Drug Regulatory Affairs
Regulatory Competence Center
Europe

Product Classification (EU) -
Boundaries and Overlaps between Medicines and Food Supplements

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Main topics

- EU rules affecting food and food supplements (FS)
- Classification
- Notification
- Overlaps between medicines and FS
- Differences between medicines and FS
- FS product development
- Conclusions

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EU rules affecting food and food supplements

Horizontal legislation

Topic	Regulation
General food law	EC No 178/2002
Labelling	EU No 1169/2011
Claims	1924/2006
Novel foods	EC No 258/97
Food additives	EC No 1331/2008
Food hygiene and production	852/2004
Food control	882/2004
Traceability	178/2002

Vertical legislation

Topic	Regulation
Food supplements - Notification - Vitamins, minerals - Herbal substances - Other substances	Directive 2002/46/EC
Fortified foods	EC No 1925/2006
Herbal products	
Dietary foods	

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Products marketed as a Food Supplement in the Member State of origin could be treated as a medicinal product in the Member State of import or vice versa.

(Legal base: Article 2.2 of Directive 2001/83/EC on medicinal products for human use, as amended)

Linex products – geographic overview of registration status

INN	EU (BG, CZ, EE, GR, HR, HU, LT, LV, PL, RO, SI, SK)			SEE (AL, BA, MK, ME, RS, XK)		
	FS	OTC	MD	FS	OTC	MD
Bifidobacterium animalis (sachets)	10	2	n.a.	3	5	n.a.
Bifidobacterium animalis (drops)	11	n.a.	n.a.	7	n.a.	n.a.
Lactobacillus acidophilus + Bifidobacterium animalis	10	3	n.a.	0	6	n.a.
Lactobacillus acidophilus + Bifidobacterium animalis + Enterococcus faecium	3	4	n.a.	0	4	n.a.
Lactobacillus casei rhamnosus + Se + Zn	3	n.a.	n.a.	0	n.a.	n.a.
Lactobacillus rhamnosus	n.a.	n.a.	1	n.a.	n.a.	3
Lactobacillus rhamnosus + Thiamine + Riboflavin + Vitamin B6 + Zinc	12	n.a.	n.a.	6 MK*	n.a.	n.a.

Legend: n.a. = No dossier available for this type of application, MK* = Macedonia as borderline medicinal product

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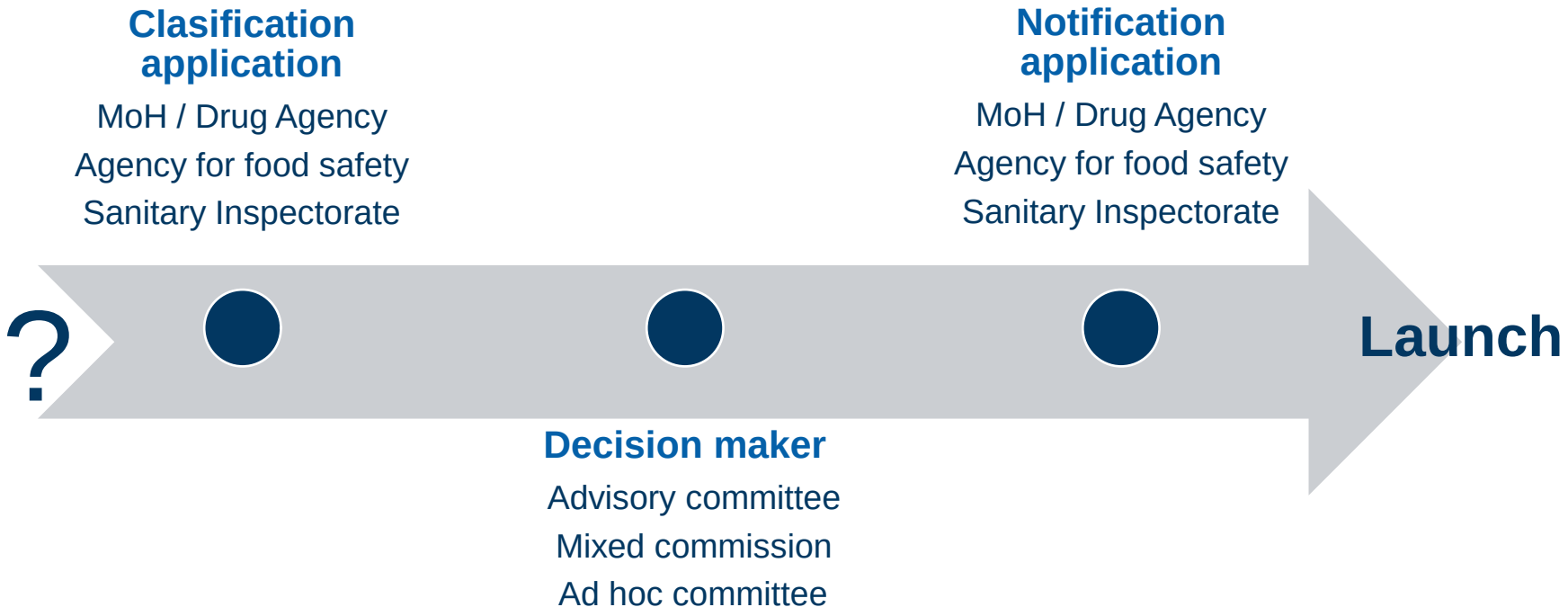
Clear steps lead us to fast outcome

Classification is generally based on a case-by-case assesment of the product taking into account all its characteristics, on a national level.



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Clear criteria for classification of products essential for all stakeholders - herbals

Criteria for classification	Drug product Example 1	Food supplement Example 1
The nature and concentration of ingredient(s)	***Echinacea purpurea* (L.)** - Expressed juice (DER 1.5-2.5:1) - Expressed juice	***Echinacea purpurea* (L.)** Herbals: less than 40% of the therapeutic dose of the substance
Indications / claims	**Therapeutic indications:** WEU: for the short-term prevention and treatment of common cold Traditional use: for treatment of small superficial wounds	**Claims:** No health claim authorized by EC/EFSA.
Presentation of the product	Prevention and/or treatment of diseases or symptoms	Benefits to be clear, accurate and based on scientific evidence
Clinical evidence	On patients	On healthy people
Level of supporting documentation	Dir.2001/83/EC (annex 1) Eudralex Volume 3 Module 3 (Drug substance, drug product)	Composition Specification of final product Labelling

Overlaps between medicines and food supplements

Two products containing the same substance and the same mechanism of action in the same presentation can not be assigned to 2 different categories in the same Member State.

Topic	Example
Key / active ingredients	Probiotics, herbals, vitamins, minerals, etc.
Excipients	Preservatives, antioxidants, flavors, fillers
Dosage forms	Solution, powders, tablets, capsules
Packaging	Bottles, blisters, sachets
Route of administration	Oral
Sales point	Pharmacy
Labelling	Purpose of use

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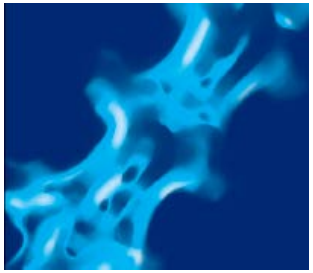
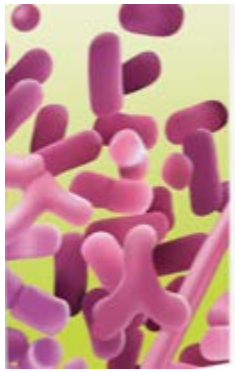
Clear criteria for classification of products essential for all stakeholders – vitamin D



Criteria for classification	Drug product Example 2	Food supplement Example 2
The nature and concentration of ingredient(s)	**Vitamin D3 Lek 1000 i.e. tablete** **Cholecalciferolum** (1)1/2 tablet (12.5 µg or 500 i.e.)/day (2) 1 tablet (25 µg or 1.000 i.e.)/day (max: 4000 IU=100 µg/day)	**Vitamin D** 15 µg (300% RDA) / tablet
Indications / claims	**Therapeutic indications:** - to prevent vitamin D deficiency(1) or - treatment of vitamin D deficiency as a supportive treatment for osteoporosis(2)	**Claims:** Food supplement with vitamin D Supports strong bones
Presentation of the product	Patient information leaflet SmPC	Benefits to be clear, accurate and based on scientific evidence
Clinical evidence	On patients	EFSA has set DRVs 15 µg per day for healthy individuals over 1 year of age
Level of supporting documentation	Dir.2001/83/EC (annex 1) Eudralex Volume 3 Module 3 (Drug substance, drug product)	Composition Specification of final product Labelling

Clear criteria for classification of products essential for all stakeholders – probiotic



Criteria for classification	Drug product Example 3	Food supplement Example 3
The nature and concentration of ingredient(s)	BIFIDOBACTERIUM ANIMALIS 1000000000 CFU	BIFIDOBACTERIUM ANIMALIS 1000000000 CFU
Indications / claims	**Therapeutic indications:** − To establish and maintain intestinal microflora balance − A probiotic against diarrhea and bloating for children and infants.	**Claims:** Special selected bifidobacteria Obligatory sentence: This food supplement cannot replace a well-balanced, varied diet.
Presentation of the product / Dosage form / posology	POWDER FOR ORAL SUSPENSION 1 sachet once to twice a day, preferably with meals	LIQUID AS DROPS 12 drops a day
Clinical evidence	On patients	Strictly following EFSA directives: no health claim for probiotic are allowed
Level of supporting documentation	Dir.2001/83/EC (annex 1) Eudralex Volume 3 Module 3 (Drug substance, drug product)	Composition Specification of final product Labelling

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Differences between medicines and food supplements

European Food Safety Authority

Consumers often do not see the differences between the products

	Drug products	Food Supplements
Quality grade of ingredients and packaging material	Pharma grade or In-house / ICH standards	Food grade
Manufacturing environment	GMP quality principals	HACCP safety norms
Purpose of use	Therapeutic indications (Authorized by Drug Agency)	Claims (EC authorized based on EFSA scientific opinion)
Posology/dosing	Clinical studies / BE studies	RDA, ULs
Quality control	Pharmacopeia standards	Food law standards
Registration	Marketing authorization	Notification or nothing
Side effects	Pharmacovigilance	Nutrivigilance
Competent authority	Drug Agency, MoH	MoH, Ministry of agriculture...
Brand name	Name X	Name Y
Responsibility for Q,S,E	MAH	Manufacturer, Importer Supplier, Distributer

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Food Supplement product development

Cross-functional teams are a prerequisite for successful FS development

Regulatory	R&D, Medical	Marketing
Registration strategy – Legislation – Classification – Documentation – Labelling – Notification – Launch	**Composition** – Vitamins and minerals – Herbal substances – Novel foods ingredients – Food Additives – Other substances – Food contact materials	**Consumer research** **Claims** **Trade names**
	Dosage forms / daily intake – Target population – Claims development and Justification of claims – Clinical studies or literature data	**Commercialization & Marketing** – Promotion and strategy – Education of consumers – Advertisement – Distribution
	Technological concepts – Production standards / Quality – Notification of establishments	
	Controls	

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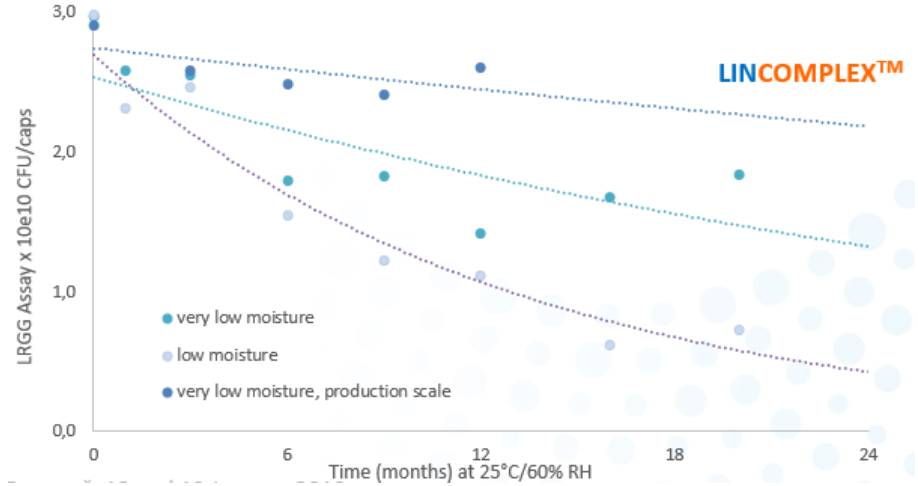
Example LINCOMPLEX™

Quality by Design

Quality integrated in technological concepts and documentation for food supplement product.

Manufactured according to GMP



High stability of probiotic

Innovative primary packaging

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Conclusions

- Harmonized EU and non EU legislation would be a privilege for all stake holders
- Manufacturers & all included in distribution chain are fully responsible for safety of the product and compliance with FS legislation
- As manufacturers we must commit to responsibility and respect EU and local legislation
- Innovative high quality food supplement products build the trust with consumers and authority

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Thank you

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Abbreviations

Abbreviation	Meaning
DA	Drug Agency
FS	Food Supplement
EFSA	European Food Safety Association
EC	European Commission
EU	European Union
GMP	Good manufacturing practice
HACCP	Hazard Analyses of Critical Control Points
ICH	International Conference on Harmonization
MA	Marketing authorization

Abbreviation	Meaning
MAH	Marketing authorization holder
MK	Macedonia
OTC	Over the counter (products)
R&D	Resource and Development
RDA	Recommended Dietary Allowance
UL	Upper Limit
VAT	Value Added Tax
Q,S,E	Quality, Safety, Efficacy

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