

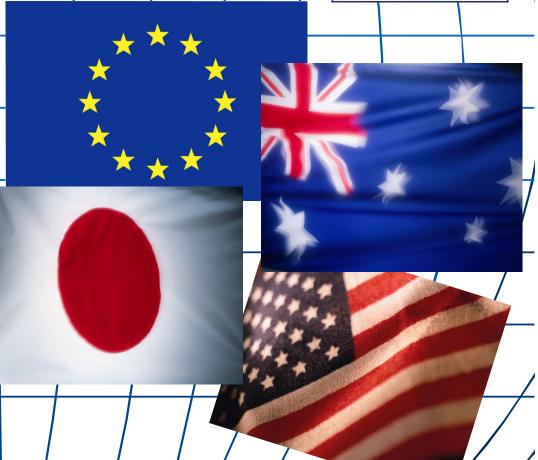


In a "nutshell":/Regulatory\basis\for\health claims Can take many forms Direct statement on a label, "Romance" copy on label Internet, leaflets, advertising Functional health claims are permitted in most countries Disease risk reduction claims are allowed in only a few countries Drug claims (treat, prevent, cure) are prohibited on foods and beverages by all countries

Multiple Governmental Approaches

- Codex Alimentarius
- European Union
- Japan
- Australia-NewZealand
- USA
- Individual countries





	o of Hoolth Claims
	n of Health Claims
▼ Codex – Guidelines	■ EU + Health Claims \
Framework for countries	 Scientific evidence review
on health claims	Positive list of HC
 Guidelines for scientific 	• 2 + yrs to review
substantiation have been developed	■ Japan – FOSHU
No positive list of HC	Significant substantiationPositive list
US – Disease ReductionClaims*	Prior reviewAbout 1 yr for review
Strong evidence-based scientific review	Australia-New Zealand –
Positive list of HC	Pending • Prior approval
Lengthy approval times also can be "qualified health claims"	High level of evidence required
	Positive list



Regulatory Harmonization for the Food and Beverage Industry

- Goals:
 - Shørt & 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



- 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



