

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 (Text with EEA relevance)

## CHAPTER II

### OBLIGATIONS OF ECONOMIC OPERATORS

#### *Article 6*

#### **Obligations of manufacturers**

1 When placing EU fertilising products on the market, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements set out in Annexes I and II.

2 Before placing EU fertilising products on the market, manufacturers shall draw up the technical documentation and carry out the relevant conformity assessment procedure referred to in Article 15, or have it carried out.

Where compliance of an EU fertilising product with the applicable requirements laid down in this Regulation has been demonstrated by that conformity assessment procedure, manufacturers shall draw up an EU declaration of conformity and affix the CE marking.

3 Manufacturers shall keep the technical documentation and the EU declaration of conformity for 5 years after the EU fertilising product covered by those documents has been placed on the market.

On request, manufacturers shall make a copy of the EU declaration of conformity available to other economic operators.

4 Manufacturers shall ensure that procedures are in place for EU fertilising products that are part of a series production to remain in conformity with this Regulation. Changes in the production process or in the characteristics of those EU fertilising products and changes in the harmonised standards, common specifications referred to in Article 14 or other technical specifications by reference to which conformity of an EU fertilising product is declared or by application of which its conformity is verified shall be adequately taken into account.

When deemed appropriate with regard to the performance of, or the risks presented by, an EU fertilising product, manufacturers shall carry out sample testing of such EU fertilising products made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming EU fertilising products and recalls of such EU fertilising products, and shall keep distributors informed of any such monitoring.

5 Manufacturers shall ensure that the packaging of the EU fertilising products which they have placed on the market bears a type number, batch number or other element allowing their identification or, where the EU fertilising products are supplied without packaging, that the required information is provided in a document accompanying each fertilising product.

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6 Manufacturers shall indicate their name, registered trade name or registered trade mark and the postal address at which they can be contacted on the packaging of the EU fertilising product or, where the EU fertilising product is supplied without packaging, in a document accompanying the EU fertilising product. The postal address shall indicate a single point at which the manufacturer can be contacted. Such information shall be in a language easily understood by end-users and market surveillance authorities and shall be clear, understandable and legible.

7 Manufacturers shall ensure that EU fertilising products are accompanied by the information required under Annex III. Where an EU fertilising product is supplied in a package, the information shall appear on a label which is affixed to that package. Where the package is too small to contain all the information, the information that cannot be provided on the label shall be provided in a separate leaflet accompanying that package. Such a leaflet shall be regarded as part of the label. Where the EU fertilising product is supplied without packaging, all the information shall be provided in a leaflet. The label and the leaflet shall be accessible for inspection purposes when the EU fertilising product is made available on the market. The information shall be in a language which can be easily understood by end-users, as determined by the Member State concerned, and shall be clear, understandable and intelligible.

8 Manufacturers who consider or have reason to believe that an EU fertilising product which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective measures necessary to bring that EU fertilising product into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where manufacturers consider or have reason to believe that an EU fertilising product which they have placed on the market presents a risk to human, animal or plant health, to safety or to the environment, they shall immediately inform the competent national authorities of the Member States in which they made the EU fertilising product available on the market to that effect, giving details, in particular, of any non-compliance and of any corrective measures taken.

9 Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the EU fertilising product with this Regulation, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by an EU fertilising product which they have placed on the market.

#### *Article 7*

#### **Authorised representative**

1 A manufacturer may, by a written mandate, appoint an authorised representative.

The obligations laid down in Article 6(1) and the obligation to draw up technical documentation referred to in Article 6(2) shall not form part of the authorised representative's mandate.

2 An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:

- a keep the EU declaration of conformity and the technical documentation at the disposal of national market surveillance authorities for 5 years after the EU fertilising product covered by those documents has been placed on the market;

- b further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of an EU fertilising product;
- c cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by EU fertilising products covered by the authorised representative's mandate.

## Article 8

### Obligations of importers

- 1 Importers shall place only compliant EU fertilising products on the market.
- 2 Before placing an EU fertilising product on the market, importers shall ensure that the appropriate conformity assessment procedure referred to in Article 15 has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the EU fertilising product is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in Article 6(5) and (6).

Where an importer considers or has reason to believe that an EU fertilising product is not in conformity with this Regulation, the importer shall not place the EU fertilising product on the market until it has been brought into conformity. Furthermore, where the EU fertilising product presents a risk to human, animal or plant health, to safety or to the environment, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

- 3 Importers shall indicate their name, registered trade name or registered trade mark and the postal address at which they can be contacted on the packaging of the EU fertilising product or, where the EU fertilising product is supplied without packaging, in a document accompanying the EU fertilising product. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

- 4 Importers shall ensure that EU fertilising products are accompanied by the information required under Annex III. Where an EU fertilising product is supplied in a package, the information shall appear on a label which is affixed to that package. Where the package is too small to contain all the information, the information that cannot be provided on the label shall be provided in a separate leaflet accompanying that package. Such a leaflet shall be regarded as part of the label. Where the EU fertilising product is supplied without packaging, all the information shall be provided in a leaflet. The label and the leaflet shall be accessible for inspection purposes when the EU fertilising product is made available on the market. The information shall be in a language which can be easily understood by end-users, as determined by the Member State concerned.

- 5 Importers shall ensure that, while an EU fertilising product is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the requirements set out in Annex I or III.

- 6 When deemed appropriate with regard to the performance of, or the risks presented by an EU fertilising product, importers shall carry out sample testing of such EU fertilising products made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming EU fertilising products and recalls of such EU fertilising products, and shall keep distributors informed of any such monitoring.

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7 Importers who consider or have reason to believe that an EU fertilising product which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective measures necessary to bring that EU fertilising product into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where importers consider or have reason to believe that an EU fertilising product which they have placed on the market presents a risk to human, animal or plant health, to safety or to the environment, they shall immediately inform the competent national authorities of the Member States in which they made the EU fertilising product available on the market to that effect, giving details, in particular, of any non-compliance and of any corrective measures taken.

8 Importers shall, for 5 years after the EU fertilising product has been placed on the market, keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.

On request, importers shall make a copy of the EU declaration of conformity available to other economic operators.

9 Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the EU fertilising product with this Regulation in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by an EU fertilising product which they have placed on the market.

#### *Article 9*

### **Obligations of distributors**

1 When making an EU fertilising product available on the market distributors shall act with due care in relation to the requirements of this Regulation.

2 Before making an EU fertilising product available on the market distributors shall verify that it is accompanied by the required documents, including the information referred to in Article 6(7) or Article 8(4) provided in the manner specified therein, in a language which can be easily understood by end-users in the Member State in which the EU fertilising product is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in Article 6(5) and (6) and Article 8(3) respectively.

Where a distributor considers or has reason to believe that an EU fertilising product is not in conformity with this Regulation, the distributor shall not make the EU fertilising product available on the market until it has been brought into conformity. Furthermore, where the EU fertilising product presents a risk to human, animal or plant health, to safety or to the environment, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.

3 Distributors shall ensure that, while an EU fertilising product is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the requirements set out in Annex I or III.

4 Distributors who consider or have reason to believe that an EU fertilising product which they have made available on the market is not in conformity with this Regulation shall make sure that the corrective measures necessary to bring that EU fertilising product into conformity, to withdraw it or to recall it, as appropriate, are taken. Furthermore, where distributors consider or have reason to believe that an EU fertilising product which they have

made available on the market presents a risk to human, animal or plant health, to safety or to the environment, they shall immediately inform the competent national authorities of the Member States in which they made the EU fertilising product available on the market to that effect, giving details, in particular, of any non-compliance and of any corrective measures taken.

5 Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the EU fertilising product with this Regulation. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by EU fertilising products which they have made available on the market.

#### *Article 10*

### **Cases in which obligations of manufacturers apply to importers and distributors**

An importer or distributor shall be considered a manufacturer for the purposes of this Regulation, and shall be subject to the obligations of the manufacturer under Article 6, where that importer or distributor places an EU fertilising product on the market under his or her name or trademark or modifies an EU fertilising product already placed on the market in such a way that compliance with this Regulation may be affected.

#### *Article 11*

### **Packaging and repackaging by importers and distributors**

Where an importer or distributor packages or repackages an EU fertilising product and is not considered a manufacturer pursuant to Article 10, that importer or distributor shall:

- (a) ensure that the packaging bears his or her name, registered trade name or registered trade mark and postal address preceded by the words 'packaged by' or 'repackaged by'; and
- (b) keep a specimen of the original information referred to in Article 6(7) or Article 8(4) at the disposal of the market surveillance authorities for 5 years after having made the EU fertilising product available on the market.

#### *Article 12*

### **Identification of economic operators**

1 Economic operators shall, on request, identify the following to the market surveillance authorities:

- a any economic operator who has supplied them with an EU fertilising product;
- b any economic operator to whom they have supplied an EU fertilising product.

2 The economic operators shall be able to present the information referred to in the first paragraph for 5 years after they have been supplied with the EU fertilising product and for 5 years after they have supplied the EU fertilising product.

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