



Brussels, **XXX**  
[...](2021) **XXX** draft

**COMMISSION DELEGATED REGULATION (EU) .../...**

**of **XXX****

**supplementing Regulation (EU) 2019/1009 of the European Parliament and of the Council by laying down criteria on agronomic efficiency and safety for the use of by-products in EU fertilising products**

(Text with EEA relevance)

## **EXPLANATORY MEMORANDUM**

### **1. CONTEXT OF THE DELEGATED ACT**

According to Article 42(7) of Regulation (EU) 2019/1009 <sup>(1)</sup>, by 16 July 2022, the Commission has to supplement Annex II, Part II, Component Material Category (CMC) 11, point 3 by laying down criteria for agronomic efficiency and safety for the use of by products within the meaning of Directive 2008/98/EC <sup>(2)</sup> in EU fertilising products. Such criteria have to reflect present product manufacturing practices, technological developments and the latest scientific evidence.

The Commission mandated its Joint Research Centre to provide scientific advice in fulfilling this task.

This delegated Regulation is based on the Report of the Commission's Joint Research Centre ('JRC') on *Technical proposals for by-products and high purity materials as component materials for EU Fertilising Products*. (link to the report when published to be added in a footnote)

### **2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT**

Pursuant to Article 44(4) of Regulation (EU) 2019/1009, experts designated by each Member State were consulted in the Commission expert group on Fertilising Products (E01320) according to the rules of the Interinstitutional Agreement on Better Law-Making of 13 April 2016<sup>3</sup>.

Details of these consultations can be found in the minutes of the meeting held on [] November 2021, as well as in the various position papers of interested stakeholders publicly available on the CIRCABC page of the group, at the following link:

<https://circabc.europa.eu/ui/group/36ec94c7-575b-44dc-a6e9-4ace02907f2f/library/b8e01334-4d39-445d-bf4e-589356d55b1f>

Member States and interested stakeholders were largely supportive of the adoption of this delegated Regulation.

The draft delegated Regulation has been published for feedback on the Better Regulation portal [to add details once the consultation is done].

The draft delegated Regulation has also been notified based on Article 2(9)(2) of the Agreement on Technical Barriers to Trade. [to add details once the consultation is done]

### **3. LEGAL ELEMENTS OF THE DELEGATED ACT**

The legal act supplements Regulation (EU) 2019/1009. The legal basis of this delegated act is Article 42(7) of Regulation (EU) 2019/1009.

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<sup>1</sup> 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.

<sup>2</sup> 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. 3–30.

<sup>3</sup> OJ L 123, 12.5.2016, p. 1–14.

# COMMISSION DELEGATED REGULATION (EU) .../...

of **XXX**

## **supplementing Regulation (EU) 2019/1009 of the European Parliament and of the Council by laying down criteria on agronomic efficiency and safety for the use of by-products in EU fertilising products**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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<sup>1</sup>, and in particular Article 42(7) thereof,

Whereas:

- (1) Regulation (EU) 2019/1009 lays down rules on the making available on the market of EU fertilising products. EU fertilising products contain component materials of one or more of the categories listed in Annex II to that Regulation. In accordance with component material category ('CMC') 11 of that Annex, EU fertilising products may contain by-products within the meaning of Directive 2008/98/EC of the European Parliament and of the Council<sup>2</sup>, with some exceptions, and which are to be registered in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council<sup>3</sup>.
- (2) Article 42(7) of Regulation (EU) 2019/1009 requires the Commission to supplement Part II, CMC 11, point 3, of Annex II, by laying down criteria for agronomic efficiency and safety for the use of by-products within the meaning of Directive 2008/98/EC in EU fertilising products. To that end, the Commission mandated its Joint Research Centre ('JRC') to provide scientific advice ([link to the report when published](#) to be added in a footnote).
- (3) By-products within the meaning of Directive 2008/98/EC build a very heterogeneous category of substances. These substances can have different physical and chemical nature, which may be obtained during various production processes. For the purpose of this Regulation, the by-products are divided in two categories, depending on their

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<sup>1</sup> OJ L 170, 25.6.2019, p. 1.

<sup>2</sup> 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).

<sup>3</sup> Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

type of agronomic efficiency. Firstly, there are by-products, which provide nutrients to plants. Secondly, there are by-products which are used as technical additives in smaller concentrations, and, even though they do not provide nutrients to plants, they are agronomically efficient as they improve the quality of the fertilising product or the safety in handling it.

- (4) For the first category, the JRC has identified by-products resulting from a variety of production processes, which contain ammonium salts, sulphate salts, phosphate salts, elemental sulphur, calcium carbonate and calcium oxide. To ensure that those by-products have a clear agronomic value and do not create adverse effects for human health and the environment, a strict purity requirement should be laid down.
- (5) For the second category, the JRC proposed to allow the use of by-products as technical additives, such as hardening, binding or filling agents. To ensure that the use of such by-products has no adverse effect on human health or the environment, a maximum concentration in the final EU fertilising product should be laid down.
- (6) In addition, the JRC assessed the most commonly used by-products according to existing practices to determine if derogatory requirements from the restrictive purity level or the low quantities allowed in EU fertilising products should be laid down for certain clearly determined categories of by-products. Those by-products have been selected based on their market potential, available data, on their current legal situation, on their use history, and on their clear agronomic value, as well as the straightforwardness of safety criteria development given the time constraints in performing the assessment. The by-products identified were mother liquor from the reaction of 5( $\beta$ -methyl-thioethyl)-hydantoin with potassium carbonate in the methionine production process, residues from mineral and ore processing and purification, post-distillation liquid from Solvay process, carbide lime from acetylene production, ferrous slags, metal salts from ore concentrate processing and metal surface treatment, and humic and fulvic acids from drinking water discolouration.
- (7) Therefore, the corresponding supplementary agronomic efficiency and safety criteria for the use of by-products should be laid down. These criteria are to apply in addition to the safety and agronomic efficiency criteria laid down in Annex I to Regulation (EU) 2019/1009.
- (8) Furthermore, some of these by-products should, depending on their production processes, comply with safety criteria limiting the content of contaminants and other substances of concern, applied in addition to those that are laid down in Annex I to Regulation (EU) 2019/1009 for the corresponding product function category, and without prejudice to Regulation (EU) 2019/1021 of the European Parliament and of the Council<sup>4</sup>.
- (9) Therefore, additional limit values should be laid down for the contaminants total chromium, thallium and vanadium. Some of the by-products may contain such contaminants as a result of the particularity of their production process. The proposed limit values for those contaminants should ensure that the use of EU fertilising products containing by-products with such contaminants does not lead to their accumulation in soil. The limit values should be determined as concentration in the final product, similar to the requirements set out in Annex I to Regulation (EU)

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<sup>4</sup> Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45).

2019/1009. This is justified by the fact that the safety criteria introduced in reply to any particular risks identified concern, as a rule, the final product and not a component material. This should facilitate the conformity assessment and market surveillance of such products, as tests are to be carried out only on the final product.

- (10) Furthermore, additional safety criteria should be laid down to limit the content of 16 polycyclic aromatic hydrocarbons (PAH<sub>16</sub>)<sup>5</sup> and, polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDD/PCDF)<sup>6</sup>. Regulation (EU) 2019/1021 lays down release reductions for PAH<sub>16</sub> and PCDD/PCDF as unintentionally produced substances during manufacturing processes, but does not introduce a limit value in such cases. Given the high risks generated by the presence of such pollutants in fertilising products, it is considered appropriate to introduce more stringent requirements than those laid down in that Regulation. Such limit values should be laid down at component material level and not as concentration in the final product, to ensure coherence with Regulation (EU) 2019/1021.
- (11) The limit values referred to in recitals (8)-(10) may not be relevant in all cases. Therefore, manufacturers should have the possibility to presume the conformity of the fertilising product with a given requirement without verification, such as testing, whenever the compliance with the said requirement follows certainly and uncontestedly from the nature or manufacturing process of the by-products belonging to CMC 11 or of the EU fertilising product containing such a by-product.
- (12) Some of the by-products may contain micronutrient selenium, which can be toxic if present in high concentration. Some may also contain chloride, which raises concerns regarding the salinity in soil. Whenever those substances are present in concentrations exceeding a certain limit, their content should be declared on the label so that the users of the fertilising product are properly informed.
- (13) Given that Regulation (EU) 2019/1009 will fully apply from 16 July 2022, it is necessary to defer the application of this Regulation to the same date,

HAS ADOPTED THIS REGULATION:

#### *Article 1*

By-products belonging to Component Material Category (CMC) 11 referred to in Part II of Annex II to Regulation (EU) 2019/1009, shall meet one the following two sets of criteria for agronomic efficiency and safety:

1. By-products providing nutrients to plants shall:
  - (a) contain at least 95 % dry matter of the by-product of ammonium salts, sulphate salts, phosphate salts, elemental sulphur, calcium carbonate or calcium oxide, or mixtures thereof;

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<sup>5</sup> Sum of naphthalene, acenaphthylene, acenaphthene, fluorene, phenanthrene, anthracene, fluoranthene, pyrene, benzo[a]anthracene, chrysene, benzo[b]fluoranthene, benzo[k]fluoranthene, benzo[a]pyrene, indeno[1,2,3-cd]pyrene, dibenzo[a,h]anthracene and benzo[ghi]perylene.

<sup>6</sup> Sum of 2,3,7,8-TCDD, 1,2,3,7,8-PeCDD; 1,2,3,4,7,8-HxCDD; 1,2,3,6,7,8-HxCDD; 1,2,3,7,8,9-HxCDD; 1,2,3,4,6,7,8-HpCDD; OCDD; 2,3,7,8-TCDF; 1,2,3,7,8-PeCDF; 2,3,4,7,8-PeCDF; 1,2,3,4,7,8-HxCDF; 1,2,3,6,7,8-HxCDF; 1,2,3,7,8,9-HxCDF; 2,3,4,6,7,8-HxCDF; 1,2,3,4,6,7,8-HpCDF; 1,2,3,4,7,8,9-HpCDF; and OCDF.

- (b) be produced as an integral part of a production process that uses as input materials substances and mixtures, other than animal by-products or derived products within the scope of Regulation (EC) No 1069/2009 of the European Parliament and of the Council<sup>7</sup>;
- (c) have an organic carbon ( $C_{org}$ ) content of no more than 0,5 % of the dry matter of the by-product;
- (d) contain no more than 6 mg/kg dry matter of polycyclic aromatic hydrocarbons (PAH<sub>16</sub>)<sup>8</sup>; and
- (e) contain no more than 20 ng WHO toxicity equivalents<sup>9</sup>/kg dry matter of the polychlorinated dibenzo-para-dioxins and dibenzofurans (PCDD/PCDF)<sup>10</sup>.

An EU fertilising product containing or consisting of by-products providing nutrients to plants shall contain no more than:

- (a) 400 mg/kg dry matter of total chromium (Cr); and
- (b) 2 mg/kg dry matter of thallium (Tl).

2. By-products used as technical additives shall:

- (a) improve the safety or agronomic efficiency of the EU fertilising product;
- (b) be present in the EU fertilising product at a total concentration of no more than 5 % by mass;
- (c) contain no more than 6 mg/kg dry matter of polycyclic aromatic hydrocarbons (PAH<sub>16</sub>)<sup>11</sup>; and
- (d) contain no more than 20 ng WHO toxicity equivalents<sup>12</sup>/kg dry matter of the polychlorinated dibenzo-para-dioxins and dibenzofurans (PCDD/PCDF)<sup>13</sup>.

<sup>7</sup> 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).

<sup>8</sup> Sum of naphthalene, acenaphthylene, acenaphthene, fluorene, phenanthrene, anthracene, fluoranthene, pyrene, benzo[a]anthracene, chrysene, benzo[b]fluoranthene, benzo[k]fluoranthene, benzo[a]pyrene, indeno[1,2,3-cd]pyrene, dibenzo[a,h]anthracene and benzo[ghi]perylene.

<sup>9</sup> van den Berg M., L.S. Birnbaum, M. Denison, M. De Vito, W. Farland, et al. (2006) The 2005 World Health Organization Re-evaluation of Human and Mammalian Toxic Equivalency Factors for Dioxins and Dioxin-like Compounds. *Toxicological sciences: an official journal of the Society of Toxicology* 93:223-241. doi:10.1093/toxsci/kfl055.

<sup>10</sup> Sum of 2,3,7,8-TCDD, 1,2,3,7,8-PeCDD; 1,2,3,4,7,8-HxCDD; 1,2,3,6,7,8-HxCDD; 1,2,3,7,8,9-HxCDD; 1,2,3,4,6,7,8-HpCDD; OCDD; 2,3,7,8-TCDF; 1,2,3,7,8-PeCDF; 2,3,4,7,8-PeCDF; 1,2,3,4,7,8-HxCDF; 1,2,3,6,7,8-HxCDF; 1,2,3,7,8,9-HxCDF; 2,3,4,6,7,8-HxCDF; 1,2,3,4,6,7,8-HpCDF; 1,2,3,4,7,8,9-HpCDF; and OCDF.

<sup>11</sup> Sum of naphthalene, acenaphthylene, acenaphthene, fluorene, phenanthrene, anthracene, fluoranthene, pyrene, benzo[a]anthracene, chrysene, benzo[b]fluoranthene, benzo[k]fluoranthene, benzo[a]pyrene, indeno[1,2,3-cd]pyrene, dibenzo[a,h]anthracene and benzo[ghi]perylene.

<sup>12</sup> van den Berg M., L.S. Birnbaum, M. Denison, M. De Vito, W. Farland, et al. (2006) The 2005 World Health Organization Re-evaluation of Human and Mammalian Toxic Equivalency Factors for Dioxins and Dioxin-like Compounds. *Toxicological sciences: an official journal of the Society of Toxicology* 93:223-241. doi:10.1093/toxsci/kfl055.

<sup>13</sup> Sum of 2,3,7,8-TCDD, 1,2,3,7,8-PeCDD; 1,2,3,4,7,8-HxCDD; 1,2,3,6,7,8-HxCDD; 1,2,3,7,8,9-HxCDD; 1,2,3,4,6,7,8-HpCDD; OCDD; 2,3,7,8-TCDF; 1,2,3,7,8-PeCDF; 2,3,4,7,8-PeCDF; 1,2,3,4,7,8-HxCDF;

## Article 2

The criteria in Article 1 do not apply to the by-products belonging to CMC 11 referred to in Part II of Annex II to Regulation (EU) 2019/1009 which comply with one of the following alternative criteria:

- (a) are mother liquor from the reaction of 5( $\beta$ -methyl-thioethyl)-hydantoin with potassium carbonate in the methionine production process;
- (b) are residues from the processing and purification of minerals and ores, if they contain calcium carbonates, magnesium carbonates, calcium sulphates, magnesium oxide, phosphate salts, and/or water-soluble salts of potassium, magnesium or sodium, in a total content of more than 60 % dry matter of the residues;
- (c) are post-distillation liquid from Solvay process;
- (d) are carbide lime from acetylene production;
- (e) are ferrous slags;

An EU fertilising product containing or consisting of ferrous slags shall contain no more than:

- (a) 400 mg/kg dry matter of total chromium (Cr);
  - (b) 2 mg/kg dry matter of thallium (Tl); and
  - (c) 600 mg/kg dry matter of vanadium (V).
- (f) are substances derived from ore concentrate processing and metal surface treatment that contain at least 2 % by mass of di- or tri-valent transition metal cations (zinc (Zn), copper (Cu), iron (Fe), manganese (Mn) or cobalt (Co)) in solution, if the free acid content (as summed hydrochloric acid, hydrofluoric acid, nitric acid and sulphuric acid) is lower than 2,5 % by mass;

An EU fertilising product containing or consisting of such substances shall contain no more than:

- (a) 400 mg/kg dry matter of total chromium (Cr);
  - (b) 2 mg/kg dry matter of thallium (Tl); and
  - (c) 600 mg/kg dry matter of vanadium (V).
- (g) are humic and fulvic acids from drinking water discolouration.

## Article 3

Where compliance with a given requirement laid down in Article 1, paragraph 1, first sub-paragraph, points (d) and (e), and second and third sub-paragraphs, Article 1, paragraph 2, points (c) and (d) and Article 2, points (e)(i)-(iii) and (f)(i)-(iii), follows certainly and uncontestably from the nature or manufacturing process of the by-products or of the EU fertilising product, as applicable, that compliance may be presumed in the conformity assessment procedure without verification, at the responsibility of the manufacturer.

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1,2,3,6,7,8-HxCDF; 1,2,3,7,8,9-HxCDF; 2,3,4,6,7,8-HxCDF; 1,2,3,4,6,7,8-HpCDF; 1,2,3,4,7,8,9-HpCDF; and OCDF.

#### *Article 4*

1. Where an EU fertilising product contains or consists of by-products referred to in Article 1(1), and in Article 2, points (b) to (f), and has a selenium (Se) content exceeding 10 mg/kg dry matter, the selenium content shall be declared.
2. Where an EU fertilising product contains or consists of by-products referred to in Article 1(1), and in Article 2, points (b), (c) and (g), and has a chloride (Cl-) content exceeding 30 g/kg dry matter, the chloride content shall be declared.

#### *Article 45*

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall apply from 16 July 2022.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

*For the Commission*  
*The President*  
*Ursula von der Leyen*