

Navigating the regulatory landscape of food supplements in the EU and the UK

PharmaSynergy - OTC
10-11 September 2026, Rome



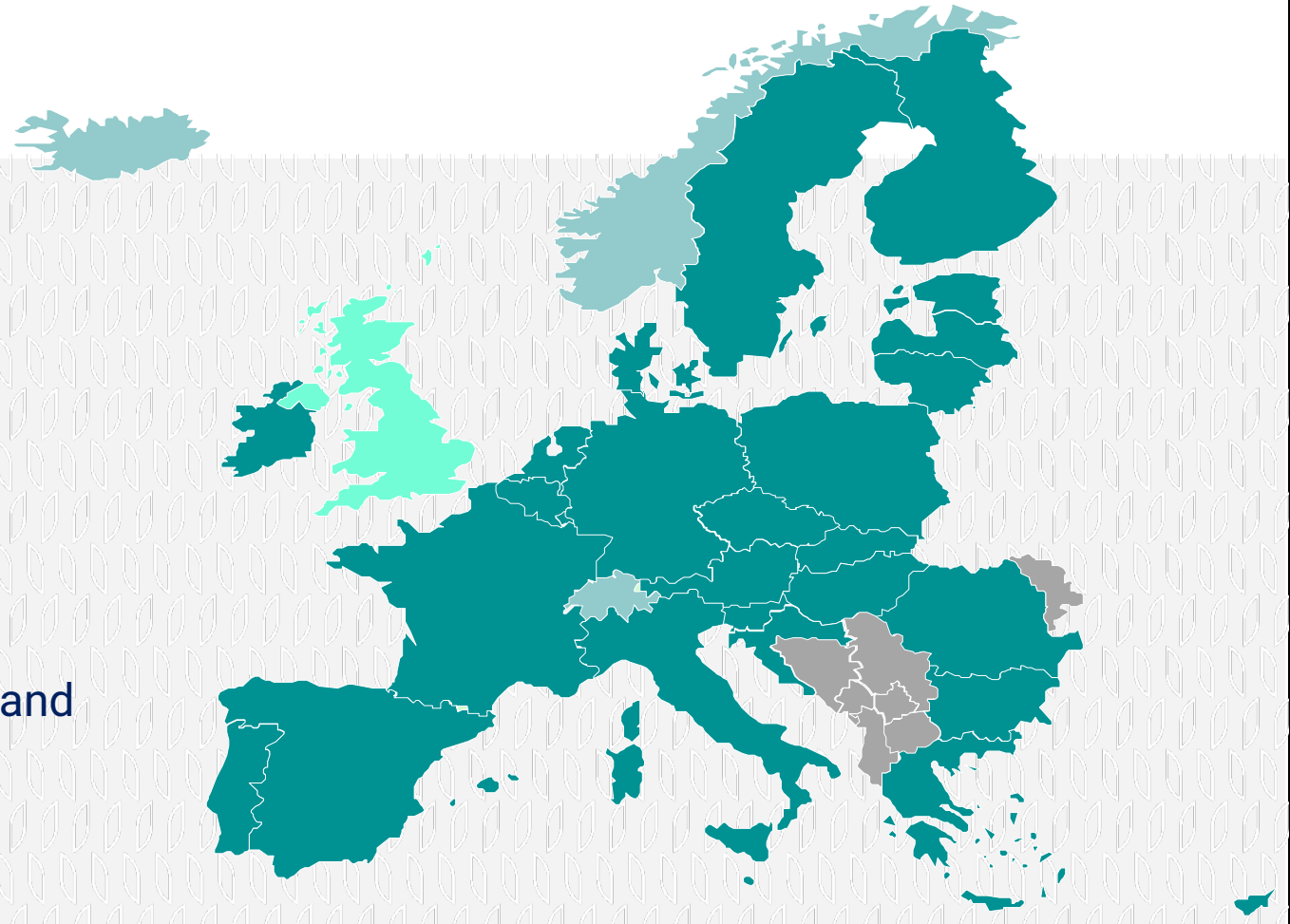
■ The European market

European Union (EU) Single Market

- European Economic Area:
 - 27 EU Member States
 - Iceland, Liechtenstein & Norway
- Switzerland.

United Kingdom

- Great Britain: England, Wales & Scotland
- Northern Ireland.



Regulatory landscape

Product classification



Definition



Permitted ingredients



Food additives, contaminants, food hygiene regulations



Labelling requirements



Nutrition and health claims:
PERMITTED USE AND SUBSTANTIATION REQUIREMENTS



Market access



■ Product classification

- **Authority:** European Food Safety Authority (EFSA) / Food Standards Agency (FSA)
- **Purpose:** To supplement diet/maintain health
- **Claims:** Nutrient content, general health
- **Safety standards:** Food safety standards

Food

- Food supplements

Medicine

- OTC medicine/supplement

- **Authority:** European Medicines Agency (EMA) / Medicines & Healthcare products Regulatory Agency (MHRA)
- **Purpose:** To treat/prevent/cure disease
- **Claims:** Medicinal or therapeutic benefits
- **Safety standards:** High; proven efficacy/quality

■ Product classification: Legal framework

EUROPEAN UNION

- EU General Food Law Regulation No. 178/2002
- Directive 2002/46/EC on food supplements
- Harmonised horizontal regulation: Food hygiene/safety and labelling
- National rules for other bioactive substances

UNITED KINGDOM

- Food law
- Food supplements regulations 2003
- Retained EU law with modifications in Great Britain: England, Scotland & Wales
- EU food law continues to apply in Northern Ireland

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;

■ Permitted ingredients in the EU

Harmonised rules: Pre-market authorisation

- Positive list of vitamins and minerals.
- List of other substances banned or restricted or with conditions.
- Novel foods/ingredients.



European Commission
regulatory decision

■ Permitted ingredients in the EU

Harmonised rules: Pre-market authorisation

- Positive list of vitamins and minerals.
- List of other substances banned or restricted or with conditions.
- Novel foods/ingredients.



Regulation updates between 2009 to 2017

ANNEX I
Vitamins and minerals which may be used in the manufacture of food supplements

1. Vitamins	2. Minerals
Vitamin A (as RE)	Calcium (mg)
Vitamin D (mg)	Magnesium (mg)
Vitamin E (mg α-TE)	Iron (mg)
Vitamin K (mg)	Copper (mg)
Vitamin B1 (mg)	Sodium (mg)
Vitamin B2 (mg)	Zinc (mg)
Niacin (mg NE)	Manganese (mg)
Pantoic acid (mg)	Sodium (mg)
Pyridoxine (mg)	Phosphorus (mg)
Selenium (mg)	Chromium (mg)
Chromium (mg)	Molybdenum (mg)
Vitamin B6 (mg)	Iodine (mg)
Folic acid (mg)	Chloride (mg)
Vitamin B12 (mg)	Phosphorus (mg)
Boron (mg)	Boron (mg)
Vitamin C (mg)	Silicon (mg)

UK ✓

■ Permitted ingredients in the EU

Harmonised rules: Pre-market authorisation

- Positive list of vitamins and minerals.
- List of other substances banned or restricted or with conditions.
- Novel foods/ingredients.



Regulation (EC) No 1925/2006, Art. 8 Procedure, Annex III:

- Prohibited: Ephedra herb; Yohimbre bark; Botanical species with HADs.
- Restricted: Green tea extracts containing epigallocatechin-3-gallate.

UK (Great Britain):

- Prohibited: Ephedra herb.
- Under scrutiny: Yohimbre bark.

■ Permitted ingredients in the EU

Harmonised rules: Pre-market authorisation

- Positive list of vitamins and minerals.
- List of other substances banned or restricted or with conditions.
- Novel foods/ingredients.



Regulation (EU) 2015/2283: Food not used for human consumption to a significant degree within the EU before 15 May 1997.

- Newly developed, innovative food, traditional food
- EU list of authorised novel foods
- EU Novel foods catalogue

UK (Great Britain):

From 1 January 2021,
Food Standards Agency
(FSA)/Food Standards
Scotland (FSS) –
Advisory Committee on
Novel Foods and
Processes (ACNFP)

■ Permitted ingredients in the EU

Harmonised rules: Pre-market authorisation

- Positive list of vitamins and minerals.
- List of other substances banned or restricted or with conditions.
- Novel foods/ingredients.

Harmonised rules: Establishments / lands

- Animal origin ingredients: EU-approved establishments.
- Relevant commodities “cocoa/coffee/oil palm/soya”: Deforestation-free covered by a due diligence statement.

Non-harmonised: National rules

- Botanicals & other bioactive substances.
- Minimum and maximum levels of vitamins and minerals.

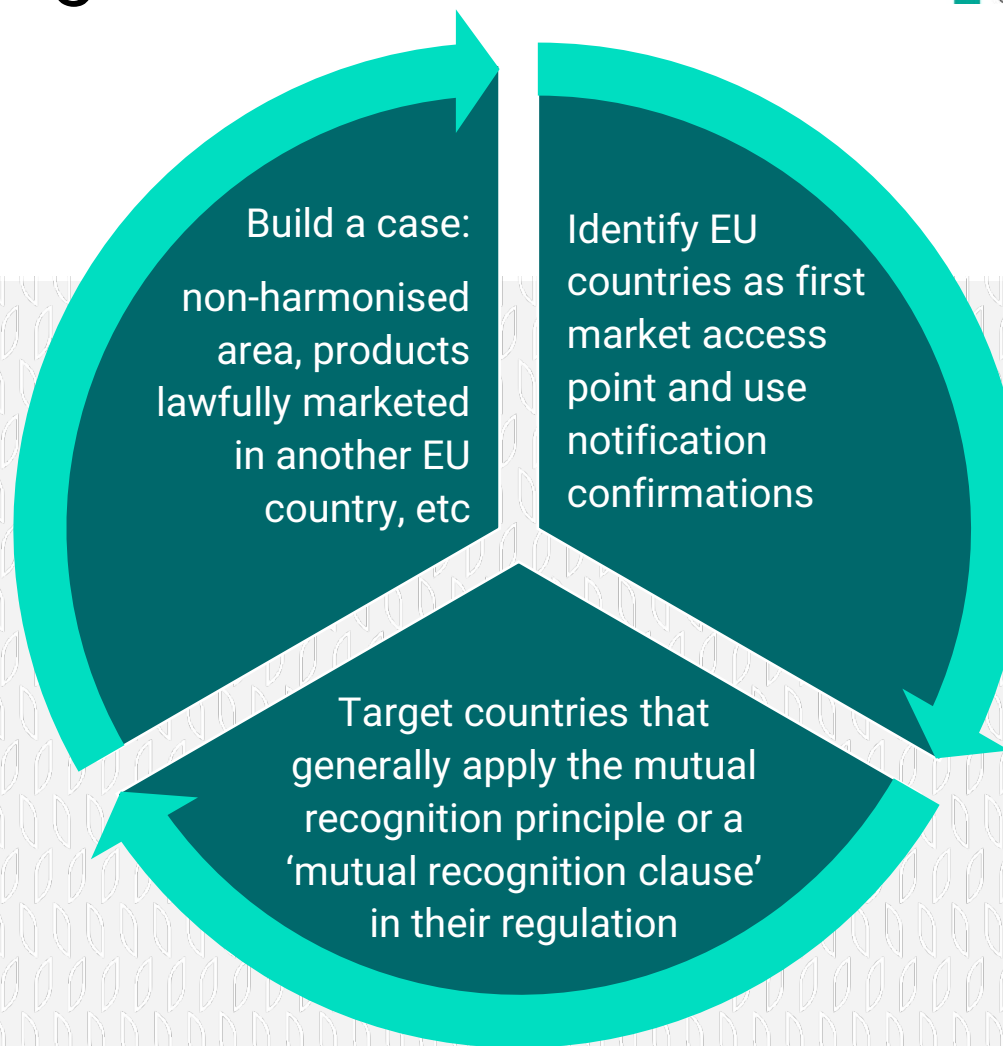
EFSA reference lists

- Probiotic microorganisms in EFSA list for Qualified Presumption of Safety (QPS) status.
- EFSA Compendium of Botanicals.

■ Opportunity for mutual recognition in the EU

Regulation (EU) 2019/515 :

‘Member States may not prohibit the sale on their territory of goods which are lawfully marketed in another Member State, even where those goods have been produced in accordance with different technical rules’.



■ Labelling requirements

01

EU General Food
Regulation No.
178/2002

02

Regulation (EU) No.
1169/2011 on Food
Information to
Consumers (FIC)

Mandatory food
information & nutrition
declaration

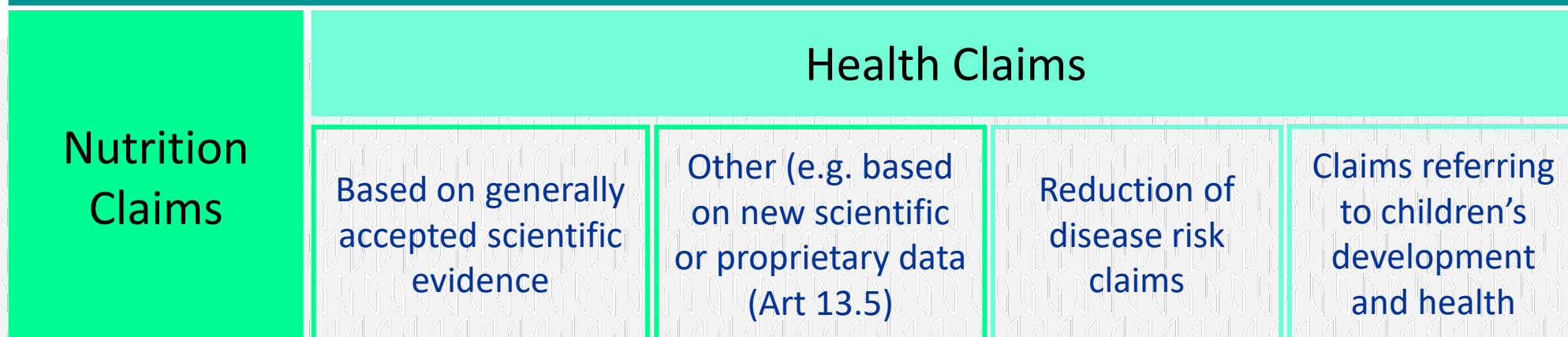
03

Directive 2002/46/EC
on Food Supplements

Specific rules on nutrition
declaration & additional
labelling requirements

Nutrition and health claims

Regulation (EC) No 1924/2006: Commercial communications- Labelling, Advertising



Art 13 – Union List of “generic” approved health claims

Art 18 Authorisation procedure

Art 14-17 Authorisation procedure

➡ **EU Register: Authorised Claims / Non-Authorised**
<https://ec.europa.eu/food/food-feed-portal/screen/health-claims/eu-register>

➡ **Great Britain Register: Authorised claims / Non-authorised**
<https://www.gov.uk/government/publications/great-britain-nutrition-and-health-claims-nhc-register>

**From 1 January 2021,
 FSA/FSS – UK
 Nutrition and Health
 Claims Committee
 (UKNHCC)**

■ Regulation (EU) 2025/40 on packaging - PPWR

2026

- Restrictions on certain single-use plastics.
- Max. limits of PFAS and of heavy metals.
- Register of producers in each EUMS.
- Extended producer responsibility.

2028

- Compostable packaging in fruits and vegetables by 12 Feb. 2028.
- Packaging marked with a harmonised label on material composition from 12 August 2028.

2030

- All packaging recyclable by 2030.
- Packaging minimisation.

2030-2040

- Minimum limits of recycled plastics in plastic packaging.

PFAS = Per- and polyfluorinated alkyl substances.

Market access procedures

Notification		No notification
Belgium	Ireland	Austria
Bulgaria	Italy	Netherlands
Croatia	Latvia	Sweden
Cyprus	Lithuania	UK
Czech Republic	Luxembourg	
Denmark	Malta	
Estonia	Poland	
Finland	Portugal	
France	Romania	
Germany	Slovakia	
Greece	Slovenia	
Hungary	Spain	

Market entry strategy - EU

STEP 1 → STEP 2 → STEP 3 → STEP 4 → STEP 5 → STEP 6

Check
status of
ingredients
against EU
harmonised
rules

Check
status of
ingredients
against
national
rules

Check
status of
ingredients
against
national
rules: GB.

Opportunity
for mutual
recognition

Labelling
rules

Labelling
rules

Opportunity
and
conditions
of use of
nutrition
and health
claims

Opportunity
and
conditions
of use of
nutrition
and health
claims

Market
access
procedures

Key considerations

- EU & UK comprehensive legal frameworks for food supplements: consumer safety, product quality and accurate information.
- Regulation and procedures for novel foods/ingredients: EU v. UK.
- Future SPS Agreement.
- Pressure for EU harmonised rules on botanicals and bioactive substances.
- Pharmacies/health & wellness stores: Rise online sales and cross-border trade.
- Need to adapt rules to new trends and scientific findings.
- Balancing innovation and consumer safety: *Need for a high-performing EFSA to boost the competitiveness of the EU agri-food sector.*



Rue de Lausanne, 7 (bte 3)
1060 Brussels | Belgium
+32 (0)2 251 04 59
davidpineda@dpeic.com



This presentation is the property of DPE International Consulting SRL
The information contained in this presentation may be subject to change as standards and regulations are in constant development
This material was used in an oral presentation and is not a complete record of the discussions
© 2026 Copyright DPE International Consulting SRL