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Health Claims for Botanical Food Supplements: Approach and Consequences for the Regulatory Framework

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European Botanical Forum

- Industry Association created in 2004
- Focuses on botanicals used in Food Supplements
- Activities
  - Yearly workshops
  - Fact file on botanicals
  - Industry contribution to the article 13 list of claims
  - EBF Quality guide
  - Partner in PlantLIBRA project

- Ongoing work
  - Quality and safety of botanicals and botanical preparation
- www.botanicalforum.eu

Content

- Botanical food supplements in the EU
- The EU Legal Framework
  - EU legislation
  - National legislation
  - Mutual recognition
  - Traditional herbal medicinal products
- Nutrition and Health Claims

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Botanicals in the EU

Botanical Food Supplements in the EU

The botanical food supplements market

- EU botanical food supplements market value: 2 Billion €
  - In Shops:
    - Retail sales valued at 1,500 Million €
  - Other channels:
    - Direct sales amounts to 400 Million €
    - Internet sales estimated at 125 Million €
- Number of botanical food supplements notified
  - BE: 3,000 per year
  - IT: 20,000 notified products (4,500 per year)
  - FR: 25,000 since notification was initiated (2006)
- Biggest markets
  - 75% of sales in France, UK, Italy, Germany

Source: EHPM EBF data 2012

Botanicals in food supplements

- Wide variety of botanicals used
  - E.g. positive lists of botanicals allowed
    - BE: positive list of > 600 botanicals
    - IT: positive list of >1,400 botanicals

- Most used botanicals in food supplements

  - *Aesculus hippocastanum*
  - *Allium sativum*
  - *Aloe Vera*
  - *Camellia sinensis*
  - *Cynara scolymus*
  - *Echinacea purpurea*
  - *Ginkgo biloba*
  - *Harpagophytum procumbens*
  - *Hypericum perforatum*
  - *Panax ginseng*
  - *Passiflora incarnata*
  - *Rhodiola rosea*
  - *Serenoa repens*
  - *Silybum marianum*
  - *Vaccinium macrocarpon*
  - *Valeriana officinalis*

Source: EHPM Survey 2011

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Botanicals in the EU

EU Legal Framework

Use of Botanicals

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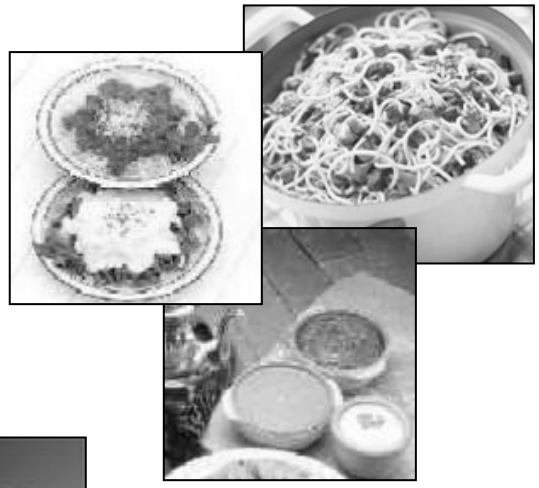
- **E.g. Garlic**

Food

Ingredient



Food Supplement

Medicinal product

Comm. E approval: support to elevated levels of blood lipids and age-dependent vascular changes

Use of Botanicals

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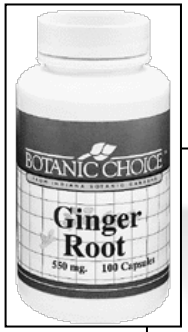
- **E.g. Ginger**

Ingredient

Food



Food Supplement

Cosmetic

Medicinal product

Comm. E approval: for dyspepsia and prevention of motion sickness

Use of Botanicals

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- **E.g. Hawthorn**

Food

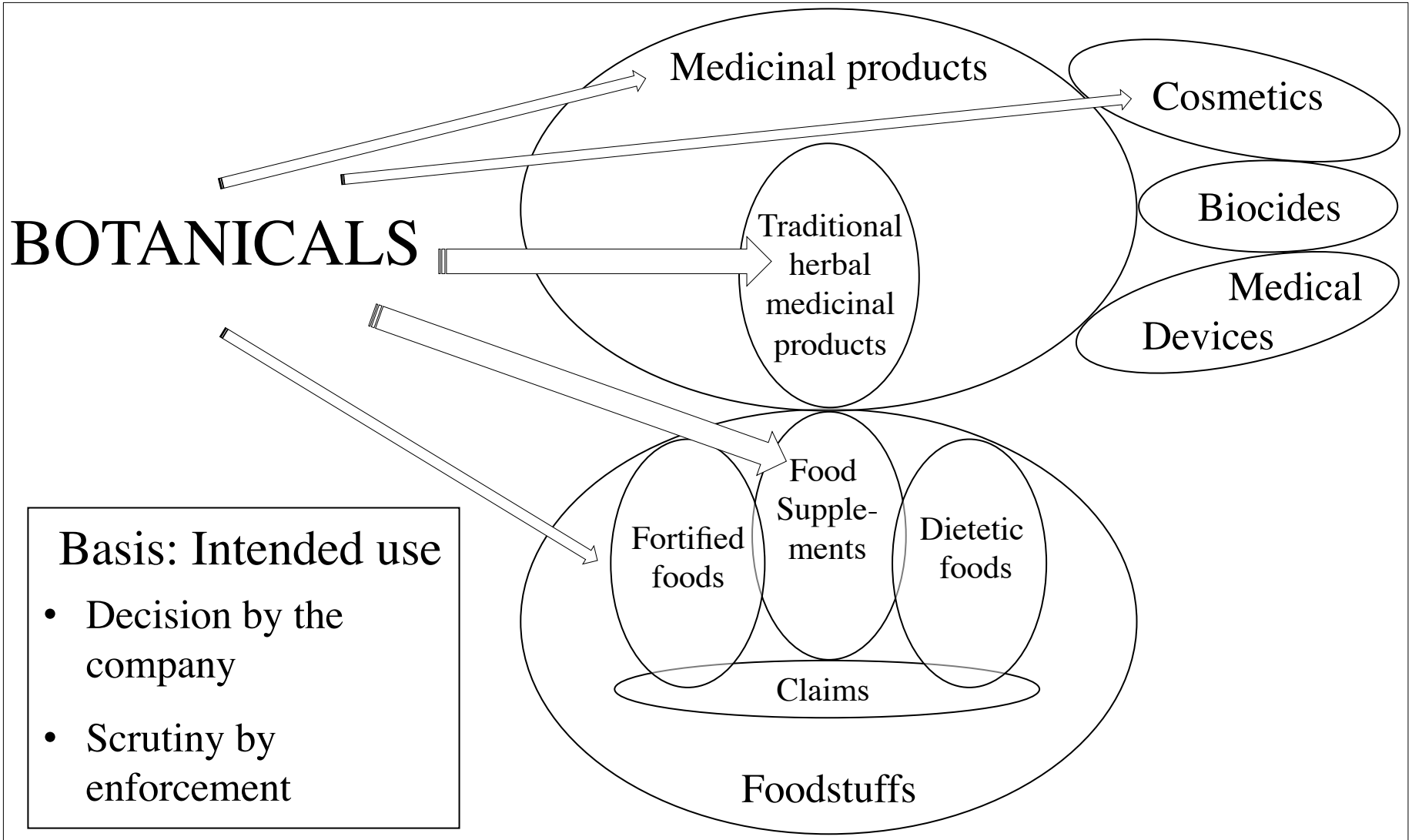
Ingredient

Food Supplement

Medicinal product

Comm. E states: traditionally to strengthen and invigorate heart and circulatory function

Borderline between legal frameworks



Use of Botanicals in legal frameworks

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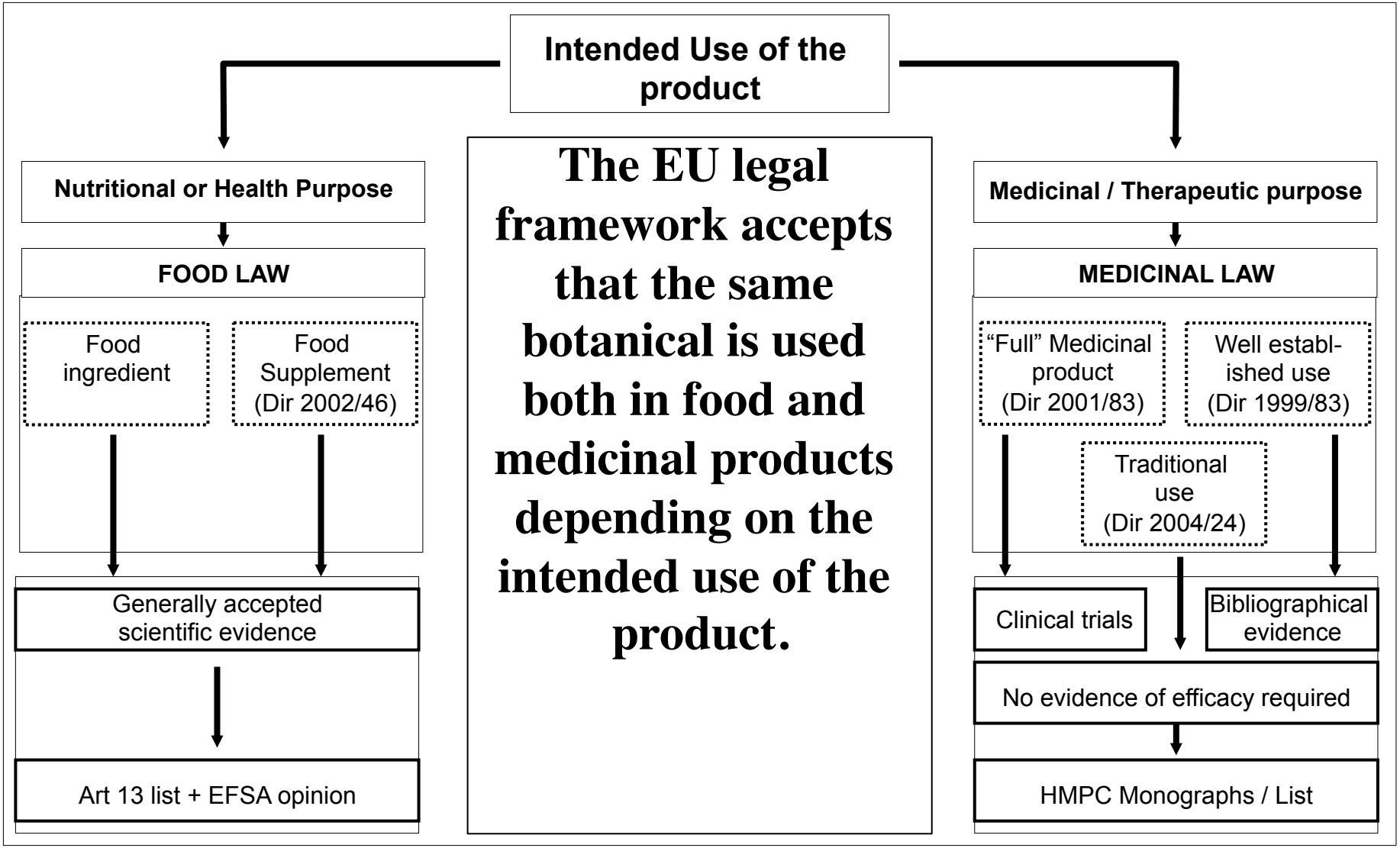

The use of botanicals in Food Supplements

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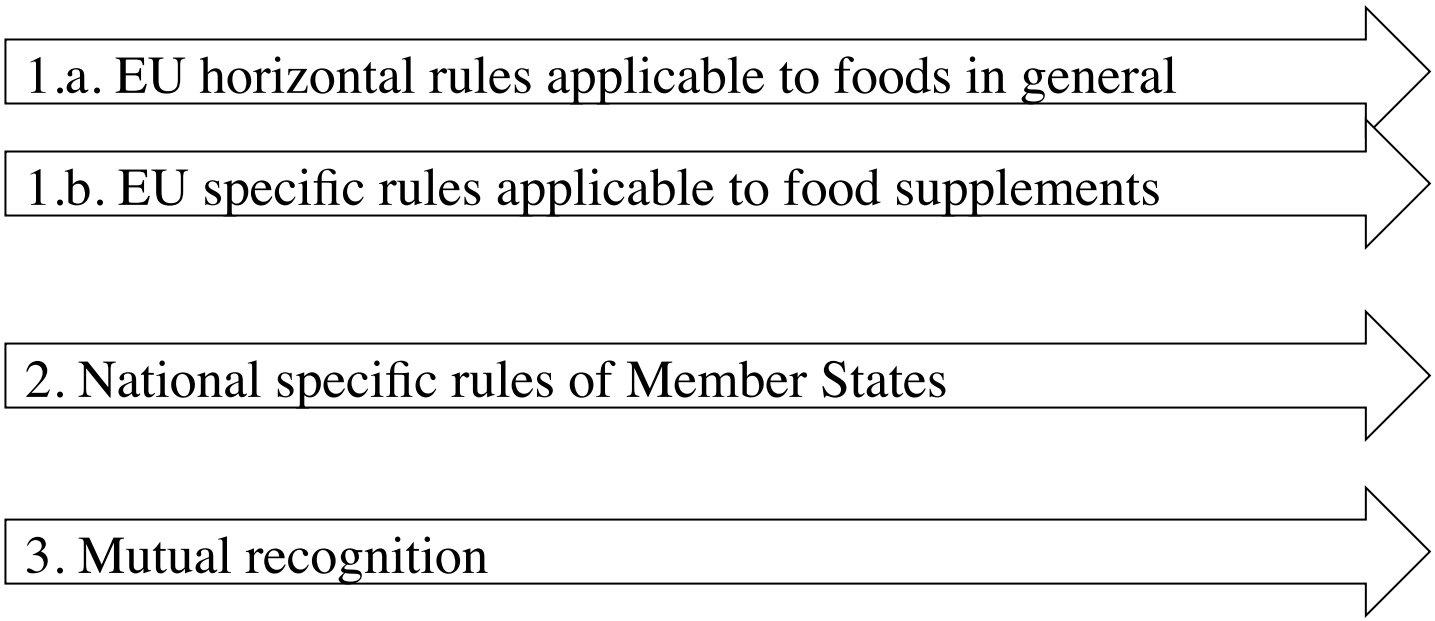
- Are regulated under food law in the EU
- Are only partially harmonised
- Are subject to



EU legislation

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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

General labelling rules

Reg EC 1169/2011

How to label content, composition, etc
Quantitative ingredient declaration (QUID)
Allergen labelling

Health Claims Regulation

Reg EC 1924/2006

Pre-marketing approval procedures
for nutrition and health claims

Fortification legislation

Reg EC 1925/2006

Risk assessment and risk management procedure in case the use of a substance would result in harmful effects

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

National Measures

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- Different attitudes
  - Botanicals considered ‘medicinal by function’
  - Traditional emphasis on food supplements or medicinal products
- Variety of risk management measures
  - Lists
    - Negative lists
    - Positive lists
  - Conditions of use
    - Restrictions
    - Maximum levels
  - Labelling requirements
  - Notification / Registration
  - Guidance / …

National Measures

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Negative List	Positive & Negative Lists	Positive List	No Lists
• Bulgaria • Czech Rep. • Finland • Hungary • Netherlands • Sweden	• Austria • Belgium • Denmark • Estonia • Ireland • Italy • Poland • Romania • Slovenia • UK	France*	• Cyprus • Germany • Greece • Latvia • Lithuania • Luxembourg • Malta • Portugal • Slovakia • Spain

* Draft law

Mutual Recognition

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- Mutual Recognition: Art 34/36 of EU Treaty
  - A Member State is obliged to accept on its territory any product lawfully marketed in another Member State
  - Unless it can show that there is a danger for health
- Regulation 764/2008
  - Scope - Procedure - Deadlines
  - Applicable from 13 May 2009
- Mandatory notification national rules
- Sometimes difficult process
  - Supported by extensive case-law
  - Not always applied by Member States
  - Infringement procedures

Further Harmonisation

- EC Report 2008
  - Further harmonisation is not feasible
    - Too many national differences
    - Scientific and methodological difficulties to be overcome
  - Further harmonisation is not necessary
    - Full food law framework is applicable
      - Legislation covers many aspects
    - Application of new legislation
      - Reg 1924/2006 Nutrition and Health Claims — Problematic
      - Reg 1925/2006 Addition of Nutrients — Applied to Yohimbe and Ephedra
      - Revision of Reg 258/1997 Novel foods — Failed in May 2011
    - Mutual Recognition

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Botanicals in the EU

Nutrition and Health Claims

Nutrition and Health Claims

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- Regulation 1924/2006: Nutrition & Health Claims
  - Since 2007: horizontal legislation
  - Scope
    - All food and food ingredients, including food supplements
    - All commercial communications
  - Pre-marketing authorisation of all health claims

  - Subject to the standard established by EFSA
    - Based on human data (randomised controlled trials)
    - Focused on demonstration of measurable improvements of validated end-points or biomarkers within a healthy population
    - No consideration of evidence of traditional use

Traditional Herbal Medicinal Products

- Traditional Herbal Medicinal Product Directive (04/2004)
  - Simplified registration procedure
    - Based on traditional use of the medicine for specified minor indications.
    - THMPs should have been in medicinal use for at least 30 year (at least 15 years must relate to the EU).
    - No need to demonstrate efficacy by clinical trials if effect and safety plausible on the basis of traditional use
  - Labelling should tells consumers that its indications are based on tradition rather than proven efficacy.
  - Transitional period for THMPs on the market before 30.04.04 to comply with the Directive until 30/04/2011.
  - Community herbal medicinal monographs developed by EMA

Discrepancies

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- Botanical Food Supplements
  - Clinical trials needed but not available.
  - Justification by companies.
  - No single claim for botanicals accepted.
- Traditional Herbal Medicinal Products (Dir 2004/24)
  - No proof of efficacy needed.
  - EMA working on traditional herbal monographs.
  - Indications not always medicinal.
- 27 September 2010
  - EC decided to remove botanicals from the claims process and start a reflection on future rules.

HMPC Monograph Vs. EFSA Claims opinions

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THPM Monograph indications	EFSA beneficial physiological effects
Symptoms of temporary fatigue and sensation of weakness	Reduction of tiredness and fatigue is
Symptomatic relief of digestive disorders such as dyspepsia […], bloating and flatulence	Reduction of gastro-intestinal discomfort is
For relief of mild symptoms of mental stress	Resistance to mental stress might be
Used to aid sleep	Reduction of sleep onset latency and improvement of sleep quality might be
For relief of […] heaviness of legs related to minor venous circulatory disturbances	Maintenance of elasticity and strength of the venous walls is
For the prophylaxis of migraine headaches after serious conditions have been excluded […]	Relief from stress-induced headache is
For the relief of minor symptoms in the days before menstruation (premenstrual syndrome)	Reduction of menstrual discomfort is
For the relief of menopausal complaints such as hot flushes and profuse sweating	Reduction of menopausal discomfort is
For the treatment of habitual constipation or in conditions in which easy defaecation with soft stool is desirable	Changes in bowel function such as reduced transit time, more frequent bowel movements, increased faecal bulk, or softer stools may be

Medicinal Law

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- Definition by virtue of Presentation
  - « any substance or combination of substances presented as having properties for treating or preventing disease in human beings »
- Definition by virtue of Function
  - « any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action […] »
- Medicinal product legislation (Dir 2001/83): Article 2.b.
  - « In cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a “medicinal product” and within the definition of a product covered by other Community legislation the provisions of this Directive shall apply »

ECJ Case Law

- Presentation criterion: Broad interpretation
  - Must cover all products, also those with no demonstrated efficacy
- Function criterion: Narrow interpretation
  - “Physiological effect” is not specific to medicinal products but is also among the criteria used for the definition of food
  - In order to preserve the effectiveness of that criterion, it is not sufficient that product has properties beneficial to health in general, but it must strictly speaking have the function of treating or preventing disease
  - Medical purpose or therapeutic effect must be present
    - Cfr. article 26: medicinal licence to be refused if therapeutic efficacy is lacking or is insufficiently substantiated

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Botanicals in the EU

The Future of Botanicals

Future of botanicals

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- 27 September 2010
  - Botanicals removed from the claims process - reflection on the future
- August 2012: EC Option Paper for the Member States
  - **Option 1: 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

Future of botanicals

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- THE DECISION MUST STILL BE TAKEN
- If it is for option 1: Considerable economic impact
  - **Loss of profitability and competitiveness**
    - Loss of sales of **25%**
    - Increased costs for clinical trials (4-500,000 € / product)
  - **Loss of employment**
    - **30-50%** of employment threatened
  - **For consumers:**
    - Less product choice
    - Increase in prices
    - Increase of sales via Internet (imports)

Source: Brookes 2010

- If it is for option 2: Opportunity to strengthen quality

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Thank you for your attention

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