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Subject:	ANNEXES to the Commission Delegated Regulation amending Annexes II, III and IV to Regulation (EU) 2019/1009 of the European Parliament and of the Council for the purpose of adding thermal oxidation materials and derivatives as a component material category in EU fertilising products

Delegations will find attached document C(2021) 4751 final (annexes part).

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ANNEXES 1 to 3

ANNEXES

to the

Commission Delegated Regulation

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

ANNEX I

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

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

"CMC 13: Thermal oxidation materials and derivatives";

(2) Part II is amended as follows:

(a) In CMC 1, point 1, the following sub-point (j) is added:

"(j) thermal oxidation materials or derivatives which are recovered from waste or are by-products within the meaning of Directive 2008/98/EC, or";

(b) In CMC 11, point 1, the following sub-point (f) is added:

"(f) thermal oxidation materials or derivatives, which are recovered from waste or are by-products within the meaning of Directive 2008/98/EC, or";

(c) The following CMC 13 is added:

"CMC 13: THERMAL OXIDATION MATERIALS OR DERIVATES

1. An EU fertilising product may contain thermal oxidation materials obtained through thermochemical conversion under non-oxygen-limiting conditions exclusively from one or more of the following input materials:

- (a) living or dead organisms or parts thereof, which are unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which are extracted from air by any means, except (*):
 - materials originating from mixed municipal waste,
 - sewage sludge, industrial sludge or dredging sludge, and
 - animal by-products or derived products within the scope of Regulation (EC) No 1069/2009;
- (b) vegetable waste from the food processing industry and fibrous vegetable waste from virgin pulp production and from production of paper from virgin pulp, if not chemically modified;
- (c) bio-waste fraction resulting from subsequent treatment operations of bio-waste separately collected for recycling within the meaning of Directive 2008/98/EC, for which incineration delivers the best environmental outcome in accordance with Article 4 of that Directive other than animal by-products or derived products within the scope of Regulation (EC) No 1069/2009;
- (d) materials resulting from a controlled microbial or thermochemical conversion process using exclusively the input materials referred to in sub-points (a), (b), and (c);
- (e) sewage sludge from municipal wastewater treatment plants, other than animal by-products or derived products within the scope of Regulation (EC) No 1069/2009;
- (f) materials from the independently operated treatment of waste water not covered by Council Directive 91/271/EEC (**) from food processing, pet food, feed, milk and drink industries, other than animal by-products or derived products within the scope of Regulation (EC) No 1069/2009;

- (g) waste within the meaning of Directive 2008/98/EC with the exception (*) of:
 - input materials referred to in sub-points (a) to (f),
 - hazardous waste within the meaning of Article 3, point 2 of Directive 2008/98/EC,
 - materials originating from mixed municipal waste,
 - bio-waste within the meaning of Article 3, point 4 of Directive 2008/98/EC resulting from separate bio-waste collection at source, and
 - animal by-products or derived products within the scope of Regulation (EC) No 1069/2009;
 - (h) auxiliary fuels (natural gas, liquefied gas, natural gas condensate, process gases and components thereof, crude-oil, coal, coke as well as their derived materials), when used to process input materials referred to in sub-points (a) to (g);
 - (i) substances which are used in production processes of the iron and steel industry; or
 - (j) substances and mixtures, with the exception (*) of:
 - input materials referred to in sub-points (a) to (i),
 - waste within the meaning of Article 3, point 1 of Directive 2008/98/EC,
 - substances or mixtures which have ceased to be waste in one or more Member States by virtue of the national measures transposing Article 6 of Directive 2008/98/EC,
 - substances formed from precursors which have ceased to be waste in one or more Member States by virtue of the national measures transposing Article 6 of Directive 2008/98/EC, or mixtures containing such substances, and
 - animal by-products or derived products within the scope of Regulation (EC) No 1069/2009.
2. Notwithstanding point 1, an EU fertilising product may contain thermal oxidation materials obtained through thermochemical conversion under non-oxygen-limiting conditions from Category 2 or Category 3 materials or derived products thereof, in accordance with the conditions set out in Article 32(1) and (2) of Regulation (EC) No 1069/2009 and in the measures referred to in Article 32(3) of that Regulation, alone or mixed with input materials referred to in point 1, provided that both of the following conditions are fulfilled:
- (a) the end point in the manufacturing chain has been determined in accordance with Article 5(2), third subparagraph of Regulation (EC) No 1069/2009;
 - (b) the conditions in points 3, 4, and 5 are met.
3. The thermal oxidation shall take place under non-oxygen limiting conditions in such a way that the gas resulting from the thermochemical conversion process is raised, after the last injection of combustion air, in a controlled and homogeneous fashion and even under the most unfavourable conditions to a temperature of at least 850°C for at least 2 seconds. These conditions shall apply to all input materials, with the exemption of:

(a) the input materials referred to in points 1(a), (b) and (h), or resulting from a controlled microbial or thermochemical conversion process using exclusively those materials, and

(b) input materials referred to in point 2,

for which a temperature of at least 450°C for at least 0.2 seconds shall apply;

4. The thermal oxidation shall take place in an incineration or combustion chamber. The chamber may only process input materials, which are not contaminated with other material streams, or input materials, other than animal by-products or derived products within the scope of Regulation (EC) No 1069/2009, which have been contaminated with other material streams unintentionally in a one-off incident resulting only in trace levels of exogenous compounds.

All of the following conditions shall be met in the plant, where the thermal oxidation takes place:

- (a) the production lines for the processing of input materials referred to in points 1 and 2 shall be clearly separated from production lines for the processing of other input materials,
- (b) the input material shall be oxidised in such a way that the total organic carbon (C_{org}) content of the resulting slags and bottom ashes is less than 3 % by dry matter of the material,
- (c) physical contact between input and output materials shall be avoided after the thermochemical conversion process, including during storage.

5. The thermal oxidation materials shall be ashes or slags, and have no more than:

- (a) 6 mg/kg dry matter of PAH₁₆(***),
- (b) 20 ng WHO toxicity equivalents (****) of PCDD/F (*****)/kg dry matter.

6. An EU fertilising product may contain derivatives from thermal oxidation materials that have been produced from the input materials referred to in points 1 and 2 that meet the conditions of point 5 and that have been manufactured by a thermochemical conversion process in accordance with points 3 and 4.

The derivative manufacturing process shall be executed so as to intentionally modify the chemical composition of the thermal oxidation material.

The derivative manufacturing process shall be of the following nature:

- (a) chemical manufacturing: derivatives are produced through one or more chemical manufacturing steps that react thermal oxidation materials with input materials referred to in sub-point 1(j) that are consumed in or used for chemical processing whereas non-biodegradable polymers shall not be used;
- (b) thermochemical manufacturing: derivatives are produced through one or more manufacturing steps that thermochemically react thermal oxidation materials with reactants referred to in points 1 and 2 that are consumed in or used for chemical processing.

Thermal oxidation materials that display one or more of the hazardous properties listed in Annex III to Directive 2008/98/EC shall not be mixed or reacted, either with waste, substances or materials with the intention of reducing hazardous substances to levels below the limit values for the hazardous property as laid down in Annex III to that Directive. Using a mass balance approach, manufacturers that use thermal

oxidation materials with hazardous properties must demonstrate the removal or transformation of the contaminants to levels below the limit values laid down in Annex III to Directive 2008/98/EC.

7. Contaminants in an EU fertilising product containing or consisting of thermal oxidation materials or derivatives must not exceed the following limit values:

- (a) total chromium (Cr): 400 mg/kg dry matter, if the thermal oxidation materials or derivatives are from input materials referred to in sub-points 1(e), (g) or (i);
- (b) thallium (Tl): 2 mg/kg dry matter, if the thermal oxidation materials or derivatives are from input materials referred to in sub-points 1(e), (g), (h) or (i);

The chlorine (Cl) content shall not be higher than 30 g/kg of dry matter. However, this limit value shall not apply to EU fertilising products produced through a manufacturing process where a Cl containing compound has been added with the intention of producing alkali metal salts or alkaline earth metal salts, and is declared in accordance with Annex III;

The vanadium (V) content shall not be higher than 600 mg/kg dry matter if the thermal oxidation materials or derivatives are from input materials referred to in sub-points 1(g) or (i).

8. The thermal oxidation materials or derivatives shall have been registered pursuant to Regulation (EC) No 1907/2006, in a dossier containing:

- (a) the information provided for by Annexes VI, VII and VIII of 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.”

(*) The exclusion of an input material from a sub-point does not prevent it from being an eligible input material by virtue of another sub-point.

(**) Council Directive 91/271/EEC of 21 May 1991 concerning urban waste-water treatment (OJ L 135, 30.5.1991, p. 40).

(***) 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.

(****) 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.

(*****) Polychlorinated dibenzo-p-dioxins and dibenzofurans.

ANNEX II

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

“7a. Where the EU fertilising product contains or consists of thermal oxidation materials or derivatives referred to in CMC 13 in Part II of Annex II and has a manganese (Mn) content above 3,5 % by mass, the manganese content shall be declared.”

ANNEX III

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

(1) Point 2.2 is amended as follows:

(a) 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 or 13 as defined in Annex II, a written description and a diagram of the production process, where each treatment, storage vessel and area is clearly identified.”;

(b) the following sub-point (ga) is inserted:

“(ga) hazardous waste calculations for EU fertilising products containing or consisting of CMC 13; the testing referred to in point 6 in CMC 13 in Part II of Annex II shall be carried out at least every year, or sooner than scheduled in case of any significant change that may affect the safety or quality of the EU fertilising product (for example processing of input material batches of different composition, modification of process conditions). For a representative input material batch that is processed at the plant, the hazardous property identified (in accordance with point 5.1.3.1) and the total mass shall be measured on the different input materials (1, ..., n) and on the output material that will be incorporated in the EU fertilising product. The incorporation rate of the hazardous property into the output material shall then be calculated as follows:

$$\text{incorporation rate (\%)} = \frac{HPC_{\text{output material}} \times M_{\text{output material}}}{\sum_{i=1}^n (HPC_{\text{input material},i} \times M_{\text{input material},i})}$$

Where:

HPC = the concentration of the hazardous property (mg/kg),

M = the total mass (kg), and

i (1-n) = the different input materials used in the production process.

The removal of the hazardous property during the production process shall be such that the incorporation rate multiplied by the concentration of the hazardous property of each individual input material is below the limit values laid down in Annex III to Directive 2008/98/EC for that hazardous property.”.

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

“5.1.1.1. For materials belonging to CMCs 3, 5, 12 and 13, 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 and 13, as defined in Annex II, the quality system shall ensure compliance with the requirements laid down 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 and 13, 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 in CMCs 3, 5, 12 and 13 laid down in Annex II.

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

- (i) the presence of hazardous or damageable substances for the process or for the quality of the final EU fertilising product;
- (ii) incompatibility with the specifications of CMCs 3, 5, 12 and 13 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 and 13, 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 and 13, the output material samples shall be taken with at least the following default frequency, or sooner than scheduled in 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 and 13, each batch or portion of production shall be assigned a unique code for quality management purposes; at least one sample per 3000 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 and 13, 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 and 13, 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 and 13, 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 and 13, 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:”.