Botanical Food Supplements
Regulatory Situation in the EU

Patrick Coppens
Use of Botanicals

- 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

• E.g. Ginger

Food

Supplement

Cosmetic

Ingredient

Medicinal product

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

- E.g. Hawthorn

Food

Food Supplement

Medicinal product

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

- Legal framework for food supplements
  - EU law
  - National legislation
  - Mutual recognition

- Issues for botanicals
  - Nutrition and Health Claims
  - Borderline with medicinal products
Legal Framework for Botanical Food Supplements
Medicinal products

- Traditional herbal medicinal products

Foodstuffs

- Health claims
- Food Supplements
- Dietetic foods
- Addition of nutrients

Medical Devices

Biocides

Cosmetics

Borderline issues =

National differences
Food Supplements
Historic perspective

• Until 2002
  - Food supplements were regulated under national law
  - Wide diversity of different rules and approaches

• 2002
  - Food Supplement Directive 46/2002/EC
  - Regulated under Food Law
  - Broad definition of a food supplement to include non-vitamin and mineral ingredients (e.g. botanicals)
  - Detailed rules only for vitamin and mineral supplements
  - Subject to a post-marketing notification procedure
Botanical Food Supplements

• **National legislation** remains applicable
  - Negative lists / Positive lists / Restrictions or modalities for use / Maximum levels / Specific labelling / …

• However
  - **Mutual Recognition** applies (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 (applicable from 13 May 2009)
  - Provisions of **Food Law** apply
    • General Food Law Regulation
    • Novel Foods Regulation
    • All applicable rules on hygiene, additives, contaminants, etc
### Requirements for food supplements

<table>
<thead>
<tr>
<th>Category</th>
<th>Relevant Regulation</th>
<th>Details</th>
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<tbody>
<tr>
<td><strong>General Food Law</strong></td>
<td>Reg EC/178/2002</td>
<td>General food safety requirements, Manufacturer responsibilities, Notification duty, Recall</td>
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<tr>
<td><strong>Food Supplements Law</strong></td>
<td>Dir 2002/46/EC</td>
<td>Definition, Permitted forms (vitamins/minerals), Maximum levels (vitamins/minerals), Specific labeling provisions</td>
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<td><strong>Food Hygiene</strong></td>
<td>Reg EC/852/2004</td>
<td>Rules for hygienic production based on the principles of HACCP, Microbiological criteria</td>
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<td><strong>Novel Foods Regulation</strong></td>
<td>Reg EC/258/97</td>
<td>Pre-marketing approval procedure for novel ingredients</td>
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<td><strong>General labelling rules</strong></td>
<td>Dir 2000/13/EC</td>
<td>How to label content, composition, etc, Quantitative ingredient declaration (QUID), Allergen labelling</td>
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<td><strong>Health Claims Regulation</strong></td>
<td>Reg EC/1924/2006</td>
<td>Pre-marketing approval procedures for nutrition and health claims</td>
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<td><strong>Fortification legislation</strong></td>
<td>Reg EC/1925/2006</td>
<td>Risk assessment and risk management procedure in case the use of a substance would result in harmful effects</td>
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<td><strong>Additives legislation</strong></td>
<td>Dir 89/1007/EEC</td>
<td>Pre-marketing approval procedures, Allowed additives, including sweeteners and colourings, Conditions of use</td>
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<td><strong>Contaminants</strong></td>
<td>Reg EC/1881/2006</td>
<td>Maximum levels of selected contaminants in ingredients that can be used in foods</td>
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<td><strong>Pesticides residues</strong></td>
<td>Reg EC/396/2005</td>
<td>Maximum residue levels</td>
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<td><strong>Extraction solvents</strong></td>
<td>Dir 2009/32/EC</td>
<td>Permitted extraction solvents</td>
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<td>Dir 1999/2/EC</td>
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Conclusion

• Botanical food supplements are subject to the extensive requirements of *food law* ensuring their safe and effective use.

• **Safety** is covered by
  • General Food Law requirements
  • Novel foods legislation
  • Hygiene rules
  • Residues and contaminants legislation

• Specific rules for the use of botanicals and other ingredients are not harmonised but subject to *national law*
  • Negative and positive lists
  • Conditions of use
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
      - Reg 1925/2006 Addition of Nutrients
      - Reg 258/1997 Novel foods
    • Mutual Recognition
Nutrition and Health Claims
Regulation 1924/2006

- **Pre-marketing approval** for all Health Claims
  - General function claims
    - Establishment of a *generic list*
  - Function claims based on new scientific evidence or with a request for the protection of proprietary data
    - Application for approval (*Article 18 procedure*)
  - Reduction of disease risk claims and Claims relating to children’s development and health
    - Application for approval (*Article 14 procedure*)

- **Scientific assessment** of Health Claims
  - By the European Food Safety Authority (EFSA)
Outcome so far

• **Article 13**
  - Many claims for essential nutrients (Vitamins / Minerals / Fatty acids)
  - Few claims for other substances (Probiotics, Botanicals, Lutein, Glucosamine)
  - No positive opinions for botanicals

• **Article 13.5**
  - Only two positive opinions

• **Article 14**
  - Few positive opinions (e.g. Phytosterols, Chewing gum and Calcium, DHA)
Reasons

- Chaotic management of the Article 13 process
  - Over 44,000 submissions
- Lack of guidance
- Poor quality of many submissions
- Many claims rejected because of formalistic reasons
  - Strong focus on the details of the application
- EFSA requires Human intervention trials
  - Demonstrating measurable effects on validated end-points or biomarkers within a healthy population
  - The value of traditional use is not recognised
Traditional Use

- **Traditional Herbal Medicinal Products (Dir 2004/24)**
  - No proof of efficacy needed
  - if on the market for 30 years (15 in EU)
  - “Having regard to [...] especially their long tradition, it is desirable to provide a special, simplified registration procedure [to] be used only where no marketing authorisation can be obtained pursuant to Directive 2001/83/EC, in particular because of a lack of sufficient scientific literature demonstrating a well-established medicinal use with recognised efficacy and an acceptable level of safety. “
  - “The long tradition [...] makes it possible to reduce the need for clinical trials, in so far as the efficacy of the medicinal product is plausible on the basis of long-standing use and experience. “

- **Nutrition and Health Claims rules (Reg 1924/2006)**
  - No consideration of Traditional use
  - Botanicals taken out of the claims process (September 2010)
Borderline with medicinal products
Intended Use of the product

The EU legal framework accepts that the same botanical is used both in food and medicinal products depending on the intended use of the product

Different principles apply

**FOOD LAW**

- Nutritional or Health Purpose
  - Food ingredient
    - Generally accepted scientific evidence
      - Art 13 list + EFSA opinion
  - Food Supplement (Dir 2002/46)

**MEDICINAL LAW**

- Medicinal / Therapeutic Purpose
  - “Full” Medicinal product (Dir 2001/83)
    - Traditional use (Dir 2004/24)
  - Well established use (Dir 1999/83)
    - Bibliographical evidence
      - Clinical trials
      - No evidence of efficacy required
      - HMPC Monographs / List
Intended Use of the product

Nutritional or Health Purpose

- Registration needed
- Not harmonised
- Safety / Quality requirements
- Limitations for dosage / duration of use
- High costs for license maintenance
- Publicity restrictions
- Distribution restrictions

Food ingredient

Food Supplement (Dir 2002/46)

- Generally accepted scientific evidence
- Art 13 list + EFSA opinion

Medicinal / Therapeutic purpose

- Legal certainty (30 years of traditional use)
- No proof of efficacy needed (plausibility)

- Registration needed
- Not harmonised
- Safety / Quality requirements
- Limitations for dosage / duration of use
- High costs for license maintenance
- Publicity restrictions
- Distribution restrictions

“Full” Medicinal product (Dir 2001/83)

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Food Law

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- Clinical trials
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Food Law
- Notification needed
- General food safety / Quality requirements
- Low or no costs for market maintenance
- No publicity restrictions
- Few distribution restrictions

Medicinal Law
- Not harmonised
- National restrictions
- Health Claims difficult
- Safety under discussion
- Mutual recognition
- Borderline issues
Frameworks are Mutually Exclusive

- **Food Legislation**
  - General Food Law (Reg 178/2002)
    - “Food shall not include Medicinal Products”

- **Medicinal Product Legislation**
  - Medicinal product Directive (Dir 2001/83):
    - “Where a product comes clearly under the definition of other product categories, in particular food, food supplements, [...] this Directive should not apply”
  - Traditional Herbal Medicinal Product Directive (Dir 04/2004)
    - “This Directive allows non-medicinal herbal products, fulfilling the criteria of food legislation, to be regulated under food legislation in the Community”
Medicinal Law

- **Definition by virtue of Presentation**
  - « any substance or combination of substances presented as having properties for treating or preventing disease in human beings »
  - Only refers to 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 [...] »
  - “modifying physiological functions” vs. “beneficial nutritional or physiological effect” ?
Medicinal Law

• **Medicinal product legislation (Article 2.b of Dir 2001/83)**
  - « 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 »
  - Superiority of medicinal law, but applies only
    - To *individual products*: Medicinal law is products-specific licensing; “medicinal by function” is contrary to this principle
    - In cases of *doubt* and requires a case-by-case assessment
    - All the product’s *characteristics* need to be considered, not only its conformity with the definition
  - And subject to review by the Courts
ECJ Case Law

• Art 2.b. : In line with ECJ Case law
  • “ [...] it is for the national authorities to determine, subject to review by the courts, for each product, having regard to all of its characteristics, in particular its composition, its pharmacological properties as they may be ascertained in the current state of scientific knowledge, the way in which it is used, the extent to which it is sold, its familiarity to the consumer and the risks which its use might entail, whether or not it constitutes a medicinal product within the meaning of the definition set out in Article 1 (2) of [the medicinal product Directive] ”

• Consequence:
  • as long as rules for Food Supplements are not harmonised, it is possible that a given product is considered as a medicinal product by one Member State and as a Food Supplement by another
  • However, the ECJ has set criteria for the assessment of the status
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 supplement
  - 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
Conclusion

- The EU legal framework accepts the use of the same botanicals in both foods and medicinal products.

- Both legal frameworks are mutually exclusive. However, in case of doubt, medicinal law applies.

- The ECJ has established extensive case law to differentiate between food and medicinal use:
  - National authorities are competent to decide.
  - Assessment must be carried out on a case-by-case basis.
  - It must take all the product’s characteristics into account.
  - A medicinal/therapeutic pharmacological property must be established.
Thank you for your attention

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