

CMC10 WEBINAR



1st July 2024

10 h to 11.30 AM CET

**Understanding the requirements
of processed manure becoming EU fertiliser
according to (EU) No. 2019/1009 Regulation**



State of play on Fertilising Product Regulation in terms of animal by-products

CERTRUST webinar on CMC 10

01 July 2014

Dr Theodora Nikolakoulou

DG GROW-F2 – Bioeconomy, chemicals and cosmetics

How animal by-products and derived products were regulated before the FPR?

ABPR

REGULATION (EC) No 1069/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 21 October 2009

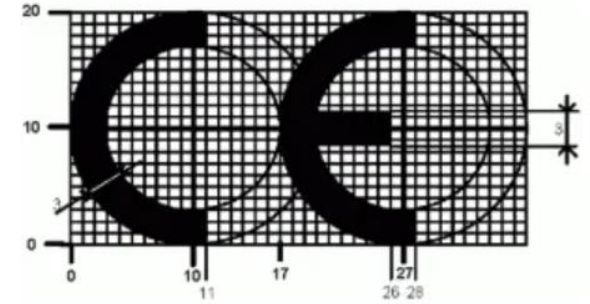
laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation)

- the use of derived products from ABPs within the scope of the ABPR in organic fertilisers or soil improvers is regulated by national rules
- national products remain under the ABPR rules and are subject to veterinary controls by national authorities

Is this still applicable?



And then comes the FPR...



New Legislative Framework (*)

Harmonised rules set on making available of **EU fertilising products** on the market

CE-marking → Free movement in the EU market

Optional harmonisation

a product regulation; does not regulate use of products or mode of application of products

The Fertilising Products Regulation is fully applicable as of 16 July 2022

(amended already by 8 Commission delegated Regulations)

[* COMMISSION NOTICE - The 'Blue Guide' on the implementation of EU product rules 2022](#)

FPR amended ABPR ...

CHAPTER VII
AMENDMENTS

Article 46

Amendments to Regulation (EC) No 1069/2009

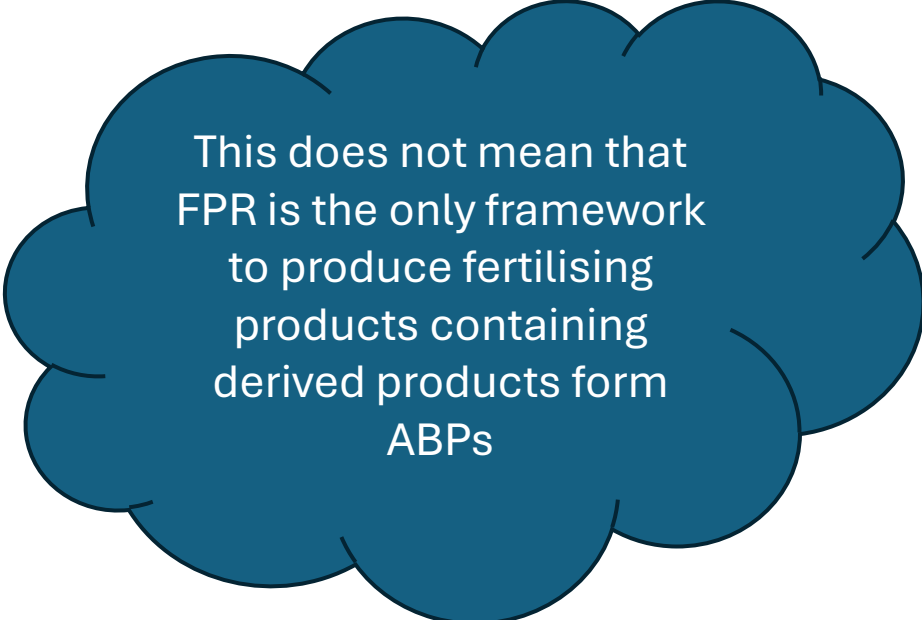
Regulation (EC) No 1069/2009 is amended as follows:

(1) in Article 5, paragraphs 2 and 3 are replaced by the following:

'2. For derived products referred to in Articles 32, 35 and 36 which no longer pose any significant risk to public or animal health, an end point in the manufacturing chain may be determined, beyond which they are no longer subject to the requirements of this Regulation.

Those derived products may subsequently be placed on the market without restrictions under this Regulation and shall no longer be subject to official controls in accordance with this Regulation.

The Commission is empowered to adopt delegated acts in accordance with Article 51a supplementing this Regulation by determining an end point in the manufacturing chain, beyond which derived products referred to in this paragraph are no longer subject to the requirements of this Regulation.



This does not mean that FPR is the only framework to produce fertilising products containing derived products from ABPs

Which materials are allowed as components ?

Animal by-products may be processed into other materials



CMC 1: Virgin material substances and mixtures

CMC 2: Plants, plant parts or plant extracts

CMC 3: Compost

CMC 4: Fresh crop digestate



CMC 5: Digestate other than fresh crop digestate

CMC 6: Food industry by-products

CMC 7: Micro-organisms

CMC 8: Nutrient polymers

CMC 9: Polymers other than nutrient polymers

CMC 10: Derived products from Animal By-Products

CMC 11: By-products within the meaning of Directive 2008/98/EC



CMC 12: Precipitated phosphate salts and derivatives



CMC 13: Thermal oxidation materials and derivatives



CMC 14: Pyrolysis and gasification material



CMC 15: High purity materials

Component materials are expected to formulate the EU fertilising product which should have one of the seven functions described in Annex I to the FPR:

Fertiliser

Liming material

Soil improver

Growing medium

Inhibitor

Plant biostimulant

Blend of fertilising products

Derived products from ABPs in EU fertilising products

derived products from Animal By-Products (ABPs)* may be incorporated in an EU fertilising product as long as:

- the end point in the manufacturing chain has been determined** and
- that end point has been reached

Commission delegated Regulation for the determination of end-points in the manufacturing chain ✓

Commission delegated Regulation for the inclusion of processed manure in CMC 10 ✓

Commission delegated Regulation for the inclusion of other derived products in CMC 10 (pending) ✓

* 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

** in accordance with the third subparagraph of Article 5(2) of Regulation (EC) No 1069/2009

Two scenarios:

ABP – animal by-product within the scope of the ABPR
DP – derived product within the scope of the ABPR

ABPs and DPs as input materials for production of CMC

- CMC 3, 5, 12, 13, 15, 14 and CMC 15 (only off gasses of some ABPs)

DPs as component materials

- CMC 10

Only if

- 1) an **end-point is determined** in the manufacturing chain in accordance with the ABPR and
- 2) it is reached before making the EU fertilising product available on the market

Only if:

- 1) an **end-point is determined** in the manufacturing chain in accordance with the ABPR,
- 2) the **DP is included** in the table in **CMC 10**, Annex II FPR and
- 3) and it is reached before making the EU fertilising product available on the market.

Which are the other materials to be included in CMC 10

- **processed frass**
- **glycerine of Category 2 and 3 materials, and other Category 2 material resulting from biodiesel process and the production of renewable fuels**
- **Category 3 materials other than glycerine**
- **processed animal protein of Category 3 materials**
- **meat-and-bone meal of Category 2 materials**
- **blood products of Category 3 materials**
- **hydrolysed protein, including hydrolysed protein derived from residues coming from the leather or textile industry**
- **dicalcium phosphate and tricalcium phosphate**
- **horns, horn products, hooves and hoof products**

[study related to CMC 10 -agronomic efficiency and safety criteria for ABPs with an end-point determined](#)

Qlab -"Research, Analytical and Quality Control Lab“, Thessaloniki, GR Email fertilizers@q-lab.gr
Last presentation of this study posted [here](#)

Which are the next steps as regards CMC 10...

- Workshop to present the interim report of the study planned for 18 July 2024 (contact fertilizers@q-lab.gr if interested)
- Final report expected in October 2024
- Based on findings, DG GROW to propose a delegated act for inclusion of materials in CMC 10
- COM Expert group for fertilising products to be consulted
- Draft act will be put for public consultation

Are you interested in other materials without an end-point determined?

- Contact your national authorities or
- Contact European associations dealing products containing ABPs
- Prepare a relevant dossier and submit to EFSA for evaluation

Available resources

DG GROW [website](#)

[CE-marking of EU fertilising products](#) (DG GROW)

Info session organised by DG GROW - How to CE mark your fertilising product ; 23 May 2022; recording available [here](#)

Guidance Document on the labelling of EU Fertilising Products; available [here](#)

FAQs document on Fertilising Products Regulation; available [here](#)

Commission Expert Group on fertilising products (documents available [here](#))

Member States competent authorities [list](#)

Market Surveillance authorities responsible for controls of products [list](#)



Do you have questions?

GROW-FERTILISING-PRODUCTS@ec.europa.eu

Thank you

Contact the EU

- [Call us 00 800 6 7 8 9 10 11](tel:0080067891011)
- [Use other telephone options](#)
- [Write to us via our contact form](#)
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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



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Which are the other materials to be included in CMC 10

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

glycerine of Category 2 and 3 materials, and other Category 2 material resulting from biodiesel process and the production of renewable fuels which fulfil the requirements set out in Chapter IV, Section 3, point 2(b), (c) and (f), of Annex IV to Regulation (EU) No 142/2011;

Category 3 materials other than glycerine, which fulfil the requirements set out in Chapter IV, Section 3, point 2(b), (c) and (f), of Annex IV to Regulation (EU) No 142/2011;

processed animal protein of Category 3 materials which fulfils the specific requirements for processed animal protein set out in Chapter II, Section 1, point A, point B(1) and (2), point B(3)(a) and point C, of Annex X to Regulation (EU) No 142/2011;

meat-and-bone meal of Category 2 materials processed with the standard processing method 1 set out in Chapter III, point A, of Annex IV and marked with glyceroltriheptanoate (GTH) as set out in Chapter V of Annex VIII to Regulation (EU) No 142/2011;

blood products of Category 3 materials which fulfil the specific requirements for blood products set out in Chapter II, Section 2, of Annex X to Regulation (EU) No 142/2011;

hydrolysed protein, including hydrolysed protein derived from residues coming from the leather or textile industry, which fulfils the specific requirements for hydrolysed protein set out in Chapter II, Section 5, point D, of Annex X to Regulation (EU) No 142/2011;

dicalcium phosphate and tricalcium phosphate which fulfil the specific requirements set out in Section 6 or 7, of Annex X to Regulation (EU) No 142/2011, respectively;

horns, horn products, hooves and hoof products which fulfil the specific requirements set out in Annex XIII to Regulation (EU) No 142/2011.



CMC10 WEBINAR

1st July 2024

The requirements of the CMC10 amendment

Ildikó Varga, Expert (Biostimulant Specialist) of CerTrust (NANDO 2806)

Understanding the requirements
of processed manure becoming EU fertiliser
according to (EU) No. 2019/1009 Regulation

Topics

- **Definitions:** EU fertiliser, PFC /CMC, manure vs. processed manure,
- Understanding of the **legal end point** of manure
- Requirements of processed manure to become CMC10
- Processing step(s) which **must be applied** to make CMC10
- Further-processing steps, that **can be applied** to make CMC10
- **Other requirements** of CMC10
- Special **labelling** requirements related to CMC10



Defintions

- **What is an EU fertiliser?**

Those kinds of products can be named as an EU fertilisers, that are in compliance with the (EU) No. 2019/1009 Regulation.

- **What is a PFC and CMC?**

PFC= Product function category → (at least one) must be chosen for the product

CMC= componet material category → most be chosen for all components

For example:

Organic soil improver *PFC3(A)*

Processed manure *CMC10*

What is manure?

‘manure’ means any excrement and/or urine of farmed animals other than farmed fish, with or without litter

(EU) 1069/2009 Regulation

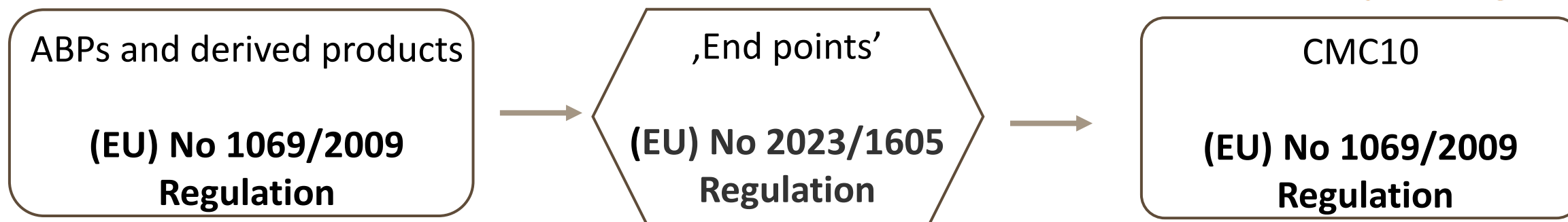
‘frass’ means a mixture of excrements derived from farmed insects, the feeding substrate, parts of farmed insects, dead eggs and with a content of dead farmed insects of not more than 5 % in volume and not more than 3 % in weight.

C. Regulation (EU) No. 142/2011 refreshed with C. Regulation (EU) 2021/1925

manure ≠ processed manure ≠ insect frass

What is processed manure?

End point & processed manure



The **Delegated Regulation (EU) 2023/1605** sets out the requirements as regards the determination of **end points**.

Article 3(d) of 2023/1605 indicates **that processed manure** shall be considered as having reached the end point as organic fertilisers and soil improvers when fulfilling the requirements set out in **Chapter I, Section 2, points (a), (b), (d) and (e), of Annex XI to Regulation (EU) No 142/2011**.

Processed manure, which reached its legal end point, can be used for further processing of CMC10.

The points of ,end point' to become a processed manure

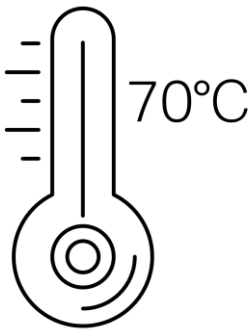


1. Those derived products (**other than imported into the Union**) that are manufactured in a fertiliser plant approved in accordance with Article **24(1), point (f)**, of Regulation (EC) No 1069/2009, shall be considered as having reached the end point.

1.a. Transport between the member states of EU: according to Article 48(1) of Regulation (EC) No 1069/2009.

2. They must come from a plant for derived products for uses outside the feed chain or **from a biogas or a composting plant** or from a plant for the manufacturing of organic fertilisers or soil improvers.

3. They shall have been subjected to a **heat treatment process of at least 70 °C for at least 60 minutes and** they shall have been subjected to reduction in spore-forming bacteria and toxin formation, where they are identified as a relevant hazard.



The points of ,end point' to become a processed manure



4. Representative samples of the manure taken during or immediately after processing at the plant in order to monitor the process must comply with the following standards:

Escherichia coli: $n = 5, c = 5, m = 0, M = 1\ 000$ in 1 g; or Enterococcaceae: $n = 5, c = 5, m = 0, M = 1\ 000$ in 1 g; **Salmonella:** absence in 25 g: $n = 5; c = 0; m = 0; M = 0$

Processed manure or processed manure products not complying with the standards in this point shall be regarded as unprocessed.

5. They must be stored in such a way that once processed contamination or secondary infection and dampness is minimised. They must therefore be stored in:

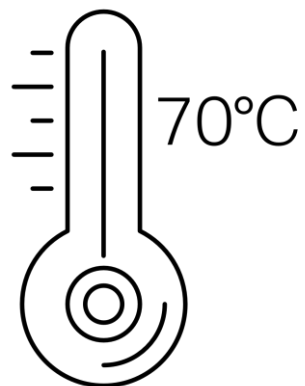
- (i) **well-sealed and insulated silos** or properly constructed storage sheds; or
- (ii) **properly sealed packs**, such as plastic bags or 'big bags'.

What does it mean in practice?



Unprocessed
manure

Requirements
of the 'End points'



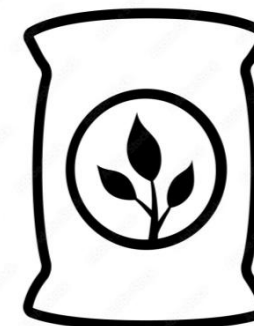
Hygenisation steps



Requirements
of the FPR



Post-treatment(s)
will result CMC10



Use as an EU fertiliser
component

How can a process manure become a CMC10?

1. Processed manure can reach the end point at the latest **36 months before signing the EU declaration of conformity** .

At least one of the following conditions must be fulfilled:

- (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;

Don't forget, plant propagule unit \neq with seed number!

- (c) the material fulfills at least one of the stability criteria set out in point 3 of CMC3/5 (**oxigen uptake rake, self-heating test, biogas residue test**)



Potential further processing steps

- (a) the processing methods referred to in **CMC 2**;
- (b) biological treatment involving **nitrification and denitrification**;
- (c) mechanical **separation of the solid and liquid fractions**;
- (d) processes to **recover nutrients and/or organic carbon**, without the intention to otherwise modify the material;
- (e) **chemical processing to modify the pH** without the intention to otherwise modify the material;
- (f) **physical processing to remove water** and to transform the material into powder, granules or pellets, without the intention to otherwise modify the material.



Other requirements of CMC10



Additives:

- (a) the additive complies with the requirement set out in point 2 of CMC 1;
(**Obligation of REACH registration**, when it is applicable.)
- (b) the concentration of the additives needed in each of the **processes does not exceed 5 %** of the weight of the processed manure or fraction used as input in the respective process.

PAH₁₆: The processed manure shall contain no more than **6 mg/kg dry matter of PAH₁₆**.

Where compliance with the requirement set out in point 1.4 follows certainly and uncontestably from the nature or the processing of the component material or the manufacturing process of the EU fertilising product, such compliance may be presumed in the conformity assessment procedure without verification (such as testing), under the responsibility of the manufacturer.

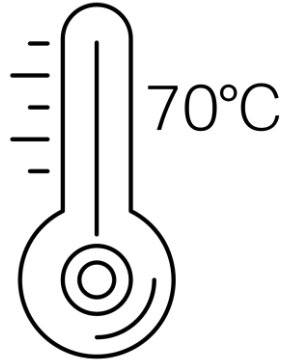
Aminopyralid, clopyralid: It is mandatory to indicate on the label **above 50 µg /kg dry matter of EU fertiliser**.

Storage: The processed manure to be used as component material in an EU fertilising product shall be stored in a way that protects it against precipitation and direct sunlight.

How could it look like in practice?



**Unprocessed
manure**



Hygenisation:

(A) min 70°C/ 1 hour treatment in a factory having a manufacturing permit according to 24(1) point f) (EU) 1069/2009

(B) *Salmonella* /*E.coli* test OK

(C) Storage is OK



Post-treatment(s):

(A) Must apply one of them to prevent seed disperaation: sieving/ pelletisation/ Rottegrad test

(B) Can be applied to increase agronomical value

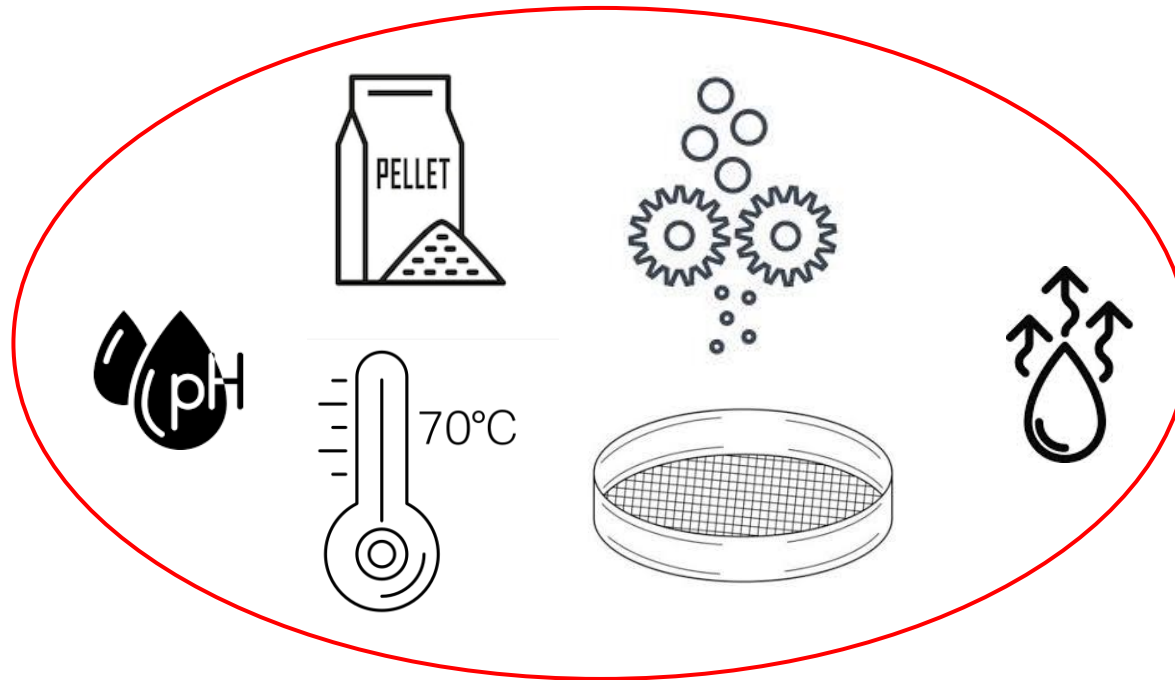


**Use CMC10
as an
EU fertiliser
component**

How could it also look like in practice?



Unprocessed
manure



The different post-processing steps
may occur either before or after
the sterilisation process.



Use as **CMC10**
in an
EU fertiliser

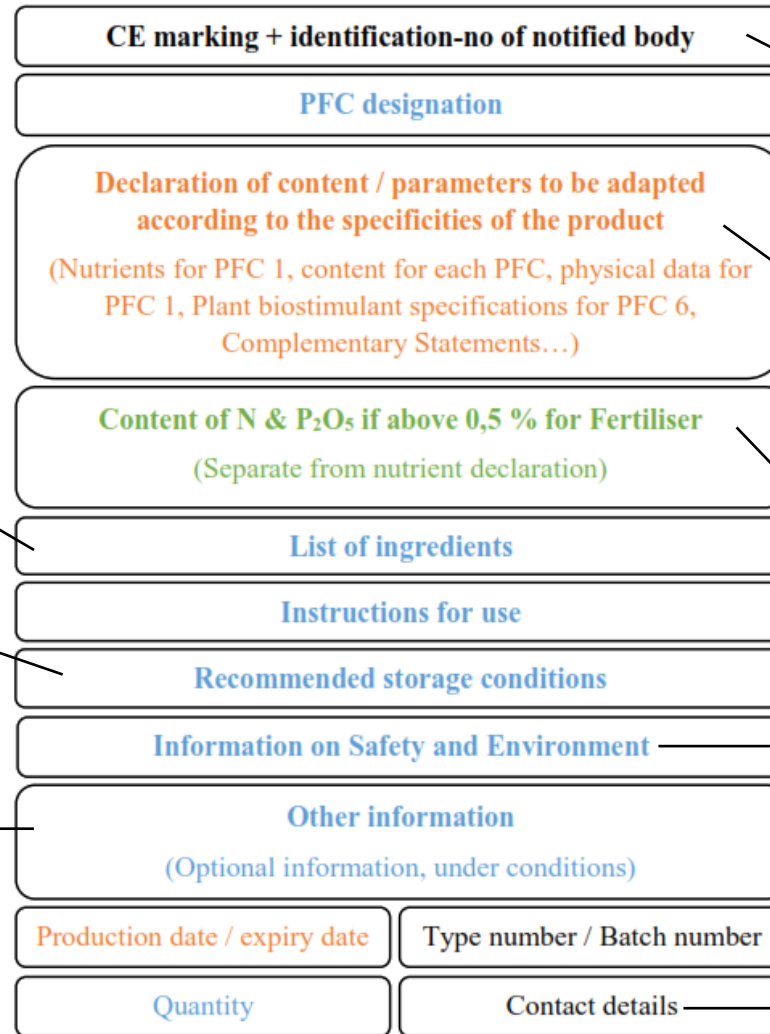
Special labelling requirements

Example for general labelling requirements of an EU fertiliser containing processed manure according to 'Guidance for labelling'.

All ingredients must be listed above 5% in dry mass in decreasing order + **ABP origin must be given.**
F.e.: CMC3 (manure originated), CMC10 (processed manure)

EU fertiliser containing CMC10 shall be stored in a way that protects it against **precipitation and direct sunlight.**

"This product may contain aminopyralid or clopyralid (.....) in accordance with Regulation (EC) 396/2005",
Limit: 50 µg aminopyralid or clopyralid/kg dry matter.



NoBo number **must only be affixed only in case** of the application of **Module D1.**

Total content of nitrogen **originated out of manure** shall be indicated:

'X% organic nitrogen from animal origin, of which Y% from manure'

Give the N, P2O5 contents, when it above 0,5 w/w%.

Give the **possible air quality impacts** of the release of ammonia + invitation to users to apply appropriate **remediation measures.**

Who is the manufacturer and distributor?
Read Chapter 2 of the FPR.

Useful links and tips



What shall a manufacturer read before application for conformity assessment procedure?

- ✓ Chapter 2 of the FPR: Obligations of economic operators
- ✓ Requirements of the TD assembling (Module B+C of Annex IV.)
- ✓ Delegated regulation of End Points determination (EU) No. 2023/1605
- ✓ Health Rules Regulation (EU) No 142/2011 (referred in the End Points determination)
- ✓ Example of DoC (see in Annex V of the FPR)
- ✓ Labelling guidance (of the related PFC)

Useful links

FPR <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32019R1009>

End Point Reg. <https://eur-lex.europa.eu/legalcontent/EN/TXT/?uri=uriserv%3AOJ.L .2023.198.01.0001.01.ENG>

Health Rules Reg. <https://eur-lex.europa.eu/eli/reg/2011/142/oj>

CMC10 Amendment <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32024R1682&qid=1718280995339>

Labelling guidance <https://ec.europa.eu/docsroom/documents/44831>

FAQ of FPR <https://ec.europa.eu/docsroom/documents/54694>

Thank you for your attention!

CerTrust
Inspection and Certification Ltd
Notified Body 2806



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ABPs in CMC 3 / CMC 5

01.07.2024

How to CE mark a product under the FPR?

- Term of manufacturer (who is indicated on the label as manufacturer)
- The responsibilities of the manufacturer (Article 6 - FPR)
- A conformity assessment procedure shall be carried out.

1.A Determine the CMC(s) of raw material(s)

1.B Check the requirements in Annex II.

- Check the requirements of CMC 3 / 5 in Annex II. (FPR)
- Input materials → Category 2 or Category 3 ABPs or derived products thereof.
- If the end point in the manufacturing chain has been determined in accordance with the third subparagraph of Article 5(2) of Regulation (EC) No 1069/2009 (ABPR).

1.B Check the requirements in Annex II.

- The delegated regulation for the end-point: (EU) 2023/1605
- Manufacturing plant approved by the authority in accordance with Article 24(1), point(f) of Regulation (EC) 1069/2009 (ABPR)
- Article 3: Gives the hygiene rules in Regulation (EU)142/2011

1.B Check the requirements in Annex II.

- Manufacturing plant requirements of Annex II: separating input / output materials and production lines from other materials
- Thermal conditions of composting or digesting processes
- Analytical requirements also shall be checked (PAH, macroscopic impurities, oxygene uptake rate or self-heating factor /Residual biogas potential)

2.A Determine the PFC of the final product

2.B Check the requirements in Annex I.

- PFC: Product Function Category
- In the case of ABP input: Organic fertiliser (PFC 1) or Soil improver(PFC 3)
- Annex I. (FPR): Heavy metal contents, microbial requirements, nutrient minimum levels (PFC1) etc.

3. Prepare the technical documentation

- Annex IV. (FPR) contains the requirements of the technical documentation in Chapter Module D1, point 2
- Labelling: According to Annex III. (FPR)
- Additional sentence because of Part I. point 4.
- „‘Farmed animals shall not be fed, either directly or by grazing, with herbage from land to which the product has been applied unless the cutting or grazing takes place after the expiry of a waiting period of at least 21 days.’”

3. Prepare the technical documentation

- Test reports (proving compliance with FPR Annex I. and Annex II.)
- Point (i):”...the commercial documents or health certificates required pursuant to that Regulation (ABP), and evidence that the derived products have reached the end point in the manufacturing chain within the meaning of that Regulation”

4. Choose the applicable Module for conformity assessment procedure

- CMC 3 and 5 are obligated to Module D1 conformity assessment procedure, where the requirement is to operate a qm system in the manufacturing plant of the EU fertiliser
- Requirements of the qm system: Annex IV. Part II. Section Module D1, point 4 and 5. (FPR)
- For CMC 3/5 (and CMC 12 to 15) additional requirements are given, such as sampling and additional audit of CMC plant.

5. Carry out the conformity assessment procedure

- Under Module D1 the manufacturer must involve a Notified Body
- We are happy to co-operate even in the preparational time for your audit
- When you are ready, the audits are carried out by our auditors in the final EU fertiliser plant and the composting / digesting plant



Certificate, DOC, CE marked EU fertiliser

Summary

- EU 2019/1009 (FPR):
- Annex I: PFC requirements (contaminants, nutrients)
- Annex II: CMC requirements (input material, manufacturing, analytics)
- Annex III: labelling requirements
- Annex IV: Module D1, technical documentation requirements
- Annex V: DOC template
- EC 1069/2009 (ABPR): Category 2,3 details, plant requirements
- (EU) 2023/1605: determining end-points for fertilisers, soil improvers
- (EU)142/2011: hygienic criteria for composting, digesting

Thank you for your attention



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