美國食品安全現代化法
進口食品監管制度介紹

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食品安全屬
各國管制問題或國際合作問題？

過去十年間食品安全議題發生如何改變？

經濟全球化對食品安全有何影響？
有哪些新興風險因此產生？

全球食品供應鏈為何？
大型連鎖食品業者之角色又為何？

自動機械化生產

大型農業革命

運輸技術發達

加工保存技術、食品科學及生物醫學進步

Food Product Traceability:

NEW CHALLENGES, NEW SOLUTIONS

食品安全治理之全球性本質

- 食品與生醫科學進步
- 跨國食品製造與零售業興起
- 產業供應鏈串聯

- 農業機械化
- 運輸與保存技術發展
- 世界貿易組織與經濟自由化

美國食品安全監管問題

CDC Home

CDC Centers for Disease Control and Prevention

CDC 24/7: Saving Lives. Protecting People.™

A-Z Index A B C D E F G H I J K L M N O P Q R S T U V W X

Estimates of Foodborne Illness in the United States

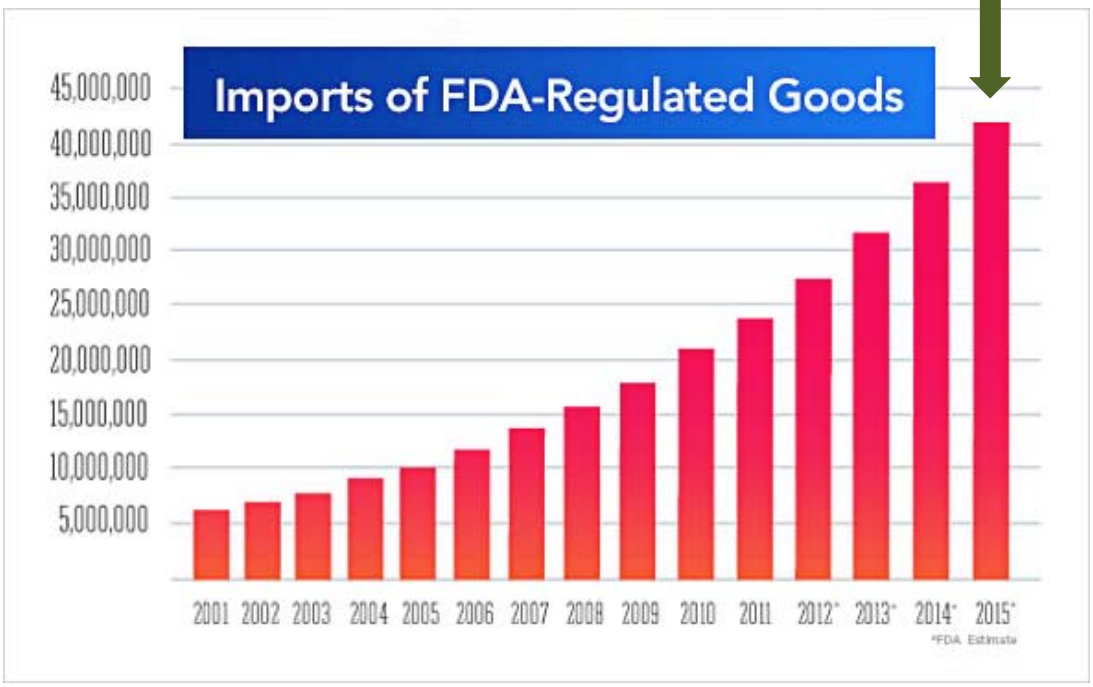
CDC estimates that each year roughly 1 in 6 Americans (or 48 million people) get sick, 128,000 are hospitalized, and 3,000 die of foodborne diseases. Estimating illnesses, hospitalizations, and deaths for various types of diseases is a common and important public health practice.

Findings
2011 Estimates of Foodborne Illness
Learn More »

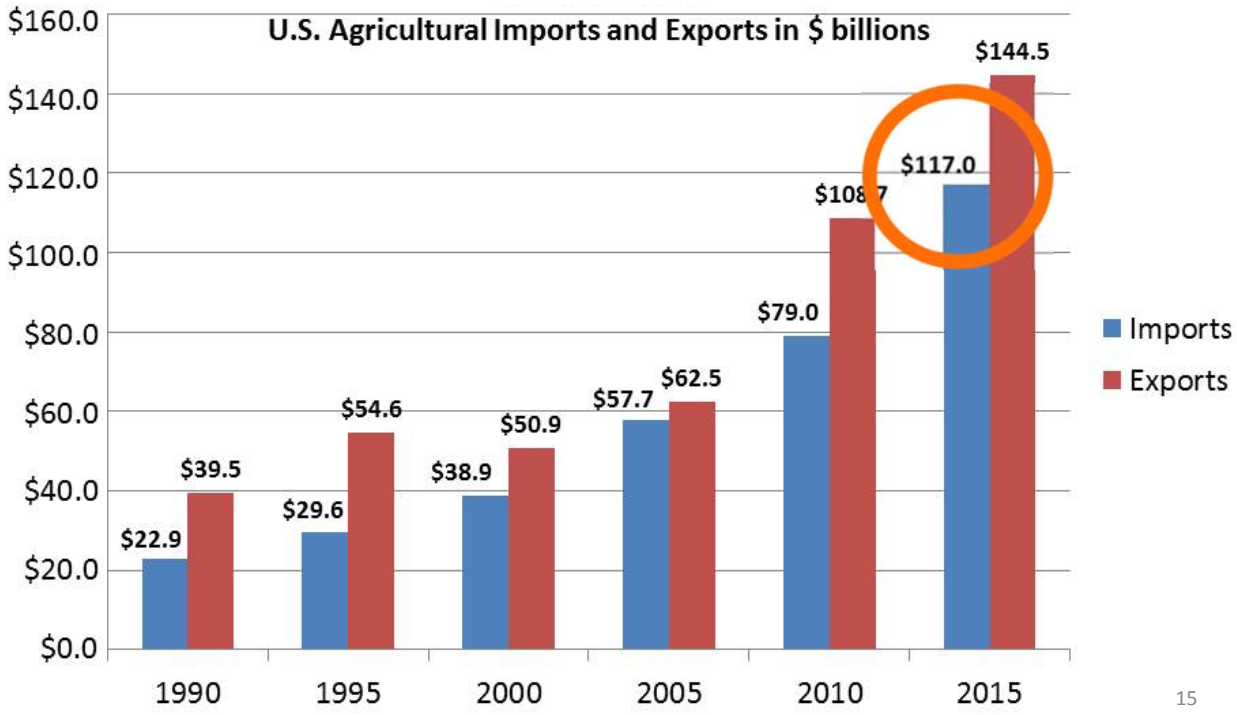
1 2 3

Estimating the number of illnesses associated with specific food sources is called foodborne illness source attribution. These analyses are the logical extension of our 2011 analyses estimating illnesses, hospitalizations, and deaths in the US. Learn more...

食品進口量逐年快速增加



農產品進口價額已超過千億美金

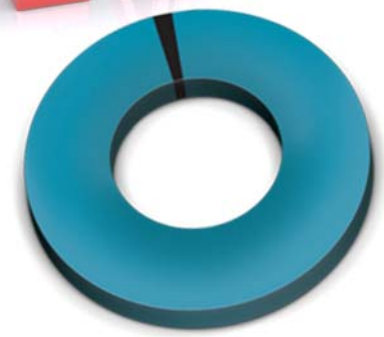


進口食品佔整體消費比超過16%
各子項目亦持續增高

91%漁產品

50%蔬菜
20%水果

2%



來自150個國家食品
透過300個港埠入美

FDA僅有能力抽查
低於2%之進口食品

FDA監管資源年年匱乏

進口至美國之外國食品業者
倍增至28萬家登記數

FDA之人力
卻僅有約30%調整

Table 3. Registered Food Facilities, FY2004-FY2012

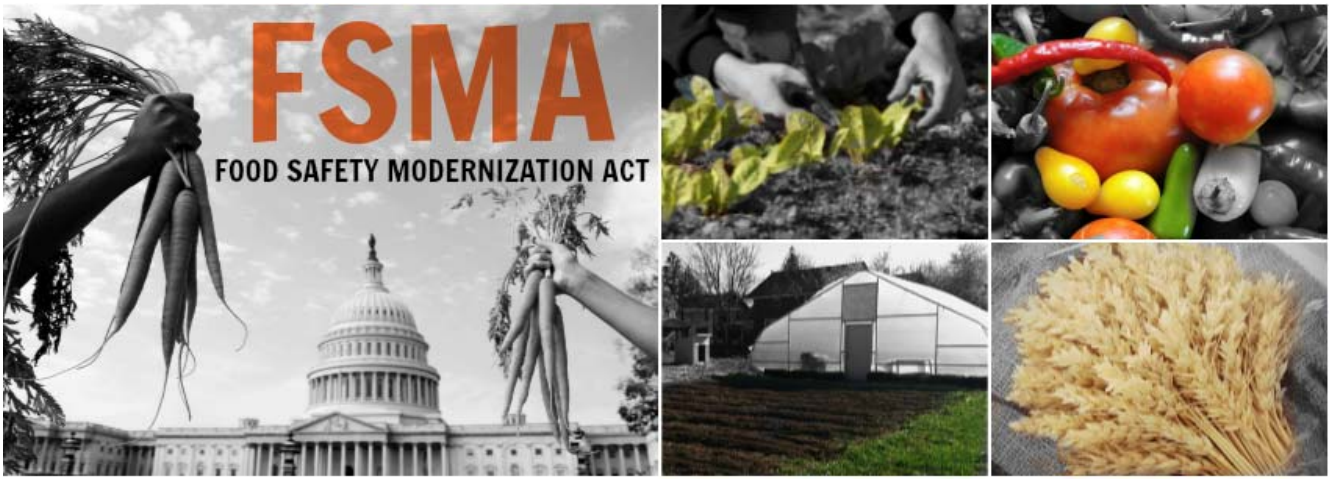
	FY04	FY05	FY06	FY07	FY08	FY09	FY10	FY11	FY12
All Registered Food Facilities	214,253	25[illegible]006	288,092	323,590	356,287	39[illegible]81	418,593	438,30[illegible]	449,859
Domestic	92,719	104,5[illegible]	115,902	129,345	141,[illegible]3	154,883	166,[illegible]	167,033	171,552
Foreign	121,534	148,451	172,190	194,245	21[illegible]584	236,398	252,433	271,[illegible]2	278,307

Table 2. FDA Food-Related Inspection Data, FY2004-FY2012

	FY04	FY05	FY06	FY07	FY08	FY09	FY10	FY11	FY12
Employees[a]	3,082	2,943	2,774	2,569	2,614	2,995	3,387	3,605	3,757
Field FTEs	2,172	2,059	1,962	1,806	1,861	2,166	2,516	2,729	2,824
HQ FTEs	910	884	812	763	753	829	871	876	933

Source: Compiled by CRS from data on registered domestic and foreign facilities under FFDCA §415 [21 U.S.C. §350d]; FDA's annual reporting requirements of these data are at FFDCA §1003 [21 U.S.C. §393]

2011年國會通過食品安全現代化法

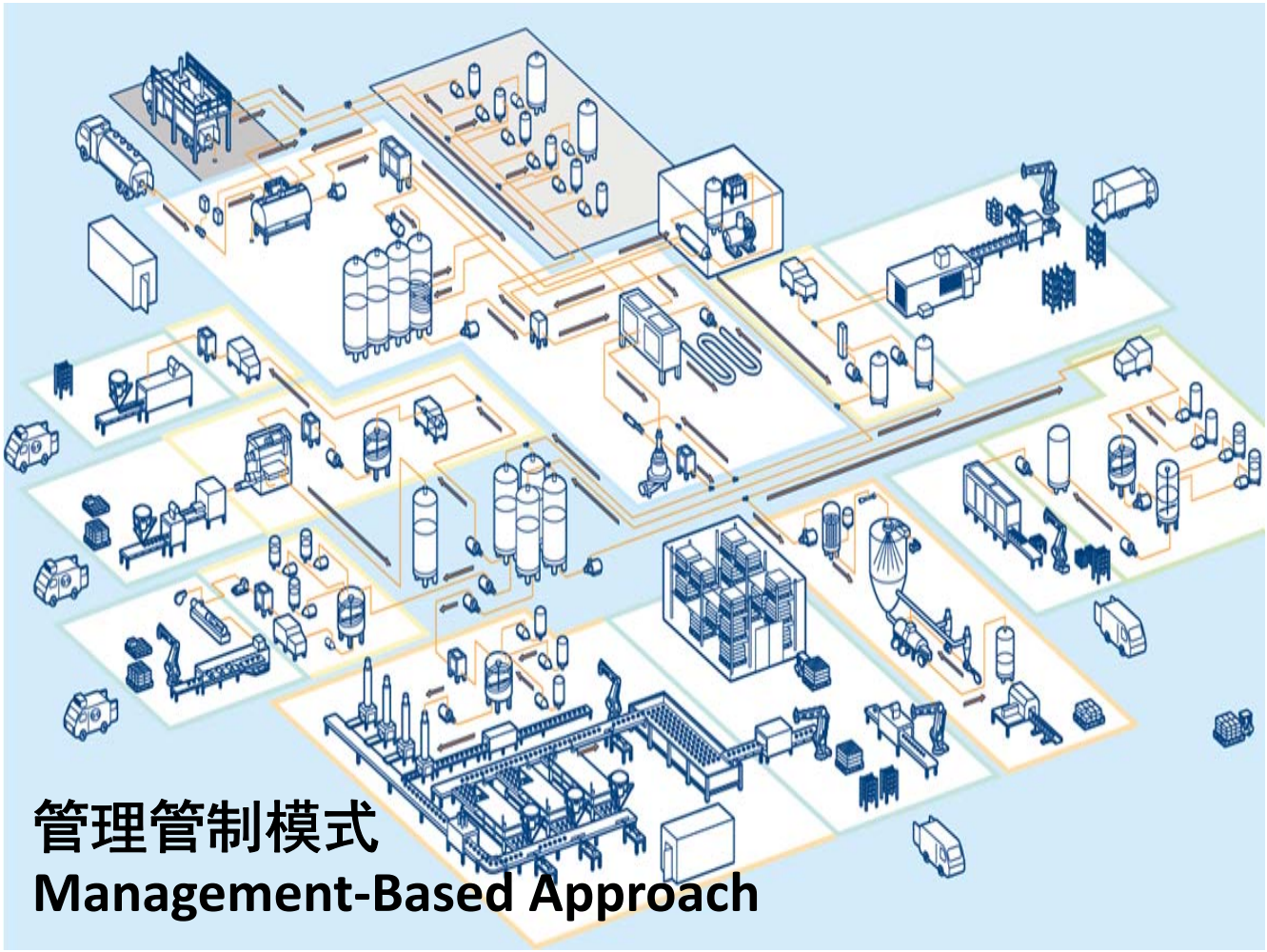


- 1938年食品藥品與化妝品法(FDCA)制定後僅有零星增修條文
- Food Safety Modernization Act (FSMA) 為70多年來最大規模改革性立法

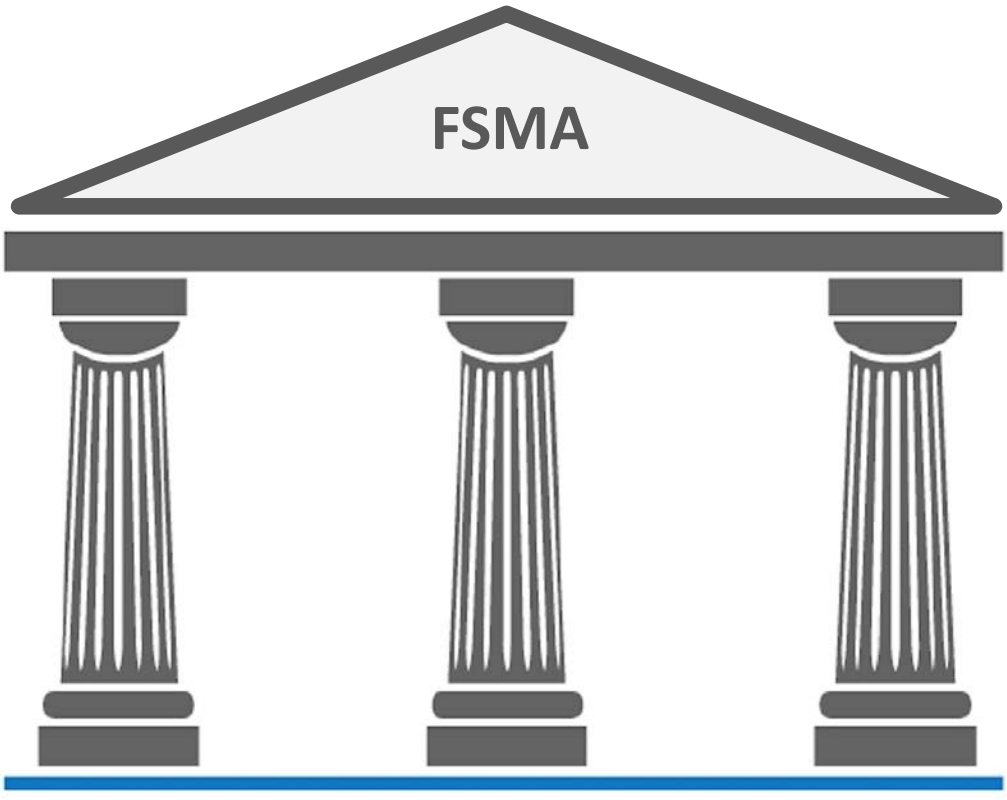
如何進行食品安全管制改革？有何制度設計選項？


EXIT
終端產品管制模式
Product-Based Approach


製程管制模式
Process-Based Approach



FSMA三大改革主軸



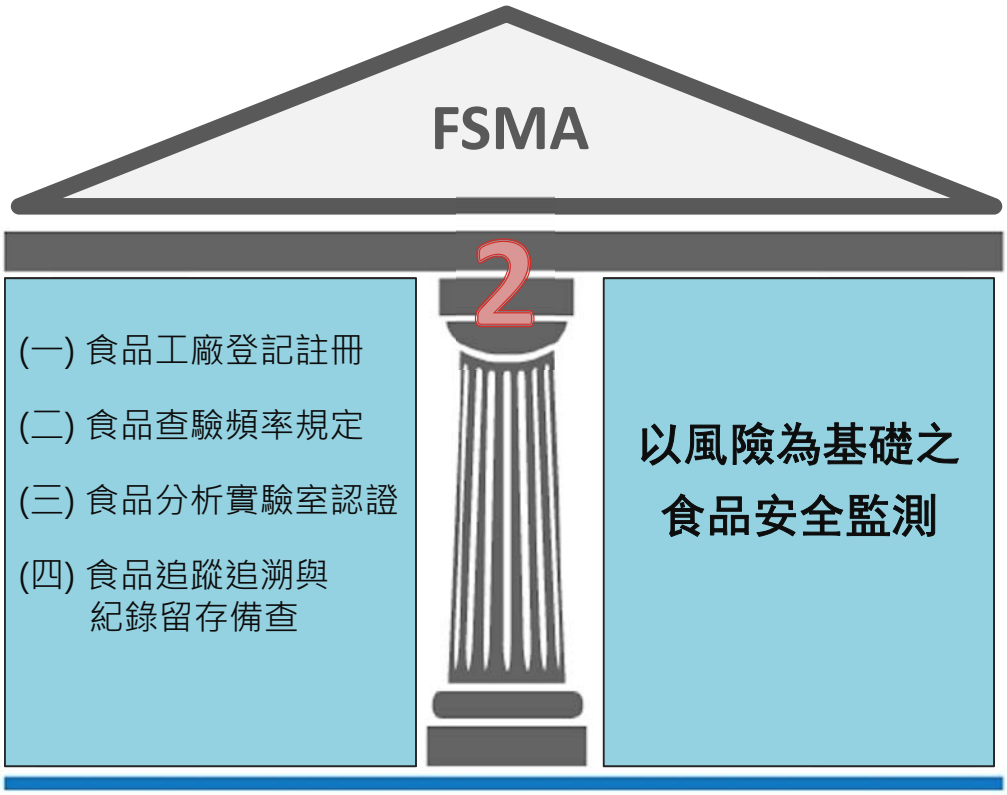
FSMA三大改革主軸

HACCP：危害分析重要管制點。Hazard Analysis and Critical Control Points

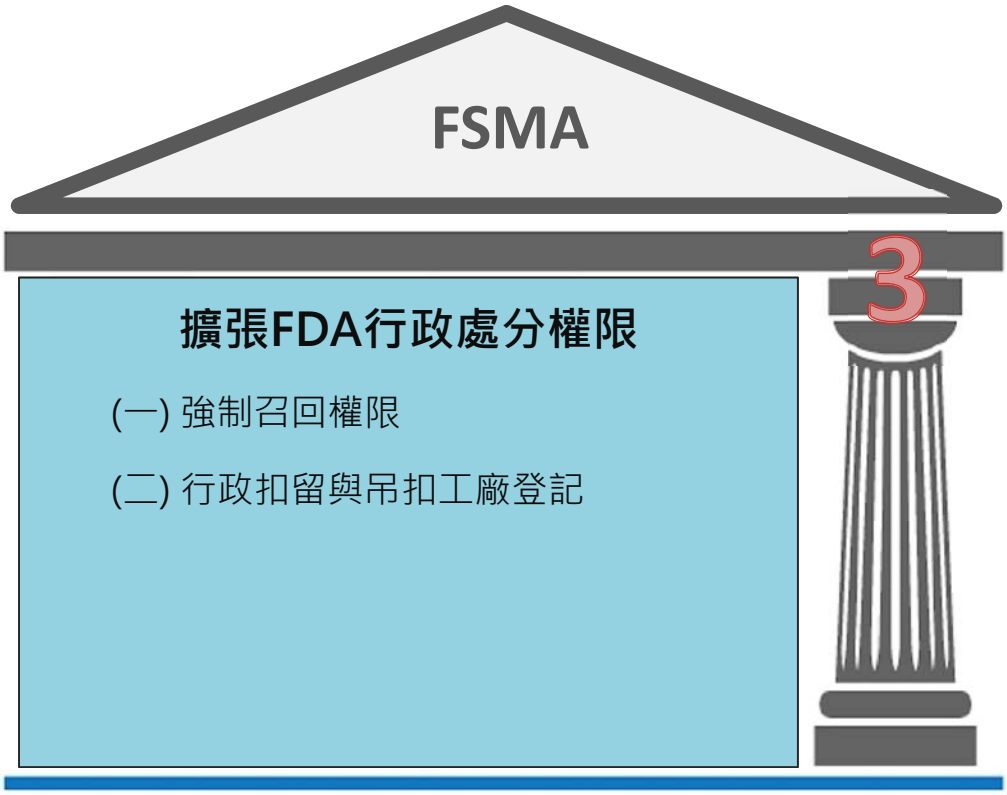
HARPC：危害分析及以風險為基礎預防控制。Hazard Analysis and Risk-Based Preventive Controls

HARPC		HACCP	
1	識別危害 (Identify Hazards)	1	識別危害 (Identify Hazards)
2	風險為主的預防管控 (Risk-based Preventive Controls)	2	決定重要管制點 (Determine CCP's)
3	效能監測 (Monitoring of Effectiveness)	3	監控方式 (Control Measures)
4	矯正措施 (Corrective Actions)	4	管控界限 (Control Limits)
5	驗證 (Verification)	5	矯正與矯正措施 (Corrections & Corrective Actions)
6	紀錄與文件資料 (Recordkeeping and Documentation)	6	驗效與驗證 (Verification & Validation)
7	重新分析 (Requirement to Reanalyze)	7	紀錄與文件資料 (Recordkeeping and Documentation)

FSMA三大改革主軸

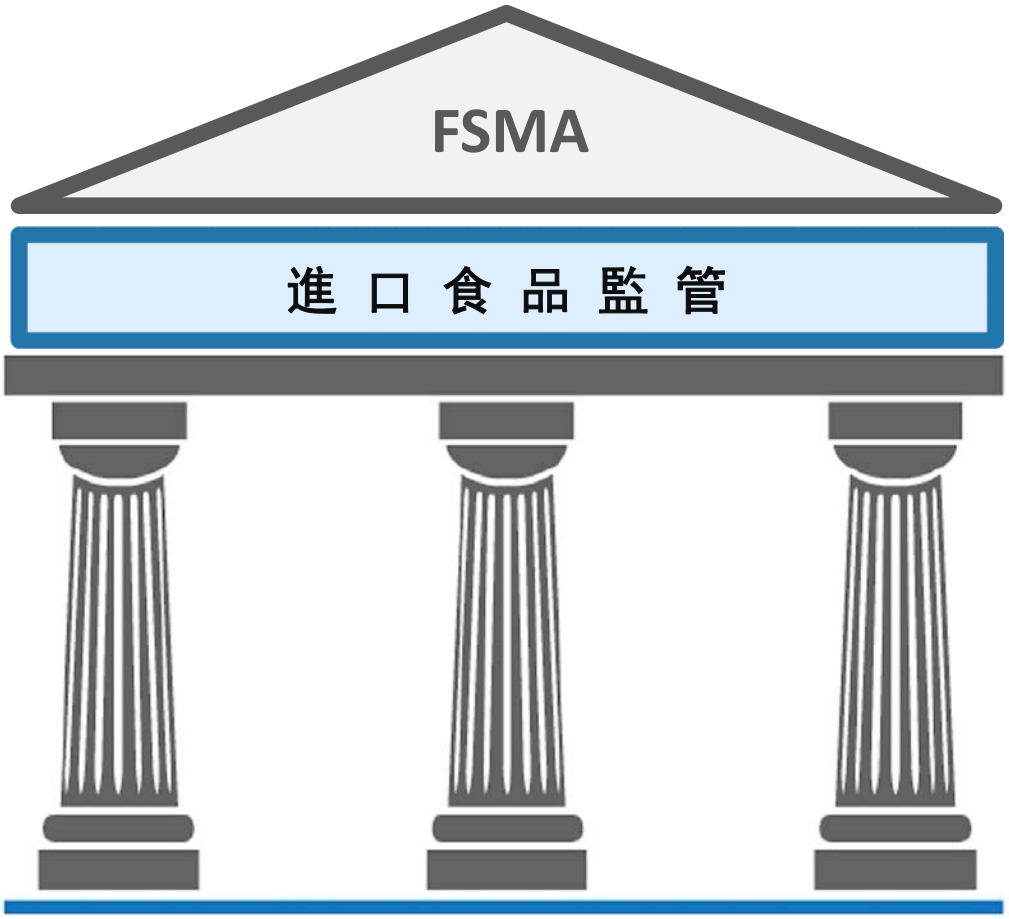


FSMA三大改革主軸



FSMA法規遵循期限（施行細則另有規定）

Business Type	Compliance Timeline As of January 1, 2016
Very small businesses < $1 million per year	**3 years** (except for records to support its status as a very small business January 1, 2016)
Businesses subject to the Pasteurized Milk Ordinance	**3 years**
Small businesses < 500 full-time equivalent employees	**2 years**
All other businesses > 500 full-time equivalent employees	**1 year**
Small business receiving facility (supplier not subject to human preventative controls rule or produce safety rule	**2 years**
Small business receiving facility (supplier IS subject to human preventative controls rule or the produce safety rule)	**2 years** (or 6 months after the supplier is require to comply, whichever is later)
All other businesses > 500 full-time equivalent employees (supplier not subject to the human preventative controls rule or produce safety rule)	**18 months**
All other businesses > 500 full-time equivalent employees (supplier IS subject to the human preventative controls rule or produce safety rule)	**6 months** after the supplier is required to comply with the rule



FSMA

進 口 食 品 監 管

國際合作

FSVP

外國供應商查證計畫
Foreign Supplier
Verification Program

VQIP

自願性合格進口商計畫
Voluntary Qualified
Importer Program

第三方稽核與認驗證制度
Third-Party Audit and Certification

FSVP 外國供應商查證計畫

- 課予國內「進口商」進口食品安全主要監管責任
  - 查證外國供應商是否符合美國食安規定
  - 查證措施包含監測出貨記錄、逐批查驗、逐批合格驗證、年度實地查廠、檢查風險分析、檢閱供應商預防控制計畫、定期抽驗等
  - 查證資料保存兩年以上，經FDA要求隨時出示
  - 須考量不同產品類別及來源國等風險
  - FSVP得透過第三方稽核員(third-party auditor)或將相關查核程序納入供應鏈管理系統中完成
- 進口商事前通知規範
  - 裝運前提供製造及運輸資訊
  - 向FDA通報任何遭其他國家拒絕入關之食品項目

- FSVP 2015 施行細則（原則上2017/5/30實施）
  - 進口商在進口食品至美國國內之前，須進行危害分析與風險評估，以決定採行至少一項合適之查證措施。
  - 查證措施須由具備教育訓練與經驗之「合格人員」執行（可為進口商受僱人員、第三方稽核員或外國政府人員）
  - 建立市場調查機制，檢討客訴資訊是否與FSVP有關
  - 若發現可能有攙偽或不實標示情形，應立即調查、採取改正措施並適時評估查證措施有效性
  - 每三年或有重大改變時重新評估、修正查證計畫
- 排除適用與例外情形
  - 排除舊法規定下應符合HACCP之海鮮、果汁與低酸性罐頭業者
  - 排除學術研究或個人使用之小額進口與酒類飲品
  - 「小型進口商」或「自特定小型供應商進口食品之進口商」得免除FSVP，適用例外規定（如年均銷售額一百萬美金以下）

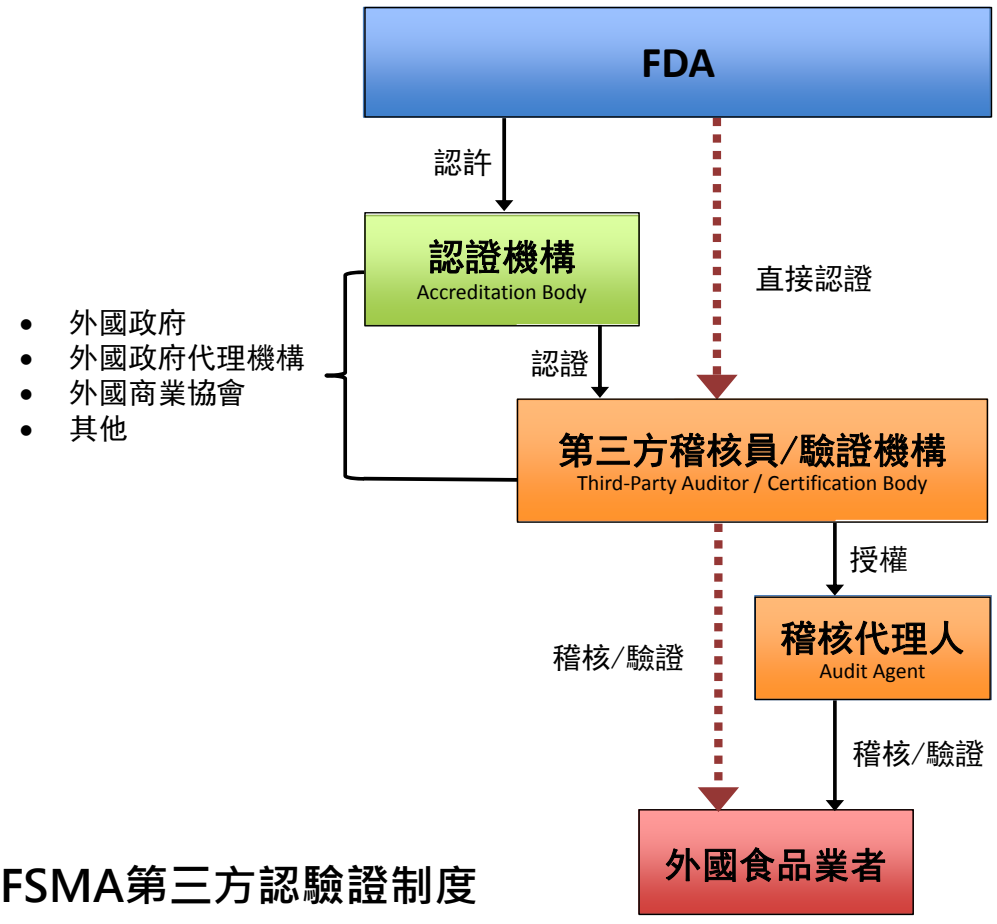
VQIP 自願性合格進口商計畫

- 考量港埠查驗人力資源有限，VQIP給予自願符合高於FSVP規定之進口商快速通關審查待遇
  - 認定程序考量申請者法規遵循歷史、食品輸出國管制能力（對等美國食安標準）、產品食安風險、蓄意攙偽風險等
  - VQIP進口商每三年重新審查，若有不合格情事得撤銷許可
  - VQIP認定程序可透過第三方認驗證制度完成（如食品設施驗證）
  - 因生物恐怖攻擊風險相對提高，FDA須諮詢國土安全部
- FDA得最終決定是否對VQIP貨品抽樣檢查及許可入境

- FDA於2016年11月公布之VQIP企業準則
  - 不具法律拘束力，但FDA將依此執行VQIP
  - 食品進口商加入VQIP，應符合多達十項適格要件
    - 如：三年以上進口食品至美國之歷史；未受行政罰或司法調查；無重大食安不良紀錄；該食品未在進口警示或召回範圍內；進口商須建立品質保證計畫並確認其外國供應商具備工廠驗證；每年定期繳納管理使用費
  - 除快速通關外，於進口食品涉及公共衛生風險之加強檢驗期間，FDA 亦將盡可能加速、便利該檢驗程序
- 仍以風險分析為基礎進行監管，FDA得不定時針對VQIP食品進行微生物抽樣檢查或定期稽核式檢驗，以確認進口商符合規定

第三方稽核與認驗證制度

- FSMA賦予FDA考量健康風險程度與產地食安記錄，而要求檢附驗證之權限
- 第三方認驗證制度為食安驗證核心，亦為FSVP與VQIP配套措施選擇之一
  - FDA認許(recognize)認證機構(accreditation body)
  - 由認證機構或FDA 直接認證(accredit)第三方稽核員或驗證機構(certification body)
  - 再由第三方稽核員或驗證機構判定外國食品業者是否符合美國食安規定，發放驗證證書
- 各機構得為外國政府機關或代表、外國商業協會、或其他經FDA認許者



FSMA第三方認驗證制度

- 「稽核」指有系統並具功能獨立性之方法觀察、調查、審查、評估及記錄受稽核者是否符合相關規定
- 依其目的不同，稽核可分為兩種類型：
  - 諮詢性稽核(consultative audit)，目的在於協助食品業者判斷其是否符合相關規定，稽核結果僅供食品業者參考
  - 管制性稽核(regulatory audit)，目的在於確認食品業者是否符合相關規定而得依法取得驗證
- 無論是否取得驗證，管制性稽核報告均須提交FDA，FDA亦得主動要求現場稽核報告與所有相關文件

- 認證機構與第三方認驗證機構皆應
  - 具備相關法律權限
  - 具備符合相關要件之能力與所需資源
  - 避免利益衝突
  - 建立品質保證程序，適時採取改正措施
  - 資料保存管理
- 監督方式
  - 認證機構監督第三方驗證機構之方式為年度表現評估，包含其自我評估、管制性稽核報告、通報 FDA 業者之食安表現
  - 認證機構亦須就上述監督進行年度自我評估，適時改正，並作成書面報告提交FDA

國際合作

- 在前述基礎上強化FDA與外國政府合作關係
  - 協助外國政府建構食品安全相關能力
  - 簽訂各類雙邊或多邊合作協議（如：資料共享；人員培訓；調和Codex；相互承認檢驗報告、實驗方法或檢測技術等）
  - 成立FDA國外辦公室，協調辦理合作事項
- 國外食品業者查廠要求
  - FSMA通過後一年內FDA須查驗至少600處外國食品工廠，並於往後五年間，每年加倍查驗數量
  - 無正當理由拒絕查驗者，構成拒絕入境理由

FDA前後成立13處國外辦公室（已撤4處）

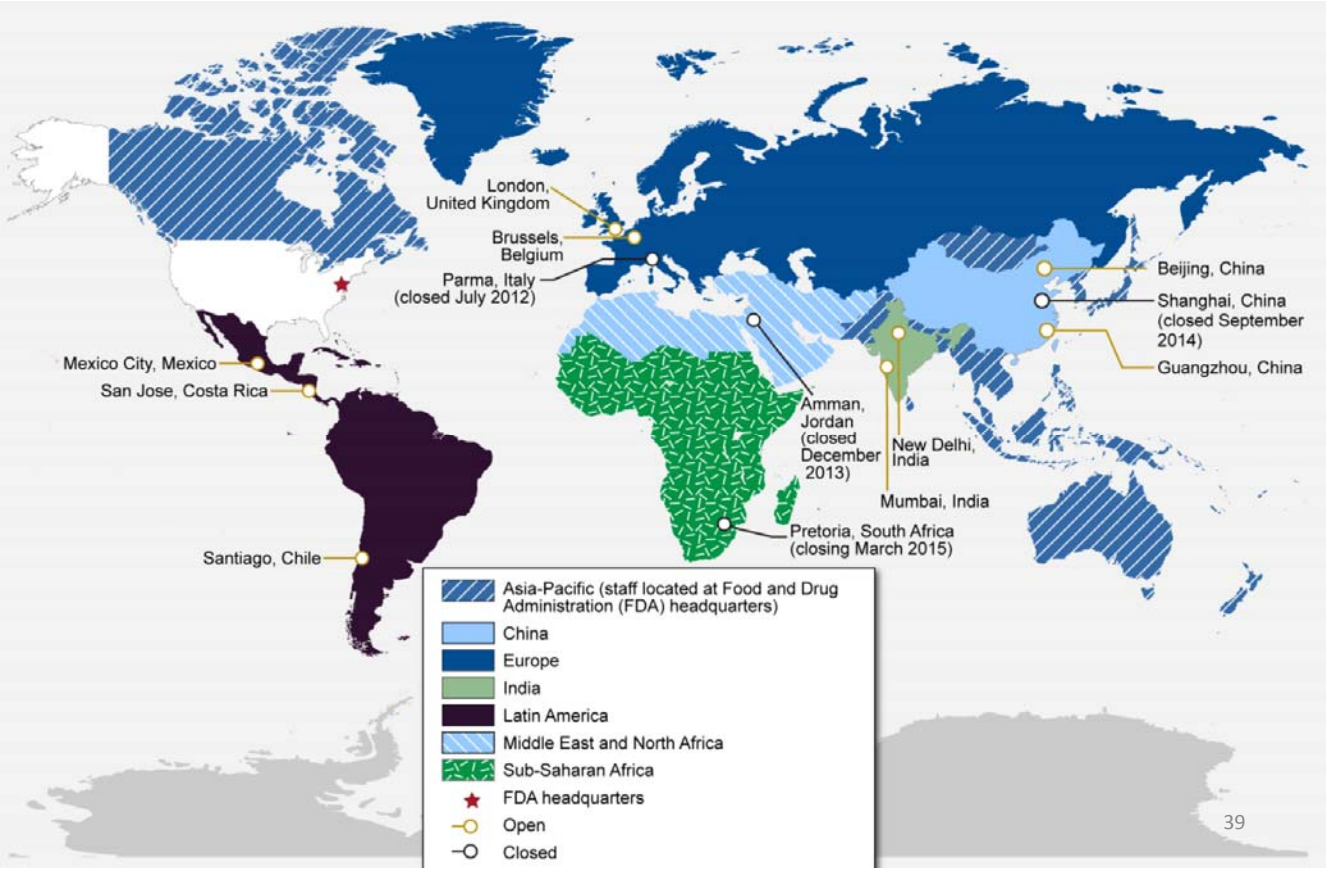


Figure 2: Top-priority Food Safety Activities, as Reported by Food and Drug Administration (FDA) Foreign Offices in 2014

Foreign office	Conducting inspections	Collecting samples	Managing recalls	Gathering and assessing information	Providing information about Food and Drug Administration (FDA)	Building relationships	Engaging in technical cooperation	Cooperating with other U.S. agencies
Asia–Pacific					✓	✓	✓	
China (Beijing)	✓			✓			✓	
China (Guangzhou)	✓			✓	✓			
Europe (Brussels)				✓	✓	✓		
Europe (London)				✓	✓	✓		
India (Mumbai)	✓			✓		✓		
India (New Delhi)	✓			✓		✓		
Latin America (Costa Rica)					✓	✓	✓	
Latin America (Mexico)					✓	✓	✓	

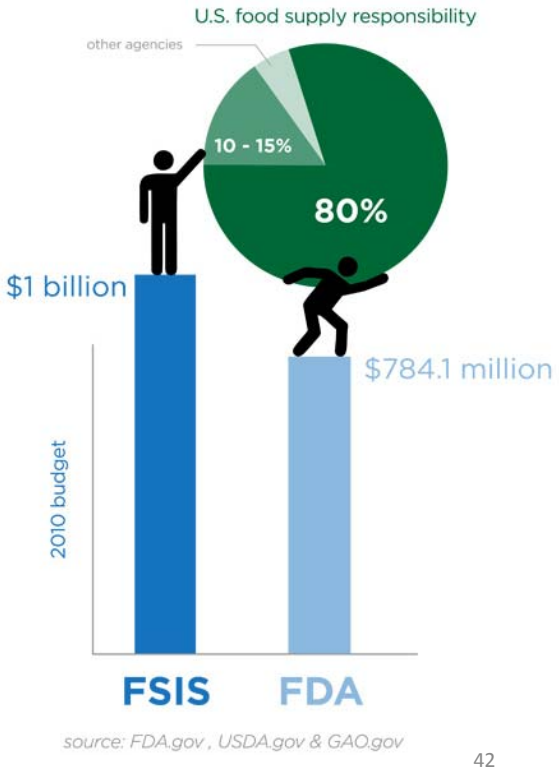
✓ Top-priority activity

Source: GAO analysis of FDA information. | GAO-15-183

制度設計罅隙

1. 無相應預算執行FSMA要求

- 經費年年不足，國會制定高標準FSMA卻無相應預算支持
  - 不許FDA收取登記費或查驗費以補充財源（僅在因食安問題須複檢時得收取行政費）
  - 前五年執行FSMA估計花費$14億，而2014年FSMA預算僅$1.4億
  - 外國查廠平均成本為$23,600/次，國內查廠$15,500/次
  - 雖陸續公布第三方認驗證制度使用費徵收規定，惟2018聯邦財政年度預算提案中大幅刪減食品安全預算
- FDA恐難有效執行FSMA「業者自我管理、FDA積極監督」之制度設計



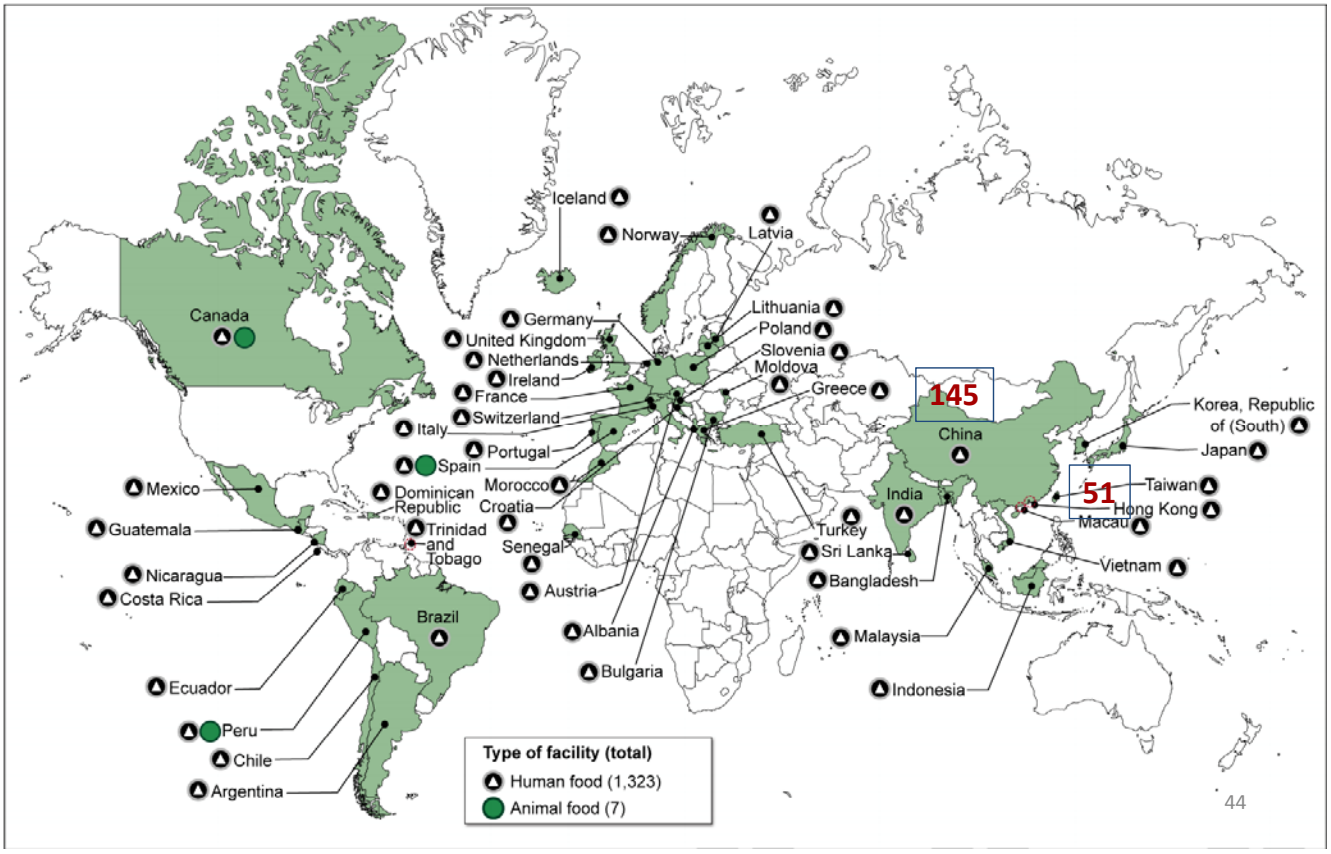
U.S. Department of Health and Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

The FSMA Funding Gap Through FY 2016

- At the time of FSMA's enactment in January 2011, the Congressional Budget Office (CBO) estimated that **implementation would require an increase of $583 million in spending subject to appropriations by FY 2015.**
- After increases totaling about $100 million in FY 2011 and 2012, HHS informed Congress in May 2013 that the remaining **FSMA funding gap was $400-450 million.**
- With a cumulative base increase of $138 million thru FY 2014, FDA estimated that the remaining **FSMA funding gap was about $300 million.**
- With the FY 2015 increase of $24 million, FDA revised the **FSMA funding gap estimate to $276 million.**
- **Congressional enactment for FY 2016 of $104.5 million in new budget authority significantly reduced the remaining funding gap** – to about $172 million – and enables FDA to maintain momentum toward successful implementation of FSMA.
- **The FY 2017 request of $25.3 million in new budget authority** helps close the FSMA funding gap by taking another step toward building state capacity to partner with FDA on produce safety and providing an additional increment of funding to implement the new FSMA import safety system. The President's Budget also continues to propose the Food Facility Registration and Inspection Fee and the Food Import Fee.

2014年FDA國外查廠共計1323次



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Thursday, June 15, 2017

FDA overseas offices lag behind FSMA inspection mandate

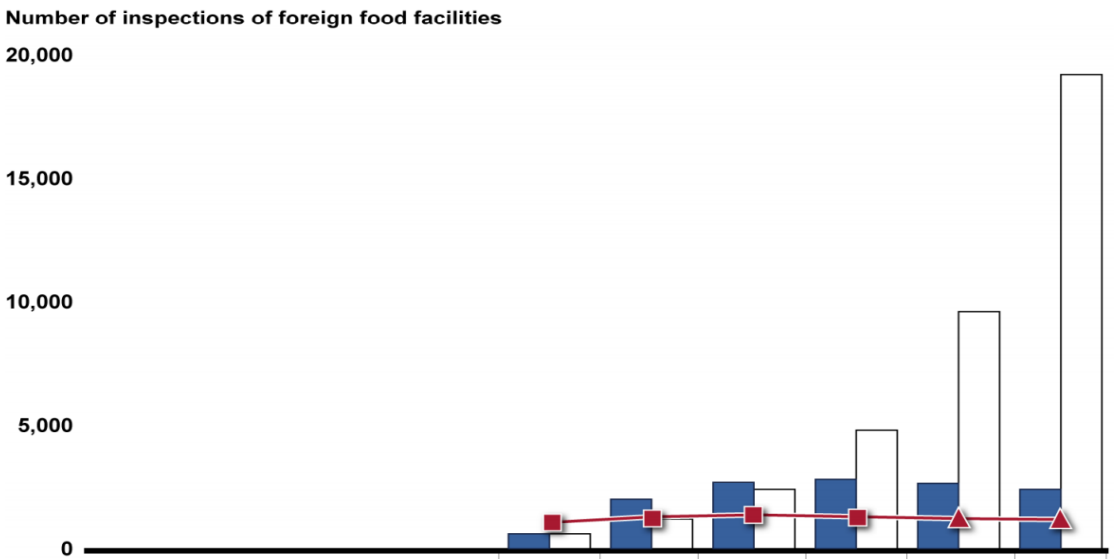
03/02/15 3:30 PM *By Sarah Gonzalez*

WASHINGTON, March 2 -- The Food and Drug Administration (FDA) is not keeping pace with a mandate that requires its overseas offices to inspect foreign food facilities, according to a Government Accountability Office (GAO) report.

In 2008, FDA established foreign offices to help prevent unsafe products from reaching U.S. borders. The Food Safety Modernization Act (FSMA), signed into law by President Barack Obama in January 2011, directed FDA to inspect at least 600 foreign food facilities in 2011 and double the number of inspections each year for the next five years.

Although FDA completed more than the requirement for 2011, with 1,002 inspections, it finished only 1,343 such inspections in 2012, a 34 percent increase from the previous year but not twice as many, as mandated. During 2013, FDA completed 1,403 such inspections, a 4 percent increase from the previous year but also less than twice the previous year's number. According to information available so far, GAO said the agency completed 1,323 inspections in 2014.

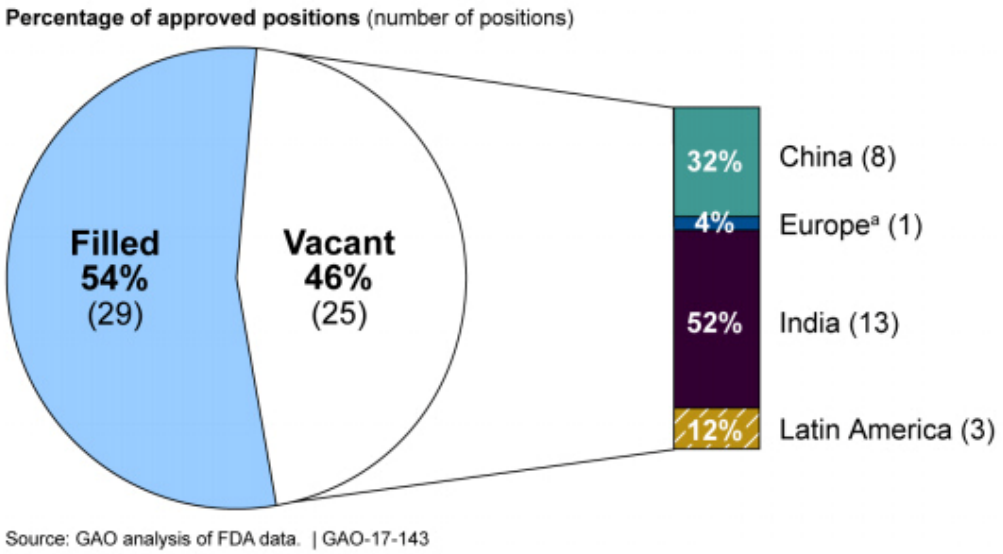
Figure 4: Food and Drug Administration (FDA) Inspections of Foreign Food Facilities Compared with FDA Food Safety Modernization Act (FSMA) Scenarios



Fiscal year	2011	2012	2013	2014	2015	2016
Food and Drug Administration (FDA) actual	1,002	1,343	1,403	1,323		
FDA planned					1,200[a]	1,200[b]
FDA Food Safety Modernization Act (FSMA) mandate	600	2,004	2,686	2,806	2,646	2,400[c]
Doubling each year	600	1,200	2,400	4,800	9,600	19,200

Sources: GAO analysis of FSMA and FDA data. | GAO-15-183

2. 進口食品監管之資源、語言與文化限制



Source: GAO analysis of FDA data. | GAO-17-143

FDA國外辦公室僅達54%配置人力

- FDA恐難於經費人力不足條件下達成FSMA境外查驗要求
  - 首年須查驗600處外國食品工廠，往後五年間每年加倍查驗數量
  - 亦即2016年FDA須查驗高達19,200處外國食品工廠，幾難達成
- 境外查驗成效維繫於相關人員能否克服語言文化障礙，與外國政府協調合作
  - FDA曾因誤讀中國製造商之名稱而造成查驗錯誤工廠，以致未能及時應對與追溯食品安全事件
  - FDA亦曾發生海外當地主管機關事前通風報信，縱容違法食品業者漏夜搬家，導致無法繼續追查之情事

3. 第三方稽核與認證潛在問題

- 食安新興產業，品質參差不齊且人員經驗、訓練皆不足。業者以利益最大化為目的，易淪為形式「清單治理」
- 兩種潛在利益衝突問題
  - 第一種與其商業模式有關，因食品業者得選擇執行稽核之廠商，競爭壓力下廠商可能為求客戶而提供「稽核彈性」
  - 第二種則為制度設計所致，因外國政府得為稽核認證機構，出口導向國家面臨「為美國食安把關」與「促進本國出口經濟」兩難
  - FSMA針對金錢關係之利益衝突規定，無法處理上述問題
- 多層次之綿長授權鏈使監督困難
  - FSMA考量人力經費限制而將責任轉予第三方分擔；惟同理，操作上殊難想見FDA如何在經費人力不足條件下有效監督

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Auditor Gave Positive Food Safety Reviews to Farms Later Linked to Outbreaks

BY **NEWS DESK** | JULY 25, 2014

The third-party food safety auditor that gave a passing review to Jensen Farms just weeks before its cantaloupe caused a deadly Listeria outbreak in 2011 also gave a positive audit to the farm that shipped romaine lettuce implicated in a more recent E. coli outbreak tied to Trader Joe's branded salads, according to documents obtained by **Food Safety News**.

California-based PrimusLabs gave a score of more than 95 percent to Ratto Bros. farms in Modesto, CA, in August 2013. Two months later, in October 2013, at least 33 people fell ill with E. coli O157:H7 in an outbreak that implicated as the most likely source of contamination romaine lettuce distributed by Ratto Bros., grown by Lake Bottom Farms, and sold in Trader Joe's and Walgreen's salads.

After the E. coli outbreak, officials with the California Department of Health visited Ratto Bros. and took environmental samples nearby. Five out of 44 samples tested positive for E. coli, though the samples were not a genetic match with the outbreak strain and were not taken on the farm.

4. 聯邦權責疊床架屋問題未解

Congressional Research Service

Comparison of Selected Agency Responsibilities for Food Safety and Quality

Agency	Responsibility
Food and Drug Administration (FDA)	• Food (but not meat)
	…etary supplements
	…ttled water
	…afood
	…ild game ("exotic" meat)
	…gs in the shell
U.S. …	…ading of raw fruit and vegetables
	…at and Poultry
	…s, processing and grading
	…rtifying organic production
Natic…	…ading of fish and seafood
Envir…	…inking water
	• Pesticide residues
Customs and Border Protection (CBP)	• Front-line enforcement and referral
Department of Justice (DOJ)	• Law enforcement
Federal Trade Commission (FTC)	• Advertising
Alcohol and Tobacco Tax and Trade Bureau (TTB)	• Alcohol

- 約12個聯邦政府機關擁具部分食安監管權限，管轄權重疊且權責不明處甚多
- 導致監管效率不佳、浪費資源及監管空窗等問題

Source: CRS, as adapted by N. D. Fortin, *Introduction to Food Regulation in the United States*, Part 1, May 2008.

聯邦食安管制權責碎裂化

FDA	USDA
其他80%-90%食品 蔬果、乳製品、加工食品	肉類、家禽類
帶殼蛋類與製品	液體、冷凍、乾燥蛋產品
雞飼料	飼雞場
香腸外皮	香腸餡肉
素食比薩	含肉比薩
海鮮	淡水鯰魚
包覆式三明治	開放式三明治
包麵皮熱狗	一般熱狗

其他問題：強制召回、豁免條款、進口商定義

- 進口食品召回執行問題
  - 問題食品召回重點並非是否為「強制」而係其「執行」；FDA因無後續監督，常有問題食品過期後仍未完成召回之情事
  - FDA如何後續追蹤或限時進口食品召回之執行，仍屬未知
- 豁免條款漏洞
  - 大型進口商可能切割採購，分別自外國小型供應商進口取得豁免資格
  - 許多開發中國家之食品業以小型為主，可能全面豁免於FSMA規定
  - 如何琢磨成本、市場競爭與公共健康，維持監管健全與平衡？
- 「進口商」定義於FSVP中必須位於美國境內，而VQIP則可位於美國以外的其他國家；兩者身份有可能但不必然重疊。定義不同，法規適用問題仍未釐清


THANK
YOU!