

國際經貿法與風險評估： SPS 到 SPS plus

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2017.5.19

WTO/SPS

Why WTO matters?

- Trade and health
- Food, medicines and medical devices are traded products, and also involving services and intellectual property.

Why WTO matters?

- WTO agreements relating to health
- -- Trade in Goods: GATT 1994, SPS, TBT(Non-tariff barriers to trade)
- -- Trade in services: GATS (medical services)
- -- Intellectual Property: TRIPS (patent on pharmaceuticals: patent linkage, undisclosed information)
- 我國食品安全衛生管理法、藥事法(醫療器材管理辦法)

WTO matters

- Can trade liberalization reconcile with health protection (domestic food safety policy and law)?
- It's up to **WTO** to decide if we may eat US beef or pork?

Why SPS agreement needs risk assessment?

- Int'l standard-making could be lengthy. Not sufficient to avoid protectionism
- US-EU long term disputes on hormone beef.
- US-led countries argued decision-making based on science and risk assessment
- From global governance: science is of universal and objective.
- Art. 2.2 Science-based with Art. 5.1 risk assessment

Art. 2: Basic rights and obligations

- Incorporate and elaborate GATT principles
- 2.1 National right to adopt SPS measures
- **2.2** Subject to “necessity” requirement, based on “scientific principles and evidence”(general cf. **5.1;5.2** specific)
- 2.3 GATT Arts. I, IV, XX, chapeau
- 嚴格科學主義 (sound science base)
- 由管制者負舉證責任 (not safe)

Art. 5: Assessment of Risk

- Framework of **risk analysis**, control and governance:
- Codex Food safety risk analysis: A guide for national food safety authorities

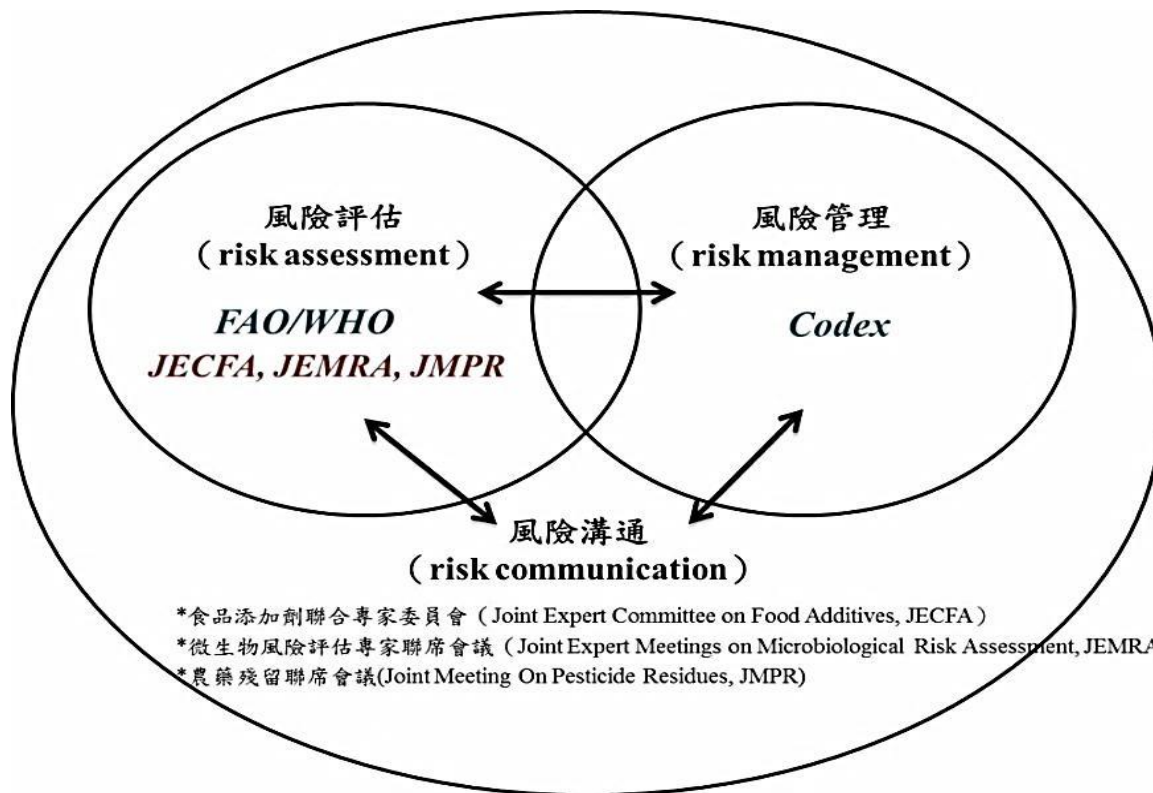
risk assessment,

risk management and

risk communication,

SPS/art. 5: except **risk assessment**, no explicitly mention risk management and communication

Codex 食品安全風險分析簡圖



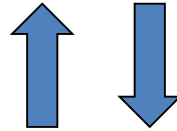
What's risk?

- Defining risk (風險): cf **damage** (實害)
- laboratory risk vs real life risk
- Definition of a risk assessment: SPS, Annex A, 4
- Cf RA on *food safety* or *disease* (animal or plant)
- Evaluation of the likelihood: probability, either quantity or quality; ascertainable risk
- Evaluation of potential

Multifaceted of risk assessment



risk manager



food producers -- risk assessor --- consumers

The work of risk assessment

- RA:
- -- evaluate scientific data,
- -- identify the hazard,
- -- decide potential (**probability**) harm to health: high or negligible

Standard of Review

- How the **WTO Panel** reviews the RA conducted by countries imposing SPS measures, two approaches:
 - - **deference**
 - - *de novo*
 - *DSU: Art.11, objective assessment of the facts*

Assessment of Risk

- Art. 5.1: Based upon risk assessments, taking into account risk assessment techniques developed by the relevant international organizations.
- **Based on**: case-by-case basis; the case law remains abstract, left to diverse interpretation

Assessment of Risk

- **The role of the Panel**; how and to what extent a Panel should do on national risk assessment?
- *US/Canada – Continued Suspension*
- Should assess whether the reasoning articulated on the basis of the scientific evidence is *objective* and *coherent*. . . Should review whether the particular *conclusions* drawn by the Member assessing the risk find *sufficient support* in the scientific evidence relied upon
- Emphasize both *reasoning* and *conclusions*; must have *justified relations* between them

Setting ALP (risk assessment or management)

- Appropriate level of protection: subject to type of risks,
- Zero to acceptable risk: no-GMO, no animal drugs residual; maximum residual level(MRL)
- Negligible risk (可忽略的風險).

Assessment of Risk

- Art. 5.2: Factors taken into account
- Art. 5.3: Add economic consideration:

Art. 5: Management of Risk

- Art. 5.4: should avoid negative trade effect
- -- 全面禁止或零風險宜(should)避免?
- Art. 5.5: (Art. 2.3)
- shall avoid arbitrary or unjustified distinctions
- Shall develop guidelines of practical implementation with SPS committee

Art. 5: Management of Risk

- Art. 5.6: **proportionality and necessity** (necessity: reasonably available test), Art. 2.2
- Art. 5.7: **Insufficient scientific evidence**: *provisionally* measures are allowed. (an indication of **precautionary principle**?)

- Art. 5.8: obligation to respond by a member applying the measures not considered consistent with int'l standards or no existence of such standards.

Art. 5.7 : insufficient scientific evidence

- WTO case law: Japan- Agriculture; Apples; *EC-Tariff Preference*; GMOs
- Article 5.7 should be viewed as a qualified **exemption** (not **exception**) from the relevant obligation in Article 2.2, which confirms the **right** of Members to enact measures where the **available** scientific evidence is ‘insufficient.’
- **Burden of proof** on the **complaining party**, not member applying the measure, **to demonstrate the inconsistency.**
- How to decide scientific evidence is sufficient or not?

insufficient scientific evidence

- (In)sufficiency of science **is fixed**? Or may change in light of the evolving nature of science
- Whether the level of protection set by imposing countries will affect the determination of sufficiency of scientific evidence?

EC-Hormones II

Art. 5: Risk Governance: Overview

- How do you evaluate Art. 5?
- The device is too **burdensome** for country using SPS measures which levels higher than int'l ones?

scientific justification plus free trade consideration

Reform on Risk Governance

- How to fix it if you think Art. 5 appears not balanced.

從SPS到SPS-PLUS

— TPP/SPS 對台灣食品安全治理的挑戰與契機，以科學證據與風險分析為重心並兼論美豬開放

大綱 Outlines

- TPP and developments of SPS plus
- TPP/SPS plus chapter 7
- 問題提出
 - 美牛、美豬 etc
- BSE
- Ractopamine
- 台灣的挑戰與契機

TPP: higher standards?

- Cf **WTO: benchmark**
- ECFA (**WTO-minus**) vs TPP (**WTO-plus**): **higher standards**
- No free lunch: exchange of concessions
- **Traditional trade barriers**: tariff barriers, market access, investment, IP etc.
- **Non-tariff barriers (NTB)**: SPS, TBT
- **Non-trade concerns(social values)**: public health, environment protection, labor etc.

邁入SPS-Plus的歷程與原因

- 近二十年來區域經濟整合趨勢盛行
 - 1990年起，區域貿易協定(Regional Trade Agreements, RTAs)數量的大幅增長。WTO會員參與RTA平均數目，由1990年的2個增加至2010年的12個。
 - 雙邊協定如美韓FTA、美澳FTA，多邊協定如跨太平洋夥伴協定(Trans-Pacific Partnership Agreement, TPP)等。
 - 要求遵守較SPS協定更高的義務，而被稱為SPS-Plus。
- 為何需要SPS-Plus？
 - 保護水平提升，風險敏銳，非關稅貿易障礙(Non-Tariff Barriers, NTBs)，已逐漸取代關稅貿易障礙。
 - 各地食安事件頻傳，國家可能採取過於嚴格的SPS措施，甚至以保護境內產業為目的制定SPS措施。
 - 為避免不必要的非關稅貿易障礙、加速區域貿易自由化。

Why SPS plus?

- For US, a country benefiting from the export of agriculture products would be more concerned with Asian countries' food safety and sanitary and phytosanitary measures.
- -- **Japan, Korea and Taiwan** etc. relying on imported food to ensure food security.
- -- Consumers are increasingly wary of **GM foods, BSE, animal drugs (ractopamine)** mainly exported from **US and Canada**

什麼是SPS-Plus？

- SPS-Plus並非某特定協定，存在於自由貿易協定或區域貿易協定SPS專章中，超越SPS協定中的義務規範均可能為SPS-Plus條款。
- 可能因簽約國所面臨的SPS議題不同，而著重於不同的SPS義務。
- 共同追求方向
 - 更為細緻化的科學證據要求
 - 在更為制度化的組織中加深合作
 - 擴張資訊共享及透明義務的廣度及深度

TPP: Chapter 7.9 SPS plus

- **International standards**
- **Scientific evidence**
- **Risk analysis**

TPP/SPS plus: International standards

- **SPS plus**
- **Strengthen “International standards”:**
- -- Codex; OIE and IPPC

SPS 國際標準—三姊妹組織

➤ 根據SPS協定附件A(3)

食品法典委員會 (Codex Alimentarius Commission, 簡稱Codex)

- 針對食品添加物、動物用藥品與農藥殘留物、污染物、分析與採樣方法及衛生實務法規與準則

世界動物衛生組織 (World Organization for Animal Health, 簡稱OIE)

- 就動物健康與人畜共同傳染病

國際植物保護公約 (International Plant Protection Convention, 簡稱IPPC)

- 就植物健康而言

TPP/SPS plus: international standards

- Cf WTO/SPS: Art. 3: an **incentive: carrot and stick**
- Art 7.9(2): one of mandates to be observed: must conform to int'l standards or

TPP/SPS對於國際標準地位的可能影響

強化透明性義務	嚴格科學證據與風險評估過程
<ul style="list-style-type: none">• 資訊分享與SPS措施揭露，使各國與國際標準之合致性得以被比較• 對於可能造成爭端之措施得以即時被察覺並進行諮商	<ul style="list-style-type: none">• 要求須根據最新的相關科學數據<ul style="list-style-type: none">• 誰擁有最新資料與數據？三姊妹組織？• 根據非主流科學觀點所做之風險評估是否被承認？
爭端預防與解決	其他業者的建議
<ul style="list-style-type: none">• 透過諮商取得共識可能影響WTO會員國在國際組織論壇(WTO, Codex etc)中的合作與立場。• 若適用爭端解決機制，將使協定更具執行力與強制力。	<ul style="list-style-type: none">• 同等性使SPS措施符合國際標準者若被承認其效力，將間接使國際標準被採納。• 風險管理優先考量對貿易限制較少者而非技術與經濟上之可行性，使得成員裁量權減少。

TPP/SPS plus: scientific evidence

- SPS plus
- Stringent “scientific evidence”
- Cf WTO/SPS: Arts. 2.2/5.2: **sufficient, available** scientific evidence (varied among WTO members)
- Art 7.9(2): based on **documented and objective** scientific evidence that **is rationally related** to the measures.

What plus? a real plus?

- **Documented:** the format unclear? publications in journals?
- Add **objectiveness:** incorporated **case law of hormones** (object and coherent)
- **is rationally related to:** incorporated case law of hormones
- **(based on: sufficiently warrant, reasonably support, rational relationship (AB, Hormones, para. 193))**

WTO case law influence and contribution

- The contribution of WTO case law to the TPP/SPS rule-making.
- WTO case law rewritten into TPP
- WTO continues its relevance and influence.

The uncertainty of science remains

- Science-based confirmed, as scientific uncertainty remains.
- press parties to apply mainstream science, as minority views (even recognized by WTO case law) may not be easily published
 - an article challenging GM food safety was withdrew.

TPP/SPS plus: risk analysis

- To require risk analysis to ensure legitimacy of food regulations has become prevailing.
- -- **risk assessment**
- -- **risk management**
- -- **risk communication**
- Codex, EU, Japan etc (Australia, New Zealand)
- Involving **procedure** and **mechanisms**

TPP/SPS plus: risk analysis

- **SPS plus**
- cf WTO/SPS: Art. 5 only explicitly “**risk assessment,**”
- TPP/SPS incorporating the procedure and mechanism of **risk analysis**

TPP/SPS plus: risk analysis in general

- Art. 7.9(4)(b):
- conduct in a manner: **documented**
- procedure: subject to **comment** by interested persons and other Parties; (as a means of risk communication)
- Art. 7.9 (6): take into account guidance of **WTO/SPS** committee and **int'l standards** (Codex, OIE, IPPC)
- -- strengthen the role of WTO and int'l standard-making regimes.

TPP/SPS plus: Risk assessment

- Cf WTO/SPS, art. 5.2:
- In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest – or disease – free areas; relevant ecological and environmental conditions; and quarantine or other treatment.
- TPP/SPS, art. 7.9(5): Risk assessment
- : “reasonably” available and relevant scientific data.

TPP/SPS plus: risk management

- Cf WTO/SPS: AB not formally recognize risk management;
- But, Art. 5.1 SPS measures (risk management) are based on risk assessment
- TPP/SPS: Art. 7.9(2) similar text
- Cf WTO/SPS:
 - Arts. 5.5 (non-discrimination); 5.6 (necessity)
 - TPP/SPS: Art. 7.9(6)(b)(c): repeat WTO/SPS, art 5.6.

TPP/SPS plus: risk management

- Repeat and confirm WTO/SPS

TPP/SPS plus: risk communication

- Definition: TPP close to Codex
- Cf WTO/SPS: art. 7 (transparency) and Annex B
- One way notification, not stringent in time and content
- TPP/SPS: art. 7.13 (transparency)
- (5) publication: legal basis and comments
- (7) (4) **Mutual** exchange: discussion in advance vs one way
- (4) 60 days comments and respond vs reasonable time
- (6) Not conform to int'l standards: provide scientific evidence vs objective and rational

問題提出

- 美牛、美豬是何問題？
- US requests
- observe int'l standards
- provide scientific evidence

What issues involved?

- **Trade** (liberalization): whose trade,
- **Public health**: consumers' food safety
- **Science**: risk assessment BSE, Ractopamine
- **Industry** (domestic pork production)
- **International institutions**: setting int'l standards (Codex, OIE etc.)

US beef 1.0: BSE

- US BSE beef: 2010
- Int'l standards: OIE sets tradability of beef with BSE in accordance with levels of risk: controlled, negligible and undetermined
- US beef then: controlled risk, except **SRMs**, certain parts can be traded
- Taiwan law: Art. 15(3): 有害人體健康之物質，包括雖非疫區而近十年內有發生牛海綿狀腦病或新型庫賈氏症病例之國家或地區牛隻之頭骨、腦、眼睛、脊髓、絞肉、內臟及其他相關產製品。

US beef 1.0: BSE

- TPP
- Int'l standards: OIE
- US beef: has been upgraded to negligible risk
- Whole beef including 內臟可貿易
- Scientific evidence: hard to prove,
- Risk analysis: 食品藥物管理署並將專家意見提送「牛海綿狀腦病專家諮詢會」，認定該6項牛肉副產品非屬內臟且非屬特定風險物質(SRM)，但因反對意見，仍未開放。

US beef (pork) 2.0: Ractopamine

- US beef and pork: 2012
- Codex: 2012 set MRL **beef 10 ppb; pork 10 ppb**
- Taiwan law: Art. 15(4): 國內外之肉品及其他相關產製品，除依中央主管機關根據國人膳食習慣為風險評估所訂定安全容許標準者外，不得檢出乙型受體素。

US beef (pork) 2.0: Ractopamine

- -- 安全容許：訂定MRL: beef 10 ppb
- -- 牛豬分離：只公告美牛標準，未告豬(不得檢出乙型受體素，零檢出), top down policy, not button up.
- -- 強制標示
- -- 排除內臟

US beef (pork) 2.0: Ractopamine

- TPP
- Int'l standards: Codex covers both beef and pork.
- Scientific evidence: hard to prove pork has higher risk
- Risk analysis: why beef not pork? Lacking risk assessment on pork.

US beef (pork) 2.0: Ractopamine

- 原本食管法第十一條第二項，即授權主管機關就動物用藥的安全容許量訂定之。此行政裁量的授權在修正版中仍舊維持，只增加需經風險評估的程序，此不可謂不進步。但母法對主管機關如何進行評估，據而做出安全容許量，以及評估程序是否符合專業、公正獨立與透明等要件未有置喙之餘地。換言之，為避免主管機關流於黑箱作業或有政治力操控之虞，風險評估之監督與控制原即應法制化。

台灣的挑戰與契機

- 加入TPP改革政策制定及提升治理品質
- 完備食安治理體系：
 - 牛豬分離已難符合國際規範
 - 以風險分析為基礎的管制架構
 - 強化風險溝通
 - 培育食安治理人才：跨領域
- 參與國際和區域標準制定

現實面運作之挑戰－我國法制

- 食品安全衛生管理法第4條第1項：「主管機關採行之食品安全管理措施應以風險評估為基礎，符合滿足國民享有之健康、安全食品以及知的權利、科學證據原則、事先預防原則、資訊透明原則，建構風險評估以及諮議體系」。
- 食品安全衛生管理法第4條第2項：「前項風險評估，中央主管機關應召集食品安全、毒理與風險評估等專家學者及民間團體組成食品風險評估諮議會為之。」
- 行政院衛生福利部因應食品安全衛生管理法第4條明訂主管機關應設置「食品風險評估諮議會」之需要，於2014年7月24日制定並修正「食品風險評估諮議會設置辦法」

現實面運作之挑戰－我國法制

- 我國風險評估定位：食管法第四條風險評估有必要進一步建置；
- 食品風險評估諮議會目前設於衛生福利部以下，關於風險評估相關內涵有必要進一步充實與強化
 - 科學原則
 - 獨立
 - 透明
- 風險評估和管理之關連需明確化。

結語與建議

➤ 修法建議

➤ Option 1:

修法提高食品風險評估諮議會(委員會)之法律位階，使風險評估與風險管理機關之位階平行且功能與職責分離。

➤ Option 2:

不提高法律位階，但強化現行食品風險評估諮議會相關法制

- Review the science opinions of science committees to ensure objectivity, independence and transparency of the risk assessment.
- Propose (advise) appropriate level of protection to risk managers(policy makers): as a bridge between RA and RM.

結語與建議

- 修法方向
- 行政院食安會報下成立獨立風險評估專門委員會
- 法源
- 定位：與風險諮議會關係
- 組成
- 與主管機關(風險管理)關係
- 風險溝通

結語與建議

- 核心理念的確保
- 自律 (risk assessors etc.)與內部查核
- 外部監督：公部門、國會、媒體、公民團體 etc.
- 司法審查：基礎、適格、事項（實質或程序）。US; EU

Challenges and Opportunities

- Whose science? The discrepancy between parties remains
- High costs and time-consuming for building a decent risk analysis regulatory regimes
- Capacity building
- Good news: not subject to dispute settlement mechanism
- Provide technical exchange and cooperation.
- -- Who leads? Japan (Food Safety Commission) or US (not
- Clear separation of RA and RM, but RC sounds good)

Challenges and Opportunities

- Provide momentum and pressure to engage in food safety governance reform
- -- investment of expertise on RA, personnel training and law
- -- realization of food safety law (both science-based and rule-based)
- Optimize the quality of decision-making without unjust non-health risk considerations
- -- the lift of Japanese radioactive contaminated food, a trade-off health with the strength of bilateral relations
- Improve the quality of food regulations align with food democracy (deliberation, participation and consensus-building)

敬請指教！

Thank you for your attention!