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

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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

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<th>Category</th>
<th>Details</th>
</tr>
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| **Codex – Guidelines** | - Framework for countries on health claims  
                        - Guidelines for scientific substantiation have been developed  
                        - No positive list of HC |
| **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 |
| **US – Disease Reduction Claims*** | - Strong evidence-based scientific review  
                                         - Positive list of HC  
                                         - Lengthy approval times  
                          *also can be “qualified health claims” |
| **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
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<thead>
<tr>
<th>Local/Regional Concepts, Global Implications</th>
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<tbody>
<tr>
<td>Individual countries</td>
</tr>
<tr>
<td>Regions</td>
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<tr>
<td>EU</td>
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<tr>
<td>MERCOSUR</td>
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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