

The growing opportunity for bio-based fertilisers in the EU

Regulation (EU) 2019/1009 unlocks new commercial opportunities for fertilisers previously excluded from the single market. Here, we look at what manufacturers of bio-based fertilising products can do to maximize the opportunity of the changes.



The new fertiliser regulation: what's changing



The new EU rules create a level playing field for EU-wide trading of mineral and bio-based fertilisers.

Manufacturers of innovative bio-based fertilising products are set to benefit from new EU legislation. On 16 July 2022, Regulation (EU) 2019/1009 laying down rules on the making available on the market of EU fertilising products came into effect, providing clarity where previously these products sat in a regulatory no man's land.

Existing EU fertiliser regulation was geared towards products composed of mined or chemically produced inorganic materials. Fertilising products such as organic fertilisers weren't covered. So, while they could be marketed as 'national fertilisers' in individual EU countries, they didn't enjoy free access to the single market.

The new rules mean this has now changed. Regulation (EU) 2019/1009 harmonises the regulatory framework for quality and safety standards, creating a level playing field for EU-wide trading of mineral and bio-based fertilisers. It also covers 'fertilising products' in the broadest sense. So, in addition to fertilisers which provide nutrients, it legislates for products such as soil improvers and growing media.

Biostimulants are one of the fertilising products covered by the new regulation. Currently, they fall into a 'grey-area' between plant protection products (regulated under (EU) 1107/2009) and fertilisers. Procedures and requirements differ significantly between EU member states, leading to confusion between applicants and evaluating authorities, but this will no longer be the case. We wrote a separate piece about how the changes will impact biostimulants here: www.tsgconsulting.com/advisory/new-eu-fertiliser-regulation



Fertilising product function categories

The new regulation applies to the design, manufacture and placing on the market of fertilising products, categorised according to function:

1. Fertilisers (including inorganic, organo-mineral and organic fertilisers) which provide nutrients

2. Liming materials for the modification of soil acidity

3. Soil improvers, which maintain, improve or protect soil properties

4. Growing media, i.e., materials other than soil provided for plants or mushrooms to grow in

5. Inhibitors, which improve the nutrient release patterns of fertiliser by delaying or stopping the activity of specific groups of microorganisms or enzymes

6. Plant biostimulants, which stimulate plant nutrition processes to improve nutrient use efficiency, tolerance to abiotic stress, quality traits and/or availability of confined nutrients in the soil or rhizosphere

7. Fertilising product blends, comprising two or more of the above product function categories

Compliance with the new regulation is not mandatory. Manufacturers of fertilising products have a choice: to utilise the new rules and enjoy free access to the single market, or operate country-by-country under pre-existing national rules. However, differences in national requirements mean the latter option is often a complicated, lengthy and costly route to international trade.



Gaining access to the single market



Products making multiple functional claims are categorised as 'fertilising product blends', meaning they must demonstrate conformity with all relevant categories.

Under the new regulation, any fertilising product that demonstrates conformity will be able to obtain CE marking. Products bearing the CE mark can be traded across the entire European Economic Area (EEA) without restrictions.

While details of the conformity assessment process are yet to be published, manufacturers can get ahead with preparation. The regulation's legislative framework sets out expectations and requirements for the fertilising product categories, component materials and labelling. Planning and data gathering for these elements can be complex and time consuming, so now is a good time to start.

Determine the product function category

Since product function category dictates overall safety and quality requirements, it's important to determine this at the earliest opportunity.

Annex I of the regulation details product function category requirements and criteria, as well as those for any sub-categories. For instance, it specifies that products categorised as 'organic fertiliser' must contain organic carbon and nutrients of solely biological origin. It outlines the limit values for various contaminants as well as zinc, copper and pathogens. And it covers the different nutrient requirements for the sub-categories of solid and liquid forms of organic fertiliser.

Demonstrating conformity with relevant requirements and criteria will be central to the product authorisation process. In some cases, a product could perform multiple functions, however it may be prudent to limit

product claims to one. Products making multiple functional claims are categorised as 'fertilising product blends', meaning they must demonstrate conformity with all relevant categories. This can be highly complex and may not be viable from a commercial perspective.

If you're considering applying for authorisation, start by assessing your product/s in relation to the product function category requirements. It may be advisable to switch to an alternative category, and in some cases, product reformulation might be necessary.



Analyse the component material categories

The new regulation also specifies component material categories for use in the manufacture of fertilising products. These encompass 11 designations:

1. Virgin material substances and mixtures
2. Plants, plant parts or plant extracts
3. Compost
4. Fresh crop digestate
5. Digestate other than fresh crop digestate
6. Food industry by-products
7. Microorganisms
8. Nutrient polymers
9. Polymers other than nutrient polymers
10. Derived products within the meaning of Regulation (EC) No 1069/2009 (laying down health rules as regards animal by-products and derived products not intended for human consumption)
11. By-products within the meaning of Directive 2008/98/EC (on waste)

As with the product function categories, the legislation describes requirements for each component material category in detail. The 'plants' designation is a good example. According to Annex II of the regulation: "An EU fertilising product may contain plants, plant parts or plant extracts having undergone no other processing than cutting, grinding, milling, sieving, sifting, centrifugation, pressing, drying, frost treatment, freeze-drying or extraction with water or supercritical CO₂ extraction."

It's useful to look at component material requirements in readiness for the authorisation process. You might start gathering data, ascertaining gaps that need to be filled or ingredient substitutions that may help with conformity. It's likely that this will involve extensive liaison with raw material suppliers, so an early start is advisable.

Think about labelling requirements

Annex III of the new regulation sets out labelling requirements for fertilising products across all product function categories and subcategories. General items for inclusion cover everything from nutrient content to instructions for intended use and recommended storage conditions. There are also specific labelling requirements for individual product function categories. For instance, organic fertilisers need to declare the ratio of organic carbon to total nitrogen.

Information about component materials must be also included on the packaging label or, if it's too small, on an accompanying leaflet. The information also needs to be in a language which is easily understood by end-users, as determined by the member state concerned.

Meeting the labelling requirements of EU legislation in an efficient and effective way can be a challenge. It's important to allow adequate time for this so it doesn't stall overall progress.

New opportunities



Manufacturers of alternative fertilisers have a golden opportunity to extend their market reach. Inorganic fertilisers are already facing scrutiny due to the energy consumption and carbon emissions associated with their production. The new regulation's stricter contaminant limits for elements such as cadmium present further challenges for these mineral and phosphate fertilisers.

Innovative bio-based fertiliser products have much to offer as the EU makes strides with its sustainability agenda. The new EU fertiliser regulation eradicates disparities that previously put these products at competitive disadvantage, opening up new opportunities for manufacturers across the EEA.



How can TSG Consulting help?

TSG's plant protection team is well-versed in the new EU fertiliser regulation. We can support you through the entire authorisation process, from determining product function category to the submission of dossiers once the authorisation process has been finalised. Find out more about our agrochemical regulatory services here: www.tsgconsulting.com/markets/#agrochemicals

Get in touch at info@tsgconsulting.com if you'd like an informal chat with our plant protection team.



About TSG Consulting

TSG Consulting provides companies with high quality regulatory and scientific consulting services. We help clients worldwide address the technical and regulatory issues in taking their products to market in multiple jurisdictions. Our scientific expertise, regulatory knowledge and understanding of local nuances enable our clients to navigate the complex and ever-changing regulatory landscape across the globe.

We serve a number of key markets and industry sectors including agricultural, industrial, consumer, food and beverage, animal health, and medical. Our teams comprise scientists and regulatory experts – many of whom have previously held positions at regulatory agencies, departments, and in industry. This combination of science, regulatory expertise and knowledge of how institutions and industry operate provides our clients with superior and well-rounded guidance. TSG Consulting has offices in Germany, Spain, UK, USA and Canada. TSG is a Science Group (London listed) company.

For further information visit us at:

www.tsgconsulting.com or
[email info@tsgconsulting.com](mailto:info@tsgconsulting.com)



TSG Consulting
1150 18th St NW
Suite 475
Washington DC
20036
USA

TSG Consulting
Concordia House
St James Business Park
Grimbald Crag Court
Knaresborough
North Yorkshire
HG5 8QB
UK