Overview of tolerance approaches for supplement products across the globe

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May 2019
WHO ARE WE

• Originally created as a body to bring together the food supplement sector in Codex Alimentarius discussion, our programme has expanded considerably.

• Our work includes partnerships with governments where supplement regulation and policy is being developed.

• IADSA also help ensure the creation of national /regional organisations across the work to help work with governments and scientific communities (e.g. ASEAN Alliance of Health Supplement Associations (AAHSA), Resource Centre in India ReCHaN)
HOW WE WORK
Tolerances

APPROACHES FOR SUPPLEMENTS
**VITAMIN & MINERAL REGULATORY SHELF-LIFE MINIMUM**

**China**
- min = 75 – 80%

**India**
- min = 100%

**Japan**
- min = 80%

**Korea**
- min = 80%

**Taiwan**
- min = 80%

**Turkey**
- min = 80%

**Brazil**
- min = 80%

**Canada**
- min = 90%

**USA**
- min = 100% added nutrient, 80% if naturally occurring (indigenous) nutrients

**EU**
- min = 80% may vary depending on label claim

**Russia**
- min = 70-80%

**China**
- min = 75-80%

**Australia**
- min = 90%

**South Africa**
- min = 80 - 90%

**Canada**
- min = 90%

**Mexico**
- min = 90%

**Colombia**
- min = 90%

**Chile**
- min = 100%

**Asean**
- min = 90%

**S. Africa**
- min = 80-90%

**EU**
- min = 80% may vary depending on label claim

**Permitted <100% label claim**

**100% label claim**
VITAMIN & MINERAL REGULATORY OVERAGES

Complex and varies widely across the globe

APPROACHES

• Limits may apply to test result vs. input
• Overage limits vary
  • Vitamins 110% – 175% label content
  • Minerals 110% - 150% label content
• Set limits for only on ingredients of safety concern (i.e. Taiwan set for Vit A & D only 180%)
• General limit to not exceed maximum safety levels
• Permit scientific rational to justify levels higher than referenced in regulation

CHALLENGES

• Limits are not always scientifically based
• Not a harmonized approach
• Governments are seeking guidance on how to address within regulatory policies

IADSA work to address
What’s Next?
Publication to provide practical information for industry and government on how to tackle tolerances to include:

• recommendations on acceptable ranges of variations between labelling and product content,
• information on supporting data to help justify levels outside the proposed ranges
• Do & Don’t list when developing approaches on tolerances
Thank you