

Regulatory landscape for biostimulants and biofertilizers in the EU/UK - status and outlook

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What's what: EU terminology



Biostimulants

(EU Fertilising Products Regulation (EU) 2019/1009, FPR):

- ▶ Substances, mixtures or microorganisms applied to plants, not as such inputs of nutrients, but nevertheless stimulate plants' natural nutrition processes. This occurs independently of the product's nutrient content with the sole aim of improving one or more of the following characteristics of the plant or the plant rhizosphere:
 - (a) nutrient use efficiency,
 - (b) tolerance to abiotic stress,
 - (c) quality traits, or
 - (d) availability of confined nutrients in the soil or rhizosphere
- ▶ Product function category (PFC) 6 [and 7: product blends]:
 - 6A. Microbial plant biostimulants (see CMC 7 below)
 - 6B. Non-microbial plant biostimulant (organic or inorganic substances including amino acids, humic substances, seaweed extracts and surfactants)
- ▶ Component material category (CMC) 7 [and 1, 2, 6, 8, 11]:
 - Micro-organisms (incl. dead/empty cells and non-harmful media)
 - No processing other than [freeze-] drying
 - *Azotobacter* spp., Mycorrhizal fungi, *Rhizobium* spp., *Azospirillum* spp. only!

Biofertilizers

(**not** an EU regulatory category; partly **within scope** of the FPR):

- ▶ ... are preparations containing living cells or latent cells of efficient strains of microorganisms that help crop plants' uptake of nutrients by their interactions in the rhizosphere when applied through seed or soil
- ▶ ... accelerate certain microbial processes in the soil which augment the extent of availability of nutrients in a form easily assimilated by plants
- ▶ ... can be grouped in different ways based on their nature and function:
 - N₂ fixing biofertilizers, e.g., *Azotobacter*, *Anabaena*, *Nostoc*, *Rhizobium*, *Frankia*, *Azospirillum*
 - P-solubilizing biofertilizers, e.g., *Bacillus subtilis*, *Pseudomonas striata*, *Penicillium* sp., *Aspergillus awamori*
 - P-mobilizing biofertilizers, e.g., *Mycorrhiza*: *Glomus* sp., *Gigaspora* sp., *Acaulospora* sp., *Scutellospora* sp. & *Sclerocystis* sp., *Laccaria* sp., *Pisolithus* sp., *Boletus* sp., *Amanita* sp., *Pezizella ericae*
 - Biofertilizers for micronutrients, e.g., *Bacillus* sp.
 - Plant growth-promoting rhizobacteria, e.g., *Pseudomonas fluorescens*

Source: EUBIA (European Biomass Industry Association)

EU regulatory in a nutshell

Option A: FPR registration



- ▶ **Regulation (EU) 2019/1009/Fertilising Product Regulation (FPR)** - applicable since 16 July 2022.
- ▶ FPR includes **mineral fertilisers, organic fertilisers, soil improvers and (plant) biostimulants** (microbial and non-microbial) .
- ▶ **Starting materials** of a fertilising product **shall be classified** in any of the current 15 **Component Material Categories (CMC)**.
- ▶ Depending on the categorization of the product and the starting materials, a modular **conformity assessment** is performed.
- ▶ Under **FPR** there is **no national registration process** (option B). The product is **CE-Marked** if it is in conformity with FPR (EU declaration of conformity).

EU regulatory in a nutshell

Option B: National scheme registrations



- ▶ Parallel to FPR, companies may **register** fertilizing products **according to national legislations** in each EU member state.
- ▶ Austria, Portugal, Finland and Denmark have **revised** their **national fertilizer regulations** to adapt them more and more **to the FPR**.
- ▶ Some EU member states (i.e., Austria and Portugal) still evaluate and register **biostimulants with microorganisms other than those listed in the FPR** under their national regulations.
- ▶ **Mutual recognition** (Regulation (EU) 2019/515) is **also admissible** in many EU Member States incl. Austria, Czech Republic, Slovakia, Germany and Portugal. → similar approach taken in UK.
- ▶ Until now, there are **no indications** from Member State authorities **that national fertilizer laws will be withdrawn**. Updates and amendments to adapt national regulations to the regulatory, legal, technical and scientific state of the art take place continuously.
- ▶ **Depending on product type** (e.g. inorganic/organic fertiliser, soil aid, plant aid, "biostimulant") registration **procedures and data requirements** may **vary significantly** between Member States.

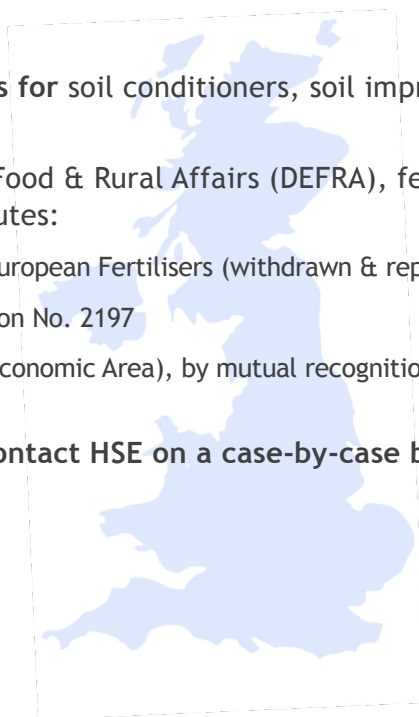
EU regulatory - FPR amendments



- ▶ Studies for the inclusion of new CMCs and additional microorganisms under CMC 7 are ongoing.
- ▶ Objectives of **positive list extension** study for **CMC 7** (Austrian Institute of Technology, AIT):
 - ▶ Developing criteria and methodologies for an assessment of „notified“ microorganisms (from EU survey)
 - ▶ Assessment of the microorganisms (> 100 strains) based on data in public domain (literature)
- ▶ Challenges:
 - ▶ Where in the process are data on *a)* the component and on *b)* the fertilizer product evaluated ?
Two-step process ? Duplication of evaluation work ?
 - ▶ No EU structure/process for evaluation → proposal of Coordination Group of Notified Bodies (NOBO), CEG-FP meeting 27 Nov. 2024
 - ▶ No data protection (relevant if strain-specific data for components are deemed necessary)
- ▶ Industry proposal for CMC7 development (EBIC):
 - ▶ Immediate inclusion of proven microorganisms (all species/strains approved on national level in Member States)
 - ▶ Continuing with ongoing AIT study with timely evaluation of notified microorganisms

UK regulatory in a nutshell

- ▶ **Currently, there are no specific regulations for soil conditioners, soil improvers and biostimulants in UK domestic legislation.**
- ▶ According to Department for Environment, Food & Rural Affairs (DEFRA), fertilisers can be placed on the UK market legally according to three routes:
 - ▶ Route 1. EU Regulation (EC) No. 2003/2003 European Fertilisers (withdrawn & replaced in EU by FPR)
 - ▶ Route 2. Under the UK 1991 Fertiliser Regulation No. 2197
 - ▶ Route 3. For members of the EEA (European Economic Area), by mutual recognition (Regulation (EU) No. 2019/515).
- ▶ **For biostimulants, it is recommended to contact HSE on a case-by-case basis.**



UK approaches

Route 1: (EC) 2003/2003

- Where a fertiliser complies with (EC): 2003/2003 it can be sold freely in the UK without further approval or registration process.
- Products that do not fall under (EC): 2003/2003 can be marketed under the domestic regime outlined in the Agriculture Act 1970, where article 66 (1) describes fertilisers as "used for the cultivation of crops or plants of any description, including trees".
- If a product does not fit within either legislation it cannot be marketed as a fertiliser in the UK.



Route 2: Original UK regulation

According to the Fertilisers regulation 1991, fertilisers for sale in the UK do not have to be registered.

This specifies the labelling and packaging of the product and places a responsibility on the manufacturer to declare the nutrient content of the product.

Route 3: MR

Mutual recognition of goods lawfully marketed in another EU Member State according to (EU) 2019/525.

It is currently unclear if this is still an acceptable route to the UK market for EU companies following Brexit.

UK outlook

- ▶ UK Government published two articles describing changes to regulations:
 - ▶ UK National Action Plan (NAP) 2025*
 - ▶ Policy paper on new approaches to ensure regulations support growth
- ▶ UK NAP :
 - ▶ Sets out the 4 government (DEFRA, Scottish Government, Welsh government & N. Ireland executive) strategy for managing pesticide use and minimising risk. Any changes will take into account the Windsor framework for N. Ireland.
 - ▶ Objectives include promotion of IPM and development of lower risk biopesticides (i.e., microbials, semiochemicals, plant-derived chemicals and other novel alternative products).
- ▶ Policy changes: over-haul the UK regulatory system**:
 - ▶ Describes how HSE and DEFRA will consult on how international approvals can be recognised to reduce the time and cost to bring chemical products to the GB market.

*<https://www.gov.uk/government/publications/uk-pesticides-national-action-plan-2025/uk-pesticides-national-action-plan-2025-working-for-a-more-sustainable-future>

** <https://www.gov.uk/government/publications/a-new-approach-to-ensure-regulators-and-regulation-support-growth/new-approach-to-ensure-regulators-and-regulation-support-growth.html>

THANK YOU
for your
attention !!!

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