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Delegations will find attached document C(2021) 4764 final - Annexes 1 to 3.

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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 pyrolysis or gasification materials 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 14: Pyrolysis and gasification materials";

(2) Part II is amended as follows:

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

“(k) pyrolysis and gasification materials, which are recovered from waste or are by-products within the meaning of Directive 2008/98/EC.”;

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

“(g) pyrolysis and gasification materials, which are recovered from waste or are by-products within the meaning of Directive 2008/98/EC.”;

(c) The following CMC 14 is added:

“CMC 14: PYROLYSIS AND GASIFICATION MATERIALS

1. An EU fertilising product may contain pyrolysis or gasification materials obtained through the thermochemical conversion under oxygen-limiting conditions of exclusively 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, 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) processing residues within the meaning of Article 2, point (t) of Directive 2009/28/EC from the production of bioethanol and biodiesel, derived from materials referred to in sub-points (a), (b) and (d);
- (d) bio-waste within the meaning of Article 3, point 4 of Directive 2008/98/EC resulting from separate bio-waste collection at source, other than animal by-products or derived products within the scope of Regulation (EC) No 1069/2009 or
- (e) pyrolysis or gasification additives which are necessary to improve the process performance or the environmental performance of the pyrolysis or gasification process, provided that those additives are consumed in chemical processing or used for such processing and that total concentration of all additives do not exceed 25 % of the fresh matter of the total input material, with the exception (*) of:
 - input materials referred to in sub-points (a) to (d),
 - 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,
- non-biodegradable polymers, and
- animal by-products or derived products within the scope of Regulation (EC) No 1069/2009.

An EU fertilising product may contain pyrolysis or gasification materials obtained through thermochemical conversion under oxygen-limiting conditions of any input material referred to in sub-points (a) to (e), or combination thereof, processed by manual, mechanical or gravitational means, by solid-liquid fractionation using biodegradable polymers, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, by composting or by anaerobic digestion.

2. The thermochemical conversion process shall take place under oxygen-limiting conditions in such a way that a temperature of at least 180°C for at least two seconds is reached in the reactor.

The pyrolysis or gasification reactor 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.

In the plant where the pyrolysis or gasification takes place, physical contacts between input and output materials shall be avoided after the thermochemical process, including during storage.

3. The pyrolysis and gasification materials shall have a molar ratio of hydrogen (H) to organic carbon (H / C_{org}) of less than 0,7, with testing to be performed in the dry and ash-free fraction for materials that have an organic carbon (C_{org}) content of less than 50 %. They shall have no more than:

- (a) 6 mg/kg dry matter of PAH₁₆ (**),
- (b) 20 ng WHO toxicity equivalents (***) of PCDD/F(****) /kg dry matter,
- (c) 0,8 mg/kg dry matter of ndl-PCB(*****),

4. Notwithstanding point 1, an EU fertilising product may contain pyrolysis or gasification materials obtained through the thermochemical conversion under oxygen-limiting conditions of 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 2 and 3 are met.

5. In the plant where the pyrolysis or gasification takes place, the production lines for the processing of input materials referred to in points 1 and 4 shall be clearly separated from production lines for the processing of other input materials.

6. In an EU fertilising product containing or consisting of pyrolysis and gasification materials:

- (a) the chlorine (Cl) content shall not be higher than 30 g/kg dry matter and
- (b) the thallium (Tl) content shall not be higher than 2 mg/kg dry matter, in case more than 5 % of pyrolysis or gasification additives relative to the fresh weight of total input material have been applied.

7. The pyrolysis and gasification material shall have been registered pursuant to Regulation (EC) No 1907/2006, in a dossier containing:

- (a) the information provided for by Annex 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.

(**) 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.

(*****) Sum of congeners PCB 28, 52, 101, 138, 153, 180.

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 and derivatives as referred to in CMC 13 in Part II in Annex II or pyrolysis or gasification materials as referred to in CMC 14 in Part II of that Annex 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) 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 or 14 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.”;

(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 and 14, 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 and 14, 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 and 14, 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, 13 and 14 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:

- the presence of hazardous or damageable substances for the process or for the quality of the final EU fertilising product,
- incompatibility with the specifications of CMCs 3, 5, 12, 13 and 14 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 and 14, 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 and 14, 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, 13 and 14, 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, 13 and 14, 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 and 14, 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 and 14, 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 and 14, 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:”.