

Global Trends in Health Supplement Regulations

National Regulatory Conference 2013
Kuala Lumpur, May 8, 2013

Michelle Stout
Regulatory Policy Director, Amway

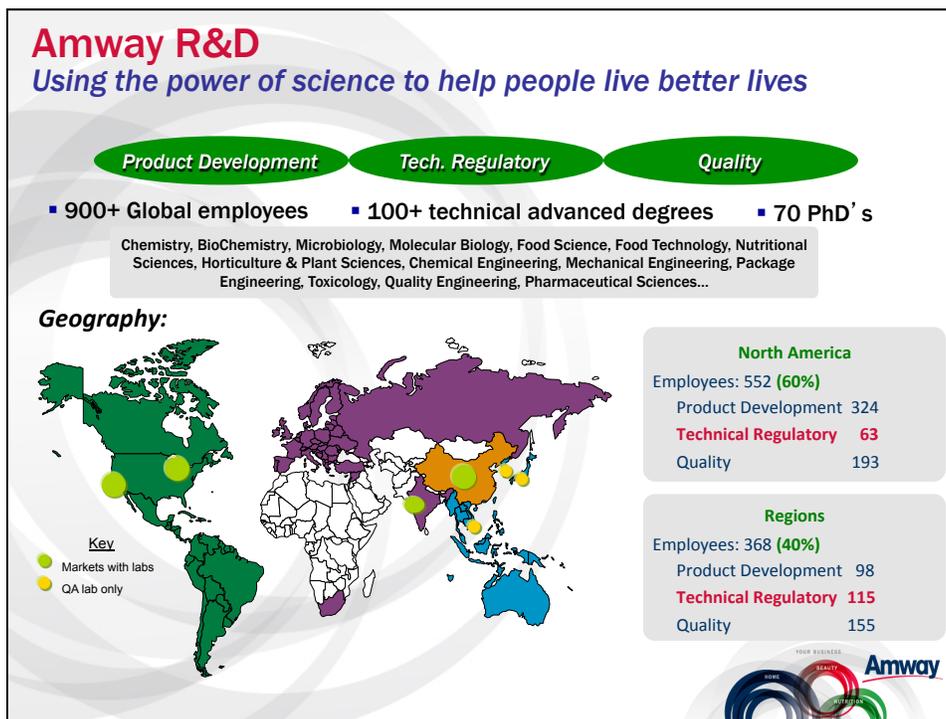
AMWAY is a GLOBAL leader

- Second largest direct-selling company in the world
- 2012 Annual sales of more than \$11.3 billion for Alticor Inc.
- More than 450 products in more than 100 countries and territories supported by more than 20,000 employees
- We've enabled more than 3 million distributors to achieve their dream of becoming entrepreneurs



Helping people live better lives!

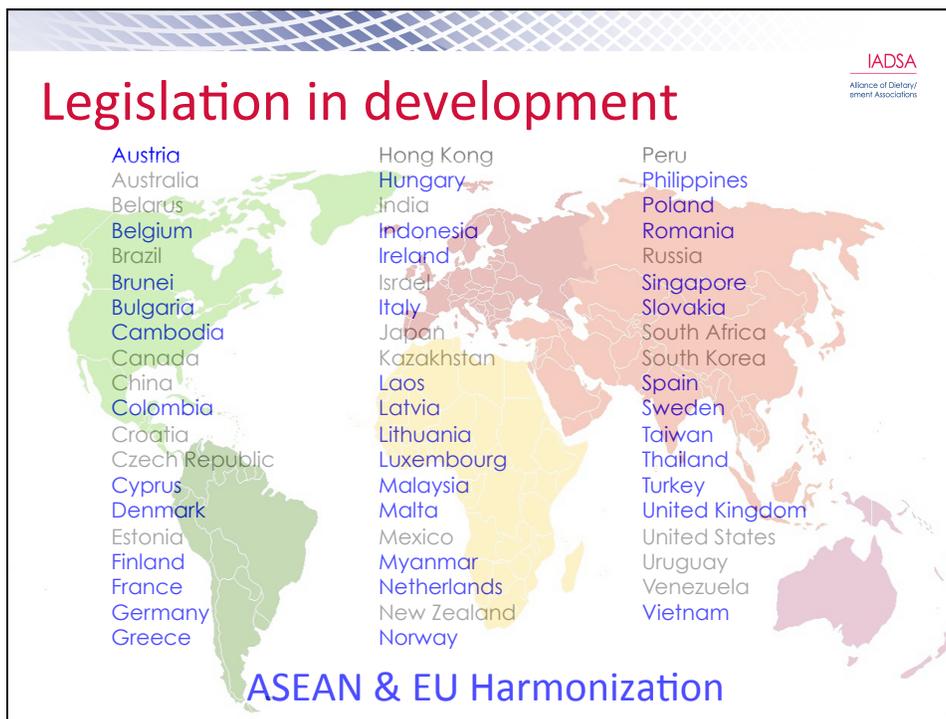




IADSA

International Alliance of Dietary/
Food Supplement Associations

- Established in 1998
- Brings together food/health supplement associations from 6 continents
- World-leading expertise in science, technical and regulatory
- Focus:
 - Provide an international platform for debate and information exchange with regulators, scientists and international experts
 - Support development of scientifically sound, legislative and political environment for the food supplement sector
- A trusted source of information about regulatory and scientific developments in the world and a trusted partner for many governments



Why so much Regulatory Change?

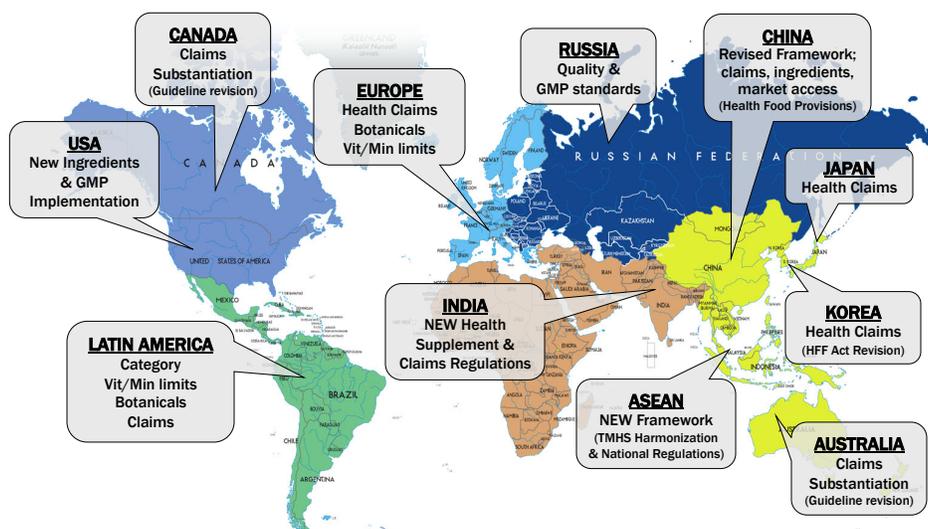
IADSA
International Alliance of Dietary
Food Supplement Associations

- **Harmonization (EU 27+ / ASEAN 10)**
- **Codex Guidelines on vitamin & mineral supplements 2005**
 - set limits based on scientific risk assessment, not multiple of RDI
- **WTO and international trade obligations**
 - working toward alignment on SPS issues and reduction of TBT
- **Consumer demand & consumer protection**
 - Estimated over US\$100 billion global market by 2014
 - Ensuring minimum standards across the sector to achieve goal of safe, quality and effective products
- **Evolution to risk based approach as markets mature**

Global Supplement Developments

IADSA
International Alliance of Dietary
Food Supplement Associations

CODEX (Global): NRVs, Fish Oil Standard, Food Additives (Mg Stearate), New Spice/herb committee



Supplement category

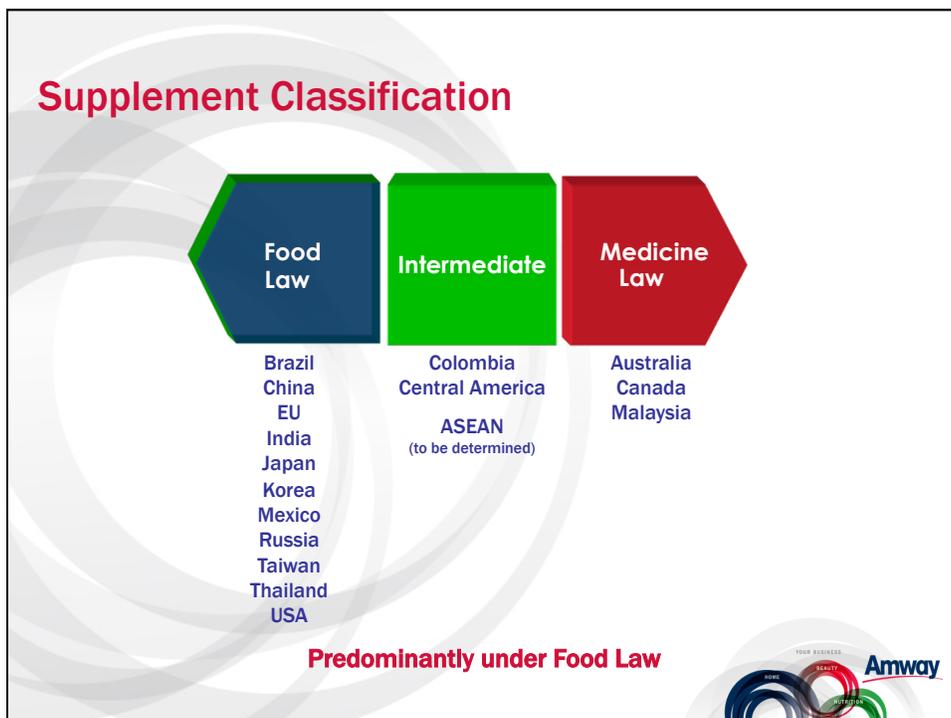
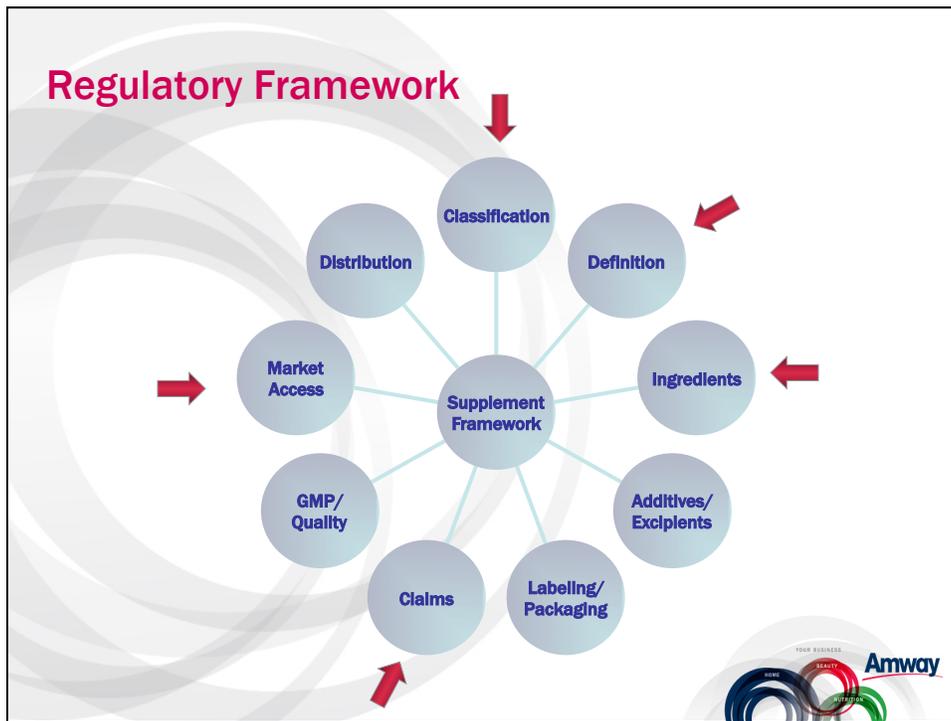
- **Vitamins & Minerals**
 - Single & multiple vitamin/mineral products
- **Botanical & Herbs**
 - Fruits, vegetables, spices, echinacea, garlic, ginseng, ginkgo biloba
- **Specialty Supplements**
 - Glucosamine, probiotics, fish oils/shark cartilage, bee products, CoQ10, amino acids

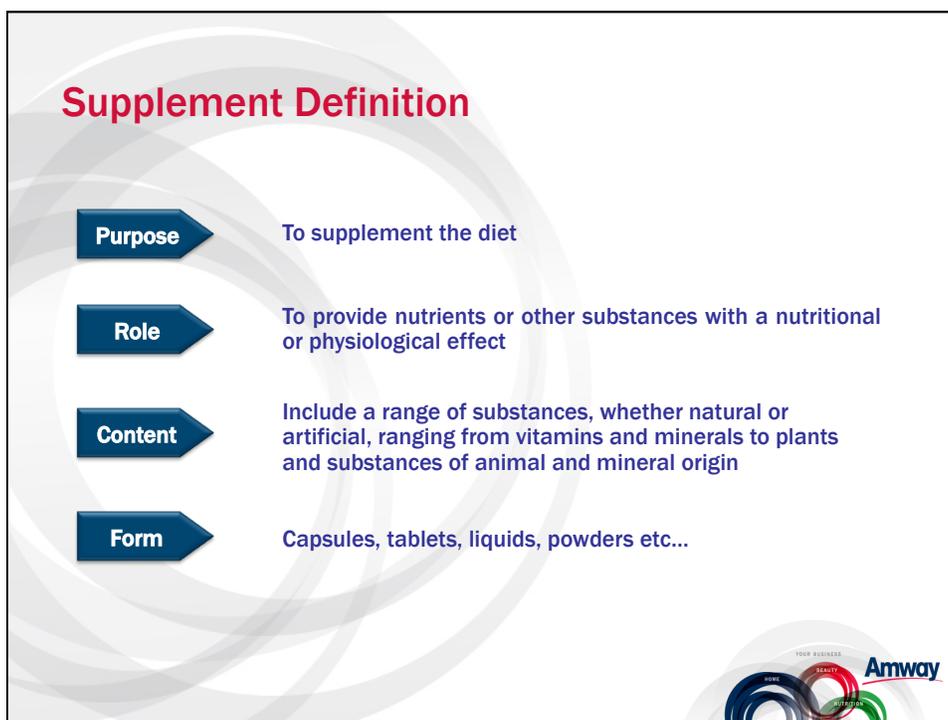
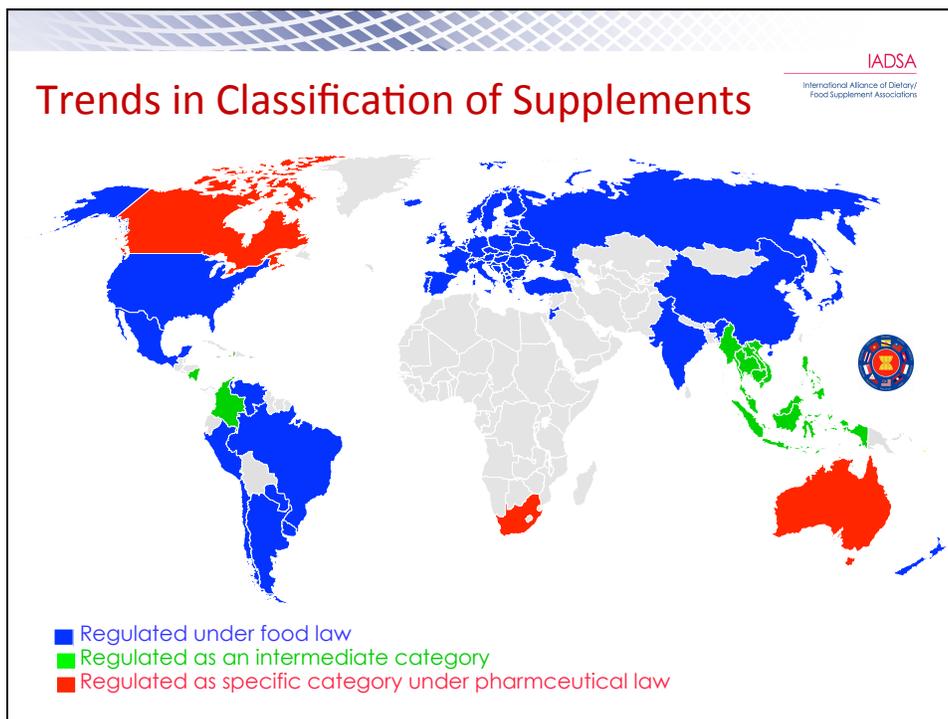


Supplement Terminology

- **Codex:** Vitamin & Mineral Food Supplements
- **ASEAN:** Health Supplements
- **Australia:** Complimentary Medicines
- **Brazil:** Foods (no supplement category)
- **Canada:** Natural Health Products (NHP)
- **China:** Health Foods
- **EU:** Food Supplements
- **Japan:** Foods (no supplement category)
- **Korea:** Health Functional Foods (HFF)
- **Russia:** Biologically Active Food Supplements (BAFS)
- **USA:** Dietary Supplements







EU Food Supplements

Directive EC/2002/46 :

*“..foodstuffs the purpose of which is to supplement the normal diet and which are **concentrated sources of nutrients or other substances with a nutritional or physiological effect**, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed **to be taken in measured small unit quantities**.”*



EU Food Supplements

Scope of ingredients

- Preamble (6)* “There is a wide range of nutrients and other ingredients that might be present in food supplements including, but not limited to,
 - vitamins,
 - minerals,
 - amino acids,
 - essential fatty acids,
 - fibre
 - various plants and herbal extracts



USA Dietary Supplements

Dietary Supplement Health & Education Act (DSHEA) - 1994

- a product (other than tobacco) intended to **supplement the diet** and that contains one or more of the following dietary ingredients:
 - vitamin
 - mineral
 - herb or other botanical
 - amino acid
 - a dietary substance used to supplement the diet
 - a concentrate, metabolite, constituent, extract
 - combination of any ingredient (named above)
 - Intended for ingestion in tablet, capsule, powder, softgels, gelcap, or liquid form
- or -
- Cannot be represented as a conventional food or for use as the sole item of a meal or of the diet



ASEAN Health Supplements

Definition from ASEAN TMHS:

..any product that is **used to supplement a diet** and to **maintain, enhance** and **improve the healthy function of human body** and contains one or more, or a combination of the following:

- a. **Vitamins, minerals, amino acids, fatty acids, enzymes, probiotics and other bioactive substances**
- b. **Substances derived from natural sources, including animal, mineral and botanical materials in the forms of extracts, isolates, concentrates, metabolite**

*It is presented in dosage forms (to be administered) **in small unit doses** such as capsules, tablets, powder, liquids and it shall not include any sterile preparations (i.e. injectable, eyedrops).*



Australia Complimentary Medicines

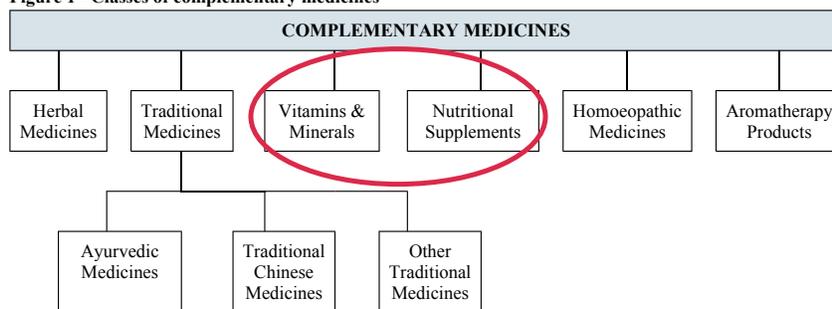
A therapeutic good consisting principally of one or more designated active ingredient in Schedule 14:

- amino acid
- charcoal
- a choline salt
- an essential oil
- plant or herbal material (or a synthetically produced substitute for material of that kind), including plant fibres, enzymes, algae, fungi, cellulose and derivatives of cellulose and chlorophyll
- a homeopathic preparation
- a microorganism
- a mineral including a mineral salt and a naturally occurring mineral
- a mucopolysaccharide
- non human animal material (or a synthetically produced substitute for material of that kind) including dried material, bone and cartilage, fats and oils, and other extracts or concentrates
- a lipid, including an essential fatty acid or phospholipid
- a substance produced by or obtained from bees, including royal jelly, bee pollen and propolis
- a sugar, polysaccharide or carbohydrate
- a vitamin or provitamin.



Australia Complimentary Medicines

Figure 1 - Classes of complementary medicines



Source: www.tga.gov.au - TGA Overview of Complimentary medicines



Australia Listed Complimentary Medicines

To be a listed medicine on the Australian Register of Therapeutic Goods (ARTG) a product:

- can only contain permitted **low risk** ingredients
- must be manufactured in accordance with the principles of GMP
- can only make indication for **health maintenance and health enhancement** or certain indications for **non-serious, self-limiting conditions**.

Note: Majority of Complimentary Medicines on market are Listed



Supplement Ingredients

Broad Range of safe ingredients

- Vitamins and minerals
- Amino acids and derivatives
- Enzymes
- Pre- and Probiotics
- Essential Fatty Acids
- Botanicals and botanical extracts
- Other bioactive substances



Vitamin & Mineral Maximum Levels

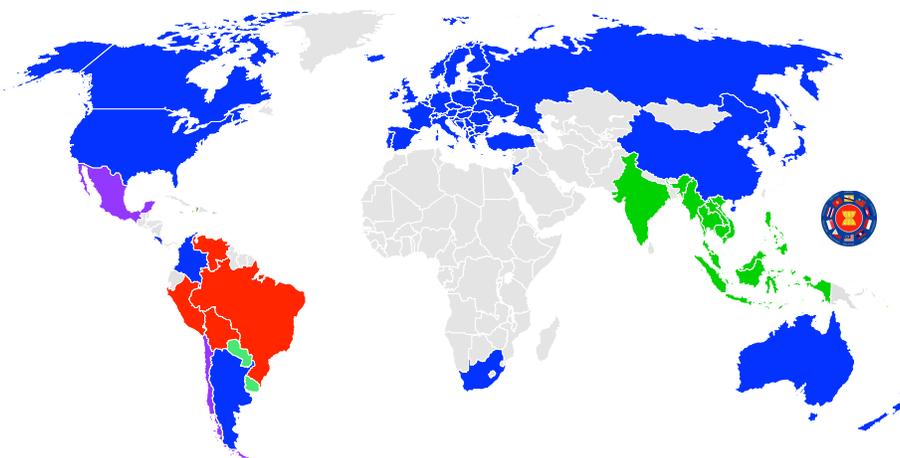
1990's
Present

- RDA was a traditional approach → **Focused on nutrient sufficiency**
- Growing understanding that optimum intakes may be higher than RDA; RDA better for developing minimum requirements
- Recognition that as long as safe, there should be the possibility for consumers to have a choice of products → **Scientific Risk Assessment**
- Reflected in the last decade in key international laws and standards
 - EU 2002
 - Codex 2005
 - China 2005
 - Korea 2008
 - ASEAN 2009

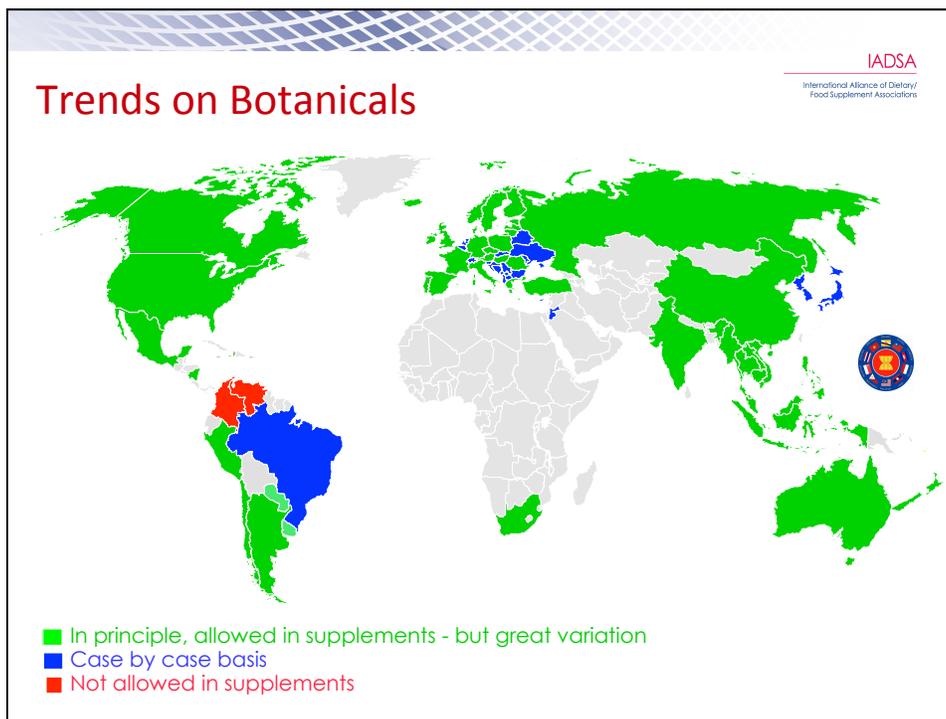


Trends on Vit & Min Maximum levels

IADSA
International Alliance of Dietary/
Food Supplement Associations

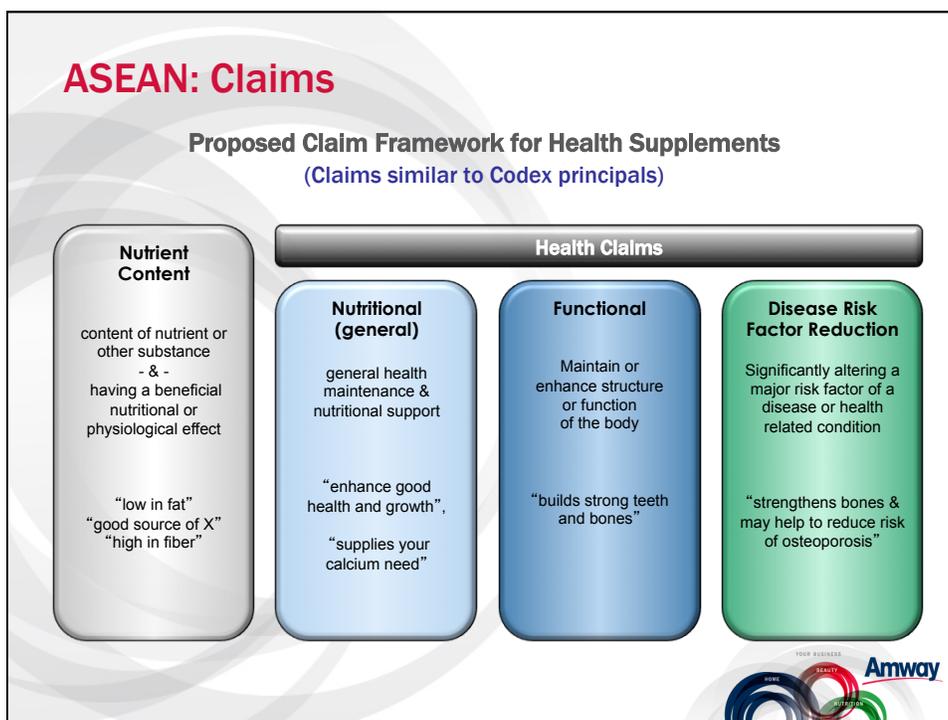
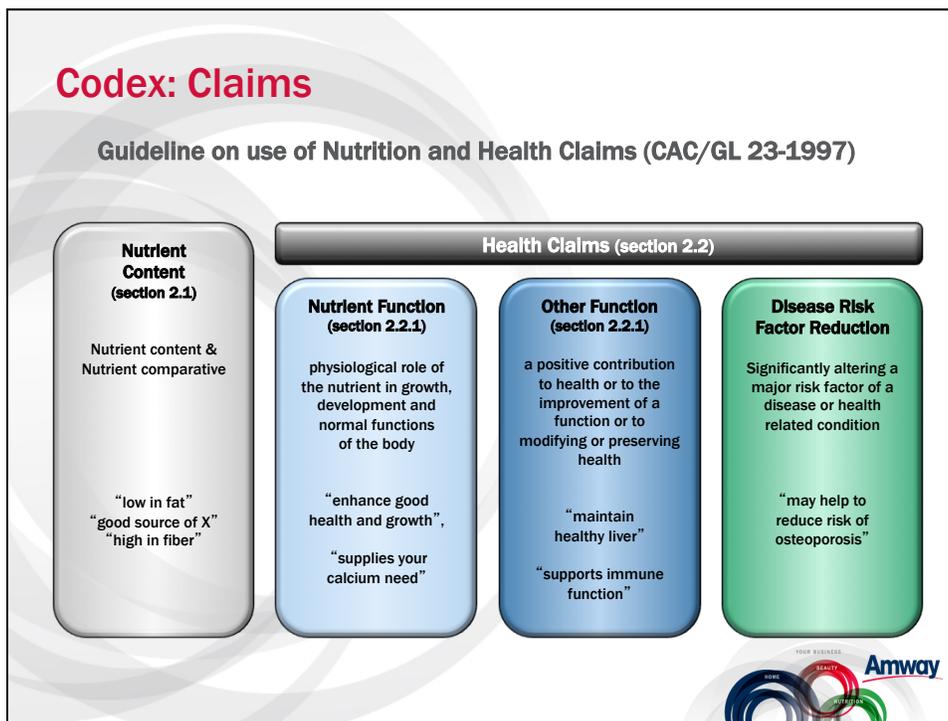


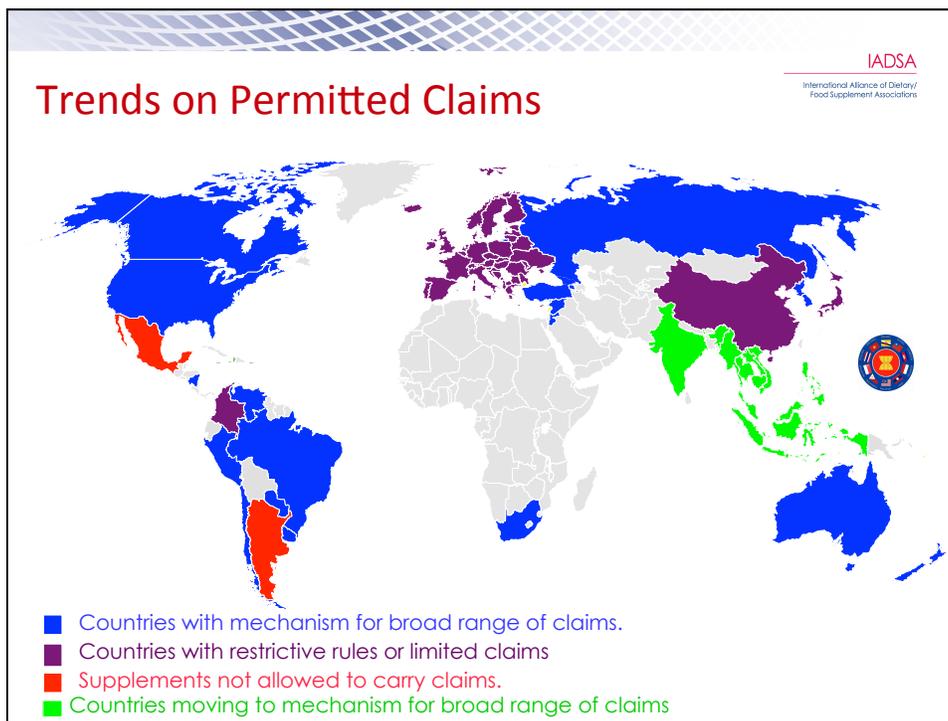
- Safety based levels
- Countries moving to safety based levels
- RDA based levels
- Intermediate scheme based levels



Claims

- **Relationship between dietary/food ingredient and the maintenance or promotion of health**
 - Nutrient Function claims
 - Other Physiological Function claims
 - Reduction of Disease Risk Claims
- **Not to prevent, treat or cure a disease (DRUG)**
 - May be allowed in markets where category is administered under pharmaceutical law if science supports claim (i.e. Canada, Australia)
- **Alignment with Codex Guidelines on Use of Nutrition and Health Claims (CAC/GL 23-1997)**





Category, ingredient & claim trends

	ASEAN In process	USA	EU	Japan	Korea	China	Australia
Category Name	Health Supplement	Dietary Supplement	Food Supplement	Food	Health Functional Food	Health Food	Listed Complim. medicine
Categorization	to be defined	Food	Food	Food	Food	Food	medicines
Vitamin & Minerals (limits based on)	✓ Safety limits	✓ Safety limits	✓ Safety limits	✓ Safety limits	✓ Safety limits	✓ Safety limits	✓ Safety limits
Botanicals	✓	✓	✓	✓	✓	✓	✓
Other Substances (i.e. fish oil, probiotics)	✓	✓	✓	✓	✓	✓	✓
Nutrient content claim	✓	✓	✓	✓	✓	✓	✓
Nutrient or Other Function claims	✓	✓	✓	✓	✓	✓	✓
Reduction of Disease Risk Claims	✓	✓	✓	✓	✓	✓	✓
Prevent, cure, or treat disease claim	NOT allowed	NOT allowed	NOT Allowed	NOT Allowed	NOT Allowed	NOT Allowed	Limited

* Variability in range of ingredients & claims

Product Placement (or market access)

“Steps that need to be taken by a company and the appropriate authority when placing a product on the market.”

Pre-Market Control Systems

- Compliance
- Notification
- Registration

Risk based approach

- based on safety of ingredients and types of claim
- “**lower risk**” = well established safety & claims
- combinations of systems for “**lower risk**” & other products



Market Access - multiple approaches

	Compliance	Notification	Registration
USA	Nutrient content claims only	- Structure/function claim (P) - new ingredients (I)	Reduction of Disease Risk claims (I)
EU	(some markets) Food Supplements	(some markets) Food Supplements (P)	new Health Claims (I) novel food ingredients (I)
Japan	Foods with: - general or nutrient claim - Foods with Nutrient Content claims (vit/min) - Standardized FOSHU		FOSHU claim (P)
Korea	Existing HFF Ingredient/Claim		New HFF ingredient claim (I)
Brazil		Vitamin & Minerals (P)	Other supplements (P)
Australia		Listed complimentary medicines (P)	Other complimentary medicines (P)
Russia			All Biologically Active Food Supplements (P)
China		considering system for vitamin/mineral products (P)	All Health Foods (P)



Conclusions

- **Trend in risk based approach to Product Placement**
 - **Simplified** requirements for **“lower risk”** products containing ingredients with well established safety and/or claims (i.e. vitamins, minerals)
- **Focus on evaluation of safety & claims at Ingredient level**
 - avoid redundancy of safety & claims data, testing and review by authorities
- **Notification offers Transparency of products on the Market**
 - controls established for ingredients, claims & manufacturing
- **Focus on Post-market monitoring and enforcement**
 - provides greater insight and control over the market than registration



Thank You!

michelle.stout@amway.com

