

## THOUGHT LEADERSHIP

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### The EU Fertilising Products Regulation — Are You Prepared?

The EU's FPR harmonises fertiliser regulations, creating new business challenges and opportunities

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**Valued at approximately \$20 billion, the European fertiliser market—dominated by France, Germany, and the UK—currently represents about 10% of the global fertiliser market. Despite the size of the market, regulation of fertilising products up to now has not been fully harmonised across Europe.**

The current fertiliser legislation in the EU, Regulation (EC) No. 2003/2003, only harmonises the quality certification process of inorganic fertilisers (i.e., EC fertilisers). However, non-EC fertilisers and other fertilising products are regulated following national rules, which can be disproportionately cumbersome. While some countries have well-developed regulatory processes for these product types, others have no legislative framework.

As of July 2022, the quality certification process of fertilising products will be harmonised across the EU through the Fertilising Products Regulation (*FPR; Regulation (EC) No. 2019/1009*). In addition to inorganic fertilisers, the FPR will harmonise the quality assessment procedures for other fertilising products, such as organic fertilisers, organo-mineral fertilisers, soil improvers, liming materials, plant biostimulants, inhibitors, and fertilising product blends.

For the EU, manufacturers, importers, and traders of fertilising products who want their products to move freely within the single market will be forced to adapt their current practices to the requirements of the FPR. However, with the UK out of the EU, it is still to be determined how certain fertilising product types covered within the framework of the FPR will be regulated in the UK.

#### Market Impact on Regional Businesses Amidst Changing Regulations

Between global and regional competition, Brexit, and constantly evolving regulatory mandates from the EU's

governing bodies, manufacturers are hard-pressed to keep up with large-scale changes. However, in addition to inorganic fertilisers, FPR will harmonise the regulation of additional fertilising product-types, opening the single market up to products worth at least \$5 billion in market value.

With 1.6 million farmers receiving almost 85% of all European agricultural subsidies, fertiliser manufacturers, traders, and distributors cannot afford to be locked out of this lucrative market by regulatory roadblocks. With the top players in the region applying market pressure on smaller regional businesses—e.g., Yara International ASA poised to establish Europe's first large-scale green ammonia project in Norway—it would be unwise for smaller regional players to allow delays in product certification under the FPR to create barriers to entry on the open fertiliser market.

Products complying with the requirements of the FPR will carry a Conformité Européenne (CE) marking and can be sold in all EU Member States without the need to fulfil additional requirements of national legislations. It is the responsibility of the business entity wishing to place a fertilising product on the EU market under the FPR to ensure that the product complies with the relevant requirements for their product type, with regards to product function, component materials, and labelling. The business entity will be required to prepare a technical dossier for evaluation by a notified body of choice for conformity with the relevant FPR requirements and to draft an EU declaration of conformity.

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## The Importance of Properly Identifying Your Product's CMC

Complying with the FPR can be challenging because a product belonging to one product function category (PFC) may contain ingredients belonging to different component material categories (CMCs). Therefore, it is important for applicants to carefully identify the CMCs applicable to each ingredient in their product. This will help ensure that the correct data requirements for each CMC are fulfilled and a complete technical dossier is submitted for evaluation. Submitting an incomplete dossier may result in a delayed quality assessment process, increased cost for businesses, or an unsuccessful application.

Different quality assessment modules are applicable depending on the PFC and CMCs relevant for the fertilising product. Although a list of all notified bodies can be accessed through the Nando Database on the European Commission webpage, applicants should be aware that not all notified bodies will have the accreditation for the quality assessment module relevant for their fertilising product. It is therefore important for businesses to seek expert guidance in identifying the relevant quality assessment module for their fertilising product and in selecting a notified body. This will facilitate their application process and ensure that their technical documentation is evaluated appropriately and in a fair manner.

If the notified body determines that the fertilising product has met all the relevant FPR requirements, it will issue a certificate to the business entity declaring that all requirements have been met. The business entity placing the product on the EU market may then affix a CE mark on the product package or on the documentation accompanying the fertilising product in case it is not packaged.

## Marketing Fertilising Products in the UK

Fertilisers designated as EC-fertilisers may continue to be sold in the UK for 2 years from 1 January 2021. Following

the transition period, products labelled EC-fertilisers may not be sold on the UK market. It is advised that fertilising products intended for sale in the UK are manufactured and labelled following the requirements in the domestic regulations, Regulation 2006 No 2468 and the Fertilisers Regulation 1991 as amended. Products previously manufactured according to the requirements for EC fertilisers may only be sold in the UK as UK fertilisers provided the manufacturer is established in the UK and an accredited UK laboratory has been used to test the product.

Besides inorganic fertilisers and liming materials, the domestic fertiliser regulations in the UK do not cover other fertilising product types incorporated into the FPR. It has not yet been determined how the quality of these fertilising product types will be assessed in the UK. Therefore, manufacturers and importers of these product types wishing to access the UK market are advised to continue monitoring regulatory changes in the UK and seek expert guidance.

With tougher standards and regulations being implemented by the EU (amidst environmental, economic, and political pressures) in almost every industry, many companies are forced to innovate and adapt quickly to continue doing business, presenting both challenges and opportunities for these organizations. The companies who can conform to the new regulations quickly will be the most likely to not only survive but thrive in these highly competitive markets.

## How Exponent Can Help

Exponent's team of experts can help you assess your fertilising products to determine the specific requirements for your product type in the EU and the UK. For compliance with the FPR, we can provide advice regarding data generation and assist you with preparing your technical dossier. We are also able to help identify competent notified bodies to evaluate your registration documents and liaise with them on your behalf.



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