



**Summary of the FAQ  
regarding the CMC 10 amendment of the FPR**

**The questions are related to the CMC10 webinar organised by  
CerTrust Ltd (NANDO 2806) on 1<sup>st</sup> July 2024.**

Monday **1st July 2024**  
**10 to 11.30 AM CET**  
info@certrust.eu

**CMC10  
WEBINAR**  
Understanding the requirements  
of **processed manure**  
becoming EU fertiliser

**CerTrust**  
dynamism, energetics, excellence

**2024**

# Table of content

<b>Abbreviations</b> .....	<b>4</b>
<b>Statement</b> .....	<b>5</b>
<b>1. The end point criteria</b> .....	<b>6</b>
1.1. Why is it necessary to fulfil the EPR requirements before making available EU fertilisers on the European single market? .....	6
1.2. What documentation is needed to prove the compliance of the end point criteria? .....	6
1.3. Why is the only accepted hygenisation method, which is given in the EPR? Why can not economical operators use other hygenisation methods? .....	6
1.4. Does a veterinarian need to confirm the end point fulfilment for every delivery of processed manure? .....	6
<b>2. Insect Frass and its potential usage in EU fertilisers</b> .....	<b>7</b>
2.1. Is insect frass the same as manure? .....	7
2.2. Is the insect frass already in the scope of the Delegated Regulation (EU) 2024/1682 (CMC10 amendment)? .....	7
2.4. How can insect frass become a component of an EU fertiliser currently? .....	7
<b>3. Processed manure as CMC 10</b> .....	<b>8</b>
3.1. When will the amendment of CMC 10 related to processed manure be officially published? .....	8
3.2. What kind of permission is needed to produce processed manure from animal by-product perspective? .....	8
3.3. What kind of requirements are set in the FPR for processed manure in CMC10? .....	8
3.4. What kind of further processing can be implemented on processed manure? .....	8
3.5. Is it possible to use any additives in process manure? .....	9
3.6. Why are hydrolysed proteins not included in CMC 10? .....	9
3.7. Are there any substances, which is prioritized to become a CMC10? Is it possible to predict a timeline as to when more substances will have reached the endpoint and be added to the list along with processed manure to CMC10? .....	9
3.8. Are all materials obtained from different post-processing belong to CMC 10? .....	9
<b>4. Manufacturing processes</b> .....	<b>10</b>
4.1. Does the requirement given in point 1.1. (b) of CMC10 mean that both pelletisation and drying must be applied, or the application of one treatment will be enough? .....	10

4.2.	Is it mandatory to fulfil the end point criteria before the criteria of CMC10 would be applied? Can hygienisation of animal by-products be done after digestion and composting? .....	10
4.3.	Are there specific conditions that would allow a manufacturing process in case of usage Category 2 and Category 3 animal by-products and derived products in CMC3 and CMC5? .....	10
<b>5.</b>	<b>Labelling and Testing</b> .....	<b>11</b>
5.1.	Are test results needed to demonstrate Aminopyralid and Clopyralid levels in technical documentation? .....	11
5.2.	Must ammonia scrubbing cells from manure be labelled under the Nitrates Directive if marketed as an inorganic EU fertiliser?.....	11
5.3.	Is the expiry date required on the label for CMC10-based EU fertilisers, or only the production date must be given? .....	11
5.4.	Are there any specific labelling requirements besides Aminopyralid and Clopyralid residue information related to processed manure? .....	11
<b>6.</b>	<b>Mixed topics</b> .....	<b>12</b>
6.1.	How should one handle such a situation, when an EU fertiliser is registered according to the FPR, but one of its intended uses is seed-covering, to put EU fertiliser-coated seed on the market? .....	12
6.2.	Does spent mushroom substrate of Agaricus bisporus, consisting of mushroom spores, mycelia, wheat straw, manure and other additives fall under CMC3?.....	12
	<b>References and useful links</b> .....	<b>13</b>

## Abbreviations

**ABPR:** Animal By-Products Regulation - Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009. <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32009R1069>

**CMC:** Component Material Category (see [Annex II](#) to the FPR)

**CMC10:** Processed manure as a component material amendment - Commission Delegated Regulation (EU) 2024/1682 of 4 March 2024 amending Regulation (EU) 2019/1009 of the European Parliament and of the Council as regards adding processed manure as a component material in EU fertilising products. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32024R1682&qid=1718280995339>

**EPR:** 'End point Regulation' - Commission Delegated Regulation (EU) 2023/1605 of 22 May 2023 supplementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council as regards the determination of end points in the manufacturing chain of certain organic fertilisers and soil improvers. <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32009R1069>

**FPR:** 'Fertilising Products Regulation' - 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. <https://eur-lex.europa.eu/eli/reg/2019/1009/oj>

**HRR:** 'Health Rules Regulation' - Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive Text with EEA relevance. <https://eur-lex.europa.eu/eli/reg/2011/142/oj>

**ND:** Nitrates Directive - Council Directive 91/676/EEC of 12 December 1991 concerning the protection of waters against pollution caused by nitrates from agricultural sources. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A01991L0676-20081211>

**PFC:** Product Function Category (see [Annex I](#) to the FPR)

**REACH:** 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, 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. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1907-20221217>

## **Statement**

This document aims at the implementation of the Fertilising Products Regulation (FPR) providing answers especially to the new CMC10 amendment for all the economic operators and other stakeholders.

The answers in this Q&A document represent the opinion of CerTrust Ltd (NANDO 2806).

## 1. The end point criteria

### 1.1. *Why is it necessary to fulfil the EPR requirements before making available EU fertilisers on the European single market?*

When an animal by-product or derived product reaches its end point according to the criteria given in the EPR at the end of the manufacturing chain as an EU fertiliser, then this material will fall under the umbrella of the FPR instead of the application of ABPR. Furthermore, only those EU fertilisers, containing animal by-products or derived products, can be CE-marked and circulated in the European common market fulfilling the requirements of both the EPR as well as the FPR. The Technical Documentation of an EU fertiliser consisting of animal by-products or derived products must contain clear evidence of fulfilling the end point criteria before the EU Declaration of Conformity would be signed.

### 1.2. *What documentation is needed to prove the compliance of the end point criteria?*

The implemented hygienisation steps that are required in the EPR must be clearly justified in the Technical Documentation.

### 1.3. *Why is the only accepted hygienisation method, which is given in the EPR? Why can not economical operators use other hygienisation methods?*

That hygienisation method is approved in the EPR, which has a positive and safe outcome provided by an EFSA assessment. In case of EU fertilisers, only the application of this approved method can be accepted as a complete fulfilment of the end point criteria. However, in case of other derived products placed on the different national markets according to other regulations, than FPR, other hygienisation methods can be still applied.

### 1.4. *Does a veterinarian need to confirm the end point fulfilment for every delivery of processed manure?*

When the application of the ABPR has reached its end point in case of an EU fertiliser, that will be documented by the manufacturer with the EU Declaration of Conformity. Thus, that no other legal reconfirmation will be needed. The EU Declaration of Conformity will mark the legal end point of the manufacturing chain. (Nevertheless, unprocessed manure and all its related actions, for example, transportation in the EU, still fall under the requirement of ABPR.)

## **2. Insect Frass and its potential usage in EU fertilisers**

### *2.1. Is insect frass the same as manure?*

No. While manure means 'any excrement and/or urine of farmed animals other than farmed fish, with or without litter' based on point 20. Article 3 of the ABPR, insect frass is 'mixture of excrements derived from farmed insects, the feeding substrate, parts of farmed insects, dead eggs and with a content of dead farmed insects of not more than 5 % in volume and not more than 3 % in weight' according to point 61. Annex I of the HRR. Thus, insect frass and manure are different materials.

### *2.2. Is the insect frass already in the scope of the Delegated Regulation (EU) 2024/1682 (CMC10 amendment)?*

No. However the hygenisation steps of end point criteria for insect frass have already been published in the EPR, but the additional requirements for becoming a CMC 10 are still pending. Currently, ongoing studies have been performed by an external contractor to determine these further requirements.

### *2.3. What kind of steps are associated with the end point criteria for insect frass?*

In point (d) Article 3 of EPR the following criteria are set: 'processed manure and processed frass which fulfil the requirements set out in Chapter I, Section 2, points (a), (b), (d) and (e), of Annex XI to Regulation (EU) No 142/2011'. It is also essential, that the end point criteria can only be fulfilled in a site located in the EU and has approval according to point (f) Article 24 (1) of the ABPR. The EPR requires the same hygenisation steps for processed manure as well as insect frass that can be found in the HRR.

### *2.4. How can insect frass become a component of an EU fertiliser currently?*

However, insect frass cannot become currently CMC10, Category 2 and Category 3 animal by-products and derived products can be used for example as an input material of CMC3 (compost), CMC5 (digestate other than fresh crop digestate), or CMC12 (ashes or ash derivates) when these inputs fulfil the requirements of the EPR during the end of the manufacturing chain. Consequently, the manufacturing process of these special CMCs must comply with the requirements of both the hygenisation steps defined in the HRR and the FPR. Nevertheless, when a so-called special CMC is presented in an EU fertiliser, the Module D1 conformity assessment procedure must be implemented to ensure the entire quality management process complies with the FPR.

### **3. Processed manure as CMC 10**

*3.1. When will the amendment of CMC 10 related to processed manure be officially published?*

The inclusion of processed manure has already been adopted and published. It means, that processed manure can already be used as a component material of an EU fertiliser.

*3.2. What kind of permission is needed to produce processed manure from animal by-product perspective?*

Manure, other than those imported into the Union, can be processed in such a plant approved under point (f) Article 24 (1) of the ABPR. Consequently, manure can be originated from any member state. Furthermore, the site must also be located in the EU and has to have a manufacturing permit for processing organic fertilisers and soil improvers from animal by-products and derived products. (Besides these requirements, the other requirements of the EPR as well as the FPR must be fulfilled during the processing of manure to become a component of an EU fertiliser.)

*3.3. What kind of requirements are set in the FPR for processed manure in CMC10?*

Processed manure can be used as a CMC10, when it reaches the end point according to the requirements of EPR no later than 36 months before signing the EU declaration of conformity for the final EU fertiliser. It is also mandatory to fulfil at least one of the following treatments or requirements to prevent weed seed dispersal:

(a) at least 90 % by dry mass of the material can pass through a sieve with a mesh of 0,25 mm;

(b) the material has been granulated under pressure, pelletised, dried at temperatures higher than 100 °C or has undergone any equivalent process that ensures that the content of viable weed seeds and plant propagules in the processed manure is no more than 3 units/l; or

(c) the material fulfils at least one of the stability criteria set out in point 5. of CMC3.

*3.4. What kind of further processing can be implemented on processed manure?*

One or more additional transformation processes can be applied to processed manure, like:

- the processing methods referred to in CMC 2;
- biological treatment involving nitrification and denitrification;
- mechanical separation of the solid and liquid fractions;
- processes to recover nutrients and/or organic carbon, without the intention to otherwise modify the material;



- chemical processing to modify the pH without the intention to otherwise modify the material;
- physical processing to remove water and to transform the material into powder,
- granules or pellets, without the intention to otherwise modify the material.

*3.5. Is it possible to use any additives in process manure?*

Yes. It is possible to use additives during both of the 'mandatory' further processing steps mentioned in question 3.3., as well as 'voluntary' further processing steps listed in question 3.4. However, the used additive must comply with the requirement set out in point 2. of CMC1. (This point refers to the REACH registration requirement of the FPR, when it is applicable.) Furthermore, the concentration of additives needed in each process must not exceed 5% of the weight of the processed manure or its used fraction.

*3.6. Why are hydrolysed proteins not included in CMC 10?*

Currently, the status of hydrolysed proteins is the same as the status of insect frass. However, the end point criteria of the ABPR application for hydrolysed proteins have already been published, but further requirements are still pending. Thus, only processed manure is included by CMC10.

*3.7. Are there any substances, which is prioritized to become a CMC10? Is it possible to predict a timeline as to when more substances will have reached the endpoint and be added to the list along with processed manure to CMC10?*

Different materials are studied in parallel without prioritizing based on the timeline. The final report is expected by the end of this year, followed by other internal procedures, which could also take further timeframe.

*3.8. Are all materials obtained from different post-processing belong to CMC 10?*

No, CMC 10 specifically covers animal by-products. Furthermore, recovered nutrients from manure may only fall under CMC10 when the processing methods have fulfilled the requirements of CMC10. Nevertheless, these manure processing steps should not include thermochemical conversion processes at high temperatures or pressures, such as liquefaction, hydrothermal carbonisation, pyrolysis, gasification or combustion, as such processes are covered under other component material categories due to the specific nature of the material transformation process.

## 4. Manufacturing processes

4.1. *Does the requirement given in point 1.1. (b) of CMC10 mean that both pelletisation and drying must be applied, or the application of one treatment will be enough?*

The following conditions are listed in this point separated with a comma: granulation under pressure, pelletisation, drying at temperatures higher than 100°C or any equivalent process. Thus, one of the listed processes, that ensures the weed seed-free material, can be used from this list. It is not mandatory to apply all of them at the same time.

4.2. *Is it mandatory to fulfil the end point criteria before the criteria of CMC10 would be applied? Can hygienisation of animal by-products be done after digestion and composting?*

The hygienisation treatment may be applied before, under and after the transformation of processed manure to an EU fertiliser, since neither the EPR nor the FPR gives no requirement of the order of the application. Consequently, the end point criteria can even fulfilled during any step of manure processing and transformation methods of manure capable of fulfilling both requirements at the same time.

4.3. *Are there specific conditions that would allow a manufacturing process in case of usage Category 2 and Category 3 animal by-products and derived products in CMC3 and CMC5?*

In case of CMC3 and CMC5 all the requirements listed in Annex 2 of the FPR must be fulfilled. Besides these requirements, compost and digestate must also fulfil the criteria of EPR, when Category 2 and Category 3 animal by-products are used as input of these CMCs.

## 5. Labelling and Testing

5.1. *Are test results needed to demonstrate Aminopyralid and Clopyralid levels in technical documentation?*

The analytical determination of aminopyralid and clopyralid levels must be implemented in such a case when the manufacturer would like to avoid the labelling obligatory of the potential risk of these residues. Therefore, the manufacturer either gives the warning information regarding the aleatory presence of pesticide residues or justifies the absence of the residues with an analytical test result.

5.2. *Must ammonia scrubbing cells from manure be labelled under the Nitrates Directive if marketed as an inorganic EU fertiliser?*

Specific recovered nutrients from manure are excluded from the Nitrates Directive under certain conditions. However, the exact details depend on the process and purity of the material. Further information can be found in the Nitrates Directive.

5.3. *Is the expiry date required on the label for CMC10-based EU fertilisers, or only the production date must be given?*

Expiry date requirements depend on the product function category, not the component material category. Thus, information regarding the expiry date requirements on the label can be found in Part 2. Annex III of the FPR. The only time limit mentioned in the CMC10 amendment refers to the maximum time period (36 months) that can not elapse between fulfilling the end point criteria and signing the EU Declaration of Conformity. However, this information must be implemented in the Technical Documentation, not on the label.

5.4. *Are there any specific labelling requirements besides Aminopyralid and Clopyralid residue information related to processed manure?*

A general labelling requirement should be introduced for EU fertilising products containing processed manure to inform end-users about the potential air quality impacts of the release of ammonia from the use of processed manure and to invite them to apply appropriate measures to reduce such impacts. Furthermore, where an EU fertilising product contains a component material from manure, the total content of nitrogen originating from manure shall also be indicated.

## 6. Mixed topics

6.1. *How one should handle such a situation, when an EU fertiliser is registered according to the FPR, but one of its intended uses is seed-covering, to put EU fertiliser-coated seed on the market?*

CE-marked products must comply with all rules, and no formulation changes are allowed post-CE marking. Seed treatment is a formulation change and seed cannot be part of an EU fertiliser. Thus, it cannot be a CE-marked product. Further information on this matter can be found in the FAQ of the FPR.

6.2. *Does spent mushroom substrate of Agaricus bisporus, consisting of mushroom spores, mycelia, wheat straw, manure and other additives fall under CMC3?*

Detailed manufacturing procedures are needed to confirm compliance with any chosen PFC and CMC since general assumptions cannot be made without specific documentation. However, only those materials can be used as a component of EU fertilisers that on one hand comply with the FPR and on the other hand, do not pose any risk to human and environmental health as well as to the food chain.

Since the spent mushroom substrate consists of both a growing medium for the cultivation of mushrooms and mushroom inoculum, such a product cannot comply with the requirements of any of the product function categories (PFCs) defined in the FPR. The spores of mushrooms cannot be a component of an EU fertilising product and therefore this type of material cannot be sold with the CE-marking.

This approach is the same as in the case of coated seeds with fertiliser, since seeds, as liveable plants, may not be CE-marked. Only the fertiliser, if sold as a separate product, could be CE-marked under the condition that it would be compliant with all the relevant provisions of the FPR.

Additionally, it is also essential that only those materials can be fit solely into CMC3, which are result of a well-defined composting treatment of one or more of the allowed input materials and which should comply with all relevant provisions of CMC3 given in the FPR.

## References and useful links

Fertiliser Product Regulation [https://eur-lex.europa.eu/eli/reg\\_impl/2018/1009/oj](https://eur-lex.europa.eu/eli/reg_impl/2018/1009/oj)

Guidance document for Labelling EU fertiliser products <https://ec.europa.eu/docsroom/documents/44801>

FAQ of FPR <https://ec.europa.eu/docsroom/documents/62214>

European Commission, Joint Research Centre, Huygens, D., *Technical proposals for processed manure as a component material for EU Fertilising Products*, Publications Office of the European Union, Luxembourg, 2024, DOI [10.2760/185544](https://doi.org/10.2760/185544) (online) <https://publications.jrc.ec.europa.eu/repository/handle/JRC128459>