The BELFRIT Project

EU developments & prospects

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Harmonization: EC Report of 2008

Market for botanical food supplements is extremely varied, both as regards the substances used and from one Member State to another;

1. Further harmonisation is not necessary
   a) Full food law framework is applicable
      - Legislation covers many aspects
   b) Application of new legislation
      - Reg. 1924/2006 Nutrition and Health Claims
      - Reg. 1925/2006 Addition of Nutrients
      - Reg. 258/1997 Novel foods
   c) Mutual Recognition

2. Further harmonisation is not feasible
   a) Too many national differences
   b) Scientific and methodological difficulties to be overcome

1. Further harmonisation is not necessary

1 a) Legal framework for botanicals in the EU

General Food Law
Reg EC 178/2002
General food safety requirements
Manufacturer responsibilities
Notification duty
Recall

Food Supplements Law
Dir 2002/46/EC
Definition
Permitted forms (vitamins/minerals)
Maximum levels (vitamins/ minerals)
Specific labeling provisions

Food Hygiene
Reg EC 852/2004
Rules for hygienic production based on the principles of HACCP
Microbiological criteria

Novel Foods Regulation
Reg EC 258/97
Pre-marketing approval procedure for novel ingredients

Fortification legislation
Reg EC 1925/2006
Risk assessment and risk management procedure in case the use of a substance would result in harmful effects

Health Claims Regulation
Reg EC 1924/2006
Pre-marketing approval procedures for nutrition and health claims

General labelling rules
Dir 2000/13/EC
How to label content, composition, etc
Quantitative ingredient declaration (QUID)
Allergen labelling

Additives legislation
Reg EC 1333/2008
Pre-marketing approval procedures
Allowed additives, including sweeteners and colourings
Conditions of use

Contaminants
Reg EC 1881/2006
Maximum levels of selected contaminants in ingredients that can be used in foods

Pesticides residues
Reg EC 396/2005
Maximum residue levels

Extraction solvents
Dir 2009/32/EC
Permitted extraction solvents

Irradiation
Dir 1999/2/EC
Permitted ingredients to be irradiated

1 b) Application of new legislation

- **Reg 1924/2006 Nutrition and Health Claims**

Botanical food supplements

- Subject to the Nutrition and Health Claims Regulation
  - Article 13 for general function claims
  - Article 13.5 for newly developed science claims
  - Article 14 for reduction of disease risk claims / children claims
- Subject to the standard established by EFSA
  - Based on human data (randomized controlled trials)
  - Focused on demonstration of measurable improvements of validated end-points or biomarkers within a healthy population
- Traditional use is not yet considered

Discrepancies

- Botanical Food Supplements
  - Clinical trials needed but not available: Rejection of all claims.
  - Justification by companies.
  - No single claim for botanicals accepted.
- Traditional Herbal Medicinal Products (Dir 2004/24)
  - No proof of efficacy needed, traditional use is accepted
  - EMA working on traditional herbal monographs.
  - Indications not always medicinal.

→ 27 September 2010

EC removed botanicals from the claims process

and started a reflection on future rules.

New developments: EU discussion

- August 2012: EC Discussion Paper
  - Option 1: Status quo - ask EFSA to continue its assessments according to the same approach as all other claims
    - All claims assessed in the same way: no unfair competition
    - Specificity of botanicals not recognised: all claims rejected
    - Medicinal claims could continue: without proof of efficacy
  - Option 2: Address the specificities of botanicals via a change of the applicable legislation
    - This would enable tradition of use as a factor for health claims
    - This would enable to include considerations of quality and safety
    - Differences between MS may not impede Free movement of goods

New developments: EU discussion

- In favour of option 1
  - Some Member States
  - Medicinal stakeholders
  - Consumer groups
  - Food Sector
    - Botanicals should only be used in medicinal products
    - Tradition of use can only apply to medicinal products, not to food
    - Consumers are being misled by unjustified claims
    - Same approach for all claims

New developments: EU discussion

- In favour of option 2
  - o A number of Member States
  - o The sector involved with botanicals (supplements & tea)
    - Option 1 would not solve any of the problems
    - Option 1 would remove all communication from botanical products
    - Option 1 would have disastrous economic consequences
    - Option 1 would bring all botanicals under medicinal law
    - Tradition of use would continue to be accepted for medicinal products
    - In favour of harmonization

• Reg 1925/2006 addition of vitamins and minerals and of certain other substances

Art. 8 → ingestion of amounts of substance greatly exceeding those under normal conditions of consumption … and/or would otherwise represent a potential risk to consumers

• "scrutiny list" procedure applied by Germany in May 2011:

Aristolochia spp., *Salvia divinorum*, *Aconitum spp.*, *Digitalis spp.*, ***Pausinystalia yohimbe***, *Dryopteris filix-mas*, *Catha edulis (Vahl)*, ***Ephedra spp.***, *Rauvolfia serpentina (L.)*, *Datura and Brugmansia spp.*

EC: Art. 8 conditions not met &
not intended to be used as legal basis to harmonize area of botanicals.

6 MS : not to create a negative list of botanicals not used in food

1 c) Mutual Recognition

- Mutual Recognition: Art 34/36 of EU Treaty
- Regulation 764/2008 (Applicable from 13 May 2009)
  - MS is obliged to accept on its territory any product lawfully marketed in another MS
  - Unless MS can show that there is a **real risk for health**

➢ Not that many demands / not that well applied by MS
➢ Not sufficient to govern borderline issues
➢ What is a real risk for health?
➢ Degression to lower level of consumer information & protection

  - Infringement procedures

2. Further harmonisation is not feasible

2 a) National legislation

- Variety of risk management measures
  - Notification: Label → Extensive dossier
  - Negative or positive lists
  - Conditions of use
    - o Restrictions
    - o Maximum levels
  - Labelling requirements – Mandatory warnings
  - Scientific advisory bodies
  - Guidance / Procedures…
- Different attitudes
  - Established markets based on food supplements or medicinal products
  - Botanicals considered 'medicinal by function'

2 b) Scientific and methodological difficulties to be overcome

➢ Guidelines on quality and safety of botanical food supplements
of national and international organizations
(EFSA, Council of Europe, AFSSA, ILSI, EBF,…)

- **EFSA SC: Guidelines & Compendium** of botanicals reported to contain toxic, addictive, psychotropic or other substances that may be of concern (updated in 2012)
- **Council of Europe: Ad hoc group of Committee of experts** on nutrition, food safety and consumer health :
  - o Quality, safety and marketing of plant-based food supplements
  - o Homeostasis, a practical tool to distinguish between foods (including food supplements) and medicinal products
  - o Populations possibly at risk' in the event of ingestion of botanical supplements.

➢ PlantLIBRA

Conclusions

- Applicable framework for botanicals in food is extensive
  - in general safety guaranteed
  - different national approaches
  - inconsistencies, discrepancies, borderline issues
  - discussion on science & TU
- Current discussion undecided
  - Although MS ask for harmonization, not unanimous
  - Deliberation & decision on high level EU

Need for science based decisions &
clear definitions & structured, reliable information on quality, safety and efficacy of botanicals