

BfR-BVL Joint Meeting: "Super(?)foods and Supplements – Risky or Healthy?" 30 June 2022

EFSA role in the assessment of health claims and novel foods including nutrient sources

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Trusted science for safe food

Signals of concern:

- Emerging Risk signals related to food supplements
- RASFF notifications
- Member States Competent authorities established a topic WG

Issues:

**Authorization/notification/
mutual recognition**

Medicine/Food

Fraud

Safety concerns

- Nutrients (i.e. *mineral* and vitamins) or other substances with a nutritional or physiological effect
- Correct nutritional deficiencies,
- Maintain an *adequate intake* of certain nutrients,
- Not medicinal products

- **EU General Food Law** [Regulation (EC) No 178/2002]
 - Food supplements = Foods
- **Food Supplements Directive** (2002/46/EC)
 - EU harmonised list of vitamins and minerals
 - Addition of substances other than vitamins and minerals is only partially harmonised in the EU
- EU sectorial legislation

Regulation (EC) No 2015/2283 on novel foods

Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods “fortification of foods”

Regulation (EC) No 609/2013 on foods for specific groups;

Regulation (EC) No 1333/2008 on food additives



Responsibility for the safety of food supplements lies with the food business operator placing the product on the market.

No EU harmonised approach

- Notification to the EU member state(s) may be required

No EU harmonised minimum or maximum levels for vitamins and minerals

- National limits

No EU harmonised use of other substances (botanicals)

- National provisions

- **Safety** and **bioavailability** of nutrient sources proposed for addition to the list of permitted substances in food supplements (Annex II of the food supplements directive)
- 2005 to 2009: comprehensive assessment by EFSA of substances used as sources of vitamins and minerals in food supplements, present on the EU market
- For new substances:

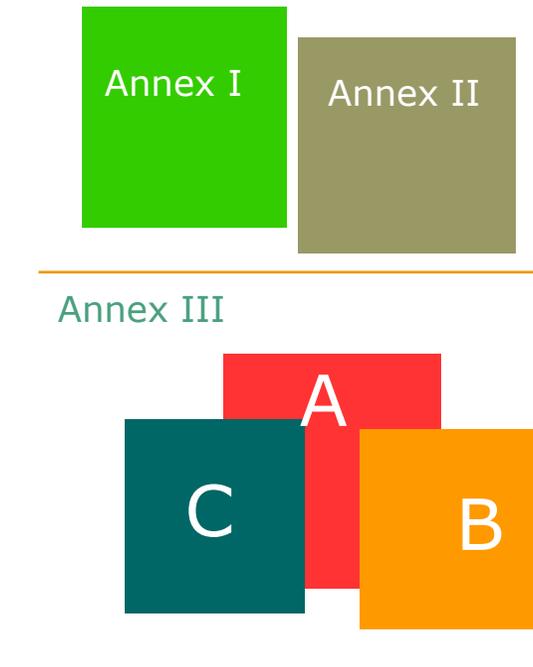


Addition of vitamins and minerals and of **certain other substances** to foods

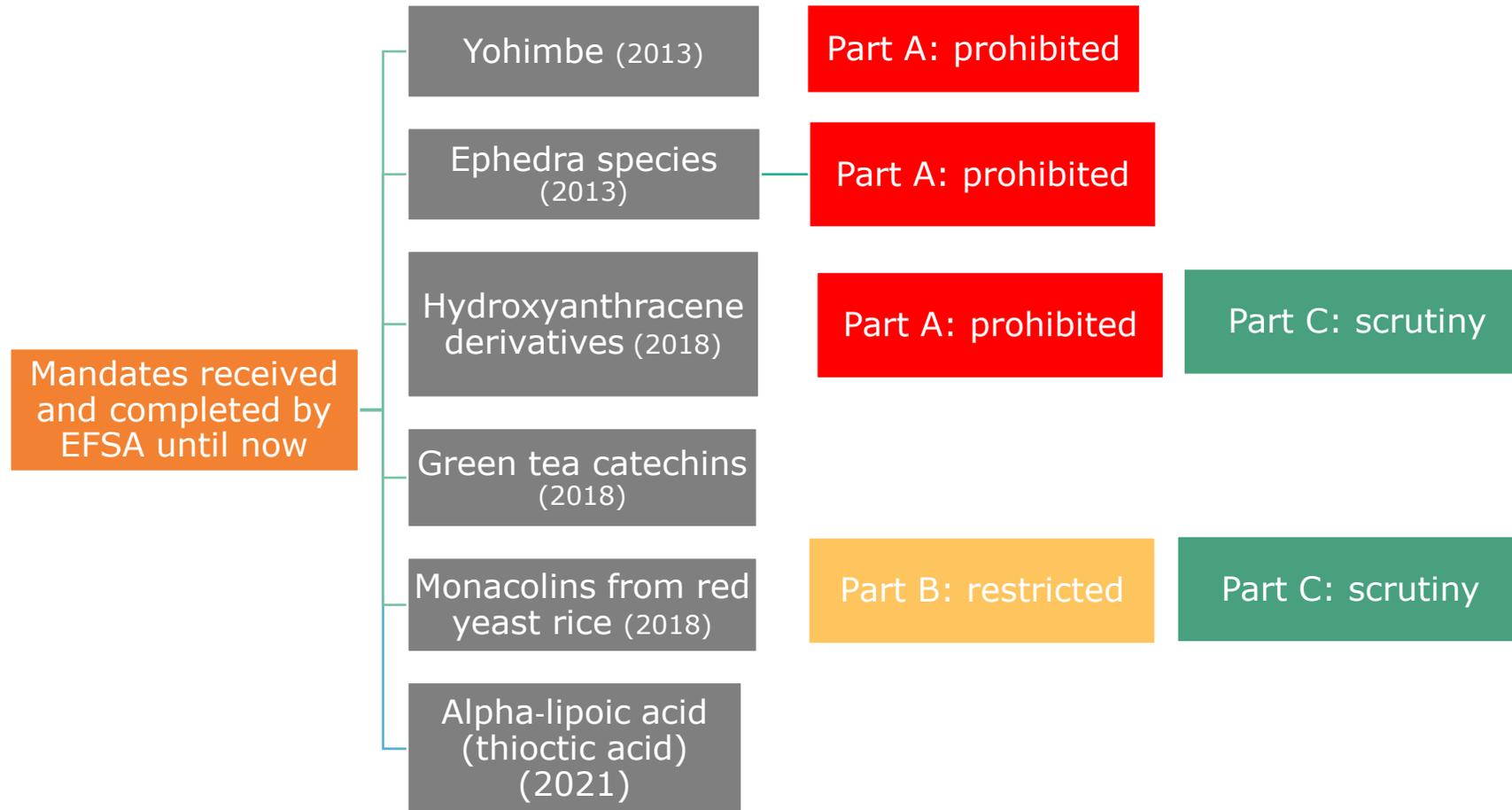
- Annex I: vitamins and minerals which may be added to foods
- Annex II: vitamin formulations and mineral substances which may be added to foods

(REG (EC) 1925/2006 and Article 8 procedure)

- **Annex III: substances whose use in foods is prohibited (A), restricted (B) or under community scrutiny (C)**



"certain Other substances"



A food or ingredient that has not been consumed to a significant degree by humans in the EU before **15 May 1997**

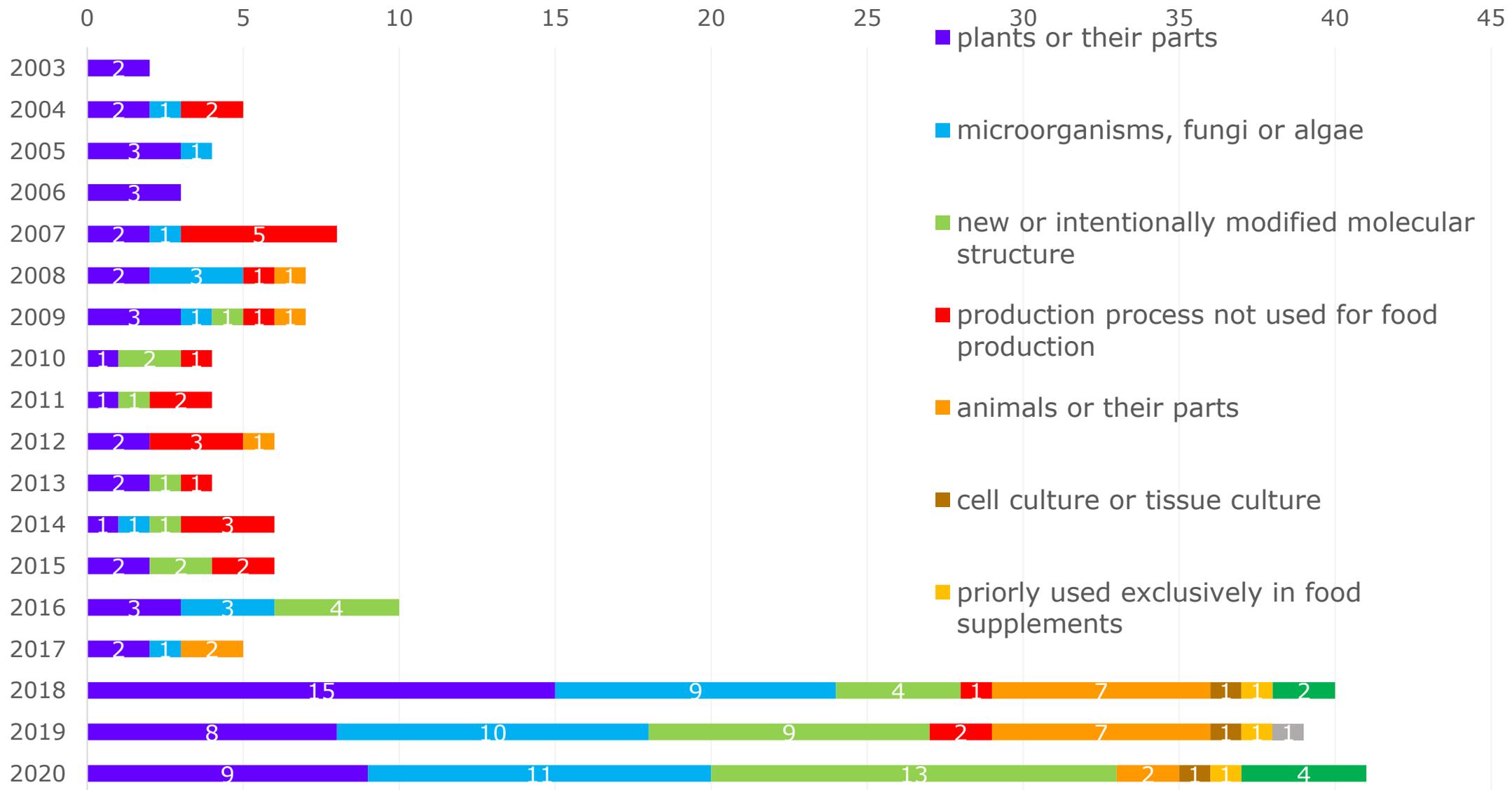
**Newly
synthesised
compounds**

**New
Sources**

**Traditional
Foods
from non-
EU
countries**

**New
Techs/
Processes**

Novel Foods by Category



Updated from Ververis et al. Food Research International, 2020.

- A (natural) food (such as salmon, broccoli, or blueberries) that is rich in compounds (such as antioxidants, fiber, or fatty acids) considered beneficial to a person's health. *Merriam-Webster Dictionary*
- A nutrient-rich food considered to be especially beneficial for health and well-being. *Oxford English Dictionary*
- A food that offers high levels of desirable nutrients, linked to promoting personal health and wellness or preventing disease and sickness. *UC Davis*

No official or legal definition of a superfood.

The marketing of products as superfoods was prohibited in the European Union unless accompanied by a specific authorized health claim supported by scientific evidence.

“Beneficial” effects of ‘superfoods’

- **Dark leafy green vegetables** – high content of fibre and nutrients which may prevent certain chronic diseases.
- **Berries** - full of nutrients and antioxidants which may prevent cardiovascular diseases and cancer and improve digestion.
- **Green tea** - antioxidant-rich with many health benefits including possible cancer prevention.
- **Eggs** - rich in high-quality protein and unique antioxidants. Eating eggs regularly do not increase the risk of heart disease or diabetes.
- **Olive oil** - one of the principle fat sources in the Mediterranean diet. It may be beneficial in reducing heart disease, diabetes and other inflammatory conditions.
- **Salmon** - source of many nutrients, especially omega-3 fatty acids. Limit your consumption of salmon to avoid potential negative effects from contaminants common in fish and seafood.
- **Legumes** - rich in many vitamins, protein and fiber. They may prevent some chronic diseases and support weight loss.
- **Nuts and seeds** - full of fibre and unsaturated fats. They may reduce risk of heart disease and support weight loss.
- **Kefir and yogurt** - fermented dairy beverages with high probiotic content.
- **Garlic** - nutrient-rich food used for supporting immune function and reducing your risk of heart disease and certain cancers.
- **Ginger** - used for its flavor and potential medicinal effects. It may be useful in treating nausea, pain and preventing certain chronic diseases.
- **Turmeric (Curcumin)** may be effective in treating and preventing chronic diseases such as cancer, heart disease and diabetes. It may also aid wound healing and pain reduction
- **Avocado** - rich in fibre, vitamins, minerals and unsaturated fats. Oleic acid is the most predominant MUFA, which is linked to reduced inflammation. Eating avocado may reduce the risk of heart disease, diabetes, metabolic syndrome and certain types of cancer.
- **Sweet potatoes** - a highly nutritious food loaded with carotenoids, which have strong antioxidant properties. They may reduce risk of certain types of cancer and are beneficial for blood sugar control.
- **Mushrooms** - unique antioxidant content. Mushrooms may also play a role in reducing inflammation and preventing certain types of cancers.
- **Seaweed** – antioxidant compounds that can reduce the risk of cancer, heart disease, obesity and diabetes

Claims Regulation (EC) No 1924/2006

Scientific assessment
EFSA

Authorisation

European Commission +
EU Member States
European Council
European Parliament scrutiny

- beneficial **nutritional** properties

nutrition claim

- relationship between a food/constituent and **health**

health claim

- food/constituent significantly reduces a **risk factor** in the development of a human disease

reduction of disease risk claim

- Food category, a food or a food constituent (e.g. a nutrient or other substance, or a fixed combination of nutrients/other substances)
- Function claims **cannot** refer to a disease
- Disease risk reduction claims **cannot** refer to reduction of the risk of a disease, but to reduction of a risk factor for disease
- Subjects with a disease **cannot** be the target population for claims made on food

Efficacy assessment. No safety assessment

- ❑ **dried prunes and normal bowel function (2012)**
<https://www.efsa.europa.eu/en/efsajournal/pub/2712>
- ❑ **Yogurts and improved digestion of lactose in yoghurt in individuals with lactose maldigestion**
<https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2010.1763>
- ❑ **Walnuts and improvement of endothelium-dependent vasodilation**
<https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2011.2074>
- ❑ **Cocoa flavanols and improvement of endothelium-dependent vasodilation**
<https://www.efsa.europa.eu/pt/efsajournal/pub/2809>

The scientific substantiation of these claims was based on human intervention studies showing an effect of the food/constituent on different outcomes which, in the context of the known mechanism(s) by which the food/constituent could exert the claimed effect.

- **Extract from kale (*Brassica oleracea*) leaves and normal vision.** Studies submitted: not randomised, in population of patients with macular degeneration.
- **Extract from *Echinacea angustifolia* and reduction of subthreshold and mild anxiety.** Studies submitted: patients with diagnosed anxiety disorders, standardization of the product.
- ***Lactobacillus paracasei* CBA L74 and defence against pathogens.** Insufficient scientific evidence for the studies provided.
- **A combination of *Lactobacillus reuteri* DSM 17938 i *Lactobacillus reuteri* ATCC PTA 5289 and gum health.** Insufficient scientific evidence: 1 study showed the effect and 1 study did not.
- **A mixture of *Lippia citriodora* leaves extract and *Hibiscus sabdariffa* flower extract and blood pressure.** Insufficient scientific evidence.

Regulatory and Scientific

- Maximum and minimum amounts of vitamins and minerals and other substances in food supplements
- Health claims scientific evidence

■ **Thank you!!!**

- NIF unit staff
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 - Eirini Kouloura

- EREN network

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