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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	14 March 2022
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
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Subject:	COMMISSION DELEGATED REGULATION (EU) …/... of 14.3.2022 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

Delegations will find attached document C(2022) 1437 final.

Encl.: C(2022) 1437 final

EUROPEAN
COMMISSION

Brussels, 14.3.2022
C(2022) 1437 final

COMMISSION DELEGATED REGULATION (EU) …/...

of 14.3.2022

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 ([1]), 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 ([2]) 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*[3].

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[4].

Details of these consultations can be found in the minutes of the meetings held on 22-23 November 2021 and on 26 January 2022, 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. The 28 contributions submitted address various technical details in the criteria laid down the delegated Regulation.

Some of these contributions concerned *the limit values for total chromium and vanadium* as laid down for ferrous slags. Various interests have been defended. Contributions from steel producers argue in favour of removing the limit values, considering that they would exclude a significant part of the by-products currently on the market and thus impede the circular economy, without having a solid scientific base proving the risks associated to the presence of

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1 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.

2 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.

3 Huygens D, Saveyn HGM, Technical proposals for by-products and high purity materials as component materials for EU Fertilising Products, JRC128459, Publications Office of the European Union, Luxembourg, 2022.

4 OJ L 123, 12.5.2016, p. 1–14.

these heavy metals. Other stakeholders brought forward arguments for introducing lower limit values.

No changes have been done to the draft delegated Regulation. The Commission considers the limit values included in the delegated Regulation as a balanced solution to promote circular economy without creating the premises for the accumulation of total chromium and vanadium in soils. This choice is based on the scientific assessment done by the JRC in the report.

It has been also flagged in the public feedback that residues from the processing or purification of sedimentary phosphate ore may contain *naturally occurring radionuclides*. In order to ensure that such by-products can be safely used in EU fertilising products, the draft delegated Regulation has been amended so as to lay down maximum levels of activity concentration values for the uranium and thorium.

Contributions have also been submitted concerning the types of by-products which could comply with the criteria. Thus, it has been argued that the criteria do not cover *organic by-products* and *high purity magnesium and potassium salts*.

No changes have been done to the draft delegated Regulation. The criteria have been developed by the JRC based on the information provided by interested stakeholders regarding the by-products already on the market. Because of the late stage of the adoption procedure, it is no longer possible to perform an in-depth assessment of the safety and agronomic efficiency criteria specific to new materials.

Some stakeholders have requested to increase *the limit value for organic carbon.* No changes have been done as the Commission considers this criterion as an important safety requirement. Materials with low organic carbon content are not creating a favourable environment for the growth of pathogens.

The draft delegated Regulation has also been notified based on Article 2(9)(2) of the Agreement on Technical Barriers to Trade. No comments have been submitted.

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.

COMMISSION DELEGATED REGULATION (EU) …/...

of 14.3.2022

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[1], 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[2], with some exceptions, which are to be registered in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council[3].

(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[4].

(3) By-products within the meaning of Directive 2008/98/EC build a very heterogeneous category of substances. These substances have different physical and chemical nature, and may be obtained during various production processes. For the purpose of this

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1 OJ L 170, 25.6.2019, p. 1.

2 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).

3 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).

4 Huygens D, Saveyn HGM, Technical proposals for by-products and high purity materials as component materials for EU Fertilising Products, JRC128459, Publications Office of the European Union, Luxembourg, 2022.

Regulation, the by-products are divided in two categories, depending on their type of agronomic efficiency. The first category concerns by-products, which provide nutrients to plants or mushrooms or improve their nutrition efficiency. The second category concerns by-products which are used as technical additives in smaller concentrations. Even though they are not directly linked to nutrition or nutrition efficiency, they do 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, or anti-dusting agents to improve the health protection of users. To ensure that the use of such by-products does not jeopardise the overall agronomic efficiency of the EU fertilising product and 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. 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 based on 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(β-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. These specific by-products should be used in EU fertilising products without having to comply with restrictive purity levels for the first category of by-products or with the purpose and a maximum concentration allowed for the second category of by-products. The reason is that such by-products are clearly identified, which allowed the JRC to thoroughly assess their agronomic value and all the specific risks they may raise.

(7) Furthermore, the corresponding supplementary safety criteria for the use of by-products should be laid down.

(8) Some of those by-products should 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[5].

(9) 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

[5] 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).

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 for such contaminants should be determined as concentration in the final product, similar to the requirements set out in Annex I to Regulation (EU) 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) Residues from the processing or purification of sedimentary phosphate ore are known to contain naturally occurring radionuclides. In order to ensure safe use of such by-products in EU fertilising products, it is appropriate to lay down maximum permitted levels of activity concentration values of naturally occurring radionuclides, from the uranium and thorium series in EU fertilising products containing such materials.

(11) Furthermore, additional safety criteria should be laid down to limit the content of 16 polycyclic aromatic hydrocarbons (PAH_{16})[6] and of polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDD/PCDF)[7]. Regulation (EU) 2019/1021 lays down release reductions for PAH_{16} 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.

(12) The limit values for contaminants, PAH_{16} and PCDD/PCDF 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 uncontestably 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.

(13) Some of the by-products may contain selenium, which can be toxic if present in high concentration. Some may also contain chloride, which may raise concerns regarding the salinity in soil. Whenever those substances are present in concentrations exceeding a certain limit, their content should be indicated on the label so that the users of the fertilising product are properly informed.

(14) 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,

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6 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.

7 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.

HAS ADOPTED THIS REGULATION:

Article 1

1. By-products belonging to Component Material Category (CMC) 11 referred to in Part II of Annex II to Regulation (EU) 2019/1009, which provide nutrients to plants or mushrooms or improve their nutrition efficiency, shall meet the following criteria for agronomic efficiency and safety:

   (a) contain at least 95 % by dry matter of ammonium salts, sulphate salts, phosphate salts, elemental sulphur, calcium carbonate or calcium oxide, or mixtures thereof;

   (b) are 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[8];

   (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_{16})[9] ;

   (e) contain no more than 20 ng WHO toxicity equivalents[10]/kg dry matter of the polychlorinated dibenzo-para-dioxins and dibenzofurans (PCDD/PCDF)[11] .

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

   (a) 400 mg/kg dry matter of total chromium (Cr);

   (b) 2 mg/kg dry matter of thallium (Tl).

2. By-products belonging to CMC 11 referred to in Part II of Annex II to Regulation (EU) 2019/1009, which are used as technical additives, shall meet the following criteria for agronomic efficiency and safety:

   (a) have the role to improve the safety or agronomic efficiency of the EU fertilising product;

   (b) are present in the EU fertilising product at a total concentration of no more than 5 % by mass;

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8 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).

9 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.

10 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.

11 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.

(c) contain no more than 6 mg/kg dry matter of polycyclic aromatic hydrocarbons (PAH_{16});

(d) contain no more than 20 ng WHO toxicity equivalents[12]/kg dry matter of the polychlorinated dibenzo-para-dioxins and dibenzofurans (PCDD/PCDF).

Article 2

1. The criteria laid down in Article 1 do not apply to by-products belonging to CMC 11 referred to in Part II of Annex II to Regulation (EU) 2019/1009, which are either of the following:

(a) mother liquor from the reaction of 5(β-methyl-thioethyl)-hydantoin with potassium carbonate in the methionine production process;

(b) 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) post-distillation liquid from Solvay process;

(d) carbide lime from acetylene production;

(e) ferrous slags;

(f) 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;

(g) humic and fulvic acids from drinking water discolouration.

2. The activity concentration values of naturally occurring radionuclides from the U-238 and Th-232 series in an EU fertilising product containing or consisting of residues from the processing or purification of sedimentary phosphate ore in accordance with paragraph 1, point (b) shall not exceed 1 kBq/kg of the product.

3. An EU fertilising product containing or consisting of by-products referred to in points (e) and (f) of the first paragraph shall contain no more than:

(a) 400 mg/kg dry matter of total chromium (Cr);

(b) 2 mg/kg dry matter of thallium (Tl);

(c) 600 mg/kg dry matter of vanadium (V).

Article 3

Where compliance with a given requirement laid down in Article 1(1), first subparagraph, points (d) and (e), Article 1(1), second subparagraph, Article 1(2), points (c) and (d), and Article 2(2) and (3), follows certainly and uncontestably from the nature or manufacturing process of the by-product or of the EU fertilising product containing such a by-product, as

[12] 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.

applicable, that compliance may be presumed in the conformity assessment procedure without verification (such as testing), at the responsibility of the manufacturer.

Article 4

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

2. Where an EU fertilising product contains or consists of by-products referred to in Article 1(1), first subparagraph and in Article 2, first paragraph, points (b), (c) and (g), and has a chloride (Cl-) content exceeding 30 g/kg dry matter, the chloride content shall be indicated, unless the EU fertilising product is produced through a manufacturing process where chloride containing substances or mixtures have been used with the intention of producing or including alkali metal salts or alkaline earth metal salts, and information on these salts is provided in accordance with Annex III.

3. When the content of selenium or chloride is indicated in accordance with paragraphs 1 and 2, it shall be clearly separated from nutrient declaration and it may be expressed as a range of values.

4. Where the fact that such an EU fertilising product contains selenium or chloride below the limit values in paragraphs 1 and 2 follows certainly and uncontestably from the nature or manufacturing process of the by-product or of the EU fertilising product containing such a by-product, as applicable, the label may contain no information on these parameters, without verification (such as testing), at the responsibility of the manufacturer.

Article 5

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, 14.3.2022

For the Commission
The President
Ursula VON DER LEYEN