

Super(?)foods and Supplements – Risky or Healthy?  
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## Borderline medicinal products/foods – limits of “dual use”

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# Medicinal product

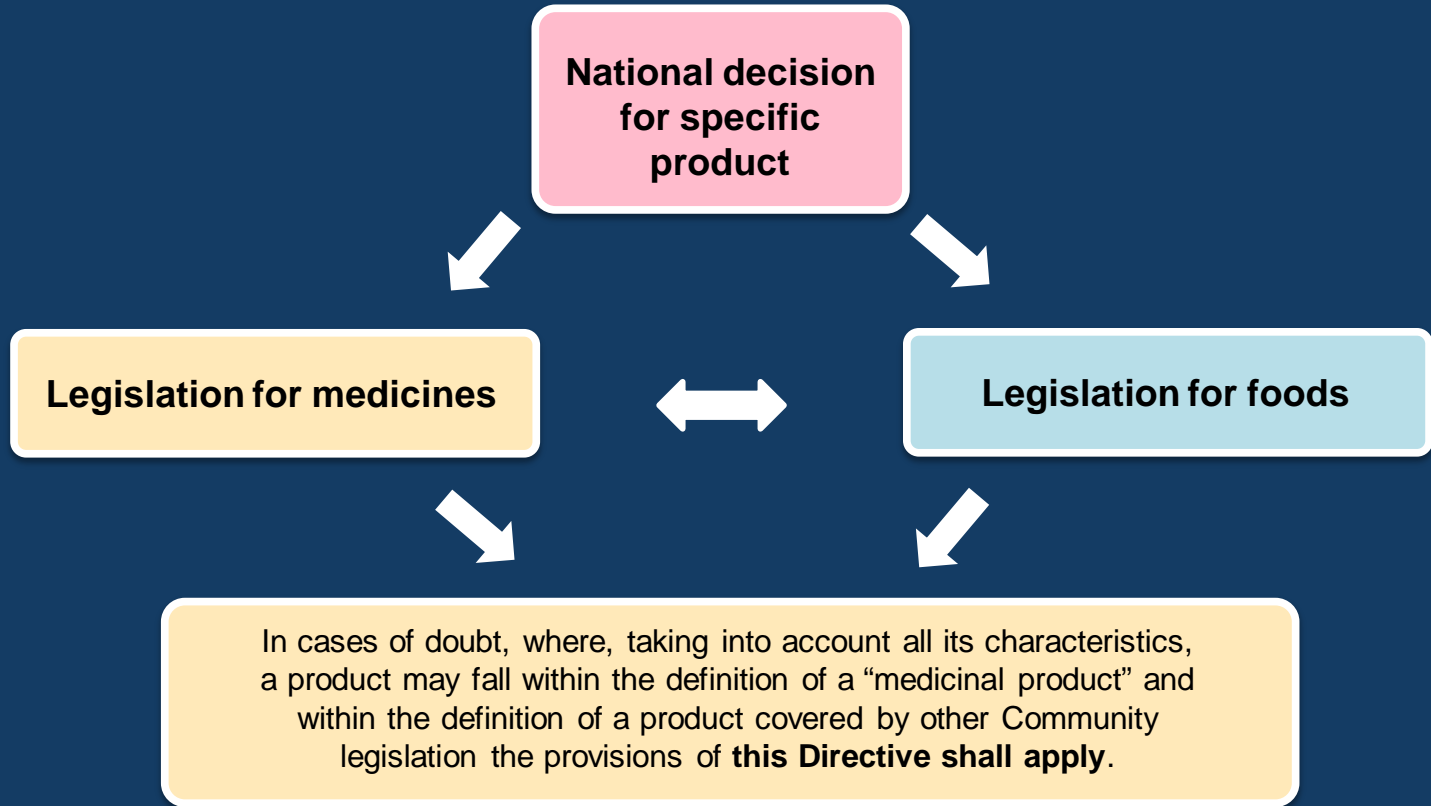
- Any substance or combination of substances presented for treating or preventing disease in human beings,
- or**
- Any substance or combination of substances which maybe administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings is likewise considered a medicinal product

Art. 1(2), 2001/83/EC

# Food supplement

'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;

Art. 2(a), 2002/46/EC



Art. 2(2), 2001/83/EC

# Melatonin – function

## General

- Endogenous hormone
- Regulates sleep
- Increased release after dusk

## Medicine

- Included in several MP
- For insomnia and jetlag
- Dosage from 0.5 mg/day

## Food

- No information as novel food
- Not restricted in 1925/2006/EC

# Melatonin – claims

<u>Art.13(1)</u>	Melatonin	Melatonin contributes to the alleviation of subjective feelings of jet lag	The claim may be used only for food which contains at least 0,5 mg of melatonin per quantified portion. In order to bear the claim, information shall be given to the consumer that the beneficial effect is obtained with a minimum intake of 0,5 mg to be taken close to bedtime on the first day of travel and on the following few days after arrival at the destination.	Alleviation of subjective feelings of jet lag	<u>2010;8(2):1467</u>	<u>Commission Regulation (EU) 432/2012 of 16/05/2012</u>	Authorised	1953
<u>Art.13(1)</u>	Melatonin	Melatonin contributes to the reduction of time taken to fall asleep	The claim may be used only for food which contains 1 mg of melatonin per quantified portion. In order to bear the claim, information shall be given to the consumer that the beneficial effect is obtained by consuming 1 mg of melatonin close to bedtime.	reduction of sleep onset latency	<u>2011;9(6):2241</u>	<u>Commission Regulation (EU) 432/2012 of 16/05/2012</u>	Authorised	1698, 1780, 4080

EU Register of nutrition and health claims made on foods (v.3.6)

# Limitations to use of health claims

The addition of substances to or the use of substances in foodstuffs is governed by specific Union and national legislation, as is the classification of products as foodstuffs or medicinal products. Any decision on a health claim in accordance with Regulation (EC) No 1924/2006 such as inclusion in the list of permitted claims referred to in Article 13(3) thereof does not constitute an authorisation to the marketing of the substance on which the claim is made, a decision on whether the substance can be used in foodstuffs, or a classification of a certain product as a foodstuff.

Preamble (17), Reg 432/2012

# Melatonin – classification outlook in EU

## Function

Classification differs between EU countries:

- No established dose limit (only medicine)
- A limit in food supplements:
  - 0.3 mg/day
  - 0.5 mg/day
  - 1.0 mg/day
  - 2.0 mg/day

## Claims

Authorised health claims only allowed to be used if the product is **not a medicine**.



# Cannabidiol (CBD) – function

## General

- From Cannabis sativa
- Non-psychootropic
- Pharmacologically active
- 100+ clinical trials

## Medicine

### Epidyolex in EU

- Oral solution, extract of Cannabis sativa
- Add-on treatment for Dravet and Lennox-Gastaut syndromes.

### Sativex in EU

- Oromucosal spray
- Combination with THC
- Relief of spasticity in multiple sclerosis.

# Cannabidiol (CBD) – novel food

Without prejudice to the information provided in the novel food catalogue for the entry relating to *Cannabis sativa* L., extracts of *Cannabis sativa* L. and derived products containing cannabinoids **are considered novel foods** as a history of consumption has not been demonstrated.

EU Novel Food catalogue for "Cannabinoids"

- 19 applications under assessment by EFSA
- Currently on hold due to data gaps and uncertainties

EFSA Journal 2022;20(6):7322

# Cannabidiol – classification outlook in EU

## Function

### Oral "CBD oils"

Classification differs between EU countries:

- Not classified by function
- Classified by function
- Dose limits

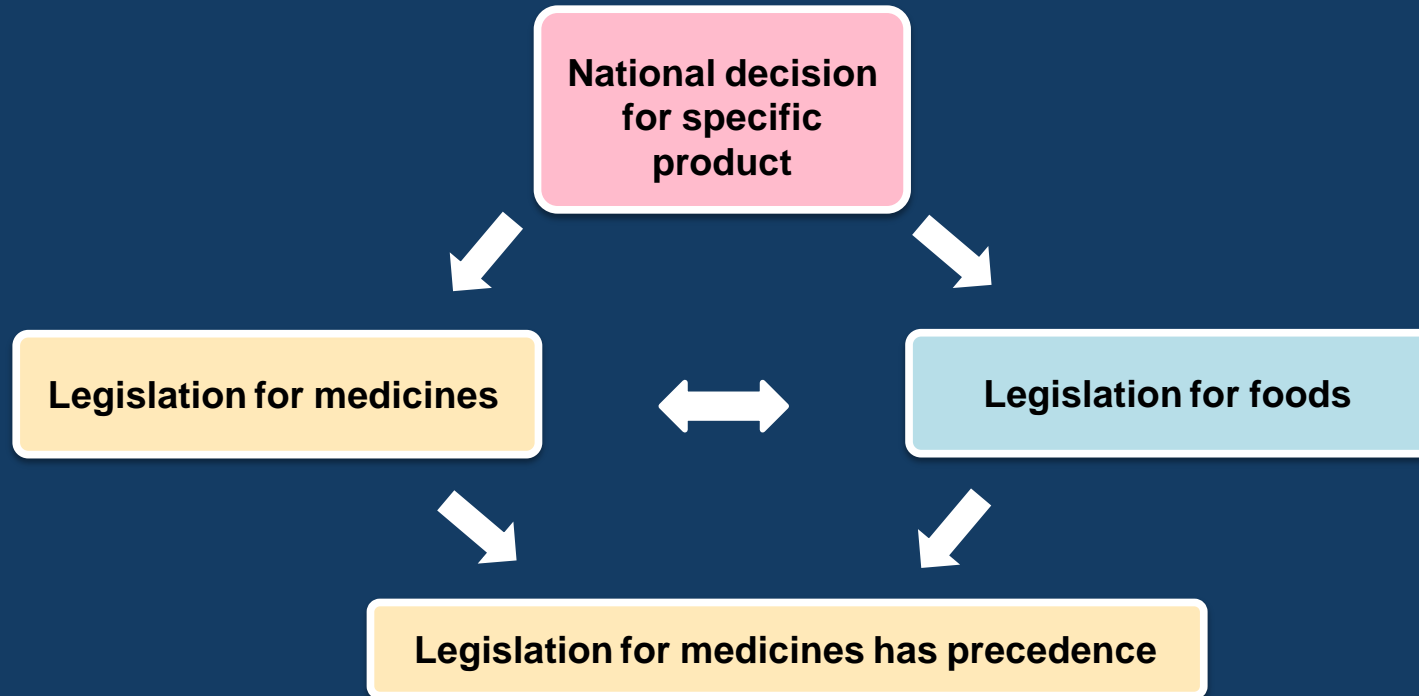
## Claims

Oral "CBD oils" are medicinal products if marketed with medical claims.

## Non-medicinal or unknown

- Herbal materials
- Food spiked with CBD, e.g. chocolate bars

# Conclusions



# Thank you for your attention!

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