出國報告(出國類別:考察)

112年考察澳大利亞輸入食品邊境查驗政策及管理實務

服務機關：衛生福利部食品藥物管理署
姓名職稱：董靜馨簡任秘書、何佳樺視察
派赴國家：澳大利亞
出國期間：112年10月15日至112年10月21日
報告時間：113年1月16日

摘要

為瞭解並搜集先進國家對於輸入食品邊境查驗之管理實務，精進我國食品輸入查驗管理及實務作法，112年度擇澳大利亞進行考察輸入食品邊境查驗政策及管理實務。本次參訪行程包含澳大利亞農業、漁業及林業部(Department of Agriculture, Fisheries and Forestry, DAFF)及其所屬雪梨地區辦事處(Sydney Regional Office)、雪梨郵務中心、雪梨機場旅客查驗站，交流有關進口食品之管理及輸入查驗作業等。該國對於輸入食品之檢疫及衛生安全皆由同一機關 DAFF 分別依據2015年生物安全法(Biosecurity Act 2015)及1992年進口食品管理法(Imported Food Control Act1992)執行，所有食品需先通過生物安全檢查，再進行食品衛生安全檢驗。

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英文縮寫-英文-中文對照表

英文縮寫	英文	中文
AIMS	Agriculture Import Management System	農產品進口管理系統
BICON	Biosecurity Import Conditions system	生物安全進口條件系統
e-Cert	Electronic certificate	電子證書
COLS	Cargo Online Lodgement System	貨物線上申報系統
COVID-19	Coronavirus disease 2019	嚴重特殊傳染性肺炎
DAFF	Department of Agriculture, Fisheries and Forestry	澳大利亞農業、漁業及林業部
FCC	Food Control Certificate	食品檢驗證明
FICA	Food Import Compliance Agreement	食品進口合規同意
FIDs	Full Import Declarations	進口食品申報
FSANZ	Food Standards Australia New Zealand	澳洲紐西蘭食品標準局
G2G	Government to government	政府對政府
HS Code	Harmonized System Code	國際商品統一分類代碼
ICS	Integrated Cargo System	報關系統
IFIA	Imported Food Inspection Advice	進口食品查驗建議
eIFIR	Imported Food Inspection Report	進口食品查驗報告
IFIS	Imported Food Inspection Scheme	進口食品查驗計劃
MPS	Mail and Passengers System	郵包及旅客系統

壹、 目的

為瞭解並搜集各國對於輸入食品邊境查驗之管理，本次擇定與我國交流密切之澳大利亞作為參訪對象。自2011年起我國與澳洲簽訂乳製品 MOU，其乳製品輸臺的查驗率為2%，近期又與澳洲有電子證書的介接，澳洲每年輸臺的食品量亦占台灣總量的第3名，且其合格率相當高。雖然澳洲主要以出口為主，但其進口貿易總額是逐年在增加的，進口品項主要為加工食品、其次為水產品、蔬果及乳製品，與我國類似，其邊境管理制度、法規與執行以及如何拓展電子證書之交換，值得我國學習。

貳、 行程及成員

一、 行程安排

日期	行程	地點
112年10月17日	1. 參訪倉儲地輸入食品查驗-美國葡萄蟲害檢查 2. 簡報輸入食品文件審查	雪梨區域辦事處 (Sydney Regional Office) 雪梨機場附近貨櫃倉儲地
112年10月18日	1. 參訪雪梨郵包生物安全查驗 2. 參訪雪梨機場入境旅客攜帶物品生物安全檢查	雪梨郵務中心 雪梨國際機場
112年10月19日	1. 簡報澳洲生物安全管理 2. 簡報台灣輸入食品管理 3. 簡報澳洲 e-CERT 4. 簡報澳洲食品安全風險評估 5. 簡報澳洲輸入食品查驗	坎培拉農業部辦公室

二、 我方成員名單

代表機關	職稱	姓名
衛生福利部 食品藥物管理署	簡任秘書	董靜馨
	視察	何佳樺

三、 澳方接待成員名單及隨團人員

代表機關	職稱	姓名
澳大利亞農業、漁業及林業部 (DAFF)	北亞處處長	Mr. James Strachan
	北亞處副處長	Ms. Lauren Cha
	北亞處資深官員	Ms. Rosemary Reilly
	進口食品處處長	Ms. Tania Martin
	進口食品處副處長	Ms. Jenny Ruthenberg
	政策評估處處長	Mr. Mark Sobey
	電子證書貿易處副處長	Ms. Corrina Linton-Smith
	獸醫師	Dr. Corrie Croton
澳洲紐西蘭食品標準局 (FSANZ)	國際策略官員	Ms. Louise Cook
	聯絡官員	Ms. Sabrina George
雪梨辦事處 (Sydney Regional Office)	北亞處副處長	Ms. Lauren Cha
	北亞處資深官員	Ms. Rosemary Reilly
雪梨郵務中心	北亞處副處長	Ms. Lauren Cha
	北亞處資深官員	Ms. Rosemary Reilly
雪梨國際機場	北亞處副處長	Ms. Lauren Cha
	北亞處資深官員	Ms. Rosemary Reilly
駐澳大利亞代表處經濟組	組長	郭妙英
	秘書	許婕安

參、 考察紀要

一、 參訪澳大利亞農業、漁業及林業部

本署代表團於112年10月19日至位於澳大利亞坎培拉之澳大利亞農業、漁業及林業部(Department of Agriculture, Fisheries and Forestry, DAFF)參訪，於其會議室進行兩國邊境查驗管理制度之交流(圖一)，澳方詳細介紹該國的管理制度，亦邀請澳洲紐西蘭食品標準局(Food Standards Australia New Zealand, FSANZ)一同出席，並針對該局如何進行風險管理作一簡報，本署亦向澳方報告我國的邊境查驗管理制度，並分享先前參訪其他國家的心得，雙方交流愉快(圖二)，本署代表團返國後參考 DAFF 官方網站之資訊，綜整澳大利亞之輸入食品邊境查驗管理制度。

圖一、於澳洲 DAFF 會議室雙方進行簡報交流。

圖二、與 DAFF、FSANZ 官員及駐澳大利亞代表處經濟組合影留念。

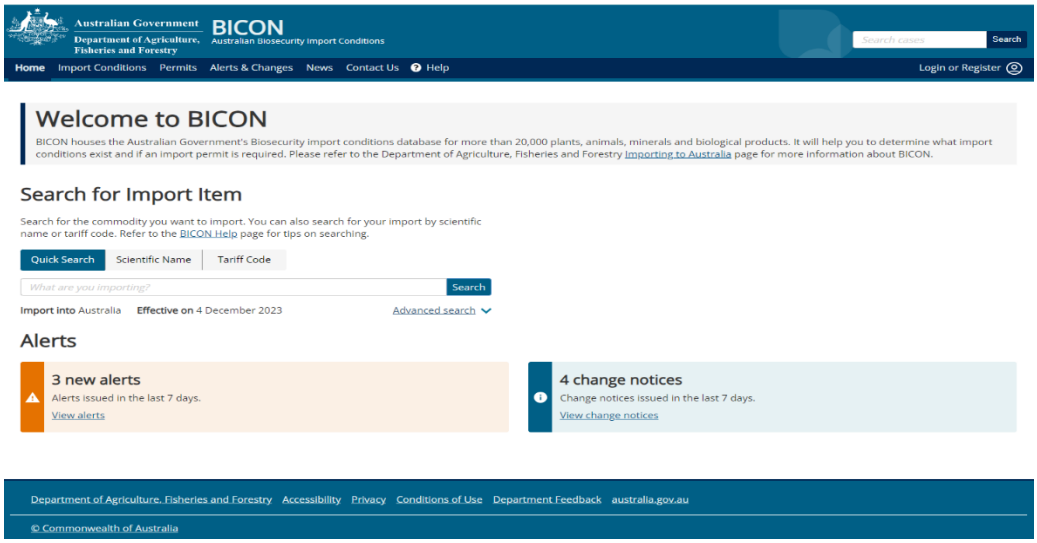
(一) 輸入食品查驗制度

澳洲政府是由六個州政府及兩個領地政府所組成的聯邦體系，共分成三個政府層級，分別為澳洲聯邦政府，州及領地政府及地方政府。「澳大利亞農業、漁業及林業部(Department of Agriculture, Fisheries and Forestry, DAFF)」屬於澳洲聯邦政府，負責加強農業、漁業和林業，創造新的及維持現有的農業出口機會，並管理澳洲的生物安全風險，以保護其價值數十億美元的農業產業。在澳洲輸入食品邊境查驗包括生物安全(Biosecurity)及食品安全(Food safety)，皆由同一機關 DAFF 執行，生物安全即為動植物檢疫，食品安全即食品衛生安全查驗，澳洲政府相當重視生物安全，所有輸入澳洲的產品(包含二手用機具)皆需通過嚴密的生物安全檢查，始進行食品安全檢查。

1. 生物安全(Biosecurity)

澳洲政府依據2015年生物安全法(Biosecurity Act 2015)及其子法規 Biosecurity (Conditionally Non-Prohibited Goods) Determination 2021 及 Biosecurity Regulation 2016執行各項生物安全法規，範圍包含輸入前、輸入時及輸入後。輸入前由科學家先進行風險分析，訂定各項產品輸入的

條件，核准的國家，並將資訊公布於 Biosecurity Import Conditions system (BICON 系統)(圖三)，此系統可查詢超過20,000植物、動物、礦物和生物產品，進口商可以查詢此系統，得知產品是否准許輸入、輸入時所需的條件、是否需要事先申請「進口准許(Import permit)」，以決定產品是否要輸入澳洲，進口商如果想要獲得最新相關輸入規定，BICON 系統亦提供訂閱服務。另有超過80%以上的產品皆須事先申請「進口准許(Import permit)」，進口商可以使用 BICON 系統申請、追蹤及管理，不同進口商不同產品皆須申請，申請時間約需20個工作日，有效期限為2年，此可加速產品到港後申請輸入之審查時效。此「進口准許(Import permit)」制度係僅適用於生物安全，非食品安全之制度，而 BICON 系統也僅供查詢生物安全相關規定，澳洲政府未來將規劃把食品安全相關規定也納入此系統。無論貨物是經由船運、空運、旅客攜帶或郵寄至澳洲，澳洲政府會先確認是否符合進口條件及具備相關的必要文件，如果皆符合才會再針對貨物及其包裝進行查驗，確認無禁止輸入的植物、泥土、昆蟲及疾病，如果澳洲政府發現有疑慮，會採取保留貨物到這個風險可以被確認或解決為止，如果查驗結果不符合規定，經准許後可採燻蒸、出口或銷毀方式處理，倘皆符合規定，則可放行。



圖三、BICON 系統可查詢超過20,000植物、動物、礦物和生物產品，進口商可以查詢此系統，得知產品是否准許輸入、輸入時所需的條件等。(https://bicon.agriculture.gov.au)

2.食品安全(Food Safety)

在澳洲，食品管理分別由4個單位各自職掌不同的部分，分別是「澳洲紐西蘭食品標準局(Food Standards Australia New Zealand, FSANZ)，負責建立國內食品標準和規範，提供進口食品風險建議，及食品回收和突發事件的國際協調；「澳洲衛生部(Australian Government Department of Health)成立協調委員會負責食品政策及食品標準的一致性，及協調食源性疾病的監視；「澳洲農業、漁業及林業部(Department of Agriculture, Fisheries and Forestry, DAFF)」負責於邊境執行進出口食品及突發事件回應；「各州及領地政府(State and Territory governments)」負責於後市場執行境內販售食品及突發事件回應。DAFF 除了負責訂定前述之生物安全法外，亦負責訂定進口食品管理法(Imported Food Control Act 1992)，及其子法規「進口食品管理規範(Imported Food Control Regulations 2019)」與「進口食品管理程序(Imported Food Control Order 2019)」。「進口食品管理規範」列出如何執行進口食品查驗計劃(Imported Food Inspection Scheme, IFIS)，「 進口食品管理程序」說明風險/非風險食品所需的證明。

在邊境所有的食品必須先通過前述的生物安全規範，再執行食品安全檢查，但並非分成二個單位執行，而是 DAFF 大部分的查驗人員皆須具備這二項查驗能力，另外目前有22位專門審查較複雜食品之人員，還有18位正在接受訓練。DAFF 執行進口食品的安全檢查係依據以風險為基礎的「進口食品查驗計劃(Imported Food Inspection Scheme, IFIS)」，並依 FSANZ 建立的食品標準(Food Standards Code)據以執行。如果 FSANZ 建議此食品存在中高風險，DAFF 會將其視為風險食品(risk food)，其餘則視為監視(或低風險)食品(surveillance food)，並依風險高低採用不同的管理方式：

(1)Emergency powers：對人體健康存有嚴重風險疑慮，DAFF 可以扣留食品28天直至疑慮釐清為止，如有必要，可再展期28天一次。DAFF 曾經針對可能有 A 肝病毒的鹽漬蛤蠣及椰棗，施以此措施。

(2)Mandatory foreign government certificates：高風險食品要求需有國外政府證明，例如：乳酪原料、牛肉及牛肉產品、乳及乳產品、部分雙殼類軟體動物及其產品。

(3)Food safety management certificates：高風險食品由進口商提供第3方機構核發的證明文件，證明國外製造廠的食品安全管理系統是通過認證且可有效控制食品安全危害，以降低檢驗率。例如：即食鮮冷藏冷凍莓果及石榴籽。

(4)At border inspection and testing：高風險食品於邊境初期皆施以100%的查驗率，監視食品則為5%的隨機查驗率，查驗項目包含外觀檢查、標示查核及檢驗。

另外可接受出口國主動申請高風險食品的「自主合規協議(Voluntary compliance arrangements)」，經與澳洲政府完成議定後，高風險食品僅需檢附證明文件(Voluntary Certification)，其初期的抽驗率可以從100%降至5%，例如：泰國的鮪魚罐頭。進口商亦可申請「食品進口合規同意(Food Import Compliance Agreement, FICA)」，進口商必須提供文件化的食品安全管理系統及進口安全且合規的食品，具有 FICA 的進口商可以僅以審核取代邊境查驗，以節省進口商的時間及金錢，DAFF 透過定期審核進口商的系統來監控其遵守的情形。

有關風險食品(Risk food)及監控食品(Surveillance food)，其查驗率如下：

(1)風險食品：初期施以100%的查驗率，連續5批合格後降為25%，再連續20批合格後降為5%，如果不合格則回復至100%的查驗率。

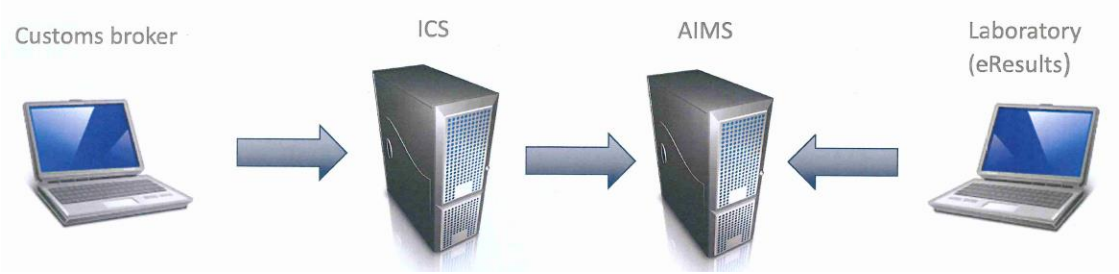
(2)監控食品：初期施以5%的查驗率，如不合格則同產地、同製造商、同產品會發布為管制食品(Holding order)，即下次輸入時會100%查驗，連續5批合格後，則可撤銷此管制。

其查驗率之調降僅考慮批數，不會將重量納入調降之因子，經現場詢問 DAFF 亦發現有少數業者會將同批產品分開申報，以快速調降查驗率，惟 DAFF 表示目前規定未將重量納入規定，邊境管理依據規定辦理。

(二) 輸入食品查驗流程

1.申報

進口商輸入所有產品皆採電子申報，稱之為 Full Import Declarations(FIDs)，進口商或其代理人(Customs brokers)於海關的 Integrated Cargo System(ICS 系統)申報產品資訊，如果是屬於 IFIS 要查驗的產品，資訊會交換至 DAFF 的 Agriculture Import Management System (AIMS)(圖四)，再根據國際商品統一分類代碼 (HS Code)，區分為風險食品、監視食品及管制(holding order)食品，如果 HS Code 還是無法分辨，DAFF 會於 ICS 系統上詢問進口商更詳細的產品資訊，例如：成分、型態或是否直接販售，以確認是否為風險食品。



圖四、報關行於海關的 ICS 系統申報，資訊交換至 AIMS 系統，實驗室檢驗結果亦傳送至 AIMS 系統。

如果該食品需檢附進口商聲明，例如：起司或水產品，或其他文件，進口商需將聲明及文件上傳至 Cargo Online Lodgement System (COLS)，一份進口商聲明文件僅能有一個產品一個製造商，聲明內容需包含符合商業發票內容之產品描述但不包含規格，以及製造廠名稱等，該聲明自簽發日起一年內有效，如果聲明內容不正確，將視為無效的聲明，如果提供虛假或誤導性資訊被認為是嚴重的犯罪行為，進口商必須保留聲明內容的佐證資料，DAFF 可能會要求進口商提供。DAFF 另訂有文件及聲明最低要求政策(Minimum documentary and import declaration requirements policy)，申報所需的相關文件及聲明必須符合該政策。

每一個申請案(Lodgement)須申報的項目有：

(1)進口商名稱

(2) 進口商地址

(3) 進口商連絡電話

(4) 貨品存置地點

(5) 貨品名稱(Line)：可多種產品(Batch)

(6) 每一個產品的批號(Lot)：指相同製造條件，相同時間生產(通常是24小時內)

(7) 檢驗實驗室候選名單

(8) 製造商名稱：可以是製造廠、加工廠、包裝廠或是生產收穫的設施，但不能是倉儲業者及貨運業者；如果供應商無法提供製造商名稱，可以申報供應商名稱。申報時是選取 ICS 系統已存在的代碼，如果無代碼，進口商可以申請新增，另如進口非供人食用、商業樣品(20 KG/L 以下)或復運進口之食品，製造商欄位可以申報通用代碼。

2.書面審查

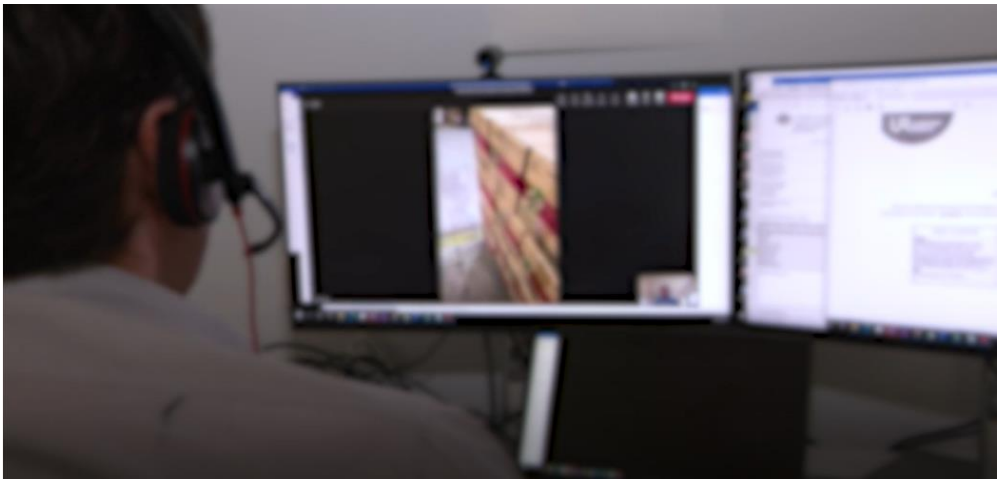
書面審查包含生物安全及食品安全二個部分，並有輔助系統可以協助篩選出需注意的產品，例如標註稅號、品名、產品描述等關鍵字，書審官員會審查完所有申報資訊及所需證明文件，及系統提供過去的紀錄，以決定是否需執行現場的外觀、標示檢查或實驗室檢查。證明文件原則掃描上傳系統即可，如有疑慮才會要求進口商提供紙本文件。如決定要執行下一步檢查，會發通知(Food Control Certificate, FCC)給進口商；如需補件或更正，亦是使用此通知與進口商聯繫。

3.臨場查驗

進口商收到 FCC 通知後，再向 DAFF 預約查驗的時間，並依 FCC 通知上所列的檢驗項目，自 DAFF 核可的實驗室名單選擇可檢驗的實驗室，如實驗室通知進口商可以接受檢查，進口商則可預約檢查，實驗室並同時通知 DAFF 將進行檢驗。檢驗費由進口商直接付給實驗室，部分實驗

室可能需事先繳納押金。各項產品之檢驗項目及標準，有公布於DAFF官網。

如屬監視食品僅需進行臨場查驗外觀及標示，可以用線上視訊方式進行查驗(Virtual inspections)(圖五)。自推出這個方式以來，第一年進行了超過500次的線上視訊查驗。



圖五、DAFF 官網展示線上視訊查驗。(圖片截自 https://www.agriculture.gov.au/biosecurity-trade/import/goods/food/inspection-testing)

如需進行臨場查驗的產品，進口商或倉儲公司需先將貨品放置倉儲地，由 DAFF 官員逕行取樣，無需進口商或代理人在場，無像我國有機邊驗放的作業。抽樣方式依產品品項(batch)及批號(lot)而訂(如表一至表三)，取樣數量依產品批號而訂，需具備代表性及足夠檢驗所需。一般每一個批號隨機取5份100公克均勻混合後進行檢驗(圖六)，如果可以會取完整包裝，如果是大包裝，會取具代表性的部分並同時維持剩餘產品的完整性，部分檢驗項目會取大於5個樣本，例如：椰子、嬰兒奶粉檢驗沙門氏菌，每一個批號需要取10份樣本；花生、開心果檢驗黃麴毒素，每一個批號需取20份樣本，但無對外公布所有產品的檢驗項目各需取幾份樣本。如果是大包裝的起司或是整尾冷凍鮪魚，會要求進口商提供人員及取樣工具協助取樣。取樣完成後，DAFF 會發電子進口食品查驗報告

(Imported Food Inspection Report, eIFIR)，內容包含取樣量及產品是否可以放行，並同時通知實驗室將收到樣品。

表一、風險食品(嚴格及一般抽驗率)、監視食品及管制食品的抽樣方式

Rate of sampling		
Item	**Number of lots in batch**	**Number of lots to be sampled**
1	1	1
2	2 to 8	2
3	9 to 15	3
4	16 to 25	5
5	26 to 50	8
6	51 or more	13

Imported Food Control Regulations 2019

表二、風險食品(抽驗率降低時)的抽樣方式

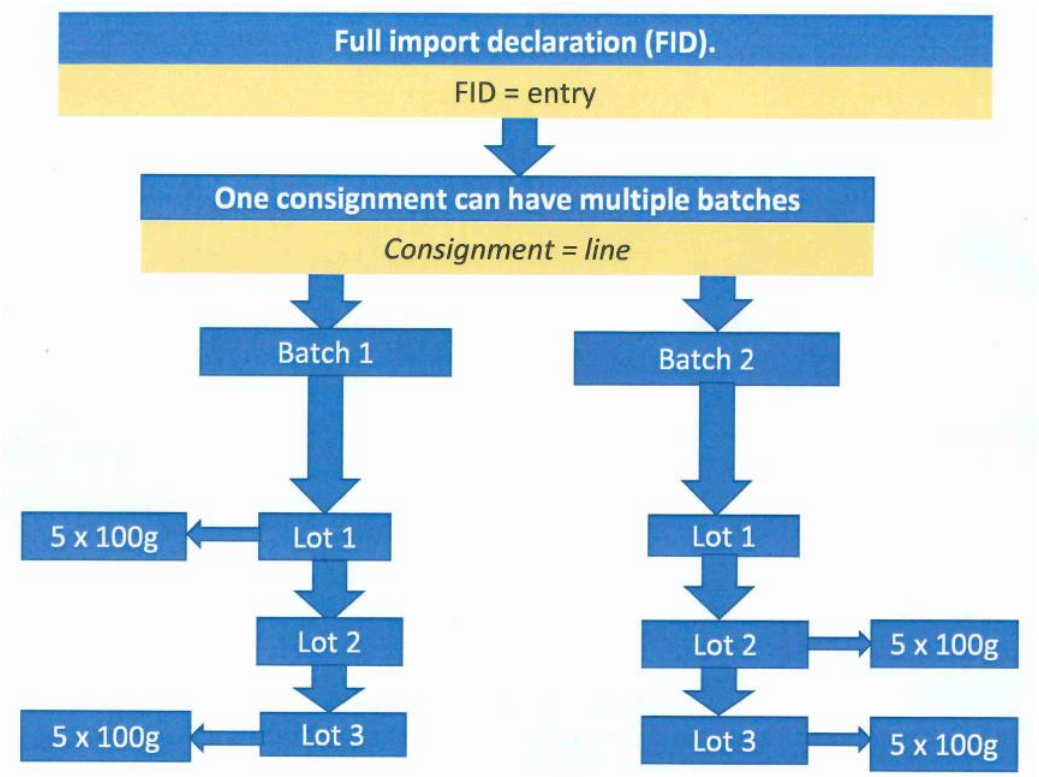
Rate of sampling		
Item	**Number of lots in batch**	**Number of lots to be sampled**
1	1	1
2	2 to 25	2
3	26 to 50	3
4	51 or more	4

Imported Food Control Regulations 2019

表三、當無批號時的抽樣方式

Rate of sampling		
Item	**Number of packages in batch**	**Number of packages to be sampled**
1	1 to 5	All of the packages
2	6 to 4,800	6
3	4,801 to 24,000	13
4	24,001 to 48,000	21
5	48,001 to 84,000	29
6	84,001 to 144,000	48
7	144,001 to 240,000	60
8	240,001 or more	72

Imported Food Control Regulations 2019



圖六、抽樣方式示意圖。

4.查驗報告及不合格後續處理

實驗室的檢驗結果會上傳到 AIMS 系統，審核完後，DAFF 會發進口食品查驗建議(Imported Food Inspection Advice, IFIA)給進口商，包含不合格原因及後續處理方式。如屬標示不合格，可以標示補正、退運或銷毀；如果是監視食品查驗不合格，DAFF 會發一個管制命令，代表之後輸入此產品皆需查驗，直到5批連續合格後；如屬於風險食品查驗不合格，代表之後採100%逐批查驗，直到符合可調降的條件。進口商不可申請複驗，但可於收到結果通知的28天內，申請重新審查，DAFF 需在10個工作天內回復。檢驗不合格的產品同時會通知出口國之大使館，並每個月於 DAFF 官網公布不合格產品資訊。

5.管制措施

除檢驗不合格可以施以管制措施外，高風險產品亦可以施以管制措施，此措施管制範圍為同產地、同製造商、同產品，如風險已降低，DAFF 將撤銷此管制措施。

6.規費

進口商申報一個 FID 的費用分為空運43元澳幣(約903元台幣)、海運63元澳幣(約1,323元台幣)，查驗規費以15分鐘為1個單位計算，書面審查每單位37元澳幣(約777元台幣)，如需補件則會增加審查時間及費用，臨場查核取樣的費用同樣以每位查驗員每單位62元澳幣(約1,302元台幣)，如果在非上班時間申請查驗，每單位需另再支付18元澳幣(約378元台幣)，且至少要支付2個單位，進口商可以申請延長作業，但 DAFF 有權拒絕在非上班時間查驗。(1元澳幣以21元台幣計算)

(三) 電子證書

澳洲為出口為主的國家，爰致力於推動電子證書，並有專門的部門在規劃、建置及與各國洽談電子證書交換的業務，目前已與10多個國家有電子證書交換，其會至當地國家政府機構確認其系統是否適合做 e-Cert 並協助建置 e-Cert 系統，如果積極處理有時1週就可以把分工、流程制定出來，1年就能建立並上線。因應 COVID-19疫情影響，澳洲政府也發現有許多國家開始改變了收受證明文件的方式，包括利用線上查證系統、電子證書資訊交換及以影本證明文件代替。澳洲政府認為電子證書是 G2G 的交換，可排除假冒的情形，同時可以先讓進口國收到證書，以達快速清關，如有問題出口國亦可以即時修改，本署亦於110年及111年完成與紐西蘭及澳洲政府電子證書之傳遞。澳洲政府目前持續與不同國際組織溝通，以期編碼能統一化，同時有一個2021年至2026年的電子證書計劃：

1.擴大及維持雙邊和多邊的電子證書交換

2. e-Cert 認證人員能力的發展

3. 最終目標為無紙化貿易

二、 參訪雪梨辦事處及貨櫃倉儲地

(一) 澳洲的邊境查驗辦事處分別位於5個城市：墨爾本、阿德雷德、布里斯本、雪梨、達爾文，共7個辦事處，負責文件審查共有約235人，以2022年為例，一共審查396,482申請案，邊境檢查站人力共約有130人，本次代表團於112年10月17日參訪業務量最大的雪梨辦事處(Sydney Regional Office)。所有要受檢的產品需先存置於倉儲地，倉儲地於地上有畫設黃色人行區(圖七)，人員必須走在此區域，進口商可以請代理人或倉儲地先行檢查產品標示、批號等資訊是否正確。查驗時由查驗人員核對申報文件與產品是否相符，逕行取樣至倉儲地內部的檢查室，無需進口商或代理人在場，並以3倍及30倍的放大鏡或顯微鏡檢查病蟲害(圖八)，如果需要燻蒸處理，倉儲地內設有燻蒸場。

圖七、雪梨機場附近貨櫃倉儲地，場內畫設人行步道範圍(左圖黃色斜線區)及待受檢之葡萄置於有冷風設備之倉儲內(右圖)。

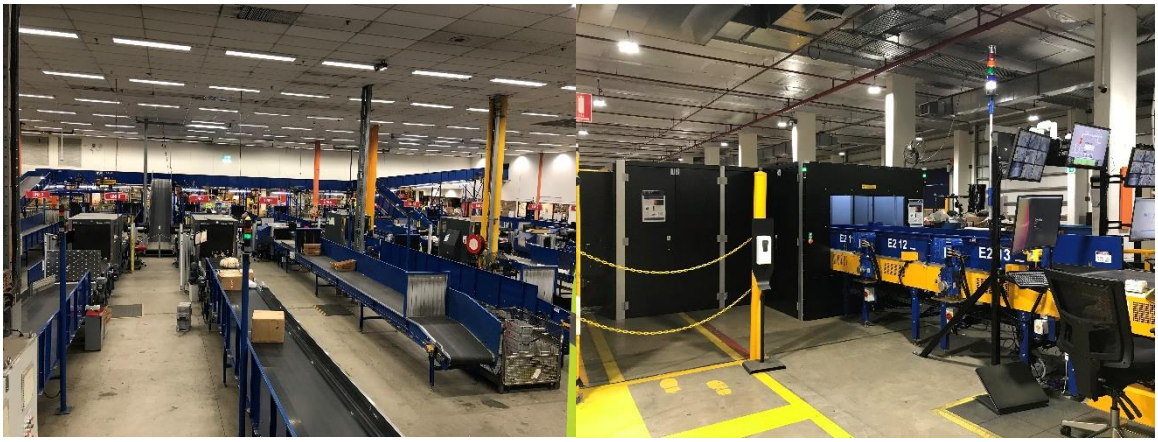
圖八、由 DAFF 官員取樣後於旁邊的檢查室以放大鏡及顯微鏡檢查蟲害等疫病(左圖) 以及貨櫃倉儲地內設置有燻蒸場(右圖)。

(二) 如尚未通過生物安全檢查的產品，外箱會貼上黃色膠帶，代表不可移動；如果通過生物安全檢查可以放行，則會貼上綠色膠帶(圖九)。食品安全檢驗時間最長需要10天左右，檢驗過程中，進口者可以將貼有封條的產品放到自己的儲存地點，但不能銷售。如果業者在這期間自行銷售，會有罰則；如果檢驗結果不合格又自行銷售，會產生更多罰則，且後續召回等一系列相關費用由業者自行承擔。

圖九、黃色膠帶代表不可移動(左圖)，綠色膠帶代表可以放行(右圖)。

三、 參訪雪梨郵務中心及雪梨國際機場

(一) 雪梨、墨爾本及布里斯本皆有郵務中心，其中雪梨是澳洲最大的郵務中心，有可容納5個貨櫃的月台，空運及海運的包裹皆先運送至郵務中心，檢查完成始再分送至澳洲各地的收件者。海關及 DAFF 的人員皆進駐在郵務中心，DAFF 主要檢查生物安全部分，利用2D X-ray 及3D X-ray 檢查包裹(圖十)，2D-Xray 掃描疑似風險產品，必要時再人工打開包裹確認，檢查時間約20分鐘，而使用3D-Xray 僅需30秒即可知道是否有高風險產品，通常用來檢查是否含有種子，亦有檢疫犬協助檢查包裹是否有生鮮葉子、肉製品等(圖十一)。如查獲郵包含有豬肉製品，因需要有獸醫證明、屠宰證明等，一般民眾很難取得該等證明文件，爰查獲即銷毀，銷毀的費用由DAFF負擔，低風險產品則退運予寄件者。郵包產品如有取樣或銷毀，會紀錄於 DAFF 內部的系統(Mail and Passengers System, MPS)，以供追溯，如無問題的郵包則不會紀錄於系統。另郵包產品如需申請許可(例如 Import Permits)後始得輸入，會寄信通知收件人限期補件。

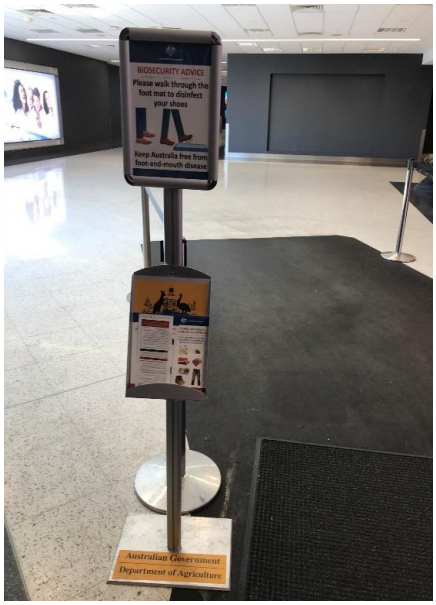


圖十、以2D X-ray 檢查包裹(左圖)，以3D X-ray 檢查包裹(右圖)。

圖十一、檢疫犬協助檢查包裹。

(二) 雪梨國際機場亦相當嚴格執行旅客攜帶行李生物安全部分，所有飛機降落打開艙門前均必需先完成機艙內外的消毒。為防範非洲豬瘟，來自特定國家的班機，旅客下機艙後必需要走在含有消毒液的地毯上(圖十二)，旅客攜帶的行李亦透過隨機打開、X-ray 或檢疫犬的檢查確認有無攜帶高風險產品。旅客如有誠實申報攜帶物品而被查到屬高風險產品，僅物品銷毀，如未誠實申報而被查獲，除物品銷毀外，另還要處以罰鍰，並同樣記錄於 Mail and Passengers System。每1單位罰鍰為313元澳幣(約6,573元台幣)，依產品風險高中低分別處以12單位、6單位及2單位罰鍰。雪梨機

場亦隨處可見以淺顯易懂的圖片，向來自世界各地的旅客宣導要誠實申報的標語(圖十三)。



圖十二、下機艙後必需走在含有消毒液的地毯。

圖十三、雪梨機場隨處可見要旅客誠實申報攜帶物品的標語。

肆、 心得與建議事項

一、 參訪心得

原預計2020年參訪的行程，因疫情關係，延至2023年順利成行，感謝澳洲官方給我們這一次機會來參訪輸入食品邊境查驗的管理制度，並提供許多協助。另感謝澳洲辦事處幫忙與促成此次參訪，以及感謝駐澳洲代表處經濟組此行之溝通與協助。本次在行前即搜尋澳洲農業部的官方網站有關輸入食品查驗法規，其官網資訊非常詳盡，除法規條文外，亦使用相當口語的方式在說明如何輸入食品進入澳洲，爰得以將不甚了解之處於實際參訪時詢問，回國後亦是參考其官網資訊完成此份報告。

以下為澳洲與我國邊境查驗制度之比較：

項目	澳洲	臺灣
法令依據	1992年進口食品管理法 (Imported Food Control Act1992) -進口食品管理規範(Imported Food Control Regulations 2019) -進口食品管理程序(Imported Food Control Order 2019)	食品安全衛生管理法 食品及相關產品輸入查驗辦法 -食品及相關產品輸入查驗作業要點
輸入食品查驗機關	檢疫與食品安全由同一機關執行(澳大利亞農業、漁業及林業部)	檢疫與食品安全分別由二機關執行(農業部防檢署與衛福部食藥署)
輸入食品查驗站及人力	文件審查共約235人，邊境查驗人力共約130人，分布在墨爾本、阿德雷德、布里斯本、雪梨、達爾文等地的7個辦事處。	編制正式人力82人及非正式人力100人分布於本署之4個港埠辦事處(基隆、桃園、臺中及高雄)
2022年受理的案件數及檢驗批數	共396,482申請案(以報單號碼計)，其中21,619個申請案、43,655個項次，共檢驗20,721個項數。	724,180批申請案(以查驗申請書案號計)，其中抽中檢驗65,680批，共檢驗66,840個項數。
申報方式	全面採電子申報，向海關的系統申報，需農部查驗的產品會將資料拋到農部的系統。	採電子申報，少量(如個人)採書面申報；大部分是分別向海關、防檢署、食藥署申報，查驗完成後再與海關資料比對，少部分採大報單。
預先申報	僅生物安全有要求大部分產品需預先申報，食品安全無預先申報制度	無

風險核判	書審官員會審查完所有申報資訊及所需證明文件，及系統提供過去的紀錄，決定是否需執行現場的外觀、標示檢查或實驗室檢查，再通知進口商。	導入大數據分析，並依進口商過去紀錄、管制條件等，受理後決定是否抽中，系統並即時回訊予進口商。
製造商申報	可以是製造廠、加工廠、包裝廠或是生產收穫的設施，但不能是倉儲業者及貨運業者；如果供應商無法提供製造商名稱，可以申報供應商名稱。申報時是選取海關申報系統已存在的代碼，如果無代碼，進口商可以申請新增，另如進口非供人食用、商業樣品(20 KG/L以下)或復運進口之食品，製造商欄位可以申報通用代碼。	除部分產品有製造廠代碼外，其餘由進口商依製造廠名稱申報，爰相同製造廠容易有因名稱縮寫不一致的情形。供商業樣品用的產品另外申請免輸入查驗。
輸入食品查驗規費	以審查、查驗時間長短來收取費用，以每15分鐘為1個單位計價。 一、審查費：一個報單的費用分為空運43元澳幣(約903元台幣)、海運63元澳幣(約1,323元台幣)，書面審查每單位37元澳幣(約777元台幣)，如需補件則會增加審查時間及費用。 二、臨場費：每1檢查人次每單位62元澳幣(約1,302元台幣)。 三、延長作業費：每單位需再加收18元澳幣(約378元台幣)，且至少要支付2個單位。 (1元澳幣以21元台幣計算) 四、檢驗費：進口商直接向實驗室繳納，部分實驗室可能需事先繳納押金。	以完稅價格計價。 一、審查費： 大宗穀物費率為0.05%。 其他食品及相關產品為0.15%。 不足300元以每件300元計收，超過十萬元者，超過之部分減半計收。 二、臨場費：依距離遠近每1檢查人次收取300元或500元，具結取樣收取1,000元。 三、延長作業費：依不同時段每1檢查人次再加收400元、1,000元或2,000元。 四、檢驗費：逐批查驗及複驗費由業者負擔，其餘由本署支應。
查驗率調控機制	一、風險食品(Risk food)：初期施以100%的查驗率，連續5批合格後降為25%，再連續20批合格後降為5%，如果不合格則回復至100%的查驗率。 二、監控食品(Surveillance food)：初期施以5%的查驗率，如不合格則同產地、	一、逐批查驗：100%抽批檢驗，合格滿5批3倍量即調降為加強抽批查驗。 二、加強抽批查驗：20%~50%抽批檢驗，合格滿5批3倍量即調降為一般抽批查驗。 三、一般抽批查驗：2%~10%抽批檢驗。

	同製造商、同產品會發布為管制食品(Holding order)，即下次輸入時會100%查驗，連續5批合格後，則可撤銷此管制。 (查驗的定義：非僅指化學檢驗，查核外觀及標示或檢附證明文件亦屬查驗，調降查驗率並不會考慮量的部分)	四、逐批查核：前一批檢驗不合格，下一批加強未抽中批者。 (查驗的定義：查核及檢驗，除了批數亦會考慮量的部分)
查驗取樣地點	如需進行臨場查驗的產品，進口商或倉儲公司需先將貨品放置倉儲地，由 DAFF 官員逕行取樣，無需進口商或代理人在場，無機邊驗放的作業。如果是大包裝的起司或是整尾冷凍鮪魚，會要求進口商提供人員及取樣工具協助取樣。 如為非高風險產品，且無需取樣檢驗，可以線上視訊查驗。	於集中查驗區，或經本署認可之特定區域實施，或機放倉，需有報驗義務人或代理人在場。 抽樣耗時或困難者，得要求拆櫃進倉或具結通關留置於業者指定倉儲中實施。
開箱數及取樣量	開箱數依批號而訂，取樣量依檢驗項目而訂，取樣後會通知進口商取樣量，但未對外公布各檢驗項目之取樣量。 開箱數依產品品項及批號而訂，取樣數量依產品批號而訂，需具備代表性及足夠檢驗所需。一般每一個批號隨機取5份100公克混勻，如果可以會取完整包裝，如果是大包裝，會取具代表性的部分並同時維持剩餘產品的完整性，部分檢驗項目會取大於5個樣本。	1件至30件開1件、31件至60件開2件、61件至100件開3件…，固體取600克、液體取1000克，可依檢驗項目所需增加取樣量，此規定公布於「食品及相關產品查驗作業要點」。
檢驗	由進口商選擇官方指定的實驗室，官方取樣後送到進口商指定之實驗室執行。	由官方取樣後送到指定的實驗室執行，進口商不可知道實驗室。
複驗	無複驗，但28日內可以申訴。	15日內可以申請複驗，由同一實驗室執行，30日內可以訴願。
放行	約有32%的產品可由經認可的人員評估文件並管理生物安全風險後放行。	全部產品皆由查驗機關審核符合規定後放行。
具結先行放行制度	無。 食品安全檢驗時間最長需要10天左右，檢驗過程中，進口者	有。 1. 填寫具結先行放行申請書，未取得輸入許可前，不得移

及違規處分	可以將貼有綠色封條的產品放到自己的儲存地點，但不能銷售。如果業者在這期間自行銷售，會有罰則；如果檢驗結果不合格又自行銷售，會產生更多罰則，且後續召回等一系列相關費用由業者自行承擔。	動、啟用或販賣，特定條件需繳納產品到岸價額2倍之保證金。違規者，沒收所收取之保證金，並於一年內暫停受理具結保管之申請，擅自販賣者，處販賣價格1-20倍罰鍰。 2. 所轄衛生局協助具結保管期間之稽查。
申報不實之處分	不會處分，有錯就是退進口商修正，會延長審查時間及費用。	處新臺幣3萬元至300萬元以下罰鍰；情節重大者，並得命其歇業、停業一定期間、廢止其公司、商業、工廠之全部或部分登記事項，或食品業者之登錄；經廢止登錄者，一年內不得再申請重新登錄。
電子證書	已與10多個國家有介接，並且直接至他國或他國至澳洲進行溝通。	透過關務署的 webservice 與澳洲及紐西蘭介接。

二、 未來規劃及建議

(一) 建議邊境檢驗不合格即採逐批查驗，減少後市場追查已輸入之相同產品

我國與澳洲的輸入查驗機制最大不同之處為，澳洲政府倘查驗不合格即會回復100%的查驗率，我國則是先提升查驗率至20%，倘不合格再提升至100%，期間可能已有80%的產品流入市面，需再請衛生局追查。為減少後市場追查所需之人力、物力，建議可改為邊境檢驗不合格即採逐批查驗，合格滿5批3倍量始調降為加強抽批查驗，再合格滿5批3倍量始調降為一般抽批查驗，意即確認產品風險降低後，始調降查驗率。此一措施亦可提升業者自主管理之責，確認產品符合我國法規始予輸入，否則，一經邊境檢驗不合格，即必須接受嚴密的檢驗監控，並且須負擔檢驗費。

(二) 於申報系統建立製造廠名稱清單，以利風險管理

現行我國之管制措施是採同報驗義務人、同產地、同貨品分類號列之產品，但也發現部分產品的不合格情形有特別集中於特定之國外製造廠，進而有管制製造廠之需求，惟我國邊境查驗自動化管理資訊系統，於申報製造廠名稱時係

由業者填寫，爰可能出現同一製造廠但因各業者申報填寫方式不同(如中文或英文、縮寫或完整名稱等)，而難以管制。建議可參考澳洲申報之方式，於系統建立製造廠清單，使用點選的方式申報，以減少各業者申報填寫方式不同的情況，並有助於我國在管制、統計各製造廠的輸入報驗情形。

(三) 評估新增規費收費項目及金額

現行我國邊境查驗收費項目有審查費、臨場費、延長作業費、通知書費、電腦傳送訊息更正費及檢驗費，其中審查費是以完稅價格為基準，採固定費率收費。惟應申報查驗之產品種類繁多，各類產品規定不同、複雜程度各異，又經常有申報資料不齊全需補件的情形，所以各案件之審查時間差異很大，但僅只收取一次固定費用，實不符合人力成本。建議可仿效澳洲的收費方式，以審查時間長短來計費，當案件須請業者補件則業者須再繳納一次審查費，此舉亦促可使業者確認好所有文件後再申請，以節省通關時間。另外因標示不合格而申請中標補正，再取得本署核發之「食品及相關產品標示改正同意暨輸入許可通知」，亦可評估加收審查費，以達使用者付費之原則。

(四) 持續擴大電子化申辦作業及電子證書交換

澳洲政府全面採用電子化申辦各項作業，證明文件除有必要須檢視正本外，原則上皆以電子檔案上傳申報系統即可，又取樣時無須業者在場，爰業者甚少有需求須親臨 DAFF 辦公室。我國自109年4月22日起實施電子化申報作業以及線上文件審查、補件通知等，已大幅減少業者須親送文件至辦公室之需求，可持續推動其他業務改採電子化申辦，以達節能、省紙及通關便捷化之目標。又澳洲是出口大國，積極推動與各國電子證書交換，電子證書亦是未來的國際趨勢，近年我國陸續規定許多產品輸入時須檢附官方證明文件，亦收到各界反應希望能透過電子證書政府間之交換取代紙本證明，我國目前已和澳洲及紐西蘭有電子證書介接，可以此經驗陸續再與其他國洽談，擴大電子證書介接的國家及產品範圍。

(五) 評估遠距視訊查驗之可行性

澳洲政府針對低風險產品可採用線上視訊方式進行查驗(Virtual inspections)，我國亦可評估視訊查驗之可行性。以基隆港為例，共有20多個貨櫃倉儲地分散於基隆市、新北市各地，同一貨櫃場又幅員遼闊需要車輛載送查驗人員至各點查驗，而消耗許多時間、油料成本。如低風險產品又僅需查核外包裝標示，可評估採視訊查驗之可行性，使查驗地點及時間更為彈性有效率，減少人力、油料之浪費，以網路代替馬路，達到節能減碳之目標。

伍、 附件

一、 澳洲生物安全管理112年10月19日簡報。

二、 澳洲電子證書112年10月19日簡報。

三、 澳洲食品安全風險評估112年10月19日簡報。

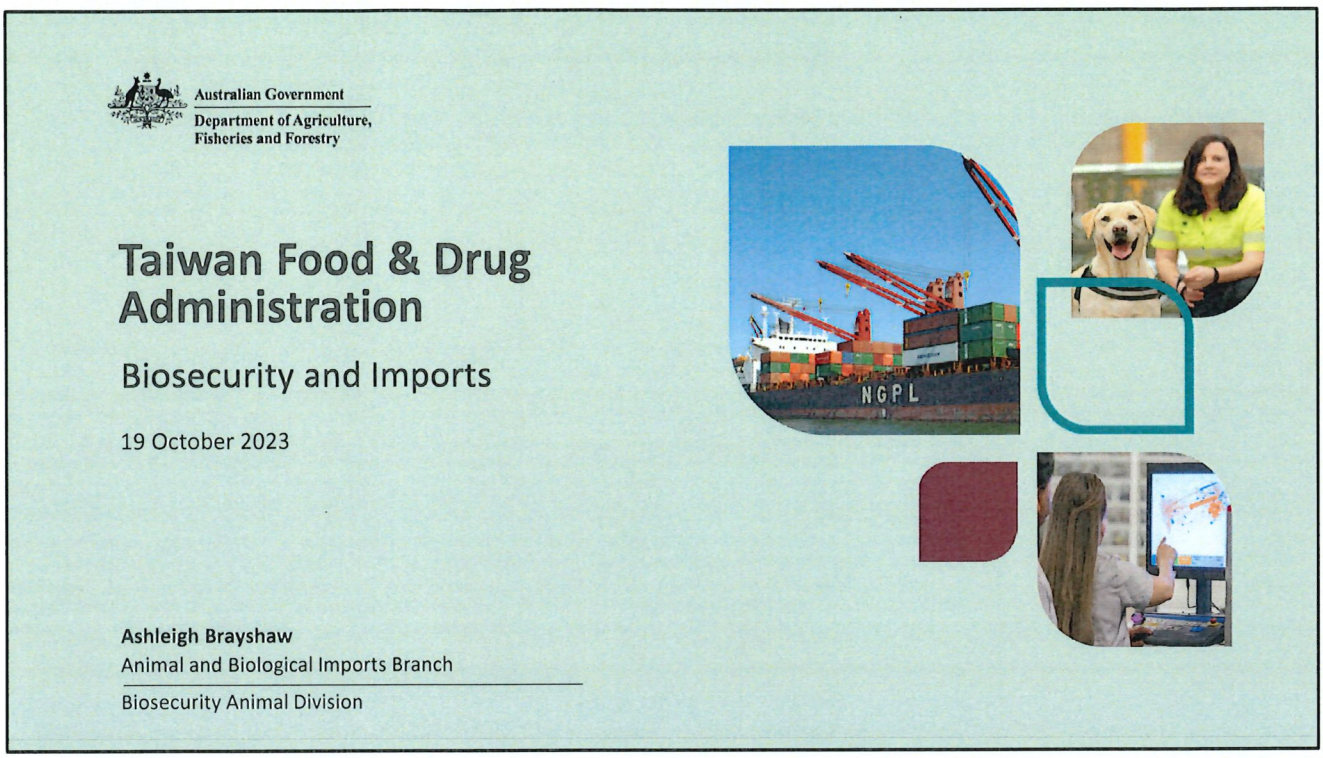
四、 澳洲輸入食品查驗112年10月19日簡報。

五、 台灣輸入食品管理112年10月19日簡報。

陸、 參考資料

一、 澳大利亞農業、漁業及林業部官方網站。2023。https://www.agriculture.gov.au/。

二、 澳洲紐西蘭食品標準局官方網站。2023。https://www.foodstandards.gov.au/food-standards-code



Hi everyone! My name is Ashleigh Brayshaw, and I am a senior technical officer in the Food Biosecurity Imports team, which sits within the Animal and Biological Imports Branch and more broadly within the Biosecurity Animal Division.

My team is responsible for implementing biosecurity policies to allow for the safe movement of animal and biological products into Australia. We provide technical advice to internal and external stakeholders, publish import conditions, and develop instructional and guidance material.

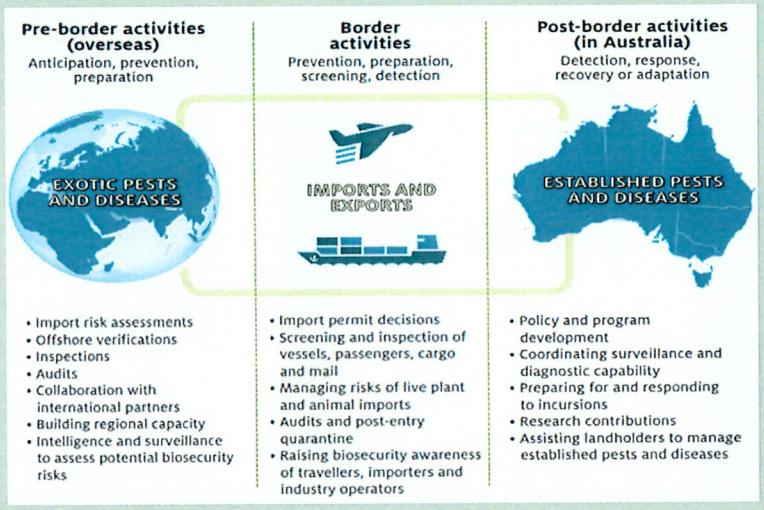
The team assess a range of goods, including:

- Dairy
- Eggs
- Retorted and unretorted meat and meat products
- Therapeutics and cosmetics for human use
- Seafood and aquatics for human consumption, and

- Animal hides, skins, and fibres

Biosecurity Continuum

Australia's approach to managing risk of incursions of exotic pests and diseases is multi-layered, involving complementary measures applied along the biosecurity continuum.



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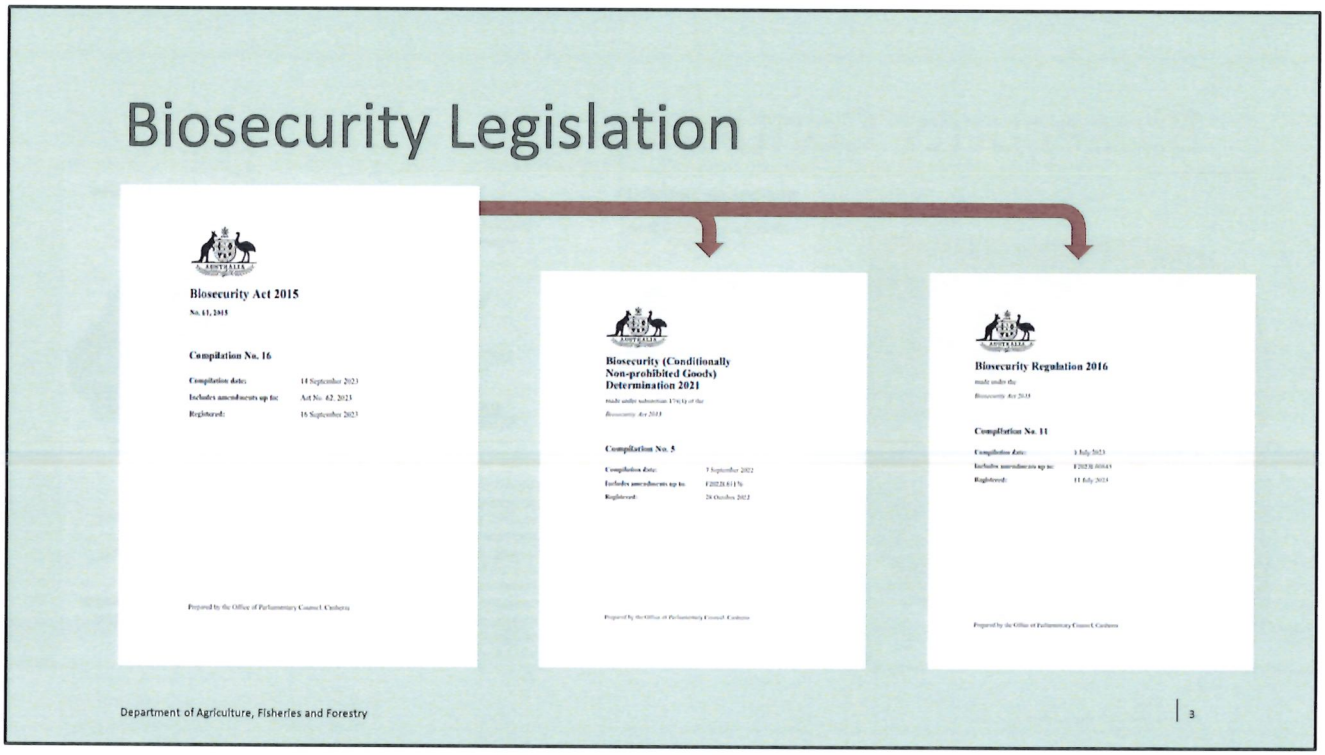
As discussed in the previous presentation, Australia's approach to managing the risk of incursion of exotic pests and diseases is multi-layered, involving complementary measures applied along the biosecurity continuum – at pre-border, border, and post-border points.

Some of the department's activities extend across the entire continuum.



The department regulates goods imported into Australia.

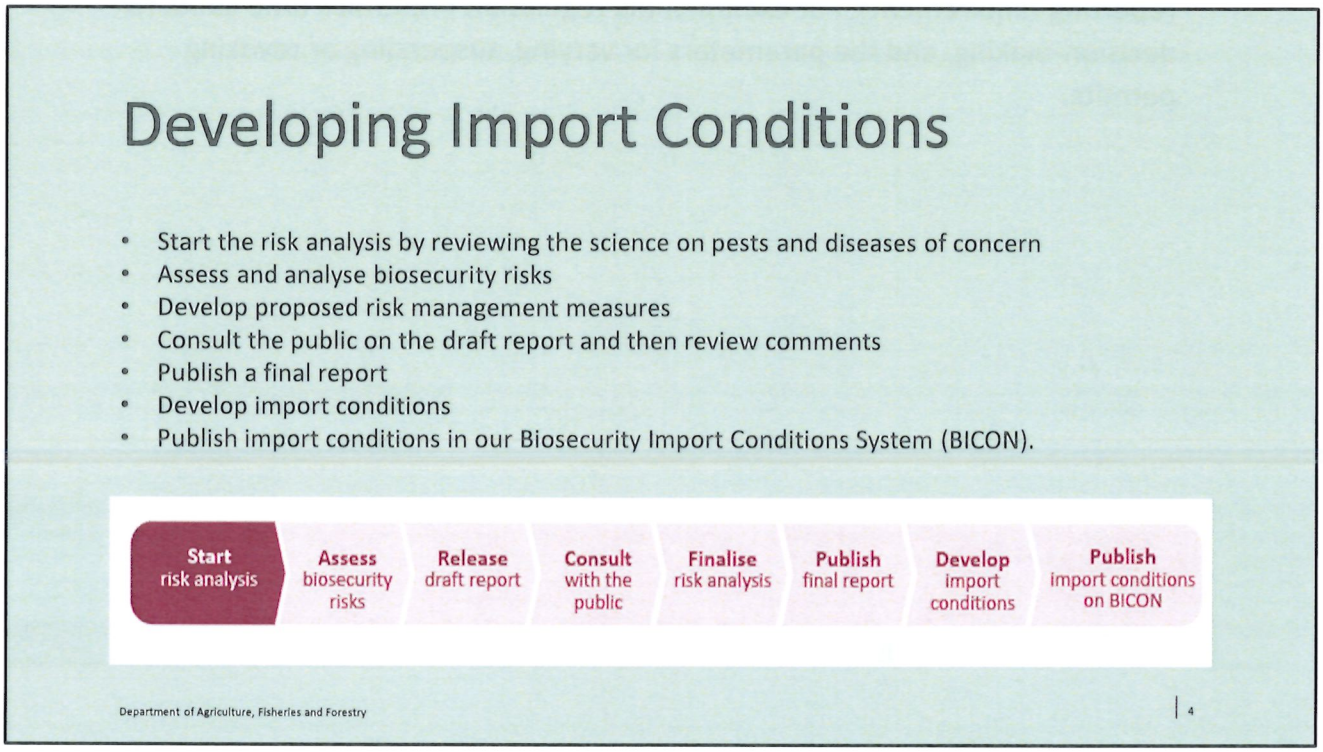
The importation of some goods is, by law, subject to certain biosecurity import conditions. Some goods are not permitted entry, while others are only allowed into Australia subject to meeting import conditions that mitigate the biosecurity risk. This may include the requirement for an import permit.

The primary legislation that provides the legal powers for all of Australia's biosecurity activities is the *Biosecurity Act 2015*.

The Biosecurity (Conditionally Non-prohibited Goods) Determination 2021 and the Biosecurity Regulation 2016 are instruments made under the Act.

- The goods determination lists alternative conditions for bringing or importing goods into Australia. If the goods determination does not list alternative conditions or the alternative conditions cannot be complied with, the goods must be covered by an import permit to be eligible for import into Australia.

- The biosecurity regulation provides information relating to the exercise of powers by officials under the Act and sets out the necessary information and reporting requirements. For example, the regulation prescribes time limits for decision-making, and the parameters for varying, suspending or revoking permits.



Australia is a member of the World Trade Organization, whose primary purpose is to ensure safe and open trade for the benefit of all its member countries. For this reason, the department must consider market access requests, also called import proposals to bring plants, animals or other goods into Australia in circumstances where import conditions have not been established.

During the assessment of these requests, our scientific experts determine if the product can be safely imported into Australia. One way they do this is by conducting an import risk analysis.

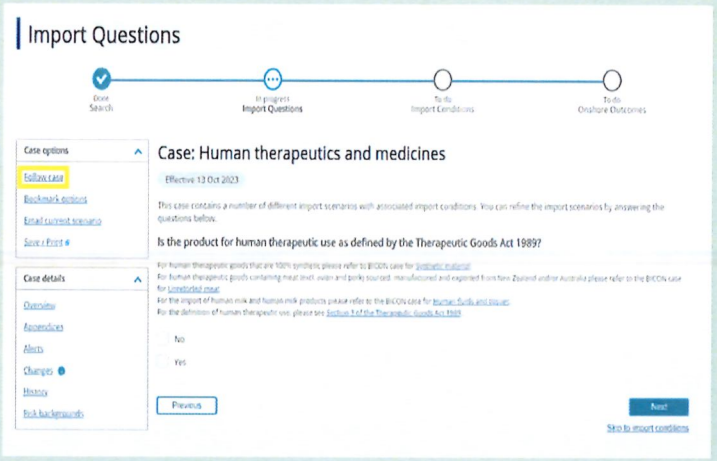
As part of this analysis, our scientific experts recommend import conditions that must be met to import the goods. If countries can meet the conditions, they are published on the departments Biosecurity Import Conditions system, BICON.

From here, imports may begin.

Biosecurity Import Conditions (BICON) System

Importers can use BICON to determine whether a commodity intended for import into Australia:

- is permitted
- is subject to import conditions
- requires supporting documentation
- requires treatment
- needs an import permit.



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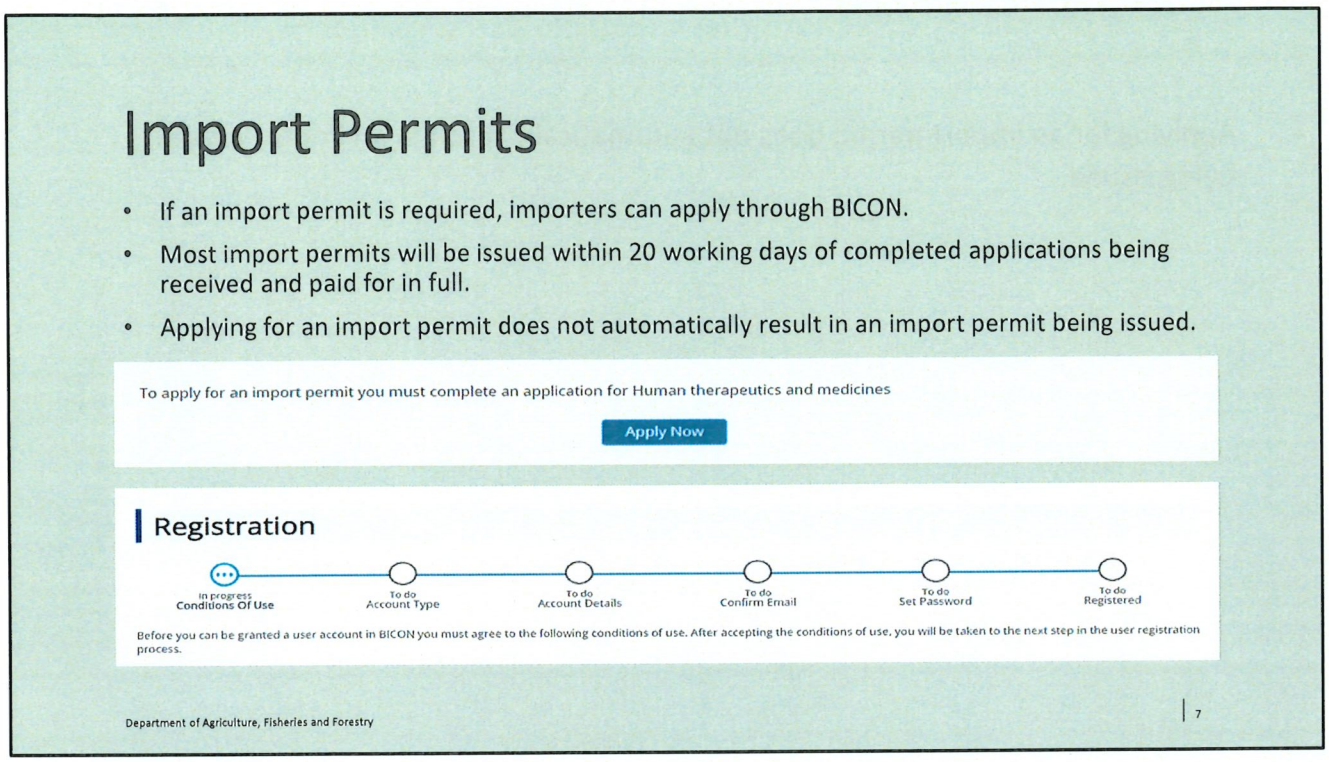
BICON houses the biosecurity import conditions for more than 20,000 plants, animals, minerals, and biological products. Importers can use BICON to determine whether a commodity intended for import into Australia:

- Is permitted.
- Is subject to import conditions, including the requirement for supporting documents, treatments, or onshore intervention, or
- Requires an import permit, including the requirement for supporting documents to accompany the permit application to ensure a biosecurity risk assessment can be conducted.

It is the importers responsibility to comply with the department's import conditions when importing into Australia.

If importers would like to stay up-to-date with the latest import conditions, they can subscribe to a BICON case to receive alerts and change notices.



If an import permit is required, importers can apply through BICON. The department will assess the application and may decide to grant an import permit subject to any conditions deemed necessary for the safe importation, use and disposal of those commodities.

Most import permits will be issued within 20 working days of completed applications being received and paid for in full. Applications may take longer if:

- They require technical assessment
- Incomplete or incorrect information is provided by the applicant
- Additional information is required to continue the assessment
- The goods are novel or have been prepared in a novel manner
- If the goods require policy advice to support the assessment

It is important to note that import permits must be obtained prior to goods arriving

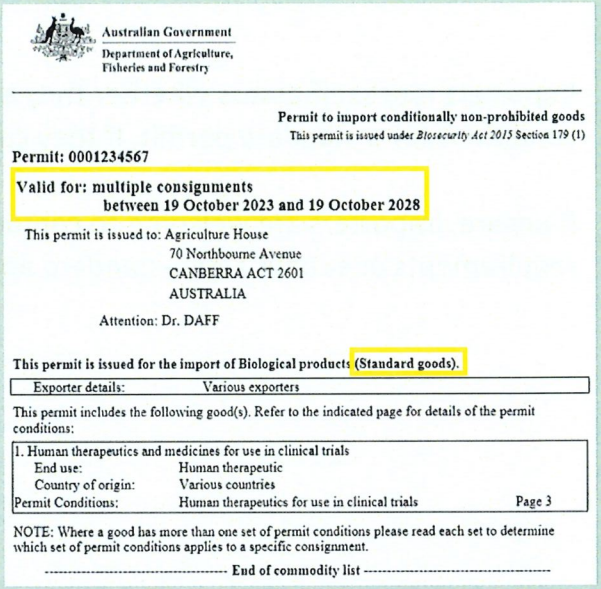
in Australia. This is because, under the *Biosecurity Act 2015*, goods become subject to biosecurity control upon entering 12 nautical miles of the Australian mainland or Australia's external territories.

Applying for an import permit does not automatically result in an import permit being issued.

Standard Permits

Standard permits contain a specific set of conditions that have been assessed by the department as being appropriate to manage biosecurity risks for a certain commodity type.

- The application process is quicker
- Applications are cheaper
- The permits are broader
- The validity period is longer



Australian Government
Department of Agriculture, Fisheries and Forestry

Permit to import conditionally non-prohibited goods
This permit is issued under *Biosecurity Act 2015* Section 179 (1)

Permit: 0001234567

Valid for: multiple consignments between 19 October 2023 and 19 October 2028

This permit is issued to: Agriculture House
70 Northbourne Avenue
CANBERRA ACT 2601
AUSTRALIA

Attention: Dr. DAFF

This permit is issued for the import of Biological products (Standard goods).

Exporter details:	Various exporters

This permit includes the following good(s). Refer to the indicated page for details of the permit conditions:

1. Human therapeutics and medicines for use in clinical trials		
End use:	Human therapeutic	
Country of origin:	Various countries	
Permit Conditions:	Human therapeutics for use in clinical trials	Page 3

NOTE: Where a good has more than one set of permit conditions please read each set to determine which set of permit conditions applies to a specific consignment.

---------- End of commodity list ----------

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The department utilises two type of permits – standard permits and non-standard permits.

A standard permit contains a specific set of conditions that have been deemed by the department as being appropriate to manage biosecurity risks for a certain commodity type, without requiring a case-by-case assessment of the goods. The department has implemented a range of standard permits to help streamline the permit application process.

The benefits of applying for a standard permit include:

- Quicker application process. With import conditions already set and no supporting documentation required to complete the biosecurity risk assessment, the department can process applications in a shorter timeframe.

- Cheaper assessments, and in some cases longer validity periods, and

- The permits are broader as they apply to a commodity type, as opposed to a single assessed good. Once approved, a standard permit may be used to import multiple goods in the same commodity type, provided all of the conditions can be met.

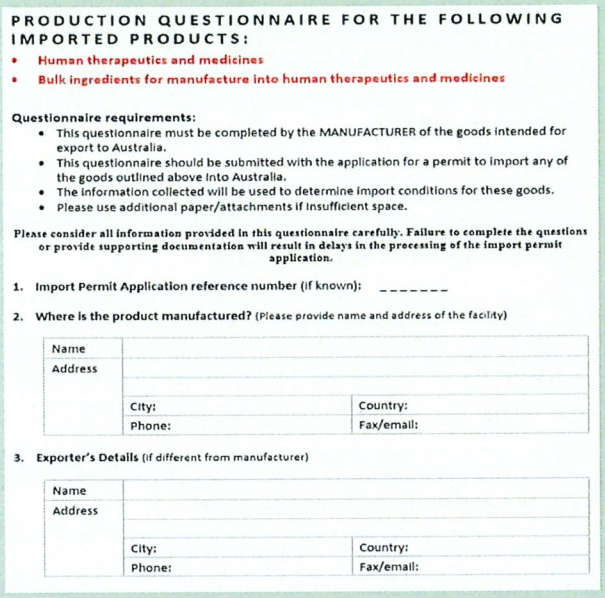
Importers must self-assess whether they are able to meet all of the import conditions for a standard permit. If they can, then they may apply.

If unsure, importers are welcome to contact to the department to clarify requirements or submit a non-standard application for assessment of their goods.

Non-Standard Permits

Non-standard permits require a detailed biosecurity risk assessment to determine whether the goods can be imported and what import conditions need to be applied.

- The permits are product specific
- Supporting documents are required



PRODUCTION QUESTIONNAIRE FOR THE FOLLOWING IMPORTED PRODUCTS:

- **Human therapeutics and medicines**
- **Bulk ingredients for manufacture into human therapeutics and medicines**

Questionnaire requirements:

- This questionnaire must be completed by the MANUFACTURER of the goods intended for export to Australia.
- This questionnaire should be submitted with the application for a permit to import any of the goods outlined above into Australia.
- The information collected will be used to determine import conditions for these goods.
- Please use additional paper/attachments if insufficient space.

Please consider all information provided in this questionnaire carefully. Failure to complete the questions or provide supporting documentation will result in delays in the processing of the import permit application.

1. **Import Permit Application reference number** (if known): _____

2. **Where is the product manufactured?** (Please provide name and address of the facility)

Name		
Address		
	City:	Country:
	Phone:	Fax/email:

3. **Exporter's Details** (if different from manufacturer)

Name		
Address		
	City:	Country:
	Phone:	Fax/email:

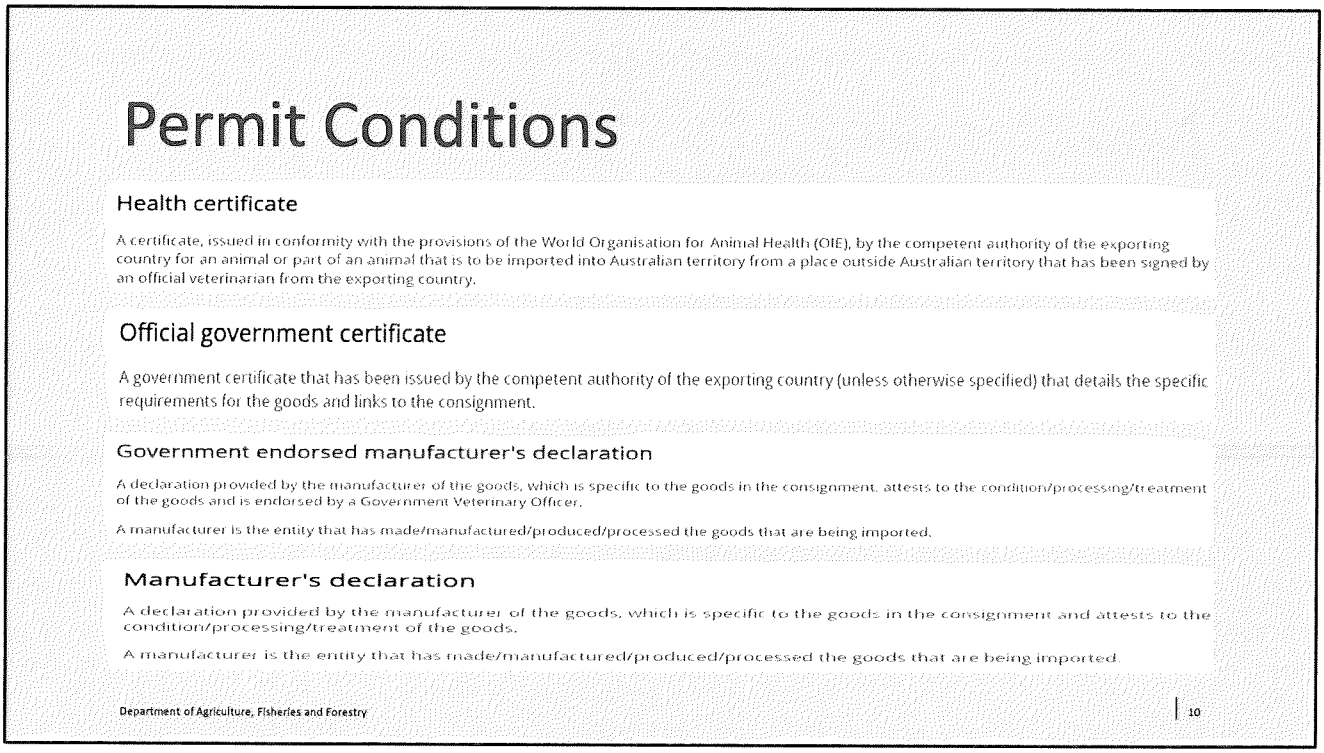
Department of Agriculture, Fisheries and Forestry

9

If the listed import conditions cannot be complied with, then a non-standard permit must be applied for.

An application for a non-standard permit will require a more detailed biosecurity risk assessment to determine whether the goods can be imported and what import conditions need to be applied. During the assessment, you may be asked to provide supporting documents, such as a questionnaire.

A questionnaire is a document to assist manufacturers in providing the information required as part of the department's biosecurity risk assessment, which were created to streamline the assessment process.



To demonstrate compliance with the permit conditions, the importer may be asked to provide documentation such as:

- A health certificate – which is a certificate issued by the overseas regulatory body of the exporting country that has been signed by an official veterinarian.

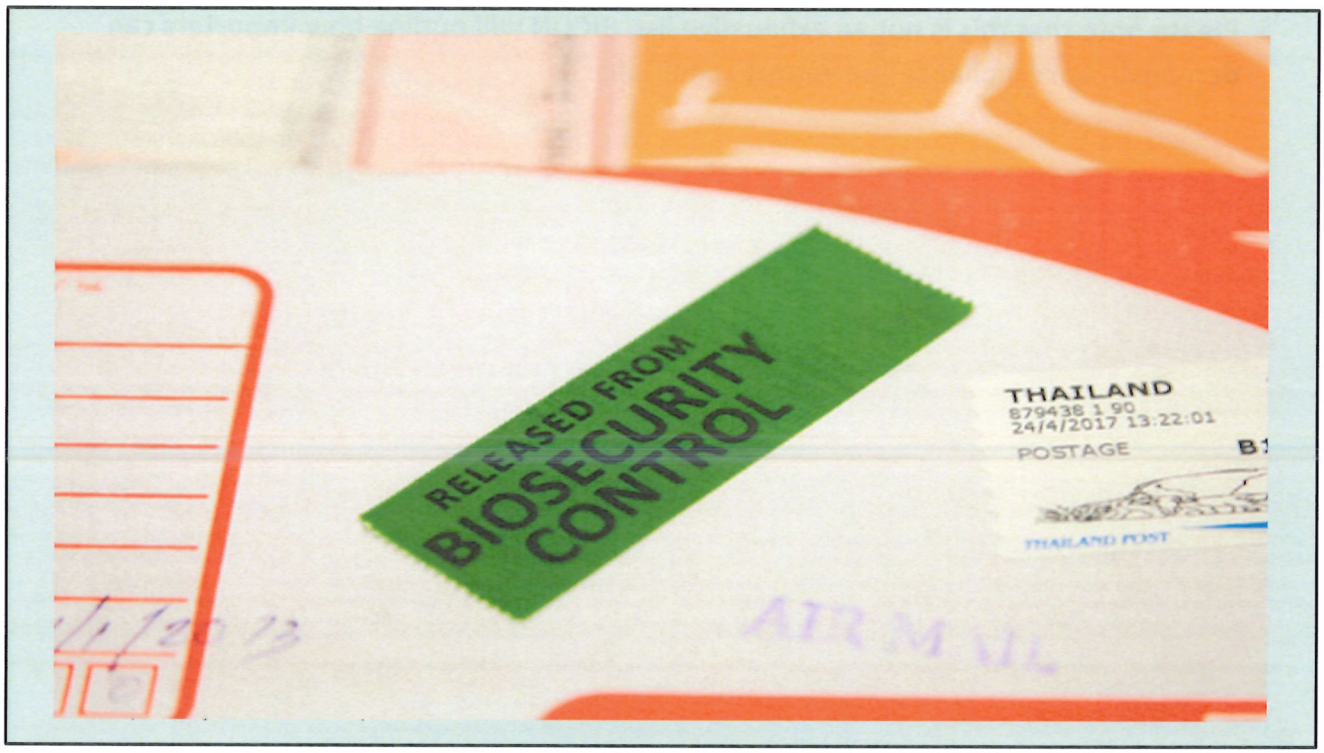
- An official government certificate – which is a certificate that has been issued by the overseas regulatory body of the exporting country that details the specific requirements for the goods.

- Government endorsed manufacturer's declaration – which is a declaration provided by the manufacturer of the goods and endorsed by a Government Veterinary Officer.

- Manufacturer's declaration – which is a declaration provided by the

manufacturer of the goods.

Please note that this is not an exhaustive list, BICON will outline how importers can demonstrate compliance the import conditions.



When goods arrive in Australia, whether it be via ships, planes, travellers, or mail, we first check that they are allowed to enter - that they meet our import conditions and that they are accompanied by the required supporting documents.

If they meet our conditions, we will inspect the goods and packaging to check for any unwanted plant material, dirt, insects, and diseases. These are known as biosecurity risk material.

If we find something of concern, we will hold the goods until the risk can be identified and addressed.

If the goods don't meet conditions, they will be treated, exported, or disposed of in an approved manner.

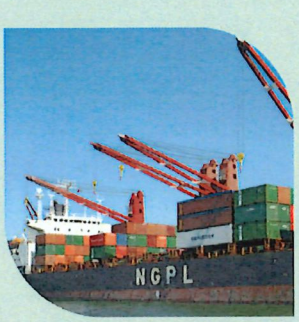
If we find the goods are free of biosecurity risk material, and all the import conditions have been met, they will be released.

Questions?

www.agriculture.gov.au

Imports@aff.gov.au

1800 900 090



Subscribe to Import Industry Advice Notices to get up to date information:

https://subscribe.agriculture.gov.au/subscribe

Australian Government

Department of Agriculture, Fisheries and Forestry

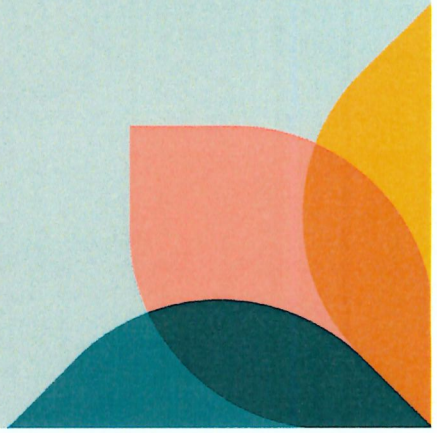
Electronic Certification

Corrina Linton-Smith

Assistant Director| eCert & Micor

Trade has changed

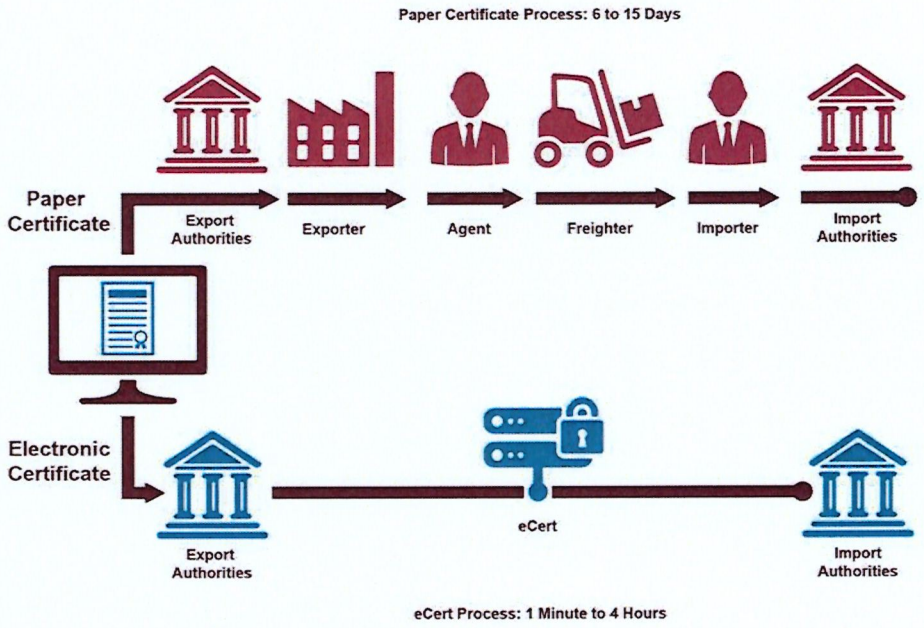
- As a result of the COVID-19 pandemic we have experienced a change in how we trade and how we provide information
- More trading partners are wanting to adopt eCert practices
- We have seen trading partners change their clearance processes, including:
  - Use of online verification tools
  - Use of electronic certification (eCert) and paperless trade
  - Acceptance of scanned copies of paper certificates



Introduction

What is eCert and our eCert expansion project?

- eCert is the secure, electronic data transmission of Sanitary and Phytosanitary (SPS) certificates
- eCert expansion project 2021-2026:
    - Expansion and Maintenance of eCert exchanges: bilateral and multilateral
    - Development of the eCert accredited person capability
    - Ultimate goal is paperless trade
- Streamlining the certification process for the department and external stakeholders
- Supports our departments digital trade strategy and Corporate Plan 2022-23

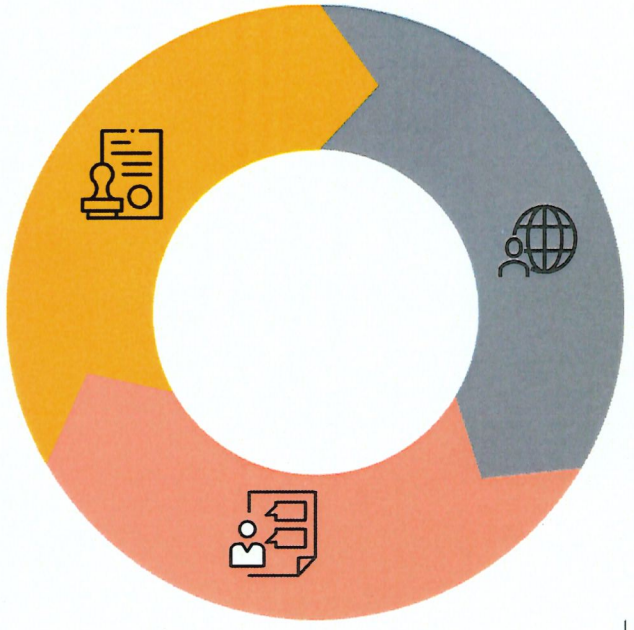


eCert benefits

Evolving certificates

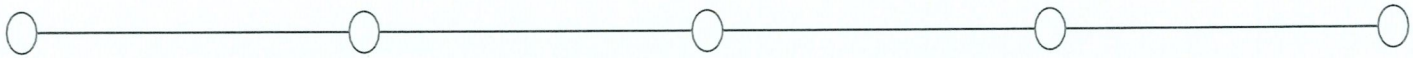
- Trading partners see eCert as an opportunity to expand:
  - New complexities are being added to our discussions
  - Requests for more information

- Various reason for changes to eCerts:
  - Automated decision making
  - Links to other systems
  - Traceability



Data Standardisation

There is a need for ongoing standards refinement in the eCert space



Data Security

The capacity and capability to adopt digital technologies is mixed, and digital technologies can give rise to trust concerns regarding data

Exchange Implementation

Currently countries individually negotiate, deploy, and maintain platforms among themselves

Harmonization

There is potential for further harmonization between economies and international organizations using the technologies and guidelines such as UN/CEFACT

Information Sharing

Opportunity to exchange best-practice guidance regarding the use of the digital technologies to develop a shared pool of expertise

Development

Australia is working towards assisting within Codex on possible future work for standardised model certificates to be used for animals and animal products.

Multilateral Group Participation

- The Codex Alimentarius Commission (Codex)
- The United Nations Centre for Trade Facilitation and Electronic Business (UN/CEFACT)
- World Organisation for Animal Health (WOAH)
- The Organisation for Economic Co-operation and Development (OECD)
- The Association of Southeast Asian Nations (ASEAN)
- Standards and Trade Development Facility (STDF)
- International Plant Protection Convention (IPPC)
- Strategic Food Safety Dialogue. SFSD

Food and Agriculture Organization of the United Nations

World Organisation for Animal Health
Founded as OIE

STDF

International Plant Protection Convention

OECD

UNECE
UN/CEFACT

Imported food legislation

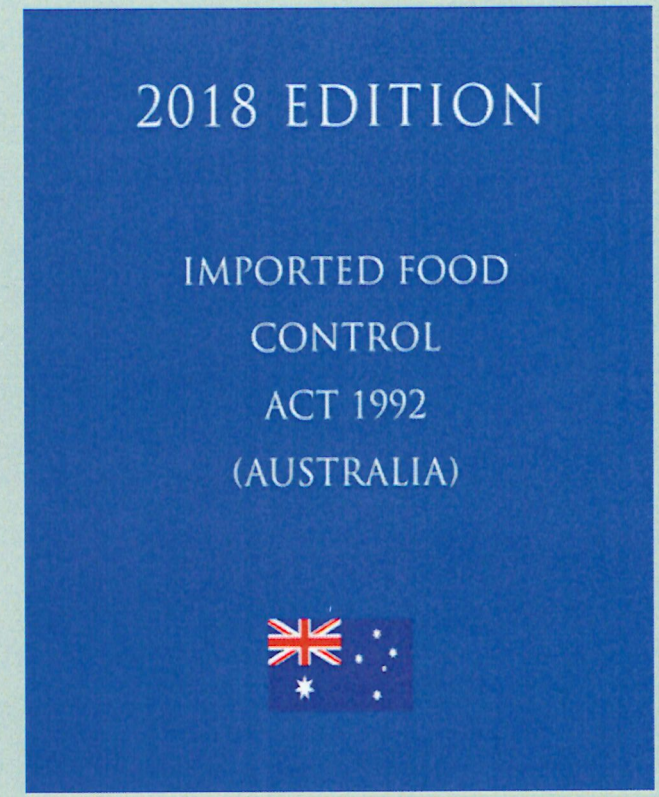
The department administers two sets of legislative requirements for imported food.

These requirements:

- protect Australia against biosecurity risks, under the **Biosecurity Act 2015**
- manage imported food safety risks, as set out in the Imported **Food Control Act 1992**.

All imported food must meet biosecurity import conditions to be allowed into the country.

We monitor imported food as part of the national food regulatory system.



Australian Import Systems

Integrated Cargo System (ICS)

All imported goods must be reported to the ICS of the Australian Border Force.

The Department of Agriculture, Fisheries and Forestry uses this information to perform an initial assessment of imported goods to determine if they pose a biosecurity risk or imported food concern.

Agriculture Import Management System (AIMS)

AIMS is the main import application used by the department. It allows us to manage risks and record actual biosecurity actions for individual consignments of imported cargo.

eCert Imports

The eCert Import application allows us to receive eCerts from overseas government agencies for import clearance. Once we have set up a secure eCert exchange with overseas agencies, we can receive eCerts from them almost instantly.

Import Management System (IMS)

IMS supports the assessment and inspection of imported goods entering Australia as cargo. It is used by biosecurity staff who assess, inspect and monitor self-assessed clearances.

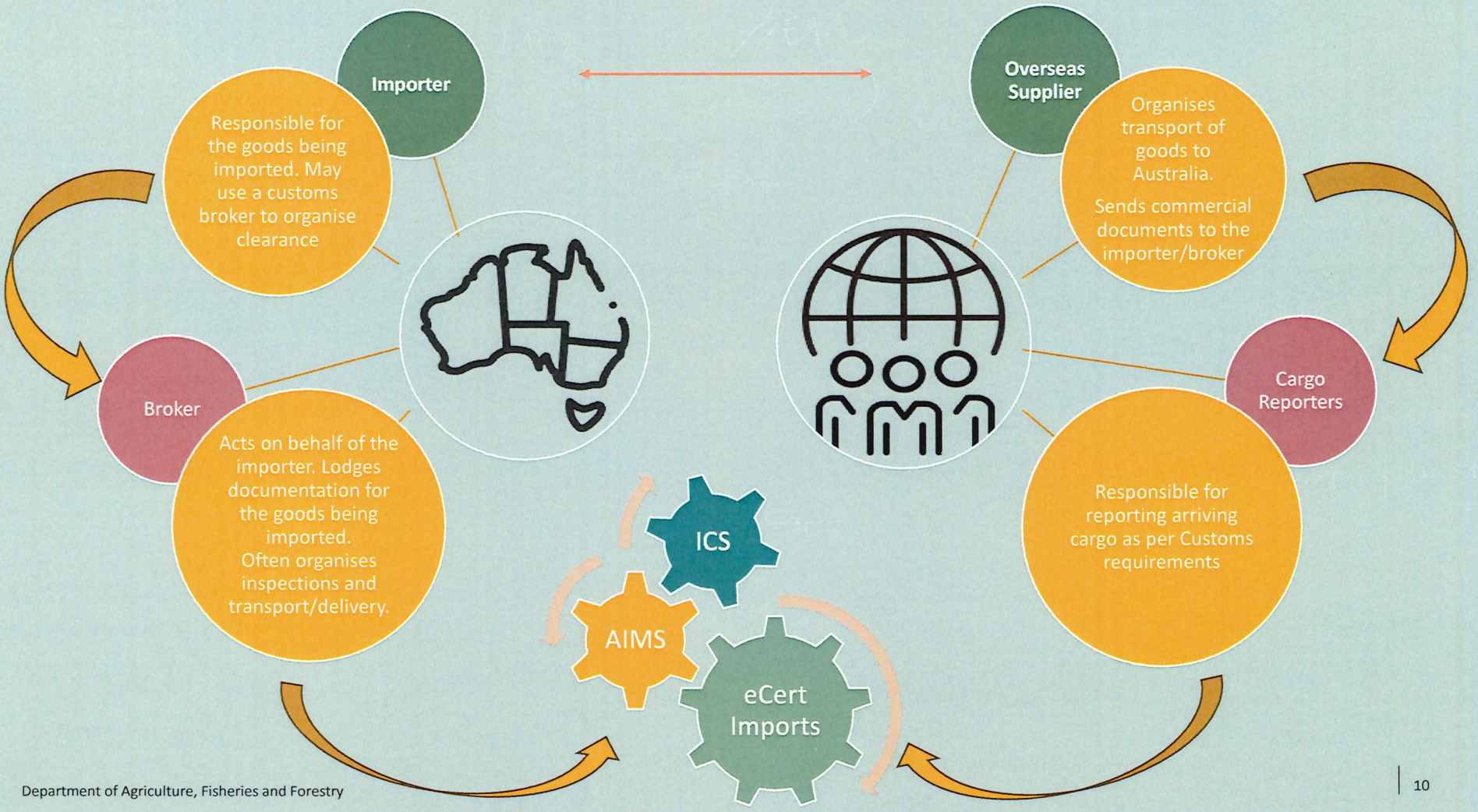
IMS integrates with the Agricultural Import Management System (AIMS), the Financial Management Information System (FMIS) and the Department of Home Affairs' ICS.

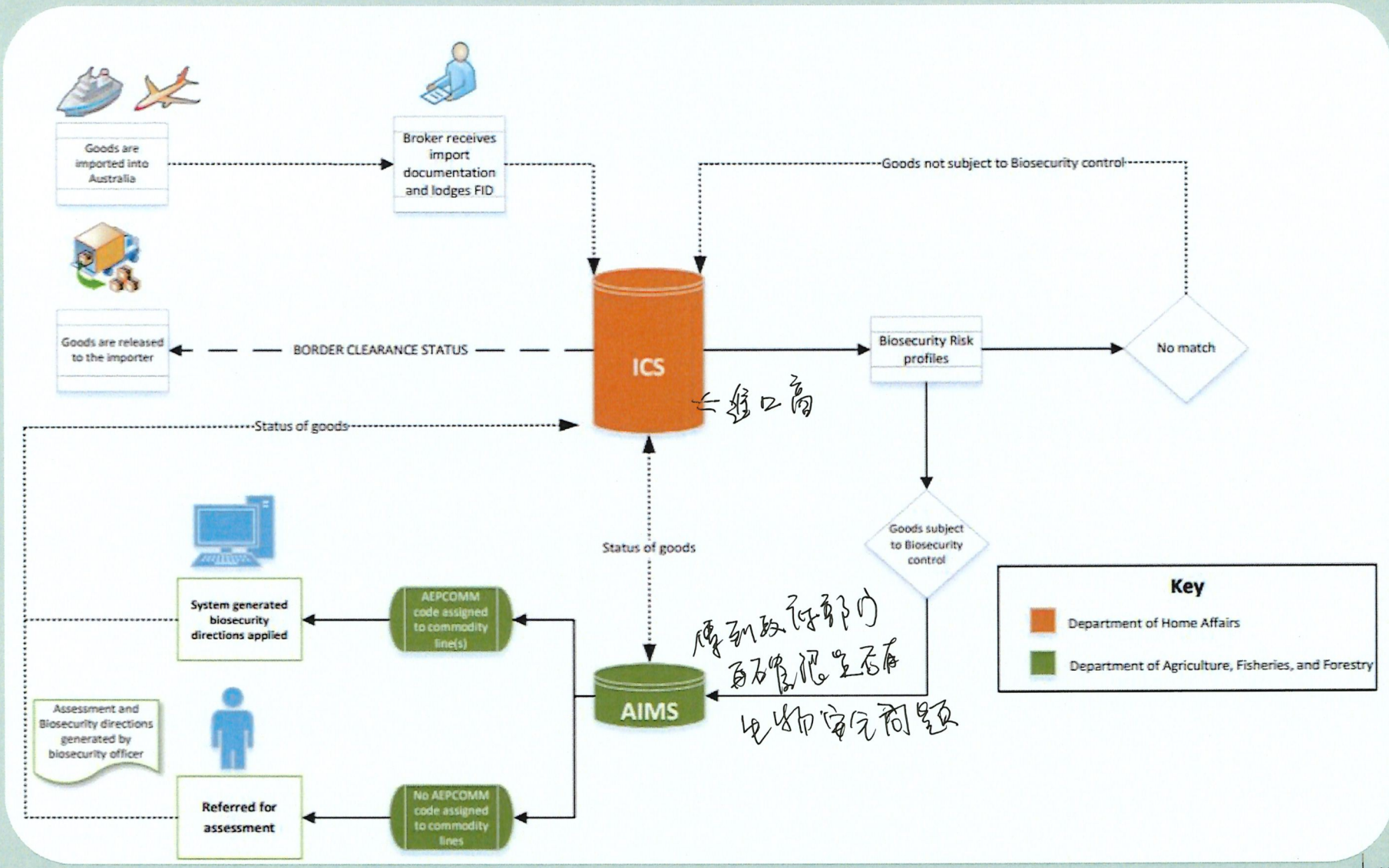
Biosecurity Import Conditions System (BICON)

BICON allows individuals and industry clients to search for import conditions related to their commodity and apply for and manage import permits.

The person in charge (usually the broker or importer) is responsible for checking BICON prior to import to find out what documentation to present to the department.

Importing cargo into Australia

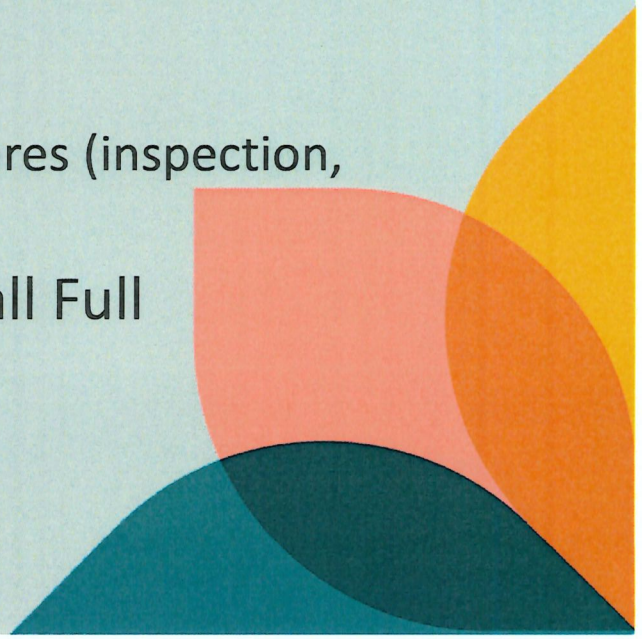



Goods are imported into Australia
Broker receives import documentation and lodges FID
Goods not subject to Biosecurity control
Goods are released to the importer
BORDER CLEARANCE STATUS
ICS
Biosecurity Risk profiles
No match
Status of goods
Status of goods
Goods subject to Biosecurity control
System generated biosecurity directions applied
AEPCOMM code assigned to commodity line(s)
AIMS
Assessment and Biosecurity directions generated by biosecurity officer
Referred for assessment
No AEPCOMM code assigned to commodity lines
Key
Department of Home Affairs
Department of Agriculture, Fisheries, and Forestry

What is AEP?

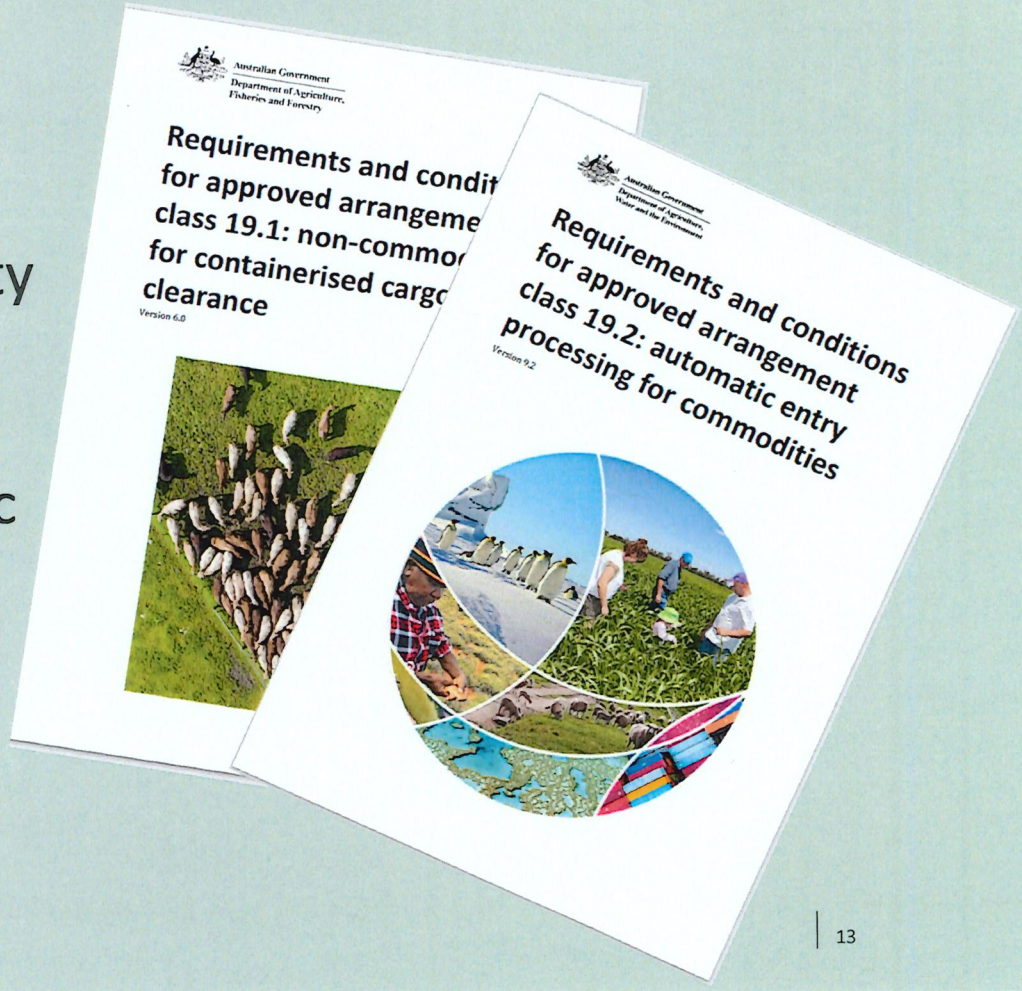
Automatic Entry Processing

- Provides the ability for accredited people (e.g. licensed customs brokers) to:
  - Assess import documentation
  - Release or direct goods for onshore Biosecurity measures (inspection, treatment)
- Currently AEP accounts for approximately 32% of all Full Import Declaration (FID) lodgements.



Approved Arrangements

- NCCC AA – Class 19.1 Non-Commodity for Containerised Cargo Clearance
- AEPCOMM AA – Class 19.2 Automatic Entry Processing for Commodities



Class 19.1 NCCC

AEP lodgement process – NCCC

- ICS General Declaration questions:

1. Are you an accredited person for non-commodity clearances?
2. Do all containers/consignments on this declaration meet non-commodity requirements and are they designated to be unpacked in a metropolitan postcode or inside the boundary of an approved port?

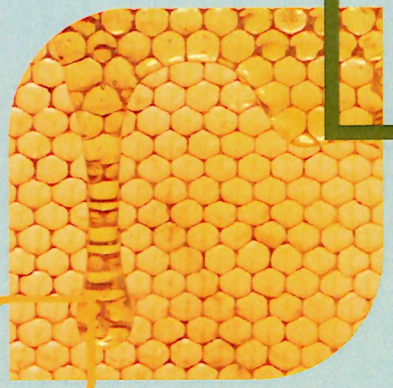
  - If 'no' to question 1, all consignments referred to the department for assessment.
  - If 'no' to question 2 - Concern Type/s must be entered
  - Concern type identifies the non-commodity risk and nominated onshore outcome.
  - System automatically adds a 'Non-Commodity' line and required direction from the Concern Type.

Class 19.2 AEPCOMM

AEPCOMM accredited brokers have the ability to assess the documentation for certain in-scope commodities, which are listed on the approved commodities webpage.

Examples of in scope commodities include:

- **Used vehicles and machinery**
- **New tyres**
- **Milled rice**
- **Manufactured wooden articles and products**
- **Unfinished timber and timber products**
- **Honey**
- **Dairy Products for Human Consumption from NZ**
- **Seafood for human consumption**



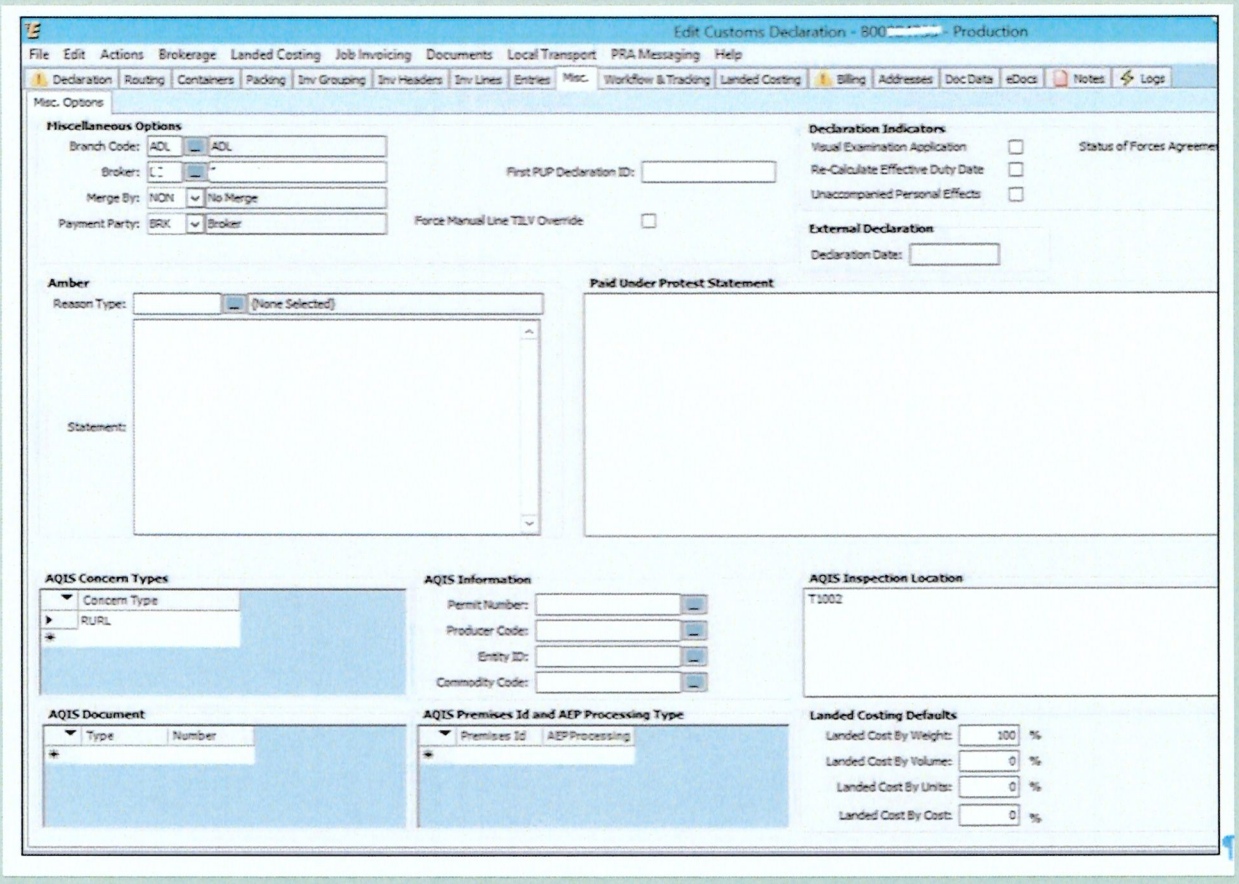
Class 19.2 AEPCOMM (continued)

AEPCOMM codes

COMMODITY CODE	OUTCOME
REL	Release
INS	Inspection
FUM	Fumigation

- AEP codes: release, inspection and fumigation are entered on each relevant line of the import declaration.
- Directions issued based on the AEPCOMM code, cargo type and commodity group.

FID lodgement process



eCert and AEPCOMM

- Currently Accredited Persons must ensure they obtain a copy of the phytosanitary certificate (or extract) prior to conducting an assessment and lodging the consignment via AEPCOMM.

- This documentary evidence must be retained and presented to the department for entries selected for AEP verification; or when a request for documentation has been made.

e cert number

Entering eCert information

eCert import exchange table

This table shows trading partners, certificate types and status of the exchanges we have established an eCert import exchange with.

Trading partner	Government certificate type	Status of exchange
New Zealand	Phytosanitary and Sanitary	Paperless*
South Korea	Phytosanitary	Parallel^

* No paper SPS certification is required for clearance. eCert is used for clearance.

^ We receive both the paper certificate and eCert together and the paper certificate is still used for clearance

AEP commodities that require eCerts

- Dairy
- Onions and shallots
- Seafood
- Timber

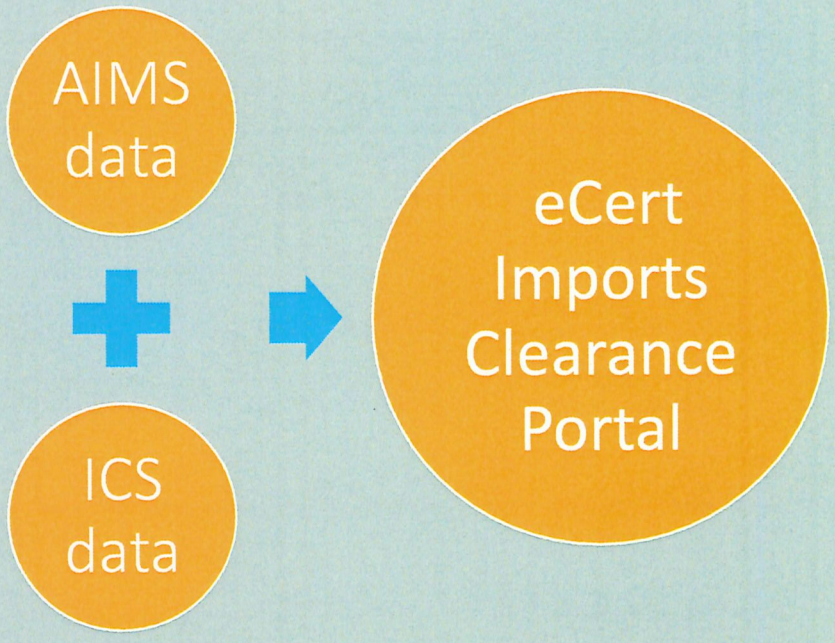
For inclusion on AEPCOMM (timing TBC):

- Beef

eCert Imports Clearance Portal

A digital solution for Accredited Persons...

- With eCert a Government-Government exchange, external persons are not able to access to AIMS
- A solution is currently being developed to allow Accredited Persons a portal in which they can access certificate data required to perform clearance assessments under AEPCOMM
- This portal will also be used to assist with Australia's domestic clearance processes



Thank you for engaging with the department's work on electronic certification!

Questions?

FOOD STANDARDS Australia • New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

Taiwan Food and Drug Administration (TFDA) visit

Tracy Hambridge and Nora Galway

Food Standards Australia New Zealand

19 October 2023

Part 1

Overview of FSANZ and the Australia and New Zealand Food Regulatory System

Tracy Hambridge

Acting Section Manager – International and Dietary Exposure Assessment

Part 2

Imported Food Risk Advice

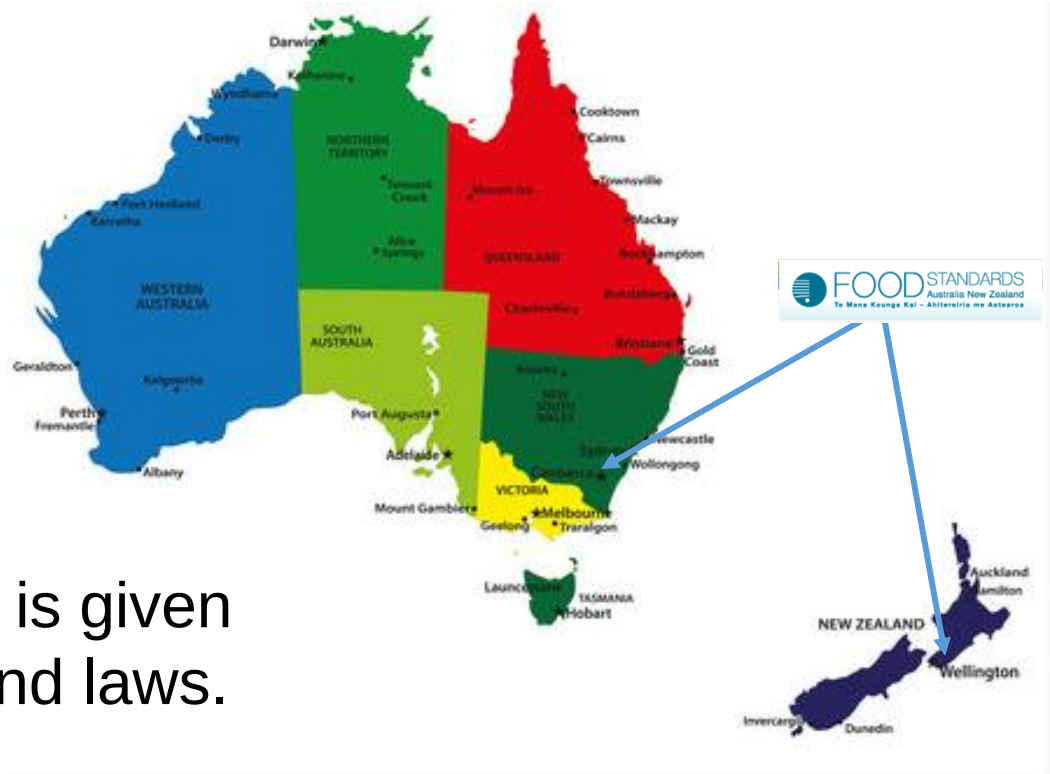
Nora Galway

Section Manager – Food Safety and Microbiology

Overview of FSANZ and the Australia and New Zealand Food Regulatory System

About Food Standards Australia New Zealand (FSANZ)

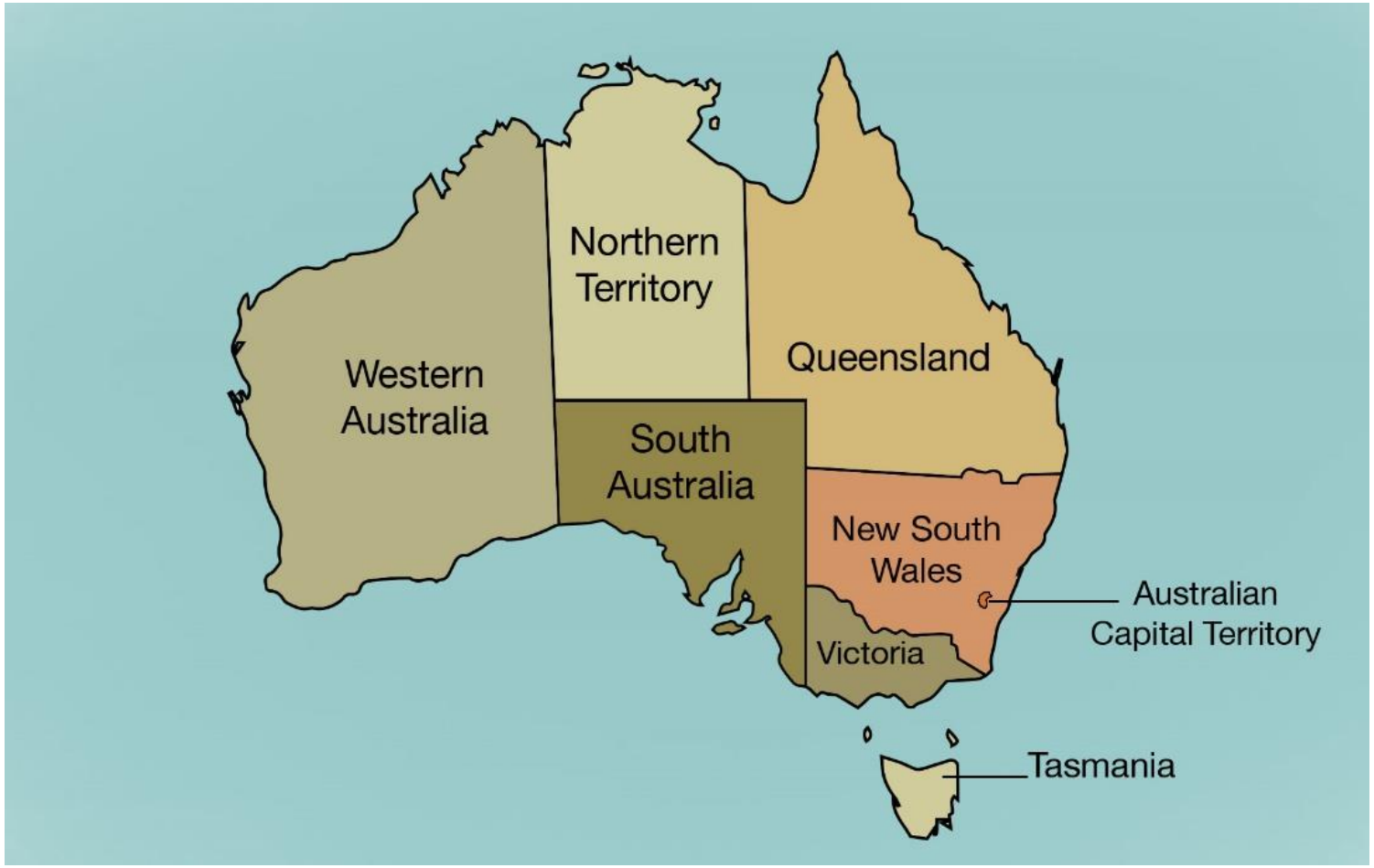
- FSANZ is an Australian statutory agency within the Health portfolio.
- Maintains a comprehensive list of food standards which are published as the *Australia New Zealand Food Standards Code* (the Code).



- The Code is a legislative instrument, that is given effect by state and territory or New Zealand laws.
- Science (risk assessment) and evidence based.
- Office in Canberra and Wellington.

Australian Government System

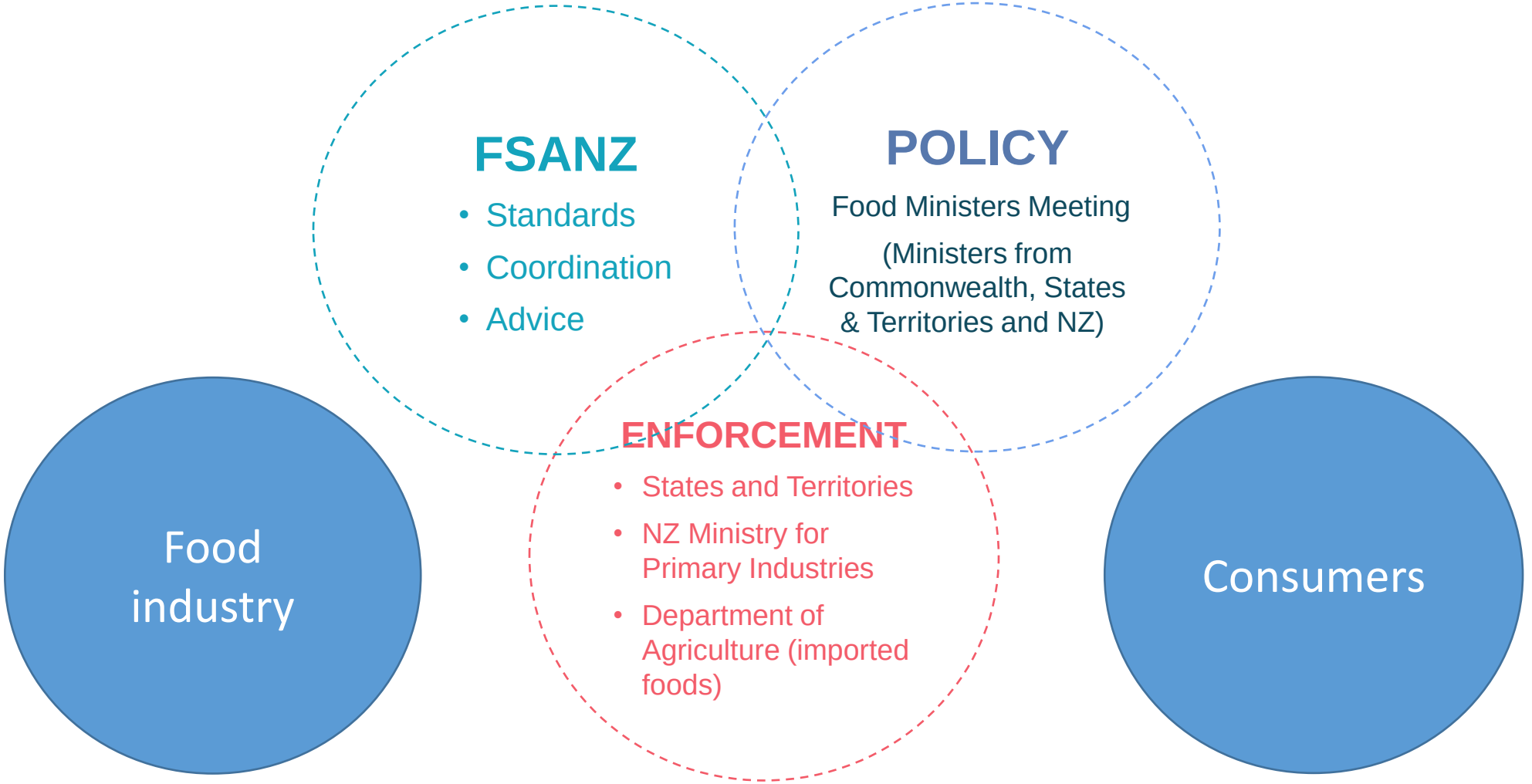
- Federal system
- Comprises Federal Government
- 6 States, and 2 main Territories
- Local Government Authorities



Where does New Zealand fit in?

- Most of the standards in the Food Standards Code also apply in New Zealand.
- *“Agreement between Australia and New Zealand establishing a System for the Development of Joint Food Standards”* (the bilateral Treaty).
- *Trans Tasman Mutual Recognition Arrangement* applies where food standards differ between Australia and New Zealand.

Australia and New Zealand's Food Regulatory Framework



FSANZ Act

Food Standards Australia New Zealand Act 1991

Act No. 118 of 1991 as amended

This compilation was prepared on 29 July 2002
taking into account amendments up to Act No. 63 of 2002

The text of any of those amendments not in force
on that date is appended in the Notes section

Prepared by the Office of Legislative Drafting,
Attorney-General's Department, Canberra

FSANZ Act

The FSANZ Act sets out four goals for the agency:

- a high degree of consumer confidence in the quality and safety of food in Australia and New Zealand
- an effective transparent and accountable regulatory framework, within which the food industry can work efficiently
- the provision of adequate information relating to food to enable consumers to make informed choices
- the promotion of consistency between Australia, New Zealand and international food standards.

About FSANZ - What else do we do?

- Undertake surveillance of the Australian food supply
  e.g. Australian Total Diet Study (ATDS)
- Coordinate food incidents and food recalls
- Provide risk advice to the Australian Department of Agriculture, Fisheries and Forestry in relation to imported food
- International engagement

About FSANZ – What we do not do

- Enforce food standards
- Set or manage food policy
- Regulate therapeutic goods or dietary supplements
- Regulate agricultural and veterinary chemicals, or industrial chemicals
- Regulate imported food

The Australia New Zealand Food Standards Code

Chapter 1

General food standards:

- Definitions
- Labelling requirements
- Use of substances added to food
- Use of new foods
- MRLs (Aus)
- Food processing requirements (Aus)

Chapter 2

Food product standards:

- Cereals
- Fruits
- Vegetables
- Dairy products
- Beverages
- Special purpose foods

Chapter 3

Food safety standards

Australia only

- Food safety programs
- Food premises and equipment

Chapter 4

Primary production standards

Australia only

- Production and processing of seafood
- Poultry meat
- Meat, and
- Other commodities

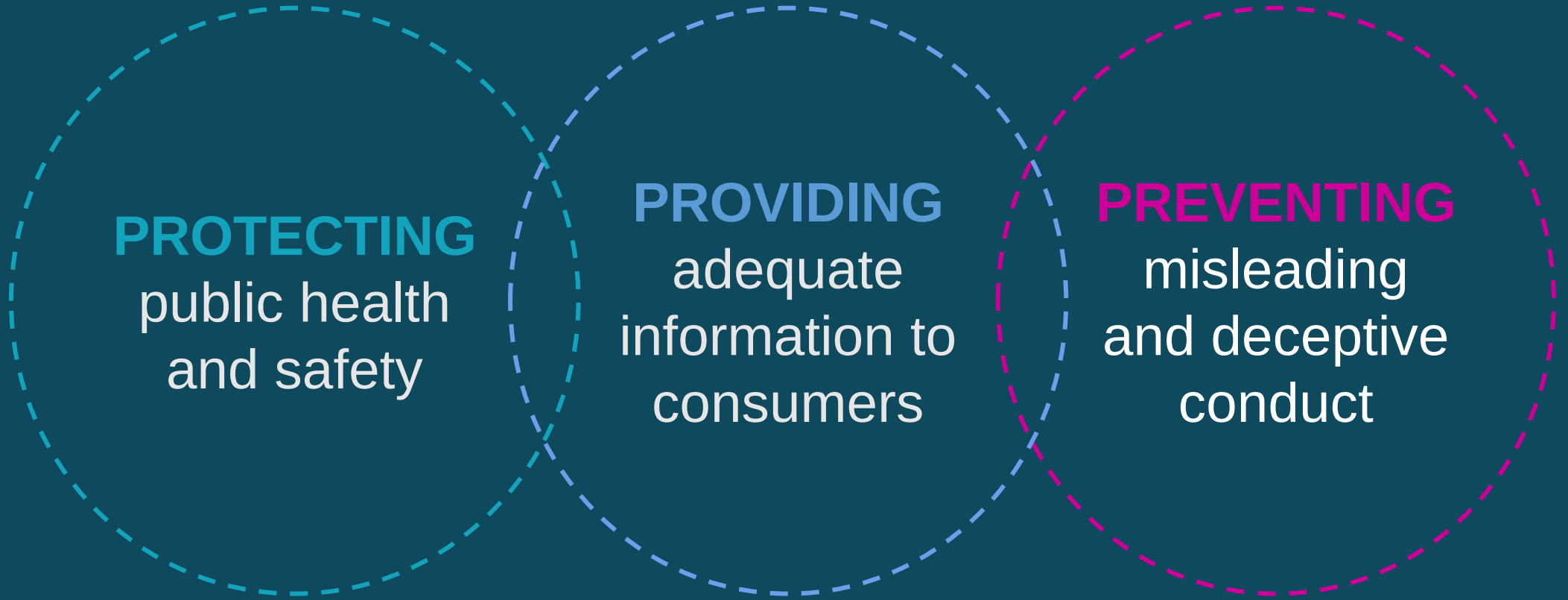
Schedules

Permissions for use of:

- substances added to food
- use of new foods
- Permitted MRLs

FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

When developing measures we consider



We also consider

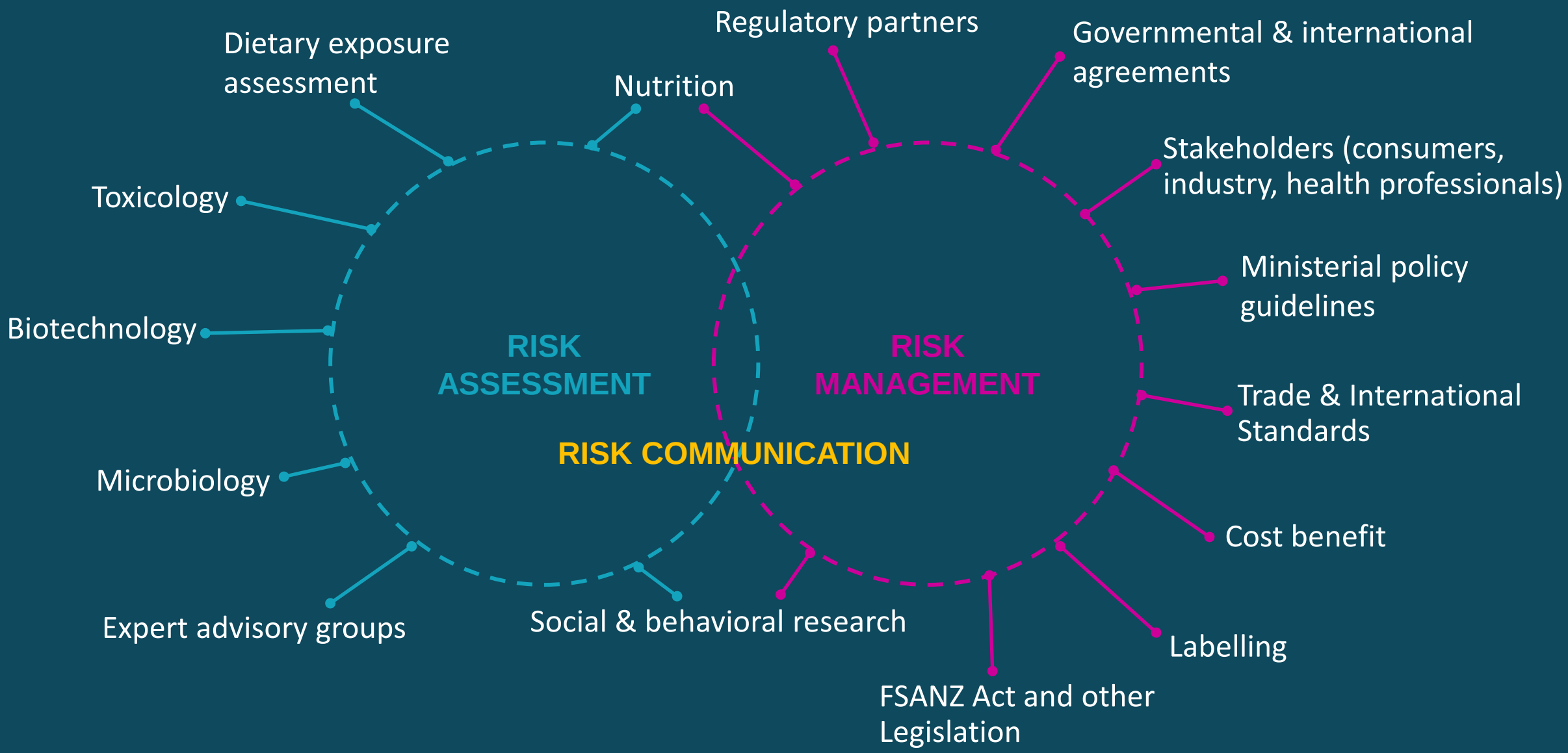
In developing or reviewing food regulatory measures and variations of food regulatory measures, FSANZ must also have regard to the following:

(a) the need for standards to be **based on risk analysis** using the **best available scientific evidence**;

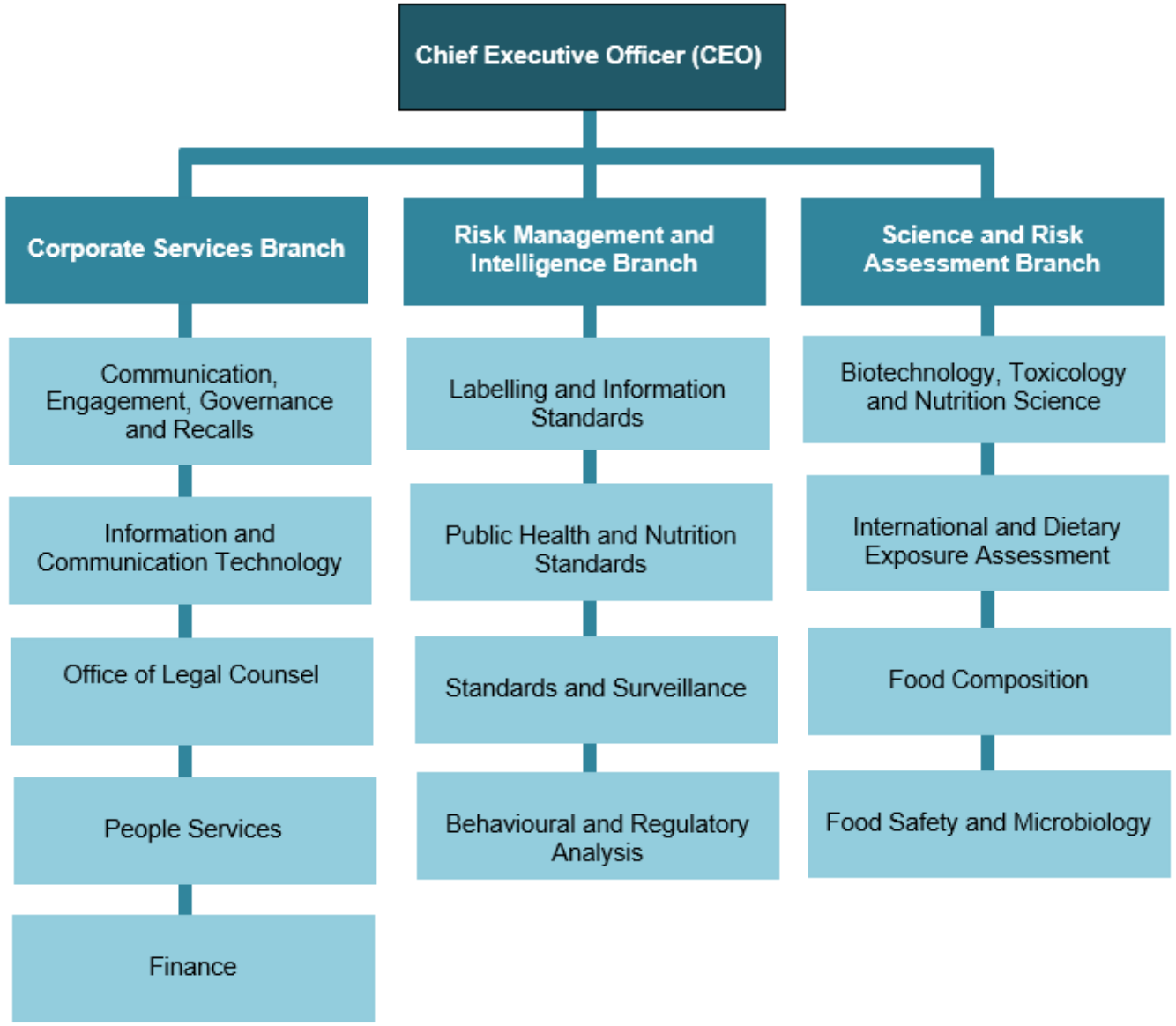
(b) the promotion of **consistency between domestic and international food standards**;

(c) the desirability of an **efficient and internationally competitive food industry**.

Things we take into account at FSANZ



About FSANZ – Our Structure



Two main pathways for setting food standards

Application

Anyone can apply
Statutory timeframes
Targets a specific standard
Public consultation
FSANZ Board approval notified to food ministers for ministers' decision.

Proposal

Initiated by FSANZ
No statutory timeframes
Large, complex changes
Extensive consultation
FSANZ Board approval notified to food ministers for ministers' decision.

International work

APEC Food Safety Cooperation Forum

FAO/WHO Expert Meetings & Consultations

Visiting Delegations

Codex Committees

International networks & liaison groups

OECD - Novel Foods & Feeds Working Group

Multilateral Relationships

Bilateral Relationships

Imported Food Risk Advice

Regulatory Environment

- Department of Agriculture, Forestry and Fisheries (DAFF)
  - Protect against biosecurity risk
  - Food safety of imported product
    - Food must meet Australian food standards
    - Risk based border inspection program

Biosecurity Act 2015

Imported Food Control Act 1992

- FSANZ
  - Develops assessment policies for imported food
  - Conducted a review of risk category foods between 2013-2016
  - Provision of requested imported food risk advice from 2017 onwards

Food Standards Australia New Zealand Act 1991

Australian state and territory jurisdictions are responsible for implementation of the Food Standards Code once food enters the country (i.e. post-border)

DAFF's risk management role

Food categories:

- **Risk food (**i.e. food posing a potentially high or medium risk to public health)

  The rate of inspection starts at 100% and then:
  - is reduced to 25% of consignments following 5 consecutive passes
  - is reduced to 5% following a further 20 consecutive passes
  - is increased back to 100% if a risk food fails inspection.
  - Some risk foods need certificates for import.

- **Surveillance food**
  - 5% of surveillance food randomly selected for border inspection against compliance with Food Standards Code; visual and labelling and range of micro/chemical hazards.

- **Compliance agreement food**

Imported Food Inspection Scheme - DAFF (agriculture.gov.au)

Provision of advice

- FSANZ provides advice on whether imported food potentially poses a medium or high risk

- FSANZ provides advice to DAFF:
  - Review of ‘risk foods’
    - (Imported Food Control Order 2001, Schedule 1)
  - In response to an incident
  - Upon request from DAFF

Schedule 1—Risk food

(suborder 4 (1))

1 Kinds of food

For suborder 4 (1), the kinds of food are each kind of food that is described in 1 or more items of the following table. Each item of the table is to be read separately and in addition to each other item.

Kinds of food that are required to be inspected, or inspected and analysed

Item	Kinds of food
1	Beef
2	Beef products
3	Cassava chips that are ready-to-eat
4	Cheese in which growth of *Listeria monocytogenes* can occur
4A	Raw milk cheese
5	Cooked chicken meat that is ready-to-eat, but is not canned
6	Coconut that is dried
7	Crustaceans, including prawns, that are cooked (whether or not chilled or frozen), but are not canned
8	Fish of the following kinds: (a) all fish in the Family Carangidae; (b) all fish in the Family Clupeidae; (c) all fish in the Family Coryphaenidae; (d) all fish in the Family Engraulidae; (e) all fish in the Family Pomatomidae; (f) all fish in the Family Scomberesocidae; (g) all fish in the Family Scombridae
8A	Fish products that contain more than 300 grams per kilogram of all or any of the kinds of fish in the families mentioned in item 8
8B	Ready-to-eat finfish
9	Manufactured meat that is cooked, including meat pastes and pâté
10	Ready-to-eat meat of the following kinds: (a) uncooked dried meat; (b) uncooked sausages; (c) uncooked spreadable sausages
11	Marinara mix (whether or not chilled or frozen)
12	Molluscs Bivalve (whether cooked or uncooked)
13	Paprika that is dried
14	Peanuts and any food that contains peanuts
15	Peanut products and any food that contains peanut products
16	Pepper that is dried
17	Pistachios and any food that contains pistachios
18	Pistachio products and any food that contains pistachio products
20	Cooked poultry paté and poultry livers that are ready-to-eat, but are not canned
21	Seaweed—brown only
22	Sesame seeds and sesame seed products
23	Human milk and human milk products

Examples of imported food risk advice provided

Market access requests

- Cooked turkey and duck meat
- Raw beef

Linked to adverse effects

- Caffeine

Food potentially containing hazards of risk to human health

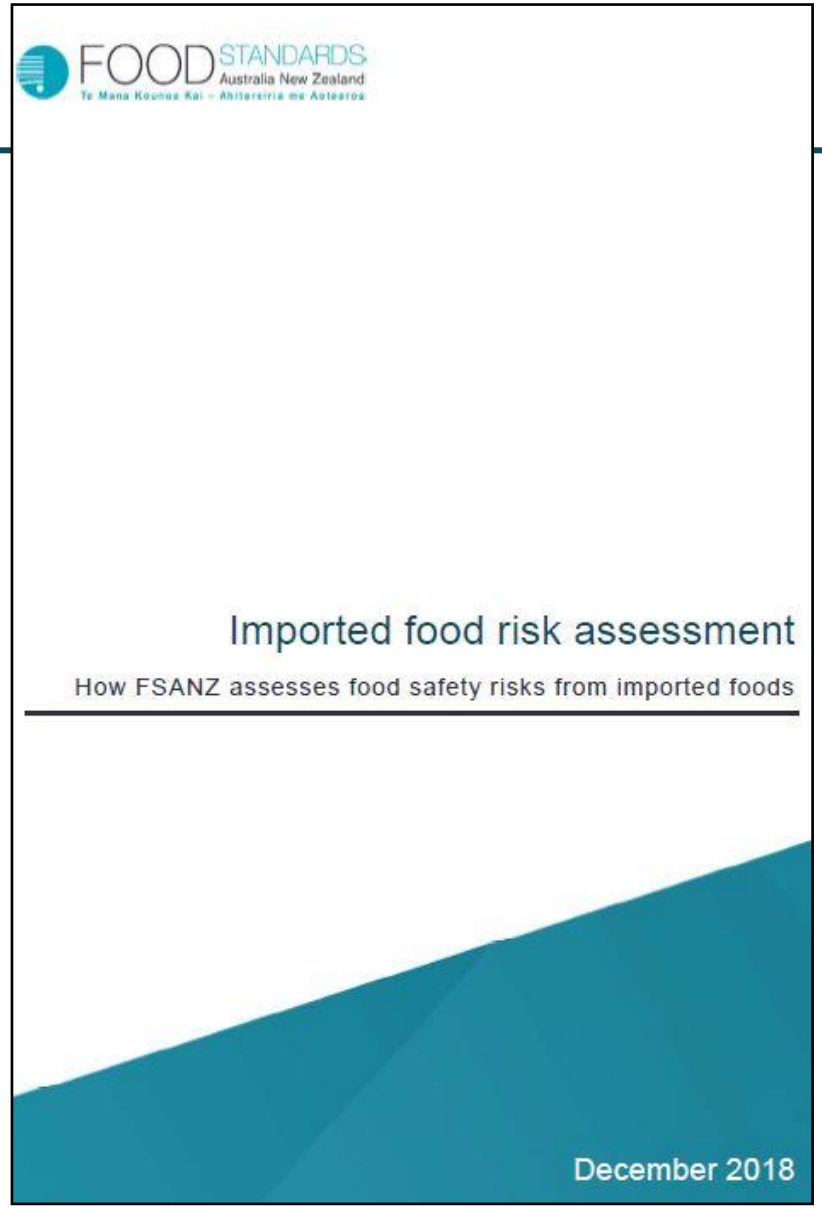
- Human milk
- Biotoxins in bivalves
- Horticultural produce

Advice provided

- To date, advice published for 112 commodity:hazard pairs

- Imported food risk assessment document detailing how the risk advice is prepared

  http://www.foodstandards.gov.au/consumer/importedfoods/Pages/default.aspx



FSANZ risk assessments

Risk Profile

Dairy — **Multiple Hazards, Multiple Foods**

Risk ranking

Seafood

Qualitative

Noroviruses in oysters — **One Pathogen:One Commodity**

Roquefort cheese, raw goat milk — **Several Pathogens:One Commodity**

Raw milk cheese — **Several Pathogens:Several Commodities**

Semi - quantitative

B. cereus in infant formula — **One Pathogen:One Commodity**

Quantitative

Campylobacter in Poultry — **One Pathogen:One Commodity**

Salmonella in Poultry

Raw cow milk — **Several Pathogens:One Commodity**

Imported foods risk statements

FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

Imported food risk statement

Fresh and frozen ready-to-eat berries and hepatitis A virus

Scope: Ready-to-eat (RTE) fresh and frozen berries, including (but not limited to) blackberries, blueberries, raspberries, strawberries, mulberries, loganberries, cranberries, bilberries, gooseberries and currants (*Ribes* genus). Retorted and dried product is not covered by this risk statement.

Recommendation and rationale
Does hepatitis A virus (HAV) in imported fresh and frozen RTE berries present a potential medium or high risk to public health: ☑ *High* ☐ *Medium* ☐ *No* FSANZ concludes that hepatitis A virus (HAV) in imported fresh and frozen RTE berries presents a potential high risk to public health. Rationale: • HAV is a serious hazard as it causes incapacitating illness of moderate duration which, in rare cases, can be life threatening. It is very infectious, with small quantities likely to cause infection. • There is strong evidence that HAV has caused foodborne illness associated with fresh and frozen RTE berries. • The method of primary production and processing can introduce contamination, and there is also the potential for post-processing contamination of the food. Berries are often eaten raw, so there is no pathogen elimination step. • Although HAV cannot replicate in food, it can survive in frozen and fresh RTE berries and still be present at the time of consumption. • In Australia, hepatitis A is uncommon and, while vaccination is available, there is a low overall seroprevalence in the population. This means a significant proportion of the Australian population are susceptible to foodborne transmission of HAV.

General description
Nature of the virus: Hepatitis A (HAV) belongs to the *Picornaviridae* family of viruses. It is a small (25–28 nm) non-enveloped icosahedral virus with a single stranded RNA genome. Like all viruses, HAV can multiply in living host cells but cannot replicate in food. However the virus can survive in food and still be present at the point of consumption. The virus can also survive in the environment and is considered to be extremely stable under a wide range of environmental conditions, including drying, freezing and heating (Codex 2012; FDA 2012; FSANZ 2013; Hollinger and Martin 2013). The host range of HAV is limited to humans and non-human primates (Hollinger and Martin 2013). In humans, HAV is transmitted via the faecal-oral route by either person-to-person contact or consumption of contaminated food or water (FSANZ 2013). HAV replicates in the liver before being released into the small intestine via the bile duct and subsequently shed in highest concentrations in faeces. Peak levels of HAV shedding in faeces occurs in the two weeks prior to the onset of clinical symptoms (up to 10^8 infectious HAV particles per gram of faeces) (Hollinger and Martin 2013). Also, increasing the temperature of heating and the type of food matrix (Bidawid et al. 2000; Codex 2012; FSANZ 2013). Also, increasing the concentration of sugar increases the resistance of HAV to heating (Deboosere et al. 2004). Cooling and freezing processes are not considered suitable for the control of viruses as they do not reduce virus infectivity to levels considered safe. In studies on enteric viruses on berries and herbs, Butot et al. (2008; 2009) showed that both freeze-drying and frozen storage for up to Asymptomatic and symptomatic infected persons are generally unaware they present a hazard at the time most virus is shed in faeces (FSANZ 2013).

FSANZ provides risk assessment advice to the Department of Agriculture, Water and the Environment on the level of public health risk associated with certain foods. For more information on how food is regulated in Australia refer to the FSANZ website or for information on how imported food is managed refer to the Department of Agriculture, Water and the Environment website.

FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

Imported food risk statement

Pure and highly concentrated caffeine products

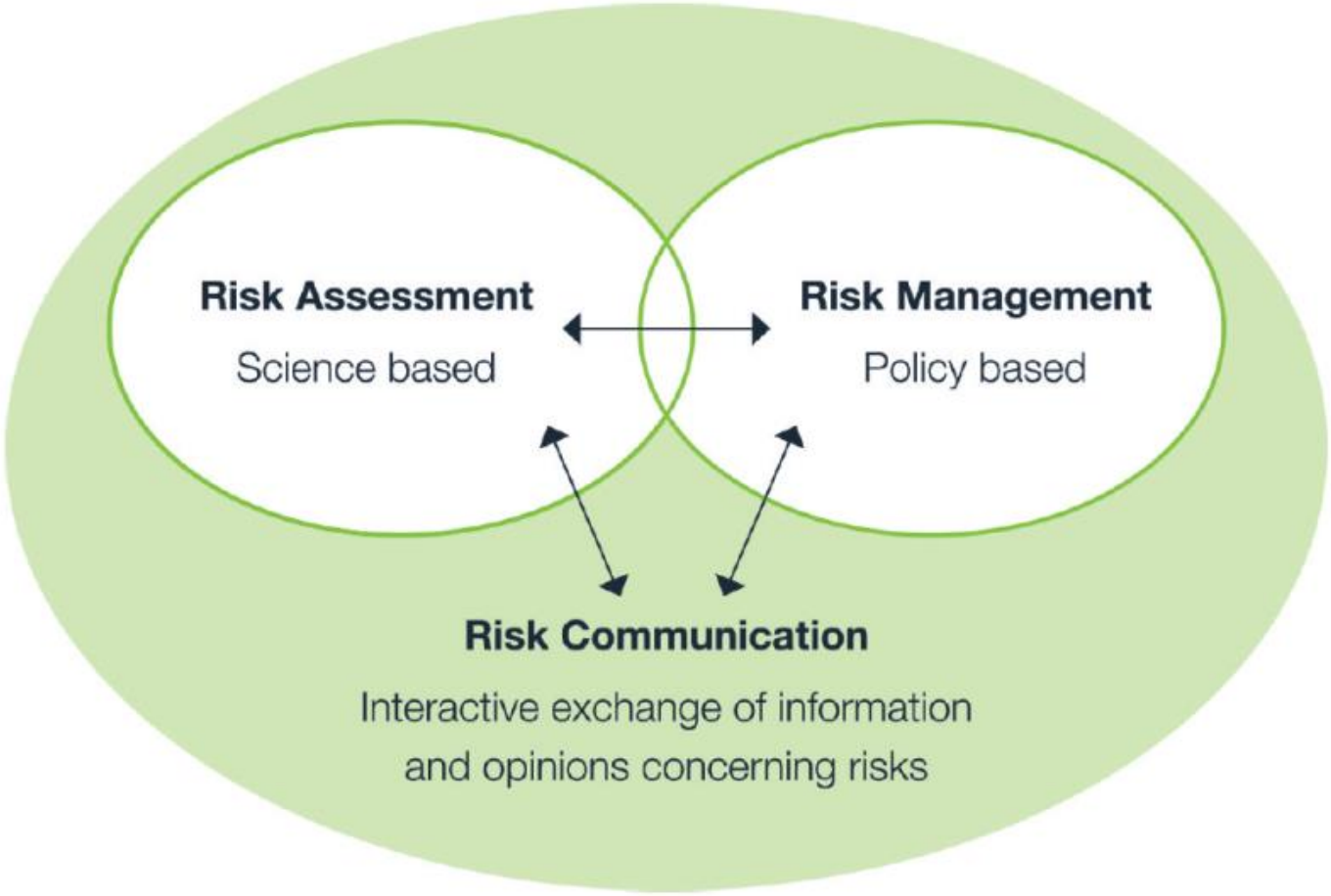
Scope: This advice applies to foods, food ingredients and beverages that contain caffeine

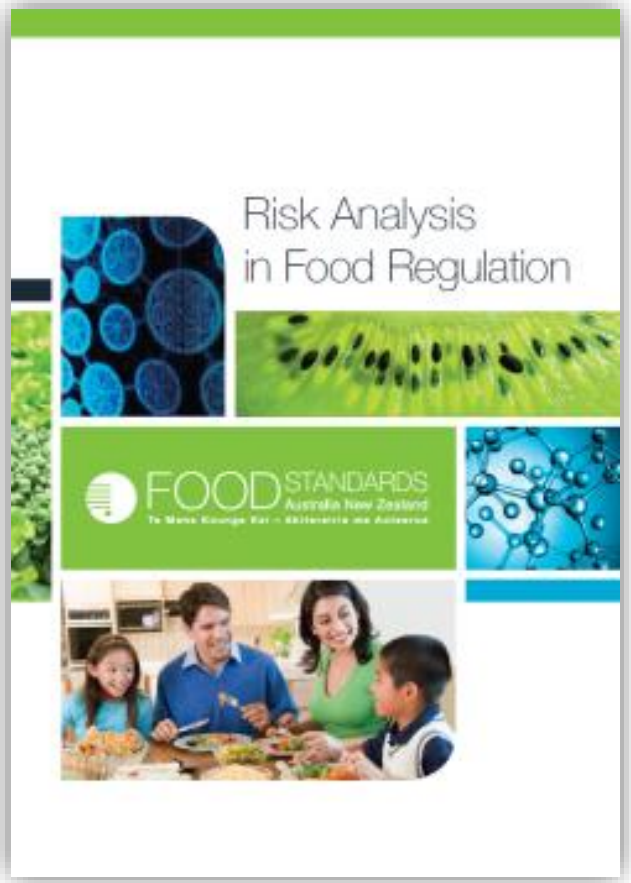
Recommendation and rationale
Does caffeine in high caffeine content food products present a potential medium or high risk to public health that may require additional management measures: ☑ *Yes* ☐ *No* Rationale: • Pure or highly purified forms of caffeine pose an unacceptable acute health risk to consumers. Ingestion of small amounts of these substances can result in severe health effects, including death. • The risk of serious health effects is compounded by the fact that these products typically need the consumer to self-measure caffeine servings, and require fine scales to weigh an appropriate dose. To manage the risk to public health, Food Standards Australia New Zealand (FSANZ) has amended Standard 1.1.1 to provide that a food sold for retail sale must not contain total caffeine present in a concentration of 1% (liquid form) or more, or 5% (powder or other non-liquid form) or more.

General description
Nature of the toxin: Caffeine is a methylxanthine alkaloid synthesized by a number of plants and naturally found in foods such as coffee, tea, cocoa, chocolate, yerba mate and guarana. Caffeine is an antagonist of adenosine receptors in the central nervous system, reducing sleepiness and promoting mental alertness, and is widely used as a mild stimulant. Caffeine also helps reduce the perception of effort, making it popular among athletes as a performance enhancer. FSANZ is also aware that a number of analogues or derivatives of caffeine exist naturally or can be chemically synthesised. Caffeine analogues are not within the scope of this advice. Adverse health effects: Acute ingestion of caffeine up to 200 mg is not associated with safety concerns in healthy adults. At higher doses, caffeine may cause adverse effects including increase in blood pressure and plasma catecholamines, and reduction of myocardial blood flow. Acute doses of 400-500 mg caffeine may cause increased anxiety in psychologically normal adults. Doses in excess 200 mg are associated with tachycardia, ventricular arrhythmia and seizures and may require urgent medical attention. t been reported at a dose of 3 000 mg, however it is more commonly associated with doses of around 5 000 to affeine. ations with lower tolerance for caffeine include children, pregnant or lactating women, people with impaired myocardial perfusion, people with certain mood disorders such as anxiety, and people

Risk analysis at FSANZ

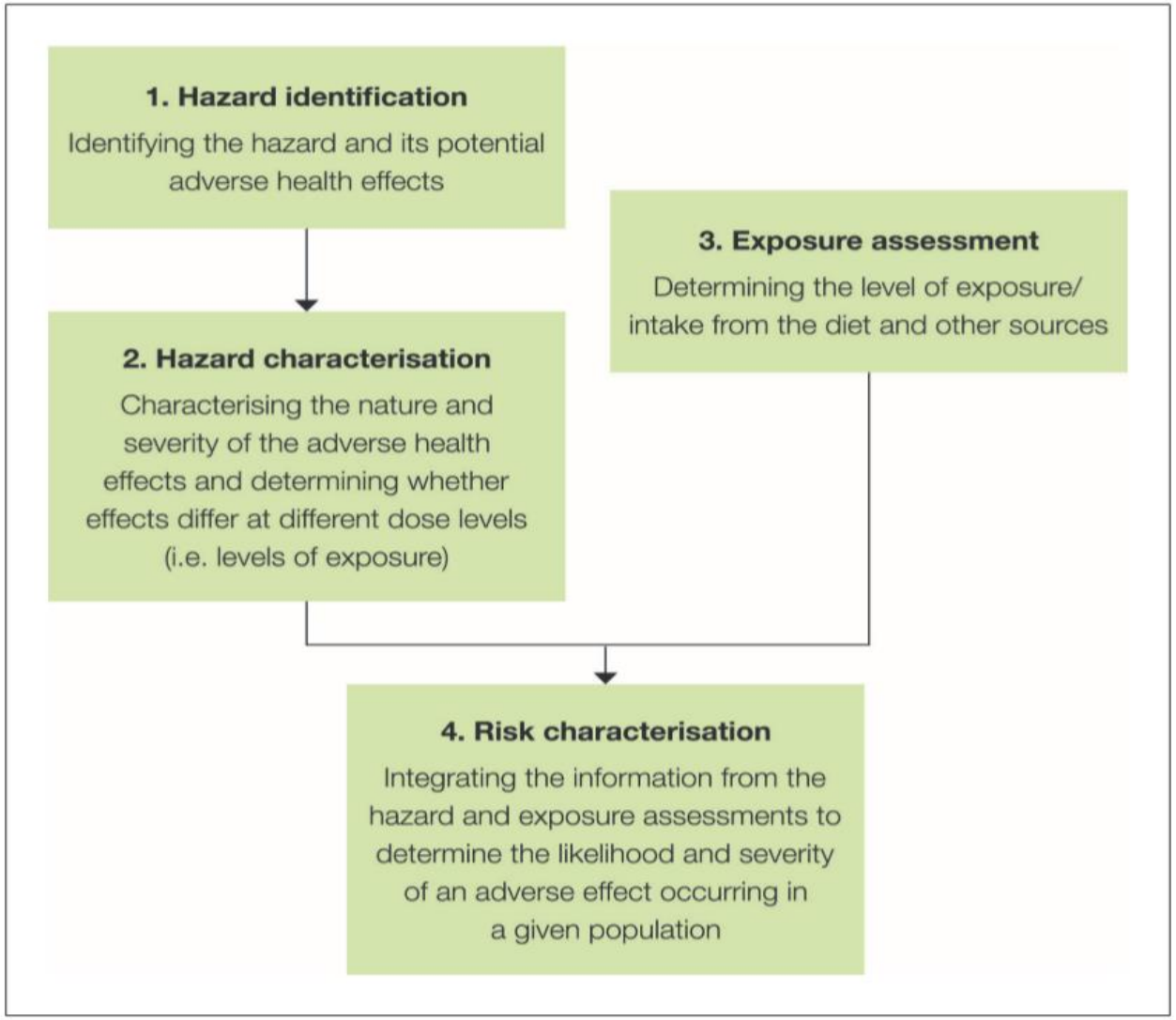
Codex risk analysis framework





http://www.foodstandards.gov.au/publications/riskanalysisfoodregulation/Pages/default.aspx

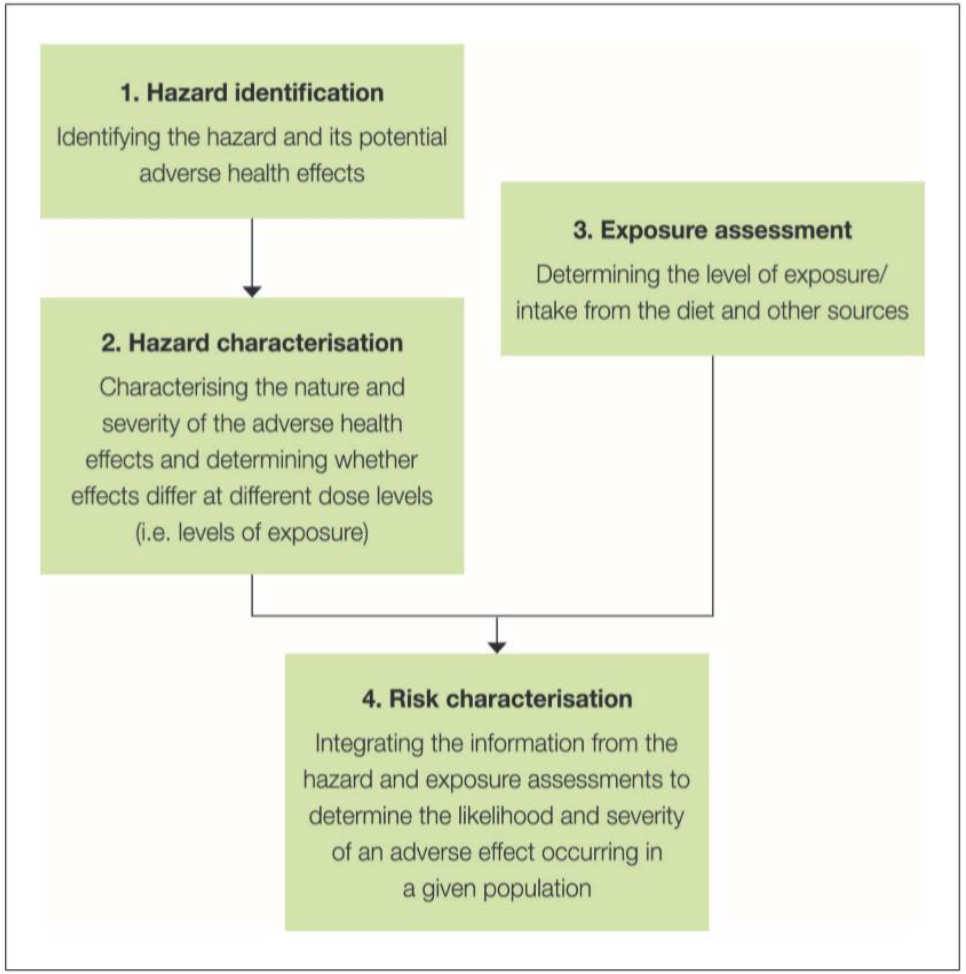
Four key steps in risk assessment



Follow the Codex risk assessment framework

Chemical risk assessment of imported foods

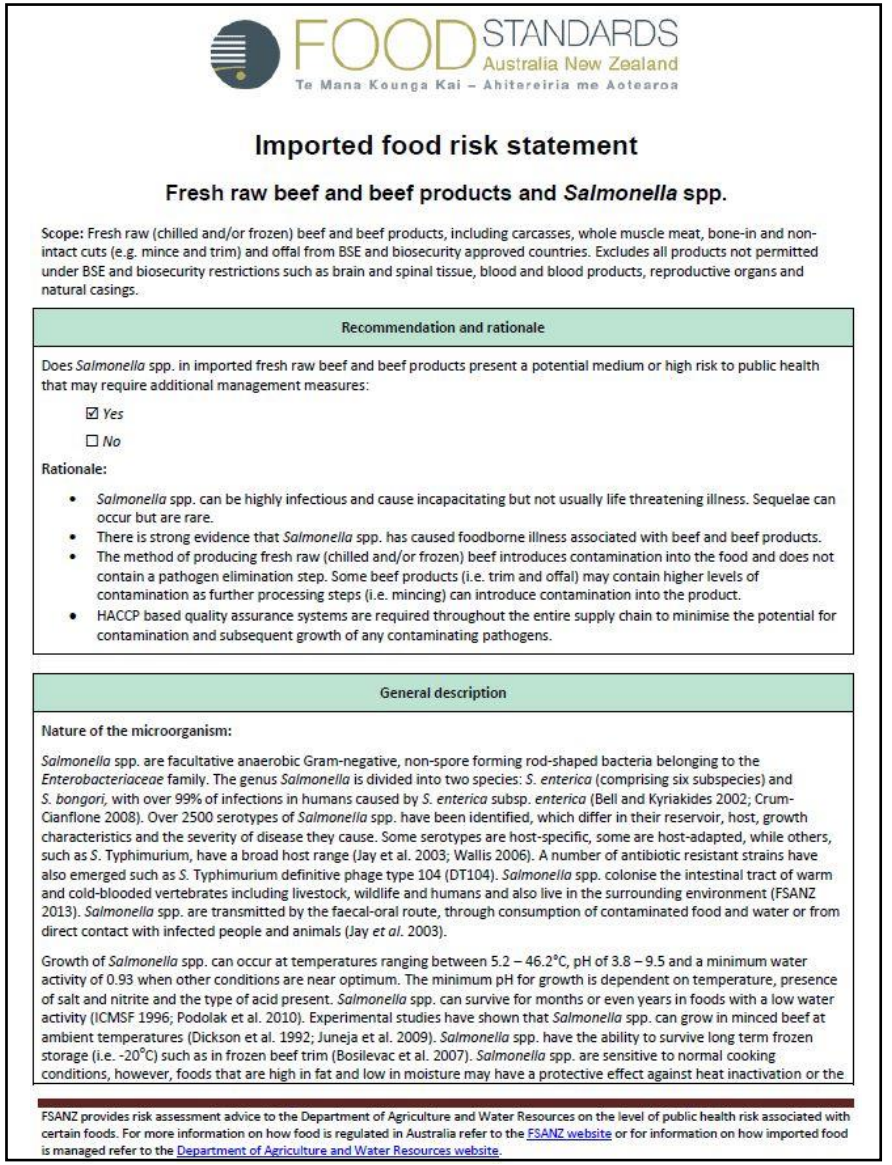
- Food chemical risk assessment is based on international best practice
- Hazard characterisation identifies heath-based guidance values (HBGVs)
  - A HBGV is a level of exposure at which there is no appreciable health risk
- Risk characterisation compares HBGV to estimated dietary exposure



Microbiological risk statements for imported foods

Summarises:

- Hazard identification
- Severity
- Risk factors
- Risk mitigation
- Outbreak data
- Surveillance data
- Level of risk



FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

Imported food risk statement

Fresh raw beef and beef products and *Salmonella* spp.

Scope: Fresh raw (chilled and/or frozen) beef and beef products, including carcasses, whole muscle meat, bone-in and non-intact cuts (e.g. mince and trim) and offal from BSE and biosecurity approved countries. Excludes all products not permitted under BSE and biosecurity restrictions such as brain and spinal tissue, blood and blood products, reproductive organs and natural casings.

Recommendation and rationale

Does *Salmonella* spp. in imported fresh raw beef and beef products present a potential medium or high risk to public health that may require additional management measures:

☑ *Yes*

☐ *No*

Rationale:

- *Salmonella* spp. can be highly infectious and cause incapacitating but not usually life threatening illness. Sequelae can occur but are rare.
- There is strong evidence that *Salmonella* spp. has caused foodborne illness associated with beef and beef products.
- The method of producing fresh raw (chilled and/or frozen) beef introduces contamination into the food and does not contain a pathogen elimination step. Some beef products (i.e. trim and offal) may contain higher levels of contamination as further processing steps (i.e. mincing) can introduce contamination into the product.
- HACCP based quality assurance systems are required throughout the entire supply chain to minimise the potential for contamination and subsequent growth of any contaminating pathogens.

General description

Nature of the microorganism:

Salmonella spp. are facultative anaerobic Gram-negative, non-spore forming rod-shaped bacteria belonging to the *Enterobacteriaceae* family. The genus *Salmonella* is divided into two species: *S. enterica* (comprising six subspecies) and *S. bongori*, with over 99% of infections in humans caused by *S. enterica* subsp. *enterica* (Bell and Kyriakides 2002; Crum-Cianflone 2008). Over 2500 serotypes of *Salmonella* spp. have been identified, which differ in their reservoir, host, growth characteristics and the severity of disease they cause. Some serotypes are host-specific, some are host-adapted, while others, such as *S.* Typhimurium, have a broad host range (Jay et al. 2003; Wallis 2006). A number of antibiotic resistant strains have also emerged such as *S.* Typhimurium definitive phage type 104 (DT104). *Salmonella* spp. colonise the intestinal tract of warm and cold-blooded vertebrates including livestock, wildlife and humans and also live in the surrounding environment (FSANZ 2013). *Salmonella* spp. are transmitted by the faecal-oral route, through consumption of contaminated food and water or from direct contact with infected people and animals (Jay *et al*. 2003).

Growth of *Salmonella* spp. can occur at temperatures ranging between 5.2 – 46.2°C, pH of 3.8 – 9.5 and a minimum water activity of 0.93 when other conditions are near optimum. The minimum pH for growth is dependent on temperature, presence of salt and nitrite and the type of acid present. *Salmonella* spp. can survive for months or even years in foods with a low water activity (ICMSF 1996; Podolak et al. 2010). Experimental studies have shown that *Salmonella* spp. can grow in minced beef at ambient temperatures (Dickson et al. 1992; Juneja et al. 2009). *Salmonella* spp. have the ability to survive long term frozen storage (i.e. -20°C) such as in frozen beef trim (Bosilevac et al. 2007). *Salmonella* spp. are sensitive to normal cooking conditions, however, foods that are high in fat and low in moisture may have a protective effect against heat inactivation or the

FSANZ provides risk assessment advice to the Department of Agriculture and Water Resources on the level of public health risk associated with certain foods. For more information on how food is regulated in Australia refer to the FSANZ website or for information on how imported food is managed refer to the Department of Agriculture and Water Resources website.

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Hazard impact assessment

- The effects of exposure to a hazard on an individual

- This assessment considers:
  - Microbial infectivity
  - Disease severity

	Severity of adverse outcome			
Infectivity	**Mild**	**Moderate**	**Serious**	**Severe**
High	Medium Impact	High Impact	Very High Impact	Very High Impact
Medium	Low Impact	Medium Impact	High Impact	Very High Impact
Low	Very Low Impact	Low Impact	Medium Impact	High Impact
Very low	Very Low Impact	Very Low Impact	Low Impact	Medium Impact

Exposure assessment

- Likelihood of exposure to the hazard

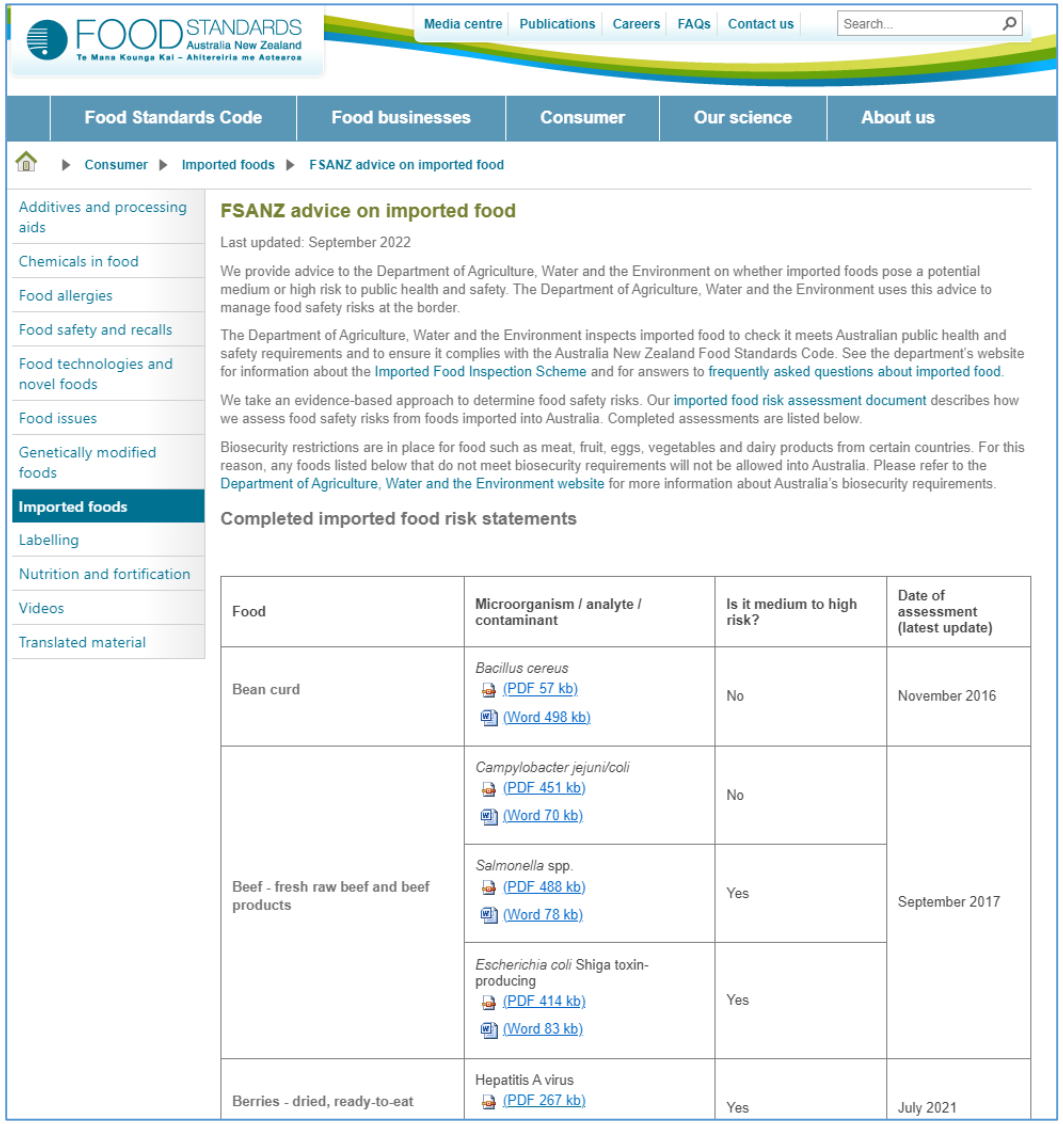
- This assessment considers:
  - Evidence that the hazard has caused foodborne illness associated with the food
  - Evidence demonstrating the presence of the hazard in the food
  - Effect of processing on level of hazard in the food
  - Food supports the growth of contaminating organism
  - Potential for post-processing contamination

Risk Characterisation

The risk characterisation matrix gives an estimation of risk by combining the hazard impact assessment with the exposure assessment

	Exposure (likelihood)				
Impact	Very low Likelihood	Low Likelihood	Medium Likelihood	High Likelihood	Very High Likelihood
Very High Impact	Medium Risk	High Risk	High Risk	High Risk	High Risk
High Impact	Low Risk	Medium Risk	Medium Risk	High Risk	High Risk
Medium Impact	Low Risk	Low Risk	Medium Risk	Medium Risk	High Risk
Low Impact	Low Risk	Low Risk	Low Risk	Medium Risk	Medium Risk
Very Low Impact	Low Risk	Low Risk	Low Risk	Low Risk	Medium Risk

In conclusion…



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Consumer ▶ Imported foods ▶ FSANZ advice on imported food

- Additives and processing aids
- Chemicals in food
- Food allergies
- Food safety and recalls
- Food technologies and novel foods
- Food issues
- Genetically modified foods
- **Imported foods**
- Labelling
- Nutrition and fortification
- Videos
- Translated material

FSANZ advice on imported food

Last updated: September 2022

We provide advice to the Department of Agriculture, Water and the Environment on whether imported foods pose a potential medium or high risk to public health and safety. The Department of Agriculture, Water and the Environment uses this advice to manage food safety risks at the border.

The Department of Agriculture, Water and the Environment inspects imported food to check it meets Australian public health and safety requirements and to ensure it complies with the Australia New Zealand Food Standards Code. See the department's website for information about the Imported Food Inspection Scheme and for answers to frequently asked questions about imported food.

We take an evidence-based approach to determine food safety risks. Our imported food risk assessment document describes how we assess food safety risks from foods imported into Australia. Completed assessments are listed below.

Biosecurity restrictions are in place for food such as meat, fruit, eggs, vegetables and dairy products from certain countries. For this reason, any foods listed below that do not meet biosecurity requirements will not be allowed into Australia. Please refer to the Department of Agriculture, Water and the Environment website for more information about Australia's biosecurity requirements.

Completed imported food risk statements

Food	Microorganism / analyte / contaminant	Is it medium to high risk?	Date of assessment (latest update)
Bean curd	*Bacillus cereus* (PDF 57 kb) (Word 498 kb)	No	November 2016
Beef - fresh raw beef and beef products	*Campylobacter jejuni/coli* (PDF 451 kb) (Word 70 kb)	No	September 2017
	Salmonella spp. (PDF 488 kb) (Word 78 kb)	Yes	
	Escherichia coli Shiga toxin-producing (PDF 414 kb) (Word 83 kb)	Yes	
Berries - dried, ready-to-eat	Hepatitis A virus (PDF 267 kb)	Yes	July 2021

[FSANZ advice on imported food (foodstandards.gov.au)]

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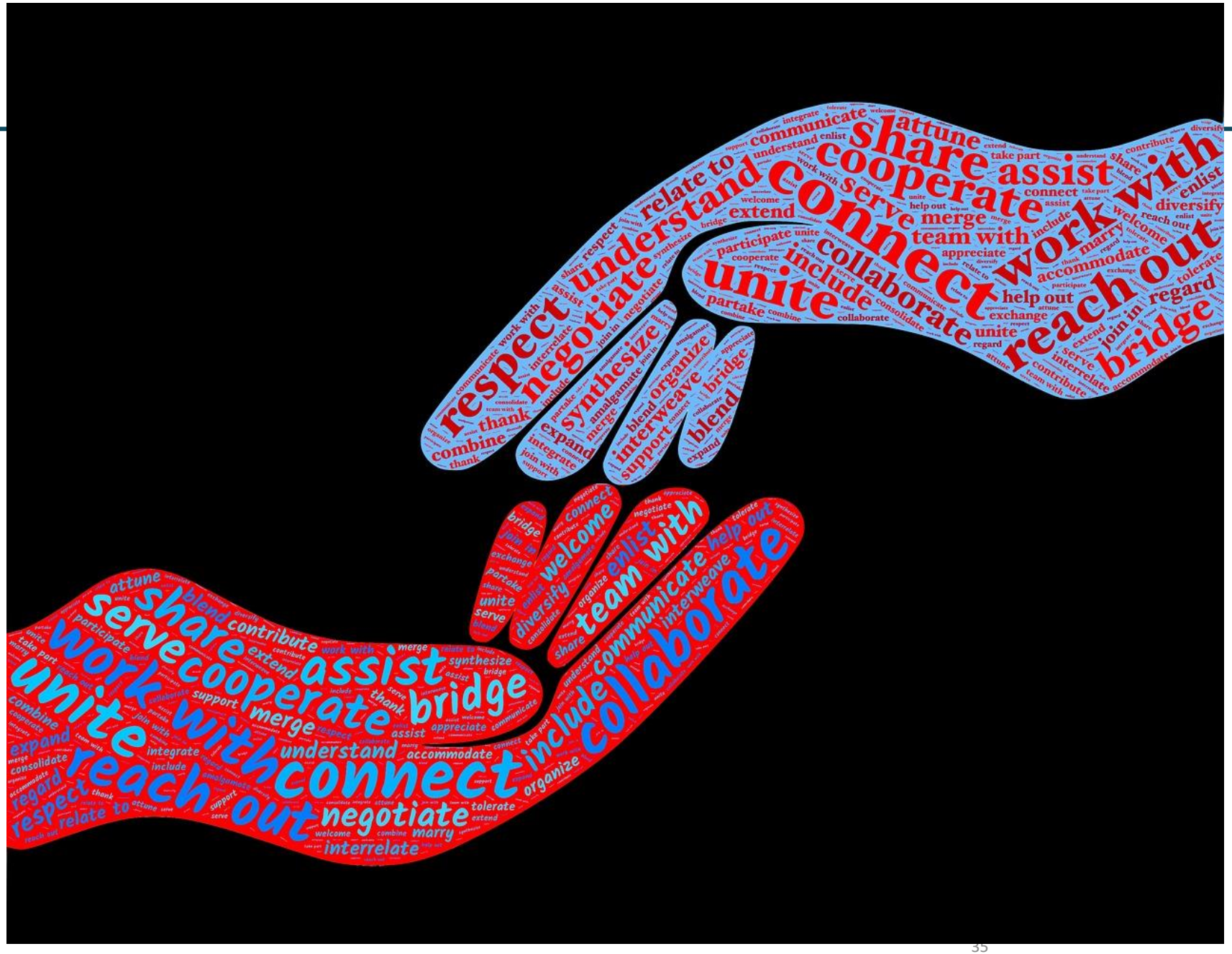

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Thank you!

Questions?

Discussion

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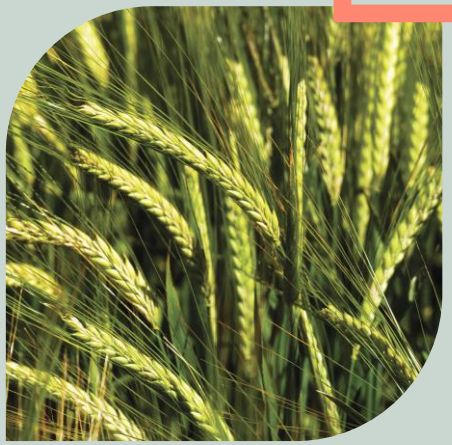
Australian Government
Department of Agriculture, Fisheries and Forestry

Australia's food safety requirements for imported food

Taiwan

19 October 2023



Tania Martin, Director
Imported Food | Residues and Food Branch

Presentation outline

- Overview of food regulatory system in Australia
- Overview of managing food safety risks
  - surveillance and risk food
  - mandatory foreign government certification
  - food safety management certificates
- How foods are profiled for inspection
- What happens when food fails inspection
- Food imported from Taiwan
- Inspection reports and compliance data

Australia's food regulatory system

FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

- Develops domestic food standards and guidance
- Provides imported food risk advice
- National coordination of food recalls and incidents

Australian Government
Department of Health

- Coordination of committees responsible for food policy and consistent implementation of food standards
- Coordination of foodborne illness surveillance

Australian Government
Department of Agriculture, Fisheries and Forestry

At the Australian border

- Enforcement of imported and exported food
- Incident response

States and territories

Post border

- Enforcement of food for sale in Australia
- Incident response

3

Imported food legislation

legislation.gov.au

The Department of Agriculture, Forestry and Fisheries is responsible for administering the following legislative requirements for imported food:

Biosecurity Act 2015

Protects Australia against biosecurity risks (harmful pests and diseases)

Clearance and inspection include quarantine inspections on animal and plant products

Imported Food Control Act 1992

Protects Australia against unsafe food

Clearance and inspection includes a high-risk inspection scheme IFIS on food products

Imported Food Control Regulations 2019

Sets out how the Imported Food Inspection Scheme (IFIS) works

Imported Food Control Order 2019

Lists foods that are risk food and foods that require certification

The food imported to Australia is required to meet any biosecurity import conditions (treatments or import permits)

Import conditions are listed in the Biosecurity Import Conditions system (BICON)

Imported Food Inspection Scheme

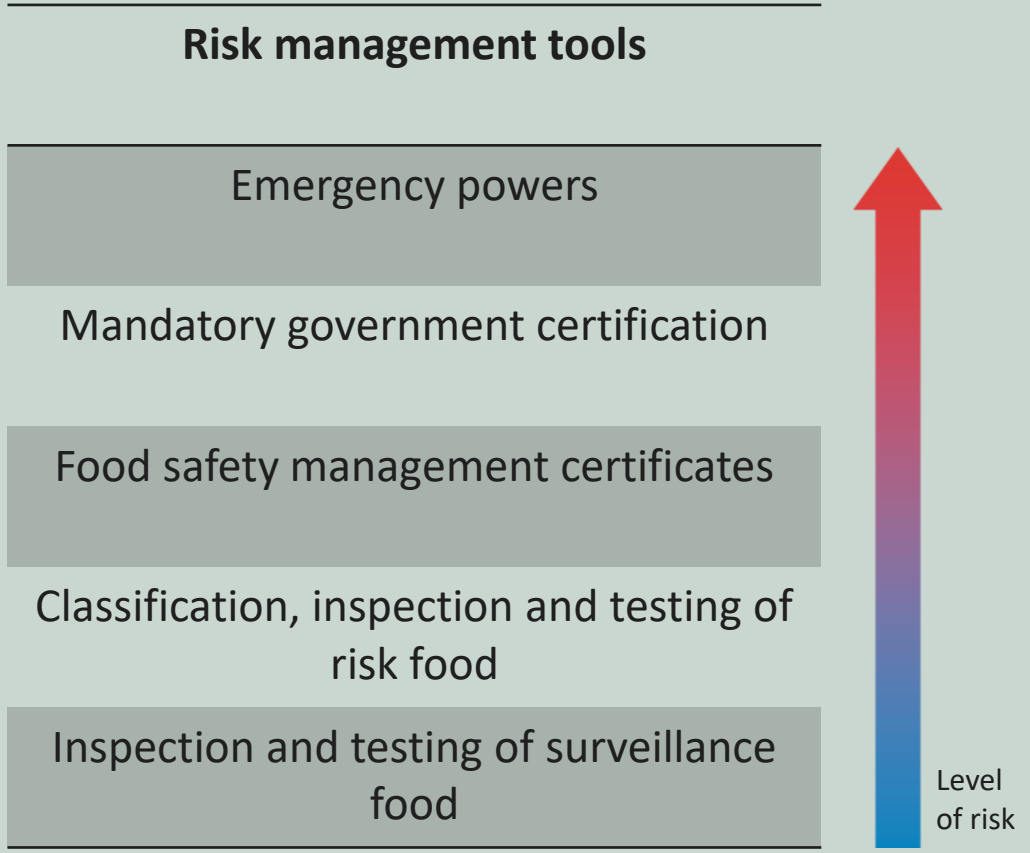
- Imported food is inspected by the Department of Agriculture, Fisheries and Forestry (the department) through a risk-based inspection program known as the Imported Food Inspection Scheme (IFIS)
- Imported food is inspected to check it is safe and compliant with Australia's food standards, primarily the Food Standards Code.
- Food imports must clear biosecurity requirements first.

Risk and surveillance food

- If FSANZ advises that a food poses a medium to high risk, we recommend to our Minister that the food is classified as a risk food in our Imported Food Control Order. We can also mandate certification for risk food.
- All other food is classified as surveillance (or low risk) food.

Risk management approach

The approach applied is proportionate to the level of risk posed to public health.

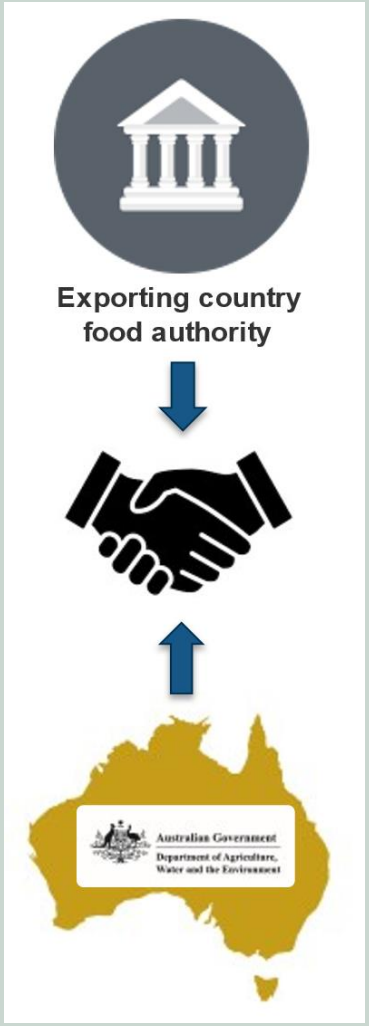


Emergency Powers

- Food suspected of posing a serious risk to human health can be held for up to 28 days while the food safety risk is investigated. More than one extension of a period up to 28 days can be made if required.
- For this holding order to be revoked, evidence must be provided to indicate that risk has been mitigated.
- We used this power in
  - 2019 – to stop further imports of salted clams associated with a hepatitis A outbreak in Australia
  - 2021 – to stop further imports of medjool dates associated with a hepatitis A outbreak in Australia

Mandatory foreign government certificates

- Required when food may pose a high risk and/or management of risks requires government management.
- Foreign government certification arrangements provide assurance food safety risks are being managed and an equivalent food safety outcome is being achieved to Australia's food regulatory system.
- Mandatory foreign government certification is required for:
    - raw milk cheese
    - beef and beef products
    - human milk and human milk products
    - certain bivalve molluscs and bivalve mollusc products (from 9 November 2023).



Food safety management certificates

- Food safety management certificates (FSMCs) can be required for risk food when there are no reliable means of verifying hazards of concern have been managed in the food by applying border testing.
- FSMCs provide assurance that the overseas producer's food safety management system identifies and effectively controls the food safety hazards of concern during the production and processing of the food.
- A valid certificate is one issued by an accredited certification body or a foreign government competent authority.
- Importers in Australia are responsible for lodging valid certificates obtained from overseas producers.
- A FSMC is **required** for **ready-to-eat fresh, chilled, frozen berries and pomegranate arils**.

At border inspection and testing

- Risk food is initially referred for border inspection at the rate of 100% with the inspection rate decreasing as compliance is demonstrated.
- Surveillance food has a 5% chance of being randomly referred for inspection.
- All food referred for inspection is subject to a:
    - **visual inspection** (looking for signs of damage, deterioration and infestation)
    - **label inspection** (verifying compliance with labelling requirements in the Food Standards Code).
- Analytical testing may also apply - Import requirements by food type

How is imported food referred to the IFIS?

The Department of Home Affairs' system, the Integrated Cargo System (ICS), manages the electronic profiling for all goods imported into Australia

We use these profiles to target food we want referred to the IFIS.

These profiles ensure the following food is referred:

- risk food
- surveillance food
- holding order food (food being specifically targeted)

Imported food profiling

Risk food

All consignments of risk food are referred to the department from the ICS.

The department uses two methods to identify risk foods:

- Referral on tariff (HS) code only, where possible. For example:
  - 0406.90.10.33 – Camembert and brie (cheese)
  - 1207.40.00.11 – Sesame seeds
- A Community Protection (CP) lodgement question. These questions are used when a tariff code could be used to declare risk food or surveillance food. Answering **yes** to an IFIS CP question will refer the food as risk food. An IFIS CP question may relate to a whole food, ingredients in a mixed or processed food or the preservation of the food. For example:
  - Do the goods contain more than 30% peanuts or pistachios or more than 30% peanut products or pistachio products?

Imported food profiling

Surveillance food

Food that is not classified as risk food, or holding order food is classified as surveillance food.

5% of surveillance food must be referred from the ICS to the IFIS

- referral is on the first four digits of the tariff code
- random process based on an algorithm in the ICS
- basically, each line within an import declaration has a 1 in 20 chance of being selected

What happens when a food fails inspection?

Surveillance food

- A holding order is applied. All future consignments of that food are referred for inspection until compliance is demonstrated, usually after five consecutive passes.
- When a holding order is revoked, inspection returns to 5% rate.

Risk food

- The rate of inspection returns to 100% until compliance is demonstrated.
- After five consecutive passes rate is reduced to 25%, following further 20 passes rate is reduced to 5%.

Who do we notify?

- We send a letter, via email, to the exporting country's embassy in Australia, to notify the embassy that a risk or surveillance food has failed.
- This does not include labelling fails, as these fails are the responsibility of the importer.

Import data – Taiwan

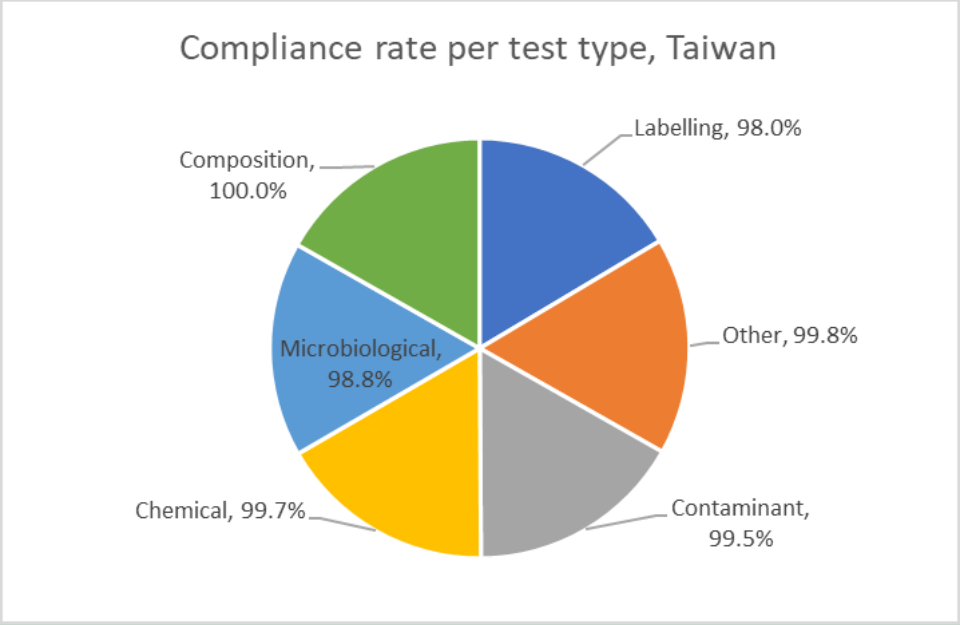
1 July 2021 – 30 June 2023

The top five commodities imported from Taiwan include:

- Miscellaneous edible preparations including sauces, mixed condiments, ice cream, soups and broths, and food preparations not specified elsewhere
- Cereals - rice, barley and other cereals
- Preparations of cereals, flour, starch or milk; pastrycooks' products - e.g. bakery goods, pasta, bread, flour
- Beverages, spirits and vinegar
- Animal, vegetable and microbial fats and oils (e.g. sesame oil, peanut oil etc)

Food from the Taiwan tested under the IFIS is highly compliant, with a 99.0% compliance rate for the period 1 July 2021 – 30 June 2023.

The below chart shows the compliance rate per food test type, for tests applied under the IFIS.



Monthly and annual reports

Monthly report on foods that have failed

We publish a monthly report - Failing food reports - Department of Agriculture

This report details the risk and surveillance foods that have failed for:

- compositional requirements e.g. contains a non-permitted additive
- because they are not permitted e.g. a prohibited plant, or fungi
- analytical testing e.g. positive detection for *Salmonella spp*.

Foods that have failed due to a label non-compliance are not included in the report.

Annual report

- We publish an annual report - Imported food data reports and surveys - DAFF (agriculture.gov.au)

IFIS inspection and testing summary 2022

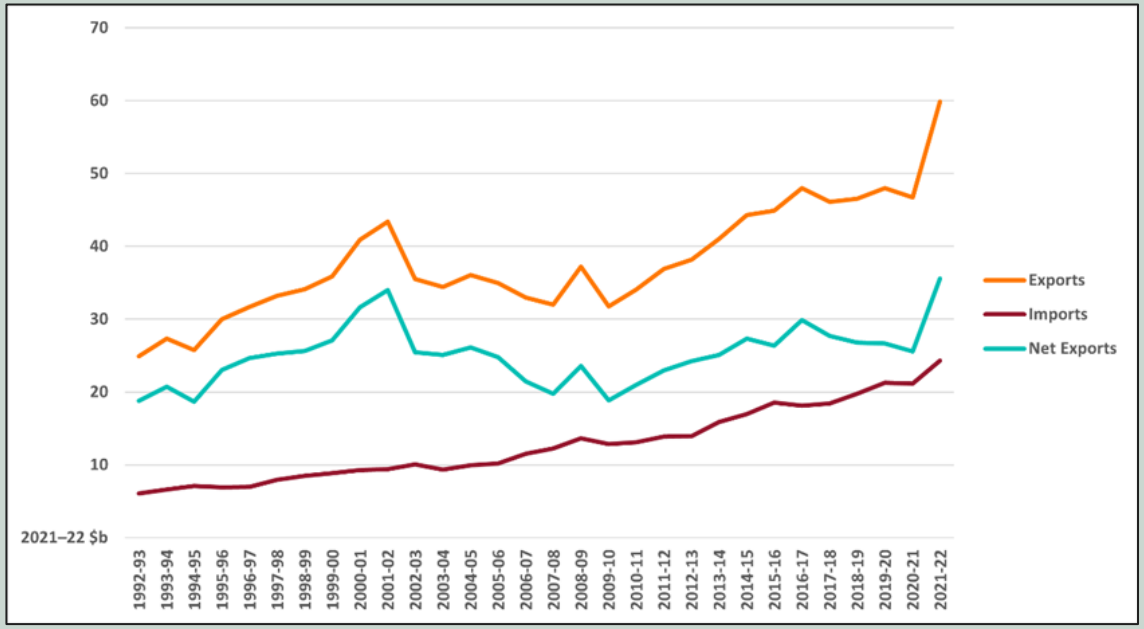
In value terms, the proportion of imports compared with exports decreased to 40.6% in 2021–22, down from 45.2% in 2020–21.

By value, New Zealand remains the major source of imports, accounting for $3.6 billion or 14.9% of the total value of food imported in 2021–22.

In 2022, fruits and vegetables were the main commodity imported, followed by processed food.

In 2022, the compliance rate for all imported food inspected was 98.4%.

Figure 1 Australian food trade, by value, 1992–93 to 2021–22



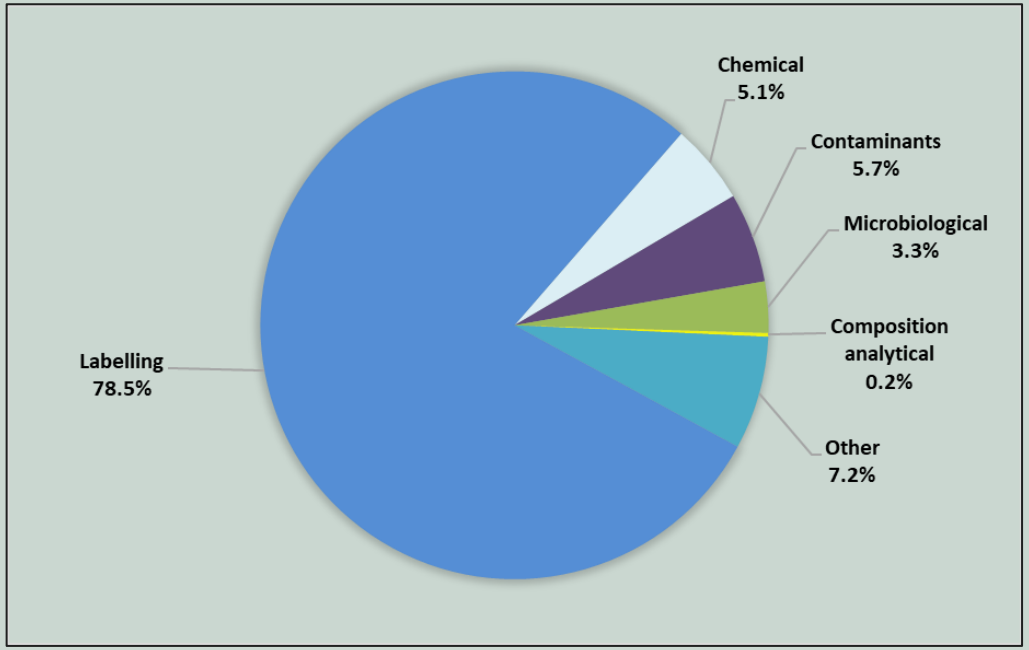
IFIS inspection and testing summary 2022

For 2022, the compliance rate for all food inspected was 98.4%.

During this period:

- 21,619 entries of imported food were referred and subject to inspection or analysis
- 43,655 lines of these entries were inspected. Of these lines
  - 23.4% were risk food
  - 71.6% were surveillance food
  - 5.0% were surveillance food subject to a Holding Order
- 130,306 tests (including label and visual checks) were conducted on the food, comprising
  - 54,605 label and composition assessments
  - 20,721 analytical tests
  - 54,980 other tests.

Figure 2 Non-compliant test results, by test type, 2022



Thank you

Questions?

Keep up-to-date on changes to imported food requirements by subscribing to our Imported Food Notices - Imported food notices - DAFF (agriculture.gov.au)

Food Hygiene and Safety Regulations on Import Foods in Taiwan

Taiwan Food and Drug Administration

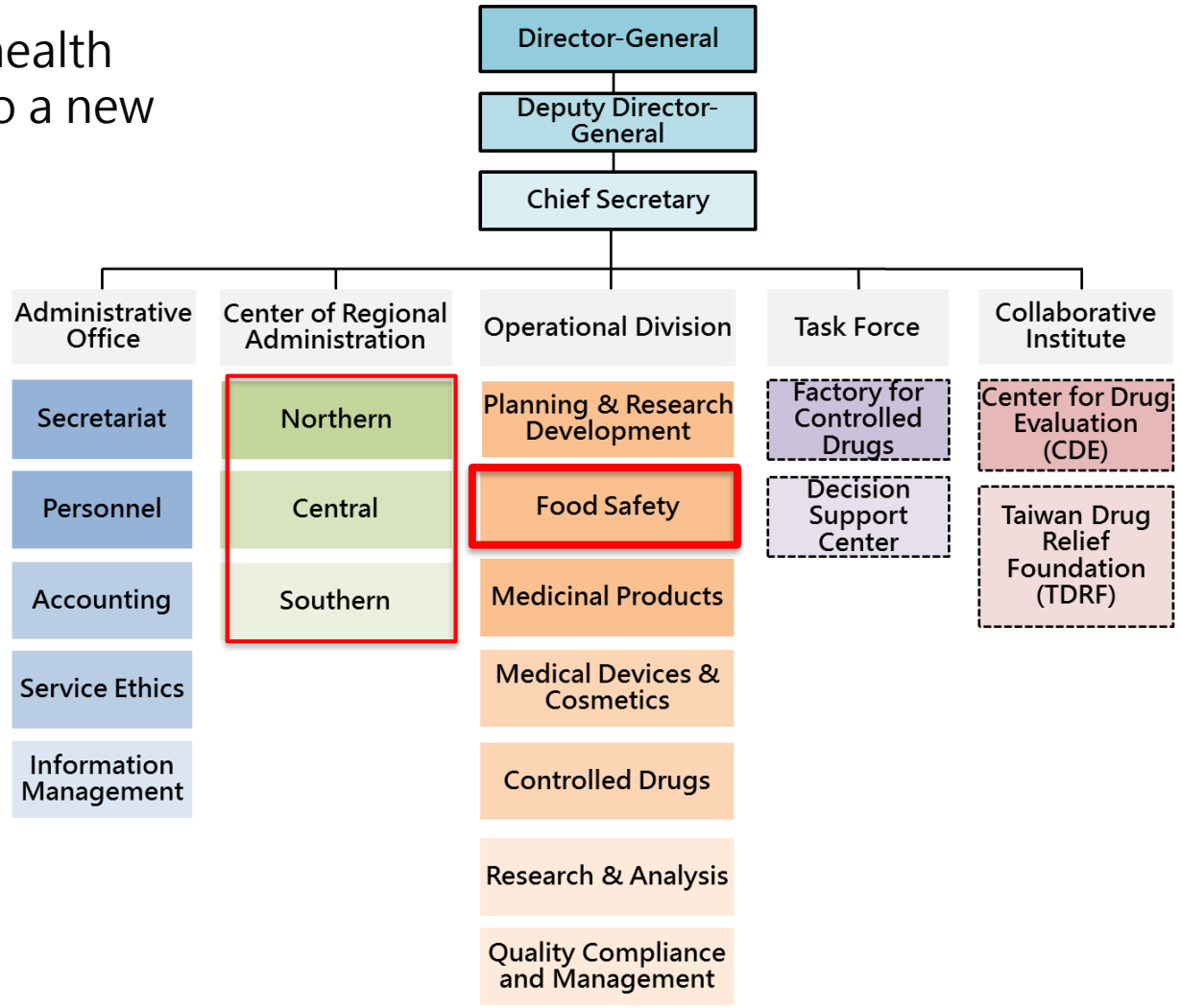
衛生福利部
食品藥物管理署
Taiwan Food and Drug Administration
http://www.fda.gov.tw/

National Competent Authority for Food Safety Management

- **Vision**

To safeguard national health and lead the nation into a new area of **food** and drug management.

TFDA



- **Mission**

To ensure the quality and safety of **food** and drugs.

衛生福利部 食品藥物管理署
Taiwan Food and Drug Administration

Imported Food Control at Border

Importers

Animal and plant products quarantine

Customs clearance

Imported food inspection

check

approval

check

approval

APHIA
(Animal and Plant Health Inspection Agency Ministry of Agriculture)

CA

TFDA

Clearance of Goods

Food Import Management & Control

Source control

- **Systematic Inspection**
  - The verification of equivalence of regulations between contries
- **Routine Inspection**

Border inspection

- **Inspection Principles**
  - Based on risk, International alert, results of post-market inspection, etc.
- **Inspection Procedures**
  - Document Review of food ingredients, additives and certificates, etc.
  - On-Site Verification: Review of food labeling and sensory evaluation
  - Sampling Analysis

Post-market inspection

- **Market inspection**
  - Higher risk
  - Higher attention
  - Higher non-compliance product categories

Offices for Imported Food Inspection at Each Border

1.Keelung Harbor Office (55%)
2.Taipei Songshan Airport Office
3.Taipei Harbor Office

4.Taoyuan Airport Office (25%)
5.Zhongli Office

6.Taichung Harbor Office (5%)
7.Taichung Internation Airport Office
8.Matsu Office

9.Kaohsiung Harbor Office (15%)
10.Kinmen Office

Imported Food Inspection Procedures

Each batch

Document Review

Application form, health/sanitary certificate, etc.

Selected batch

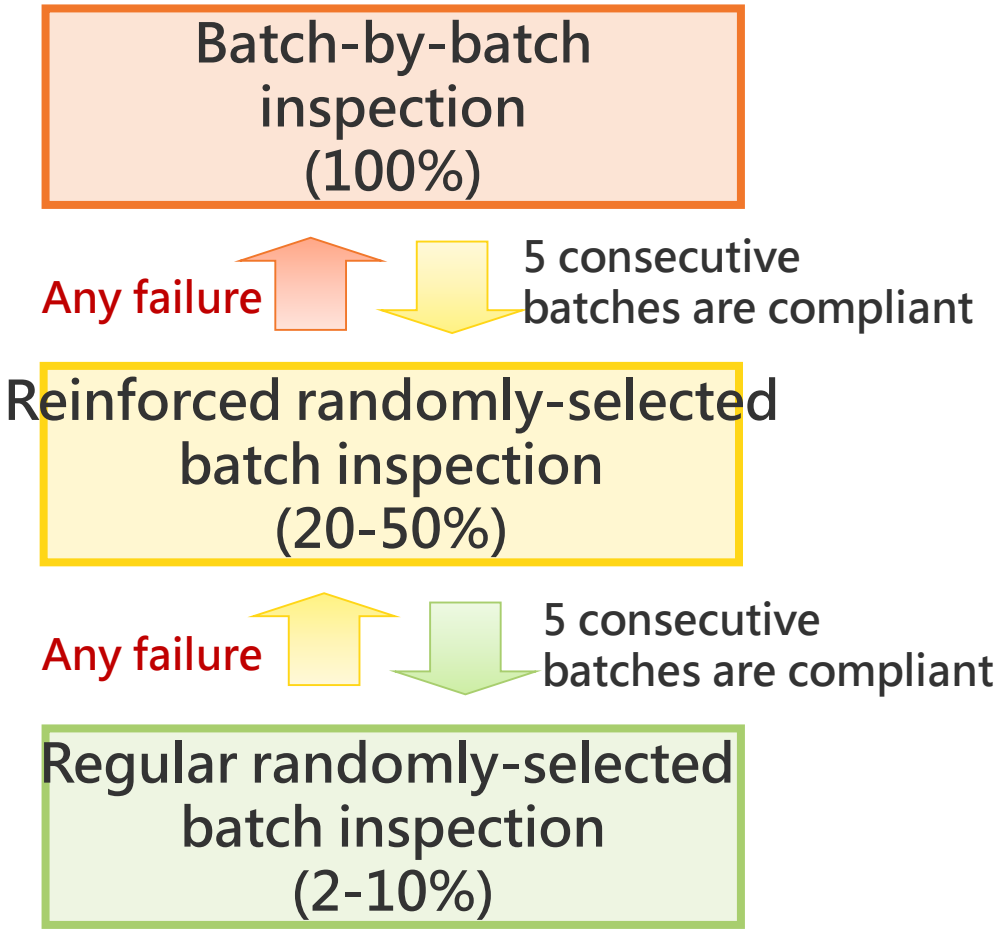
On-site Verification

Visual and label inspection

Sampling analysis

Conduct sensory, chemical, biological, or physical examination

Risk Control of Imported Food Inspection



Risk factors

- Non-compliance records of border inspections
  -Importers
  -Establishment
  -Exporting countries
- International alerts
- Results of post-market inspection

Monitoring International alert

Monitor the website information from countries over the world

- US FDA, Canadian Food Inspection Agency, EFSA, Food Standards Australia New Zealand, etc.

Take action

- strengthen border management according to the risk level
- withdraw and destroy the products if already imported.

“Prior Release System”

- **“Prior Release” is formulated for imported products which are**

-required for examinations that take more than five days,

-sampling is difficult in the container yard,

-perishable goods,

-direct loading onto cargo ships without available storage facilities at the port.

- **“Prior Release” products must be stored at locations registered with the municipal or county (city) competent authorities.**
- **Actions for preventing “Prior Release” products to be moved, used or sold before obtaining the import permit.**

-Guarantee bond

-Affixing non-reversible sealing tapes to the outer box

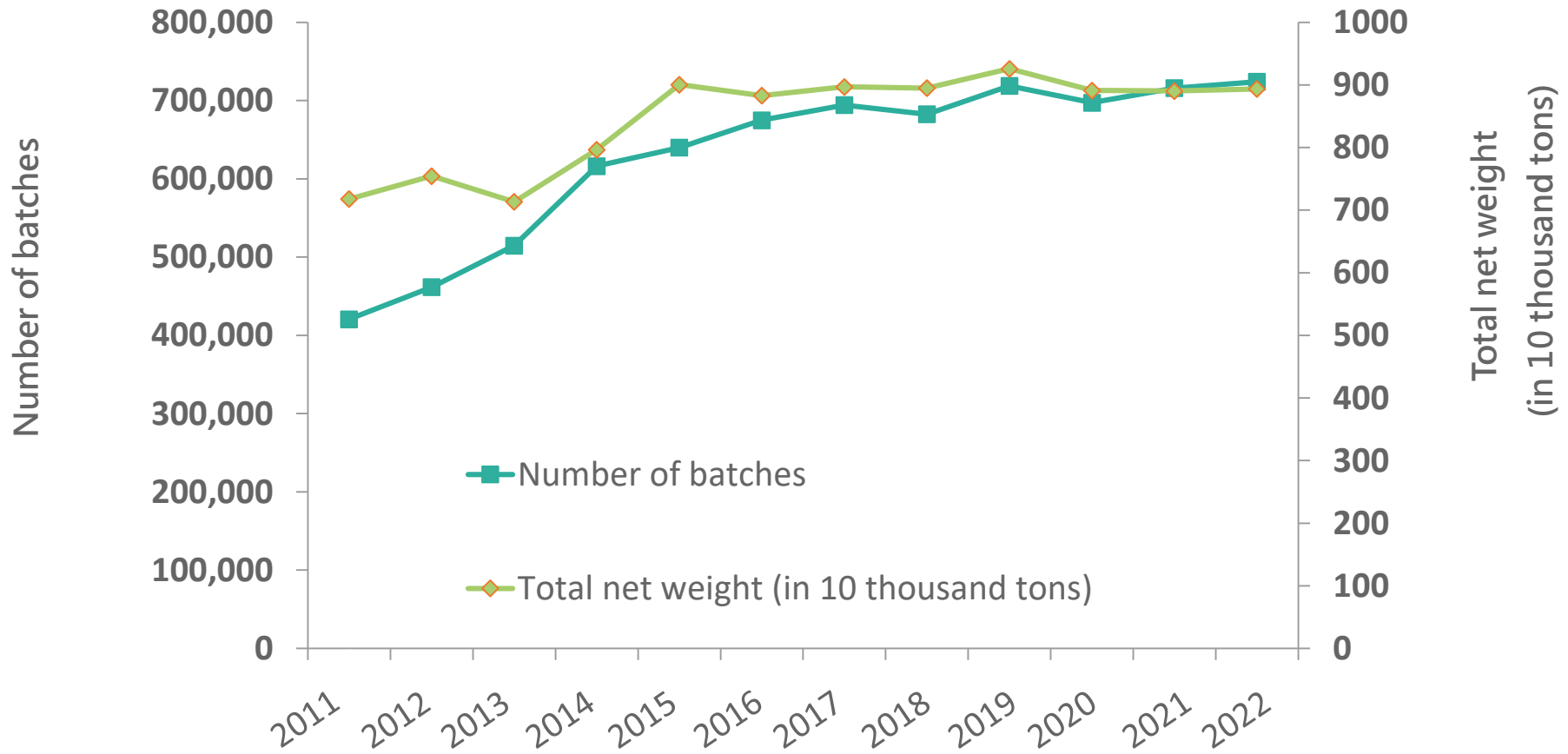
-Unexpected check by municipal or county (city) competent authorities

衛生福利部
食品藥物管理署
Taiwan Food and Drug Administration

Information Disclosure of Non-Compliance
(in Chinese)

https://www.fda.gov.tw/UnsafeFood/UnsafeFood.aspx

Quantity of Imported Food from 2011-2022

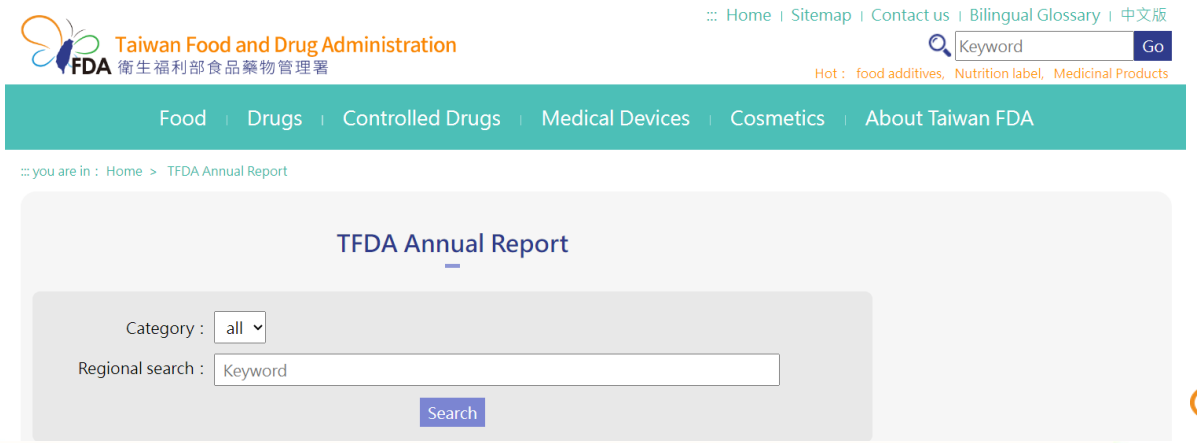


Overview of Imported Food Inspection in 2021-2022

	Inspection batches	Random sampling batches(ratio)	Failed batches	Passing rate
2021	715,929	57,601 (8.05%)	846	98.50%
2022	724,180	65,680 (9.07%)	664	98.99%

TFDA Annual Report

https://www.fda.gov.tw/ENG/siteList.aspx?sid=4050

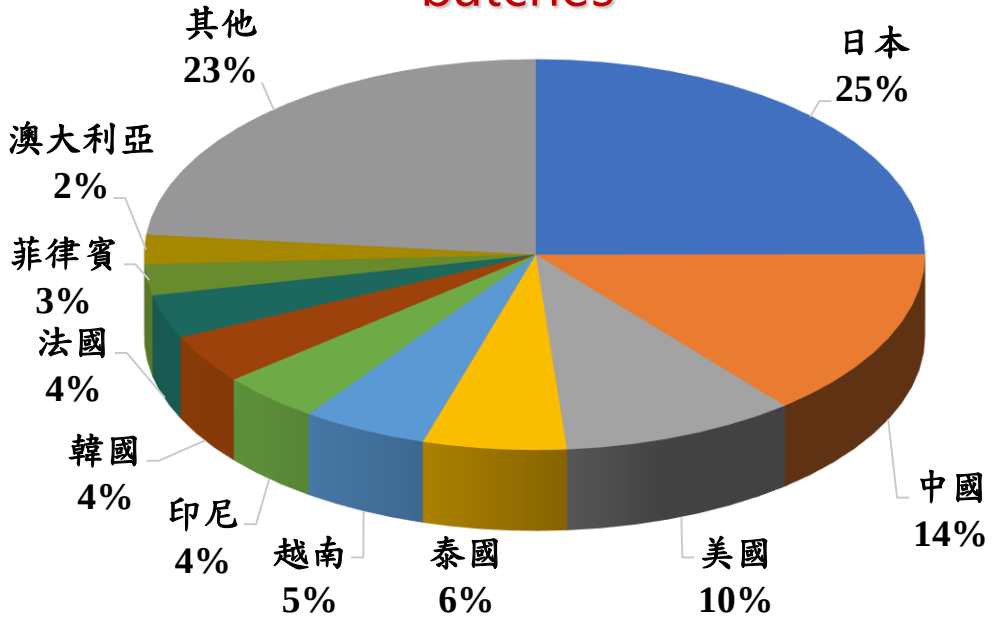


Overview of Imported Food in 2022

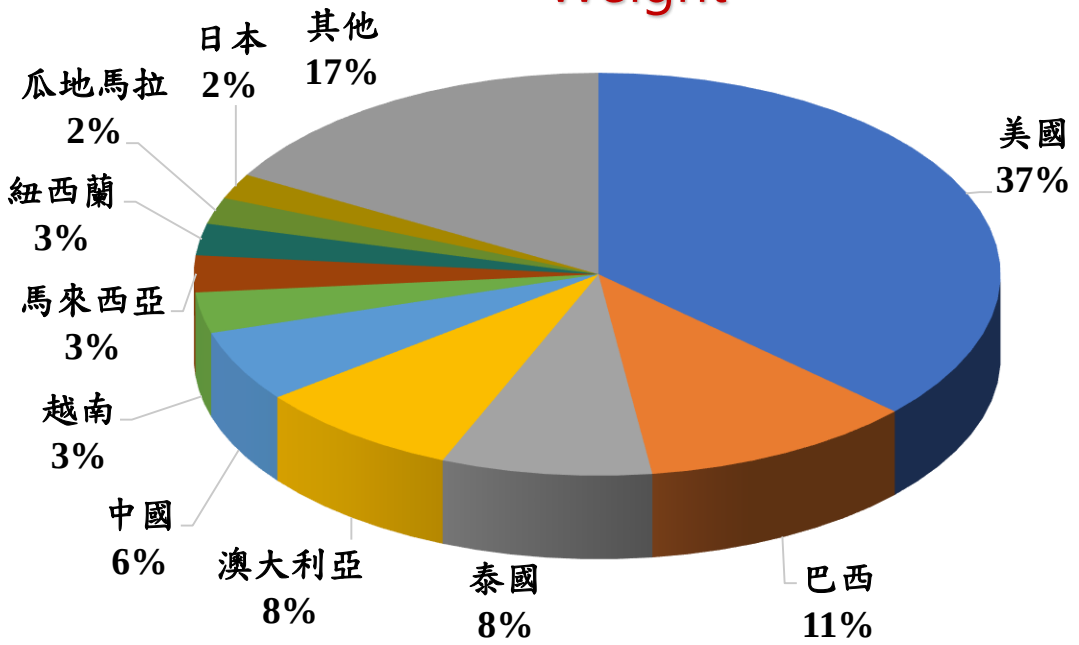
Main Countries of Origin:

- By batch: Japan, China, US, Thailand and Vietnam
- By weight: US, Brazil, Thailand, Australia and China

Number of batches



Weight



Top 5 Imported Foods from Australia in 2022

Ranking	Sub-category	Number of batches	ratio
1	Fresh, chilled, frozen beef	3,769	21.42%
2	Fresh, chilled crustaceans	2,504	14.23%
3	Fresh, chilled, frozen beef offal	1,346	7.65%
4	Cereals and grains	983	5.59%
5	Dairy product	885	5.03%

Ranking	Sub-category	Total net weight (in 10 thousand tons)	ratio
1	Cereals and grains	39.67	53.56%
2	Salts	16.78	22.66%
3	Edible oils	3.01	4.06%
4	Products of cereals and grains	2.79	3.77%
5	Fresh, chilled, frozen beef	2.22	3.00%

Total number of batches：17,592
Total net weight (in 10 thousand tons) ：74.06

International Exchange Activities

- **2017 Visited Ministry of Health, Labour and Welfare(MHLW) in Japan**

  Put a green sticker with sampling quantity on case after inspecting

- **2017 Visited The Netherlands Food and Consumer Product Safety Authority(NVWA) in Netherlands**

  There is a clean and spacious inspection areas in the container yards, and the containers are directly dragged to the inspection area for checking and sampling.

- **2018 Visited Agri-Food & Veterinary Authority of Singapore(AVA) in Singapore**

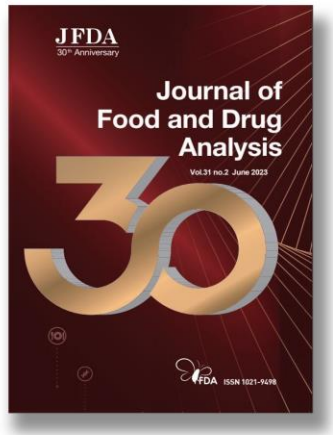
  The declaration of imported foods is carried out by a single system with multiple units.

- **2019 Visited Ministry of Food and Drug Safety(MFDS) in South Korea**

  Electronic declaration was used for inspection.

Journal of Food and Drug Analysis

Free for publication



Frequency: Quarterly
ISSN: 1021-9498
Specialty: food, medicine, traditional Chinese medicine, toxicology, medical devices, drugs, and cosmetics

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Call for Papers

Aim and Scope

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Indexed in: Scopus, Embase, PubMed, PubMed Central

Abstracting: Biochemistry & Biophysics Citation Index MEDLINE®, EMBASE, FSTA (Food Science and Technology Abstracts), Research Alert, BIOSIS Previews, ScienceDirect, Chemical Abstracts Service, Scopus, Science Citation Index Expanded, Abstracts of Chinese Medicines

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