european botanicalforum

# 55th International Congress & Annual Meeting of the Society for Medicinal Plant Research

## Gesellschaft für Arzneipflanzenforschung – GA

## Workshop 1

2 September 2007

GRAZ

# 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

Ingredient

Food


Cosmetic


Food Supplement


Medicinal product

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

# Use of Botanicals

- E.g. Hawthorn

**Ingredient**


**Food**


**Food Supplement**


**Medicinal product**

*Comm. E states: <u>traditionally</u> to strengthen and invigorate heart and circulatory function*

# Food Supplements Historic perspective

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

- The way to harmonisation
  - 1991
    - **Discussion paper indicated that food supplements contain wide range of ingredients and asked which should the tackled first.**
  - 1997
    - **Discussion Paper suggested that focus of initial legislative action should be vitamins and minerals.**
  - 2002
    - **Directive established broad definition of a food supplement to include non-vitamin and mineral ingredients but lies down detailed rules only for vitamin and mineral supplements.**

# The Food Supplements Directive

- Food Supplements Directive 2002/46
  - Definition of Food Supplement
    - Botanical ingredients are included
  - Harmonised rules on vitamins and minerals
    - Which can be used and under what chemical form
    - Maximum levels still to be established
      - Jun 2006: EC discussion paper - consultation
      - Jul 2007: EC orientation paper
  - Report on the advisability to establish specific rules for other substances (Art 4.8) by Jul 2007
    - Expected in autumn
  - Notification procedure for Food Supplements

# Legislation applicable to Food Supplements

- The General Food Law Regulation 178/2002
  - Definition of Food
  - Lays down the General Food Law Requirements
    - Responsibilities, in market surveillance and recall, notification, …
  - Creation and competences of the European Food Safety Authority (EFSA - Parma, It)

- Novel Foods Regulation 258/97
  - Covers food ingredients derived from plants that have not been on the market in significant amounts prior to May 1997
  - Provides for a procedure of pre-marketing authorisation following the submission of a file demonstrating safety

# Legislation applicable to Food Supplements

- Regulation 1924/2006 on nutrition and health claims
  - Definition of health claims including reduction of disease risk claims (RDRC)
  - Procedures for claims approval (involving EFSA)
    - **Nutrition claims: permitted if in the Annex**
    - **Health claims based on generally accepted scientific evidence: permitted if included in a positive list (by 2010)**
    - **New health claims or claims including a request for protection of proprietary data: permitted after authorisation (art 18 procedure)**
    - **RDRC and claims relating to children: permitted after authorisation (art 14 procedure)**

# Legislation applicable to Food Supplements

- Regulation 1925/2006 relating to the addition of vitamins and minerals and of certain other substances to foods (fortification)
  - Chapter III: Restrictions on certain other substances
    - **Covers substances used under conditions that would result in the ingestion of amounts of the substance greatly exceeding those reasonably expected to be ingested under normal conditions of consumption of a balanced and varied diet**
    - **Safety evaluation by EFSA**
    - **Management options for inclusion in three lists:**
      - Prohibited substances
      - Substances subject to conditions of use
      - Substances under scrutiny

# Legislation applicable to Food Supplements

- All other EU legislation applicable to foodstuffs
  - Additives
  - Enzymes
  - Flavouring substances
  - Residues
  - Contaminants
  - Hygiene and food safety rules
  - Labelling
  - Advertising
  - …

# Borderline with Food Supplements

- Medicinal Product Directive 2001/83, as amended by Directive 2004/27.
  - Definition of Medicinal Product
  - Mechanism to decide “In cases of doubt”: superiority of medicinal law
  - Registration requirements for medicinal products

- Traditional Herbal Medicinal Product Directive 2004/24.
  - Definition of Traditional Herbal Medicinal Products (THMP)
  - Registration requirements for THMP
  - Committee for Herbal Medicinal Products
    - Community monographs - List

# Food Supplements Directive

- Definition:

  "'food supplements' means **foodstuffs** the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or **other substances with a nutritional or physiological effect**, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities."

# Botanical Food Supplements

- Fall under the definition of Food Supplement
- Are on the market in all Member States since decades
- National legislation remains applicable
  - Without prejudice to the provisions of the Treaty
    - Art 28 and 36: free movement of goods
  - Without prejudice to provisions of applicable Community rules
    - General Food Law Regulation
    - Novel Foods Regulation
    - All applicable rules on hygiene, additives, contaminants, etc

# “Mutual Recognition”
# “Free Movement of Goods”

- Laid down in article 28 of the Treaty:
  - **Prohibition of quantitative restrictions** on imports of products and/or measures having equivalent effects, which thus constitute obstacles to the free movement of products
- Exceptions possible: article 30 of the Treaty:
  - Article 28 shall not preclude prohibitions or restrictions […] justified on grounds of […] **the protection of health and life of humans** […]
- Confirmed in “Cassis de Dijon” - Case (C-120/78) and subsequent case law

# “Mutual Recognition”
# “Free Movement of Goods”

- Each Member State is obliged to accept on its territory products that have been lawfully manufactured and/or marketed in one of the 25 EU Member States or in Turkey, or an EEA country (Iceland, Liechtenstein, and Norway)

- Member States may only restrict the importation and marketing of products where they can demonstrate that the restrictive measures
  - are necessary in order to satisfy mandatory requirements such as
    - the protection of public health,
    - the fairness of commercial transactions,
    - and the defence of the consumer, and
  - are proportionate

# “Mutual Recognition”
# “Free Movement of Goods”

- Burden of proof is upon the Member State
- The Mandatory Notification of Technical Standards (Directive 98/34/CE).
- Selected court cases against Germany, Austria, France, Denmark and The Netherlands
- Reasoned opinion of the European Commission against Spain for systematically considering products containing certain plants as medicinal products without carrying out the mandatory case-by-case assessment on their safety

# Food Supplements in relation to Medicinal Law

- Food Supplements Directive (2002/46).
  - Recital 6: There is a wide range of [..] ingredients that might be present in food supplements including […] various plants and herbal extracts.
  - Article 4.8: Not later than 12 July 2007, the Commission shall submit [..] a report on the advisability of establishing specific rules […] substances with a nutritional or physiological effect […]

- Traditional Herbal Medicinal Product Directive (2004/24).
  - Recital 12: This Directive allows non-medicinal herbal products, fulfilling the criteria of food legislation, to be regulated under food legislation in the Community.

# Food Supplements in relation to Medicinal Law

- Medicinal Product Directive 2001/83, as amended by Directive 2004/27
  - Recital 7: Where a product comes clearly under the definition of other product categories, in particular food, food supplements, medical devices, biocides or cosmetics, this Directive should not apply
  - Definition was modified to be able to include novel medicinal therapies, such as gene therapy, radiopharmaceutical products and certain medicinal products for topical use, …

# Definition of medicinal product

- Definition: Presentation Criterion:

  *"Any substance or combination of substance presented as having properties for treating or preventing disease in human beings"*

  – Only refers to properties for treating or preventing disease in human beings.
  – Directives on Labelling (2000/13, art 2.b), Foodstuffs intended for Particular Nutritional Uses (Directive 89/398, art 6.1) and Food Supplements (Directive 2002/46, art 6.2) clearly indicate that the labelling, presentation and advertising must not attribute to the said foodstuffs the property of preventing, treating or curing a human disease, or refer to such properties.
  – Health Claims Regulation introduces rules for Reduction of Disease Risk Claims.

# Definition of medicinal product

- Definition: Function Criterion:

  *"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, or to making a medical diagnosis"*

  – "Restoring, correcting or modifying physiological functions" is stronger than "substances with a beneficial nutritional or physiological effect or other health advantage" included in the Health Claims Regulation.
  – "By exerting a pharmacological, immunological or metabolic action": Introduced in order to make it possible to cover medicinal products such as gene therapy, radiopharmaceutical products as well as certain medicinal products for topical use.

# European Court of Justice Case Law

- Case-by-case approach:
  - "[…] 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.

# European Court of Justice Case Law

- Medicinal Product Directive 2001/83, as amended by Directive 2004/27 :
  - Article 2.2: 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.
  - Applies only
    - To individual products, not substances
    - In cases of doubt
    - And taking into account all its characteristics
  - Subject to review by the Court

# European Court of Justice Case Law

- Pharmacological properties:
  - Exceptional and therapeutic activity required.
    - Cfr. history of EU medicinal legislation
    - Cfr. soap, surgical antiseptic, …
    - Cfr. rat poison, insecticides, …
    - Cfr. cosmetics: effect is not sufficient
  - 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
  - Intended use.

# Legal framework will further clarify

- Food Supplements
  - Harmonisation continues under the Food Supplements Directive
  - New food ingredients: approval under Novel Foods Regulation
  - Claims: approval under Claims Regulation
  - Substances where a safety issue arise: safety assessment under the Addition of Nutrients Regulation

- Traditional Herbal Medicinal Products
  - THMG Monographs
  - THMP List
  - Registration as medicinal product: Pre-marketing authorisation

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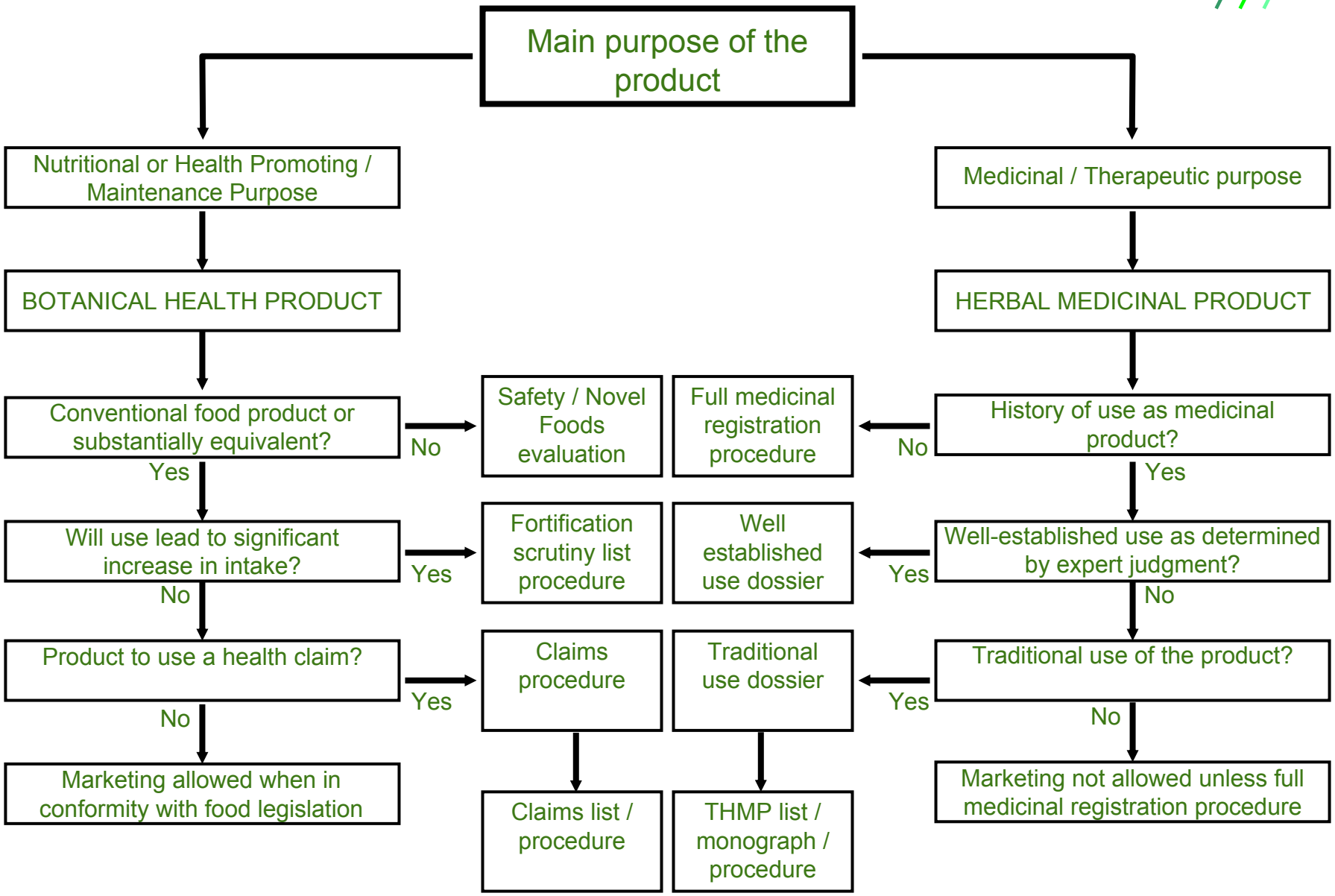

# Conclusions

- The current legal framework allows the continued co-existance of Botanical Food Supplements and (Traditional) Herbal Medicinal Products co-exist in the EU
- The legal framework for Botanical Food Supplements is under development, with the Claims and the Addition of Nutrients Regulations as important regulatory instruments
- It is the responsibility of the manufacturer to decide under what legal framework to market his product, in conformity with the rules of that legal framework
- The intended use of the product and presence of a therapeutic effect are key for deciding between food and medicinal law
- These principles are supported by EU Case law.

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# Thank you for your attention

PATRICK COPPENS
Secretary-General

EUROPEAN BOTANICAL FORUM
Rue De l'Association 50 - 1000 BRUSSELS
+32-(0)2-209.11.50 - patrickcoppens@erna.be - www.erna.org