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COMPET 180
ENV 281
CHIMIE 29
IND 87
DELACT 53

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	22 March 2022
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2022) 1422 final
Subject:	COMMISSION DELEGATED REGULATION (EU) …/... of 22.3.2022 amending Annexes II, III and IV to Regulation (EU) 2019/1009 of the European Parliament and of the Council for the purpose of adding recovered high purity materials as a component material category in EU fertilising products

Delegations will find attached document C(2022) 1422 final.

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EUROPEAN
COMMISSION

Brussels, 22.3.2022
C(2022) 1422 final

COMMISSION DELEGATED REGULATION (EU) …/...

of 22.3.2022

amending Annexes II, III and IV to Regulation (EU) 2019/1009 of the European Parliament and of the Council for the purpose of adding recovered high purity materials as a component material category in EU fertilising products

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Regulation (EU) 2019/1009[1] 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 Article 42(1) of Regulation (EU) 2019/1009, the Commission is empowered to adopt delegated acts in accordance with Article 44 adapting Annex II to technical progress and facilitating internal market access and free movement for EU fertilising products, which have a potential to be the subject of significant trade on the internal market and for which there is scientific evidence that they do not present a risk to human, animal or plant health, to safety or to the environment and that they do ensure agronomic efficiency. Regulation (EU) 2019/1009 repeals Regulation (EC) No 2003/2003[2] and will apply as of 16 July 2022.

When assessing the safety and agronomic efficiency criteria needed for the use of by-products belonging to Component Material Category 11 in accordance to Article 42(7), the Commission's Joint Research Centre ('JRC') has identified certain high purity materials recovered from waste with a high agronomic value which could be used as component materials in EU fertilising products. The JRC assessment is included in the Report on *Technical proposals for by-products and high purity materials as component materials for EU Fertilising Products*[3].

The report includes technical proposals on eligible input materials and recovery operations for such high purity materials, quality requirements and quality management systems.

In accordance with Article 42(3) of Regulation (EU) 2019/1009, the Commission may only adopt delegated acts pursuant to that Article to include materials in Annex II to the Regulation that cease to be waste following a recovery operation, if recovery rules in that Annex, adopted no later than the inclusion, ensure that the materials comply with the conditions laid down in Article 6 of Directive 2008/98/EC[4]. This delegated regulation establishes recovery rules for high purity materials ensuring that they comply with the conditions laid down in Directive 2008/98/EC. Consequently, the requirement set out in Article 42(3) of Regulation (EU) 2019/1009 is fulfilled.

In this context, this delegated Regulation amends Annex II to Regulation (EU) 2019/1009 by adding recovered high purity materials as a new Component Material Category, Annex III, by adding specific labelling requirements, and Annex IV by setting up the legal framework for the relevant conformity assessment for EU fertilising products containing such materials.

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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.

2 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).

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 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.

This initiative feeds into the measures announced in the 2020 Circular Economy Action Plan[5], one of the main blocks of the European Green Deal[6], as it creates new opportunities for the use of by-products and of recovered waste, contributing to the well-functioning of the EU market for secondary raw materials.

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[7].

Details of these consultations can be found in the minutes of the meetings held on 22-23 November 2021 and 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. 9 contributions have been submitted.

Most of the contributions received concern the relationship between this Delegated Regulation introducing CMC 15 on recovered high purity materials and the Delegated Regulation supplementing Regulation (EU) 2019/2009 by laying down safety and agronomic efficiency criteria for by-products.

In this context, it is useful to clarify that CMC 15 covers recovered high purity materials. Whenever a high purity material is obtained from input materials other than waste, then it may fall under CMC 1 or CMC 11 in Annex II to Regulation (EU) 2019/1009, depending on the qualification of the material.

Concerns have also been expressed on the recovered high purity *magnesium and potassium salts*. No corresponding changes have been done to the draft delegated Regulation, because the JRC has not assessed the safety and agronomic efficiency criteria specific to these newly indicated materials.

Based on the feedback received, the draft delegated Regulation has been amended to include the recovery of high purity materials from a gas purification or emission control process designed to remove nutrients from off-gases derived from additional input materials.

Thus, it will be allowed to recover high purity materials from off-gases generated by various processes using plants and plant parts as input materials. While plants and plant parts, as such, are present in bio-waste, they were excluded from the initial draft, if they did not have the

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5 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: A new Circular Economy Action Plan For a cleaner and more competitive Europe, COM/2020/98 final.

6 Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions: The European Green Deal, COM/2019/640 final.

7 OJ L 123, 12.5.2016, p. 1–14.

waste status. However, irrespective of the legal qualification of the plants as such, the recovery of nutrients from the off-gases generated from various processes using plants as input materials is not raising additional safety concerns.

In addition, it has been included the possibility to collect off-gases from the composting and digestion of *Category 2 and Category 3 materials and products derived thereof*, within the meaning of Regulation (EC) No 1069/2009[8] and in the conditions laid down in CMCs 3 and 5 in Annex II to Regulation (EU) 2019/1009. This change implies that purification processes of off-gases produced during, for instance, digestion of bio-waste containing also animal by-products, which is a common practice, will be allowed. By cross-referring to the conditions laid down in CMCs 3 and 5 in Annex II to Regulation (EU) 2019/1009, additional safety of resulting high purity materials is ensured.

Concerns have also been expressed regarding *the testing for pathogens*. Some stakeholders were of the view that the general rule of allowing the manufacturers not to perform a test for the presence of pathogens, in certain conditions and under their own responsibility, should be maintained. However, the Commission is of the view that, at least as regards the recovery of high purity materials from off-gases, this systematic testing is necessary. This is justified by the types of input materials allowed therein – various types of sludge and waste water, certain animal by-products and manure. The limit values for pathogens should not apply only in those cases where certain processes have been followed. Based on the comments received, an additional exemption from the testing requirement has been introduced in the situation of certain incineration processes, which, because of the high temperatures involved, do not raise concerns regarding the presence of pathogens in the resulting high purity materials.

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 amends Regulation (EU) 2019/1009. The legal basis of this delegated act is Article 42(1) of Regulation (EU) 2019/1009.

[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).

COMMISSION DELEGATED REGULATION (EU)

…/... of 22.3.2022

amending Annexes II, III and IV to Regulation (EU) 2019/1009 of the European Parliament and of the Council for the purpose of adding recovered high purity materials as a component material category 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(1) 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.

(2) In accordance with Article 42(1) of Regulation (EU) 2019/1009, the Commission is empowered to adopt delegated acts in accordance with Article 44 for the purpose of adapting Annex II to technical progress.. Pursuant to Article 42(3) of Regulation (EU) 2019/1009 read in conjunction with Article 6 of Directive 2008/98/EC of the European Parliament and of the Council[2], the Commission may include in the component material categories materials that cease to be waste following a recovery operation if such materials are to be used for specific purposes, have an existing market or demand and their use do not lead to overall adverse environmental or human health impacts.

(3) The Commission's Joint Research Centre ('JRC') has identified certain high purity materials which could be recovered from waste and used as component materials in EU fertilising products[3].

(4) The high purity materials identified by the JRC are ammonium salts, sulphate salts, phosphate salts, elemental sulphur, calcium carbonate and calcium oxide. All those materials are covered by Regulation (EC) No 2003/2003 of the European Parliament

[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] 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.

and of the Council[4], have a significant market demand and have proven their high agronomic value during a long history of use in the field.

(5) As a first measure to ensure both safety and agronomic efficiency, a minimum purity requirement of high purity materials should be laid down. According to the information available in JRC's assessment report, a 95 % purity, expressed in terms of the dry matter of the material, will ensure high agronomic efficiency with low risks to the environment, health and safety. While, for some materials, this high purity is set at more ambitious levels than those required by Regulation (EC) No 2003/2003, it is estimated that such a higher purity is achievable based on existing practices.

(6) In addition, it is appropriate to specify that high purity materials are recovered from waste following two types of processes: processes that isolate salts or other elements through (a combination of) advanced purification methods, such as crystallisation, centrifugation or liquid-liquid extraction, often applied in (petro-)chemical industries; and gas purification or emission control processes designed to remove nutrients from off-gases.

(7) Therefore, the content of certain impurities, pathogens or contaminants which are specific to those materials, or the content of organic carbon should be limited, based on the JRC assessment report. Such criteria should apply in addition to the safety criteria 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].

(8) Consequently, additional limit values should be laid down for the contaminants total chromium and thallium. Some of the high purity materials may contain such contaminants as a result of the input materials and the processes they are obtained from. The proposed limit values for those contaminants should ensure that the use of EU fertilising products containing high purity materials with such contaminants does not lead to their accumulation in soil. In addition, requirements on the content of pathogens should be introduced for all EU fertilising products containing or consisting of high purity materials given the broad variety of processes they could be obtained from and the waste streams allowed as input materials. The limit values for both the contaminants and the pathogens 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 also facilitate the market surveillance of such products, as tests are to be carried out only on the final product.

(9) 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-

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4 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).

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).

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.

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.

(10) These limit values may not be relevant for all high purity materials to be included as a new component material category. 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 the recovery process of the respective high purity material or of the manufacturing process of the EU fertilising product.

(11) As an additional safety measure, the high purity materials should be registered based on Regulation (EC) No 1907/2006 of the European Parliament and of the Council[8], in the extensive conditions already laid down in Regulation (EU) 2019/1009 for chemical substances in other component material categories. This should ensure that the manufacturers take into account the use as a fertilising product when performing the risk assessment under that Regulation and that the registration is done also for low tonnage materials.

(12) Furthermore, some of the high purity materials may be available on local markets in quantities that exceed demand. To ensure that market demand for high purity materials exists and that their long-term storage under suboptimal conditions does not lead to adverse environmental impacts, it is appropriate to limit the period of time during which they can be used as component materials for EU fertilising products after they have been generated. Manufacturers should be required to sign the EU declaration of conformity for the EU fertilising product containing the said material within that period.

(13) Based on the above, the Commission concludes that high purity materials if recovered following the recovery rules suggested in JRC's assessment report, ensure agronomic efficiency within the meaning of Article 42(1), first subparagraph, point (b)(ii), of Regulation (EU) 2019/1009. Furthermore, they comply with the criteria laid down in Article 6 of Directive 2008/98/EC. Finally, if compliant with the other requirements in Regulation (EU) 2019/1009 in general and in Annex I to that Regulation in particular, they would not present a risk to human, animal or plant health, to safety or to the environment within the meaning of Article 42(1), first subparagraph, point (b)(i), of

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[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.

[8] 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).

Regulation (EU) 2019/1009. Such materials would also have a useful purpose as they would replace other raw materials used in the production of EU fertilising products. Therefore, recovered high purity materials should be included in Annex II to Regulation (EU) 2019/1009.

(14) Furthermore, given the fact that high purity materials are recovered waste within the meaning of Directive 2008/98/EC, they should be excluded from component material categories 1 and 11 of Annex II to Regulation (EU) 2019/1009 pursuant to Article 42(1), third subparagraph, of that Regulation.

(15) Some of the high purity materials 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. Annex III to Regulation (EU) 2019/1009 should be amended accordingly.

(16) It is important to ensure that when fertilising products contain high purity materials, they are subject to an appropriate conformity assessment procedure including a quality system assessed and approved by a notified body. Therefore, it is necessary to amend Annex IV to Regulation (EU) 2019/1009 to provide for a conformity assessment appropriate for such fertilising products.

(17) Given that the requirements set out in Annexes II and III to Regulation (EU) 2019/1009 and the conformity assessment procedures set out in Annex IV to that Regulation are to apply as of 16 July 2022, it is necessary to defer the application of this Regulation to the same date,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EU) 2019/1009 is amended as follows:

(1) Annex II is amended in accordance with Annex I to this Regulation;

(2) Annex III is amended in accordance with Annex II to this Regulation;

(3) Annex IV is amended in accordance with Annex III to this Regulation.

Article 2

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

It shall apply from 16 July 2022.

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

Done at Brussels, 22.3.2022

For the Commission
The President
Ursula VON DER LEYEN