Global Trends in Health Supplement Regulations

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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!
Amway R&D
Using the power of science to help people live better lives

- 900+ Global employees
- 100+ technical advanced degrees
- 70 PhD’s

Chemistry, BioChemistry, Microbiology, Molecular Biology, Food Science, Food Technology, Nutritional Sciences, Horticulture & Plant Sciences, Chemical Engineering, Mechanical Engineering, Package Engineering, Toxicology, Quality Engineering, Pharmaceutical Sciences...

Geography:

North America
Employees: 552 (60%)
Product Development 324
Technical Regulatory 63
Quality 193

Regions
Employees: 368 (40%)
Product Development 98
Technical Regulatory 115
Quality 155

IADSA

- 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
Legislation in development

ASEAN & EU Harmonization

Focus of regulation

- Classification
- Definition
- Benefits and safety of food supplement ingredients.
- Scientific justification of health claims
- Quality of food supplements
- Requirements for market access
- Monitoring products once they are on the market.
Why so much Regulatory Change?

- 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

- CODEX (Global): NRVs, Fish Oil Standard, Food Additives (Mg Stearate), New Spice/herb committee
- USA: New Ingredients & GMP Implementation
- CANADA: Claims Substantiation (Guideline revision)
- EUROPE: Health Claims Botanicals Vit/Min limits
- RUSSIA: Quality & GMP standards
- CHINA: Revised Framework; claims, ingredients, market access (Health Food Provisions)
- JAPAN: Health Claims
- KOREA: Health Claims (HFF Act Revision)
- AUSTRALIA: Claims Substantiation (Guideline revision)
- LATIN AMERICA: Category Vit/Min limits Botanicals Claims
- ASEAN: New Framework (TMHS Harmonization & National Regulations)
- INDIA: New Health Supplement & Claims Regulations
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
Regulatory Framework

Supplement Classification

Predominantly under Food Law
Trends in Classification of Supplements

- Regulated under food law
- Regulated as an intermediate category
- Regulated as specific category under pharmaceutical law

Supplement Definition

- **Purpose**: To supplement the diet
- **Role**: To provide nutrients or other substances with a nutritional or physiological effect
- **Content**: Include a range of substances, whether natural or artificial, ranging from vitamins and minerals to plants and substances of animal and mineral origin
- **Form**: Capsules, tablets, liquids, powders etc...
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 & Educations 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*

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**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

- 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

- Safety based levels
- Countries moving to safety based levels
- RDA based levels
- Intermediate scheme based levels
Trends on Botanicals

- In principle, allowed in supplements - but great variation
- Case by case basis
- Not allowed in supplements

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)
Codex: Claims
Guideline on use of Nutrition and Health Claims (CAC/GL 23-1997)

Nutrient Content (section 2.1)
- Nutrient content & Nutrient comparative
  - "low in fat"
  - "good source of X"
  - "high in fiber"

Health Claims (section 2.2)
- Nutrient Function (section 2.2.1)
  - physiological role of the nutrient in growth, development and normal functions of the body
  - "enhance good health and growth",
  - "supplies your calcium need"

- Other Function (section 2.2.1)
  - a positive contribution to health or to the improvement of a function or to modifying or preserving health
  - "maintain healthy liver"
  - "supports immune function"

- Disease Risk Factor Reduction
  - Significantly altering a major risk factor of a disease or health related condition
  - "may help to reduce risk of osteoporosis"

ASEAN: Claims
Proposed Claim Framework for Health Supplements
(Claims similar to Codex principals)

Nutrient Content
- content of nutrient or other substance & having a beneficial nutritional or physiological effect
  - "low in fat"
  - "good source of X"
  - "high in fiber"

Nutritional (general)
- general health maintenance & nutritional support
  - "enhance good health and growth"
  - "supplies your calcium need"

Functional
- Maintain or enhance structure or function of the body
  - "builds strong teeth and bones"

Disease Risk Factor Reduction
- Significantly altering a major risk factor of a disease or health related condition
  - "strengthens bones & may help to reduce risk of osteoporosis"
Supplements not allowed to carry claims.

Countries with restrictive rules or limited claims

Countries with mechanism for broad range of claims

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

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<td>USA</td>
<td>Nutrient content claims only</td>
<td>- Structure/function claim (P)</td>
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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!

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