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Botanical Food Supplements Regulatory Situation in the EU

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**Society for Medicinal Plant and
Natural Product Research**
Gesellschaft für Arzneipflanzen - und
Naturstoff-Forschung

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Use of Botanicals

- E.g. Garlic



Food

Food
Supplement

Ingredient



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



Food
Supplement

Cosmetic



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: traditionally to strengthen and invigorate heart and circulatory function





Content

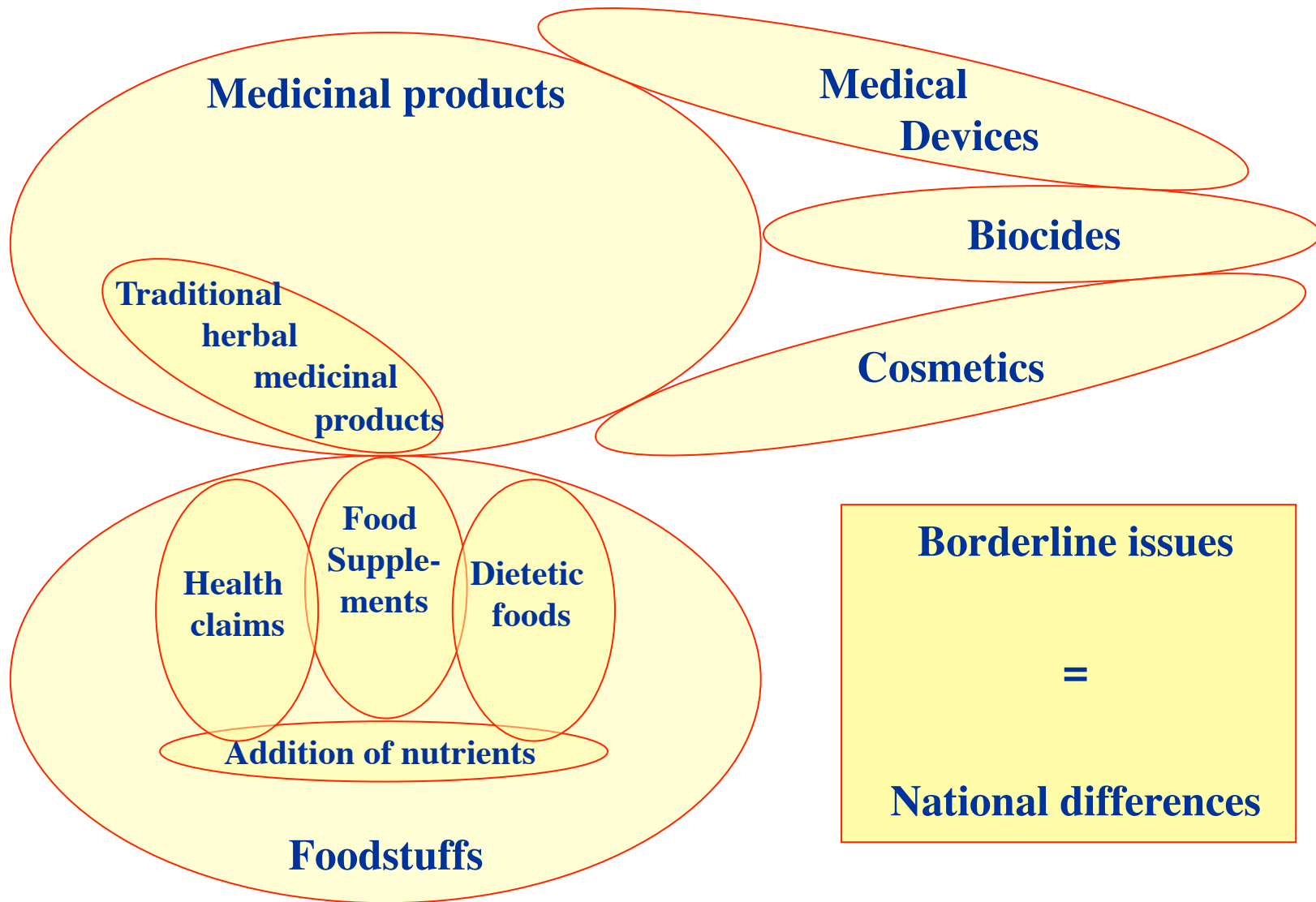
- Legal framework for food supplements
 - EU law
 - National legislation
 - Mutual recognition
- Issues for botanicals
 - Nutrition and Health Claims
 - Borderline with medicinal products



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Legal Framework for Botanical Food Supplements





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

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

Dir 2000/13/EC

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

Dir 89/1007/EEC

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



Botanical food supplements in the EU

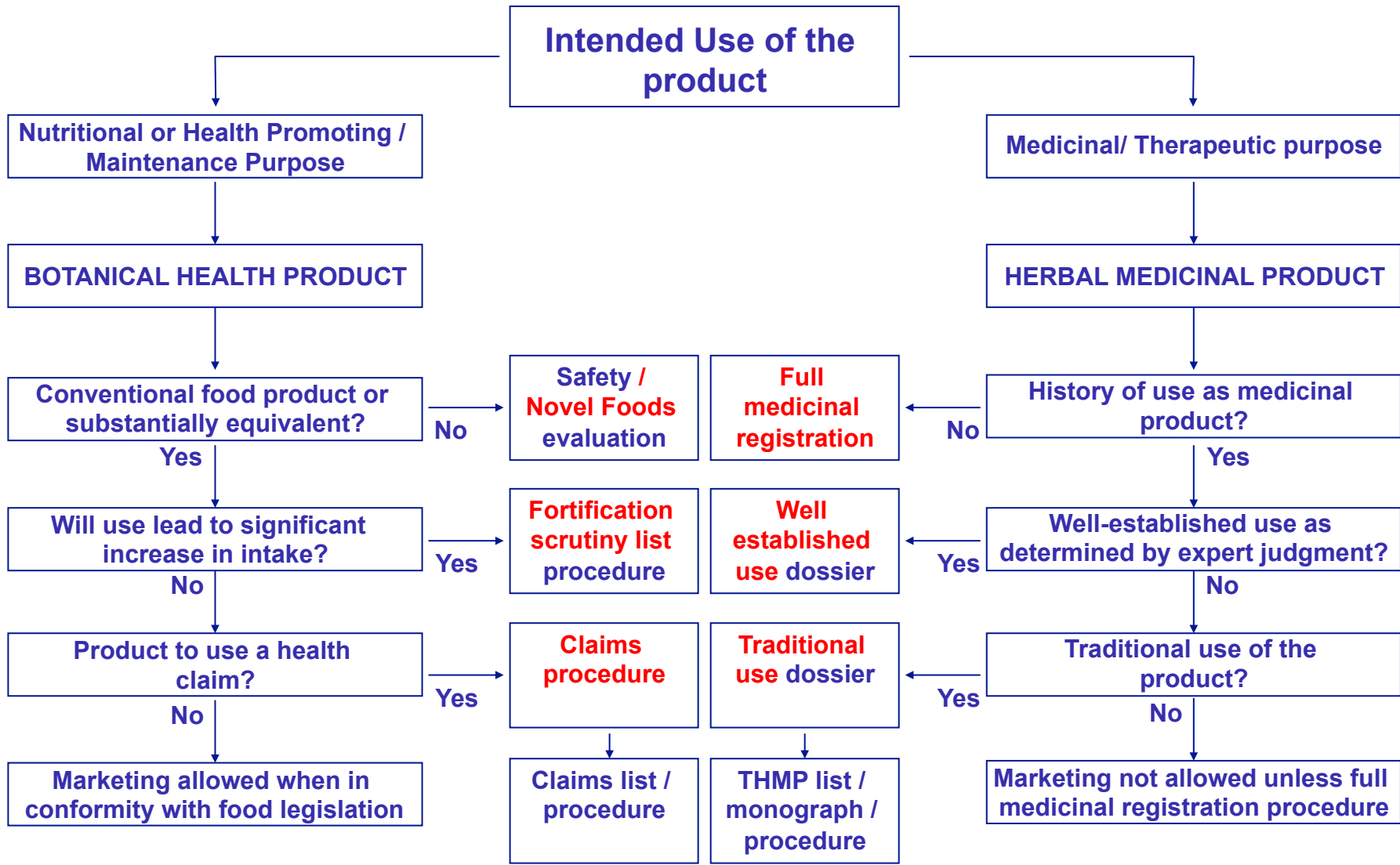
		AUSTRIA	BELGIUM	BULGARIA	CYPRUS	CZECH REPUBLIC	DENMARK	ESTONIA	FINLAND	FRANCE	GERMANY	GREECE	HUNGARY	IRELAND	ITALY	LATVIA	LITHUANIA	LUXEMBOURG	MALTA	NETHERLANDS	POLAND	PORTUGAL	ROMANIA	SLOVAKIA	SLOVENIA	SPAIN	SWEDEN	UNITED KINGDOM	
Botanicals & botanical extracts	Aloe (<i>Aloe vera</i> (L.))	E	✓	E	E	C	L	✓	C	A	C	*	C	✓	✓	✓	E	✓	✓	✓	✓	✓	✓	C	L/C	✓	✓	C	
	Ginkgo (<i>Ginkgo biloba</i>)	E	L	E	E	L	✓	*	C	A	*	*	L	*	C	L	E	✓	✓	✓	✓	✓	✓	L	*	*	*	C	
	Ginseng (<i>Panax ginseng</i>)	E	✓	E	E	L	L	✓	C	A	*	L	L	C	✓	L	E	✓	✓	✓	✓	✓	✓	✓	L	✓	✓	C	
	Garlic (<i>Allium sativum</i> (L.))	✓	✓	E	E	C	✓	✓	✓	A	C	✓	L	C	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	L	*	*	C	
	Green tea extract (<i>Camellia sinensis</i>)	E	L/C	E	E	C	E	✓	✓	A	C/A	✓	L	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	*	✓	C
	Garcinia extract (<i>Garcinia cambogia</i>)	E	✓	E	E	L	*	C	✓	A	*	*	L	*	✓	✓	E	✓	✓	✓	✓	✓	✓	✓	C	*	E	*	
	Guarana extract (<i>Paullinia cupana</i>)	C	✓	E	E	C	L	✓	✓	A	C/A	*	L	C	✓	L	E	✓	✓	✓	✓	✓	✓	✓	✓	✓	*	✓	✓

Symbols	✓	Permitted for use in food supplements either under national law or internal guidelines.
	L	Permitted for use in food supplements - maximum level established.
	C	Permitted for use in food supplements under specific conditions (eg type of extract, ingredients combination in the final product, etc)
	E	Permission may be given on a case by case basis following evaluation, considering issues such as ingredient function.
	A	Not currently permitted. May be permitted following a pre-marketing authorisation.
	*	Not permitted for use in food supplements, or regarded as medicinal.

Botanical food supplements in the EU

		AUSTRIA	BELGIUM	BULGARIA	CYPRUS	CZECH REPUBLIC	DENMARK	ESTONIA	FINLAND	FRANCE	GERMANY	GREECE	HUNGARY	IRELAND	ITALY	LATVIA	LITHUANIA	LUXEMBOURG	MALTA	NETHERLANDS	POLAND	PORTUGAL	ROMANIA	SLOVAKIA	SLOVENIA	SPAIN	SWEDEN	UNITED KINGDOM	
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	Ginkgo (<i>Ginkgo biloba</i>)	E	L	E	E	L	✓	✗	C	A	✗	✗	L	✗	C	L	E	✓	✓	✓	✓	✓	✓	✓	L	✗	✗	✗	C
	Ginseng (<i>Panax ginseng</i>)	E	✓	E	E	L	L	✓	C	A	✗	L	L	C	✓	L	E	✓	✓	✓	✓	✓	✓	✓	✓	L	✓	✓	C
	Garlic (<i>Allium sativum</i> (L.))	✓	✓	E	E	C	✓	✓	✓	A	C	✓	L	C	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	L	✗	✗	C
	Green tea extract (<i>Camellia sinensis</i>)	E	L/C	E	E	C	E	✓	✓	A	C/A	✓	L	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓	C
	Garcinia extract (<i>Garcinia cambogia</i>)	E	✓	E	E	L	✗	C	✓	A	✗	✗	L	✗	✓	✓	E	✓	✓	✓	✓	✓	✓	✓	✓	C	✗	E	✗
	Guarana extract (<i>Paullinia cupana</i>)	C	✓	E	E	C	L	✓	✓	A	C/A	✗	L	C	✓	L	E	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓	✓

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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

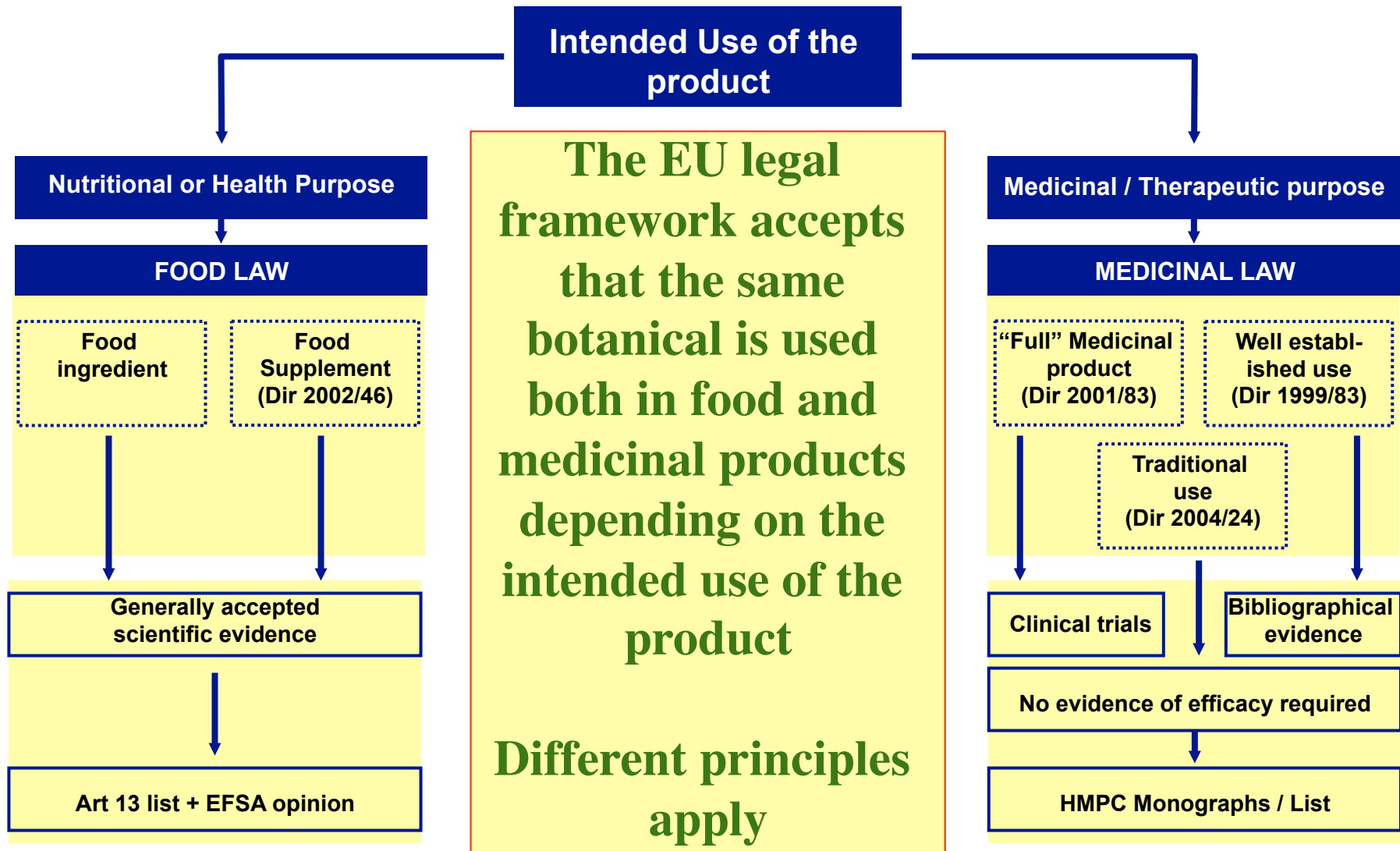


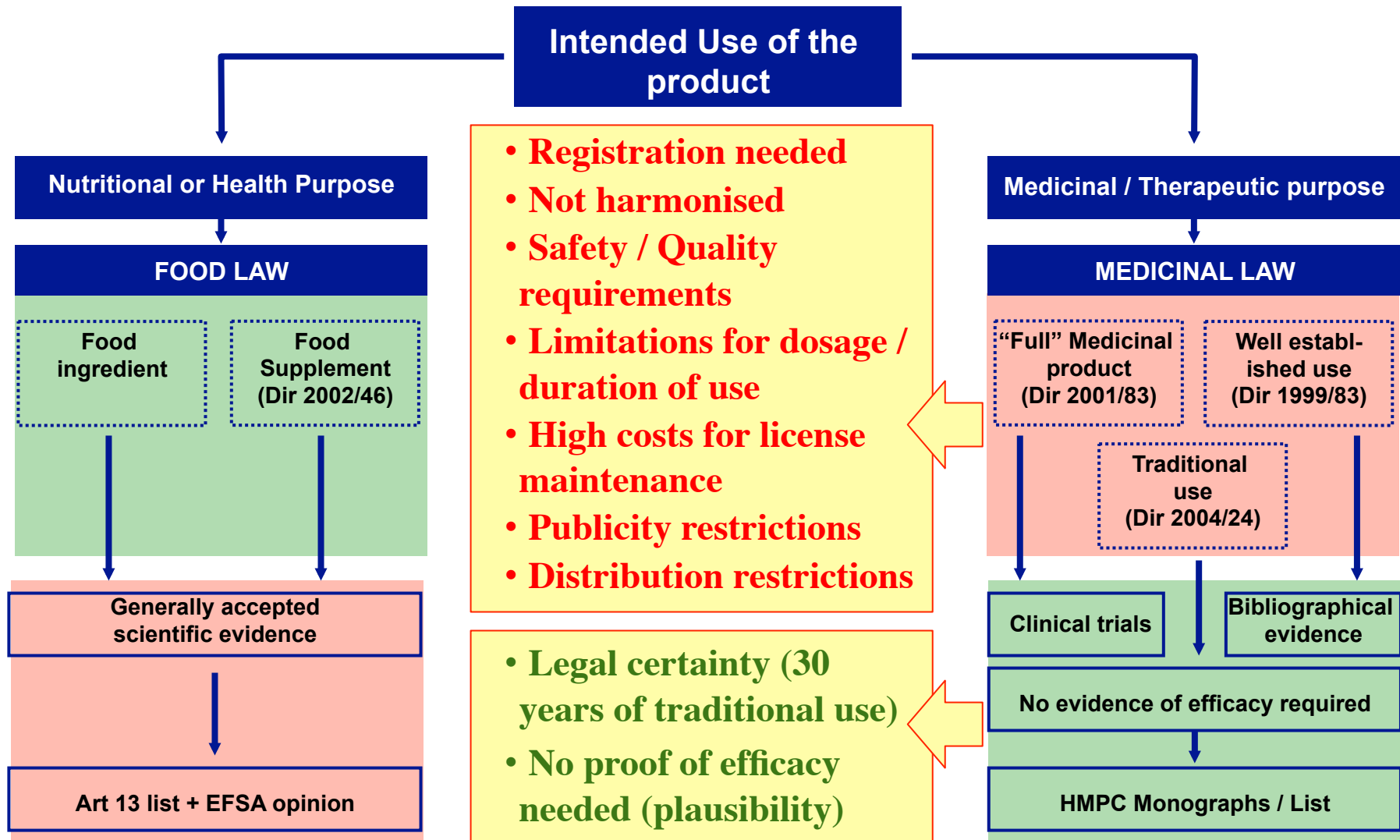
Traditional Use

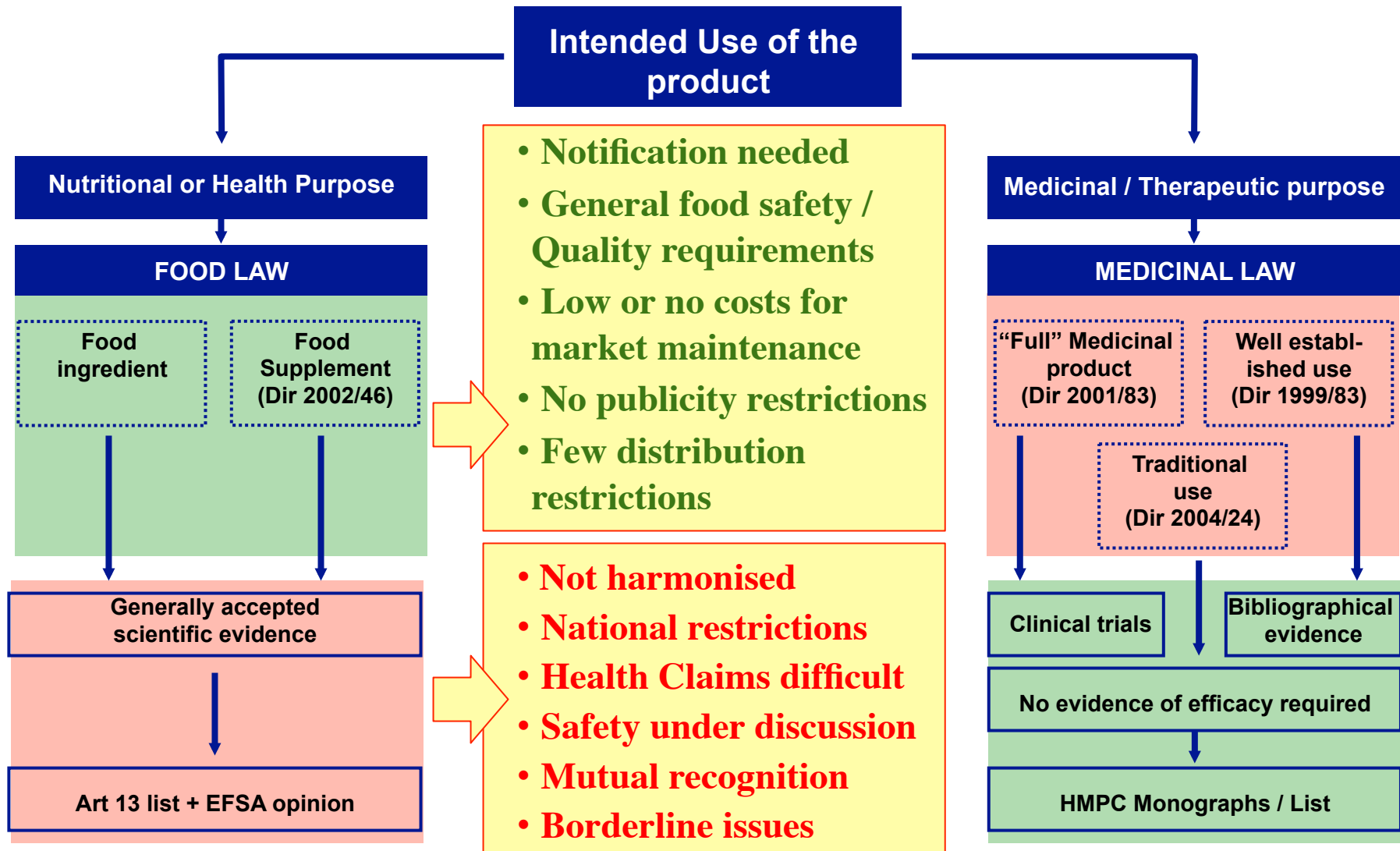
- **Traditional Herbal Medicinal Products (Dir 2004/24)**
 - No proof of efficacy needed
 - if on the market for 30 years (15 in EU)
 - “ Having regard to [...] especially their **long tradition**, it is desirable to provide a special, **simplified registration procedure** [to] be used only where no 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









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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