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Opportunities for Harmonization in Food/Supplement Regulation

Kevin C. Kenny, J.D., LL.M.

The Orchid Hotel, Mumbai
PFNDAI Workshop
23 Mar 2017



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**Regulatory Focus: Food & Consumer Products,
Chemical Product Safety Compliance:**

- **4,600 users across 77 countries**
- **Coverage of 207 countries and 18 Economic Communities**

PRODUCTS:

- **Reference**
- **Formulation Compliance Analysis**
 - Red light/Green Light
- **Decernis Horizon Scanning**
- **Supply Chain Compliance Management**

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Food & Supplement Challenge:

- **200+ Countries**
- **40 Major Languages**
- **1,359 Food Additive Regs/Drafts/ Notices/Amendments across 89 countries since 1 Jan 2017(!)**
 - USA 219 (includes warning letters and 114 recalls)
 - EU 104 (includes 29 EFSA opinions)
 - Canada 96 (includes 68 recalls!)
 - Korea 63
 - Taiwan 62
 - India 55
 - Kenya 42
 - California 41

= Not Enough Harmonization



Why Harmonize Supplements and Food Additives?

- **Today: Lists, food categories, usages and specifications are non-harmonized making international trade of food-related products difficult & expensive.**
- **Major developed markets such as the EU, US and Japan have had detailed food regulatory systems in place for years: non-harmonized**
- **More “Mosaic” = Less Safety!**



So, what does Harmonization mean?



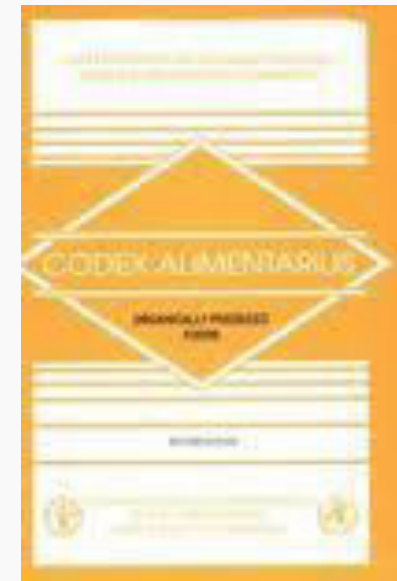


Plan

- **Codex Alimentarius (105 Countries)**
- **European Union (52 Countries)**
- **Eurasian Economic Union (5 Countries)**
- **SIECA (8 Countries)**
- **Mercosur (6 Countries)**
- **ASEAN (10 Countries)**
- **GCC (6 countries)**



- **Established 1963 (FAO & WHO)**
- **Today:**
 - **187 Member countries + 1 Int. Org (EU)**
 - **240 Codex Observers**
 - 56 IGOs
 - 168 NGOs
 - 16 UN
- **Primary Goal: Develop harmonised international food standards, guidelines and codes of practice**





General Subject Committees

Acronym	Codex Committee	Id	Doc Ref	Host Country
CCCF	Contaminants in Foods	CX-735	CX/CF	NL
CCFA	Committee on Food Additives	CX-711	CX/FA	CN
CCFH	Food Hygiene	CX-712	CX/FH	US
CCFICS	Food Import and Export Certification and Inspection Systems	CX-733	CX/FICS	AU
CCFL	Food Labelling	CX-714	CX/FL	CA
CCGP	General Principles	CX-716	CX/GP	FR
CCMAS	Methods of Analysis and Sampling	CX-715	CX/MAS	HU
CCNFSDU	Nutrition and Foods for Special Dietary Uses	CX-720	CX/NFSDU	DE
CCPR	Pesticide Residues	CX-718	CX/PR	CN
CCRVDF	Residues of Veterinary Drugs in Foods	CX-730	CX/RVDF	US

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Countries which directly follow Codex Additives (75)

Angola	Cambodia	Guyana	Namibia	Senegal
Anguilla	Cape Verde	Haiti	Nepal	Seychelles
Antigua & Barbuda	Cayman Islands	Honduras	Nicaragua	Sierra Leone
Azerbaijan	Congo	Iran	Nigeria	South Sudan
Bahamas	Costa Rica	Iraq	Oman	St. Lucia
Bahrain	Cuba	Ivory Coast	Pakistan	Tanzania
Bangladesh	Curacao	Jamaica	Panama	Tajikistan
Barbados	Dominican Republic	Jordan	Papua New Guinea	Trinidad/Tobago
Belize	El Salvador	Kuwait	Peru	Turkmenistan
Benin	Eritrea	Laos	Qatar	UAE
Bermuda	Ethiopia	Maldives	Rwanda	Uganda
Bolivia	Fiji	Mali	Saint Kitts and Nevis	Uzbekistan
Botswana	Georgia	Mauritania	Saint Lucia	Yemen
Burkina Faso	Ghana	Mozambique	Samoa	Zambia
Burundi	Guatemala	Myanmar	Saudi Arabia	Zimbabwe



If no local regulation for individual substance, follow Codex Additives (30+)

Argentina: Article 2 of Decree §2092 states: "... all foods, condiments, beverages, or their raw material and food additives which are manufactured, fractioned, preserved, transported, sold, or exposed, must comply with the CAA requirements. ... **GOA also considers products from countries which have food controls comparable to those of Argentina, or when they use the *Codex Alimentarius (FAO/OMS)* standards, to be in compliance with Argentine standards."**

Algeria	Fiji	Philippines	Turkey
Argentina	Indonesia	Serbia	Ukraine
CARICOM	Kazakhstan	SIECA	Uzbekistan
Colombia	Kenya	South Africa	Venezuela
Ecuador	Peru	Thailand	Vietnam



Additives

- Codex STAN 192-1995 General Standard for Food Additives

Labelling/Claims

- General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985)
- Codex Standard for Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991)
- Guidelines on Nutrition Labelling (CAC/GL 2-1985)
- General Guidelines on Claims (CAC/GL 1-1979)
- Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997)

Supplements/Food Fortification

- Guidelines for Vitamin and Mineral Food Supplements (CAC/GL 55 - 2005)
- General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 9-1987)



• **Advantages**

- Brings everybody to the table
- Transparency: Freely, electronically available
- Arabic, Chinese, English, French, Spanish, Russian
- Makes it possible for less advanced countries to catch up in a hurry

• **Disadvantages**

- Glaciers sometimes move faster
- Purely voluntary
- US, EU will never agree to drop 50 years of legislation



European Union: 27.5 Countries

28 European Union Member Countries

 Austria	 Belgium	 Bulgaria
 Croatia	 Cyprus	 Czech Republic
 Denmark	 Estonia	 Finland
 France	 Germany	 Greece
 Hungary	 Ireland	 Italy
 Latvia	 Lithuania	 Luxembourg
 Malta	 Netherlands	 Poland
 Portugal	 Romania	 Slovakia
 Slovenia	 Spain	 Sweden
 United Kingdom		

EU: Harmonization History

Year	Pre 1957	1957	1967	1973	1992	2004	2011
# Member States	0	6	6	9	15	25	27
Legislation Type	National	Directives	Harmonized Directives			Regulations	Union Lists
Community Name	European Coal and Steel Community	European Economic Community (EEC)	European Communities		European Community		European Union
Sample Regulation	Arrêté du 28 juin 1912 Coloration et l'emballage des denrées alimentaires et des boissons	Directive of 23 October 1962 on approximation of rules of Member States concerning colouring matters authorised for use in foodstuffs	Directive 67/548/EEC Annex I		Directive 2002/46 on Food Supplements	Regulation (EC) No 1333/2008: Food additives	Regulation (EU) No 1129/2011: Union List of Food Additives
Special Events		Treaty of Rome	Customs Union	Schengen Treaty 1985	Maastricht Treaty	Euro introduced 2002	Lisbon Treaty 2009



EU

Advantages of Approach

- **Directives were a huge step forward**
- **Today: Regulations → better!**
 - Single European Standard
 - Absolute consistency in theory
(Lex Britannia!)
 - Clarity: Less 'homework' for industry
 - More even enforcement
 - Substantially lowers cost of compliance



EU 27.5 + other countries (24)

• + Candidate Members

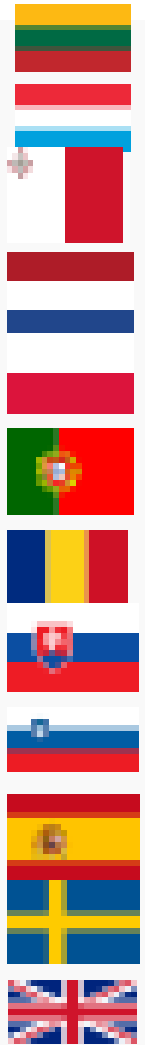
- **Turkey** + Albania, Iceland, Macedonia, Montenegro, Serbia

• + EEA Members

- Iceland
- Lichtenstein
- Norway

• + "Under the influence"

- EU: Bosnia & Herzegovina, Kosovo
- ES: Canary Islands
- FR: French Polynesia, French Guiana, Guadeloupe, Martinique, Mayotte, Reunion, Saint-Martin
- NL: Aruba, Curaçao and Sint Maarten
- PT: Azores, Madeira





Cornerstone Regulations

- **Additives**

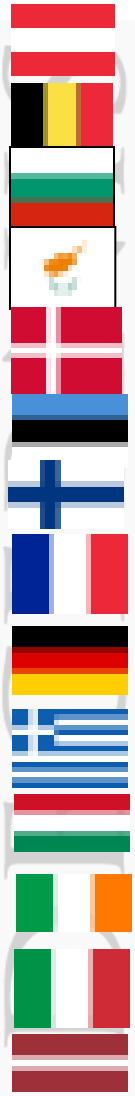
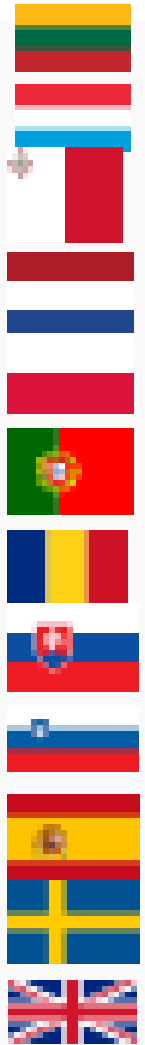
- Regulation (EC) No 1333/2008 on Food additives

- **Labelling/Claims**

- Regulation (EC) No 1924/2008 on Nutrition & Health Claims

- **Supplements/Food Fortification**

- EU: Directive 2002/46: Food Supplements
- EU: Regulation (EC) No 258/97 on Novel Foods
- EU: Regulation (EC) No 1925/2006 on Fortification
- EFSA Botanicals Compendium (2012)
- Belgium
- Czech Republic
- Denmark
- Germany
- Italy
- ...





Eurasian Economic Union EEU (1 Jan 2015)

Member States:



Armenia **2 Jan 2015**



Belarus **1 Jan 2010**



Kazakhstan **1 Jan 2010**



Kyrgyzstan **21 May 2015**



Russia **1 Jan 2010**



Eurasian Economic Union EEU



BLR



KAZ



RUS



ARM

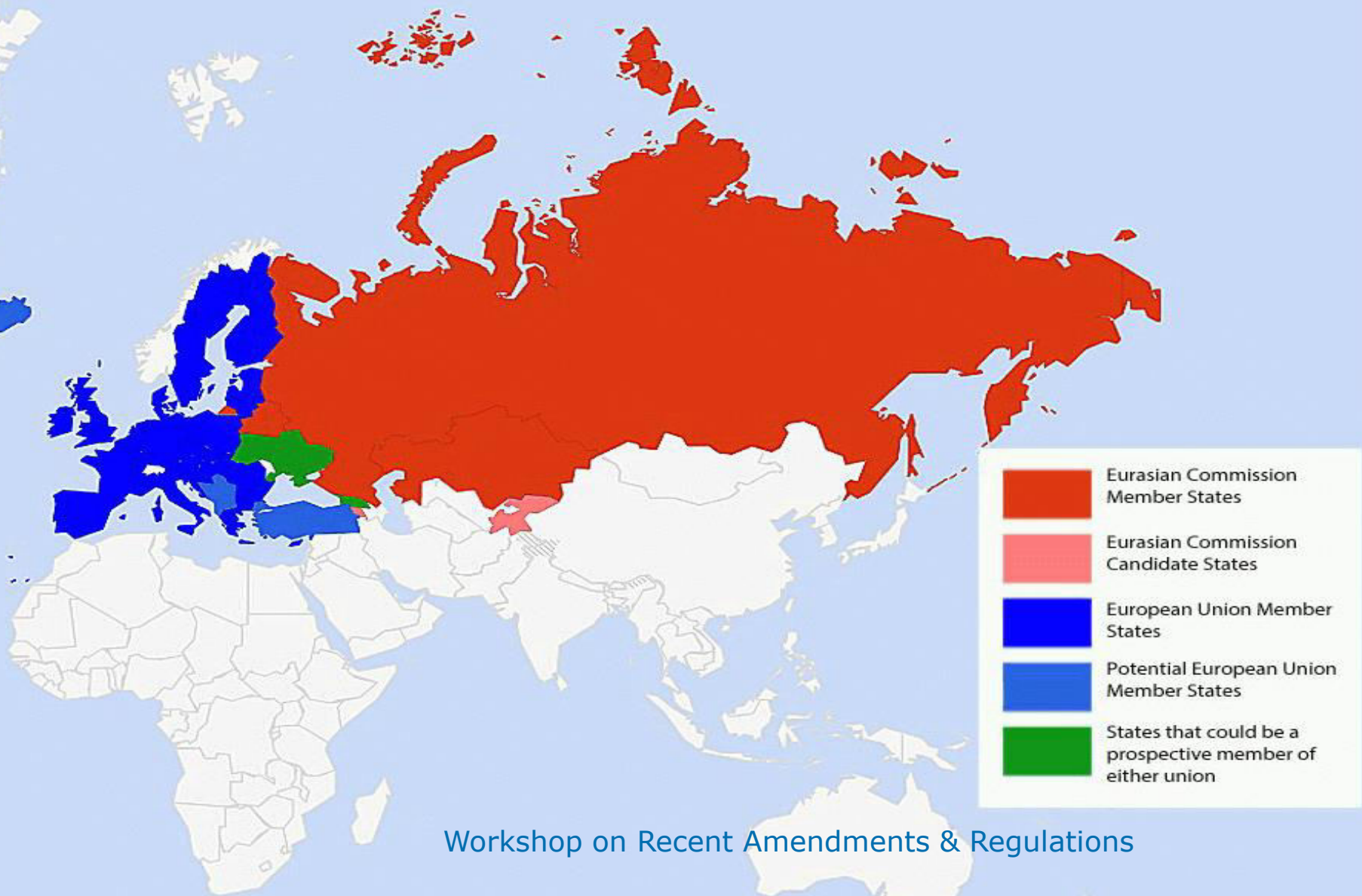


KGZ

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Eurasian Economic Union

EEU



Workshop on Recent Amendments & Regulations



Cornerstone Regulations

- TR TS 005/2011 "Safety of Packaging"
- TR TS 015/2011 "Safety of Grain"
- TR TS 021/2011 "Food Safety"
- TR TS 022/2011 "Labelling of Food Products"
- TR TS 023/2011 "Juice Products from Fruits and Vegetables"
- TR TS 024/2011 "Oils and Fats"
- TR TS 027/2012 "Specialized Food Products, including Dietary Therapeutic and Dietary Prophylactic Nutrition"
- TR TS 029/2012 "Food Additives, Flavorings & Technological Aids"
- TR TS 033/2013 "Milk and Dairy Products"

EEU TR prevail over national regs of member states.

Russia: Still significant non-harmonized national Regs:

- Biologically Active Food Supplements (BAFS)
- Positive & Negative Lists
- GOST Standards



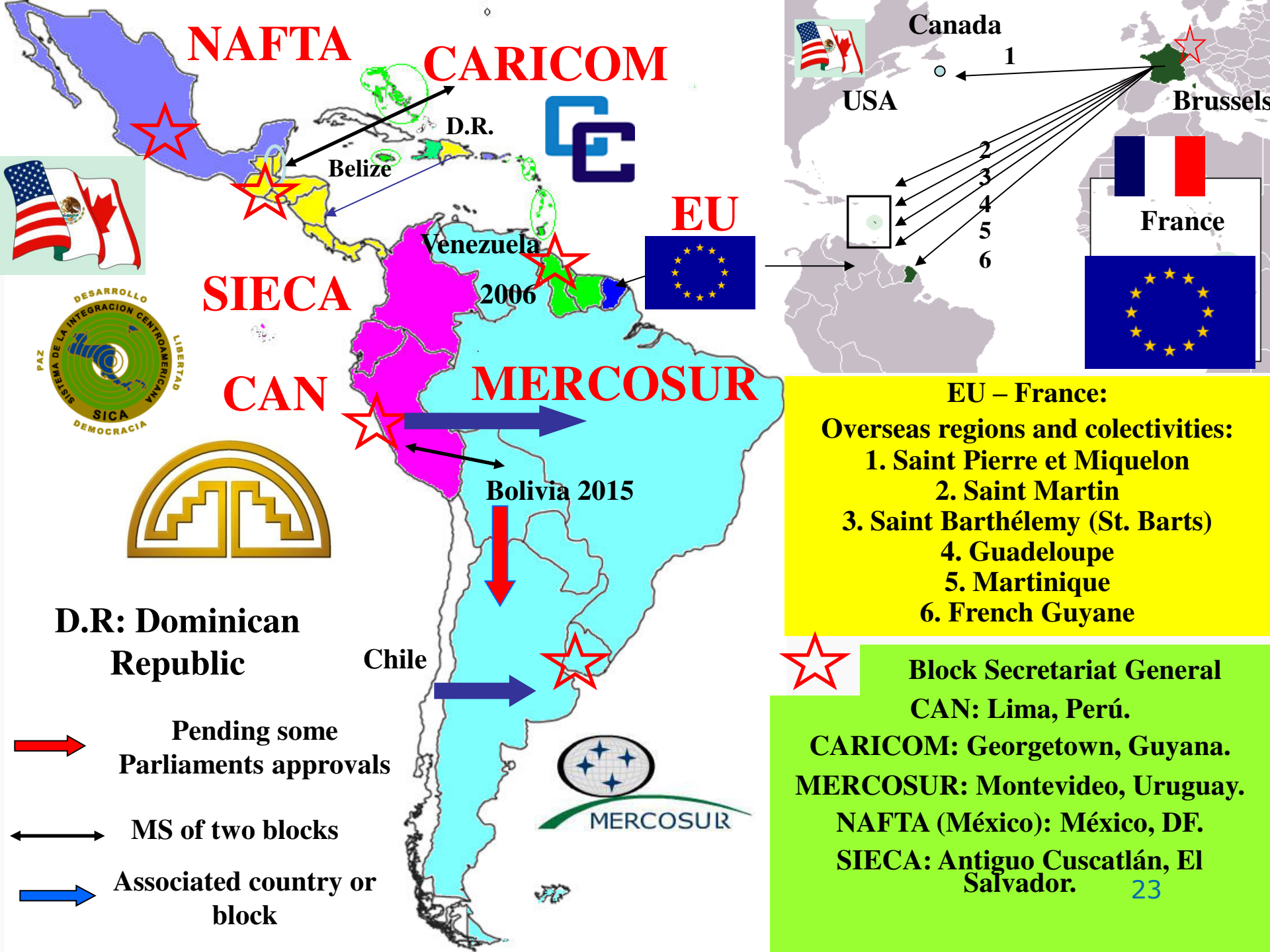
Latin American Trend:

Harmonization

Following slide provided by

Prof. ALEJANDRO ARIOSTI

**National Institute of Industrial Technology (INTI) –
Argentina**



NAFTA

CARICOM

SIECA

CAN

MERCOSUR

EU

Canada

USA

Brussels

France

D.R.

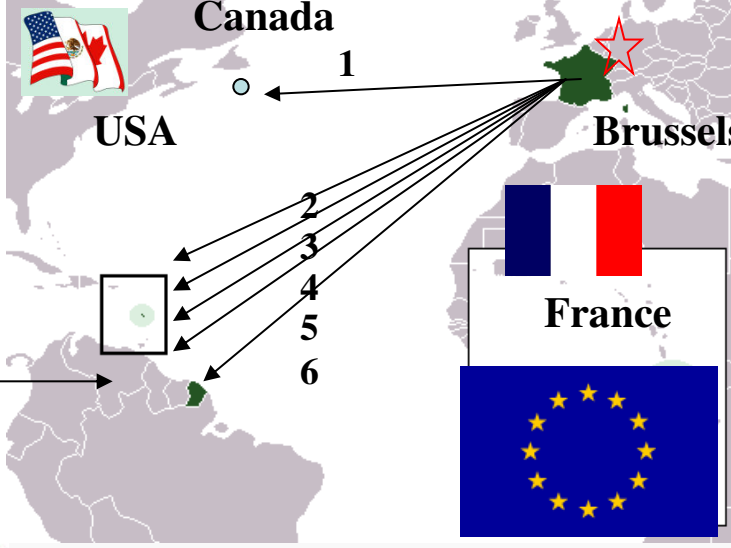
Belize

Venezuela

2006

Bolivia 2015

Chile



EU – France:
Overseas regions and colectivities:
 1. Saint Pierre et Miquelon
 2. Saint Martin
 3. Saint Barthélemy (St. Barts)
 4. Guadeloupe
 5. Martinique
 6. French Guyane

★ **Block Secretariat General**
CAN: Lima, Perú.
CARICOM: Georgetown, Guyana.
MERCOSUR: Montevideo, Uruguay.
NAFTA (México): México, DF.
SIECA: Antigua Cuscatlán, El Salvador.

D.R: Dominican Republic

Pending some Parliaments approvals

MS of two blocks

Associated country or block



Central America



Secretaría de Integración Económica Centroamericana (SIECA)
Central America Secretariat of Economic Integration

Consejo de Ministros de Economía de Centroamérica (COMIECO)

Central American Council of Ministers of Economic Integration

Reglamento Técnico Centroamericano (RTCA)
Central American Technical Regulation

Countries: Belize, Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, Panama + Dominican Republic (associate member)



COMEICO: RTCA



RTCA 67.04.54:10 [Processed Foods and Beverages. Food Additives]

- Entered into force
November 2012
- 405 pages

UPDATING:

Annex IV:

**4.2: Technical
Regulation will
automatically update
whenever Codex CCFA
updates**

ANEXO DE LA RESOLUCIÓN No. 283-2012 (COMIECO-LXII)

REGLAMENTO TÉCNICO CENTROAMERICANO

RTCA 67.04.54:10

Alimentos y Bebidas Procesadas. Aditivos Alimentarios.

CORRESPONDENCIA: Este Reglamento técnico es una adaptación de la norma Codex Stan 192-1995. (Rev. 6-2005) Norma General de Aditivos Alimentarios.

ICS 67.050

RTCA 67.04.54:10

Reglamento Técnico Centroamericano, editado por:

- Ministerio de Economía, MINECO
- Organismo Salvadoreño de Reglamentación Técnica, OSARTBC
- Ministerio de Fomento, Industria y Comercio, MIFIC
- Secretaría de Industria y Comercio, SIC
- Ministerio de Economía, Industria y Comercio, MRIC



MERCOSUR



Flag	Country	UN Population Est. 1 May 2016
	Brazil	206,116,000
	Argentina	43,590,400
	Venezuela	31,028,700
	Bolivia	10,985,059
	Paraguay	6,854,536
	Uruguay	3,480,222



23 Mar

MERCOSUR

Venezuela: July 2012

Bolivia: July 2015

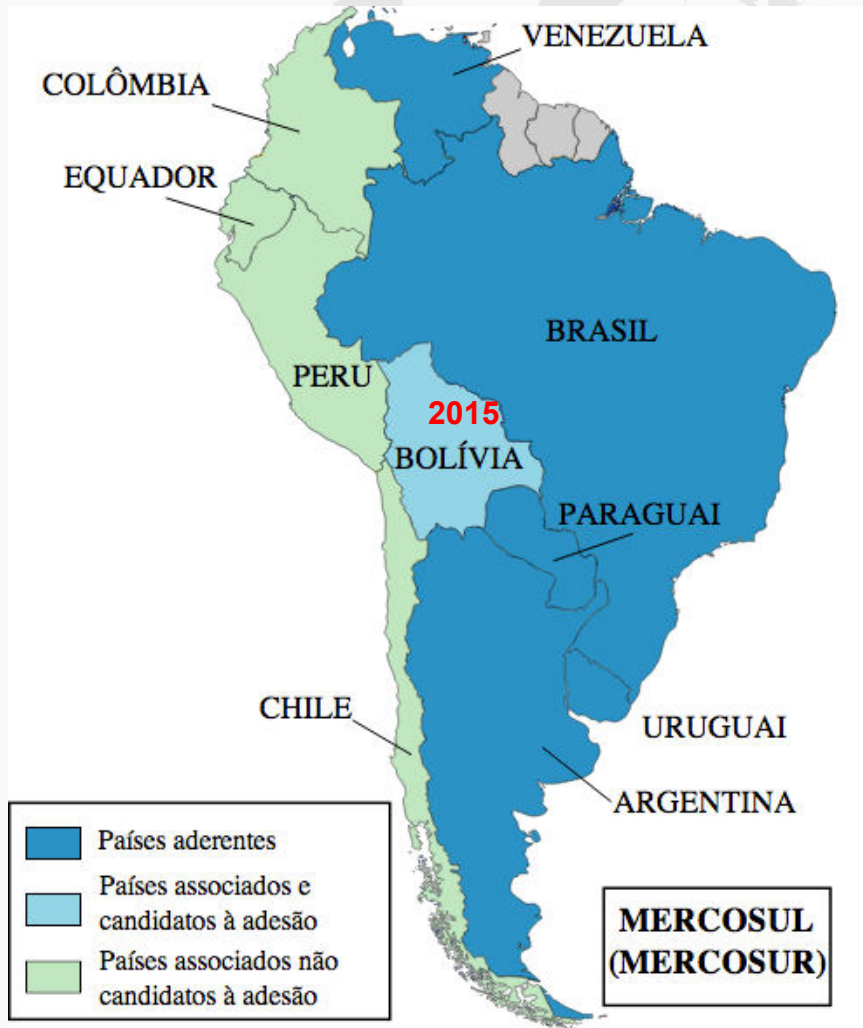
MERCOSUR = 84% of SA GDP

Total Population: 302,054,917

Workshop on Trade & Regulatory Aspects of Regulations



MERCOSUR



Associate members:

- Chile
- Colombia
- Ecuador
- Guyana
- Peru
- Suriname

Observers:

- Mexico
- New Zealand



- **MERCOSUR in its harmonization process reviews:**
 - US FDA
 - European Union
 - Council of Europe
- **MERCOSUR resolutions: similar to EU Directives and require transposition into national legislation**
- **Differences exist in implementation and interpretation**
- **Cannot rely on EU or US Approvals, must be on Mercosur Positive lists**



MERCOSUR



Additives

- GMC/RES No 34/10 on Food Additives permitted at GMP
- GMC/Res. 11/06 Technical Regulation on Harmonized General List of Food Additives & Their Functional Classes

Labelling & Claims

- GMC/Res. 26/03 - Technical Regulation on the Labeling of Packaged Foods
- GMC/Res. 44/03 - Technical Regulation on Nutritional Labeling of Packaged Goods

Supplements/Food Fortification

- GMC/RES No 10/07: List of Botanical Species



SOUTHEAST ASIA



- Brunei Darussalam
- Cambodia
- Indonesia
- Laos
- Malaysia
- Myanmar
- Philippines
- Singapore
- Thailand
- Vietnam

**Regional
Organization:**

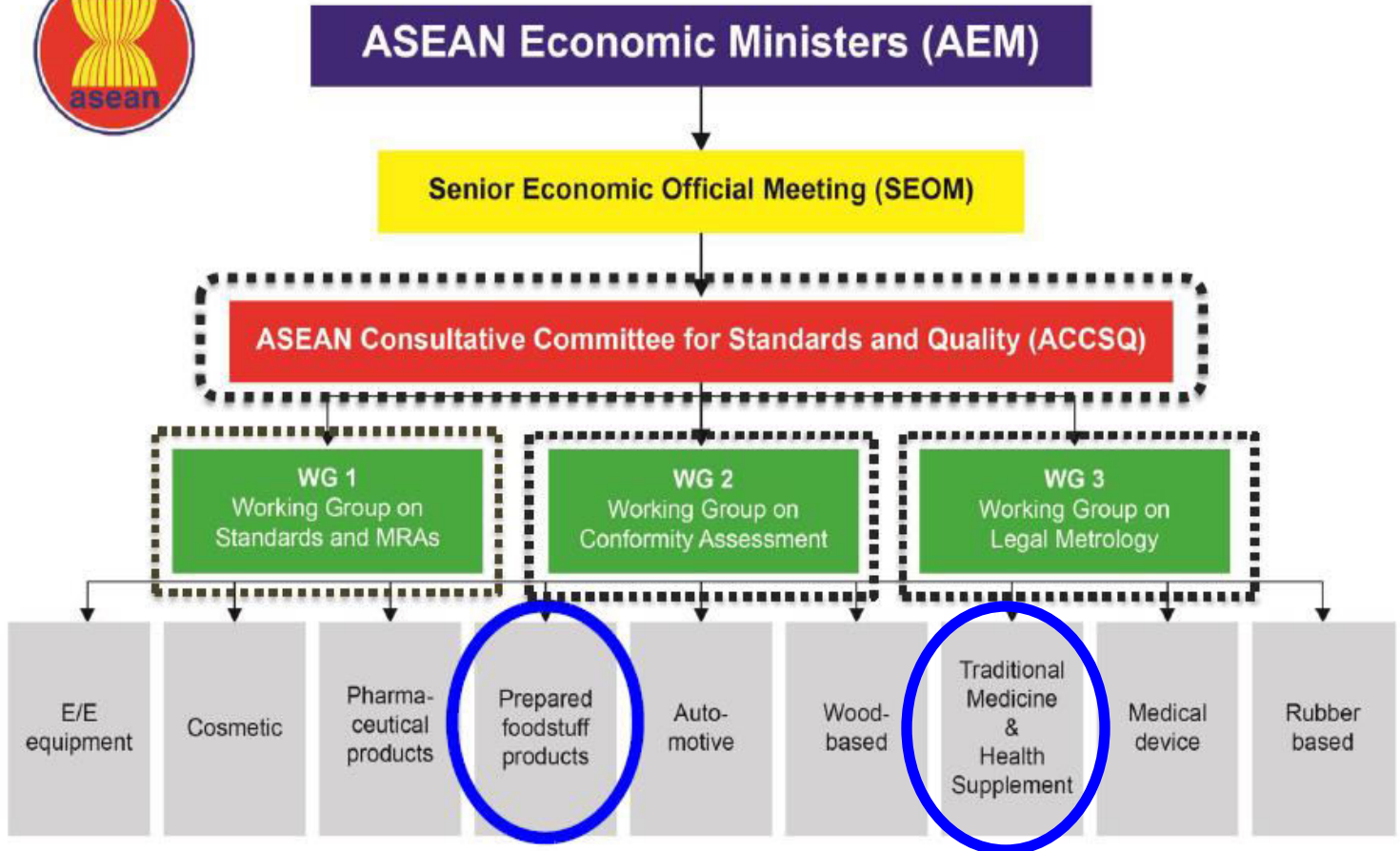
ASEAN

**Expert Group on
Food Safety
(AEGFS)**

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ASEAN



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ASEAN



- **Goal: Launch of "ASEAN Economic Community (AEC) intended in 2015**
- **ASEAN Common Food Control Requirements (ACFCR)**

Website for updates and info:

<http://www.aseanfoodsafetynetwork.net/>



ASEAN FOOD SAFETY NETWORK

"TRADITIONAL
ASEAN SPIRIT & CORPORATION"

Powered by ACFS, Thailand Coordinator

Tue, Sep 29 2015 | 18:43:18 | @ 530 .beats

HOME

Search

Current Issues

- 21 August 2015 : U.S. prohibits "Artificial Trans Fats" in processed foods **NEW !!**

- 14 August 2015 : EU's new MLs of pesticides in foods and feeds **NEW !!**

- 9 July 2015 : ASEAN Food Reference Laboratories (AFRLs) **NEW !!**

- 4 June 2015 : ASEAN's Progress on the harmonization of food control and safety requirements and principles **NEW !!**

- 13 November 2014 : USDA's New Inspection System for Poultry Products

[More](#)



Background

ASEAN Food Safety Network (AFSN) was established accordingly with the resolution of the 25th meeting of the ASEAN Ministers on Agriculture and Forestry - AMAF (2003 in Malaysia). The purpose of the establishment of the AFSN is to be a channel for ASEAN Member States to exchange information relevant to food safety.

Consequently, Thailand conducted an elaboration of the website which has been launched at www.aseanfoodsafetynetwork.net since September 2004. So far, Thailand, as a coordinator of the AFSN, has worked closely with good effort and cooperation of all national focal points assigned by individual Member States. [More+](#)

ASEAN
Consultative Network



ASEAN Task Force
on Codex (ATFC)



ASEAN Expert Group
on Food Safety (AEGFS)



ASEAN
HALAL FOOD



Strengthening ASEAN Risk
Assessment Capability to Support
Food Safety
Measures Project



ASEAN RAPID ALERT SYSTEM
FOR FOOD AND FEED





ASEAN: Implementation Harmonized Standards



Obligations of ASEAN Member States for harmonised standards referenced in Harmonised Regulatory Regimes:

- Adopt the harmonised standard as the national standard, **or,**
- Use harmonised standard directly in its relevant regulations, **and**
- Take all necessary action to ensure that all competing national standards are withdrawn.



ASEAN: Implementation Harmonized Standards



ASEAN AGREEMENT ON HEALTH SUPPLEMENTS

The Governments of Brunei Darussalam, the Kingdom of Cambodia, the Republic of Indonesia, the Lao People's Democratic Republic, Malaysia, the Republic of the Union of Myanmar, the Republic of the Philippines, the Republic of Singapore, the Kingdom of Thailand and the Socialist Republic of Viet Nam, Member States of the Association of Southeast Asian Nations (hereinafter collectively referred to as "Member States" or individually as "Member State");

CONSIDERING the importance of ensuring safety, quality and efficacy/claimed benefits of Health Supplements in order to protect consumers in the ASEAN region;

NOTING the diversity of regulatory regime in consideration of the national context, capacity, priorities and legislations;

DESIRING to harmonise and implement the technical requirements and guidelines for Health Supplements so as to reduce technical barriers to trade among ASEAN Member States and contributing to the ASEAN Economic Integration initiatives without compromising the safety, quality and efficacy/claimed benefits of these products,

HAVE AGREED AS FOLLOWS:

ARTICLE 1 OBJECTIVES

The objectives of the ASEAN Agreement on Health Supplements (hereinafter referred to as "Agreement") are:

- a) To enhance cooperation amongst Member States in ensuring the safety, quality and efficacy/claimed benefits of Health Supplements marketed in ASEAN region; and,
- b) To facilitate trade of Health Supplements through the harmonised technical requirements and guidelines without compromising the safety, quality and efficacy/claimed benefits of these products.

ARTICLE 2 DEFINITION

Major Developments in 2016!



Guidance for Supplements:



- ASEAN Guidelines on **GMP for Traditional Medicines / Health Supplements**
- ASEAN Guiding Principles for Inclusion into or Exclusion from the **Negative List of Substances** for Traditional Medicines and Health Supplements
- ASEAN Guiding Principles for Inclusion of Active Substances into the **Restricted List** for Traditional Medicines and Health Supplements
- ASEAN General Principles for Establishing **Maximum Levels of Vitamins and Minerals** in Health Supplements
- ASEAN Guiding Principles for the **Use of Additives and Excipients** in Traditional Medicines and Health Supplements
- Guidance Notes on **Control of Pesticides** in Traditional Medicines and Health Supplements

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GCC/GSO



Gulf Cooperation Council (GCC)

مجلس التعاون الخليجي

- Founded 25 April 1981
- Economic cooperation
- Coordination on Standards
- Dominated by Saudi Arabia
- **Yemen**
is also +/- a GSO member but has followed food-related standards since 2002.



- **All GCC Members are Codex Members**



GCC/GSO



هيئة التقييس
ادول مجلس التعاون ادول الخليج العربية
GCC Standardization Organization

GCC Standardization Organization

- Bahrain
- Kuwait
- Oman
- Qatar
- Saudi Arabia
- United Arab Emirates
- Yemen



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GCC/GSO



هيئة التقييس
ادول مجلس التعاون ادول الخليج العربية
GCC Standardization Organization

Additives

- GSO Technical Regulation No.: 2500/2015 Additives Permitted for Use in Foodstuffs
- GSO Technical Regulation No.: 995/2015 Sweeteners Permitted in Food

Labelling & Claims

- GSO Technical Regulation No.: 9/2013 Labeling of Prepackaged Foodstuffs (GCC)
- GSO Standard No.: 2233/2012 Requirements of nutritional labelling

Supplements/Food Fortification

- GSO CAC/GL Standard No.: 55/2015 Guidelines for Vitamins and Mineral Food Supplements

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Individual Country Influence: USA & Japan

USA

American Samoa

Aruba (both US and EU)

Bahamas (both US and Codex)

Bermuda

Cayman Islands

Guam

Jamaica (both US and Codex)

Peru

US Virgin Islands

Also:

Japan as major influence for Food Additives and FoSHU in Asia



United States => Mosaic

New State, County and Municipal Regulations in:

- **California (Cities!)**
- **Connecticut**
- **Maine**
- **New York (counties!)**
- **Oregon**
- **Washington**



Trends

- **Codex/EU remain largest groupings**
- **Substantial harmonization efforts underway through Regional Blocks which are growing.**
- **Intra-Country Harmonization – substantial recent food safety overhauls in:**
 - China, India, Indonesia, others.
 - Streamlining of regulatory regimes (China, India)
 - Clearer governmental responsibilities for promulgation, enforcement (India FSSAI)
- **USA: opposite trend – Federal vs. State vs. Municipal**



Thank you!

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