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CRN-I Symposium

Scientific Symposium, Nutrition Issues in Codex: Health Claims and Nutrient Reference Values

11 November 2011

Maurits Lugard

Overview

- Regulatory Food Supplement Restrictions
- Relevant Legal Framework: WTO Rules
- Application WTO Rules to:
  - RDA-based Maximum Nutrient Content Levels
  - Application of EU Health Claims Regulation

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Regulatory Food Supplement Restrictions

- Several countries restrict or are considering to restrict the sale of vitamin and mineral food supplements by establishing maximum levels of nutrient content based solely on Recommended Dietary Allowances (RDA)

- EU Health Claims Regulation as applied by the European Food Safety Authority (EFSA) and European Commission will result in prohibition of majority of health claims

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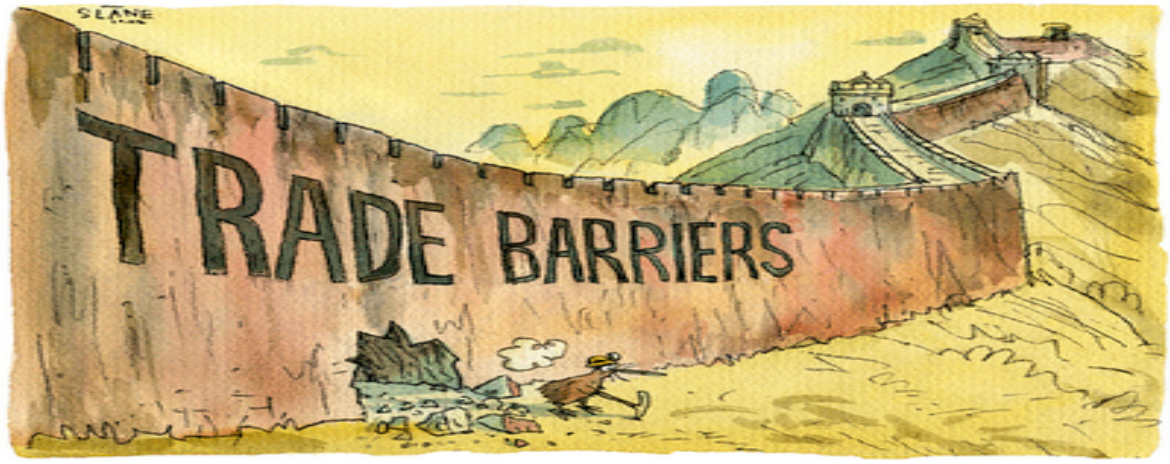
Relevance WTO Rules

- Rules of World Trade Organization can be used to address these restrictions
  - legal arguments should be part of advocacy strategy
  - WTO dispute settlement mechanism can be used by WTO Members to enforce violations of WTO rules



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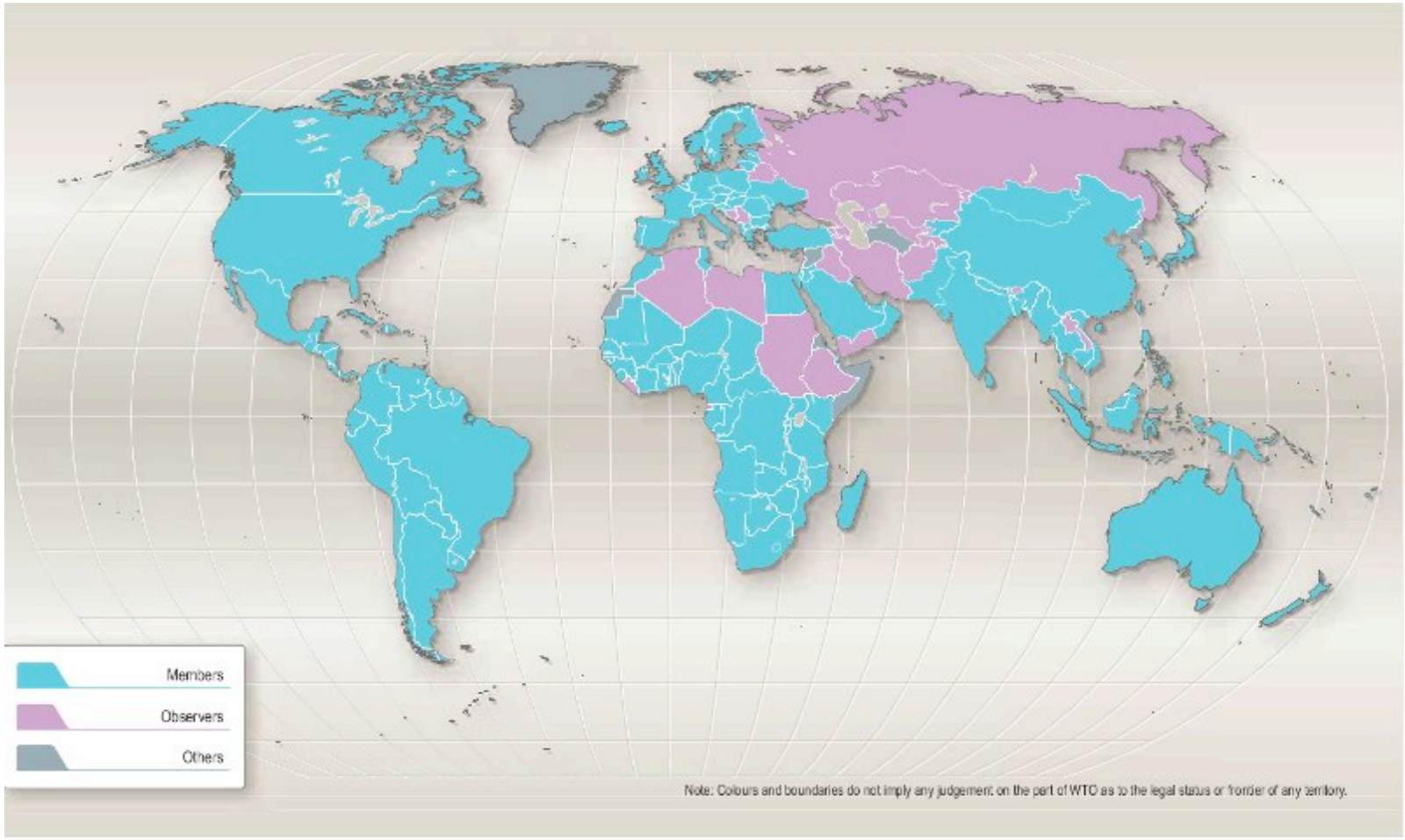
WTO Membership



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Applicable WTO Rules

- WTO agreements relevant for food supplements
  - **GATT 1994**: applies to trade in goods between WTO Members
  - **SPS Agreement**: applies to sanitary and phytosanitary measures of WTO Members aimed at the protection of human, animal and plant life and health
  - **TBT Agreement**: applies to technical regulations and standards of WTO Members
- Health-related measures are addressed by both the SPS Agreement and TBT Agreement, but a measure cannot simultaneously be subject to both

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RDA-Based Maximum Levels of Nutrient Content for Vitamin and Mineral Food Supplements

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Maximum Nutrient Content Levels

- Several WTO Members restrict or are considering to restrict sale of vitamin and mineral food supplements by establishing maximum levels of nutrient content

- Regulations are either in the form of
  - food regulations that prohibit production and/or sale of food supplements exceeding RDA-based limits, or
  - pharmaceutical regulations that classify all or some classes of food supplements as pharmaceutical products

- Likely justification: to protect human health

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Relevance SPS Agreement (1)

- SPS Agreement requires SPS measures to be enacted and maintained:
  - on the basis of scientific evidence and a risk assessment, or
  - on the basis of a relevant international standard

- In addition, SPS measures must be consistent with principles of non-discrimination and national treatment
- **Important**: SPS Agreement can apply irrespective of whether food supplements are regulated under food or drug regulations

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Relevance SPS Agreement (2)

- SPS Agreement urges Members to base measures on international standards such Codex standards
- Relevant Codex standard: Codex Guidelines for Vitamins and Mineral Food Supplements
  - **explicitly warns against** setting maximum levels solely based on recommended nutrient intakes such as RDA
- SPS Agreement allows WTO Members to adopt higher level of protection than achieved by Codex standard if
  - there is a scientific justification, or
  - as a consequence of level of protection deemed appropriate by Member based on scientific risk assessment

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Violation of SPS Agreement

- Certain WTO Members' RDA-based maximum nutrient content levels appear to violate
  - Articles 2.2, 5.1 and 5.2 of SPS Agreement: they are **not based on risk assessment or maintained with sufficient scientific evidence**
  - Articles 2.3 and 5.5 of SPS Agreement: food supplement importers must comply with **standards more burdensome than those applied to producers of conventional foods** with similar qualities
  - Article 3.3 of SPS Agreement: they **exceed level of protection of relevant Codex standard without scientific justification or risk assessment**

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Relevance TBT Agreement

- TBT Agreement disciplines all technical regulations, voluntary standards and conformity assessment procedures, to extent not covered by SPS Agreement

- Objective TBT Agreement: ensure that such measures do not function as **unnecessary obstacles to international trade**

- Claims under SPS and TBT Agreement are **mutually exclusive**: if argued that national RDA-based restrictions are not covered by SPS Agreement, they are subject to TBT rules because they are "technical regulations"

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Violation of TBT Agreement (1)

- To the extent that restrictions are covered by TBT Agreement they appear to violate:

  - Article 2.2 TBT Agreement: they have the effect of creating **unnecessary obstacles to international trade** by being **more trade-restrictive than necessary** to protect consumer health

    - Less trade-restrictive alternatives are available to obtain level of protection, e.g.: labeling with maximum intake information combined with higher maximum nutrient levels based on a risk assessment

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Violation of TBT Agreement (2)

- Article 2.1 TBT Agreement: to the extent that imported food supplements are "like" conventional foods of national origin, they accord **less favourable treatment to imported food supplements**

  - for example: multi-vitamin/nutritional beverages will probably be considered to be "like" conventional beverages

  - imposing RDA-based restrictions or drug-based regulations subjects food supplements to more onerous requirements than "like" conventional food products

Violation of TBT Agreement (3)

- Article 2.4 TBT Agreement: they are **not based on the relevant Codex standard without justification**

  - RDA-based maximum levels contradict the Codex standard, and can therefore not be based on the standard

  - No justification: difficult to argue that Codex standard is ineffective or inappropriate to protect human health in this context

  - Immaterial whether regulations proceeded the Codex standard – regulations should have been reassessed

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Violation GATT 1994 (1)

- Finally, both food and drug regulations with RDA-based restrictions also:
  - appear to violate Article III:4 of GATT 1994, because, to the extent that imported food supplements are "like" certain conventional foods, they **discriminate** against imported food supplements

    - the restrictions detrimentally affect the internal sale and use of food supplements by preventing the sale of imported food supplements with nutrient content exceeding RDA-based maximums

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Violation GATT 1994 (2)

- Furthermore, the violation of Article III:4 of GATT 1994
  - **Is not justified** under Article XX of GATT 1994, because the restrictions are not "necessary" to protect human health and are applied in a manner that would constitute a disguised restriction on international trade
    - While RDA-based restrictions may contribute to protecting consumers from adverse effects of excessive intakes, this is significantly outweighed by severe impact of outright prohibition on non-conforming food supplements
    - Safety-based labeling requirements, e.g., would also protect consumers similarly to RDA-based restrictions

EU Health Claims Regulation

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Overview EU Health Claims Regulation (1)

- Adopted in December 2006 and regulates the use of nutrition and health claims made with respect to food products

- All health claims must be (1) assessed by EFSA and (2) specifically authorized by European Commission based on EFSA's analysis

- Objective is to inform consumers and protect them against misleading health claims

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Overview EU Health Claims Regulation (2)

- Three different assessment procedures:
  - Article 13(1) "general function" health claims included in list of existing health claims submitted by Member States
  - Article 13(5) health claims not covered by list of existing health claims and not subject to Article 14
  - Article 14 health claims related to reduction of disease risk and children's development and health

- List of permitted Article 13(1) claims was supposed to be adopted by January 31, 2010 – now expected by end of 2010 / early 2011

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Overview EU Health Claims Regulation (3)

- Restrictive application by EFSA resulted in negative opinion on more than 85 % of claims relating to food supplements not containing vitamins or minerals
- Main issues:
  - EFSA failed to weigh the totality of evidence
  - applied drug-like standards to claims for food products
  - failed to apply different standards to different claims
- If European Commission follows EFSA opinions, all these claims can no longer be used once list of permitted claims is published

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Relevance TBT Agreement

- TBT Agreement applies to EU Health Claims Regulation because it is a "technical regulation"
  - it sets forth product characteristics in the form of labeling requirements;
  - compliance with the labeling requirements is mandatory; and
  - the requirements apply to an identifiable group of products: foods
- And provides for "conformity assessment procedure"
  - before health claims can be used they must be assessed by EFSA and authorized by EU legislator

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Violation TBT Agreement (1)

- Restrictive application of EU Health Claims Regulation by EFSA and European Commission appears to violate Article 2.2 TBT Agreement:
  - it is **more trade restrictive than necessary** to achieve the objective of preventing misleading health claims on food products and creates an **unnecessary obstacle** to international trade

    - trade restrictive impact severe if European Commission acts in accordance with EFSA opinions
    - more reasonable EFSA assessment standard would not lead to significant risks for consumers and would still prohibit misleading and deceptive claims

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Violation TBT Agreement (2)

- In addition, the procedures to assess conformity of health claims with legal requirements as applied by EFSA appear to violate Article 5.1.2 TBT Agreement:
  - they are **applied more strictly than necessary** to prevent the use of misleading health claims in the EU
    - EFSA did not take into account totality of available scientific evidence and does not weigh all the evidence
    - EFSA applied drug-like standards to claims for food products and rejected many studies as "not pertinent"
    - EFSA failed to apply different standards to different claims and subjected all claims to highest standards
  - approach **goes beyond legal standards** and prevents products with health claims supported by evidence from being marketed in the EU

efsa
European Food Safety Authority

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More detailed legal memoranda have been published on CRN website

Questions/Comments

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