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CEN reply

to the call for evidence for an evaluation and fitness check of the Fertilising Products Regulation.

CEN/TC 223 'Soil improvers and growing media' and CEN/TC 260 'Fertilizers and liming materials' have collected the following aspects for the European Commission to take into consideration for future developments of the FPR. CEN is at the disposal of the European Commission to discuss these matters in further detail.

GENERAL REMARKS:

As several interlaboratory studies and the analysis of their results are still ongoing, it is important to inform the European Commission that the findings presented below are not yet exhaustive. These results may be further supplemented once all ILSs have been completed and their outcomes fully assessed.

From the very beginning, the aim of the Fertilising Products Regulation (FPR) was to create standardization of the specifications for fertilizing products. During the development of the FPR, the European Commission stated their intention was to simplify access to the European market and to make product quality and quantity labelling more comparable based on European Standards. In many respects, these aims have not been fully fulfilled, which has led to a low level of acceptance of the FPR by stakeholders:

1. The FPR is complex and not in all cases easy to comprehend, especially by SMEs. The complexity of the essential requirements of the Regulation has an impact on the development of the standards needed to support it.
2. Limit values for human pathogens and other parameters have been set without the relevant European standards in place. Following typical scientific practice, analytical standards should be developed first, and then limit values are set.
3. Costs for analyses, personnel and bureaucratic hurdles (conformity assessment) are high compared to current costs based on national laws/ regulations/ordinances.
4. Due to inappropriate specifications set in the FPR, long-established growing media components are non-compliant and cannot be used.

TECHNICAL REMARKS:

Related to microbiological aspects

1. The criteria for *Escherichia coli* (*E. coli*) and enterococci (*Enterococcaceae* before) should be removed as limit value for the product function categories (PFC) "Organic fertiliser", "Organic

soil improver" and "Growing media". The absence of *Salmonella* spp. in these PFCs forms an adequate hygienic parameter for the final product assessment.

Explaining the issue: The limit for *E. coli* or enterococci in growing media is an issue; namely for those with very little or no peat. The limit value (< 1.000 CFU/g) can be reached directly after sanitation of the growing media constituents (CMCs). *E. coli* or enterococci are never zero, which means that the number of CFU may increase again during storage, transport or mixing process. That is different to *Salmonella*, which has to be absent. Please consider that *E. coli* a ubiquitous bacterial species but not all strains are pathogens.

The limits for pathogens were taken over from EU 142/2011 (Section 3) as a control of the sanitation process:

"Representative samples of the digestion residues or compost taken during or immediately after transformation at the biogas plant or composting at the composting plant in order to monitor the process must comply with the following standards:
Escherichia coli: n = 5, c = 1, m = 1 000, M = 5 000 in 1 g;
or
Enterococcaceae: n = 5, c = 1, m = 1 000, M = 5 000 in 1 g;

- *n = number of samples to be tested;*
- *m = threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all samples does not exceed m;*
- *M = maximum value for the number of bacteria; the result is considered unsatisfactory if the number of bacteria in one or more samples is M or more; and*
- *c = number of samples the bacterial count of which may be between m and M, the sample still being considered acceptable if the bacterial count of the other samples is m or less."*

2. The procedure for controlling pathogens as stated in the FPR FAQs unfortunately does not work in practice. In practice, the production process is such that various growing media constituents (CMC) like wood fiber, composts, peat etc. are mixed directly with fertilizer and, if necessary, lime. According to the FPR, this is PFC 7. In that case, PFC 4 does not really exist in practice. Products regulated by the FPR are not stored under cooling conditions (which is the case with e.g. foodstuffs). Especially peat reduced or peat free growing media blends (PFC 7) contain large amounts of microorganisms, which are also useful. A sanitation process for PFC 4 or PFC 7 is not possible because you would change the characteristics of the product.
3. We kindly request the European Commission to redefine PFC 4 as a Growing Media that entails the addition of fertilizers, lime, and more. This means that there is only a limit for Salmonella spp. but not for E. coli or enterococci in PFC 4. This approach follows the Swiss adoption of their Fertilizer Regulation to the FPR.
4. The TCs strongly recommend that microbiological limit values not be directly transferred from one regulatory framework (e.g., the Animal By-Products Regulation – ABPR) to another (e.g., the Fertilising Products Regulation – FPR) without a thorough assessment of the specific characteristics of the respective matrices (see also point 1). In the ABPR, microbiological parameters such as *E. coli* and enterococci are primarily used as process indicators to verify the effectiveness of sanitation steps during treatment. These parameters, however, do not reliably reflect the microbiological status of final products, particularly due to the natural regrowth of these organisms under ambient conditions—a phenomenon that does not compromise product quality.

   Moreover, the limit values for *E. coli* and enterococci in the FPR have been set more stringently than those in the ABPR (Regulation (EU) No 142/2011), despite the lack of evidence supporting their relevance for organic and biologically active matrices such as compost and digestate. In contrast, *Salmonella* spp. has proven to be a more reliable indicator organism, with extensive experience supporting its use in assessing the hygienic safety of such products.

   It is also important to note that the microbiological limits in the FPR were established prior to the validation of the corresponding analytical methods. Whether these limits are appropriate for complex, microbially dynamic products like compost remains uncertain. Historical data show

that *E. coli* counts in such materials can reach levels in the millions, underscoring the need for a more nuanced and evidence-based approach to microbiological criteria.

Related to growing medium

1. The FPR states: *"A growing medium shall be an EU fertilising product other than soil in situ, the function of which is for plants or mushrooms to grow in."* Such growing media must not contain other PFCs. If a growing medium contains other PFCs, then it is considered a PFC 7. These definitions contradict national rules and scientific understanding.

   Explanation and reasoning: The meaning of terms and their definitions was extremely important in the development of the FPR. The FPR definition for growing media should reflect the standard global definition of growing media. Renowned growing media scientists[1] have indeed adopted the FPR definition for growing media but have included a crucial note:

   > *"A growing medium consists of a single bulky (volume building) component or a mix of such components to which additives i.e. fertilizer and liming material are usually added."*

   In other words, growing media almost always contains additives such as lime, fertilizer, plant biostimulants, and/or others. The FPR definition for growing media reads:

   > *"Material other than soil in situ, the function of which is for plants or mushrooms to grow in".*

   To grow in, bulky component materials (CMCs) need to be admixed with additives i.e. liming material and fertilizer – otherwise plants will not grow.

   In addition, the Guidelines for Labelling[2] have adopted a definition for growing media which reads:

   > *"A growing medium cannot contain fertilisers, liming materials, plant biostimulants or products belonging to other PFCs."*

   Per se, this definition means that (except for e.g. pre-shaped mineral wool, expanded clay) plants will not grow in a growing medium because, for example, essential nutrients are missing. The Guidelines for Labelling add the following:

   > *"This type of growing medium (PFC 4) is placed on the market for exceptional applications where the addition of products belonging to other PFCs is not essential. It will also serve as the basis for Fertilising Product Blends (PFC 7) containing other PFCs. Any growing medium (PFC 4) blended with one or more products of any other PFC (for example fertiliser, liming material, plant biostimulants) is a PFC 7."*

   These misinterpretations of what a growing medium is have led to frustration by experts when developing standards in support of the FPR. National regulations and Growing Media Quality Assurance Associations acknowledge the fact that growing media generally contain fertilizer, liming material, plant biostimulants, and/or other additives (PFCs) and do not differ between 'growing media' and 'growing media blends'. In practice the current PFC 4 is insignificant and superfluous.

2. We kindly request the European Commission to revise the temperature limit of 100 °C in the production of wood fibers as it is one of the main component materials of growing media.

   Explanation and reasoning: Manufacturers of growing media are increasingly committed to using more sustainable bulky (volume-building) component materials. For example, wood fibers and buffered coconut coir have been successfully used in growing media for decades – with increasing proportions by volume – without harming humans, plants or animals. The FPR however does not allow for the use of these components.

   Wood fibers and other plant fibers (incl. future circular components):

   Fiberization (fraying) of wood chips and other plant material occurs at temperatures of about 100 °C and often higher temperatures. The FPR sets a temperature limit of <100 °C for this process. This imposes a ban on the use of wood fibers manufactured at temperatures above

[1] Caron et al. in Acta Hortic. 1377. ISHS 2023. DOI 0.17660/ActaHortic.2023.1377.116 XXXI IHC – Proc. Int. Symp. on Innovative Technol. and Prod. Strategies for Sustainable Controlled Environ. Hortic. Eds.: Y. Rouphael and J.-C. Michel

[2] COMMUNICATION FROM THE COMMISSION concerning the visual appearance of the label on EU fertilising products referred to in Annex III to Regulation (EU) 2019/1009 of the European Parliament and of the Council dated 18.2.2021

100 °C. Therefore, we kindly request the European Commission to reconsider the temperature limit.

Related to the designation of CMCs and PFCs

1. Please consider broadening the definition of CMC 9 to "Polymers other than nutrient polymers and CMC 8: Nutrient polymers".
2. Consider adding a CMC category End of Waste: clear pathway next to by-product to End of Waste.
3. Please consider broadening PFC definitions. This would allow growing media and soil improver products to be classified in more categories. For example mineral wool in PFC 1 Inorganic Fertilizer, PFC 2 Liming Material, PFC 3B Inorganic Soil Improver, and PFC 7 Fertilizing Product Blend (Composed of 2 or more PFCs)… PFC 3B fits the TCs initiative by definition.
4. In the TC's technical opinion, more elements can be chelating agents than described in the FPR, and the TCs would suggest that the definition should be broader. They refer to Annex II, Part II, CMC 1, point 3(a) [i-ii] Chelating agent:

   "*The chelating agent shall be an organic substance consisting in a molecule which: (i) has two or more sites that donate electron pairs to a central transition metal cation (zinc (Zn), copper (Cu), iron (Fe), manganese (Mn), magnesium (Mg), calcium (Ca) or cobalt (Co)), and (ii) is large enough to form a five- or six- membered cyclic structure.*"

   For broadening the definition, we kindly request the European Commission to either remove the list of elements (zinc, copper, iron etc.), or to include more elements.
5. The current wording in the FPR for CMC 8 Nutrient Polymers includes degradation requirements that appear scientifically and technically unfeasible. Specifically, the requirement that "*3. The final degradation products shall be only ammonia (NH_3), water and carbon dioxide (CO_2)*" is restrictive and does not reflect the complexity of nutrient polymer degradation in real-world conditions. This requirement is problematic for several reasons:
   a. it is limited to products containing nitrogen (NH_3) only, while theoretically the category is also open to other nutrient polymers that the sector may develop in the future (i.e. containing phosphorus, potassium, etc.;
   b. analytical results don't show only ammonia (NH_3) as a final product, but also nitrites (NO_2^-) and predominantly nitrates (NO_3^-);
   c. analytical results don't show only carbon dioxide (CO_2) as a final product;
   d. production of "new microbial cellular constituents (biomass)" isn't considered.

   In light of these considerations, the TCs believe that the requirement should be reformulated as follows or similar:

   "*3. The final degradation products shall be mineral salts (which depend on the nature of the nutrient polymer), carbon dioxide (CO2), water and new microbial cellular constituents (biomass).*"

   Furthermore, the requirements for CMC 8 were formulated with methylene urea in mind only, as it is the only fertilizer made with formaldehyde and has a nitrogen content that is soluble in phosphate buffer at 100 °C. Therefore, they appear to reflect a specific case of a nutrient polymer, which contrasts with requirement 1. which is instead generic.
6. Annex I, Part II, PFC 5(A), 2. (nitrification inhibitor) states

   "*The ammoniacal nitrogen (NH3-N) oxidation rate shall be measured by: (a) ammoniacal nitrogen (NH_3-N) disappearance, or (b) the sum of nitrite nitrogen (NO_2^-) and nitrate nitrogen (NO_3^-) production with respect to time.*"

   As the determination of nitrite and nitrate formation give systematically different results from a), we kindly request the European Commission to delete (b).
7. Related to Annex I, Part II, PFC 5(A), 2. (nitrification inhibitor)

"*Compared to a control sample where the nitrification inhibitor has not been added, a soil sample containing the nitrification inhibitor shall show a 20 % reduction in ammoniacal nitrogen (NH_3-N) oxidation rate based on an analysis carried out 14 days after application at the 95 % confidence level.*"

According to preliminary ILS results under Standardization Request M/564, the combination of 20% reduction with 14 days of testing seems to be unsuitable for evaluation and does not correspond to the usual objectives of the application of a nitrification inhibitor. If more solid ILS results are available, proposals for adapted requirements will be made and the European Commission is invited to take appropriate action (e.g. adaption of percentage of inhibition or modification of required time period).

8. Related to Annex I, Part II, PFC 5(C), 2. (urease inhibitor)

   "*Compared to a control sample where the urease inhibitor has not been added, an in vitro test containing the urease inhibitor …*"

   An *in vitro* test without the use of soil is not suitable for the intended purpose (assessing the efficacy of a urease inhibitor). The use of soil material is mandatory for soil applied inhibitors. We kindly request to European Commission to replace "an *in vitro* test containing" with "a soil sample containing".

Related to chemical parameters

1. Annex II, Part II, CMC 12, point 12 of the FPR does not specify whether Aluminium and Iron should be measured as total (acid-soluble) or water-soluble content. Therefore, we kindly request the European Commission to specify whether the mentioned parameters refer to total content or only the water-soluble portion.
2. For
   a. Annex II, Part II, CMC 13, point 7
   b. Annex II, Part II, CMC 14, point 6 (b)
   c. Annex II, Part II, CMC 15, point 5 (b)

   The points do not clarify whether the limit values for Vanadium and Thallium should be measured as total content (acid-soluble) or as water-soluble content. Therefore, we kindly request the European Commission to specify whether the limit values refer to total content or only the water-soluble portion.
3. In the FPR, both the terms PCDD/F and PCDD/PCDF are present. Both terms mean the same. Therefore, we kindly request the European Commission to harmonize these definitions.
4. In the FPR, both the terms Chloride and Chlorine are present and are mistakenly used interchangeably. Therefore, we kindly request the European Commission to adapt the term Chlorine to Chloride, because Chloride is the water-soluble and plant-available form of Chlorine.