

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2022/1171

of 22 March 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 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.

⁽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.

⁽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).

- (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 (PAH₁₆) ⁽⁶⁾ and of polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDD/PCDF) ⁽⁷⁾. Regulation (EU) 2019/1021 lays down release reductions for PAH₁₆ 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.

⁽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.

⁽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-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).

- (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 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 March 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

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

(1) in Part I, the following point is added:

‘CMC 15: Recovered high purity materials’;

(2) Part II is amended as follows:

(a) in CMC 1, point 1 is amended as follows:

(i) at the end of sub-point (j), the word ‘or’ is deleted;

(ii) in sub-point (k), ‘.’ is replaced by ‘, or’;

(iii) the following sub-point (l) is added:

‘(l) ammonium salts, sulphate salts, phosphate salts, elemental sulphur, calcium carbonate or calcium oxide, which are recovered from waste within the meaning of Article 3, point 1, of Directive 2008/98/EC.’;

(b) in CMC 11, point 1 is amended as follows:

(i) at the end of sub-point (f), the word ‘or’ is deleted;

(ii) in sub-point (g), ‘.’ is replaced by ‘, or’;

(iii) the following sub-point (h) is added:

‘(h) ammonium salts, sulphate salts, phosphate salts, elemental sulphur, calcium carbonate or calcium oxide, which are recovered from waste within the meaning of Article 3, point 1, of Directive 2008/98/EC.’;

(c) the following CMC 15 is added:

‘CMC 15: RECOVERED HIGH PURITY MATERIALS

(1) An EU fertilising product may contain a recovered high purity material, which is ammonium salt, sulphate salt, phosphate salt, elemental sulphur, calcium carbonate or calcium oxide, or mixtures thereof, of a purity of at least 95 % dry matter of the material.

(2) The high purity material shall be recovered from waste generated from:

(a) 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 ⁽¹⁾, or

(b) a gas purification or emission control process designed to remove nutrients from off-gases derived from one or more of the following input materials and facilities:

(i) substances and mixtures, other than waste within the meaning of Article 3, point 1, of Directive 2008/98/EC;

(ii) plants or plant parts;

(iii) bio-waste within the meaning of Article 3, point 4, of Directive 2008/98/EC, resulting from separate bio-waste collection at source;

(iv) urban and domestic waste waters within the meaning of Article 2, points 1 and 2, respectively, of Directive 91/271/EEC ⁽²⁾;

(v) sludge within the meaning of Article 2, point (a), of Directive 86/278/EEC ⁽³⁾, which displays no hazardous properties listed in Annex III to Directive 2008/98/EC;

(vi) waste within the meaning of Article 3, point 1, of Directive 2008/98/EC, and fuels input to a waste co-incineration plant as defined in Directive 2010/75/EU of the European Parliament and of the Council ⁽⁴⁾ and operated according to the conditions of that Directive, on condition that these inputs display no hazardous properties listed in Annex III to Directive 2008/98/EC;

- (vii) Category 2 or Category 3 materials or derived products thereof, in accordance with the conditions set out in Article 32(1) and (2) and in the measures referred to in Article 32(3) of Regulation (EC) No 1069/2009, provided that the off-gases are derived from a composting or digestion process in accordance with CMCs 3 and 5, respectively, in Annex II to this Regulation;
- (viii) manure within the meaning of Article 3, point 20, of Regulation (EC) No 1069/2009 or derived products thereof; or
- (ix) livestock housing facilities.

The input materials referred to in points (i) to (vi) shall not contain animal by-products or derived products within the scope of Regulation (EC) No 1069/2009.

- (3) The high purity material shall have an organic carbon (C_{org}) content of no more than 0,5 % dry matter of the material.
- (4) The high purity material shall contain no more than:
 - (a) 6 mg/kg dry matter of polycyclic aromatic hydrocarbons (PAH_{16}) ^(?);
 - (b) 20 ng WHO toxicity equivalents ^(?)/kg dry matter of the polychlorinated dibenzo-para-dioxins and dibenzofurans (PCDD/PCDF) ^(?).
- (5) An EU fertilising product containing or consisting of high purity materials 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).
- (6) Where compliance with a given requirement laid down in points 4 and 5 (such as absence of a given contaminant) follows certainly and uncontestably from the nature or the recovery process of the high purity material or the manufacturing process of the EU fertilising product, that compliance may be presumed in the conformity assessment procedure without verification (such as testing), under the responsibility of the manufacturer.
- (7) Where for the product function category of an EU fertilising product containing or consisting of high purity materials referred to in point 2(b) no requirements regarding *Salmonella* spp., *Escherichia coli* or *Enterococcaceae* have been laid down in Annex I, those pathogens in the EU fertilising product shall not exceed the limits set out in the following table:

Micro-organisms to be tested	Sampling plans			Limit
	n	c	m	M
<i>Salmonella</i> spp.	5	0	0	Absence in 25 g or 25 ml
<i>Escherichia coli</i> or <i>Enterococcaceae</i>	5	5	0	1 000 in 1 g or 1 ml

Where:

n = number of samples to be tested,

c = number of samples where the number of bacteria expressed in colony forming units (CFU) is between m and M,

m = threshold value for the number of bacteria expressed in CFU that is considered satisfactory,

M = maximum value of the number of bacteria expressed in CFU.

- (8) The compliance of an EU fertilising product containing or consisting of high purity materials referred to in point 2(b) with requirements in point (7), or with the requirements for *Salmonella* spp., *Escherichia coli* or *Enterococcaceae* set out in Annex I for the corresponding PFC of the EU fertilising product shall be verified via testing, in accordance with point 5.1.3.1 in Module D1 – quality assurance of the production process in Part II of Annex IV.

The requirements in point (7) and the requirements for *Salmonella* spp., *Escherichia coli* or *Enterococcaceae* set out in Annex I for the corresponding PFC of an EU fertilising product consisting only of high purity materials referred to in point 2(b) shall not apply, when the high purity materials or all of the biogenic input materials used have undergone one of the following processes:

- (a) pressure sterilisation through the heating to a core temperature of more than 133 °C for at least 20 minutes at an absolute pressure of at least 3 bars, whereby the pressure must be produced by the evacuation of all air in the sterilisation chamber and the replacement of the air by steam ('saturated steam');
- (b) processing in a pasteurisation or hygienisation unit that reaches a temperature of 70 °C for at least one hour.

The requirements in point (7) and the requirements for *Salmonella* spp., *Escherichia coli* or *Enterococcaceae* set out in Annex I for the corresponding PFC of an EU fertilising product consisting only of high purity materials referred to in point 2(b) shall not apply, where the off-gases derive from an incineration process as defined in Directive 2010/75/EU.

- (9) High purity materials that are stored in a way that does not protect them against precipitation and direct sunlight may be added to an EU fertilising product only if they have been manufactured maximum 36 months before signing the EU declaration of conformity for the respective EU fertilising product.
- (10) The high purity material shall have been registered pursuant to Regulation (EC) No 1907/2006, with a dossier containing:
 - (a) the information provided for by Annexes VI, VII and VIII to Regulation (EC) No 1907/2006, and
 - (b) a chemical safety report pursuant to Article 14 of Regulation (EC) No 1907/2006 covering the use as a fertilising product,

unless explicitly covered by one of the registration obligation exemptions provided for by Annex IV to Regulation (EC) No 1907/2006 or by points 6, 7, 8, or 9 of Annex V to that Regulation.

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- (¹) 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).
 - (²) Council Directive 91/271/EEC of 21 May 1991 concerning urban waste-water treatment (OJ L 135, 30.5.1991, p. 40).
 - (³) Council Directive 86/278/EEC of 12 June 1986 on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture (OJ L 181, 4.7.1986, p. 6).
 - (⁴) Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17).
 - (⁵) 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.
 - (⁶) 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.
 - (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.

ANNEX II

In Part I of Annex III to Regulation (EU) 2019/1009, the following point 7b is inserted:

- ‘7b. Where the EU fertilising product contains or consists of high purity materials referred to in Part II, CMC 15, of Annex II and:
- (a) has a selenium (Se) content exceeding 10 mg/kg dry matter, the selenium content shall be indicated;
 - (b) 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.

When the content of selenium or chloride is indicated in accordance with point (a) and (b), it shall be clearly separated from nutrient declaration and it may be expressed as a range of values

Where the fact that such an EU fertilising product contains selenium or chloride below the limit values in points (a) and (b) follows certainly and uncontestably from the nature or recovery operation of the high purity material or the production process of the EU fertilising product containing such a material, as applicable, the label may contain no information on these parameters, without verification (such as testing), at the responsibility of the manufacturer.’.

ANNEX III

In Part II of Annex IV to Regulation (EU) 2019/1009, Module D1 (Quality assurance of the production process) is amended as follows:

(1) in point 2.2, sub-point (d) is replaced by the following:

‘(d) drawings, schemes, descriptions and explanations necessary for the understanding of the manufacturing process of the EU fertilising product, and, in relation to materials belonging to CMCs 3, 5, 12, 13, 14 or 15 as defined in Annex II, a written description and a diagram of the production or recovery process, where each treatment, storage vessel and area is clearly identified.’;

(2) in point 5.1.1.1, the introductory wording is replaced by the following:

‘5.1.1.1. For materials belonging to CMCs 3, 5, 12, 13, 14 and 15, as defined in Annex II, senior management of the manufacturer’s organisation shall.’;

(3) point 5.1.2.1 is replaced by the following:

‘5.1.2.1. For materials belonging to CMCs 3, 5, 12, 13, 14 and 15, as defined in Annex II, the quality system shall ensure compliance with the requirements specified in that Annex.’;

(4) point 5.1.3.1 is amended as follows:

(a) the introductory wording is replaced by the following:

‘5.1.3.1. For materials belonging to CMCs 3, 5, 12, 13, 14 and 15, as defined in Annex II, the examinations and tests shall comprise the following elements.’;

(b) sub-points (b) and (c) are replaced by the following:

‘(b) Qualified staff shall carry out a visual inspection of each consignment of input materials and verify compatibility with the specifications of input materials laid down in CMCs 3, 5, 12, 13, 14 and 15 in Annex II [OR: as defined in Annex II].

(c) The manufacturer shall refuse any consignment of any given input material where visual inspection raises suspicion of any of the following:

- the presence of hazardous or damaging substances for the process or for the quality of the final EU fertilising product,
- incompatibility with the specifications laid down in CMCs 3, 5, 12, 13, 14 and 15 in Annex II [OR: as defined in Annex II], in particular by presence of plastics leading to exceedance of the limit value for macroscopic impurities.’;

(c) sub-point (e) is replaced by the following:

‘(e) Samples shall be taken on output materials, to verify that they comply with the specifications laid down in CMCs 3, 5, 12, 13, 14 and 15, as defined in Annex II, and that the properties of the output material do not jeopardise the EU fertilising product’s compliance with the relevant requirements laid down in Annex I’;

(d) in sub-point (fa), the introductory wording is replaced by the following:

‘(fa) For materials belonging to CMCs 12, 13, 14 and 15, the output material samples shall be taken with at least the following default frequency, or sooner than scheduled in the case of any significant change that may affect the quality of the EU fertilising product.’;

(e) sub-point (fb) is replaced by the following:

‘(fb) For materials belonging to CMCs 12, 13, 14 and 15, each batch or portion of production shall be assigned a unique code for quality management purposes. At least one sample per 3 000 tonnes of these materials or one sample per two months, whichever occurs sooner, shall be stored in good condition for a period of at least two years.’;

(f) sub-point (g)(iv) is replaced by the following:

‘(iv) for materials belonging to CMCs 12, 13, 14 and 15, measure retainer samples referred to in sub-point (fb) and take the necessary corrective actions to prevent possible further transport and use of that material.’;

(5) in point 5.1.4.1, the introductory wording is replaced by the following:

‘5.1.4.1. For materials belonging to CMCs 3, 5, 12, 13, 14 and 15, as defined in Annex II, the quality records shall demonstrate effective control of input materials, production, storage and compliance of input- and output materials with the relevant requirements of this Regulation. Each document shall be legible and available at its relevant place(s) of use, and any obsolete version shall be promptly removed from all places where it is used, or at least identified as obsolete. The quality management documentation shall at least contain the following information:’;

(6) in point 5.1.5.1, the introductory wording is replaced by the following:

‘5.1.5.1. For materials belonging to CMCs 3, 5, 12, 13, 14 and 15, as defined in Annex II, the manufacturer shall establish an annual internal audit program in order to verify the compliance of the quality system with the following components:’;

(7) in point 6.3.2, the introductory wording is replaced by the following:

‘6.3.2. For materials belonging to CMCs 3, 5, 12, 13, 14 and 15, as defined in Annex II, the notified body shall take and analyse output material samples during each audit, and those audits shall be carried out with the following frequency:’.
