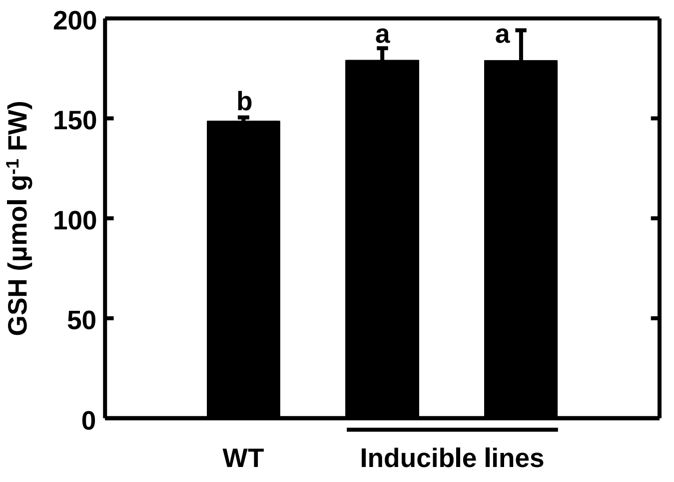


Changes of GSH content in genome edited and inducible lines

(a) Attenuation of GSH levels using genome editing



(b) Enhancement of GSH levels using an estrogen-inducible system



Effect of dehydration on phenotypes in genome edited and inducible lines

WT	Genome-edited lines		Estrogen-inducible lines	

	WT	Genome-edited lines		Estrogen-inducible lines	
GSH content	100%	72%	45%	115%	114%
Survival rate	16%	28%	33%	0%	0%

Acknowledgements

Prof. Chwan-Yang Hong & Lab members

APEC 2023 UNITED STATES SEATTLE | USDA | Agriculture & Food Systems Institute

HLPDAB: HIGH LEVEL POLICY DIALOGUE ON AGRICULTURAL BIOTECHNOLOGY

Workshop on Reducing Redundancies and Facilitating Efficiencies:

Regulatory and Policy Solutions for Oversight of Agricultural Biotechnologies

Seattle, USA | July 30-31, 2023 | 08:45-17:00 (PDT/UTC-7)

This two-day, in-person workshop will continue the tradition of working together across APEC economies to identify regulatory and policy solutions for science-based and risk-proportionate oversight of agricultural biotechnologies that mitigate climate change, strengthen supply chains, increase food security, and facilitate trade. Participants will explore the potential impacts of regulatory redundancies and ways to reduce these redundancies, and the feasibility of developing a "Policy Approaches Document" to promote regulatory efficiencies and sustained information sharing to help streamline agricultural biotechnology product approvals and facilitate trade.

Agenda

Day 1 – Sunday, July 30

Time	Presentation/Activity	Presenter/Lead
Session 1 - Facilitating Regulatory Cooperation: Key Concepts		
08:45	*Welcome and Opening Remarks*	*Ms. Jennifer Lappin* Director New Technologies & Production Methods Division Foreign Agricultural Service U.S. Department of Agriculture The United States

Time	Presentation/Activity	Presenter/Lead
09:05	*Overview of Agenda*	*Dr. Bhavneet Bajaj* Manager, Scientific Programs Agriculture & Food Systems Institute The United States
09:15	*Keynote Presentation: Necessary Ingredients for Successful Regulatory Cooperation*	*Dr. Andrew F. Roberts* Chief Executive Officer Agriculture & Food Systems Institute The United States
09:45	*Moderated Q&A Session*	*Dr. Bhavneet Bajaj*
10:00	*Tea Break*	
Session 2 - Regulatory Cooperation Success Stories		
10:20	*Opening Remarks for Session 2*	*Dr. Andrew Roberts*
10:30	*Regulatory Cooperation Success Stories* • India's Journey to the OECD Mutual Acceptance of Data and Towards Excellence	*Dr. Ekta Kapoor* (recorded presentation) Scientist "E" National GLP Compliance Monitoring Authority Department of Science and Technology India Vice-Chair OECD Working Group on Good Laboratory Practice
10:50	*Regulatory Cooperation Success Stories* • African Medicines Regulatory Harmonization Programme (AMRH)	*Ms. Chimwemwe Chamdimba* (recorded presentation) Head African Medicines Regulatory Harmonization (AMRH) Programme South Africa
11:10	*Regulatory Cooperation Success Stories* • Towards a Harmonized Approach to Safety Assessment of Food Derived from Genetically Engineered Plants in South Asia	*Dr. Bhavneet Bajaj*
11:30	*Moderated Q&A Session*	*Dr. Andrew Roberts*
12:00	*Lunch Break*	
Session 3 - Potential for Regulatory Cooperation in the APEC HLPDAB		
13:00	*Opening Remarks for Session 3*	*Dr. Andrew Roberts*
13:10	*Breakout Groups*	*All Participants*
14:30	*Tea Break*	
14:50	*Breakout Groups* (continued)	*All Participants*

Time	Presentation/Activity	Presenter/Lead
16:00	*Recap of Session 3*	*Dr. Andrew Roberts*
16:30	*Wrap Up of Day 1 and Closing Remarks*	*Dr. Bhavneet Bajaj*

Day 2 – Monday, July 31

Time	Presentation/Activity	Presenter/Lead
08:45	*Recap of Day 1 and* *Overview of the Agenda for Day 2*	*Dr. Bhavneet Bajaj*
	Session 4 - Regulatory Cooperation, Safety Assessments, and Trade in Products of Agricultural Biotechnology	
09:00	*Opening Remarks for Session 4*	*Dr. Andrew Roberts*
09:05	*International Guidance on Safety Assessment of Foods Derived from rDNA Organisms*	*Dr. Flerida Carino* Consultant Philippine Food and Drug Administration Consultant National Committee on Biosafety Department of Science and Technology The Philippines
09:30	*Elements of Environmental Risk Assessment of Products of Agricultural Biotechnology*	*Dr. Kylie Tattersall* Director - Plant Evaluation Section Office of the Gene Technology Regulator Australia
09:55	*Trade in Agricultural Biotechnology:* *Role of the Sanitary and Phytosanitary (SPS) and Technical Barriers to Trade (TBT) Agreements*	*Mr. Robert Ahern* Director - WTO Agricultural Affairs Office of the United States Trade Representative The United States
10:20	*Moderated Discussion*	*Dr. Andrew Roberts*
10:45	*Tea Break*	
	Session 5 - Building Trust: Knowledge Sharing and Enabling Regulatory Cooperation	
11:05	*Opening Remarks for Session 5*	*Dr. Bhavneet Bajaj*
11:10	*Development of Health Canada – Food Standards Australia New Zealand (FSANZ) Safety Assessment Sharing Initiative*	*Mr. Jordan Bean* (virtual) Senior Scientific Project Coordination Biologist Health Canada Canada
11:35	*Regulation of Genetically Engineered Crops in Paraguay*	*Prof. Danilo Fernandez Rios* Research Professor University of Asuncion Paraguay

Time	Presentation/Activity	Presenter/Lead
12:00	*Knowledge Sharing and Enabling Regulatory Cooperation: Argentina's Perspective*	*Dr. Dalia Lewi* Director of Bioeconomy Secretariat of Agriculture, Livestock & Fisheries Argentina
12:30	*Moderated Q&A Session*	*Dr. Bhavneet Bajaj*
12:45	*Lunch Break*	
13:45	*Honduras - Guatemala - El Salvador Agreement*	*Dr. Pedro Rocha* International Specialist in Biotechnology & Biosafety Inter-American Institute for Cooperation on Agriculture Costa Rica
14:10	*Genome Editing Policies, Research and Development in Japan*	*Mr. Yukio Uchida* Deputy Director-General Agriculture, Forestry and Fisheries Research Council Ministry of Agriculture, Forestry and Fisheries Japan
14:35	*Moderated Q&A Session*	*Dr. Bhavneet Bajaj*
Session 6 - Benefits of Regulatory Cooperation for Agricultural Biotechnology		
14:45	*Opening Remarks for Session 6*	*Dr. Andrew Roberts*
14:50	*Regulatory Collaboration: Types, Benefits, and Challenges*	*Dr. Abby Simmons* Regulatory Manager CropLife International The United States
15:15	*Outline of Policy Approaches Document for Regulatory Cooperation and Alignment on Agricultural Biotechnology*	*Mr. Jeffrey V. Nawn* Chief Executive Officer/Founder North Hill Group The United States
15:40	*Moderated Discussion*	*Dr. Andrew Roberts*
16:10	*Workshop Summary and Closing Remarks*	*Ms. Jennifer Lapin*
16:20	*Meeting Adjourns*	

Post-Event Survey

We would like to gather your feedback on how well the event was organised 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/yq4uMsjXYEEmHNi9A

Workshop on Reducing Redundancies and Facilitating Efficiencies:

Regulatory and Policy Solutions for Oversight of Agricultural Biotechnologies

Session 3 – Potential for Regulatory Cooperation in the APEC HLPDAB

Session 3 of the workshop will be conducted as a breakout session. Participants will be assigned group numbers and will be asked to team with others in their group. There will be 8-10 people in each group. The goal of the session is to exchange information about the regulatory systems for agricultural biotechnology in APEC economies and draw out the commonalities to support regulatory cooperation with the objective of reducing barriers to trade in products of modern biotechnology. To facilitate discussion within the groups, the moderator will pose some questions through an interactive platform (Mentimeter) that the participants will be able to respond to in real-time.

This exercise will be conducted in three parts, which will involve a discussion of the following topics within each breakout group.

Part 1: Discussion of the High-Level Protection Goals of APEC Economies

To prepare for part 1, participants should be familiar with their economy's high-level environmental protection goals and the regulatory framework for products of modern biotechnology in their respective economy. Protection goals identify environmental components that are valued and should be protected. These may include, for example, components of the physical environment such as air and water quality, as well as plants and animals which are endangered or otherwise valued, diversity of species, and sustainability of ecosystems services, among others. Protection goals are usually identified in laws or policy documents and further refined in regulations. A regulatory framework can be thought of as the combination of laws, policies, and regulations, together with the responsible implementing agency and any guidance provided to applicants or the regulated community.

Part 2: Discussion of the Elements of the Administrative Process Followed in the Regulation of Products of Modern Biotechnology in Agriculture

To prepare for part 2, participants should be familiar with the regulatory framework in their respective economy. The details are not important, but a general idea will be useful for the discussion. Some economies, such as the United States and Canada, use existing laws to regulate the products of modern biotechnology, while other economies, including Australia and the Republic of Korea, have enacted new laws or acts. Accordingly, the regulatory frameworks are implemented under specific laws, and government agencies are tasked with overseeing the regulation of these products. There may be full-time risk assessors who are tasked with evaluating the safety of the products of modern biotechnology, or the government agency may rely on the opinion of expert committees or scientific advisory panels.

Whatever may be the process in an economy, for this part of the exercise, it will be useful for participants to identify specific regulations or guidelines, implementing agencies, and how they work.

Part 3: Discussion of the Value and Forms of Regulatory Cooperation

This part of the exercise will involve discussions around the similarities in the way various APEC economies regulate products of agricultural biotechnology and the value of cooperation to benefit from these products. This discussion will be guided by Mentimeter and will focus on the benefits of regulatory cooperation, the different mechanisms, and barriers to such cooperation.

APEC High Level Policy Dialogue on Agricultural Biotechnology Meeting (HLPDAB)
Seattle, Washington, United States
Seattle Convention Center, Summit Building – Terrace
August 1, 2023: 8.00AM-12.00 PM. PDT (GMT-7)
Meeting Agenda

Schedule	Time	Agenda
8:00-8:30	30 mins	**Check In / Login and System Checks** • Virtual delegates to login using the assigned usernames [Economy/Surname] • Check of audio and visual connections
8:30-9:00	30 mins	**Session 1: Opening Session** • Welcome by HLPDAB Chair, Jennifer Lappin, United States • Welcome by HLPDAB Deputy Chair, Dr. Dina Lida Gutiérrez Reynoso, Peru • Introduction of the heads of delegation, HLPDAB Chair • Adoption of the meeting agenda, HLPDAB Chair • Remarks by United States Under Secretary, Alexis Taylor
9:00-9:15	15 mins	**Session 2: Progress of HLPDAB**
		• Outcome report HLPDAB 2022, Thailand, HLPDAB Chair 2022 • Summary of APEC 2023 activities, United States
9:15-9:30	20 mins	**Break**
9:35-10:00	25 mins	**Session 2: Progress of HLPDAB (cont.)**
		• APEC member economies are invited to make brief updates on agriculture biotechnology issue/policies in their economies and share biotech projects related to the HLPDAB
10:00-10:40	40 mins	**Session 3: Panel Discussion on "Linking Agricultural Biotechnology, Climate Mitigation and Adaptation to the**

Schedule	Time	Agenda
		Advancement of Food Security and Supply Chain Resiliency”
		• Presentations from the Philippines, the United States, and Vietnam • Open discussion
10:40-11:00	20 mins	**Session 4: Review of Policy Approaches Document Outline**
		• Progress report on the development of the draft Policy Approaches Document by the HLPDAB, United States • Open discussion
11:00-11:15	15 mins	**Session 5: APEC Project Management Updates**
		• APEC Secretariat update of HLPDAB projects and follow up issues
11:15-closing	15 mins	**Session 6: Closing Session**
		• Summary of meeting discussions, final deliberations by HLPDAB Chair • Closing remarks by HLPDAB Deputy Chair Dr. Dina Lida Gutiérrez Reynoso

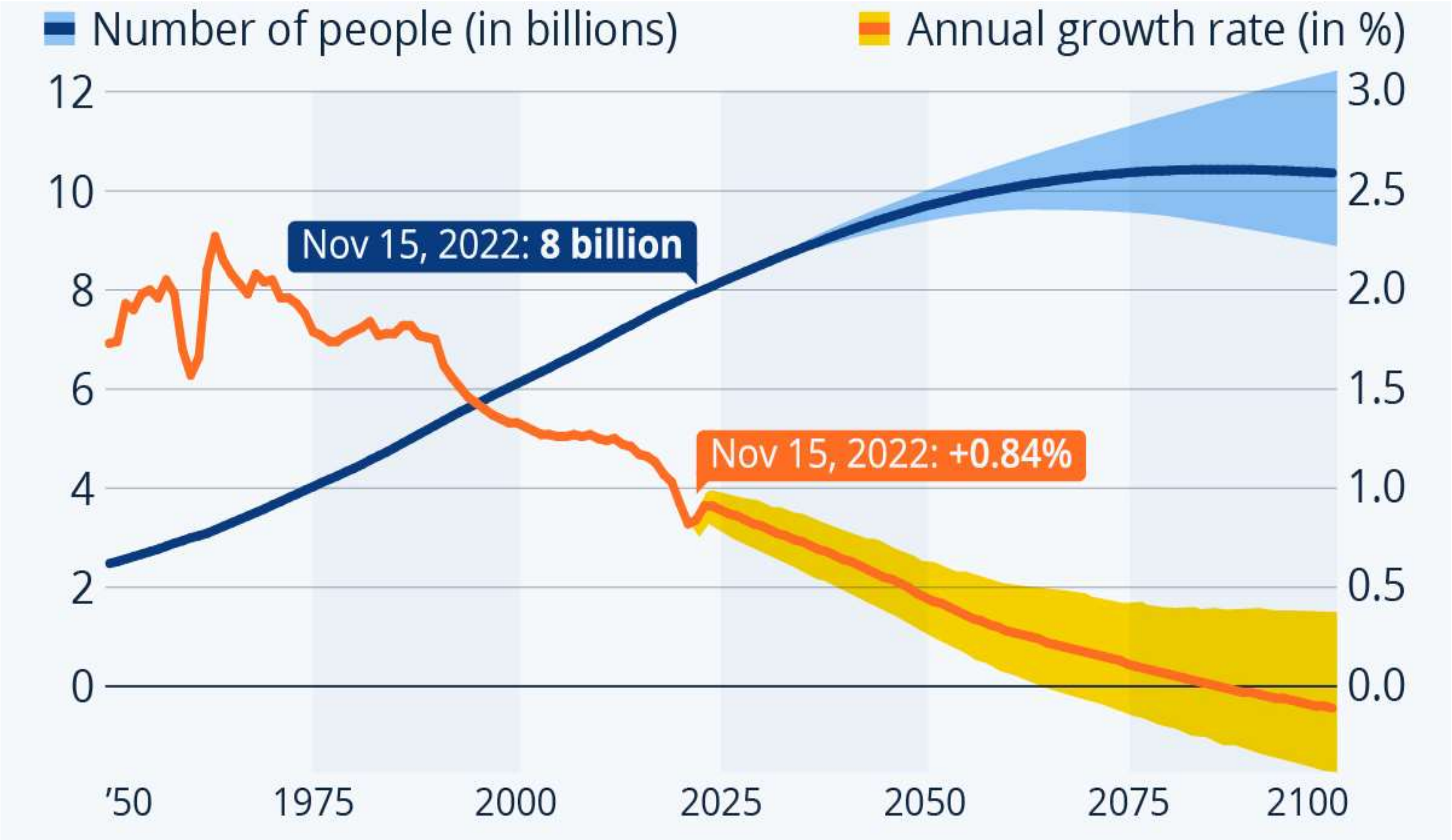
Linking Agricultural Biotechnology, Climate Mitigation and Adaptation to the Advancement of Food Security and Supply Chain Resiliency

CLARO N. MINGALA, PhD
Philippines
2023 APEC HLPDAB Plenary Dialogue
01 August 2023

Asia-Pacific Economic Cooperation

APEC 2023 UNITED STATES

The Global Challenge: Feeding the World Sustainably by 2050



Source: https://www.statista.com/chart/28744/world-population-growth-timeline-and-forecast/

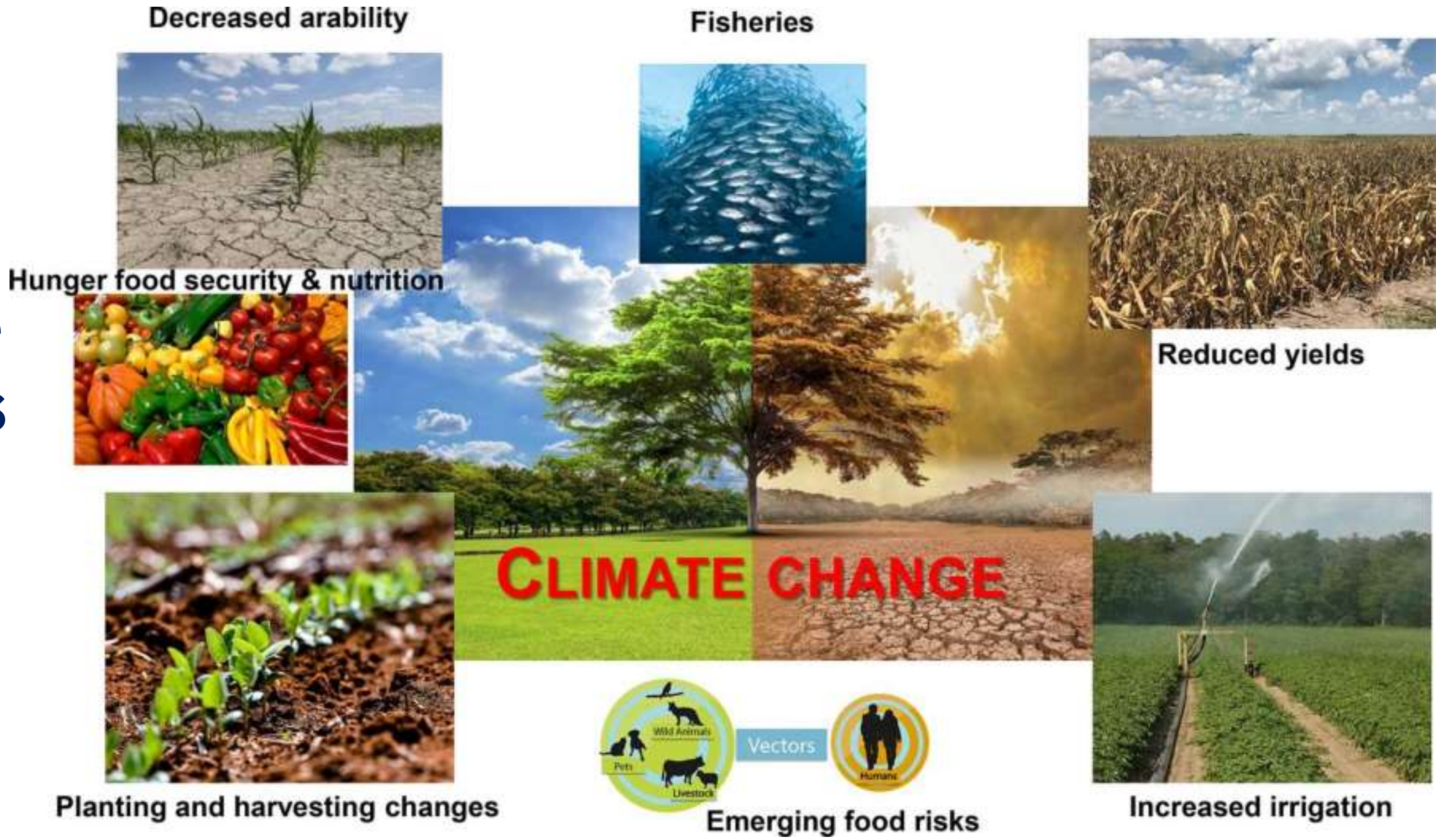
Increase Food Production Without Expanding Agricultural Land

Reduce Growth In Demand for Food and Other Agricultural Products

Reduce Greenhouse Gas Emissions from Agricultural Production

APEC Asia-Pacific Economic Cooperation

Impact of Climate Change on Food Systems



Asia-Pacific Economic Cooperation

Source: https://www.sciencedirect.com/science/article/pii/S0963996920302817

The Role of Technological Innovation

Contribution of Biotech Crops to Food Security, Sustainability, and Climate Change

Biotechnology Development in the Philippines: Part of Agri- Modernization

- Biotechnology is the Philippine government's response in the call for **sustainable agricultural modernization**

Research for Development

- Crop varieties that are high-yielding, early-maturing, sturdier against pests and diseases, climate-resilient, more nutritious, and cost-efficient
- Breeds/strains of livestock and fisheries focused on increased production, climate resiliency (heat-tolerance), resistant to diseases
- Vaccine development and disease detection protocols for emerging diseases in crop, livestock, and fisheries

Biotechnology Development in the Philippines: Part of Agri- Modernization

Strengthening Capacities

- Manpower development for research for development, regulators, and policymakers
- Facility upgrading to manage products of biotechnology/ modern innovations

Policy Research

- Policy studies in support to the advancement of biotechnology in r4d, management of biotech products

Advocacy (Strategic Communication)

- Technology promotion
- Policy outreach activities
- General advocacy

APEC Asia-Pacific Economic Cooperation

Philippine Initiatives on Climate Mitigation and Adaptation through Biotechnology

Reduction of Greenhouse Gas Emissions from Agricultural Production

Source of GHGs	Target	Technology
N_2O emission from annually cultivated soils (16.2%)	25% reduction in total N2O emission (Total annually cultivated area = 8.017 Million hectares)	Cropland management + precision agriculture + **Biotech crops**

Additional Measures to Reduce Carbon Footprint of Agricultural Products

(Reduction of GHG emission per unit produce)

Technology
Use of pest-resistant crops
Use of biocontrol agents
Microbial inoculation to reduce inorganic fertilizer requirement
Use of fast-growing climate resilient crops/livestock/aquaculture species

Asia-Pacific Economic Cooperation

Source: DA-CRAO, 2022

GM Crops Approved for Commercial Propagation

Golden Rice / Malusog Rice

Bt Eggplant

Asia-Pacific Economic Cooperation

First Gene-Edited Crop approved in the Philippines

Department of Agriculture
BUREAU OF PLANT INDUSTRY
692 San Andres Street, Malate, Manila, Philippines
Email Address: info@buplant.da.gov.ph
Tel. No.: (02) 8525-7909, (02) 8525-2987 | Website: buplant.da.gov.ph

JAS-ANZ

CERTIFICATE OF NON-COVERAGE FROM JDC NO.1 S2021
BPI-PBI-CNC No. 23-001

This is to certify that the gene-edited banana plant ***(Musa acuminata)*** with reduced browning trait obtained through CRISPR/Cas9 and developed by **TROPIC BIOSCIENCES** with address at **NORWICH RESEARCH PARK, INNOVATION CENTRE, NR4 7GJ** is officially determined as **NON-GENETICALLY MODIFIED ORGANISM** and does not fall under the coverage of the DOST-DA-DENR-DOH-DILG Joint Department Circular No.1 s2021 (JDC No.1 s2021) based on the scientific evidence(s) presented by the Product Developer.

This decision is based on the conducted Technical Consultation for Evaluation and Determination procedure described in DA Memorandum Circular No. 08 s2022 "Rules and Regulation to Evaluate and Determine when Products of Plant Breeding Innovations (PBIs) are Covered under the DOST-DA-DENR-DOH-DILG Joint Department Circular No.1 s2021."

This certificate does not exempt the product developer's compliance with other relevant regulations of the Department of Agriculture and other government agencies such as, but not limited to, those involving plant quarantine, pest risk analysis, varietal registration, plant variety protection and crop-specific standards and programs, where warranted.

This certification shall have no expiration and shall remain valid hereafter unless revoked through the process of appeal.

The product developer shall immediately notify the BPI in writing of any issues or new information that may affect this decision.

Issued on this 15th day of March year 2023 at the Bureau of Plant Industry, San Andres St., Malate, Manila.

GERALD GLENN F. PANGANIBAN, Ph.D.
Director
Bureau of Plant Industry

Source: http://biotech.da.gov.ph/upload/Certificate_of_NonCoverage.pdf

Source: https://www.isaaa.org/kc/cropbiotechupdate/article/default.asp?ID=20135

The first gene-edited product to go through the Philippines' gene editing regulatory process.

Can potentially reduce food waste and CO_2 emissions by more than 25%, as over 60% of exported bananas go to waste before reaching the consumer.

Asia-Pacific Economic Cooperation

Ways Forward

To ensure an enabling environment for biotechnology undertakings:

1. Implementation of a clear, predictable, science-based, and risk-proportionate regulations

2. Establishment of an adaptive and responsive policies that can adapt to rapid advancements and emerging technologies

3. Forster international cooperation and harmonization of regulatory standards to streamline global biotech development and facilitate cross-border research and trade

4. Adequate/sufficient funding for biotech, research, and innovation

5. Education and Public Awareness

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附件8

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Products and Approaches to Support Climate Mitigation and Adaptation and Food Security

Adam Cornish
United States of America

Agenda Item 3 – Linking Agricultural Biotechnology, Climate Mitigation and Adaptation to the Advancement of Food Security and Supply Chain Resiliency

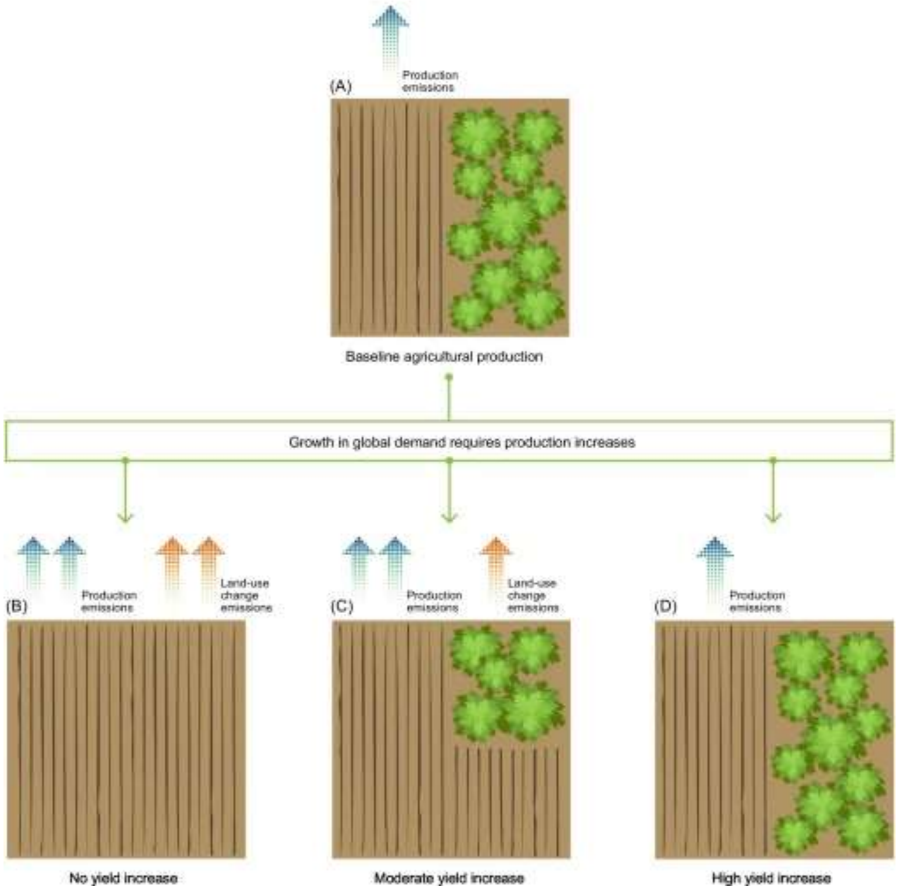
1 August 2023

Advancing Free Trade for Asia-Pacific Prosperity

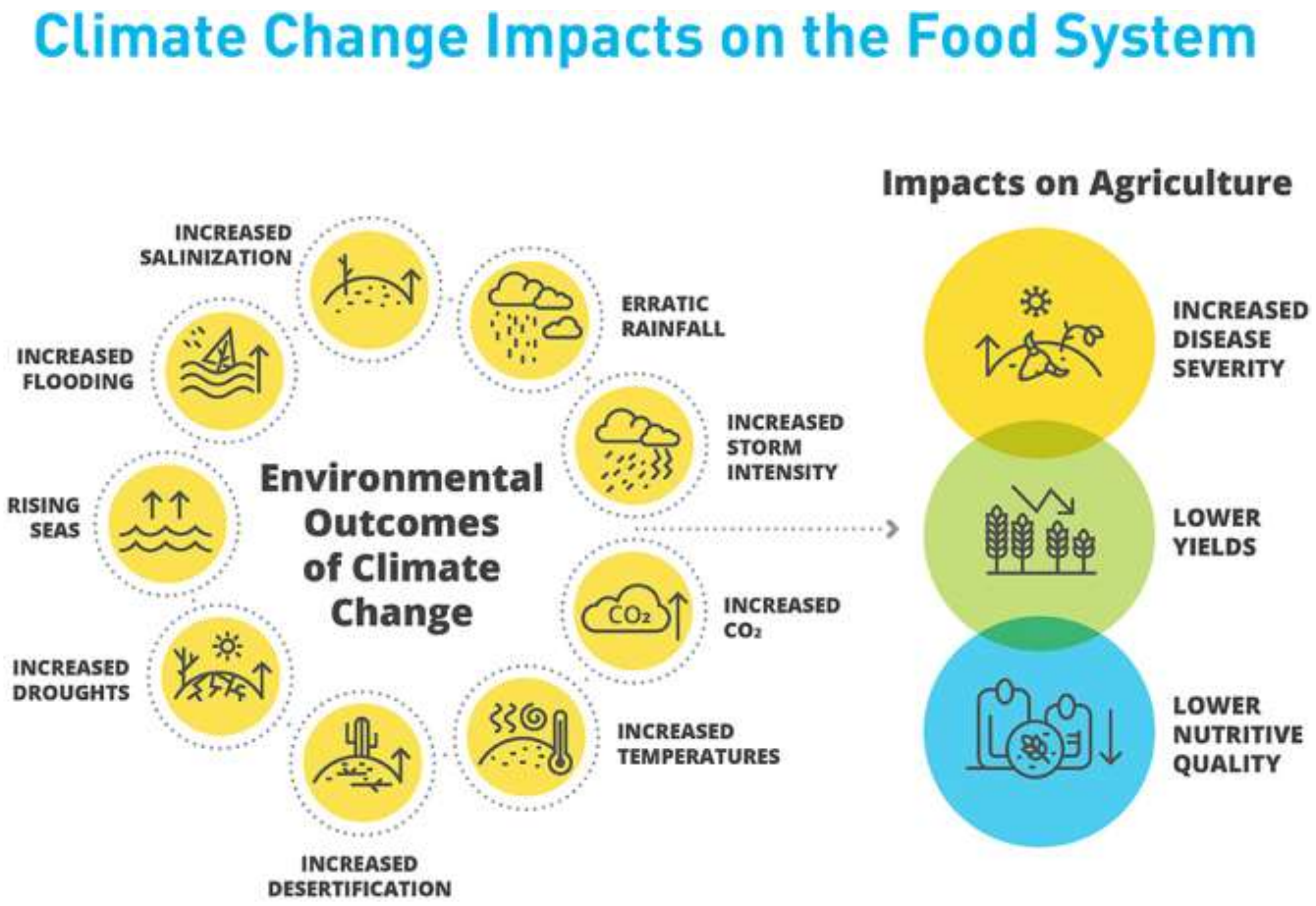
APEC 2023 UNITED STATES SEATTLE

Our APEC Neighborhood – We Are All Connected

Climate Impacts in APEC

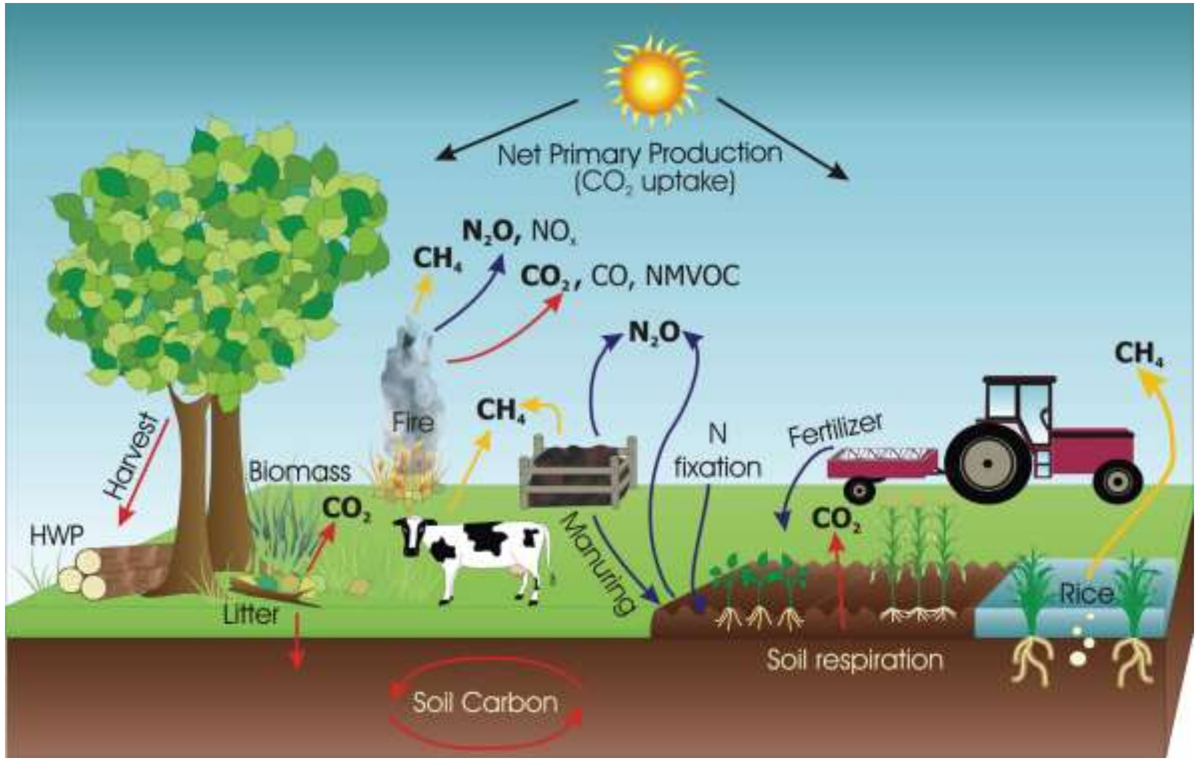


Kovak et al. 2022 - Trends in Plant Science

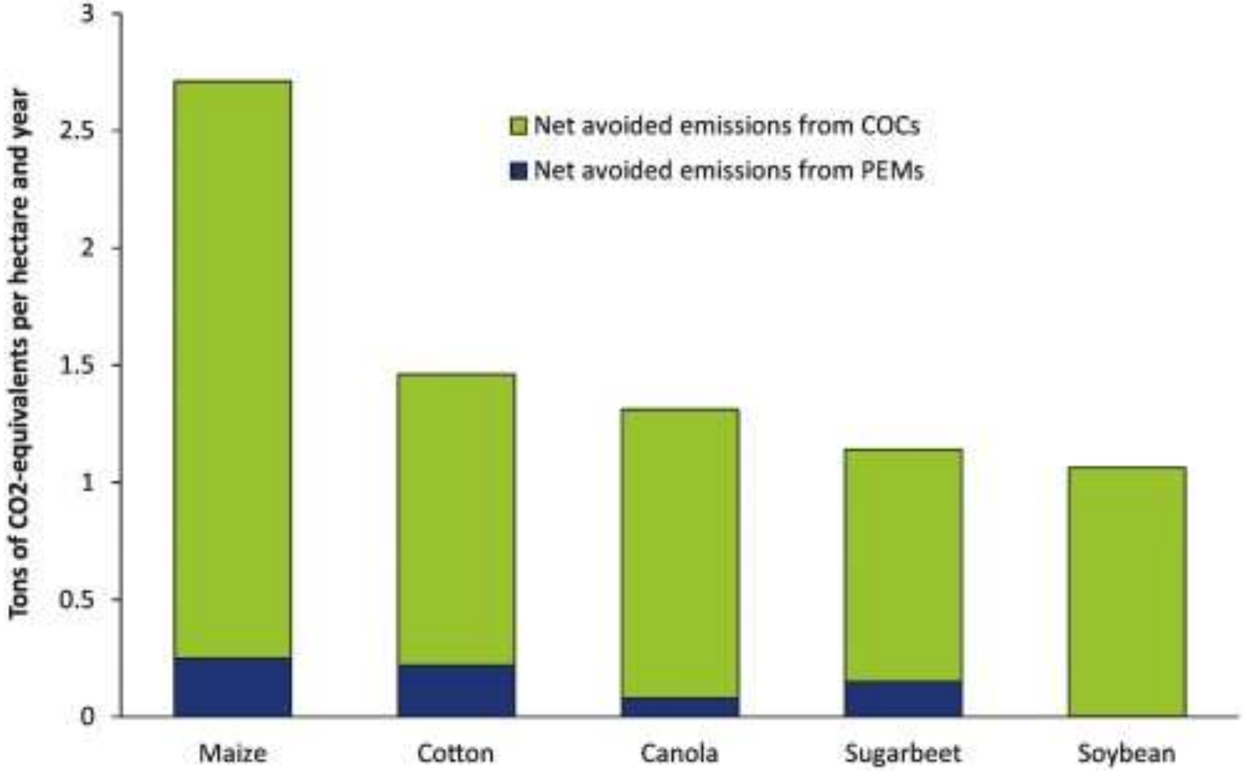


Karavolias et al. 2021 Fronteirs in Sustainable Food Systems

Potential for Mitigating Greenhouse Gases

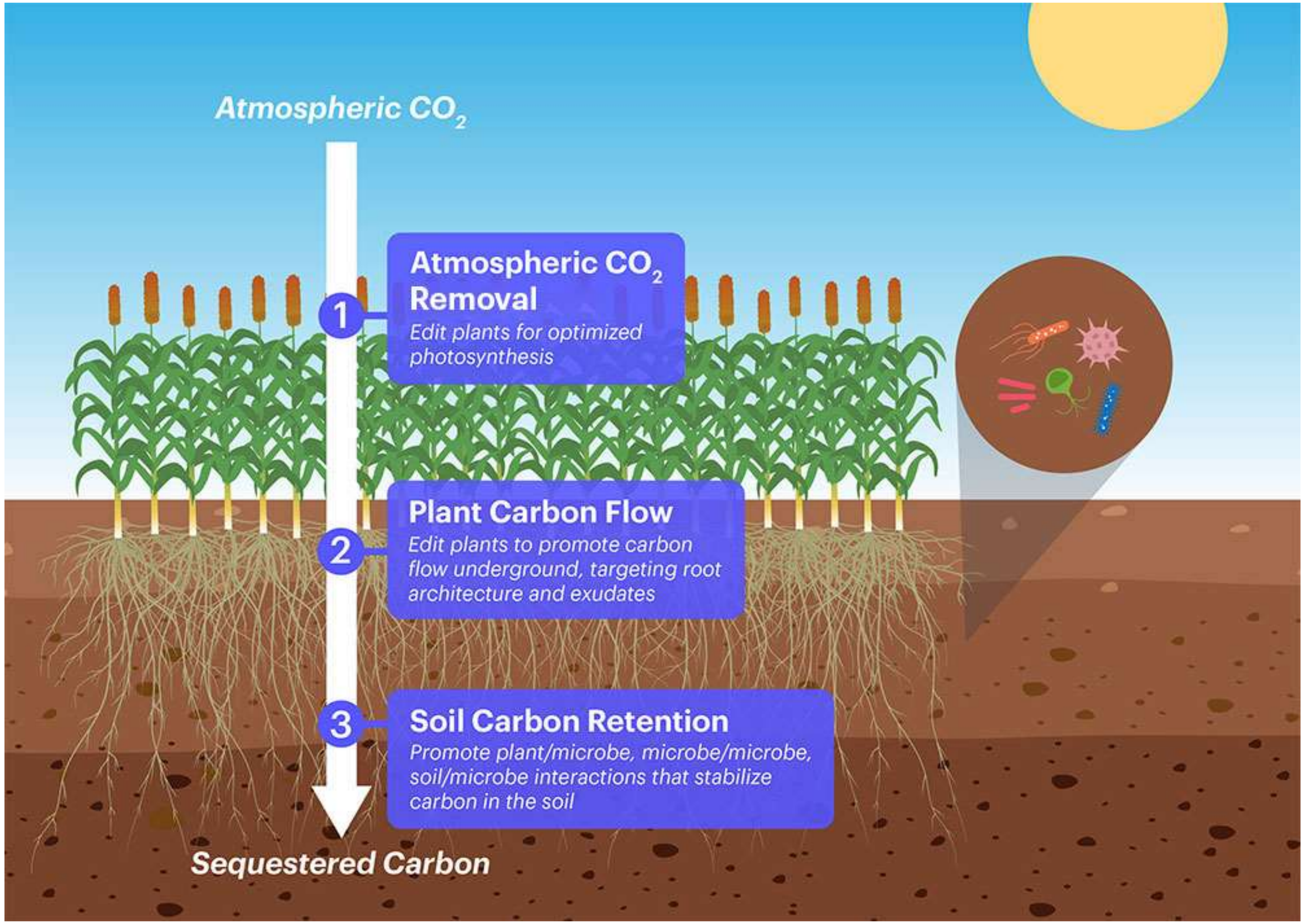


https://www.ecosystemmarketplace.com/articles/14979/

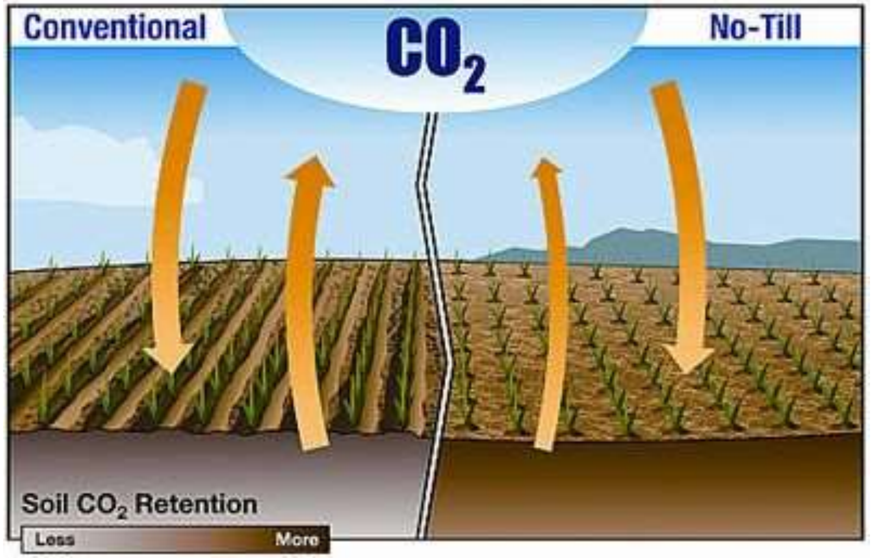


Kovak et al. 2022 – Trends in Plant Science

Sequestering Carbon



https://innovativegenomics.org/news/crispr-carbon-removal/



https://science.howstuffworks.com/environmental/green-science/conservation-agriculture.htm#pt1

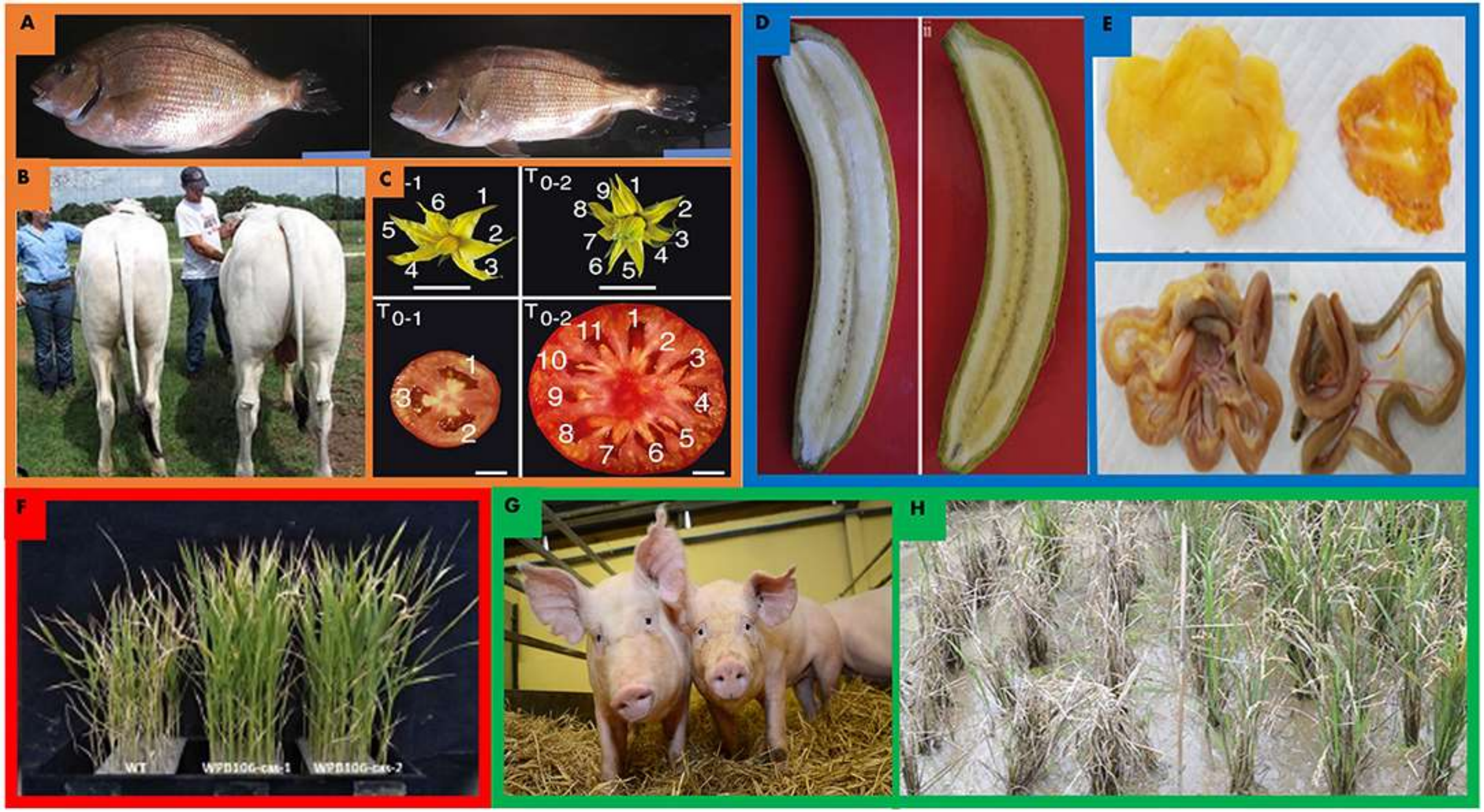
Adapting to Climate Change

https://futurecow.com/genetics-sinba/

Dar et al. 2020 - Sustainability

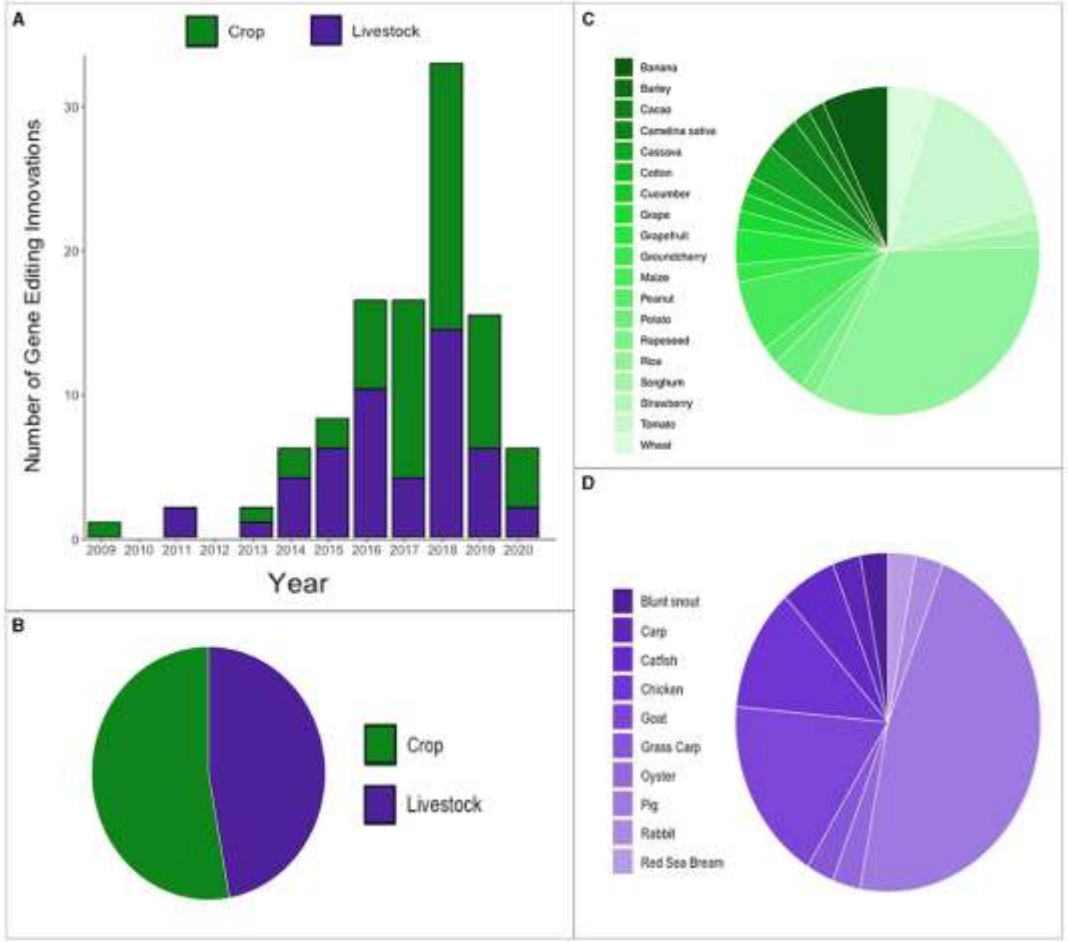
https://www.science.org/content/article/modified-plants-may-need-less-nitrogen

Ensuring Food Security

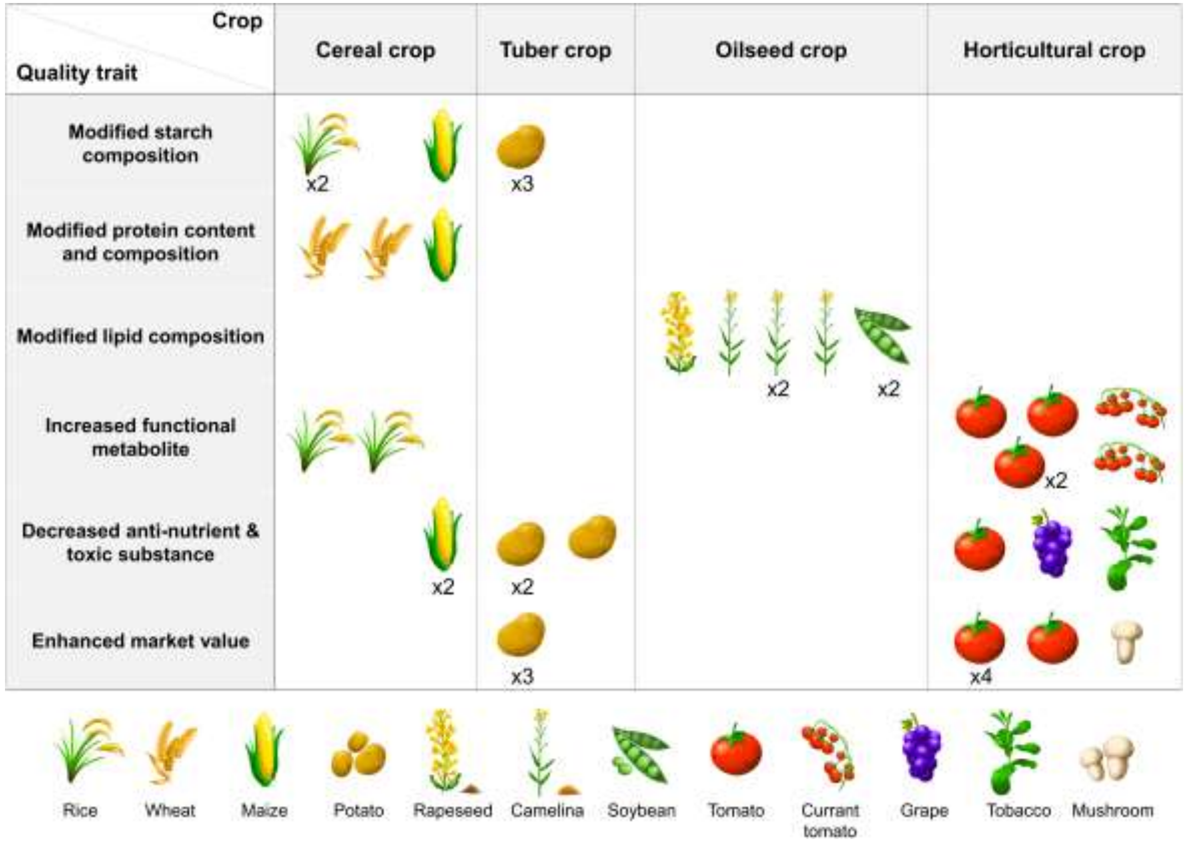


Karavolias et al. 2021- Frontiers in Sustainable Food Systems

Genome Editing – Enabling the Future



Karavolias et al. 2021 - Frontiers in Sustainable Food Systems



Ku et al. 2020 - Frontiers in Plant Science

Panel Discussion
on
Linking Agricultural Biotechnology, Climate Mitigation and Adaptation to the Advancement of Food Security and Supply Chain Resiliency

Nguyen T. T. Thuy PhD.
Department of Science, Technology and Environment
Ministry of Agriculture and Rural development, Viet Nam

Asia-Pacific Economic Cooperation

APEC 2023 UNITED STATES

Issues addressed

- Economies worldwide are facing food crises and due to conflict and natural disasters;
- High cereal prices, less rural people (who feed the cities); becoming major emitters of greenhouse gases;
- Impacts of climate change on food security are global, regional and local. It will affect agricultural food systems worldwide, including exporters and importers;
- Many impacts, such as increased land degradation and soil erosion, changes in water availability, biodiversity loss, more frequent and more intense pest and disease outbreaks as well as natural disasters, especially Covid-19 pandemic need to be addressed across sectors;
- Climate change will increase food shortages and distribution of disease vectors, greater health and life risks of population.

Issues (cont…)

- Climate change will result in additional food insecurities;
- Communities must protect themselves against the possibility of food-shortage emergencies; appropriate use of resources to preserve livelihoods, lives and property;
- It is imperative to identify and institutionalize mechanisms that enable to cope with climate change impacts;
- This requires collaborative thinking and responses to the issues generated by the interaction of food security, climate change and sustainable development nexus;
- Anticipatory adaptation, climate mitigation and technology innovation should attempt to improve resilience to future and uncertain impacts.

Agricultural Biotechnology: A Vital Tool to Address Food Security and Climate Change

- Modern breeding techniques, genetic engineering and genome editing will provide new varieties with designable trait such as drought, disease, salt tolerance; nutrient use; yield and self life increase; water use efficiency etc.;
- Farmers can adopt an integrated set of tools, including biotech crops, that are climate resilient and can better withstand various stresses, including drought, heat and flooding;
- In addition, researchers are designing many traits with the goal of reducing greenhouse gas emissions and conserving water and land, while increasing yields;
- Regulatory environments that allow these products to come to the market and public acceptance are also essential to our efforts in Feed the Future.

Please note: *Material provide in this slide is compiled from post written by Dr. Aruna Kilaru and Dr. Chris Peterson, USDA Foreign Agricultural Service. For more in formation please visit https://agrilinks.org/post/agricultural-biotechnology-vital-tool-address-food-security-and-climate-change*

Viet Nam identifies

- Agriculture as the backbone of the economy, contributing to improving the people's livelihoods, maintaining stability; ensuring food security;
- Agriculture is ensuring livelihoods for over 60% of the population living in rural areas; accounting for 30% of the national labor force and 12% of GDP. From one of the underdeveloped economies in agriculture, had to import food, Viet Nam is now becoming one of the world's leading exporters of agricultural products;
- Biotechnology development is an important driving force to carry out the process of renewing the growth model, restructuring the agriculture, ensuring food security and environmental sustainability;
- Unifying awareness on development and application of biotechnology in Agriculture;
- Focusing on developing and effectively applying biotechnology in Agricultural production;
- Building human resources in agi-biotechnology, increasing investment in facilities to meet the requirements of agri-biotechnology research, development and application, especially in the form of Public - Private Partnership (PPP);
- Promoting international cooperation in agri-biotechnology.

Asia-Pacific
Economic Cooperation

2023/SOM3/HLPDAB/019
Agenda Item: IV

High Level Policy Dialogue on Agricultural Biotechnology Policy Approaches Document Outline

Purpose: Consideration
Submitted by: HLPDAB Chair

High Level Policy Dialogue on Agricultural Biotechnology
Seattle, United States
1 August 2023

APEC HIGH-LEVEL POLICY DIALOGUE ON AGRICULTURAL BIOTECHNOLOGY
POLICY APPROACHES DOCUMENT OUTLINE
Final: 16 July 2023

I. Introduction

- This Outline provides the structure for an "Agricultural Biotech Regulatory Cooperation and Alignment" Policy Approaches Document (PAD), the goal of which is to provide tools and resources that will aid APEC member economies in developing, adopting, and implementing policies and best practices that reduce the regulatory burden on products of agricultural biotechnology, resulting in increased partnership and investment both within and between the economies, while also recognizing each economy's unique needs. In addition, the PAD recognizes that there may be challenges to moving toward greater biotech regulatory cooperation and alignment in APEC economies, e.g., resource constraints, political will, and legal infrastructure. However, considering the growing importance of agricultural biotechnologies in the APEC economies, the PAD aims to provide a catalyst for dialogue and a collection point for the universe of approaches economies can draw upon as they scan the horizon, seeking ways to meet these challenges in order to innovate and meet future productivity, sustainability and food security goals.
- The PAD will take into consideration the feedback received via an APEC member survey conducted in June 2023. Based on that feedback, member economies are most eager for:
  - Practical approaches to regulatory cooperation and alignment
  - Capacity building tools
  - Communications strategies

II. Potential Benefits of Greater Cooperation and Alignment of Agricultural Biotech Policies and Regulations in APEC Economies

- APEC member economies concur that many benefits can be realized from greater regulatory cooperation and alignment regarding agricultural biotech products. Among those are economic and innovation benefits, such as greater resource efficiencies and increased investment in research and development that can contribute to overall economic development. Cooperation and alignment may also reduce barriers to trade in agricultural biotech products, enhancing global supply chain resilience and food security across APEC economies, and promoting global best practices and standards. Moreover, the sharing of expertise can increase risk assessment and risk management capacity among in APEC economies. Benefits to consumers could include improved transparency in the regulatory process and consumer protection via enhanced regulatory alignment, while increased adoption of crops across APEC economies can contribute to greater food security, economic prosperity, adaptation to and mitigation of climate change effects, and environmental sustainability. The PAD could highlight the potential benefits as they relate to various groups, e.g.,

  - Farmer
  - Consumers
  - Developers
  - Traders
  - Regulators

III. Approaches to Greater Cooperation and Alignment of Agricultural Biotech Policies and Regulations in APEC Economies and Capacity Building Tools

- The approaches that economies can use to enhancing regulatory cooperation and alignment run across a wide spectrum. This section will explore many of the options that economies may wish to consider and provide a snapshot of tools and resources that are already available to enhance cooperation and alignment.
- Agricultural biotech regulatory cooperation and alignment many take many forms. Below is a range of options to consider.
  - Information sharing
    - Exchange of decision documents
    - Scientific cooperation, e.g., joint research projects and workshops
    - Data portability (e.g., development of a standardized platform for data sharing)
    - Centralized database for regulatory approaches, dossiers, risk assessments, authorizations
    - Best practices for risk assessment
    - Best practices for risk management
    - Increased communication
  - Consistent Requirements, Disclosures, and Assessments
    - Consistent and aligned data requirements
    - Centralized dossier template
    - Consistent risk assessment standards and practices
    - LLP Policies and or approaches
  - Sharing Risk Assessment and Regulatory Approval Resources
    - Mutual recognition of risk assessments
    - Approval reciprocity
    - Recognition of authorizations made by another economy

- Many resources and tools are readily available for APEC economies that wish to utilize to build their capacity. These include online databases, group and custom-made trainings, exchange programs for risk assessors and competent authorities. A short list of available resources and tools is provided in the Appendix to this Outline.

IV. Case Studies – Best Practices and Lessons Learned

- The following case studies on biotech 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
    - WHO Biosafety Risk Assessment (sharing templates)
    - Global LLP Initiative
  - Alignment of Regulatory Requirements, Disclosures and Assessments
  - Vietnam's expedited regulatory approval of imported products for direct use
  - Sharing Risk Assessment and Regulatory Approval Resources
    - Health Canada – Australia/New Zealand (FSANZ)
    - Argentina-Brazil (MOU on mutual recognition of genome-edited traits)
    - Mercosur (LLP Agreement – reduce trade disruptions)
    - Paraguay (recognition of approval status in other countries)
  - Case Studies from non-ag biotech
    - Medical device industry
    - MRL harmonization initiatives

V. Future Direction

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

Appendix -- Resource Documents and Links

- Overview of key ag-biotech regulatory differences across APEC economies: "Update of the APEC Baseline Study..." for the APEC HLPDAB November 2018
- Online Databases
  - FAO GM Foods Platform
  - Biosafety Clearing House
- Global LLP Initiative

- WHO Biosafety Risk Assessment
- Global Farmers Network
- Group Trainings
    - Michigan State University
        - Ag Biotech, Biosafety and Technology Transfer
        - Plant Breeding 2 Fight Hunger: An Online Certificate Course
        - Science & Technology Communication Course
    - International Service for the Acquisition of Agri-biotech Applications (ISAAA)
- Individualized Trainings via the Inter-American Institute for Cooperation on Agriculture