

International Harmonization of Health Claims in Food Labeling: Food and beverage industry perspective

Food Claims: Truth and Myths
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Overview

- Health claims used by food and beverage industry
- Diverse global approaches to health claims
- Complexities for regional and multinational companies
- Need for international harmonization
- Evidence-based scientific decision-making required

In a “nutshell”: Regulatory basis for health claims

- Can take many forms
 - Direct statement on a label,
 - “Romance” copy on label,
 - Internet, leaflets, advertising
- Functional health claims are permitted in most countries
- Disease risk reduction claims are allowed in only a few countries
- Drug claims (treat, prevent, cure) are prohibited on foods and beverages by all countries

Multiple Governmental Approaches

- Codex Alimentarius
- European Union
- Japan
- Australia-New Zealand
- USA
- Individual countries



Varied Regulation of Health Claims

■ Codex – Guidelines

- Framework for countries on health claims
- Guidelines for scientific substantiation have been developed
- No positive list of HC

■ US – Disease Reduction Claims*

- Strong evidence-based scientific review
- Positive list of HC
- Lengthy approval times

*also can be “qualified health claims”

■ EU – Health Claims

- Scientific evidence review
- Positive list of HC
- 2+ yrs to review

■ Japan – FOSHU

- Significant substantiation
- Positive list
- Prior review
- About 1 yr for review

■ Australia-New Zealand – Pending

- Prior approval
- High level of evidence required
- Positive list

Complexities for Regional/Multinational Food and Beverage Companies

- Multiple formulations required
- Burden on R&D resources
- Lengthy regulatory approval times
- Geographic barriers for cross-border and regional trade
- Highly varied labeling requirements

Regulatory Harmonization for the Food and Beverage Industry

■ Goals:

- Short & Medium Term:

Identify and eliminate or minimize specific local regulatory barriers

- Long Term:

Harmonization of horizontal, not vertical standards

■ Codex should be the default value

■ Global totality of available scientific evidence and evaluation should be uniform

Importance of Codex

- Baseline for international food and beverage standards, and food labeling and claims guidelines
- Facilitates cross-border trade
- Basis for harmonization of national regulations
- Key reference point in WTO disputes



Regulatory Harmonization for the Food and Beverage Industry

- Harmonization can—
 - Capitalize on the best science
 - Maximize regional and global R&D and innovation
 - Promote strong, sustainable growth for businesses
 - Stimulate multi-disciplinary environment with trust

Regulatory Harmonization for the Food and Beverage Industry

- Harmonization can—
 - Reduce complex and multiple approval processes
 - Minimize unpredictable outcomes
 - Lessen regulatory inconsistencies
 - Diminish uneven application of market rules

Local/Regional Concepts, Global Implications

**Individual
countries**

Regions

EU

MERCOSUR

Codex



Summary

- Real barriers exist
- Need for global and regional harmonization is critical
- Collaboration with industry needed
- Evidence-based science must guide regulations and health claim approvals