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Information on Regulation (EU) 2019/1009 laying down rules on the making available on the market of EU fertilising products

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Introduction

1. The purpose of this document is to inform all interested parties, which includes Government Departments, agencies and industry stakeholders, about the new Regulation on Fertilising Products (FPR). The new Regulation (EU) 2019/1009 lays down rules on the making available on the market of EU fertilising products. It repeals Regulation (EC) No 2003/2003[1] and amends Regulation (EC) No 1069/2009[2] and Regulation (EC) No 1107/2009[3]. Regulation (EU) No 2019/1009 will apply in Ireland from 16th July 2022.

Background

2. Fertilising products are used to improve plant growth and to increase crop yields. However, as the world population keeps increasing, the use of nitrogen, phosphorous and potassium mineral fertiliser is associated with challenges as regards security of supply, health and the environment.

3. EU Regulation (EC) No 2003/2003 relating to fertilisers allows for fertilisers to be designated as 'EC fertilisers' which can be placed on the market across the EU. The regulation almost exclusively covers fertilisers from mined or chemically produced inorganic materials and includes a list of the specified types of EC fertilisers.

4. In March 2016, the EU Commission put forward a legislative proposal on fertilising products as part of the circular economy action plan which aims to help EU industry become more sustainable and competitive, foster sustainable economic growth and generate new jobs.

5. This proposal had a number of objectives including to broaden the scope of current fertiliser Regulations to include a wider range of fertilising products and to encourage a greater use of recycled and organic materials as fertilisers for crops. The proposal aimed to modernise the conformity assessment and market surveillance in line with the new legislative framework for product legislation. For each of the fertilising products (and their subcategories) as well as for

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[1] Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers (OJ L 304, 21.11.2003, p. 1).

[2] Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1).

[3] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

each of the component materials used to produce them, the proposal introduces specific harmonised requirements regarding quality, safety and labelling.

6. The new EU Fertiliser Products Regulation (EU) No. 2019/1009 entered into force on 5th June 2019 and will apply from 16th July 2022. Until the FPR comes into effect on 16th July 2022, the existing rules apply. The current rules for the sale and marketing of fertiliser in Ireland is provided for under both Irish and EU Regulations. Fertiliser manufacturers can choose to market their products under SI 248/1978[4] (Marketing of Non-EEC Fertilisers Regulations, 1978) or Regulation (EC) No 2003/2003 relating to fertilisers.

Main objectives of the Regulation

7 It opens the single market for fertilising products which are not currently covered by harmonisation rules, such as organic and organo-mineral fertilisers, soil improvers, inhibitors, plant biostimulants, growing media or blends.

8 The FPR harmonises EU rules for products derived from recycled or organic materials and by-products, and provides rules to recover nutrients from such materials for fertilising purposes. As a result, it will improve the efficiency of supply chains and create an internal market for fertilisers made from recycled or organic materials in the EU, turning waste management problems into economic opportunities.

9 It lays down common rules on safety, quality and labelling requirements for fertilising products.

10 The FPR introduces limits for contaminants for the first time. This will guarantee a high level of soil protection and reduce health and environmental risks.

11 The Regulation provides for more detailed labelling requirements to improve the information that is available to farmers and fertiliser users.

12 Contrary to most other product harmonisation Regulations in the EU and taking into account the principles of better regulation and subsidiarity, the Regulation maintains optional harmonisation and does not prevent non-harmonised fertilisers from being made available on the internal market in accordance with national law and the general free movement rules. Compliance with harmonised rules therefore remain optional and are only required for fertiliser products which are CE marked. The FPR therefore offers the possibility for manufacturers who do not wish to CE-mark their products to choose to comply with National Regulations. Manufacturers will still be able to sell their products in other EU countries under National rules depending on mutual recognition between the Member States. This dual approach will prevent

[4] Statutory Instrument No. 248/1978 – Marketing on Non-EEC Fertiliser Regulations, 1978

market disruption and at the same time create new opportunities for producers of CE fertilisers – both organic and inorganic.

Scope of the Regulation

13 The regulation covers 7 Product Function Categories (PFCs) of EU fertilising products. They are designated as follows:

- Fertiliser:
    - Organic fertiliser
    - Organo-mineral fertiliser
    - Inorganic fertiliser
- Liming material
- Soil improver
- Growing medium
- Inhibitor
- Plant biostimulant
- Fertilising product blend

14 An EU fertilising product shall only consist of component materials complying with the requirements for one or more of the Component Material Categories (CMCs). The designation of the CMCs include:

- Virgin material substances and mixtures
- Plants, plant parts or plant extracts
- Compost
- Fresh crop digestate
- Digestate other than fresh crop digestate
- Food industry by-products
- Micro-organisms
- Nutrient Polymers
- Polymers other than nutrient polymers
- Derived products within the meaning of Regulation (EC) No 1069/2009
- By-products within the meaning of Directive 2008/98/EC[5]

Draft Delegated Acts have been published for public consultation to include 3 further CMCs and the conditions for their use, namely;

- Precipitated phosphate salts and derivates
- Thermal oxidation materials and derivates
- Pyrolosis and gasification materials

[5] Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3).

15 The FPR will replace Regulation (EC) No 2003/2003 which does not include fertilisers produced from recovered or organic materials.

16 The FPR does not apply to:

- animal by-products or derived products which are subject to the requirements of Regulation (EC) No 1069/2009 when made available on the market
- plant protection products covered by the scope of Regulation (EC) No 1107/2009

17 The new Regulation provides for EU fertilising products that are manufactured from materials such as recycled biodegradable waste. Criteria are laid down in accordance with which material that constitutes waste, as defined in Directive 2008/98/EC, can cease to be waste, if it is contained in a compliant EU fertilising product.

18 The Regulation amends Regulation (EC) No 1069/2009 which provides for determining end points in the manufacturing chain for certain derived animal by-products which no longer pose any significant risk to public or animal health. Beyond this point, such derived products will no longer be subject to the requirements of Regulation (EC) No 1069/2009 and EU fertilising products containing such derived products in accordance with the FPR will therefore be granted free movement on the internal market.

19 The rules of the regulation apply to the design, manufacture and placing on the market of EU fertilising products. The regulation does not apply to the use or the mode of application of the EU fertilising products.

Main requirements of the Regulation

20 The Regulation introduces CE marking of fertiliser for the first time. The definition of an "EU fertilising product" means a fertilising product which is CE marked when made available on the market. The CE marking is fixed by the manufacturer to the product (on each individual package or on the accompanying document in the case of unpackaged products) if the product complies with the rules of the Regulation.

21 The regulation sets out rules for EU fertilising products carrying the CE marking including requirements for:

- maximum levels of contaminants and pathogens (disease-causing microorganisms);
- minimum content of nutrients and other relevant characteristics depending on the category of the product;
- labelling.

22 The Regulation puts in place a new conformity assessment system to provide for quality assurance for fertiliser products that are available on the market. The new system will ensure that testing the conformity of EU fertilising products is performed in a reliable and reproducible

manner. Test methods to support and underpin conformity assessment of fertilising products are currently being developed in conjunction with the European Committee for Standardisation (CEN).

23 The CE marking may only be used if the conformity assessment requirements and procedures have been successfully completed. There are 4 different conformity assessment procedure modules and the applicability of these modules to EU fertilising products will depend on the product function category to which the fertiliser product belongs and to the category of the component materials used to produce them. Conformity assessment procedures for certain products set out in the Regulation require the intervention of conformity assessment bodies, which are notified by the Member States to the Commission.

24 Articles 6-12 of the Regulation sets out the responsibilities and obligations of economic operators in detail. The term "economic operator" includes manufacturers, authorised representatives, importers and distributors. The Regulation sets out the different obligations that correspond to the role of each economic operator.

25 The central obligations on economic operators are to ensure that only compliant EU fertilising products may be placed on the market. In situations where economic operators who consider or have reason to believe that an EU fertilising product which they have placed on the market is not in conformity with the Regulation, they are required to immediately take the corrective measures necessary to bring that EU fertilising product into conformity, to withdraw it or to recall it, as appropriate. Economic operators are also obliged to inform the market surveillance authorities if a product presents a risk to human, animal or plant health, safety or the environment.

26 Importers and distributors may decide to act as manufacturers of a product by marketing it under their own name/trademark or if they make changes to the product which may affect its conformity. In such cases, these operators are also subject to the manufacturer obligations including conformity assessment.

27 The Regulation increases the responsibilities of all economic operators in terms of traceability and market surveillance. Economic operators must ensure the traceability of the EU fertilisers they market, and at the request of the market surveillance authorities, they must be able to inform them of any economic operator from whom they have purchased a specific EU fertilising product and any economic operator to whom they have supplied it.

28 Provisions relating to market surveillance and the control of EU fertilising products are set out including a procedure at national level for handling EU fertilising products presenting a risk. Where market surveillance authorities have sufficient reason to believe that an EU fertilising product presents a risk to human, animal or plant health, to safety or to the environment, this procedure allows for market surveillance authorities to assess the compliance of the product concerned with the new EU fertiliser Regulation and, if necessary, require the economic

operator to take corrective action. This procedure also includes a coordination mechanism between EU Member States and the Commission for non-compliant EU fertilising products marketed throughout the EU.

Free movement

29 EU countries cannot restrict the free movement of EU fertilising products for reasons relating to composition, labelling or other aspects covered by the Regulation if those products comply with the rules of the Regulation.

30 EU countries can maintain or adopt rules relating to human health and the environment (which comply with the EU treaties) which concern the use of EU fertilising products, as long as they do not require EU compliant products to be modified or influence the conditions for making them available on the market.

Actions by the Department of Agriculture, Food and the Marine

31 A new Statutory Instrument will be prepared and published by the Department of Agriculture, Food and the Marine to give effect to the new Regulation in Ireland.

32 The Department of Agriculture, Food and the Marine will inform the Commission of its procedures for the assessment and notification of conformity assessment bodies and the monitoring of such notified bodies.

33 The Department of Agriculture, Food and the Marine will engage directly with relevant and affected stakeholders as required to inform them about the requirements of the new Regulation.

Attachments

34 Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003 (*OJ L 170, 25.6.2019, p. 1–114)*

35 Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers *(OJ L 304, 21.11.2003, pp. 1-194)*