

Dietary and Food Supplements Market entry of the EU

16th ISANH Conference Middle East
World Congress on
Antioxidants

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Regulatory Framework Food Supplements

General Food Law Regulation 178/2002/EC

laying down the general principles and requirements of food law

Food Supplements - Directive 46/2002/EC

- harmonized list of vitamins and minerals and their forms that may be used to make food supplements

Discussion Paper on the setting of maximum and minimum amounts for vitamins and minerals in foodstuffs

http://ec.europa.eu/food/safety/docs/labelling_nutrition-vitamins_minerals-discus_paper_amount_vitamins_en.pdf

Regulatory Framework Food Supplements

Regulation 1925/2006/EC

List of the vitamin formulations and mineral substances which may be added to food

Regulation 1924/2006/EC

on nutrition and health claims made on foods

Health claims

Food supplement market is a claims-driven market

Health claims must be scientifically substantiated!

Most science has not been targeted to health claim substantiation - do not fulfil the criteria for health claim substantiation

Health claims

Health claim substantiation requires specific mind-set

- Claimed effect - beneficial to human health
- Study design - appropriate for its purpose
- Target population - representative of the general population
- Techniques and questionnaires - validated
- Statistical analysis - itt; no post-hoc analyses

Novel Foods?

- Gum Acacia
- Vine shoots
- Conifers (Pinus spp.)
- Polyphenols from cocoa bean shells
- Pomegranate peel extract
- Sumac fruit
- Saffron extract
- Curcumin

Novel Foods

New Regulation: 2015/2283

Not yet into force!

Products from third countries - requirements/history of safe use.

EFSA

History of safe use

DATA REQUIREMENTS - OVERVIEW

1. Description of the Traditional Food
 2. Production process
 3. Compositional data
 4. Specifications
 5. Data from experience of continued use for a least 25 years
- „History of safe food use“
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graph TD; 1[1. Description of the Traditional Food]; 2[2. Production process]; 3[3. Compositional data]; 4[4. Specifications]; 5[5. Data from experience of continued use for a least 25 years]; 1 --- B1[]; 2 --- B1; 3 --- B1; 4 --- B1; B1 --- H[„History of safe food use“]; 5 --- B2[]; B2 --- H;
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# EFSA

## History of safe use

### EXPERIENCE OF USE

#### 5. Data from experience of use

##### 5.1. Experience of food use in a third country

- Extent of use
- Characteristics of the population group(s) of consumers
- Role of the Traditional Food in the diet
- Precautions for the preparation and restrictions of use
- Human data (if available)

Type of data: include scientific publications, scientific expert opinions, monographs, information from international or national organisations, governmental documentation, figures on cultivation, harvesting, sales, trade, cookbooks, recipes, anecdotal data.

# Proposed conditions of use for the EU market

1. Target population
2. Proposed uses and use levels
3. Intended role in the diet
4. Precautions and restrictions of use

# Regulatory requirements market entry food supplements in EU

- Compliance to food regulations
- GMP certification
- Notification (e.g. through Belgium)
- Novel food authorization



*Thank you!*

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