Technical study in support of a guidance document for the elaboration of the technical documentation of EU fertilising products

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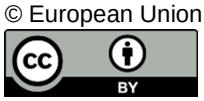

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This document is not legally binding and seeks only to provide useful guidance to stakeholders including manufacturers, notified bodies and market surveillance authorities. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.

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Abstract

This report is the result of the-technical study performed for the Commission, DG GROW F2, under tender GROW/2022/MVP/0014 'Technical study in support of a guidance document for the elaboration of the technical documentation of EU fertilising product'.

Technical documentation must contain all relevant data and documentation necessary to verify that the product meets all the requirements imposed on it by the FPR. A product's technical documentation is a compilation of documents and contains documents written by the manufacturer (such as a product description) and other parties (such as certificates and analytical reports). Manufacturers of fertilising products with CE marking are obligated to draw up the technical documentation. Importers are obliged to ensure that the manufacturer has drafted the technical documentation.

The technical study on the Guidance document for the elaboration of the technical documentation consists of five parts.

- **Part I** provides the general background information on the legislative framework, the FPR and the technical documentation and the applicable modules for the conformity assessment of products according to the FPR.
- **Part II** contains the detailed information per Product Function Category (PFC).
- **Part III** contains the detailed information per Component Material Category (CMCs).
- **Part IV** contains a list of standards, with reference to parameters that they can be used for.
- **Part** V is an open IT tool for the generation of product specific checklists for the technical documentation.

The parts I, II and III and information on part V are included in this report. The part IV is published separately as an excel file.

Part I

General background

Contents

1 Introduction

1.1 Legislative framework

The Fertilising Products Regulation (FPR) EU/2019/1009 applies since 16 July 2022. The FPR is the first deliverable under the first Circular Economy Action Plan of the European Commission. The FPR has been further developed via delegated Regulations to reinforce the Circular Economy and build upon the objectives of the second Circular Economy Action Plan (part of the Green Deal).

The FPR replaced Regulation (EC) No 2003/2003 relating to EC Fertilisers, which applied mainly to traditional inorganic fertilisers and limes out of various raw materials. The FPR extends the scope of the EU rules to include fertilising products out of waste recovered materials or by-products. The FPR also introduces safety criteria for the environmental effects and risks to human and animal health posed by fertilising products. A new element is the detailed conformity assessment procedure that will ensure the conformity of the EU fertilising products with CE marking to the requirements of the FPR.

The FPR follows the New Legislative Framework. The goal of the new legislative approach is to improve the internal market and strengthen the conditions for placing a wide range of products on the EU market.

The New Legislative Framework[1] consists of:

- Decision 768/2008 on a common framework for the marketing of products, which includes reference provisions to be incorporated whenever product legislation is revised. In effect, it is a template for future product harmonisation legislation.
- Regulation (EC) 765/2008 setting out the requirements for accreditation and the market surveillance of products, partly replaced by
- Regulation (EU) 2019/1020 on market surveillance and compliance of products.

The New Legislative Framework introduces measures that aim to improve market surveillance and boost the quality of conformity assessments. It clarifies the use of CE marking and creates a toolbox of measures for use in product legislation. It also introduces new tasks for existing stakeholders (manufacturers and market surveillance authorities) and introduces new stakeholders (Notified Bodies). A comprehensive guidance on the implementation of EU product rules can be found in the Blue Guide on the implementation of the product rules 2022[2].

The FPR lays down optional harmonisation rules for placing EU fertilising products onto the market in the EU. Fertilising products may also be placed onto the market via national legislation. In the latter case, once a product is legally on the market in one member state, it can be made available on the market in other member states via the mutual recognition principle[3] as laid down in Regulation (EU)

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[1] Background information (and links to the Regulations) on the New Legislative Framework can be found at https://single-market-economy.ec.europa.eu/single-market/goods/new-legislative-framework_en

2 Blue guide on implementation of products rules 2022 in all EU languages can be found at https://ec.europa.eu/docsroom/documents/18027/attachments/1/translations

[3] Background information (and links to regulations) can be found at https://ec.europa.eu/docsroom/documents/18027/attachments/1/translations

2019/515 on the Mutual Recognition[4]. More details are available in the Guidance document on mutual recognition of goods[5] for more information on mutual recognition and market harmonisation. This report covers only EU fertilising products, and not fertilising products placed on the market based on national rules.

1.2 Stakeholders in conformity assessment

The FPR sets out responsibilities for the stakeholders involved in the conformity assessment of EU fertilising products. As it introduces for the first time the new legislative framework in this field, its requirements are still new to many stakeholders dealing with fertilising products.

1.2.1 Manufacturers

The **manufacturers** have new obligations in comparison with the repealed regulation (EC) No 2003/2003 on EC fertilisers. Based on the FPR, manufacturers have to:

- ensure compliance with the requirements of Annex I (product function), Annex II (components), Annex III (labelling) and Annex IV (conformity assessment);
- draw up the technical documentation (TD);
- carry out the relevant conformity assessment procedure, where needed in collaboration with a 'notified body' in line with Annex IV (conformity);
- draw up an EU declaration of conformity (EU DOC) and affix the CE marking;
- keep TD and EU DOC for 5 years.

1.2.2 Market surveyance authorities

For the **market surveillance authorities**, the extension of the scope of the FPR to new product categories and the introduction of the conformity assessment procedures and harmonised standards implies a more diverse group of fertilising products and more complex procedures compared to the market surveillance of EC fertilisers under Regulation (EC) No 2003/2003.
The FPR puts in place procedures for market surveillance authorities in case of:

- non-compliant products;
- formal non-compliance,
- compliant products which present a risk.

The market surveillance authorities are responsible for taking the appropriate measures in any of such cases.

A list of national market surveillance authorities can be found on the website EC DG GROW on the implementation of market surveillance in Europe.

1.2.3 Notified Bodies

The FPR has introduced **Notified Bodies (NoBo)** as a new stakeholder in the fertilising product conformity assessment. The notified bodies will have to get familiar with fertilising products manufacturing and with the specific requirements imposed by the FPR on the assessment and certification of EU-fertilising products. Notified bodies have various tasks depending on the Module, as defined in Annex IV of the FPR.

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[4] Regulation (EU) 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No 764/2008

[5] Guidance document on the mutual recognition of goods lawfully marketed in another Member state can be found at https://ec.europa.eu/docsroom/documents/45593

A list of NoBos for the FPR can be found at the website of EC DG GROW on the NANDO (|New Approach Notified and Designated Organisations).

1.3 Background on the technical study

As a first step in the conformity assessment, the manufacturers will have to compile the technical documentation. The technical documentation contains all the information that a manufacturer needs to demonstrate that the product complies with the prerequisites of the FPR. This includes various elements (information on the composition of the product and the production process, tests results of various analyses, etc.).

The compilation of the technical documentation has proved a difficult task, for both manufacturers of products covered for the first time by harmonisation rules, and for manufacturers of EC-fertilisers that are now faced with new obligations. Especially for small and medium enterprises (SME) the task of compiling the technical documentation provides a challenge.

This study will constitute the basis for a guidance document on the technical documentation for an EU-fertilising product. It will provide a detailed overview of all technical information needed for the elaboration of all technical documentation of EU fertilising products for all conformity assessment modules.

The guidance document will be essential support for:

- manufacturers in establishing the mandatory technical documentation for CE-marked fertilising products.
- Notified Bodies, that will rely on such guidelines when assessing the technical documentation of EU fertilising products.
- market surveillance authorities, who will also benefit from the guidance document.

The guidance document is intended as a unique tool to help the industry bring EU fertilising products to the market. It will be particularly useful to SMEs in the field of fertilising products. Numerous SMEs are dealing with products covered for the first time by EU rules, and they have limited resources to invest in consultancy services.

Moreover, the guidance is intended to document a common understanding of the requirements set by the FPR as regards the development of the technical documentation and thus ensure a uniform implementation. The stakeholders have different roles and responsibilities in drafting and assessing the technical documentation. This will require a uniform understanding and interpretation of the requirements and specifications set by the FPR on the technical documentation. Although not legally binding, the guidance document will represent a commonly accepted manual for the elaboration of the technical documentation of these products.

1.4 Outcomes of the technical study

The technical study on the Guidance document for the elaboration of the technical documentation consists of five parts.

- **Part I** provides the general background information on the legislative framework, the FPR and the technical documentation and the applicable modules for the conformity assessment of products according to the FPR.
- **Part II** contains the detailed information per Product Function Category (PFC).
- **Part III** contains the detailed information per Component Material Category (CMCs).
- **Part IV** contains a list of standards, with reference to parameters that they can be used for.

- **Part V** is an open IT tool for the generation of product specific checklists for the technical documentation.

The parts I, II and III and information on part V are included in this report.

The part IV is published separately as an excel file.

2 General obligations on the technical documentation

The FPR lays down the general obligation for the **manufacturers** of EU fertilising products.
They can be summarised as:

- ensure compliance with the requirements on product function, as defined in Annex I;
- ensure compliance with the requirements on component materials, as defined in Annex II;
- draft a product label according to prerequisites, as defined in Annex III;
- draw up the technical documentation (TD) to demonstrate the compliance of the product with the provisions of the FPR;
- carry out the relevant conformity assessment procedure, as described in Annex IV;
- draw up the EU Declaration of Conformity (EU DoC) and affix the CE marking.

The compilation of the technical documentation is the obligation of the manufacturer of the EU fertilising product. The other economic operators (**authorised representatives, importers, distributors**) do also have obligations.

The general obligations of the different economic operators are referred to in Articles 6(1) (2) and (3), 7, 8(1) (2) and (8), 41(1)(d) of the FPR. The applicable provisions of the FPR are listed below. A table with the detailed texts of the FPR comparing the obligations of the manufacturers, authorised representatives and importers is given in ANNEX B **Obligations of economic operations.**

Article 6 states the obligations of manufacturers:

(1) When placing EU fertilising products on the market, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements set out for the PFC (FPR Annex I) and CMCs (FPR Annex II).

(2) Manufacturers shall draw up the required technical documentation and carry out -or have carried out- the applicable conformity assessment procedure. This must be done before the product is put on the market.
Where compliance of an EU fertilising product with the applicable requirements of the FPR has been demonstrated by that conformity assessment procedure, manufacturers shall draw up an EU Declaration of Conformity and affix the CE marking.

(3) Manufacturers shall keep the technical documentation and the EU declaration of conformity for a period of 5 years after the fertilising product has been placed on the market.

(4) On request, manufacturers shall make a copy of the EU declaration of conformity available to other economic operators.

Article 7 states the obligation of authorised representatives:

(1) Authorised representatives do not have the obligation to ensure that the product complies with the requirements of the PFCs and CMCs. The obligation to draw up technical documentation is not part of an authorised written representative's mandate.

(2) The written mandate given by the manufacturer to an authorised representative shall allow the authorised representative:

a) To keep the EU declaration of conformity and the technical documentation at the disposal of national market surveillance authorities for 5 years after the EU fertilising product covered by those documents has been placed on the market,

b) upon reasoned request from a competent national authority, provide the authority with all information and documentation necessary to demonstrate conformity of an EU fertilising product.

c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by EU fertilising products covered by the authorised representative's mandate.

Article 8(2) and 8(8) state the obligations of importers:

(2) Importers shall ensure that the manufacturer has carried out the appropriate conformity assessment procedure before placing an EU fertilising product on the market.
They shall further ensure that the manufacturer has drawn up the technical documentation.
Where an importer considers or has reason to believe that an EU fertilising product is not in conformity with this Regulation, the importer shall not place the EU fertilising product on the market until it has been brought into conformity.
Furthermore, where the EU fertilising product presents a risk to human, animal or plant health, to safety or to the environment, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

(8) Importers shall, for 5 years after the EU fertilising product has been placed on the market, keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities, Importers shall ensure that the technical documentation can be made available to those authorities upon their request.
They shall further, upon reasoned request from a competent national authority, provide the authority with all information and documentation demonstrating conformity of an EU fertilising product.

Article 41(1)(d) states the obligation of Members states on the formal non-compliance:

When a Member State finds that the technical documentation of an EU fertilising product is unavailable or incomplete, the Member state shall require the relevant economic operator to put an end to the non-compliance.

3 Technical documentation

3.1 Technical documentation in general

The FPR contains several provisions related to technical documentation. The technical documentation is drawn up by the manufacturer, as this is the operator who knows the design, production, and composition of the EU fertilising product.

When a manufacturer intends to bring a product on the market as an EU fertilising product with CE marking, the manufacturer must prove the compliance of the product with the specifications in the FPR. All documents that prove compliance criteria or otherwise support or clarify the proof, are compiled in a dossier. This dossier is referred to as the "technical documentation". More information on the technical documentation of CE-marked product and responsibilities of stakeholders are given in the Blue Guide on the implementation of EU product rules, document 2022/C 248/01.

This obligation for the technical documentation applies to every EU fertilising product that is placed on the EU market, whatever its geographical origin is. It is the responsibility of the manufacturer to draw up the required technical documentation. This drawing up of the technical documentation cannot form part of the authorised representative's mandate.

The technical documentation must be kept for 5 years after the EU fertilising product has been placed on the market[6]. This is the responsibility of the manufacturer, or the authorised representative established within the EU. Importers shall ensure that the manufacturer has drawn up the technical documentation. All economic operators must make available all information and documentation necessary to demonstrate the conformity of the fertilising product upon reasoned request.

As a rule, the technical documentation shall contain all relevant data or details that are necessary to ensure that EU fertilising products comply with the requirements of the FPR. The details included in the documentation depend on the nature of the EU fertilising product.

Drawing up the technical documentation by the manufacturer does not imply that the manufacturer has to draw up each document in the documentation. As mentioned above, it is a compilation of documents. The technical documentation may contain documents that are drawn up by others: e.g. the EU Declaration of Conformity signed by the authorised representative, an EC type certificate delivered by a Notified Body, test reports provided by laboratories, etc.

Manufacturer or importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the EU fertilising product with this Regulation, in a language which can be easily understood by that authority. Furthermore, in case that presence of a Notified Body is mandatory, manufacturer shall provide it with all the information and documentation. In none of the

[6] *More information can be found in the Blue Guide 2014, Section 2.3: "As for "making available", the concept of placing on the market refers to each individual product, not to a type of product, and whether it was manufactured as an individual unit or in series."*

above two cases, can the manufacturer argue that requested documentation contains confidential information (e.g. commercial confidentiality).

NoBos and Member State authorities are under the legal obligation to ensure that technical information they collect while performing their activities remains confidential[7], according to the principles laid down in their national legislation. Manufacturers, therefore, have no grounds for fearing that sensitive information they provide to NoBos or national market surveillance authorities in the context of market surveillance, might be disclosed.

There is no obligation to share technical documentation with economic operators or any other actor in the supply chain. They can rely on the CE marking of the product and the EU Declaration of Conformity (EU DoC) as drawn up by the manufacturer as proof that the product is compliant with the FPR.

The technical documentation will be unique to an individual EU fertilising product, however much of the content may be repeated for the part that is pertinent across a range of similar EU fertilising products.

Technical documentation does not have to be a single file in hard copy. Information can be stored in any format and in various locations within a company. It is important to ensure that the technical documentation is kept up to date so that it reflects any changes to the product, legislation or standards. If, for example, something in the production process changes, the manufacturer might need to re-do the conformity assessment and draw up a new technical documentation. The original TD must be kept for five years from the moment the manufacturer has placed the last product of that type on the market.

3.2 Technical documentation

The technical documentation covers the design, manufacture and intended use of the product, and specifies the applicable requirements of the FPR. In rare cases, it also covers requirements out of national law, such as derogations from the cadmium limit values for phosphate fertilisers. The technical documentation enables conformity assessment of an EU fertilising product with the relevant requirements.

Part I of the Annex IV to the FPR specifies the applicable conformity assessment modules, depending on the function and the component materials of a product. Part II of Annex IV gives a description of conformity assessment procedures and the requirements on the technical documentation.

An overview of the general requirements and the module specific requirements on the technical documentation are shown in Table I. A detailed overview of the requirements for each Module is given in Annex 0 to this report.

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[7] *Information on the **safeguarding of confidential commercial information** by the Notified Bodies, notifying authorities, competent national authorities and member states can be found in the Blue Guide on the implementation of EU product rules 2022, (Blue Guide §5.2.3-§7.4.1-§7.6.3).*

*To help in ensuring the **protection of confidential data or intellectual property rights**, the technical documentation provided to notified bodies has to be limited to that which is required solely for the purpose of assessing conformity to the legislation (Blue Guide §5.2.3)*

Table I. General requirements on technical documentation as laid down in Annex IV PART II 2.2 of the FPR.

Regulation extract	suggested content	Elaboration
COMMON ELEMENTS for ALL MODULES		
A general description of the EU fertilising product, the selected PFC(s), the claimed function(s) and the intended use	A general description of the product	Paragraph 3.3
	The product function category of the product according to its claimed function	Paragraph 3.3
	A description of the intended use	Paragraph 3.3 0
A list of component materials used, the CMCs as referred to in Annex II to which they belong and information about their origin or manufacturing process,	A list of components and to which component material category they belong	Paragraph 3.4 0
	For each component, a description of where the component comes from or how it was manufactured	Paragraph 3.4
The EU declarations of conformity for the component EU fertilising products of the fertilising product blend,	Only for fertilising product blends (PFC 7): declarations of conformity (DOC) of the component EU fertilising products	Paragraph 3.4
Drawings, schemes, descriptions, and explanations necessary for the understanding of the manufacturing process of the EU fertilising product,	Drawings, schemes, or descriptions to explain the manufacturing process	Paragraph 3.5
	Text accompanying drawings and schemes required to understand them	Paragraph 3.5
A specimen of the label or the leaflet, or both, referred to in Article 6(7) containing the information required in accordance with Annex III,	A copy of the product label or leaflet	Paragraph 3.5
A list of the harmonised standards referred to in Article 13, common specifications referred to in Article 14 and/or other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied,	A list of all standards and specification for the measurements and test that have been done demonstrate the compliance of the product with the PFC and CMC requirements. For each listed item, indicate for which requirement it was used.	paragraph 3.7
Results of calculations made, examinations carried out, etc.,	Any other results, calculations, or studies carried out on the product related to compliance with requirements.	Paragraph 3.8
Test reports	Test reports of the measurements and tests done to demonstrate the compliance with the requirements for the PFC and CMCs.	paragraph 3.8
Where the EU fertilising product contains or consists of by- products within the meaning of Directive 2008/98/EC, technical and administrative evidence that the by-products comply with the criteria established by delegated act referred to in Article 42(7) of this Regulation, and with the national measures transposing Article 5(1) of Directive 2008/98/EC and, where applicable, implementing acts referred to in Article 5(2) or national measures adopted under Article 5(3) of that Directive,	For any component which belongs to CMC 11, documentation that the material fulfils the conditions for a by-products laid down in Article 5(1) of Directive 2008/98/E, and reference to national transposition in national law. . that the material meets the criteria on CMC 11 as laid down in detail in COMMISSION DELEGATED REGULATION (EU) 2022/973.	paragraph 3.10

MODULE A, B+C and D1		
Where the EU fertilising product contains total chromium (Cr) above 200 mg/kg dry matter, information about the maximum quantity and exact source of total chromium (Cr).	If the total chromium content in the product exceeds 200 mg/kg dry matter, additional information like test reports or calculations showing the maximum quantity of total chromium (Cr), and documents from suppliers, showing the origin to specify the source.	paragraph 0
Modules A1		
The test reports from product checks for oil retention and detonation resistance	Test reports of detonation resistance and oil retention tests done to demonstrate the compliance with the requirements for the PFC	paragraph 3.8
The names and addresses of the sites, and of the operators of the sites, at which the product and its principal components were manufactured.	The names and addresses of the sites, and of the operators of the sites, at which the product and its principal components were manufactured.	paragraph 3.12
Modules B+C and D1		
Where the EU fertilising product contains or consists of derived products within the meaning of Regulation (EC) No 1069/2009, the commercial documents or health certificates required pursuant to that Regulation, and evidence that the derived products have reached the end point in the manufacturing chain within the meaning of that Regulation,	For any product that consist of or contains components that are derived of Animal by-products: the commercial documents or certificates as required under the EU regulations on ABP and the evidence for the 'end-point in the manufacturing chain' for that regulation.	Paragraph 3.11
MODULE D1		
For EU fertilising products containing or consisting of CMC 13: hazardous waste calculations; 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).	Only for products containing materials from CMC 13 hazardous waste calculations should be done.	Paragraph 3.12

3.3 General description and designated PFC

The technical documentation must include a general description of the EU fertilising product. This description must clearly state the **PFC designation**, **claimed function**, and any **other claims** about the product or its function, and a description of the intended use.

The **designation of the product function category** of the product according to its claimed function should be given, including all subcategory numbers and letters.

The general description should clearly state the claimed function of the product. Typically, the function claim of the products is described in the first point under the PFC description.

Claims that are made about the product must be allowed within the scope of the FPR and the product's PFC. The claims that are made must be supported by the technical documentation. In particular: claims, statements, or visual representations that the EU fertilising product **prevents or treats plant diseases**

or protects plants against harmful organisms, cannot be made. Products that do have these functions are explicitly excluded from the scope of the FPR and are **regulated under the PPP-R** (Plant Protection Products Regulation, Regulation (EC) 1107/2009[8]).

Claims unrelated to the product's function**,** such as 'sustainable' or 'environmentally friendly' must be supported by reference to legislation, or clearly identified guidelines, standards, or schemes, with which the EU fertilising product complies.

For products made available to non-professional users, rules on green claims have been introduced by Directive (EU) 2024/825 amending:

- Articles 6 and 7 of Directive 2005/29/EC with regard to commercial practices that are considered to be misleading, and therefore prohibited, on the basis of a case-by-case assessment, and
- Annex I to Directive 2005/29/EC, with the addition of specific misleading practices which are in all circumstances considered unfair, and therefore prohibited.

More comprehensive criteria for the content, substantiation and communication of green claims are to be laid down based on the Commission proposal for a Green Claims Directive COM 2023/166 (link to proposal here).

The description of the intended use is an obligatory element of the label and therefore included in the technical documentation with a specimen of the label or the leaflet (see paragraph 3.6).

3.4 Component materials

A **list of all component materials**. This list shall include all materials that are present in the product, including those that are present in quantities <5%. The list does not include the precursors of the materials that were used to produce the component materials.

The **designation of the component material category (CMC) to which they belong**. For each material, it should be stated to which CMC they belong.

For each component, **information about their origin or manufacturing process**. This could include information such as: explanation on feedstock material used, so that it is clear that it fits into the limited feedstock list of a CMC. Or a description on the precursors used to show that no waste has been used to produce a CMC 1 material. This could be done based on documents from suppliers, if the precursors or component material is bought as such, or by describing the manufacturing process of the component material, when the manufacturer of the EU fertilising product also produces the component material.

When the product concerns a **fertilising product blend (PFC 7)**, the component EU Fertilising products are regarded as the components. The technical documentation should contain the EU declarations of conformity for the component EU fertilising products of the blend.

3.5 Information on the manufacturing process

Drawings, schemes, descriptions, and explanations which are required for understanding the manufacturing process of the EU fertilising product.

[8] *Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC*

For products with materials belonging to CMCs 3, 5, 12, 13, 14 or 15 (Module D1) a written description and a diagram of the production or recovery process, where each treatment, storage vessel and area is clearly identified.

3.6 Specimen of the label or the leaflet

A **specimen of the label or the leaflet**, or both, referred to in Article 6(7) containing the information required in accordance with Annex III of the FPR. More information on the labelling can be found in the Guidance document on labelling EU fertilising products. This guidance also contains clear examples of labels for all PFCs.

3.7 List of standards or specifications

List of standards or specifications used to demonstrate the compliance of the product and its components to the requirements of the PFC (Annex I part 2 of the FPR) and the CMCs (Annex II part 2 of the FPR).

All tests for verifying the conformity of products shall be performed in a reliable and reproducible manner. In the event that harmonised standards or common specifications are only partly used, clearly state which part was used.

The **harmonised standards (hEN)** will be drafted by the CEN and national standardisation institutions in cooperation with stakeholders and experts. Products for which the requirements set out in Annexes I, II, and III are demonstrated by these standards or parts thereof are assumed to conform with the requirements. The reference to hEN which could be used to prove compliance with the requirements in the FPR will be published in the Official Journal of the EU. No standards have been published yet.

The **CEN technical specifications** are published as a concept for the hEN. However, contrary to hEN the technical specifications do not provide a presumption of conformity. Generally, they are assumed to be sufficient to demonstrate compliance with the requirements of Annexes I, II and III in the absence of the hEN. The technical specifications can be obtained from the national EN associations. With the adoption of the relevant hENs all corresponding CEN/TSs will be repealed. This means that test reports should be updated with references to Ens. In case the testing method is the same in both TS and EN there will be no need to redo tests. This may however not be the case for hENs that have different testing methods in comparison to the corresponding TSs.

The use of the hEN (or CEN technical specifications) is not mandatory. **Other relevant specifications or standards** can be applied. In that case, the manufacturer has to show that these standards or tests are reliable and reproducible.

A list of standards will be compiled as part IV of this study. These will clearly state for which requirements they may be used. Any results of calculations, studies or examinations carried out on the product to demonstrate the compliance with requirements of Annexes I, II and III should be given.

For products containing or consisting of **CMC 13 materials (Module D1)**, the TD must include the calculation on the removal of the hazardous property during the production process.

For requirements where the manufacturer presumes compliance under its responsibility without testing, a detailed examination explaining why the compliance is beyond doubt and a test report is not needed should be included. Such details could relate to the manufacturing process which, for instance, would make impossible the presence of certain pathogens.

3.8 Test reports and calculations

The results of the calculations made and examinations carried out should be complemented by the test reports of the analyses, trials, or reviews carried out on the product or its components to demonstrate conformity with the requirements of the FPR, using the standards or specifications in the list of standards or specifications under section 3.7.

Only for PFC 1(C)(I)(a)(i-ii)(A**) and** blends (PFC 7) with 28 % or more by mass of nitrogen (N) as a result of ammonium nitrate (NH_4NO_3)), test reports of detonation resistance and oil retention tests done to demonstrate the compliance with the requirements for the PFC under the Module A1.

For products containing or consisting of CMC 13 materials (Module D1)**,** the TD must include the calculation on the removal of the hazardous property during the production process.

3.9 Chromium content

When total chromium content in an EU fertilising product under Modules A, B+C, or D1 exceeds 200 mg/kg dry matter information a+ specification of the exact source of total chromium should be given.

For products with a total chromium (Cr) content exceeding 200 mg/kg dry matter (only Modules A, B+C, or D1**)** information on the maximum quantity of total chromium (Cr) in the product must be included in the TD.

3.10 By-products of CMC 11

Where the EU fertilising product contains or consists of by-products belonging to CMC 11, the TD should contain information demonstrating that the material is considered as a by-product according to the conditions of the Waste Framework Directive (WFS) 3, with a reference to the in national legislation into which the article 5.1, 5.2 or 5.o the WFD is transposed.

The TD should contain information to demonstrate that the material complies with the prerequisites and criteria for CMC 11 materials (as established by delegated REGULATION[9] (EU) 2022/973 of 14 March 2022).

3.11 End-point for ABP-derived component materials

Where EU fertilising products contain or consist of materials (CMC 3, 5 or 10, Module B+C or D1) derived from animal by-products (ABP) within the meaning of Animal By-Product Regulation (EC) No 1069/2009 (ABPR**)** the TD should contain the information as required by the ABP-R for the ABPs that are used for the production of the EU fertilising product, and the evidence that the material has reached the end point the end point in the manufacturing chain as defined in Delegated Regulation (EU) 2023/1605.

3.12 Names and addresses

Only under Module A1 (for products belonging to PFC 1(C)(I)(a)(i-ii)(A**) and** blends (PFC 7) with 28 % or more by mass of nitrogen (N) as a result of ammonium nitrate (NH_4NO_3)), the TD should contain

[9] *delegated REGULATION (EU) 2022/973 of 14 March 2022 supplementing Regulation (EU) 2019/1009 of the European Parliament and of the Council by laying down criteria on agronomic efficiency and safety for the use of by-products in EU fertilising products, as referred to in Article 42(7) of the FPR.*

information on the names and addresses of the sites, and of the operators of the sites, at which the product and its principal components were manufactured.

4 Conformity assessment modules in the FPR

4.1 Conformity assessment modules in the FPR

Conformity assessment procedures cover both the product's composition and production. Manufacturers are responsible for the execution of conformity assessment for both the composition and the production process of the EU fertilising product, even if they subcontract (part) of design or production. For more general information and background on conformity assessment modules see 'The Blue Guide on the implementation of EU product rules 2022".

In the composition phase the manufacturer ensures the conformity of the EU fertilising product to the requirements of the Fertilising Products Regulation:

- identifies the applicable requirements,
- carries out an adequate analysis and assessment of the risk(s).

In the production phase the manufacturer:

- takes all measures necessary so that the manufacturing process ensures compliance of the manufactured products with the applicable requirements,
- carries out detailed tests and controls,
- monitors the compliance of the products.

Module	Description
A Internal production control	Covers both design and production. The manufacturer ensures the conformity of the products to the requirements of the FPR (no EU-type examination).
A1 Internal production control plus supervised product testing	Covers both design and production. The manufacturer ensures the conformity of the products to the requirements of the FPR (no EU-type examination). + Tests on specific aspects of the product carried out by an in-house accredited body or other entity, under the responsibility of a notified body chosen by the manufacturer.
B EU-type examination	Covers design (is always followed by module C which covers the production). A notified body examines the technical design and verifies and attests that it meets the requirements of the FPR by issuing an EU-type examination certificate.
C Conformity to EU-type based on internal production control	Covers production and follows module B. Manufacturer must internally control its production in order to ensure product conformity against the EU-type approved under module B.
D1 Quality assurance of the production process	Covers both design and production. The manufacturer operates a production (manufacturing part and inspection of final product) quality assurance system in order to ensure conformity to the FPR requirements. The notified body assesses the production quality system.

4.2 Determination of the applicable Module

Which procedure can be followed for a product depends on the product function category (PFC) and its components material category (CMC) (Figure 4-1). The applicability and requirements for each module in the FPR are described in ANNEX IV to the FPR. An extensive overview of combinations of PFCs and CMCs and which modules are available for products of such combinations is given in Annex C to this guidance document.

Modules A1, B, and D1 require the involvement of a notified body. A list of NoBos for EU fertilising products can be found on the NANDO website[10] of the EC.

No notified body	Need notified body		
Module A	**Module A1**	**Modules B +C*** **	**Module D1**
PFC 1*- 4, if composed exclusively of one or more of CMC 1 (excl. Inhibiting compounds), CMC 4, 6, 8, and/or 11	**PFC 1 I(I)(a)(i-ii)(A)** (ammonium nitrate fertiliser of high nitrogen content)	**PFC 1*- 6**, if composed exclusively of one or more of CMC 1 (incl. inhibiting compounds), 2, 4, 6, 7, 8, 9, 10, and/or 11	**PFC 1*- 6**, if composed of one or more of CMC 1 (incl. inhibiting compounds), 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, and/or 15
PFC 7**	**PFC 7** with 28% or more of nitrogen from such a fertiliser	**PFC 7****	**PFC 7****

* Except PFI(C)(I)(a)(i-ii)(A) (ammonium nitrate fertiliser of high nitrogen content), for which Module A1 is mandatory
** except PFC 7 with 28% or more of nitrogen from a fertiliser belonging to I 1 (C)(I)(a)(i-ii)(A) (ammonium nitrate fertiliser of high nitrogen content), for which Module A1 is mandatory
*** Module B is always followed by Module C, which is performed by the manufacturer without involvement of notified body

Figure 4-1. Overview of which conformity assessment procedure modules are available depending on the product function category (PFC) of a product and the component material categories (CMC) of its components (Modified from DG GROW 2022).

The first step for determining to which criteria the product has to comply and which assessment procedure can be followed, is determining the PFC to which the product belongs. The criteria for each PFC can be found in ANNEX I to the FPR. If a product complies with the criteria of multiple PFCs 1-6, the manufacturer may choose one of those PFC, or claim all the functions of multiple PFCs, provided that the conditions for each PFC are fulfilled. In the latter case, the product would then belong to PFC 7 (as a 'functional' blend) after having followed the conformity assessment for each of the component PFCs 1-6. See the FPR-FAQ document questions 7.2 and 7.3.

Next, for each component of the product, the manufacturer needs to determine to which 'component material category' (CMC) it belongs. The FPR currently has 15 CMCs which are described in ANNEX II to the FPR. Any material that does not meet the criteria or description of one of the CMCs laid out in ANNEX II cannot be used in the production of an EU fertilising product.

Once the PFC has been determined and all components have been categorised, a conformity assessment procedure can be determined. Within the FPR, the following conformity assessment procedures[11] are available: Module A, Module A1, Module B followed by Module C, and Module D1. A flow chart to determine the applicable conformity assessment module is given in Figure 4-2. When several conformity assessment modules are applicable, it is up to the manufacturer to decide which module to use.

[10] https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&sort=country&dir_id=159361

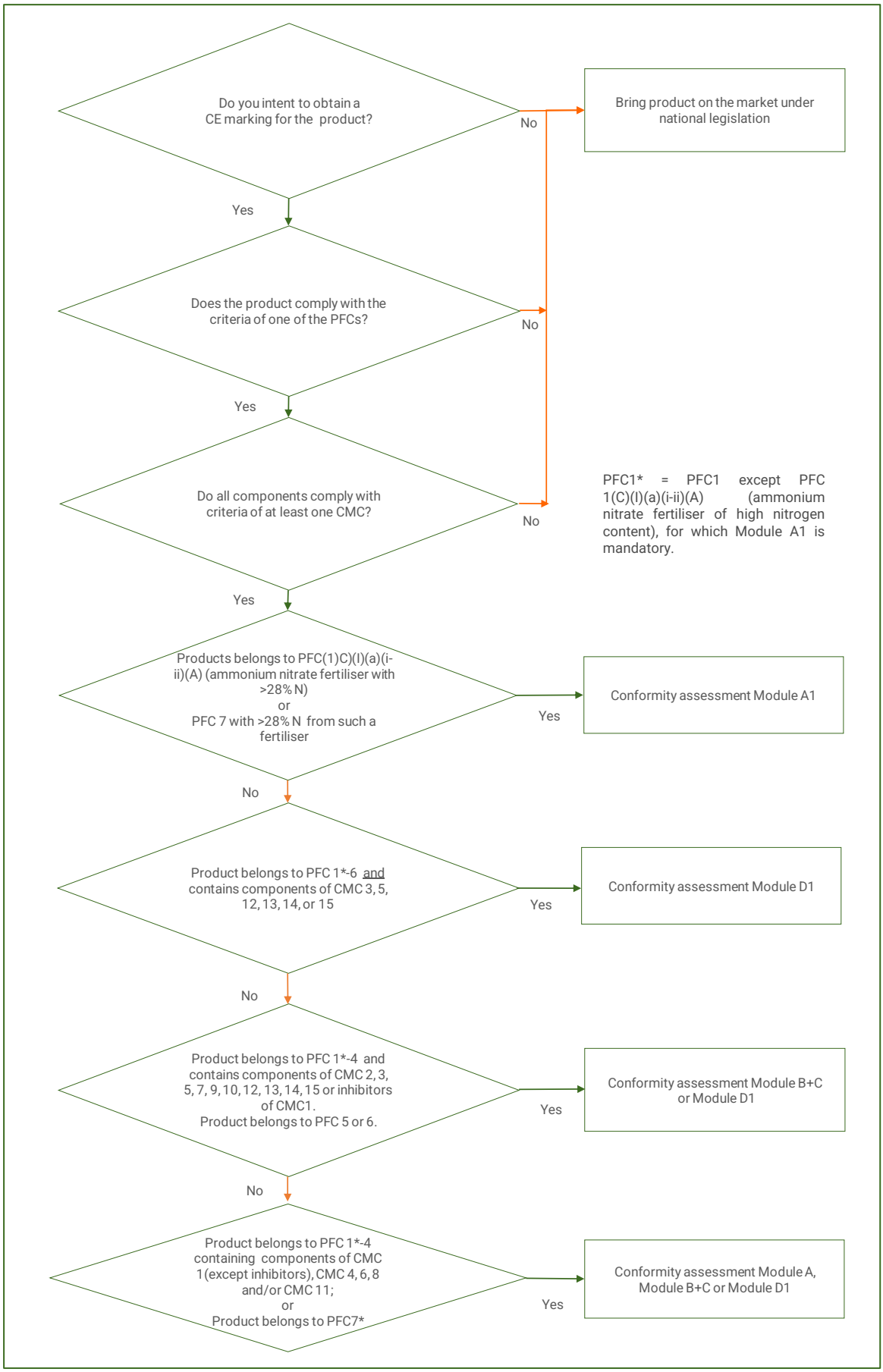


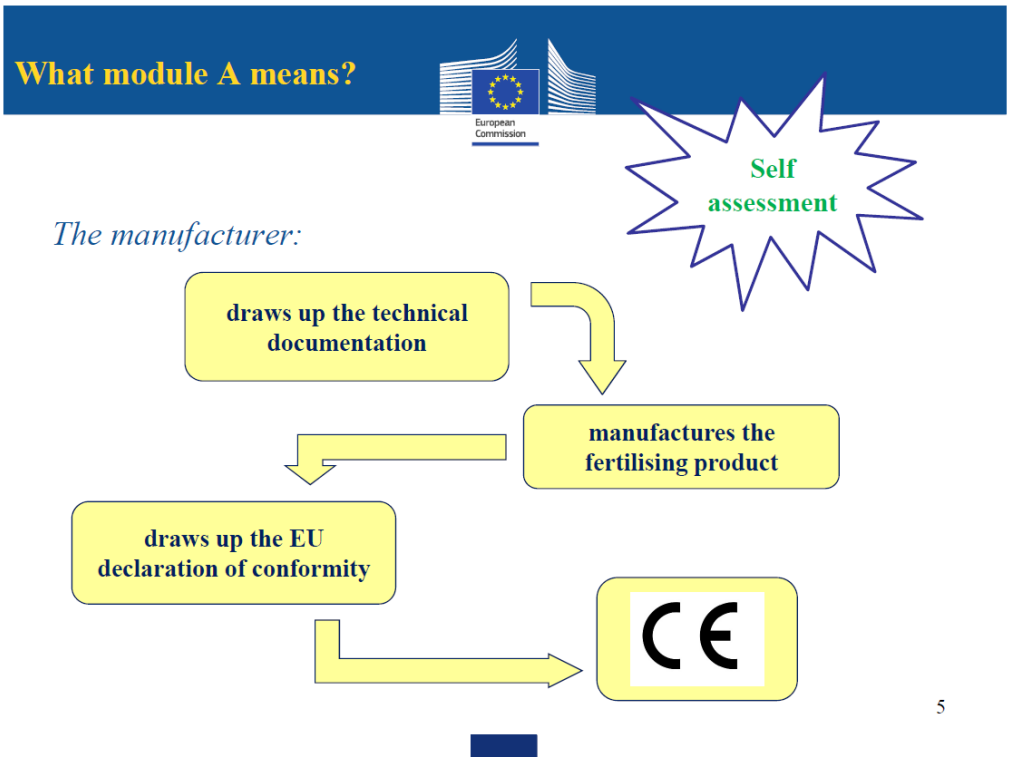
Figure 4-2 Flow chart determining the applicable conformity assessment modules (Annex IV to the FPR).

4.3 MODULE A

Module A is a "First-party conformity assessment or self-verification": the manufacturer applies all relevant quality and safety requirements and puts in place an internal production control procedure. This module does not require involvement of a notified body; a manufacturer may however use the services of an external party.

This self-assessment module can be applied for products of low complexity which present a low risk for the public interest. More specifically, this module can be chosen for products which solely consist of virgin materials (CMC 1), except for inhibiting compounds, fresh crop digestates (CMC 4), food industry by-products (CMC 6), nutrient polymers (CMC 8), and/or by-products as specified in CMC 11. Module A may also be used for products which belong to PFC 7.

Module A may not be used for ammonium nitrate fertilisers with an N content ≥28% by mass (PFC 1(C)(I)(a)(i-ii)(A)), fertilising product blends (PFC 7) of such a fertiliser which have an N content ≥28% by mass, inhibitors (PFC 5), and plant biostimulants (PFC 6).

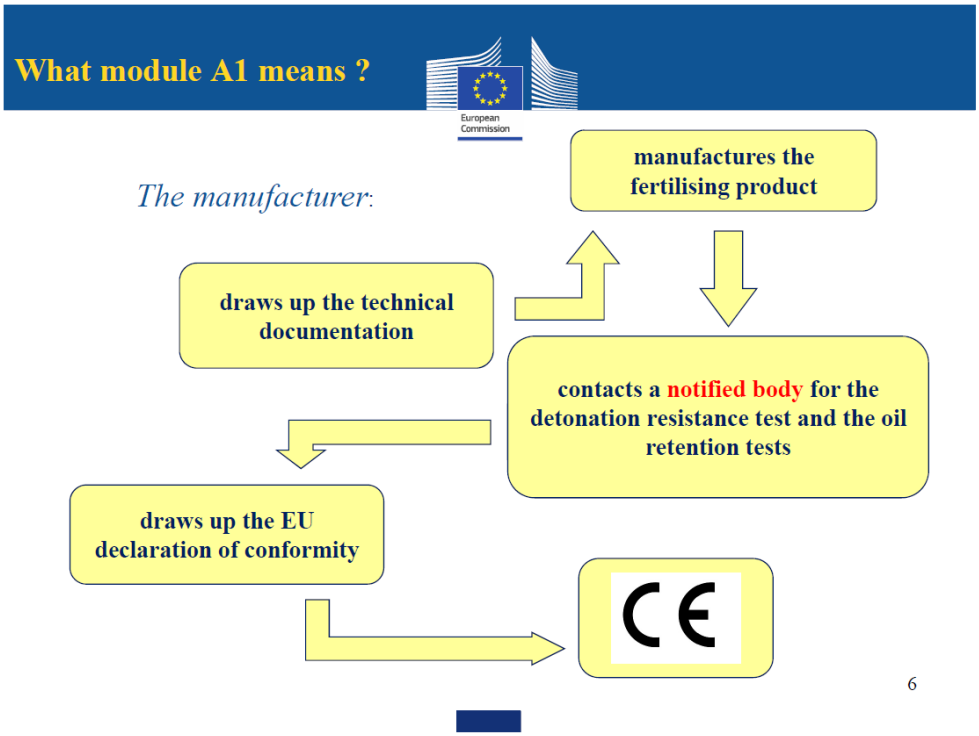


4.4 MODULE A1

Conformity assessment procedure includes the first-party conformity assessment or self-verification of module A, to which additional testing on certain aspects by a notified body is required.

Module A1 must be used for strait or compound solid ammonium nitrate fertilisers (PFC 1(C)(I)(a)(i-ii)(A))with an N content of 28% or more by mass and fertilising product blends (PFC 7) containing with an N content of 28% or more by mass from such a fertiliser . This module requires the involvement of a NoBo to ensure that the product is safe with regard to explosions.

On products for which the conformity assessment must be done using Module A1, additional checks must be performed as described in Annex IV PART 2 under module A1 point 4: checks on oil retention and detonation resistance. These tests shall be done periodically on behalf of the manufacturer under the responsibility of the NoBo chosen by the manufacturer.



4.5 MODULES B+C

The third procedure is a "Third party verification": the manufacturer submits the product design to an EU-type examination carried out by a notified body (module B - third party conformity assessment) and puts in place the conformity to type procedure based on internal production control (module C).

Module B covers only the design phase. The EU fertilising product type (EU-type) examination is the part of a conformity assessment procedure in which a notified body examines the technical design of a product and verifies and attests that the technical design of the product meets the requirements of the FPR by issuing an EC-type examination certificate.

Module C covers only the production phase and follows module B. The manufacturer ensures himself the conformity of the products to the type described in the EC-type examination certificate and to the requirements of the FPR. Its common point with module A is that the manufacturer ensures himself the conformity of its products; under module C however, this conformity is evaluated against an approved EC-type certificate resulted under module B. This module C does not require involvement of a notified body; a manufacturer may however use the services of an external party.

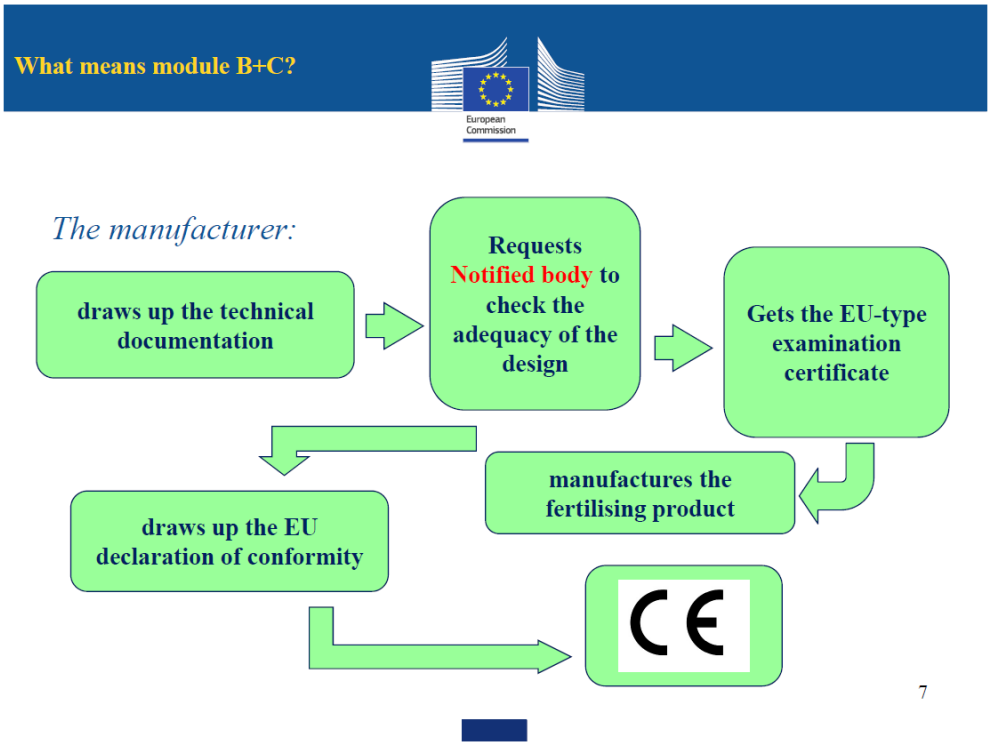
No details are given on how a manufacturer has to ensure the internal production control. When Modules B+C is used as the conformity assessment procedure, the manufacturer will apply documentation to a NoBo of their choice for EU-type examination. The NoBo will examine the technical documentation to assess the adequacy of the technical design of the fertilising product. The NoBo will further verify that samples of the product have been manufactured in conformity with the technical

documentation and identify the elements which have been designed in accordance with the applicable provisions of the relevant standards and specifications.

When a manufacturer modifies a product which has an EU-type examination certificate held by a NoBo in such a way that it may affect the conformity, the manufacturer shall then inform the NoBo. Such modifications require additional approval in the form of an addition to the original EU-type examination certificate.

The Module B+C procedure can be chosen for products containing one or more of the following components: inhibiting compounds as specified in CMC 1, materials from plants (CMC 2), polymers other than nutrient polymers (CMC 9), and derived products (CMC 10).

This procedure may also be used for all products for which Module A is applicable.



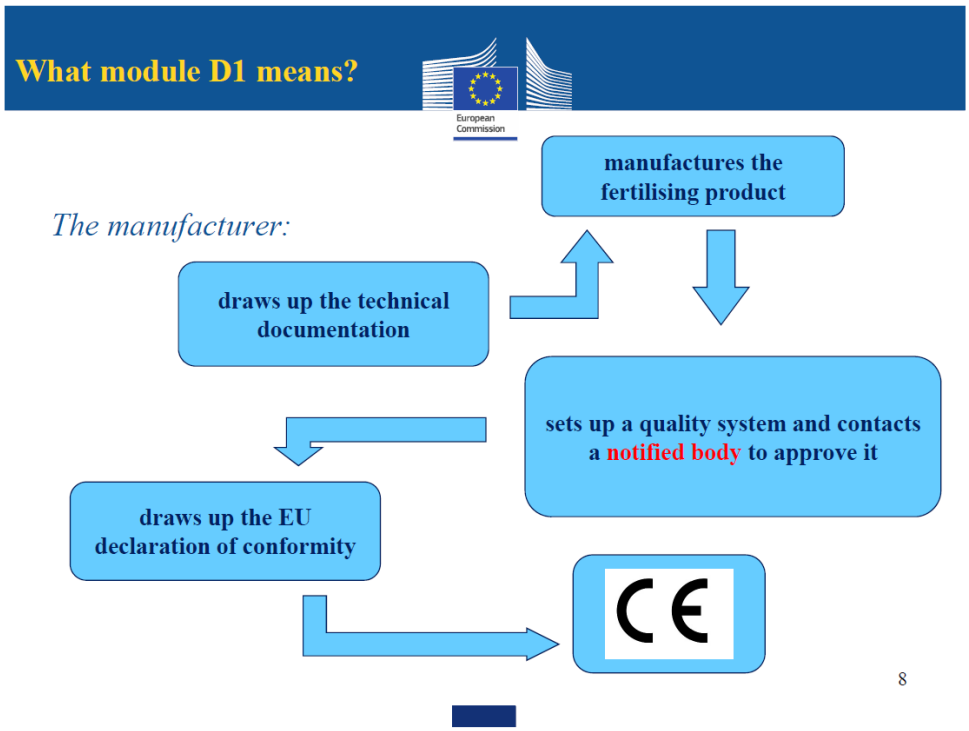
4.6 MODULE D1

The last applicable procedure is quality assurance of the production process (Module D1).

This module can be chosen for all products except for ammonium nitrate fertilisers with an N content of 28% or more by mass (PFC 1(C)(I)(a)(i-ii)(A)), and fertilising product blends consisting of such a fertiliser and which contains an N content of 28% or more by mass.

Module D1 (quality assurance of the production process) implies setting up a quality system for the production process to ensure the compliance of the EU fertilising products with the FPR. In Annex IV of the FPR there are detailed requirements concerning the objective of the quality system and the organisational structure which has to be put in place. The quality system has to be assessed by a notified body. The notified body is also surveying the functioning of approved quality systems, in order to make sure that the manufacturers comply with their obligations. Annex IV contains special

requirements for products containing certain CMCs where various waste streams may be used as input materials.



Annexes

A. Guidance documents

Guidance documents EU product rules

The Blue Guide on EU product rules

The Blue Guide[12] on the implementation of EU product rules is the main reference document on implementation of legislation based on the New Legislative Framework (NLF). The guide aims to explain elements of the NLF and market surveillance. The latest version of the guide stems from 2022 and reflects the most recent changes in legislation. The guide holds no legal force but is purely intended as guidance document for a better understanding of EU product rules and the uniform and coherent application of these rules across sectors.

The Blue Guide describes the history of EU rules to enable a single open market within the Union and how they evolved. This gives a good impression of why the NLF was set up and how it works in general.

The Blue Guide gives a more detailed explanation of concepts such as 'placing on the market', the actors in the supply chain and their obligations (e.g. manufacturers, importers, and authorised representatives).

On technical documentation the Blue Guide says the following. 'Technical documentation is intended to provide information on the design, manufacture and operation of the product'. A manufacturer must draw up technical documentation which contains information which demonstrates conformity of the product to the applicable requirements. The Bleu guide also covers the conformity assessment modules.

Guidance document on labelling EU fertilising products

This guidance document[13] provides straightforward guidance on the implementation of the labelling requirements set out in Annex III to the FPR. It was drafted by a task force of EU Member State representatives and industry stakeholders in consultation with the Commission Expert Group

The guidance contains 12 chapters. The first deals with overall rules on labelling based on the FPR provisions and has four paragraphs which read like an FAQ. The second chapter covers general requirements on labelling as set out in Annex III to the FPR. The following chapters cover specific requirements for each PFC with PFC 1 having four chapters (PFC 1 in general, organic fertilisers, organo-mineral fertilisers, and inorganic fertilisers).

The guidance on labelling also contains a detailed overview table with the information required with reference to the related clause.

FAQ on the FPR

The Frequently Asked Questions (FAQs) on the FPR aims in facilitating the implementation of the Fertilising Products Regulation ('FPR') by providing guidance to both national authorities and economic

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[12] Commission notice 2022/C 247/01. The 'Blue Guide' on the implementation of EU product rules 2022. More background information can be found at https://single-market-economy.ec.europa.eu/news/blue-guide-implementation-product-rules-2022-published-2022-06-29_en.

[13] 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 2021/C 119/01.
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2021.119.01.0001.01.ENG

operators. In this regard, this document focuses on issues that could raise difficulties in practice. Although not legally binding the answers provided have been discussed and endorsed in the Commission expert group on fertilisers.

The FAQs related to Regulation (EU) 2019/1009 on fertilising products, version of 21 March 2024: https://ec.europa.eu/docsroom/documents/58634

Guidance document of the Notified Bodies

The coordination group of Notified Bodies for the FPR has several Guidance documents. These documents are not legally binding by promote the harmonised understanding and application of the conformity assessment provisions among the Notified Bodies during their certification activities.

- Guidance document on the assessment of PFC 6 Plant biostimulants
- Criteria for accepting test reports
- Clarification and resolutions document (for instance on verification of REACH registration).

These documents can be found at the CIRCABC page of the Coordination group of notified bodies:

Other guidance documents

For the technical documentation, some elements refer to other EU legislation which apply to EU fertilising products or their components. This will not be elaborated on in the guidance document, but links to useful guidance on the requirements will be given.

Guidance documents on related EU laws

Guidance documents on legislation related to the FPR such as on REACH, CLP, and POPs and waste.

- Guidance documents on REACH can be found here:
  https://echa.europa.eu/guidance-documents/guidance-on-reach
  https://echa.europa.eu/nl/support/registration
- Guidance documents on CLP can be found here:
  https://echa.europa.eu/guidance-documents/guidance-on-clp
- COM(2018)32 Communication on the interface between chemical, product and waste legislation
  https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A52018DC0032

Guidance documents developed at the national level

Belgium:

- On borderline products: plant protection, biostimulant or fertilising products? (English, Dutch, French and German, with examples in Dutch or French:
  https://fytoweb.be/nl/gewasbeschermingsmiddelen/specifieke-middelen/borderline-producten

Netherlands:

- Guidance document on the distinction between waste, product or by-product legal state.
  https://lap3.nl/service/english/
- Decision support for the question Waste or not waste (in Dutch *Leidraad afval of niet*):
  https://www.afvalcirculair.nl/onderwerpen/afval/
- Webtool for the evaluation of the question Waste or not waste (in Dutch *Leidraad afval of niet*):
  https://www.afvalcirculair.nl/onderwerpen/afval/toetsing-afval/

Guidance documents by industry stakeholders

REACH for fertilizers: A platform created by Fertilizers Europe, with specific tools for both the REACH registrants of fertiliser substances and the fertilizer manufacturers.
https://www.reachfertilizers.com/
This website includes the Fertilizers Environmental Exposure (FEE) tool for the environmental exposure assessment, taking into account the local scenario for direct emissions to soil and surface water.
Overview of Regulatory Perspectives: REACH, Plant Protection and Animal by-Products Presentation by Verni, 2019 SOFIE 1st summit.
https://phosphorusplatform.eu/images/Conference/SOFIE2019/Alessio-Verni-SILC-Fertilizzanti-SOFIE%20ESPP-2019.pdf

The website of EUROFEMA (European Organic Fertilizer Manufacturing Association) does contain a presentation on 'The 6 steps to CE marking'. The six steps are:

1. CE or NOT
2. Classify
3. Fit Gap analysis
4. Label
5. Create your technical dossier
6. Get CE Marked

For the compilation of the TD, it does however not offer detailed information. The presentation can be found at:
https://eurofema.eu/wp-content/uploads/2022/10/EUROFEMA-presentation-info-session.pdf

The website of the Dutch association of fertiliser manufacturers, Meststoffen Nederland, contains instruction leaflets on the labelling of EU fertilising products in compliance with Annex III to the FPR. It includes a series of 10 hands-on instruction leaflets on the labelling of specific PFCs, with a subdivision for the different types of fertilising products (*in Dut*ch). The headings follow the structure of the general template used in the EU guidance document on labelling, and reference is made to the example labels therein. The instruction leaflets can be found at (in Dutch):
https://www.meststoffennederland.nl/dossiers/regelgeving/productie-en-distributie/etikettering

B. Obligations of economic operations on TD

Obligations of manufacturers	Obligations of authorised representatives	Obligations of importers
Article 6(1) FPR When placing EU fertilising products on the market, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements set out in Annexes I and II	*7.1. A manufacturer may, by a written mandate, appoint an authorised representative.*	*8.1. Importers shall place only compliant EU fertilising products on the market.*
Article 6(2) FPR Before placing EU fertilising products on the market, manufacturers shall draw up the technical documentation and carry out the relevant conformity assessment procedure referred to in Article 15, or have it carried out. Where compliance of an EU fertilising product with the applicable requirements laid down in this Regulation has been demonstrated by that conformity assessment procedure, manufacturers shall draw up an EU declaration of conformity and affix the CE marking.	Article 7(1) FPR: The obligation s laid down in Article 6(1) and the obligation to draw up technical documentation referred to in Article 6(2) shall not form part of the authorised representative's mandate.	Article 8(2) FPR Before placing an EU fertilising product on the market, importers shall ensure that the appropriate conformity assessment procedure referred to in Article 15 has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the EU fertilising product is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in Article 6(5) and (6). Where an importer considers or has reason to believe that an EU fertilising product is not in conformity with this Regulation, the importer shall not place the EU fertilising product on the market until it has been brought into conformity. Furthermore, where the EU fertilising product presents a risk to human, animal or plant health, to safety or to the environment, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

Article 6(3) FPR Manufacturers shall keep the technical documentation and the EU declaration of conformity for 5 years after the EU fertilising product covered by those documents has been placed on the market. On request, manufacturers shall make a copy of the EU declaration of conformity available to other economic operators.	Article 7(2)(a) FPR keep the technical documentation at the disposal of national market surveillance authorities for 5 years after the EU fertilising product covered by those documents has been placed on the market; Article 7(2)(b) FPR further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of an EU fertilising product; Article 7(2)(c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by EU fertilising products covered by the authorised representative's mandate.	Article 8.8 Importers shall, for 5 years after the EU fertilising product has been placed on the market ensure that the technical documentation can be made available to market surveillance authorities, upon request. On request, importers shall make a copy of the EU declaration of conformity available to other economic operators.

C. Detailed conformity assessment procedures table

Table II. Applicability of the conformity assessment procedures for fertilising products within the meaning of Regulation (EU) 2019/1009 (based on version 1.2 of the Conformity assessment table for products, on CIRCABC page of the Fertiliser expert group (Link here).

Products	Applicable procedures	Articles/Annexes	Procedures' applicability limitations
Fertilising products as specified in PFC 1 to 4 composed solely of materials covered by one or more of the following CMCs: CMC 1 (except inhibiting compounds as specified in CMC 1 point 4), CMC 4, CMC 6, CMC 7, CMC 8, CMC 11.	Internal production control (module A),	Articles 13, 14(2)-(3), 15, 16 Annex IV, Part I, point 1 Annex IV, Part II, Module A Annex V	Except for ammonium nitrate fertilisers of high nitrogen content as specified in PFC 1 (C)(I)(a)(i-ii)(A)
	EU-type examination (module B) followed by conformity to type based on internal production control (module C), or	Articles 13, 14(2)-(3), 15, 16, 20-36 Annex IV, Part I, point 3 Annex IV, Part II, Module B+C Annex V	
	Quality assurance of the production process (module D1).	Articles 13, 14(2)-(3), 15, 16, 20-36 Annex IV, Part I, point 4 Annex IV, Part II, Module D1 Annex V	
Fertilising product blends as specified in PFC 7	Internal production control (module A),	Articles 13, 14(2)-(3), 15, 16 Annex IV, Part I, point 1 Annex IV, Part II, Module A Annex V	Except for fertilising product blends containing 28% or more by mass of nitrogen (N) from a fertilising product as specified in PFC 1 (C)(I)(a)(i-ii)(A)
	EU-type examination (module B) followed by conformity to type based on internal production control (module C), or	Articles 13, 14(2)-(3), 15, 16, 20-36 Annex IV, Part I, point 3 Annex IV, Part II, Module B+C Annex V	
	Quality assurance of the production process (module D1).	Articles 13, 14(2)-(3), 15, 16, 20-36 Annex IV, Part I, point 4 Annex IV, Part II, Module D1 Annex V	

Products	Applicable procedures	Articles/Annexes	Procedures' applicability limitations
Ammonium nitrate fertilisers of high nitrogen content as specified in PFC 1 (C)(I)(a)(i-ii)(A)	Internal production control plus supervised product testing (module A1)	Articles 13, 14(2)-(3), 15, 16, 20-36 Annex IV, Part I, point 2 Annex IV, Part II, Module A1 Annex V	
Fertilising product blends as specified in PFC 7 containing 28% or more by mass of nitrogen (N) from a fertilising product as specified in PFC 1 (C)(I)(a)(i-ii)(A)	Internal production control plus supervised product testing (module A1)	Articles 13, 14(2)-(3), 15, 16, 20-36 Annex IV, Part I, point 2 Annex IV, Part II, Module A1 Annex V	
Fertilising products as specified in PFC 1 to 4 containing materials covered by one or more of the following CMCs: CMC 2, CMC 9, CMC 10.	EU-type examination (module B) followed by conformity to type based on internal production control (module C), or	Articles 13, 14(2)-(3), 15, 16, 20-36 Annex IV, Part I, point 3 Annex IV, Part II, Module B+C Annex V	Except for a) ammonium nitrate fertilisers of high nitrogen content as specified in PFC 1 (C)(I)(a)(i-ii)(A) and b) fertilising products containing materials covered by CMC 3, CMC 5, CMC 12, CMC 13 or CMC 14
	Quality assurance of the production process (module D1)	Articles 13, 14(2)-(3), 15, 16, 20-36 Annex IV, Part I, point 4 Annex IV, Part II, Module D1 Annex V	Except for ammonium nitrate fertilisers of high nitrogen content as specified in PFC 1 (C)(I)(a)(i-ii)(A)
Inhibitors as specified in PFC 5 or Fertilising products containing inhibiting compounds as specified in CMC 1, point 4	EU-type examination (module B) followed by conformity to type based on internal production control (module C), or	Articles 13, 14(2)-(3), 15, 16, 20-36 Annex IV, Part I, point 3 Annex IV, Part II, Module B+C Annex V	Except for a) ammonium nitrate fertilisers of high nitrogen content as specified in PFC 1 (C)(I)(a)(i-ii)(A) and b) fertilising products containing materials covered by CMC 3, CMC 5, CMC 12, CMC 13 or CMC 14
	Quality assurance of the production process (module D1)	Articles 13, 14(2)-(3), 15, 16, 20-36 Annex IV, Part I, point 4 Annex IV, Part II, Module D1 Annex V	Except ammonium nitrate fertilisers of high nitrogen content as specified in PFC 1 (C)(I)(a)(i-ii)(A)
Plant biostimulants as specified in PFC 6	EU-type examination (module B) followed by conformity to type based on internal production control (module C), or	Articles 13, 14(2)-(3), 15, 16, 20-36 Annex IV, Part I, point 3 Annex IV, Part II, Module B+C Annex V	Except products containing materials covered by CMC 3, CMC 5, CMC 12, CMC 13 or CMC 14
	Quality assurance of the production process (module D1)	Articles 13, 14(2)-(3), 15, 16, 20-36 Annex IV, Part I, point 4 Annex IV, Part II, Module D1 Annex V	

Products	Applicable procedures	Articles/Annexes	Procedures' applicability limitations
Fertilising products as specified in PFCs 1 to 6 containing materials covered by at least one of the following CMCs: CMC 3, CMC 5, CMC 12, CMC 13, CMC 14.	Quality assurance of the production process (module D1)	Articles 13, 14(2)-(3), 15, 16, 20-36 Annex IV, Part I, point 4 Annex IV, Part II, Module D1 Annex V	Except ammonium nitrate fertilisers of high nitrogen content as specified in PFC 1 (C)(I)(a)(i-ii)(A)

D. Required documentation for Modules A, A1, B+C, D1

Table III. Requirements of the technical documentation of an EU fertilising product per conformity assessment procedure module, as laid down in Annex IV of the FPR.

MODULE A	MODULE A1	MODULE B + C	MODULE D1
2.2. The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and intended use of the EU fertilising product. The technical documentation shall contain, where applicable, at least the following elements:	2.2. The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and intended use of the EU fertilising product. The technical documentation shall contain, where applicable, at least the following elements:	2.2. The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and intended use of the EU fertilising product. The technical documentation shall contain, where applicable, at least the following elements:	2.2. The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and intended use of the EU fertilising product. The technical documentation shall contain, where applicable, at least the following elements:
(a) a general description of the EU fertilising product, the PFC corresponding to the claimed function of the EU fertilising product and description of the intended use,	(a) a general description of the EU fertilising product, the PFC corresponding to the claimed function of the EU fertilising product and description of the intended use,	(a) a general description of the EU fertilising product, the PFC corresponding to the claimed function of the EU fertilising product and description of the intended use,	(a) general description of the EU fertilising product, the PFC corresponding to the claimed function of the EU fertilising product and description of the intended use,
(b) a list of component materials used, the CMCs as referred to in Annex II to which they belong and information about their origin or manufacturing process,	(b) a list of component materials used, the CMCs as referred to in Annex II to which they belong and information about their origin or manufacturing process,	(b) a list of component materials used, the CMCs as referred to in Annex II to which they belong and information about their origin or manufacturing process,	(b) a list of component materials used, the CMCs as referred to in Annex II to which they belong and information about their origin or manufacturing process,
(c) the EU declarations of conformity for the component EU fertilising products of the fertilising product blend,	(c) the EU declarations of conformity for the component EU fertilising products of the fertilising product blend,	(c) the EU declarations of conformity for the component EU fertilising products of the fertilising product blend,	(c) the EU declarations of conformity for the component EU fertilising products of the fertilising product blend,

MODULE A	MODULE A1	MODULE B + C	MODULE D1
(d) drawings, schemes, descriptions and explanations necessary for the understanding of the manufacturing process of the EU fertilising product,	(d) drawings, schemes, descriptions and explanations necessary for the understanding of the manufacturing process of the EU fertilising product,	(d) drawings, schemes, descriptions and explanations necessary for the understanding of the manufacturing process of the EU fertilising product,	(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, 14 or 15 as defined in Annex II, a written description and a diagram of the production or recovery process, where each treatment, storage vessel and area is clearly identified,
(e) a specimen of the label or the leaflet, or both, referred to in Article 6(7)containing the information required in accordance with Annex III,	(e) a specimen of the label or the leaflet, or both, referred to in Article 6(7) containing the information required in accordance with Annex III,	(e) a specimen of the label or the leaflet, or both, referred to in Article 6(7) containing the information required in accordance with Annex III,	(e) a specimen of the label or the leaflet, or both, referred to in Article 6(7) containing the information required in accordance with Annex III,
	(f) the names and addresses of the sites, and of the operators of the sites, at which the product and its principal components were manufactured,		
(f) a list of the harmonised standards referred to in Article 13, common specifications referred to in Article 14 and/or other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied,	(g) a list of the harmonised standards referred to in Article 13, common specifications referred to in Article 14 and/or other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied,	(f) a list of the harmonised standards referred to in Article 13, common specifications referred to in Article 14 and/or other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied,	(f) a list of the harmonised standards referred to in Article 13, common specifications referred to in Article 14 and/or other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied,
(g) results of calculations made, examinations carried out, etc.,	(h) results of calculations made, examinations carried out, etc.,	(g) results of calculations made, examinations carried out, etc.,	(g) results of calculations made, examinations carried out, etc.,

MODULE A	MODULE A1	MODULE B + C	MODULE D1
			(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: * (see the calculation formula below this table). 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,
(h) test reports,	(i) test reports, including the reports from product checks for oil retention and detonation resistance, referred to in point 4 and	(h) test reports,	(h) test reports,

MODULE A	MODULE A1	MODULE B + C	MODULE D1
		(i) where the EU fertilising product contains or consists of derived products within the meaning of Regulation (EC) No 1069/2009, the commercial documents or health certificates required pursuant to that Regulation, and evidence that the derived products have reached the end point in the manufacturing chain within the meaning of that Regulation,	(i) where the EU fertilising product contains or consists of derived products within the meaning of Regulation (EC) No 1069/2009, the commercial documents or health certificates required pursuant to that Regulation, and evidence that the derived products have reached the end point in the manufacturing chain within the meaning of that Regulation,
(i) where the EU fertilising product contains or consists of by- products within the meaning of Directive 2008/98/EC, technical and administrative evidence that the by-products comply with the criteria established by delegated act referred to in Article 42(7) of this Regulation, and with the national measures transposing Article 5(1) of Directive 2008/98/EC and, where applicable, implementing acts referred to in Article 5(2) or national measures adopted under Article 5(3) of that Directive,	(j) where the EU fertilising product contains or consists of by- products within the meaning of Directive 2008/98/EC, technical and administrative evidence that the by-products comply with the criteria established by delegated acts referred to in Article 42(7) of this Regulation, and with the national measures transposing Article 5(1) of Directive 2008/98/EC and, where applicable, implementing acts referred to in Article 5(2) or national measures adopted under Article 5(3) of that Directive.	(j) where the EU fertilising product contains or consists of by- products within the meaning of Directive 2008/98/EC, technical and administrative evidence that the by-products comply with the criteria established by delegated act referred to in Article 42(7) of this Regulation, and with the national measures transposing Article 5(1) of Directive 2008/98/EC and, where applicable, implementing acts referred to in Article 5(2) or national measures adopted under Article 5(3) of that Directive, and	(j) where the EU fertilising product contains or consists of by- products within the meaning of Directive 2008/98/EC, technical and administrative evidence that the by-products comply with the criteria established by delegated act referred to in Article 42(7) of this Regulation, and with the national measures transposing Article 5(1) of Directive 2008/98/EC and, where applicable, implementing acts referred to in Article 5(2) or national measures adopted under Article 5(3) of that Directive, and
(j) where the EU fertilising product contains total chromium (Cr) above 200 mg/kg dry matter, information about the maximum quantity and exact source of total chromium (Cr).		(k) where the EU fertilising product contains total chromium (Cr) above 200 mg/kg dry matter, information about the maximum quantity and exact source of total chromium (Cr).	(k) where the EU fertilising product contains total chromium (Cr) above 200 mg/kg dry matter, information about the maximum quantity and exact source of total chromium (Cr).

* For Module D1, 2.2g(a):

The incorporation rate of the hazardous property into the output material shall then be calculated as follows:

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

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.

Part II

PFC

Contents

Abstract

This report is the result of the technical study performed for the Commission, DG GROW F2, under tender GROW/2022/MVP/0014 'Technical study in support of a guidance document for the elaboration of the technical documentation of EU fertilising product'.

It contains guidelines for drafting technical documentation for EU fertilisng products on the PFC level.

Technical documentation must contain all relevant data and documentation necesary to verify that the product meets all the requirements imposed on it by the FPR. A product's technical documentation is a compilation of documents and contains documents written by the manufacturer (such as a product description) and other parties (such as certificates and analytical reports). Manufacturers of fertilising products with CE marking are obligated to draw up the technical documentation. Importers are obliged to ensure that the manufacturer has drafted the technical documentation.

The different product function categories (PFCs) have generic and specific requirements on the technical documentation. All requirements for each PFC are listed in separate chapters, that can be used as 'standalone' guidances.

Product Function Categories

DESIGNATION OF PFCs (Annex I Part I of the FPR consolidated version of 16.03.2023)

1. Fertiliser
    - A. Organic fertiliser
        - I. Solid organic fertiliser
        - II. Liquid organic fertiliser
    - B. Organo-mineral fertiliser
        - I. Solid organo-mineral fertiliser
        - II. Liquid organo-mineral fertiliser
    - C. Inorganic fertiliser
        - I. Inorganic macronutrient fertiliser
            - (a) Solid inorganic macronutrient fertiliser
                - (i) Straight solid inorganic macronutrient fertiliser
                    - (A) Straight solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content
                - (ii) Compound solid inorganic macronutrient fertiliser
                    - (A) Compound solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content
            - (b) Liquid inorganic macronutrient fertiliser
                - (i) Straight liquid inorganic macronutrient fertiliser
                - (ii) Compound liquid inorganic macronutrient fertiliser
        - II. Inorganic micronutrient fertiliser
            - (a) Straight inorganic micronutrient fertiliser
            - (b) Compound inorganic micronutrient fertiliser

2. Liming material

3. Soil improver
    - A. Organic soil improver
    - B. Inorganic soil improver

4. Growing medium

5. Inhibitor
    - A. Nitrification inhibitor
    - B. Denitrification inhibitor
    - C. Urease inhibitor

6 Plant biostimulant
    - A Microbial plant biostimulant
    - B non-microbial plant biostimulant

7. Fertilising product blend

List of abbreviations

ABP Animal By-Product

ABP-R Animal By-Products Regulation - 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, OJ L 300, 14.11.2009, p. 1–33

CLP Classification, Labelling and Packaging Regulation - Regulation (EC) 1272/2008 of the European Parliament and of the Council of 16 December 2008 laying down rules on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

CMC Component Material Category (see Annex II to the FPR).

ECHA European Chemicals Agency

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, OJ L 170, 25.6.2019, p. 1–114.

NoBo Notified body,

PAH_{16} Refers to 16 polycyclic aromatic hydrocarbons, it is calculated as the 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

PFC Product Function Category (see Annex I to the FPR).

PPP-R Plant Protection Product Regulation - Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, OJ L 309, 24.11.2009, p. 1–50.

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, OJ L 396, 30.12.2006, p. 1–850.

SDS Safety Data Sheet

MSDS Material Safety Data Sheet

WFD Waste Framework Directive - Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, OJ L 312, 22.11.2008, p. 3–30.

1 A. PFC 1.A Organic fertilisers

1 A. 1. General product description and designated PFC

The technical documentation must include a general description of the product. This description must clearly state the PFC designation, claimed function, and any other claims about the product or its function. Claims that are made about the product must be allowed within the scope of the FPR and the product's PFC. All claims that are made must be supported by the technical documentation.

PFC designation

Organic fertilisers should be designated as either:

- PFC.1.A.I Solid organic fertiliser, or
- PFC.1.A.II Liquid organic fertiliser.

Claimed function

The function of organic fertilisers is to provide nutrients to plants or mushrooms.

Other claims

Any additional claims that are made on the label must be supported by examination or testing of these properties or functioning. The technical documentation should contain test reports or references to scientific literature that underpin the claims.

Where is it suggested that products possess unique characteristics, the technical documentation should contain a description of how the product differs from similar products, where applicable with calculations or schemes to underpin the difference.

For claims unrelated to the product's function, such as 'sustainable' or 'environmentally friendly' or 'allowed to be used in organic agriculture', the technical documentation should contain references and links to legislation, clearly identified guidelines, standards, or schemes with which the EU fertilising product complies to underpin the claims.

RESOURCES

Criteria for the content, substantiation and communication of **green claims** will be laid down in the Green Claims Directive (link to Commission's proposal COM 2023/166 here) and the Greenwashing Directive (EU) 2024/825 (link to consolidated version here).

Rules and definitions for **organic production and labelling** are laid down in the Regulation (EU) 2018/848 on organic production, a link to the consolidated version can be found here. An **input list** of the materials that are authorised be used in organic production is established in Regulation (EU) 2021/1165, a link to the consolidated version can be found here.

FAQ

See the FAQ document on the FPR to check:

- Whether 'organic fertilisers' in the meaning of the ABPR a**re** covered by the FPR? (Q1.4)
- Whether PFC 1.A. Organic fertilisers are allowed to the used in organic farming production (Q1.5)

1 A. 2. List of component materials

The technical documentation must contain a list of all the product's component materials. This list must include all materials that are present in the product, including those that are present in quantities <5% by dry weight. The list does not include the precursors of the materials that were used to produce the component materials.

For each listed component, it must be demonstrated that the component is compliant with the requirements and criteria of that CMC. Information on the technical documentation required for each CMC material is given in PART III of this guidance document.

The biological origin of the material should be evident from the component description.

Where materials that are known to have a pesticidal or other plant protection effect are used as a component material, a document should be included to explain and account for, why at the proposed use instructions, the resulting EU fertilising product complies with the conditions of the FPR and does not have a pesticide function.

RESOURCES

Rules and definitions for **plant protection products and active substances** are laid down in Regulation (EC) No 1107/2009 on plant protection products (PPP-R). A link to the consolidated version can be found here.

The **list of approved 'active substances'** under the scope of the PPP-R can be found in Regulation (EU) No 540/2011, a link to the consolidated version can be found here.

Information and examples on **'borderline' products** can be found in the document "Borderline products' from the Belgian government website FYTOWEB (link here) and the document 'SANCO Doc 6621-99' on Scope and borderline issues 1107/2009 (link to the consolidated version from DG SANTE/E4 here).

FAQ

See the FAQ document on the FPR to check:

- What may **EU fertilising products contain/consist of**? (Q8.1)
- Whether **materials with a content of <5%** in the final product must be considered in the technical documentation? (Q9.2)
- How to **demonstrate that the product consists 'solely' of CMC** materials? (Q8.2)
- Whether it is necessary to **indicate the % of each component**? (Q8.2)
- When materials are considered as a component or as **a precursor, additive or reactant**? (Q8.10)
- What is considered as **a material of biological origin**? (Q7.9)
- Whether **methylene urea, isobutylidene, urea, crotonylidene urea, or synthesised amino acid**s are considered **materials of biological origin**? (Q7.5 & 7.9)
- If substances that have a **plant protection effect** can be used as a component in EU fertilising products? (Q1.3)
- How should the manufacturer perform the conformity assessment of component materials belonging to a **CMC bought from third parties** and provide information about their origin or manufacturing? (Q10.13)
- How can manufacturers comply with the requirements in Module D1 if they **buy the component materials (compost for instance) and do not produce them themselves**? (Q10.19)

1 A. 3. Information on the manufacturing process

The technical documentation must include information on the manufacturing process for the purpose of assessing conformity.

Describe the manufacturing process of the product. Provide a summary of the steps involved in mixing and processing the materials for the manufacture of the final formulated product. Use drawings, schemes, descriptions and explanations where necessary for the understanding of the manufacturing process of the EU fertilising product. Where relevant describe conditions and the chemical reactions generated during the production process and the materials and processing additives used. From the description, it should be evident which materials are used as a precursor and which materials are present as a component in the final product.

RESOURCE

Information on the obligations of manufacturers, Notified Bodies, notifying authorities, competent national authorities, and member states with regards to CE marked product rules and technical documentation can be found in the Blue Guide on the implementation of EU product rules 2022. A link to the Blue Guide, document 2022/C 248/01, can be found can be found here.

Information on the **safeguarding of confidential commercial information** by the Notified Bodies, notifying authorities, competent national authorities and member states can be found in the Blue Guide §5.2.3-§7.4.1-§7.6.3.

To help ensure the **protection of confidential data or intellectual property rights**, the technical documentation provided to notified bodies has to be limited to that which is required solely for the purpose of assessing conformity to the legislation (Blue Guide §5.2.3).

FAQ

See the FAQ document on the FPR to check:

- How to perform the conformity assessment if parts of the production process are **subcontracted to another company** (Q10.5)
- When materials are considered as a **component or as a precursor, additive or reactant**? (Q8.13)

1 A. 4. Specimen of the label or leaflet

A specimen of the label or the leaflet, or both, referred to in Article 6(7) of the FPR containing the information required in accordance with Annex III of the FPR. More information on the labelling can be found in the Guidance on the labelling of EU fertilising products. That guidance also contains clear examples of product labels for each PFC.

1 A. 5. Examinations to demonstrate compliance

To demonstrate compliance with the product requirements, the manufacturer must subject the product to tests, trials, analyses or any other examination or calculation**.** All examinations for verifying the conformity of products must be performed in a reliable and reproducible manner. This may be done by the manufacturers themself or by an external party. The results of these tests should be recorded in one or several test report(s) in the technical documentation.

However, where compliance with a given requirement (such as the absence of a given contaminant) follows certainly and uncontestably from the nature or manufacturing process of an EU fertilising product, that compliance can be presumed in the conformity assessment procedure without verification (such as testing), at the responsibility of the manufacturer (ANNEX I PART II. 4, FPR). In that case, a

statement from the manufacturer in which the compliance is explained and motivated should be added to the technical documentation.

For organic fertilisers, the following requirements are set in the FPR:

Related provision	Summary	Suggested content
PFC 1A specific requirements		
Annex I PFC 1 (A) 1	Contains organic carbon of biological origin	List of components description that supports the biological origin of the Corg present
Annex I PFC 1 (A) 1	Contains nutrients of biological origin	List of components description that supports the biological origin of the nutrients present
Annex I PFC 1 (A)(I) 1	Physical form is solid or liquid	Self-evident
Annex I PFC 1 (A)(I) 2	Minimum content of N, P and or K	Test report
Annex I PFC 1 (A)(I) 3	Minimum content of C_{org}	Test report
Annex I PFC 1 (A) 2 and 3	Product may not exceed content limits for Cd, Cr VI, Hg, Ni, Pb, As, biuret ($C_2H_5N_3O_2$), Cu, and Zn.	Test report
Annex I PFC 1 (A) 4	Pathogens in the product may not exceed pathogen limits (*Salmonella spp*., *Escherichia coli* or *Enterococcaceae*)	Test report
General PFC requirements		
Annex III I.1.8	Additional claims by manufacturer:	Measurement of verifiable factors to support additional claims on product
Annex IV MODULE A/B+C/D1 2.2	If the total chromium content in the product exceeds 200 mg kg^{-1} dry matter	Information specifying the exact source and the maximum quantity of total chromium (Cr)

Organic fertilisers must have a minimum content of organic C and the primary macronutrients nitrogen (N), phosphorus (P_2O_5), or potassium (K_2O). Compliance can be demonstrated with lab reports on the analyses of the product's contents of declared nutrients and C organic.

The technical documentation should include an adequate analysis and assessment of the risk(s) of the product. For a PFC 1(A) product the applicable risks concern contents of heavy metalsand the presence of pathogens. Compliance can be demonstrated with a lab report on the analysis of the product's contents of heavy metals. If the contents are reported on 'fresh' product basis, the dry matter content or moisture content must also be analysed and calculations to express contents on dry matter bases must be included in the technical documentation. Pathogens must not exceed the set limits. Demonstrate compliance by including pathogen analysis reports. Note that at least five samples must be tested.

If the total chromium content exceeds 200 mg kg^{-1} dry matter, a document giving the maximum content and exact source of chromium must be included.

In addition to the risks covered by the set requirements, there might be aspects not covered by the listed requirements on heavy metals and arsenic. Where such risks for a specific product or component are commonly known by diligent manufacturers operating in that field, the technical documentation should identify them and document how they have been addressed.

RESOURCES

More information of the Notified Bodies on
- accreditation of testing laboratories,
- the validity of test reports in time,
- the core criteria for laboratories and subcontracting of laboratories,
- acceptance of test reports using internal testing methods, national methods, CEN/ISO standards, or peer-reviewed studies
- ring test participation of laboratories

can be found in the document **Criteria for accepting test reports** of the Coordination Group of NoBos, available in the library on the CIRCABC page of the Commission expert group on fertilising products.

FAQ

See the FAQ document on the FPR to check:
- How to prove compliance with the requirement for **bioavailable nickel, inorganic arsenic or hexavalent chromium** (Q7.14)
- Does the **Persistent Organic Pollutants** Regulation apply to EU fertilising products? (Q1.7)
- What is expected by '**adequate analysis and assessment of the risk**(s) to be included in the technical documentation'? (Q10.11)
- Is there **a list of approved laboratories** to check the conformity with various requirements, such as contaminant content? (Q 10.4)
- Is **accreditation of the laboratory** used mandatory or advisable? (Q10.4)
- Whether it is **mandatory to use the harmonised standards** (Q10.3)
- How to do conformity assessment when **harmonised standards** are not adopted (Q10.3)

1 A. 6. Test report

The results of the calculations and examinations to demonstrate compliance with the requirements must be supported by the reports of the analyses, trials, or reviews carried out on the product and its components. All test reports and review papers should be included in the technical documentation.

1 A. 7. List of standards or specifications

The technical documentation must include a list of standards and specifications which have been used to demonstrate compliance of the product and its components with the relevant requirements of part 2 of Annex I to the FPR and of part 2 of Annex II to the FPR. In the event of partly applied harmonised standards or common specifications, clearly state which part was used.

A list of standards and specifications which may be used for each requirement can be found in PART IV of this guidance.

Besides harmonised standards, the references of which have been published in the Official Journal of the EU, other relevant specifications or standards can be applied. In that case, the manufacturer must show that the testing methods in these standards are reliable and reproducible.

RESOURCE

More information of the Notified Bodies on acceptance of test reports using internal testing methods, national methods, CEN/ISO standards, or peer-reviewed studies can be found in the document Criteria for accepting test reports of the Coordination Group of NoBos, available in the library on the CIRCABC page of the Commission expert group on fertilising products.

FAQ

See the FAQ document on the FPR to check:

- Whether it is **mandatory to use the harmonised standards** (Q10.3)
- Is there a **list of approved laboratories** to check the conformity with various requirements, such as contaminant content? (Q 10.4)
- How to do conformity assessment when **harmonised standards** are not adopted (Q10.3)

1 A. 8. List of suggested documents

It is suggested to include at least the following documents in the technical documentation:

a. A general description of the product including the PFC designation, claimed functions
b. A list of component materials, their CMC designation, and the documentation demonstrating compliance of the components with their CMC (see part III for details).
c. Drawings, schemes, descriptions, and/or explanations required for understanding the manufacturing process of the EU fertilising product.
d. A specimen of the product's label, leaflet, or both.
e. A list of standards used in the conformity assessment procedure which also indicates for which requirement each standard was used.
f. Test reports on the product's contents of chromium, cadmium, hexavalent chromium, mercury, nickel, lead, copper, zinc, chloride, arsenic, organic carbon, nutrients, pathogens, and biuret.
g. Results of calculations and examinations.
h. Documents in support of any additional claims.
i. Identified risks of the product to human, animal or plant health, to safety or to the environment not covered by aspects in Annex I or II of the FPR and documents demonstrating how these risks have been addressed.

1 B. PFC1.B Organo-mineral fertiliser

1 B. 1. General product description and designated PFC

The technical documentation must include a general description of the product. This description must clearly state the PFC designation, claimed function, and any other claims about the product or its function. Claims that are made about the product must be allowed within the scope of the FPR and the product's PFC. All made claims must be supported by the technical documentation.

PFC designation and claimed function

Organo-mineral fertilisers should be designated as either:

- PFC.1.B.I Solid organo-mineral fertiliser, or
- PFC.1.B.II Liquid organo-mineral fertiliser.

Claimed function

The function of organo-mineral fertilisers is to provide nutrients to plants or mushrooms.

Other claims

Any additional claims that are made on the label must be supported by examination or testing of these properties or functioning. The technical documentation should contain test reports or references to scientific literature that underpin the claims.

Where is it suggested that products possess unique characteristics, the technical documentation should contain a description of how the product differs from similar products, where applicable with calculations or schemes to underpin the difference.

For claims unrelated to the product's function, such as 'sustainable' or 'environmentally friendly' or 'allowed to be used in organic agriculture', the technical documentation should contain references and links to legislation, clearly identified guidelines, standards, or schemes with which the EU fertilising product complies to underpin the claims.

RESOURCES

Criteria for the content, substantiation and communication of **green claims** will be laid down in the Green Claims Directive (link to Commission proposal COM(2023)166 here) and in the Greenwashing Directive (EU) 2024/825 (link to consolidated version here).

Rules and definitions for **organic production and labelling** are laid down in Regulation (EU) 2018/848 on organic production, a link to the consolidated version can be found here. A lists of the materials that are authorised to be used in organic production is established in Regulation (EU) 2021/1165, a link to the consolidated version can be found here.

FAQ

See the FAQ document on the FPR to check:

- Whether '**organic fertilisers' in the meaning of the ABPR** covered by the FPR? (Q1.4)

1 B. 2. List of component materials

The technical documentation must contain a list of all the product's component materials. This list must include all materials that are present in the product, including those that are present in quantities <5% by dry weight. The list does not include the precursors of the materials that were used to produce the component materials.

For each listed component, it must be demonstrated that the component is compliant to the requirements and criteria of that CMC. Information on the technical documentation required for each CMC material is given in PART III of this guidance document.

The biological origin of the material should be evident from the component description.

Where materials that are known to have a pesticidal or other plant protection effect are used as a component material, a document should be included to explain and account for, why at the proposed use instructions, the resulting EU fertilising product complies with the conditions of the FPR and does not have a pesticide function.

RESOURCES

Rules and definitions for **plant protection products and active substances** are laid down in Regulation (EC**) No** 1107/2009 on plant protection products (PPPR). A link to the consolidated version can be found here.

The **list of approved 'active substances'** under the scope of the PPP-R can be found in Regulation (EU)No 540/2011, a link to the consolidated version can be found here.

Information and examples on **'borderline' products** can be found in the document "Borderline products' from the Belgian government website FYTOWEB (link here) and the document 'SANCO Doc 6621-99' on Scope and borderline issues 1107/2009 (link to t**he** consolidated version from DG SANTE/E4 here).

FAQ

See the FAQ document on the FPR to check:

- **What may EU fertilising products contain/consist of**? (Q8.1)
- Whether **materials with a content of <5%** in the final product must be considered in the technical documentation? (Q9.2)
- How to **demonstrate that the product consists 'solely' of CMC materials**? (Q8.2)
- Whether it is necessary **to indicate the % of each component**? (Q8.2)
- When materials are considered as a component or as a **precursor, additive or reactant**? (Q8.13)
- If substances that have a **plant protection effect** can be used as a component in EU fertilising products? (Q1.3)
- How should the manufacturer perform the conformity assessment of **component materials belonging to a CMC bought from third parties** and provide information about their origin or manufacturing? (Q10.13)
- How can manufacturers comply with the requirements in Module D1 if they **buy the component materials (compost for instance) and do not produce them themselves**? (Q10.19)

1 B. 3. Information on the manufacturing process

The technical documentation must include information on the manufacturing process for the purpose of assessing conformity.

Describe the manufacturing process of the product. Provide a summary of the steps involved in mixing and processing the materials for the manufacture of the final formulated product. Use drawings, schemes, descriptions and explanations necessary for the understanding of the manufacturing process of the EU fertilising product. Where relevant describe conditions and the chemical reactions generated during the production process and the materials and processing additives used. From the description, it should be evident which materials are used as a precursor and which materials are present as a component in the final product.

RESOURCE

Information on the obligations of manufacturers, Notified Bodies, notifying authorities, competent national authorities and member states with regards to CE marked product rules and technical documentation can be found in the Blue Guide on the implementation of EU product rules 2022. A link to the Blue Guide, document 2022/C 248/01, can be found can be found here.

Information on the **safeguarding of confidential commercial information** by the Notified Bodies, notifying authorities, competent national authorities and member states can be found in the Blue Guide §5.2.3-§7.4.1-§7.6.3.

To help ensure the **protection of confidential data or intellectual property rights**, the technical documentation provided to notified bodies has to be limited to that which is required solely for the purpose of assessing conformity to the legislation (Blue Guide §5.2.3).

FAQ

See the FAQ document on the FPR to check:

- How to perform the conformity assessment if parts of the production process are **subcontracted to another company** (Q10.5)
- When materials are considered as a component or as a **precursor, additive or reactant**? (Q8.13)

1 B. 4. Specimen of the label or leaflet

A specimen of the label or the leaflet, or both, referred to in Article 6(7) of the FPR containing the information required in accordance with Annex III of the FPR should be included in the technical documentation. More information on the labelling can be found in the Guidance on the labelling of EU fertilising products. That guidance also contains clear examples of product labels for each PFC.

1 B. 5. Examinations to demonstrate compliance

To demonstrate compliance with the product requirements, the manufacturer must subject the product to tests, trials, analyses or any other examination or calculation. All examinations for verifying the conformity of products must be performed in a reliable and reproducible manner. This may be done by the manufacturer themself or by an external party. The results of these tests should be recorded in one or several test report(s) in the technical documentation.

However, where compliance with a given requirement (such as the absence of a given contaminant) follows certainly and uncontestably from the nature or manufacturing process of an EU fertilising product, that compliance can be presumed in the conformity assessment procedure without verification

(such as testing), at the responsibility of the manufacturer (ANNEX I PART II. 4, FPR). In that case, a statement from the manufacturer in which the compliance is explained and motivated should be added to the technical documentation.

For the organo-mineral fertilisers, the following requirements are set in the FPR.

Related provision	Regulation extract	
PFC 1B specific requirements		
Annex I PFC 1 (B).1	Contains one or more inorganic fertilisers as specified in PFC 1(C)	List of components with descriptions that support the inorganic fertiliser origin
Annex I PFC 1 (B) 1	Contains one or more materials with organic carbon and nutrients of biological origin	List of components description that supports the biological origin of the nutrients present
Annex I PFC 1 (B)(I) 1	Physical form is solid or liquid	Self-evident
Annex I PFC 1 (B)(I) 2	Minimum content of N, P and/or K	Test report
Annex I PFC 1 (B) 3 and 4	Product may not exceed content limits for Cd, Cr VI, Hg, Ni, Pb, inorganic As, biuret ($C_2H_5N_3O_2$), Cu, Zn.	Test report
Annex I PFC 1 (B) 5	Pathogens in the product may not exceed pathogen limits (*Salmonella spp.*, *Escherichia coli* or *Enterococcaceae*)	Test report
Annex I PFC 1 (B) 1	Contains minimum content of organic carbon	Test report
General PFC requirements		
Annex III I.1.8	Additional claims by manufacturer:	Measurement of verifiable factors to support additional claims on product
Annex IV MODULE A/B+C/D1 2.2	If the total chromium content in the product exceeds 200 mg kg^{-1} dry matter	Information specifying the exact source and maximum quantity of total chromium (Cr)

Organo-mineral fertilisers must contain a minimum content of the primary nutrients N, P_2O_5 and/or K_2O, and a minimum content of organic carbon. Each physical unit must contain organic carbon (C_{org}) and all nutrients in their declared content. A physical unit refers to one of the component pieces of a product, such as granules or pellets. Compliance can be demonstrated with lab reports on the analyses of the product's contents of declared nutrients and C organic.

The technical documentation should include an adequate analysis and assessment of the risk(s) of the product. For a PFC 1(B) product the applicable risks concern contents of heavy metals and the presence of pathogens. Compliance can be demonstrated with a lab report on the analysis of the product's contents of heavy metals. If the contents are reported on 'fresh' product basis, the dry matter content or moisture content must also be analysed and calculations to express contents on dry matter bases must be included in the technical documentation. Pathogens must not exceed the set limits. Demonstrate compliance by including pathogen analysis reports. Note that at least five samples must be tested.

If the total chromium content exceeds 200 mg kg^{-1} dry matter, a document giving the maximum content and exact source of chromium must be included.

In addition to the risks covered by the set requirements, there might be aspects not covered by listed requirements on heavy metals and arsenic. Where such risks for a specific product or component are commonly known by diligent manufacturers operating in that field, the technical documentation should identify them and document how they have been addressed.

RESOURCES

More information of the Notified Bodies on
- accreditation of testing laboratories,
- the validity of test reports in time,
- the core criteria for laboratories and subcontracting of laboratories,
- acceptance of test reports using internal testing methods, national methods, CEN/ISO standards, or peer-reviewed studies
- ring test participation of laboratories

can be found in the document **Criteria for accepting test reports** of the Coordination Group of NoBos, available in the library on the CIRCABC page of the Commission expert group on fertilising products.

FAQ

See the FAQ document on the FPR to check:
- How to prove compliance with the requirement for **bioavailable nickel, inorganic arsenic or hexavalent chromium** (Q7.14)
- Do the limit values **for pathogens in precipitated phosphate salts** (CMC 12) apply at the level of the component material or of the product **(**Q8.34)
- Does the **Persistent Organic Pollutants Regulation** apply to EU fertilising products? (Q1.7)
- What is expected by '**adequate analysis and assessment of the risk(s)** to be included in the technical documentation'? (Q10.11)
- Is **accreditation of the laboratory** used mandatory or advisable, and is **there a list of approved laboratories** to check the conformity with various requirements, such as contaminant content? (Q 10.4)
- How to do conformity assessment when **harmonised standards** are not adopted, and whether it is mandatory to use the harmonised standards (Q10.3)

1 B. 6. Test Reports

The results of the calculations and examinations to demonstrate compliance with the requirements must be supported by the reports of the analyses, trials, or reviews carried out on the product and its components. All test or trial reports and review papers should be included in the technical documentation.

1 B. 7. List of standards or specifications

The technical documentation must include a list of standards and specifications which have been used to demonstrate compliance of the product and its components to the requirements of the PFC (Annex I part 2 of the FPR) and the CMCs (Annex II part 2 of the FPR). In the event of partly applied harmonised standards or common specifications, clearly state which part was used.

Besides harmonised standards, the references of which have been published in the Official Journal of the EU, other relevant specifications or standards can be applied. In that case, the manufacturer must show that the testing methods in these standards are reliable and reproducible.

RESOURCE

More information of the Notified Bodies on acceptance of test reports using internal testing methods, national methods, CEN/ISO standards, or peer-reviewed studies can be found in the document **Criteria for accepting test reports** of the Coordination Group of NoBos, available in the library on the CIRCABC page of the Commission expert group on fertilising products.

FAQ

See the FAQ document on the FPR to check:

- Whether it is mandatory to use the **harmonised standards** (Q10.3)
- Is there a **list of approved laboratories** to check the conformity with various requirements, such as contaminant content? (Q 10.4)
- How to do conformity assessment when **harmonised standards** are not adopted (Q10.3)

1 B. 8. List of suggested documents

It is suggested to include at least the following documents in the technical documentation:

a. A general description of the product including the PFC designation, claimed function, and intended use.
b. A list of component materials, their CMC designation, and the documentation demonstrating compliance of the components with their CMC (see part III for details).
c. Drawings, schemes, descriptions, and/or explanations required for understanding the manufacturing process of the EU fertilising product.
d. A specimen of the product's label, leaflet, or both.
e. A list of standards used in the conformity assessment procedure which also indicates for which requirement each standard was used.
f. Reports on the product's contents of chromium, cadmium, hexavalent chromium, mercury, nickel, lead, copper, zinc, chloride, arsenic, organic carbon, nutrients, pathogens, and biuret.
g. Results of calculations and examinations.
h. Documents in support of any additional claims.
i. Identified risks of the product to human, animal or plant health, to safety or to the environment not covered by aspects in Annex I or II of the FPR and documents demonstrating how these risks have been addressed.

1 C.I. PFC 1.C.I Inorganic macronutrient fertiliser

1 C.I 1. General product description and designated PFC

The technical documentation must include a general description of the product. This description must clearly state the PFC designation, claimed function, and any other claims about the product or its function. Claims that are made about the product must be allowed within the scope of the FPR and the product's PFC. All made claims must be supported by the technical documentation.

PFC designation and claimed function

Inorganic macronutrient fertilisers should be designated as one of the following subcategories:

- PFC.1.C.I.a.i. Straight solid inorganic macronutrient fertiliser,
- PFC.1.C.I.a.i.A. Straight solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content,
- PFC.1.C.I.a.ii. Compound solid inorganic macronutrient fertiliser
- PFC.1.C.I.a.ii.A Compound solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content,
- PFC.1.C.I.b.i. Straight liquid inorganic macronutrient fertiliser,
- PFC.1.C.I.b.ii. Compound liquid inorganic macronutrient fertiliser,

Claimed function

The function of inorganic fertilisers is to provide nutrients to plants or mushrooms.

Other claims

Any additional claims that are made on the label must be supported by examination or testing of these properties or functioning. The technical documentation should contain test reports or references to scientific literature that underpin the claims.

Where is it suggested that products possess unique characteristics, the technical documentation should contain a description of how the product differs from similar products, where applicable with calculations or schemes to underpin the difference.

For claims unrelated to the product's function, such as ‘sustainable’ or ‘environmentally friendly’ or ‘allowed to be used in organic agriculture’, the technical documentation should contain references and links to legislation, clearly identified guidelines, standards, or schemes with which the EU fertilising product complies to underpin the claims.

For inorganic macronutrient fertilisers that are labelled as a mineral fertiliser, the technical documentation should demonstrate that the product meets the corresponding requirements of Annex III Part II point 4 of PFC 1.

RESOURCES

Criteria for the content, substantiation and communication of **green claims** will be laid down in the Green Claims Directive (link to Commission proposal here)COM(2023)166 and in the Greenwashing Directive (EU) 2024/825 (link to consolidated version here).

Rules and definitions for **organic production and labelling** are laid down in Regulation (EU) 2018/848 on organic production, a link to the consolidated version can be found here. A list of the materials that are authorised be used in organic production is established in Regulation (EU) 2021/1165, a link to the consolidated version can be found here.

FAQ

See the FAQ document on the FPR to check:

- What is the **maximum content of organic carbon** (C_{org}) that fertiliser may contain? (Q7.4)
- How to **classify products with inhibitors**? (Q7.13)

1 C.I 2. List of component materials

The technical documentation must contain a list of all the product's component materials. This list must include all materials that are present in the product, including those that are present in quantities <5% by dry weight. The list does not include the precursors of the materials that were used to produce the component materials.

For each listed component, it must be demonstrated that the component is compliant with the requirements and criteria of that CMC. Information on the technical documentation required for each CMC material is given in PART III of this guidance document.

Where materials that are known to have a pesticidal or other plant protection effect, such as for instance copper or calcium cyanamide, are used as a component material, a document should be included to explain and account for, why at the proposed use instructions, the resulting EU fertilising product complies with the conditions of the FPR and does not have a pesticide function.

RESOURCES

Rules and definitions for **plant protection products and active substances** are laid down in Regulation (EC) No 1107/2009 on plant protection products (PPPR). A link to the consolidated version can be found here.

The **list of approved 'active substances'** under the scope of the PPP-R can be found in Regulation (EU) No 540/2011, a link to the consolidated version can be found here.

Information and examples on **'borderline' products** can be found in the document "Borderline products' from the Belgian government website FYTOWEB (link here) and the document 'SANCO Doc 6621-99' on Scope and borderline issues 1107/2009 (link to **the** consolidated version from DG SANTE/E4 here).

FAQ

See the FAQ document on the FPR to check:

- What may **EU fertilising products contain/consist of**? (Q8.1)
- Whether **materials with a content of <5%** in the final product must be considered in the technical documentation? (Q9.2)
- How to demonstrate that the product **consists 'solely' of CMC materials**? (Q8.2)
- Whether it is necessary **to indicate the % of each component**? (Q8.2)

- When materials are considered as a component or as a **precursor, additive or reactant**? (Q8.13)
- If substances that have a **plant protection effect** can be used as a component in EU fertilising products? (Q1.3)
- How should the manufacturer perform the conformity assessment of component **materials belonging to a CMC bought from third parties** and provide information about their origin or manufacturing? (Q10.13)

1 C.I 3. Information on the manufacturing process

The technical documentation must include information on the manufacturing process for the purpose of assessing conformity.

Describe the manufacturing process of the product. Provide a summary of the steps involved in mixing and processing the materials for the manufacture of the final formulated product. Use drawings, schemes, descriptions and explanations necessary for the understanding of the manufacturing process of the EU fertilising product. Where relevant describe conditions and the chemical reactions generated during the production process and the materials and processing additives used. From the description, it should be evident which materials are used as a precursor and which materials are present as a component in the final product.

RESOURCE

Information on the obligations of manufacturers, Notified Bodies, notifying authorities, competent national authorities and member states with regards to CE marked product rules and technical documentation can be found in the Blue Guide on the implementation of EU product rules 2022. A link to the Blue Guide, document 2022/C 248/01, can be found can be found here.

Information on the **safeguarding of confidential commercial information** by the Notified Bodies, notifying authorities, competent national authorities and member states can be found in the Blue Guide §5.2.3-§7.4.1-§7.6.3.

To help ensure the **protection of confidential data or intellectual property rights**, the technical documentation provided to notified bodies has to be limited to that which is required solely for the purpose of assessing conformity to the legislation (Blue Guide §5.2.3).

FAQ

See the FAQ document on the FPR to check:

- How to perform the conformity assessment if parts of the production process are **subcontracted to another company** (Q10.5)
- When materials are considered as a component or as a **precursor, additive or reactant**? (Q8.13)

1 C.I 4. Specimen of the label or leaflet

A specimen of the label or the leaflet, or both, referred to in Article 6(7) of the FPR containing the information required in accordance with Annex III of the FPR should be included in the technical documentation. More information on the labelling can be found in the Guidance on the labelling of EU fertilising products. That guidance also contains clear examples of product labels for each PFC.

1 C.I 5. Examinations to demonstrate compliance

To demonstrate compliance with the product requirements, the manufacturer must subject the product to tests, trials, analyses or any other examination or calculation**.** All examinations for verifying the conformity of products must be performed in a reliable and reproducible manner. This may be done by the manufacturer themself or by an external party. The results of these tests should be recorded in one or several test report(s) in the technical documentation.

However, where compliance with a given requirement (such as the absence of a given contaminant) follows certainly and uncontestably from the nature or manufacturing process of an EU fertilising product, that compliance can be presumed in the conformity assessment procedure without verification (such as testing), at the responsibility of the manufacturer (ANNEX I PART II. 4, FPR). In that case, a statement from the manufacturer in which the compliance is explained and motivated should be added to the technical documentation.

For the inorganic macronutrient fertilisers, the following requirements are set in the FPR:

Related provision	Regulation extract	suggested content
PFC 1C specific requirements		
Annex I PFC (C) 1	An inorganic fertiliser is a fertiliser which is not an organic- or organo-mineral fertiliser.	A product description
Annex I PFC (C) 2	The product may not exceed thresholds for pathogens if it contains organic carbon content >1% by mass.	Either a description of the origin of the organic carbon to show it does not need to pass the pathogen criteria or an analysis report to prove that it passes the criteria for pathogens.
Annex III Part II PFC1 4	Products that are labelled as mineral fertilisers must meet criteria for contents of C_{org} and declared P and N.	Test report
PFC 1C I specific requirements		
Annex I PFC (C)(I) 1	Must contain N, P, K, Ca, Mg, Na, and or S	A product description
Annex I PFC (C)(I) 2 & 3	Product may not exceed content limits for Cd, Cr VI, Hg, Ni, Pb, As, biuret ($C_2H_5N_3O_2$), perchlorate (ClO_2), Cu, and Zn.	Test report
PFC 1C I a specific requirements		
Annex I PFC 1(C)(I)(a)	The product is solid	Self-evident
PFC 1C I a i specific requirements		
Annex I PFC 1(C)(I)(a)(i) 1& 2	The product contains at least minimum contents of only one declared macronutrient N, P, K, Ca, Mg, Na, or S **OR** only one of declared primary nutrients N, P, K plus one or more declared secondary nutrients Ca, Mg, Na, or S. The sum of declared nutrients must have a certain value.	Test report
PFC 1C I a ii specific requirements		
Annex I PFC 1(C)(I)(a)(ii) 1 & 2	The product contains at least minimum contents of at least two declared primary	Test report

	macronutrients N, P, K **OR** at least two declared secondary macronutrients Ca, Mg, Na, and S. The sum of declared nutrients must have a certain value. Total Na content (Na_2O) must be below the threshold.	
PFC 1C I a i-ii A specific requirements		
Annex I PFC 1(C)(I)(a)(i-ii)(A) 1	Must contain >= 28% by mass of ammonium nitrate (NH_4NO_3)	Test report
Annex I PFC 1(C)(I)(a)(i-ii)(A) 2	No compounds in the product react with ammonium nitrate	A product description
Annex I PFC 1(C)(I)(a)(i-ii)(A) 3	The product is only made available in packaged form. The seal or opening must be visibly and irreparably damaged upon opening.	A description of the packaging
Annex I PFC 1(C)(I)(a)(i-ii)(A) 4	The product must pass the oil retention test	Oil retention test executed under the supervision of a NoBo
Annex I PFC 1(C)(I)(a)(i-ii)(A) 5	The product must pass the detonation resistance test	Detonation test under the supervision of a NoBo
Annex I PFC 1(C)(I)(a)(i-ii)(A) 6	The combustible material content does not exceed the limits	Test report
Annex I PFC 1(C)(I)(a)(i-ii)(A) 7	A solution of 10 g of a straight or compound solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content in 100 ml of water must have a pH of at least 4,5.	Test report
Annex I PFC 1(C)(I)(a)(i-ii)(A) 8	The product may not contain more than a given fraction of fine particles	Sieve analysis report
Annex I PFC 1(C)(I)(a)(i-ii)(A) 9	The product does not exceed limits for Cu and Cl content.	Test report
PFC 1C I b specific requirements		
Annex I PFC 1(C)(I)(b)	A liquid fertiliser must be liquid	Self-evident
PFC 1C I b i specific requirements		
Annex I PFC 1(C)(I)(b)(i) 1 + 2	The product contains at least minimum contents of only one declared macronutrient N, P, K, Ca, Mg, Na, or S **OR** only one of declared primary nutrient N, P, K plus one or more declared secondary nutrients Ca, Mg, Na, or S. Sum of declared nutrients must have certain value. Sodium content may not exceed a threshold.	Test report
PFC 1C I b ii specific requirements		
Annex I PFC 1(C)(I)(b)(ii) 1	The product contains at least minimum contents of at least two declared primary macronutrients N, P, K **OR** at least two declared secondary macronutrients Ca, Mg, Na, and S. The sum of declared nutrients must have a certain value. Total Na content (Na_2O) must be below the threshold.	Test report

General PFC requirements		
Annex III I.1.8	Additional claims by manufacturer:	Measurement of verifiable factors to support additional claims on product
Annex IV MODULE A/B+C/D1 2.2	If the total chromium content in the product exceeds 200 mg kg^{-1} /kg dry matter	Information specifying the source and exact quantity of total chromium (Cr)

Inorganic macronutrient fertilisers must have a certain nutrient content which differs depending on whether it is a straight or compound fertiliser and whether it is in solid or liquid form. Ammonium nitrate fertiliser of high nitrogen content must always have at least 28% by mass of nitrogen from ammonium nitrate. Compliance can be demonstrated with laboratory testing reports on the analyses of the product's contents of declared nutrients and the sodium oxide content.

The technical documentation should include an adequate analysis and assessment of the risk(s) of the product. A PFC 1C I inorganic macronutrient fertiliser must not exceed threshold limits for heavy metals, perchlorate (ClO_4^-), and biuret ($C_2H_5N_3O_2$). Compliance can be demonstrated with test reports on the analyses of the product's contents of contaminants. If the contents are reported on 'fresh' product basis, the dry matter content or moisture content must also be analysed and calculations to express contents on dry matter bases must be included in the technical documentation. For PFC 1(C)(I)(a)(i-ii)(A), the product checks for oil retention and detonation resistance, following the specifications in Annex IV, part II to the FPR, under Module A1 point 4 must be demonstrated by a test report.

Inorganic fertiliser products that contain more than 1% by mass of organic carbon (except C_{org} from methylene urea, isobutylidene urea and crotonylidene urea) must not exceed the pathogen limits. Compliance can be demonstrated by including pathogen analysis reports. Note that at least five samples must be tested.

If the total chromium content exceeds 200 mg kg^{-1} dry matter, a document giving the maximum content and exact source of chromium must be included.

In addition to the risks covered by the set requirements, there might be aspects not covered by listed requirements on heavy metals and other contaminants. Where such risks for a specific product or component are commonly known by diligent manufacturers operating in that field, the technical documentation should identify them and document how they have been addressed.

RESOURCES

More information of the Notified Bodies on
- accreditation of testing laboratories,
- the validity of test reports in time,
- the core criteria for laboratories and subcontracting of laboratories,
- acceptance of test reports using internal testing methods, national methods, CEN/ISO standards, or peer-reviewed studies
- ring test participation of laboratories

can be found in the document **Criteria for accepting test reports** of the Coordination Group of NoBos, available in the library on the CIRCABC page of the Commission expert group on fertilising products.

FAQ

See the FAQ document on the FPR to check:
- How to prove compliance with the requirement for **hexavalent chromium** (Q7.14)
- What is the **maximum content of organic carbon** (C_{org}) that a fertiliser may contain? (Q7.4)
- Does organic carbon from **methylene urea, isobutylidene urea and crotonylidene urea** count when determining if an inorganic fertiliser has less than 1 % organic carbon? (Q7.5)

- May manufacturers place on the market organo-mineral or inorganic phosphate fertilisers that do not comply with the **solubility requirements of mineral fertilisers**? (Q7.11)
- Do the limit values for **pathogens in precipitated phosphate salts** (CMC 12) apply at the level of the component material or of the product (Q8.34)
- Does the **Persistent Organic Pollutants (POP) Regulation** apply to EU fertilising products? (Q1.7)
- What is expected by '**adequate analysis and assessment of the risk(s)** to be included in the technical documentation'? (Q10.11)
- Is there **a list of approved laboratories** to check the conformity with various requirements, such as contaminant content? (Q 10.4)
- Is **accreditation of the laboratory** used mandatory or advisable? (Q10.4)
- Whether it is mandatory to use the **harmonised standards** (Q10.3)
- How to do conformity assessment when **harmonised standards** are not adopted (Q10.3)

1 C.I 6. Tests reports

The results of the calculations and examinations to demonstrate compliance with the requirements must be supported by the reports of the analyses, trials, or reviews carried out on the product and its components. All test reports and review papers should be included in the technical documentation.

1 C.I 7. List of standards or specifications

The technical documentation must include a list of standards and specifications which have been used to demonstrate compliance of the product and its components to the requirements of the PFC (Annex I part 2 of the FPR) and the CMCs (Annex II part 2 of the FPR). In the event of partly applied harmonised standards or common specifications, clearly state which part was used.

A list of standards and specifications which may be used for each requirement can be found in PART IV of the guidance.

Besides harmonised standards, the references of which have been published in the Official Journal of the EU, other relevant specifications or standards can be applied. In that case, the manufacturer must show that the testing methods in these standards are reliable and reproducible.

RESOURCE

More information of the Notified Bodies on acceptance of test reports using internal testing methods, national methods, CEN/ISO standards, or peer-reviewed studies can be found in the document **Criteria for accepting test reports** of the Coordination Group of NoBos, available in the library on the CIRCABC page of the Commission expert group on fertilising products.

FAQ

See the FAQ document on the FPR to check:

- Whether it is mandatory to use the **harmonised standards** (Q10.3)
- Is there a **list of approved laboratories** to check the conformity with various requirements, such as contaminant content? (Q 10.4)
- How to do conformity assessment when **harmonised standards** are not adopted (Q10.3)

1 C.I 8. List of suggested documents

It is suggested to include at least the following documents in the technical documentation (for ammonium nitrate fertilisers of high N content, more documents are required):

a. A general description of the product including the PFC designation, claimed function, and intended use.
b. A list of component materials, their CMC designation, and the documentation demonstrating compliance of the components with their CMC (see part III for details).
c. Drawings, schemes, descriptions, and/or explanations required for understanding the manufacturing process of the EU fertilising product.
d. A specimen of the product's label, leaflet, or both.
e. A list of standards used in the conformity assessment procedure which also indicates for which requirement each standard was used.
f. Reports on the product's contents of chromium, cadmium, hexavalent chromium, mercury, nickel, lead, copper, zinc, chloride, arsenic, organic carbon, nutrients, pathogens (when containing > 1% C_{org} by mass from non-excluded C_{org} sources), perchlorate, sodium oxide, and biuret.
g. Results of calculations and examinations.
h. Documents in support of any additional claims.
i. Identified risks of the product to human, animal or plant health, to safety or to the environment not covered by aspects in Annex I or II of the FPR and documents demonstrating how these risks have been addressed.

1 C.II. PFC 1.C.II Inorganic micronutrient fertiliser

1 C.II 1. General product description and designated PFC

The technical documentation must include a general description of the product. This description must clearly state the PFC designation, claimed function, and any other claims about the product or its function. Claims that are made about the product must be allowed within the scope of the FPR and the product's PFC. All made claims must be supported by the technical documentation.

PFC designation and claimed function

Inorganic micronutrient fertilisers must be designated as one of the following subcategories:

- PFC.1.C.II.a Straight inorganic micronutrient fertiliser, or
- PFC.1.C.II.b Compound inorganic micronutrient fertiliser.

Function claim

The function of inorganic micronutrient fertilisers is to provide nutrients to plants or mushrooms.

Other claims

Any additional claims that are made on the label must be supported by examination or testing of these properties or functioning. The technical documentation should contain test reports or references to scientific literature that underpin the claims.

Where is it suggested that products possess unique characteristics, the technical documentation should contain a description of how the product differs from similar products, where applicable with calculations or schemes to underpin the difference.

For claims unrelated to the product's function, such as 'sustainable' or 'environmentally friendly' or 'allowed to be used in organic agriculture', the technical documentation should contain references and links to legislation, clearly identified guidelines, standards, or schemes with which the EU fertilising product complies to underpin the claims.

RESOURCES

Criteria for the content, substantiation and communication of **green claims** will be laid down in the Green Claims Directive (link to Commission proposal COM(2023)166 here) and the Greenwashing Directive (EU) 2024/825 (link to consolidated version here).

Rules and definitions for **organic production and labelling** are laid down in Regulation (EU) 2018/848 on organic production, a link to the consolidated version can be found here. A list of the materials that are authorised be used in organic production is established in Regulation (EU) 2021/1165, a link to the consolidated version can be found here.

1 C.II 2. List of component materials

The technical documentation must contain a list of all the product's component materials. This list must include all materials that are present in the product, including those that are present in quantities <5% by dry weight. The list does not include the precursors of the materials that were used to produce the component materials.

For each listed component, it must be demonstrated that the component is compliant with the requirements and criteria of that CMC. Information on the technical documentation required for each CMC material is given in PART III of this guidance document.

Where materials that are known to have a pesticidal or other plant protection effect are used as a component material, a document should be included to explain and account for, why at the proposed use instructions, the resulting EU fertilising product complies with the conditions of the FPR and does not have a pesticide function.

RESOURCES

Rules and definitions for **plant protection products and active substances** are laid down in Regulation (EC**) No**1107/2009 on plant protection products (PPPR). A link to the consolidated version can be found here.

The **list of approved 'active substances'** under the scope of the PPP-R can be found in Regulation (EU) No 540/2011, a link to the consolidated version can be found here.

Information and examples on **'borderline' products** can be found in the document "Borderline products' from Belgian government website FYTOWEB (link here) and the document 'SANCO Doc 6621-99' on Scope and borderline issues 1107/2009 (link to the consolidated version from DG SANTE/E4 here).

FAQ

See the FAQ document on the FPR to check:

- **What may EU fertilising products contain/consist** of? (Q8.1)
- Whether materials with **a content of <5%** in the final product must be considered in the technical documentation? (Q9.2)
- How to demonstrate that the product **consists 'solely' of CMC materials**? (Q8.2)
- Whether it is necessary **to indicate the % of each**b? (Q8.2)
- When materials are considered as a component or as a **precursor, additive or reactant**? (Q8.13)
- If substances that have a **plant protection effect** can be used as a component in EU fertilising products? (Q1.3)
- How should the manufacturer perform the conformity assessment of component **materials belonging to a CMC bought from third parties** and provide information about their origin or manufacturing? (Q10.13)

1 C.II 3. Information on the manufacturing process

The technical documentation must include information on the manufacturing process for the purpose of assessing conformity.

Describe the manufacturing process of the product. Provide a summary of the steps involved in mixing and processing the materials for the manufacture of the final formulated product. Use drawings, schemes, descriptions and explanations necessary for the understanding of the manufacturing process of the EU fertilising product. Where relevant describe conditions and the chemical reactions generated during the production process and the materials and processing additives used. From the description,

it should be evident which materials are used as a precursor and which materials are present as a component in the final product.

RESOURCE

Information on the obligations of manufacturers, Notified Bodies, notifying authorities, competent national authorities and member states with regards to CE marked product rules and technical documentation can be found in the Blue Guide on the implementation of EU product rules 2022. A link to the Blue Guide, document 2022/C 248/01, can be found can be found here.

Information on the **safeguarding of confidential commercial information** by the Notified Bodies, notifying authorities, competent national authorities and member states can be found in the Blue Guide §5.2.3-§7.4.1-§7.6.3.

To help ensure the **protection of confidential data or intellectual property rights**, the technical documentation provided to notified bodies has to be limited to that which is required solely for the purpose of assessing conformity to the legislation (Blue Guide §5.2.3).

FAQ

See the FAQ document on the FPR to check:

- How to perform the conformity assessment if parts of the production process are **subcontracted to another company** (Q10.5)
- When materials are considered as a component or as a **precursor, additive or reactant**? (Q8.10)

1 C.II 4. Specimen of the label or leaflet

A specimen of the label or the leaflet, or both, referred to in Article 6(7) of the FPR containing the information required in accordance with Annex III of the FPR should be included in the technical documentation.

More information on the labelling can be found in the Guidance on the labelling of EU fertilising products. That guidance also contains clear examples of product labels for each PFC.

1 C.II 5. Examinations to demonstrate compliance

To demonstrate compliance with the product's requirements, the manufacturer must subject the product to tests, trials, analyses or any other examination or calculation**.** All examinations for verifying the conformity of products must be performed in a reliable and reproducible manner. This may be done by the manufacturer themself or by an external party. The results of these tests should be recorded in one or several test report(s) in the technical documentation.

However, where compliance with a given requirement (such as the absence of a given contaminant) follows certainly and uncontestably from the nature or manufacturing process of an EU fertilising product, that compliance can be presumed in the conformity assessment procedure without verification (such as testing), at the responsibility of the manufacturer (ANNEX I PART II. 4, FPR). In that case, a statement from the manufacturer in which the compliance is explained and motivated should be added to the technical documentation.

For the inorganic micronutrient fertilisers, the following requirements are set in the FPR:

Related provision	Regulation extract	Suggested content
PFC 1C specific requirements		
Annex I PFC (C) 1	An inorganic fertiliser is a fertiliser which is not an organic- or organo-mineral fertiliser.	Product description
Annex I PFC (C) 2	The product may not exceed thresholds for pathogens if it contains a certain amount of organic C	If the organic carbon content >1% by mass. Either a description of the origin of the organic carbon to show it does not need to pass the pathogen criteria or an analysis report to prove that it passes the criteria for pathogens.
PFC 1C II specific requirements		
Annex I PFC1(C)(II) 1	Supplies B, Co, Cu, Fe, Mn, Mo, or Zn to plants or mushrooms	Test report
Annex I PFC1(C)(II) 2	The product must be packaged	Description of the packaging
Annex I PFC1(C)(II)	Product may not exceed content limits for As, Cd, Pb, Hg, Ni in proportion to the micronutrient content.	Test report
PFC 1C II.a specific requirements		
Annex I PFC 1(C)(II)(a) 1	Must only have one declared micronutrient	Test report
Annex I PFC 1(C)(II)(a) 2	The product meets the description and criteria of one typology given in the table under this provision Annex I PFC1(C)(II)(a) 2	Product description and Test report
PFC 1C II.b. specific requirements		
Annex I PFC 1(C)(II)(b) 1	Contains at least two declared micronutrients	Product label or description
Annex I PFC 1(C)(II)(b) 2	The product contains at least 2% by mass micronutrients when liquid or at least 5% when solid.	Test report
General PFC requirements		
Annex III I.1.8	Additional claims by the manufacturer.	Measurement of verifiable factors to support additional claims on product
Annex IV MODULE A/B+C/D1 2.2	If the total chromium content in the product exceeds 200 mg kg^{-1} dry matter	Information specifying the source and exact quantity of total chromium (Cr)

Compound inorganic micronutrient fertilisers (PFC 1C II b) must have more than one declared nutrient. The summed content of declared nutrients of such a fertiliser must be at least 2% by mass when in liquid form or at least 5% by mass when the product is in solid form.

Straight inorganic micronutrient fertilisers (PFC 1 C II a) must have a single declared micronutrient, belong to one of the typologies of Annex I PFC(C)(II)(a) and comply with the corresponding description and minimum micronutrient content requirements.

Compliance with the micronutrient contents can be demonstrated with laboratory testing.

A product in PFC 1 C II inorganic micronutrient fertiliser must not exceed the limit values of arsenic, cadmium, lead, mercury, and nickel, expressed in mg in proportion to the total micronutrient content expressed in kg. Compliance can be demonstrated with a lab report on the analysis of the product's contents of these heavy metals. If the contents are reported on a product basis, calculations to express contents in proportion to the total micronutrient content must be included in the technical documentation. As an example: a straight inorganic micronutrient fertiliser aimed at providing copper contains 100 g Cu kg^{-1} product. As the product contains 0.1 kg micronutrient per kg product, the limit values expressed per kg product must also be multiplied by 0.1. Thus, this product may contain 100 mg As, 20 mg Cd, 60 mg Pb, 10 mg Hg, and 200 mg Ni per kg.

Inorganic fertiliser products that contain more than 1% by mass of organic carbon (C_{org}), must not exceed the limits for pathogens. Demonstrate compliance by including pathogen analysis reports. Note that at least five samples must be tested.

If the total chromium (Cr) content exceeds 200 mg kg^{-1} dry matter, information must be provided on the maximum quantity and the exact source of chromium in the production.

In addition to the risks covered by the set requirements, there might be aspects not covered by listed requirements on heavy metals and other contaminants. Where such risks for a specific product or component are commonly known by diligent manufacturers operating in that field, the technical documentation should identify them and document how they have been addressed.

RESOURCES

More information of the Notified Bodies on
- accreditation of testing laboratories,
- the validity of test reports in time,
- the core criteria for laboratories and subcontracting of laboratories,
- acceptance of test reports using internal testing methods, national methods, CEN/ISO standards, or peer-reviewed studies
- ring test participation of laboratories

can be found in the document **Criteria for accepting test reports** of the Coordination Group of NoBos, available in the library on the CIRCABC page of the Commission expert group on fertilising products.

FAQ

See the FAQ document on the FPR to check:
- Can a **micronutrient solution fertiliser** contain just one form of a straight micronutrient inorganic fertiliser? **(**Q7.12)
- How to prove compliance with the requirement for **hexavalent chromium** (Q7.14)
- What is the **maximum content of organic carbon (Corg)** that a fertiliser may contain? (Q7.4)
- Does organic carbon from **methylene urea, isobutylidene urea, and crotonylidene urea** count when determining if an inorganic fertiliser has less than 1 % organic carbon? (Q7.5)
- Does the **Persistent Organic Pollutants** regulation apply to EU fertilising products? (Q1.7)
- What is expected by '**adequate analysis and assessment of the risk(s)** to be included in the technical documentation'? (Q10.11)
- Is there a **list of approved laboratories** to check the conformity with various requirements, such as contaminant content? (Q 10.4)
- Is **accreditation of the laboratory** used mandatory or advisable? (Q10.4)
- Whether it is mandatory to use the **harmonised standards** (Q10.3)

- How to do conformity assessment when **harmonised standards** are not adopted (Q10.3)

1 C.II 6. Test reports

The results of the calculations and examinations to demonstrate compliance with the requirements must be supported by the reports of the analyses, trials, or reviews carried out on the product and its components. All test reports and review papers should be included in the technical documentation of partly applied harmonised standards or common specifications, clearly state which part of a standard or specification was used.

1 C.II 7. List of standards or specifications

The technical documentation must include a list of standards and specifications which have been used to demonstrate compliance of the product and its components with the relevant requirements of part 2 of Annex I to the FPR and of part 2 of Annex II to the FPR. In the event of partly applied harmonised standards or common specifications, clearly state which part was used.

A list of standards and specifications which may be used for each requirement can be found in PART IV of this guidance.

Besides harmonised standards, the references of which have been published in the Official Journal of the EU, other relevant specifications or standards can be applied. In that case, the manufacturer must show that the testing methods in these standards are reliable and reproducible.

RESOURCE

More information of the Notified Bodies on acceptance of test reports using internal testing methods, national methods, CEN/ISO standards, or peer-reviewed studies can be found in the document **Criteria for accepting test reports** of the Coordination Group of NoBos, available in the library on the CIRCABC page of the Commission expert group on fertilising products.

FAQ

See the FAQ document on the FPR to check:

- Whether it is mandatory to use the **harmonised standards** (Q10.3)
- Is there a **list of approved laboratories** to check the conformity with various requirements, such as contaminant content? (Q 10.4)
- How to do conformity assessment when **harmonised standards** are not adopted (Q10.3)

1 C.II 8. List of suggested documents

It is suggested to include at least the following documents in the technical documentation:

a. A general description of the product including the PFC designation, claimed function, and intended use. For straight inorganic micronutrient fertilisers, also indicate the product's typology.
b. A list of component materials, their CMC designation, and the documentation demonstrating compliance of the components with their CMC (see part III for details).

c. Drawings, schemes, descriptions, and/or explanations required for understanding the manufacturing process of the EU fertilising product.
d. A specimen of the product's label and, if relevant, also of the leaflet.
e. A list of standards used in the conformity assessment procedure which also indicates for which requirement each standard was used.
f. Reports on the product's contents of chromium, cadmium, hexavalent chromium, mercury, nickel, lead, copper, zinc, chloride, arsenic, organic carbon, nutrients, pathogens (when containing >1% C_{org} by mass from non-excluded C_{org} sources), perchlorate, and sodium oxide.
g. Results of calculations and examinations.
h. Documents in support of any additional claims.
i. Identified risks of the product to human, animal or plant health, to safety or to the environment not covered by aspects in Annex I or II of the FPR and documents demonstrating how these risks have been addressed.

2 PFC 2 Liming material

2.1 General product description and designated PFC

The technical documentation must include a general description of the product. This description must clearly state the PFC designation, claimed function, and any other claims about the product or its function. Claims that are made about the product must be allowed within the scope of the FPR and the product's PFC. All made claims must be supported by the technical documentation.

PFC designation

Liming materials are designated as PFC 2.

Function claim

The function of liming materials is to correct soil acidity.

Other claims

Any additional claims that are made on the label must be supported by examination or testing of these properties or functioning. The technical documentation should contain test reports or references to scientific literature that underpin the claims.

Where is it suggested that products possess unique characteristics, the technical documentation should contain a description of how the product differs from similar products, where applicable with calculations or schemes to underpin the difference.

For claims unrelated to the product's function, such as 'sustainable' or 'environmentally friendly' or 'allowed to be used in organic agriculture', the technical documentation should contain references and links to legislation, clearly identified guidelines, standards, or schemes with which the EU fertilising product complies to underpin the claims.

RESOURCES

Criteria for the content, substantiation and communication of **green claims** will be laid down in the Green Claims Directive (link to Commission proposal COM(2023)166 here) and the Greenwashing Directive (EU) 2024/825 (link to consolidated version here).

Rules and definitions for **organic production and labelling** are laid down in Regulation (EU) 2018/848 on organic production, a link to the consolidated version can be found here. A list of the materials that are authorised be used in organic production is established in Regulation (EU) 2021/1165, a link to the consolidated version can be found here.

2.2 List of component materials

The technical documentation must contain a list of all the product's component materials. This list must include all materials that are present in the product, including those that are present in quantities <5% by dry weight. The list does not include the precursors of the materials that were used to produce the component materials.

For each listed component, it must be demonstrated that the component is compliant with the requirements and criteria of that CMC. Information on the technical documentation required for each CMC material is given in PART III of this guidance document.

Furthermore, a liming material must contain oxides, hydroxides, carbonate,s and/or silicates of calcium (Ca), and/or magnesium (Mg). This must also be evident from the description of the product's component(s).

FAQ

See the FAQ document on the FPR to check:

- **What may EU fertilising products contain/consist of**? (Q8.1)
- Whether materials with a **content of <5%** in the final product must be considered in the technical documentation? (Q9.2)
- How to demonstrate that the **product consists 'solely' of CMC materials**? (Q8.2)
- Whether it is necessary to **indicate the % of each component**? (Q8.2)
- When materials are considered as a component or as a **precursor, additive or reactant**? (Q8.10)
- How should the manufacturer perform the conformity assessment of component **materials belonging to a CMC bought from third parties** and provide information about their origin or manufacturing? (Q10.13)

2.3 Information on the manufacturing process

The technical documentation must include information on the manufacturing process for the purpose of assessing conformity.

Describe the manufacturing process of the product. Provide a summary of the steps involved in mixing and processing the materials for the manufacture of the final formulated product. Use drawings, schemes, descriptions and explanations necessary for the understanding of the manufacturing process of the EU fertilising product. Where relevant describe conditions and the chemical reactions generated during the production process and the materials and processing additives used. From the description, it should be evident which materials are used as a precursor and which materials are present as a component in the final product.

RESOURCE

Information on the obligations of manufacturers, Notified Bodies, notifying authorities, competent national authorities, and member states with regards to CE marked product rules and technical documentation can be found in the Blue Guide on the implementation of EU product rules 2022. A link to the Blue Guide, document 2022/C 248/01, can be found can be found here.

Information on the **safeguarding of confidential commercial information** by the Notified Bodies, notifying authorities, competent national authorities and member states can be found in the Blue Guide §5.2.3-§7.4.1-§7.6.3.

To help ensure the **protection of confidential data or intellectual property rights**, the technical documentation provided to notified bodies has to be limited to that which is required solely for the purpose of assessing conformity to the legislation (Blue Guide §5.2.3).

FAQ

See the FAQ document on the FPR to check:

- How to perform the conformity assessment if **parts of the production process are subcontracted** to another company (Q10.5)
- When materials are considered as a component or as a **precursor, additive or reactant**? (Q8.13)

2.4 Specimen of the label or leaflet

A specimen of the label or the leaflet, or both, referred to in Article 6(7) of the FPR containing the information required in accordance with Annex III of the FPR should be included in the technical documentation. More information on the labelling can be found in the Guidance on the labelling of EU fertilising products. That guidance also contains clear examples of product labels for each PFC.

2.5 Examinations to demonstrate compliance

To demonstrate compliance with the product requirements, the manufacturer must subject the product to tests, trials, analyses or any other examination or calculation. All examinations for verifying the conformity of products must be performed in a reliable and reproducible manner. This may be done by the manufacturer or by an external party. The results of these tests should be recorded in one or several test report(s) in the technical documentation.

However, where compliance with a given requirement (such as the absence of a given contaminant) follows certainly and uncontestably from the nature or manufacturing process of an EU fertilising product, that compliance can be presumed in the conformity assessment procedure without verification (such as testing), at the responsibility of the manufacturer (ANNEX I PART II. 4, FPR). In that case, a statement from the manufacturer in which the compliance is explained and motivated should be added to the technical documentation.

Related provision	Provision summary	suggested content
PFC 2 specific requirements		
Annex I PFC2 4 a	Liming materials must have a minimum neutralising value	Test report
Annex I PFC2 4 b	Liming materials must have a minimum reactivity	Test report
Annex I PFC2 4 c	Liming materials must have a minimum grain size	Sieve analyses report
Annex III PFC2	Total CaO and MgO, have to be declared on the label expressed as % by mass	Test report
Annex I PFC2 2&3	Product may not exceed content limits for Cd, Cr VI, Hg, Ni, Pb, As, Cu, Zn	Test report
Additional PFC requirements		

Annex III I.1.8	Additional claims by the manufacturer	Measurement of verifiable factors to support additional claims on product
Annex III I.1.9	Claim low in chloride	Test report
Annex IV MODULE A/B+C/D1 2.2 k	Information specifying the source and exact quantity of total chromium (Cr)	Only if the total chromium content in the product exceeds 200 mg kg^{-1} dry matter

There are three criteria related to the agronomic efficiency of liming products, one for the neutralising value, one for the product's reactivity, and one for the grain size. Compliance with each criterion can be demonstrated with a test report of the appropriate analysis.

The contents of CaO and MgO in the product should be measured as these should be declared on the product label.

The technical documentation should include an adequate analysis and assessment of the risk(s) of the product. For a PFC 2 product the applicable risks concern contents of heavy metals. Compliance can be demonstrated with a lab report on the analysis of the product's contents of heavy metals. If the contents are reported on 'fresh' product basis, the dry matter content or moisture content must also be analysed and calculations to express contents on dry matter bases must be included in the technical documentation.

If the total chromium content exceeds 200 mg kg^{-1} dry matter, a document giving the maximum content and exact source of chromium must be included.

The phrase 'poor in chloride' or similar may only be used if the chloride (Cl-) content is below 30 g kg^{-1} dry matter.

In addition to the risks covered by the set requirements, there might be aspects not covered by listed requirements on heavy metals. Where such risks for a specific product or component are commonly known by diligent manufacturers operating in that field, the technical documentation should identify them and document how they have been addressed.

RESOURCES

More information of the Notified Bodies on
- accreditation of testing laboratories,
- the validity of test reports in time,
- the core criteria for laboratories and subcontracting of laboratories,
- acceptance of test reports using internal testing methods, national methods, CEN/ISO standards, or peer-reviewed studies
- ring test participation of laboratories

can be found in the document **Criteria for accepting test reports** of the Coordination Group of NoBos, available in the library on the CIRCABC page of the Commission expert group on fertilising products.

FAQ

See the FAQ document on the FPR to check:
- How to prove compliance with the requirement for **hexavalent chromium** (Q7.14)
- Does the **Persistent Organic Pollutants** Regulation apply to EU fertilising products? (Q1.7)
- What is expected by '**adequate analysis and assessment of the risk(s)** to be included in the technical documentation'? (Q10.11)
- Is there a **list of approved laboratories** to check the conformity with various requirements, such as contaminant content? (Q 10.4)
- Is **accreditation of the laboratory** used mandatory or advisable? (Q10.4)

- Whether it is mandatory to use the **harmonised standards** (Q10.3)
- How to do conformity assessment when **harmonised standards** are not adopted (Q10.3)

2.6 Test reports

The results of the calculations and examinations to demonstrate compliance with the requirements must be supported by the reports of the analyses, trials, or reviews carried out on the product and its components. All test reports and review papers should be included in the technical documentation of partly applied harmonised standards or common specifications, clearly state which part of a standard or specification was used.

2.7 List of standards or specifications

The technical documentation must include a list of standards and specifications which have been used to demonstrate compliance of the product and its components with the relevant requirements of part 2 of Annex I to the FPR and of part 2 of Annex II to the FPR. In the event of partly applied harmonised standards or common specifications, clearly state which part was used.

A list of standards and specifications which may be used for each requirement can be found in PART IV of this guidance.

Besides harmonised standards, the references of which have been published in the Official Journal of the EU, other relevant specifications or standards can be applied. In that case, the manufacturer must show that the testing methods in these standards are reliable and reproducible.

RESOURCE

More information of the Notified Bodies on acceptance of test reports using internal testing methods, national methods, CEN/ISO standards, or peer-reviewed studies can be found in the document **Criteria for accepting test reports** of the Coordination Group of NoBos, available in the library on the CIRCABC page of the Commission expert group on fertilising products.

FAQ

See the FAQ document on the FPR to check:

- Whether it is mandatory to use the **harmonised standards** (Q10.3)
- Is there a **list of approved laboratories** to check the conformity with various requirements, such as contaminant content? (Q 10.4)
- How to do conformity assessment when **harmonised standards** are not adopted (Q10.3)

2.8 List of suggested documents

It is suggested to include at least the following documents in the technical documentation:

a. A general description of the product including the PFC designation, claimed function, and intended use.
b. A list of component materials, their CMC designation, and the documentation demonstrating compliance of the components with their CMC (see part III for details).
c. Drawings, schemes, descriptions, and/or explanations required for understanding the manufacturing process of the EU fertilising product.

d. A specimen of the product's label, leaflet, or both.
e. A list of standards used in the conformity assessment procedure which also indicates for which requirement each standard was used.
f. Reports on the product's contents of cadmium, hexavalent chromium, mercury, nickel, lead, copper, zinc, arsenic, magnesium oxide, and calcium oxide.
g. Report on the grain size of the product.
h. Report on the product's neutralising value.
i. Report on the product's reactivity.
j. Results of calculations and examinations.
k. Documents in support of any additional claims
l. Identified risks of the product to human, animal or plant health, to safety or to the environment not covered by aspects in Annex I or II of the FPR and documents demonstrating how these risks have been addressed.

3 PFC 3 Soil improver

3.1 General product description and designated PFC

The technical documentation must include a general description of the product. This description must clearly state the PFC designation, claimed function, and any other claims about the product or its function. Claims that are made about the product must be allowed within the scope of the FPR and the product's PFC. All made claims must be supported by the technical documentation.

PFC designation and claimed function

A soil improver must be designated as one of the following subcategories:

- PFC.3.A Organic soil improver, or
- PFC.3.B Inorganic soil improver.

Claimed function

The function of a soil improver is to maintain, improve, or protect the physical or chemical properties, the structure or the biological activity of the soil to which it is added. The product description should describe which of the soil properties are targeted by the product.

Other claims

Any additional claims that are made on the label must be supported by examination or testing of these properties or functioning. The technical documentation should contain test reports or references to scientific literature that underpin the claims.

Where is it suggested that products possess unique characteristics, the technical documentation should contain a description of how the product differs from similar products, where applicable with calculations or schemes to underpin the difference.

For claims unrelated to the product's function, such as ‘sustainable’ or ‘environmentally friendly’ or ‘allowed to be used in organic agriculture’, the technical documentation should contain references and links to legislation, clearly identified guidelines, standards, or schemes with which the EU fertilising product complies to underpin the claims.

RESOURCES

Criteria for the content, substantiation and communication of **green claims** will be laid down in the Green Claims Directive (link to Commission proposal COM(2023)166 here) and the Greenwashing Directive (EU) 2024/825 (link to consolidated version here).

Criteria and definitions for the **EU Ecolabel** are laid down in COM Decision (EU) 2022/1244 establishing the EU Ecolabel criteria for growing media and soil improvers. A link to the consolidated version can be found here.

Rules and definitions for **organic production and labelling** are laid down in Regulation (EU) 2018/848 on organic production, a link to the consolidated version can be found here. A list of the materials that are authorised be used in organic production is established in Regulation (EU) 2021/1165, a link to the consolidated version can be found here.

FAQ

See the FAQ document on the FPR to check:

- Whether **'soil improvers' in the meaning of the ABPR** are covered by the FPR? (Q1.4)
- Whether PFC 3.A. Organic soil improvers are allowed to the used in **organic farming production** (Q1.5)

3.2 List of component materials

The technical documentation must contain a list of all the product's component materials. This list must include all materials that are present in the product, including those that are present in quantities <5% by dry weight. The list does not include the precursors of the materials that were used to produce the component materials.

For each listed component, it must be demonstrated that the component is compliant with the requirements and criteria of that CMC. Information on the technical documentation required for each CMC material is given in PART III of this guidance document.

The biological origin of the material should be evident from the description of the components of the organic soil improver.

Where materials that are known to have a pesticidal or other plant protection effect are used as a component material, a document should be included to explain and account for, why at the proposed use instructions, the resulting EU fertilising product complies with the conditions of the FPR and does not have a pesticide function.

RESOURCES

Rules and definitions for **plant protection products and active substances** are laid down in Regulation (EC**) No**1107/2009 on plant protection products (PPPR). A link to the consolidated version can be found here.

The **list of approved 'active substances'** under the scope of the PPP-R can be found in Regulation (EU) No 540/2011, a link to the consolidated version can be found here.

Information and examples on **'borderline' products** can be found in the document "Borderline products' from the Belgian government website FYTOWEB (link here) and the document 'SANCO Doc 6621-99' on Scope and borderline issues 1107/2009 (link to the consolidated version from DG SANTE/E4 here).

FAQ

See the FAQ document on the FPR to check:

- **What may EU fertilising products contain/consist of**? (Q8.1)
- Whether materials with a **content of <5%** in the final product must be considered in the technical documentation? (Q9.2)
- How to demonstrate that the product **consists 'solely' of CMC materials**? (Q8.2)

- Whether it is necessary to **indicate the % of each component**? (Q8.2)
- When materials are considered as a component or as **a precursor, additive or reactant**? (Q8.10)
- What is considered a **material of biological origin**? (Q7.9)
- Whether **methylene urea, isobutylidene urea, crotonylidene urea, or synthesised amino acids** are considered materials of biological origin? (Q7.5)
- If substances that have a **plant protection effect** can be used as a component in EU fertilising products? (Q1.3)
- How should the manufacturer perform the conformity assessment of component materials belonging to a **CMC bought from third parties** and provide information about their origin or manufacturing? (Q10.13)
- How can manufacturers comply with the requirements in Module D1 if they **buy the component materials (compost for instance) and do not produce them themselves**? (Q10.19)

3.3 Information on the manufacturing process

The technical documentation must include information on the manufacturing process for the purpose of assessing conformity.

Describe the manufacturing process of the product. Provide a summary of the steps involved in mixing and processing the materials for the manufacture of the final formulated product. Use drawings, schemes, descriptions and explanations necessary for the understanding of the manufacturing process of the EU fertilising product. Where relevant describe conditions and the chemical reactions generated during the production process and the materials and processing additives used. From the description, it should be evident which materials are used as a precursor and which materials are present as a component in the final product.

RESOURCE

Information on the obligations of manufacturers, Notified Bodies, notifying authorities, competent national authorities and member states with regard to CE marked product rules and technical documentation can be found in the Blue Guide on the implementation of EU product rules 2022. A link to the Blue Guide, document 2022/C 248/01, can be found can be found here.

Information on the **safeguarding of confidential commercial information** by the Notified Bodies, notifying authorities, competent national authorities and member states can be found in the Blue Guide §5.2.3-§7.4.1-§7.6.3.

To help ensure the **protection of confidential data or intellectual property rights**, the technical documentation provided to notified bodies has to be limited to that which is required solely for the purpose of assessing conformity to the legislation (Blue Guide §5.2.3).

FAQ

See the FAQ document on the FPR to check:

- How to perform the conformity assessment if parts of the production process are **subcontracted to another company** (Q10.5)
- When materials are considered as a component or as a **precursor, additive or reactant**? (Q8.10)

3.4 Specimen of the label or leaflet

A specimen of the label or the leaflet, or both, referred to in Article 6(7) of the FPR containing the information required in accordance with Annex III of the FPR should be included in the technical documentation. More information on the labelling can be found in the Guidance on the labelling of EU fertilising products. That guidance also contains clear examples of product labels for each PFC.

3.5 Examinations to demonstrate compliance

To demonstrate compliance with the product requirements, the manufacturer must subject the product to tests, trials, analyses or any other examination or calculation. All examinations for verifying the conformity of products must be performed in a reliable and reproducible manner. This may be done by the manufacturer themself or by an external party. The results of these tests should be recorded in one or several test report(s) in the technical documentation.

However, where compliance with a given requirement (such as the absence of a given contaminant) follows certainly and uncontestably from the nature or manufacturing process of an EU fertilising product, that compliance can be presumed in the conformity assessment procedure without verification (such as testing), at the responsibility of the manufacturer (ANNEX I PART II. 4, FPR). In that case, a statement from the manufacturer in which the compliance is explained and motivated should be added to the technical documentation.

The following requirements apply to EU soil improvers:

Related provision	Provision summary	Suggested content
PFC 3 specific requirements		
Annex I PFC3	The function of a soil improver is to maintain, improve or protect the physical or chemical properties, structure, or biological activity of the soil.	Product description indicating which and how the soil property, structure or activity is modified
PFC 3 A organic soil improver requirements		
Annex I PFC3 A 1	An organic soil improver must consist of material 95 % of which is of solely biological origin.	List of components description that supports the biological origin of the nutrients present
Annex I PFC3 A 2 & 3 & 4	Products may not exceed content limits for Cd, Cr VI, Hg, Ni, Pb, inorganic As, Cu, Zn, and pathogens.	Test report
Annex I PFC3 A 5	An organic soil improver shall contain 20 % or more dry matter.	Test report
Annex I PFC3 A 6	Organic carbon (C org) content in an organic soil improver must be at least 7,5 % by mass.	Test report
PFC 3 B inorganic soil improver requirements		
Annex I PFC3 B 2 & 3 & 4	Must not exceed limits for Cd, Cr VI, Hg, Ni, Pb, inorganic As, Cu, Zn, and pathogens.	Test report

General PFC requirements		
Annex III I.1.8	Additional claims by manufacturer:	Measurement of verifiable factors to support additional claims on product
Annex IV MODULE A/B+C/D1 2.2	If the total chromium content in the product exceeds 200 mg kg^{-1} dry matter	Information specifying the source and exact quantity of total chromium (Cr)

Compliance can be demonstrated with a lab report on the analysis of the product's contents of heavy metals. If the contents are reported on 'fresh' product basis, the dry matter content or moisture content must also be analysed and calculations to express contents on dry matter bases must be included in the technical documentation.

Pathogens must not exceed the set limits. Demonstrate compliance by including pathogen analysis reports. Note that at least five samples must be tested.

If the total chromium content exceeds 200 mg kg^{-1} dry matter, a document giving the maximum content and exact source of chromium must be included.

Compliance with the requirements for dry matter content and organic carbon content of organic soil improvers can be demonstrated with an analysis report of these parameters.

RESOURCES

More information of the Notified Bodies on
- accreditation of testing laboratories,
- the validity of test reports in time,
- the core criteria for laboratories and subcontracting of laboratories,
- acceptance of test reports using internal testing methods, national methods, CEN/ISO standards, or peer-reviewed studies
- ring test participation of laboratories

can be found in the document **Criteria for accepting test reports** of the Coordination Group of NoBos, available in the library on the CIRCABC page of the Commission expert group on fertilising products.

FAQ

See the FAQ document on the FPR to check:
- How to prove compliance with the requirement for **inorganic arsenic or hexavalent chromium** (Q7.14)
- Does the **Persistent Organic Pollutants Regulation** apply to EU fertilising products? (Q1.7)
- What is expected by '**adequate analysis and assessment** of the risk(s) to be included in the technical documentation'? (Q10.11)
- Is there a **list of approved laboratories** to check the conformity with various requirements, such as contaminant content? (Q 10.4)
- Is **accreditation of the laboratory** used mandatory or advisable? (Q10.4)
- Whether it is mandatory to use the **harmonised standards** (Q10.3)
- How to do conformity assessment when **harmonised standards** are not adopted (Q10.3)

3.6 Test reports

The results of the calculations and examinations to demonstrate compliance with the requirements must be supported by the reports of the analyses, trials, or reviews carried out on the product and its

components. All test or trial reports and review papers should be included in the technical documentation.

3.7 List of standards or specifications

The technical documentation must include a list of standards and specifications which have been used to demonstrate compliance of the product and its components with the relevant requirements of part 2 of Annex I to the FPR and of part 2 of Annex II to the FPR. In the event of partly applied harmonised standards or common specifications, clearly state which part was used.

A list of standards and specifications which may be used for each requirement can be found in PART IV of this guidance.

Besides harmonised standards, the references of which have been published in the Official Journal of the EU, other relevant specifications or standards can be applied. In that case, the manufacturer must show that the testing methods in these standards are reliable and reproducible.

RESOURCE

More information of the Notified Bodies on acceptance of test reports using internal testing methods, national methods, CEN/ISO standards, or peer-reviewed studies can be found in the document **Criteria for accepting test reports** of the Coordination Group of NoBos, available in the library on the CIRCABC page of the Commission expert group on fertilising products.

FAQ

See the FAQ document on the FPR to check:

- Whether it is mandatory to use the **harmonised standards** (Q10.3)
- Is there **a list of approved laboratories** to check the conformity with various requirements, such as contaminant content? (Q 10.4)
- How to do conformity assessment when **harmonised standards** are not adopted (Q10.3)

3.8 List of suggested documents

It is suggested to include at least the following documents in the technical documentation:

a. A general description of the product including the PFC designation, claimed function, and intended use.
b. A list of component materials, their CMC designation, and the documentation demonstrating compliance of the components with their CMC (see part III for details).
c. Drawings, schemes, descriptions, and/or explanations required for understanding the manufacturing process of the EU fertilising product.
d. A specimen of the product's label, leaflet, or both.
e. A list of standards used in the conformity assessment procedure which also indicates for which requirement each standard was used.
f. Reports on the product's contents of chromium, cadmium, hexavalent chromium, mercury, nickel, lead, copper, zinc, chloride, arsenic, organic carbon, and pathogens (except for inorganic soil improvers with a low organic carbon content).
g. Results of calculations and examinations.
h. Documents in support of any additional claims.

i. Identified risks of the product to human, animal or plant health, to safety or to the environment not covered by aspects in Annex I or II of the FPR and documents demonstrating how these risks have been addressed.

4 PFC 4 Growing medium

4.1 General product description and designated PFC

The technical documentation must include a general description of the product. This description must clearly state the PFC designation, claimed function, and any other claims about the product or its function. Claims that are made about the product must be allowed within the scope of the FPR and the product's PFC. All made claims must be supported by the technical documentation.

PFC designation and claimed function

Growing media should be designated as PFC.4.Growing medium.

Growing media are products, other than soil in situ, the function of which is for plants (including algae) or mushrooms to grow in. The term 'soil in situ' means soil in the field.

Other claims

Any additional claims that are made on the label must be supported by examination or testing of these properties or functioning. The technical documentation should contain test reports or references to scientific literature that underpin the claims.

Where is it suggested that products possess unique characteristics, the technical documentation should contain a description of how the product differs from similar products, where applicable with calculations or schemes to underpin the difference.

For claims unrelated to the product's function, such as 'sustainable' or 'environmentally friendly' or 'allowed to be used in organic agriculture', the technical documentation should contain references and links to legislation, clearly identified guidelines, standards, or schemes with which the EU fertilising product complies to underpin the claims.

RESOURCES

Criteria for the content, substantiation and communication of **green claims** will be laid down in the Green Claims Directive (link to Commission proposal COM(2023)166 here) and the Greenwashing Directive (EU) 2024/825 (link to consolidated version here).

Criteria and definitions for the **EU Ecolabel** are laid down in COM Decision (EU) 2022/1244 establishing the EU Ecolabel criteria for growing media and soil improvers. A link to the consolidated version can be found here.

4.2 List of component materials

The technical documentation must contain a list of all the product's component materials. This list must include all materials that are present in the product, including those that are present in quantities <5%

by dry weight. The list does not include the precursors of the materials that were used to produce the component materials.

For each listed component, it must be demonstrated that the component is compliant with the requirements and criteria of that CMC. Information on the technical documentation required for each CMC material is given in PART III of this guidance document.

Where materials that are known to have a pesticidal or other plant protection effect are used as a component material, a document should be included to explain and account for, why at the proposed use instructions, the resulting EU fertilising product complies with the conditions of the FPR and does not have a pesticide function.

RESOURCES

Rules and definitions for **plant protection products and active substances** are laid down in Regulation (EC) No 1107/2009 on plant protection products (PPP-R). A link to the consolidated version can be found here.

The **list of approved 'active substances'** under the scope of the PPP-R can be found in Regulation (EU) No 540/2011, a link to the consolidated version can be found here.

Information and examples on **'borderline' products** can be found in the document "Borderline products' from the Belgian government website FYTOWEB (link here) and the document 'SANCO Doc 6621-99' on Scope and borderline issues 1107/2009 (link to the consolidated version from DG SANTE/E4 here).

FAQ

See the FAQ document on the FPR to check:

- **What may EU fertilising products contain/consist of?** (Q8.1)
- Whether materials with a **content of <5%** in the final product must be considered in the technical documentation? (Q9.2)
- How to demonstrate that the product **consists 'solely' of CMC** materials? (Q8.2)
- Whether it is necessary to **indicate the %** of each component? (Q8.2)
- When materials are considered as a component or as a **precursor, additive or reactant**? (Q8.13)
- If substances that have a **plant protection effect** can be used as a component in EU fertilising products? (Q1.3)
- How should the manufacturer perform the conformity assessment of component materials belonging to a **CMC bought from third parties** and provide information about their origin or manufacturing? (Q10.13)
- How can manufacturers comply with the requirements in Module D1 if they **buy the component materials** (compost for instance) and do not produce them themselves? (Q10.19)

4.3 Information on the manufacturing process

The technical documentation must include information on the manufacturing process for the purpose of assessing conformity.

Describe the manufacturing process of the product. Provide a summary of the steps involved in mixing and processing the materials for the manufacture of the final formulated product. Use drawings, schemes, descriptions and explanations necessary for the understanding of the manufacturing process of the EU fertilising product. Where relevant describe conditions and the chemical reactions generated during the production process and the materials and processing additives used. From the description, it should be evident which materials are used as a precursor and which materials are present as a component in the final product.

RESOURCE

Information on the obligations of manufacturers, Notified Bodies, notifying authorities, competent national authorities and member states with regard to CE marked product rules and technical documentation can be found in the Blue Guide on the implementation of EU product rules 2022. A link to the Blue Guide, document 2022/C 248/01, can be found can be found here.

Information on the **safeguarding of confidential commercial information** by the Notified Bodies, notifying authorities, competent national authorities and member states can be found in the Blue Guide §5.2.3-§7.4.1-§7.6.3.

To help ensure the **protection of confidential data or intellectual property rights**, the technical documentation provided to notified bodies has to be limited to that which is required solely for the purpose of assessing conformity to the legislation (Blue Guide §5.2.3).

FAQ

See the FAQ document on the FPR to check:

- How to perform the conformity assessment if parts of the production process are **subcontracted to another company** (Q10.5)
- When materials are considered as a component or as a **precursor, additive or reactant**? (Q8.10)

4.4 Specimen of the label or leaflet

A specimen of the label or the leaflet, or both, referred to in Article 6(7) of the FPR containing the information required in accordance with Annex III of the FPR should be included in the technical documentation. More information on the labelling can be found in the Guidance on the labelling of EU fertilising products. That guidance also contains clear examples of product labels for each PFC.

4.5 Examinations to demonstrate compliance

To demonstrate compliance with the product requirements, the manufacturer must subject the product to tests, trials, analyses or any other examination or calculation. All examinations for verifying the conformity of products must be performed in a reliable and reproducible manner. This may be done by the manufacturer themself or by an external party. The results of these tests should be recorded in one or several test report(s) in the technical documentation.

However, where compliance with a given requirement (such as the absence of a given contaminant) follows certainly and uncontestably from the nature or manufacturing process of an EU fertilising product, that compliance can be presumed in the conformity assessment procedure without verification (such as testing), at the responsibility of the manufacturer (ANNEX I PART II. 4, FPR). In that case, a statement from the manufacturer in which the compliance is explained and motivated should be added to the technical documentation.

For growing media, the following requirements are given:

Related provision	Summary of provision	Suggested document
PFC 4 specific requirements		
Annex I PFC 4 1	A growing medium must be an EU fertilising product other than soil in	Product description

	situ, the function of which is for plants or mushrooms to grow in.	
Annex I PFC 4 2	Products may not exceed content limits for Cd, Cr VI, Hg, Ni, Pb, As, Cu, and Zn. For certain mineral growing media, the limit for Ni applies to bioavailable Ni.	Test report
Annex I PFC 4 4	Must not exceed limits for pathogens	Test report
General PFC requirements		
Annex III I.1.8	Any additional claims by the manufacturer.	Measurement of verifiable factors to support additional claims on product
Annex IV MODULE A/B+C/D1; 2.2	If the total chromium content in the product exceeds 200 mg kg^{-1} dry matter	Information specifying the source and exact quantity of total chromium (Cr)

The technical documentation should include an adequate analysis and assessment of the risk(s) of the product. For a PFC 4 product the applicable risks concern contents of heavy metals and the presence of pathogens. Compliance can be demonstrated with a lab report on the analysis of the product's contents of heavy metals. If the contents are reported on 'fresh' product basis, the dry matter content or moisture content must also be analysed and calculations to express contents on dry matter bases must be included in the technical documentation. Pathogens must not exceed the set limits. Demonstrate compliance by including pathogen analysis reports. Note that at least five samples must be tested.

If the total chromium content exceeds 200 mg kg^{-1} dry matter, a document giving the maximum content and exact source of chromium must be included.

In addition to the applicable risks covered by the requirements defined for the PFC 4, there might be aspects not covered by the listed requirements on heavy metals and arsenic. Where such risks for a specific product or component are commonly known by diligent manufacturers operating in that field, the technical documentation should identify them and document how they have been addressed.

RESOURCES

More information of the Notified Bodies on
- accreditation of testing laboratories,
- the validity of test reports in time,
- the core criteria for laboratories and subcontracting of laboratories,
- acceptance of test reports using internal testing methods, national methods, CEN/ISO standards, or peer-reviewed studies
- ring test participation of laboratories

can be found in the document **Criteria for accepting test reports** of the Coordination Group of NoBos, available in the library on the CIRCABC page of the Commission expert group on fertilising products.

FAQ

See the FAQ document on the FPR to check:
- How to prove compliance with the requirement for **hexavalent chromium** (Q7.14)
- Does **the Persistent Organic Pollutants** Regulation apply to EU fertilising products? (Q1.7)
- What is expected by '**adequate analysis and assessment of the risk(s**) to be included in the technical documentation'? (Q10.11)

- Is there a **list of approved laboratories** to check the conformity with various requirements, such as contaminant content? (Q 10.4)
- Is **accreditation of the laboratory** used mandatory or advisable? (Q10.4)
- Whether it is mandatory to use the **harmonised standards** (Q10.3)
- How to do conformity assessment when **harmonised standards** are not adopted (Q10.3)

4.6 Test reports

The results of the calculations and examinations to demonstrate compliance with the requirements must be supported by the reports of the analyses, trials, or reviews carried out on the product and its components. All test or trial reports and review papers should be included in the technical documentation.

4.7 List of standards or specifications

The technical documentation must include a list of standards and specifications which have been used to demonstrate compliance of the product and its components with the relevant requirements of part 2 of Annex I to the FPR and of part 2 of Annex II to the FPR. In the event of partly applied harmonised standards or common specifications, clearly state which part was used.

A list of standards and specifications which may be used for each requirement can be found in PART IV of this guidance.

Besides harmonised standards, the references of which have been published in the Official Journal of the EU, other relevant specifications or standards can be applied. In that case, the manufacturer must show that the testing methods in these standards are reliable and reproducible.

RESOURCE

More information of the Notified Bodies on acceptance of test reports using internal testing methods, national methods, CEN/ISO standards, or peer-reviewed studies can be found in the document **Criteria for accepting test reports** of the Coordination Group of NoBos, available in the library on the CIRCABC page of the Commission expert group on fertilising products.

FAQ

See the FAQ document on the FPR to check:

- Whether it is mandatory to use the **harmonised standards** (Q10.3)
- Is there a **list of approved** laboratories to check the conformity with various requirements, such as contaminant content? (Q 10.4)
- How to do conformity assessment when **harmonised standards** are not adopted (Q10.3)

4.8 List of suggested documents

It is suggested to include at least the following documents in the technical documentation:

a. A general description of the product including the PFC designation, claimed function, and intended use.
b. A list of component materials, their CMC designation, and the documentation demonstrating compliance of the components with their CMC (see part III for details).

c. Drawings, schemes, descriptions, and/or explanations required for understanding the manufacturing process of the EU fertilising product.
d. A specimen of the product's label, leaflet, or both.
e. A list of standards used in the conformity assessment procedure which also indicates for which requirement each standard was used.
f. Reports on the product's contents of cadmium, hexavalent chromium, mercury, (bioavailable) nickel, lead, copper, zinc, arsenic, and pathogens.
g. Results of calculations and examinations.
h. Documents in support of any additional claims.
i. Identified risks of the product to human, animal or plant health, to safety or to the environment not covered by aspects in Annex I or II of the FPR and documents demonstrating how these risks have been addressed.

5 PFC 5 Inhibitor

5.1 General product description and designated PFC

The technical documentation must include a general description of the product. This description must clearly state the PFC designation, claimed function, and any other claims about the product or its function. Claims that are made about the product must be allowed within the scope of the FPR and the product's PFC. All made claims must be supported by the technical documentation.

PFC designation and claimed function

An inhibitor's function is to improve the nutrient release patterns of fertilisers by delaying or stopping the activity of specific groups of microorganisms or enzymes. The designation and specific functions of inhibitors are either:

- PFC 5(A): Nitrification inhibitor
  A nitrification inhibitor has the function to inhibit the biological oxidation of ammoniacal nitrogen (NH_3-N) to nitrite nitrogen (NO_2^-), thus slowing the formation of nitrate nitrogen (NO_3^-).
- PFC 5(B): denitrification inhibitor
  A denitrification inhibitor has the function to inhibit the formation of nitrous oxide (N_2O) by slowing down or blocking the conversion of nitrate (NO_3^-) to dinitrogen (N_2) without influencing the nitrification process as described in PFC 5(A).
- PFC 5(C): urease inhibitor
  A urease inhibitor has the function to inhibit hydrolytic action on urea (CH_4N_2O) by the urease enzyme, primarily targeted to reduce ammonia volatilisation.

Other claims

Any additional claims that are made on the label must be supported by examination or testing of these properties or functioning. The technical documentation should contain test reports or references to scientific literature that underpin the claims.

Where is it suggested that products possess unique characteristics, the technical documentation should contain a description of how the product differs from similar products, where applicable with calculations or schemes to underpin the difference.

For claims unrelated to the product's function, such as ‘sustainable’ or ‘environmentally friendly’ or 'allowed to be used in organic agriculture', the technical documentation should contain references and links to legislation, clearly identified guidelines, standards, or schemes with which the EU fertilising product complies to underpin the claims.

RESOURCES

Criteria for the content, substantiation and communication of **green claims** will be laid down in the Green Claims Directive (link to Commission proposal COM(2023)166 here) and the Greenwashing Directive (EU) 2024/825 (link to consolidated version here).

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FAQ

See the FAQ document on the FPR to check:

- How to **classify products with** inhibitors? (Q7.13)

5.2 List of component materials

The technical documentation must contain a list of all the product's component materials. This list must include all materials that are present in the product, including those that are present in quantities <5% by dry weight. The list does not include the precursors of the materials that were used to produce the component materials.

For each listed component, it must be demonstrated that the component is compliant with the requirements and criteria of that CMC. Information on the technical documentation required for each CMC material is given in PART III of this guidance document.

FAQ

See the FAQ document on the FPR to check:

- **What may EU fertilising products contain/consist of**? (Q8.1)
- How to demonstrate that the product **consists 'solely' of CMC materials**? (Q8.2)
- Whether it is necessary to **indicate the % of each component**? (Q8.2)
- When materials are considered as a component or as a **precursor, additive or reactant**? (Q8.13)
- If substances that have a **plant protection effect** can be used as a component in EU fertilising products? (Q.13)
- How should the manufacturer perform the conformity assessment of component materials belonging to a **CMC bought from third parties** and provide information about their origin or manufacturing? (Q10.13)

5.3 Information on the manufacturing process

The technical documentation must include information on the manufacturing process for the purpose of assessing conformity.

Describe the manufacturing process of the product. Provide a summary of the steps involved in mixing and processing the materials for the manufacture of the final formulated product. Use drawings, schemes, descriptions and explanations necessary for the understanding of the manufacturing process of the EU fertilising product. Where relevant describe conditions and the chemical reactions generated during the production process and the materials and processing additives used. From the description, it should be evident which materials are used as a precursor and which materials are present as a component in the final product.

RESOURCE

Information on the obligations of manufacturers, Notified Bodies, notifying authorities, competent national authorities and member states with regard to CE marked product rules and technical documentation can be found in the Blue Guide on the implementation of EU product rules 2022. A link to the Blue Guide, document 2022/C 248/01, can be found can be found here.

Information on the **safeguarding of confidential commercial information** by the Notified Bodies, notifying authorities, competent national authorities and member states can be found in the Blue Guide §5.2.3-§7.4.1-§7.6.3.

To help ensure the **protection of confidential data or intellectual property rights**, the technical documentation provided to notified bodies has to be limited to that which is required solely for the purpose of assessing conformity to the legislation (Blue Guide §5.2.3).

FAQ

See the FAQ document on the FPR to check:

- How to perform the conformity assessment if parts of the production process are **subcontracted to another company** (Q10.5)
- When materials are considered as a component or as a **precursor, additive or reactant**? (Q8.13)

5.4 Specimen of the label or leaflet

A specimen of the label or the leaflet, or both, referred to in Article 6(7) of the FPR containing the information required in accordance with Annex III of the FPR should be included in the technical documentation. More information on the labelling can be found in the Guidance on the labelling of EU fertilising products. That guidance also contains clear examples of product labels for each PFC.

5.5 Examinations to demonstrate compliance

To demonstrate compliance with the product requirements, the manufacturer must subject the product to tests, trials, analyses or any other examination or calculation**.** All examinations for verifying the conformity of products must be performed in a reliable and reproducible manner. This may be done by the manufacturer themself or by an external party. The results of these tests should be recorded in one or several test report(s) in the technical documentation.

However, where compliance with a given requirement (such as the absence of a given contaminant) follows certainly and uncontestably from the nature or manufacturing process of an EU fertilising product, that compliance can be presumed in the conformity assessment procedure without verification (such as testing), at the responsibility of the manufacturer (ANNEX I PART II. 4, FPR). In that case, a statement from the manufacturer in which the compliance is explained and motivated should be added to the technical documentation.

For PFC 5 inhibitors, the following quality requirements are given.

Related provision	Regulation extract	Suggested document
PFC 5 specific requirements		
Annex I PFC 5(A). 2	20 % reduction in ammoniacal nitrogen (NH_3 -N) oxidation rate compared to a control sample	Test report

Annex I PFC 5(B). 2	20 % reduction in the rate of nitrous oxide (N_2O) release compared to a control sample	Test report
Annex I PFC 5(C). 2	20 % reduction in the rate of hydrolysis of urea (CH_4N_2O) compared to a control sample	Test report
General PFC requirements		
Annex III I.1.8	Any additional claims by the manufacturer.	Measurement of verifiable factors to support additional claims on product
Annex IV MODULE B+C/D1 2.2 k	If the total chromium content in the product exceeds 200 mg kg^{-1} dry matter	Information specifying the source and exact quantity of total chromium (Cr)

Compliance with the criteria on reduction rate can demonstrated with the test report of the applicable measurements.

The technical documentation should include an adequate analysis and assessment of the risk(s) of the product.

If the total chromium content exceeds 200 mg kg^{-1} dry matter, a document giving the maximum content and exact source of chromium must be included.

RESOURCES

More information of the Notified Bodies on
- accreditation of testing laboratories,
- the validity of test reports in time,
- the core criteria for laboratories and subcontracting of laboratories,
- acceptance of test reports using internal testing methods, national methods, CEN/ISO standards, or peer-reviewed studies
- ring test participation of laboratories

can be found in the document **Criteria for accepting test reports** of the Coordination Group of NoBos, available in the library on the CIRCABC page of the Commission expert group on fertilising products.

FAQ

See the FAQ document on the FPR to check:
- Does the **Persistent Organic Pollutants** Regulation apply to EU fertilising products? (Q1.7)
- What is expected by '**adequate analysis and assessment of the risk(s)** to be included in the technical documentation'? (Q10.11)
- Is there **a list of approved laboratories** to check the conformity with various requirements, such as contaminant content? (Q 10.4)
- Is **accreditation of the laboratory** used mandatory or advisable? (Q10.4)
- Whether it is mandatory to use the **harmonised standards** (Q10.3)
- How to do conformity assessment when **harmonised standards** are not adopted (Q10.3)

5.6 Test reports

The results of the calculations and examinations to demonstrate compliance with the requirements must be supported by the reports of the analyses, trials, or reviews carried out on the product and its components. All test or trial reports and review papers should be included in the technical documentation.

5.7 List of standards or specifications

The technical documentation must include a list of standards and specifications which have been used to demonstrate compliance of the product and its components with the relevant requirements of part 2 of Annex I to the FPR and of part 2 of Annex II to the FPR. In the event of partly applied harmonised standards or common specifications, clearly state which part was used.

A list of standards and specifications which may be used for each requirement can be found in PART IV of this guidance.

Besides harmonised standards, the references of which have been published in the Official Journal of the EU, other relevant specifications or standards can be applied. In that case, the manufacturer must show that the testing methods in these standards are reliable and reproducible.

RESOURCE

More information of the Notified Bodies on acceptance of test reports using internal testing methods, national methods, CEN/ISO standards, or peer-reviewed studies can be found in the document **Criteria for accepting test reports** of the Coordination Group of NoBos, available in the library on the CIRCABC page of the Commission expert group on fertilising products.

FAQ

See the FAQ document on the FPR to check:

- Whether it is mandatory to use the **harmonised standards** (Q10.3)
- Is there a **list of approved laboratories** to check the conformity with various requirements, such as contaminant content? (Q 10.4)
- How to do conformity assessment when **harmonised standards** are not adopted (Q10.3)

5.8 List of suggested documents

It is suggested to include at least the following documents in the technical documentation:

a. A general description of the product including the PFC designation, claimed function, and intended use.
b. A list of component materials, their CMC designation, and the documentation demonstrating compliance of the components with their CMC (see part III for details).
c. Drawings, schemes, descriptions, and/or explanations required for understanding the manufacturing process of the EU fertilising product.
d. A specimen of the product's label, leaflet, or both.
e. A list of standards used in the conformity assessment procedure which also indicates for which requirement each standard was used.
f. Reports on the product's contents of total chromium.
g. Results of calculations and examinations.
h. Documents in support of any additional claims.
i. Identified risks of the product to human, animal or plant health, to safety or to the environment not covered by aspects in Annex I or II of the FPR and documents demonstrating how these risks have been addressed.

6 PFC 6 Plant biostimulant

6.1 General product description

The technical documentation must include a general description of the product. This description must clearly state the PFC designation, claimed function, and any other claims about the product or its function. Claims that are made about the product must be allowed within the scope of the FPR and the product's PFC. All made claims must be supported by the technical documentation.

PFC designation and claimed function

A plant biostimulant product designation is either:

- PFC 6(A). Microbial plant biostimulant, or
- PFC 6(B). Non-microbial plant biostimulant

The claimed function of plant biostimulants is "to stimulate plant nutrition processes independently of the product's nutrient content with the sole aim of improving one or more of the following characteristics of the plant or the plant rhizosphere:

- nutrient use efficiency,
- tolerance to abiotic stress
- quality traits,
- availability of confined nutrients in the soil or rhizosphere.

The general product description should specify which of the characteristics is/are improved by the plant biostimulant. These characteristics should preferably be complemented by the more specific claimed effects. For example, a product that claims to increase tolerance to abiotic stress could, specifically, increase tolerance to both drought and cold. In such a case, both specific function claims should be mentioned in the product description. Both claims will need to be supported by evidence included in the technical documentation.

Other claims

Any additional claims that are made on the label must be supported by examination or testing of these properties or functioning. The technical documentation should contain test reports or references to scientific literature that underpin the claims.

Where is it suggested that products possess unique characteristics, the technical documentation should contain a description of how the product differs from similar products, where applicable with calculations or schemes to underpin the difference.

For claims unrelated to the product's function, such as ‘sustainable’ or ‘environmentally friendly’ or 'allowed to be used in organic agriculture', the technical documentation should contain references and links to legislation, clearly identified guidelines, standards, or schemes with which the EU fertilising product complies to underpin the claims.

RESOURCES

Criteria for the content, substantiation and communication of **green claims** will be laid down in the Green Claims Directive (link to Commission's proposal COM 2023/166 here) and the Greenwashing Directive (EU) 2024/825 (link to consolidated version here).

Rules and definitions for **organic production and labelling** are laid down in the Regulation (EU) 2018/848 on organic production, a link to the consolidated version can be found here. An **input list** of the materials that are authorised to be used in organic production is established in Regulation (EU) 2021/1165, a link to the consolidated version can be found here.

Information on more **specific definitions of the characteristics and attributes of biostimulants** are given in the CEN norm CEN/TSA 17724:2022(E) on terminology and the forthcoming harmonised norm on Terminology for biostimulants (Fpr EN17724).

The technical specification (CEN/TS 17700-1 to 17700-5) or the forthcoming harmonised norms (Fpr EN17700-1 to 17700-5) **provide guidance on how to demonstrate plant biostimulant claims and the terminology of such claims.**

FAQ

See the FAQ document on the FPR to check:

- Whether manufacturers are allowed to **declare nutrient contents in a plant biostimulant**? (Q9.4)

6.2 List of component materials

The technical documentation must contain a list of all the product's component materials. This list must include all materials that are present in the product, including those that are present in quantities <5% by dry weight. The list does not include the precursors of the materials that were used to produce the component materials.

For each listed component, it must be demonstrated that the component is compliant with the requirements and criteria of that CMC. Information on the technical documentation required for each CMC material is given in PART III of this guidance document.

The biological origin of the material should be evident from the component description.

Where materials that are known to have a pesticidal or other plant protection effect are used as a component material, a document should be included to explain and account for, why at the proposed use instructions, the resulting EU fertilising product complies with the conditions of the FPR and does not have a pesticide function.

RESOURCES

Rules and definitions for **plant protection products and active substances** are laid down in Regulation (EC) No 1107/2009 on plant protection products (PPP-R). A link to the consolidated version can be found here.

The **list of approved 'active substances'** under the scope of the PPP-R can be found in Regulation (EU) No 540/2011, a link to the consolidated version can be found here.

Information and examples on **'borderline' products** can be found in the document "Borderline products' from the Belgian government website FYTOWEB (link here) and the document 'SANCO Doc 6621-99' on Scope and borderline issues 1107/2009 (link to the consolidated version from DG SANTE/E4 here).

FAQ

See the FAQ document on the FPR to check:

- **What may EU fertilising products contain/consist of**? (Q8.1)
- Whether materials with a **content of <%5% in the final** product must be considered in the technical documentation? (Q9.2)
- How to demonstrate that the product **consists 'solely' of CMC materials**? (Q8.2)
- Whether it is necessary to **indicate the % of each component**? (Q8.2)
- When materials are considered as a component or as a **precursor, additive or reactant**? (Q8.13)
- Can microbial plant biostimulants contain **other component materials than those belonging to CMC 7**? (Q8.33)
- If substances or microorganisms that have a **plant protection effect** can be used as a component in EU fertilising products? (Q.1.3)
- How should the manufacturer perform the conformity assessment of component materials belonging to a **CMC bought from third parties** and provide information about their origin or manufacturing? (Q10.13)
- How can manufacturers comply with the requirements in Module D1 if **they buy the component materials (compost for instance) and do not produce them themselves**? (Q10.19)

6.3 Information on the manufacturing process

The technical documentation must include information on the manufacturing process for the purpose of assessing conformity.

Describe the manufacturing process of the product. Provide a summary of the steps involved in mixing and processing the materials for the manufacture of the final formulated product. Use drawings, schemes, descriptions and explanations necessary for the understanding of the manufacturing process of the EU fertilising product. Where relevant describe conditions and the chemical reactions generated during the production process and the materials and processing additives used. From the description, it should be evident which materials are used as a precursor and which materials are present as a component in the final product.

RESOURCE

Information on the obligations of manufacturers, Notified Bodies, notifying authorities, competent national authorities and member states with regard to CE marked product rules and technical documentation can be found in the Blue Guide on the implementation of EU product rules 2022. A link to the Blue Guide, document 2022/C 248/01, can be found can be found here.

Information on the **safeguarding of confidential commercial information** by the Notified Bodies, notifying authorities, competent national authorities and member states can be found in the Blue Guide §5.2.3-§7.4.1-§7.6.3.

To help ensure the **protection of confidential data or intellectual property rights**, the technical documentation provided to notified bodies has to be limited to that which is required solely for the purpose of assessing conformity to the legislation (Blue Guide §5.2.3)

FAQ

See the FAQ document on the FPR to check:

- How to perform the conformity assessment if **parts of the production process are subcontracted to another company** (Q10.5)
- When materials are considered as a component or as a **precursor, additive or reactant**? (Q8.10)

6.4 Specimen of the label or leaflet

A specimen of the label or the leaflet, or both, referred to in Article 6(7) of the FPR containing the information required in accordance with Annex III of the FPR should be included in the technical documentation. More information on the labelling can be found in the Guidance on the labelling of EU fertilising products. That guidance also contains clear examples of product labels for each PFC.

6.5 Examinations to demonstrate compliance

To demonstrate compliance with the product requirements, the manufacturer must subject the product to tests, trials, analyses or any other examination or calculation. All examinations for verifying the conformity of products must be performed in a reliable and reproducible manner. This may be done by the manufacturer themself or by an external party. The results of these tests should be recorded in one or several test report(s) in the technical documentation.

However, where compliance with a given requirement (such as the absence of a given contaminant) follows certainly and uncontestably from the nature or manufacturing process of an EU fertilising product, that compliance can be presumed in the conformity assessment procedure without verification (such as testing), at the responsibility of the manufacturer (ANNEX I PART II. 4, FPR). In that case, a statement from the manufacturer in which the compliance is explained and motivated should be added to the technical documentation.

For the plant biostimulants, the following requirements are given:

Related provision	Provision summary	suggested content
PFC 6 specific requirements		
Annex I Part 2 PFC 6.1	Support for product function claim	Product trials
Annex I PFC 6.2 & 3	The product may not exceed content limits for Cd, Cr VI, Hg, Ni, Pb, As, Cu, and Zn.	Test report
PFC 6(A) Microbial plant biostimulant specific requirements		
Annex I PFC 6 A 2	The product does not exceed limits for pathogens	Test report
Annex III, part II, PFC(6A)	The intentionally added strains are indicated and their concentration is expressed in a manner relevant to the micro-organism	Test report
Annex I PFC 6 A 3	When liquid, the pH must be optimal for the contained micro-organisms	Test report
PFC 6(B) Non-microbial plant biostimulant specific requirements		
Annex I PFC 6 B 2	The product does not exceed limits for pathogens	Test report
General PFC requirements		
Annex III I.1.8	Measurement of verifiable factors to support additional claims on product	

Annex MODULE B+C/D1 2.2 k	IV	Chromium origin and content must be indicated if the total chromium content in the product exceeds 200 mg kg-1 dry matter.	Information specifying the source and exact quantity of total chromium (Cr)

Liquid PFC 6(A) products must have a pH optimal for the contained micro-organisms and for plants. Compliance can be demonstrated with pH test results and a reference to the optimal pH or range of pH for the contained microorganisms and plants.

A product in PFC 6 may not exceed the limits of heavy metals. Compliance can be demonstrated with the laboratory report with results of the analysis of the product's contents of heavy metals and pathogens.

If the total chromium (Cr) content exceeds 200 mg kg^{-1} dry matter, information must be provided on the maximum quantity and the exact source of chromium in the product.

Pathogens in plant biostimulants must not exceed the limits. Compliance can be demonstrated with the laboratory report with results of the analysis of the product's contents of pathogens. Note that at least five samples must be tested to demonstrate compliance with pathogen criteria.

RESOURCES

The technical specification (CEN/TS 17700-1 to 17700-5) or the forthcoming harmonised norms (Fpr EN17700-1 to 17700-5) for biostimulants provide guidance on the testing of product claims for biostimulants.

More information on the trial assessment under PFC 6 by the NoBos is given in the document FPR-NB-PFC6-subgroup Guidelines-assessments**.** This document contains an extensive list of questions and clarifications that all Notified Bodies are required to comply with according to the Blue Guide on EU product rules (§6.5 and 6.6).

More information of the Notified Bodies on

- accreditation of testing laboratories,
- the validity of test reports in time,
- the core criteria for laboratories and subcontracting of laboratories,
- acceptance of test reports using internal testing methods, national methods, CEN/ISO standards, or peer-reviewed studies
- ring test participation of laboratories

can be found in the document Criteria for accepting test reports of the Coordination Group of NoBos.

FAQ

See the FAQ document on the FPR to check:

- How to prove compliance with the requirement for **bioavailable nickel, inorganic arsenic or hexavalent chromium** (Q7.11)
- Does the **Persistent Organic Pollutants** Regulation apply to EU fertilising products? (Q1.7)
- What is expected by '**adequate analysis and assessment of the risk(s)** to be included in the technical documentation'? (Q10.11)
- Is there a **list of approved laboratories** to check the conformity with various requirements, such as contaminant content? (Q 10.4)
- Is **accreditation of the laboratory** used mandatory or advisable? (Q10.4)
- Whether it is mandatory to use the **harmonised standards** (Q10.3) (See also the starting statements and the resolution 6-7-8 in FPR-NB-PFC6-subgroup Guidelines-assessments)
- How to do conformity assessment when **harmonised standards** are not adopted (Q10.3)

6.6 Test reports

The results of the calculations and examinations to demonstrate compliance with the requirements must be supported by the reports of the analyses, trials, or reviews carried out on the product and its components. All test or trial reports and review papers should be included in the technical documentation.

6.7 List of standards or specifications

The technical documentation must include a list of standards and specifications which have been used to demonstrate compliance of the product and its components with the relevant requirements of part 2 of Annex I to the FPR and of part 2 of Annex II to the FPR. In the event of partly applied harmonised standards or common specifications, clearly state which part was used.

A list of standards and specifications which may be used for each requirement can be found in PART IV of this guidance.

Besides harmonised standards, the references of which have been published in the Official Journal of the EU, other relevant specifications or standards can be applied. In that case, the manufacturer must show that these standards or tests are reliable and reproducible.

RESOURCE

More information of the Notified Bodies on acceptance of test reports using internal testing methods, national methods, CEN/ISO standards, or peer-reviewed studies can be found in the document **Criteria for accepting test reports** of the Coordination Group of NoBos, available in the library on the CIRCABC page of the Commission expert group on fertilising products.

FAQ

See the FAQ document on the FPR to check:

- Whether it is mandatory to use the **harmonised standards** (Q10.3)
- Is there a **list of approved laboratories** to check the conformity with various requirements, such as contaminant content? (Q 10.4)
- How to do conformity assessment when **harmonised standards** are not adopted (Q10.3)

6.8 List of suggested documents

It is suggested to include at least the following documents in the technical documentation:

a. A general description of the product including the PFC designation, claimed function, and intended use.
b. A list of component materials, their CMC designation, and the documentation demonstrating compliance of the components with their CMC (see part III for details).
c. Drawings, schemes, descriptions, and/or explanations required for understanding the manufacturing process of the EU fertilising product.
d. A specimen of the product's label, leaflet, or both.
e. A list of standards used in the conformity assessment procedure which also indicates for which requirement each standard was used.
f. Reports on the product's contents of total chromium, heavy metals, and pathogens
g. Results of calculations and examinations.
h. Documents in support of any additional claims.

i. Identified risks of the product to human, animal or plant health, to safety or to the environment not covered by aspects in Annex I or II of the FPR and documents demonstrating how these risks have been addressed.

7 PFC 7 Fertilising product blend

7.1 General product description and designated PFC

PFC designation and claimed function

The product description of a PFC 7 Blend should give the designations of all EU fertiliser products in the blend.

A blend can be produced by blending two or more EU fertilising products from PFC 1 to PFC 6. A blend can also consist of a single material or composition that fulfils the conditions under two of the PFCs 1 to 6 (including relevant requirements of Annex II and Annex III) and which has followed the conformity assessment for both product function categories.

RESOURCES

Criteria for the content, substantiation and communication of **green claims** will be laid down in the Green Claims Directive (link to Commission proposal COM(2023)166 here) and the Greenwashing Directive (EU) 2024/825 (link to consolidated version here).

Rules and definitions for **organic production and labelling** are laid down in Regulation (EU) 2018/848 on organic production, a link to the consolidated version can be found here. A list of the materials that are authorised be used in organic production is established in Regulation (EU) 2021/1165, a link to the consolidated version can be found here.

FAQ

See the FAQ document on the FPR to check:

- **What is a fertilising product blend** (Q7.15)
- **Functional blend:** How can an EU fertilising product, consisting of one single material or single composition of materials, belongs to PFC 7 (Q7.3)
- What does **the technical documentation of a blend have to contain** (Q10.14)

7.2 Component materials

The technical documentation must contain a list of the EU fertilising products that the blend is composed of. This list should also indicate the fractions of each component EU fertilising product in the blend.

The manufacturer of a blend must be in possession of the EU declaration of conformity of each of the component EU fertilising products.

Given that the fertilising product blend is a mix of compliant EU fertilising products, all the specific requirements concerning certain component materials have been already included in the technical documentation of the component EU fertilising products and do not have to be verified again in the blend.

FAQ

See the FAQ document on the FPR to check:

- Can a fertilising product blend **contain another fertilising product blend**? (Q7.14)
- Do blenders have to **check the blend against all the requirements** of the EU fertilising products it consists of? (Q10.8)
- What **components may a blend contain**? (Q7.2 and Q7.3)

7.3 Information on the manufacturing process

The technical documentation should include information on the production such as descriptions, drawings, schemes, and explanations which are required for understanding the blending process of the fertilising product blend.

The blending must not change the nature of each component EU fertilising product and must not have an adverse effect on human, animal or plant health, on safety, or on the environment, under reasonably foreseeable conditions of storage or use of the fertilising product blend.

Provide a summary of the steps involved in blending the EU fertilising products that make up the blend, where relevant with a flow scheme.

For blends containing coated EU fertilising products, a calculation on the percentage of EU fertiliser in the blend coated with a coating agent must be included.

RESOURCE

Information on the obligations of manufacturers, Notified Bodies, notifying authorities, competent national authorities and member states with regard to CE marked product rules and technical documentation can be found in the Blue Guide on the implementation of EU product rules 2022. A link to the Blue Guide, document 2022/C 248/01, can be found can be found here.

Information on the **safeguarding of confidential commercial information** by the Notified Bodies, notifying authorities, competent national authorities and member states can be found in the Blue Guide §5.2.3-§7.4.1-§7.6.3.

To help ensure the **protection of confidential data or intellectual property rights**, the technical documentation provided to notified bodies has to be limited to that which is required solely for the purpose of assessing conformity to the legislation (Blue Guide §5.2.3)

FAQ

See the FAQ document on the FPR to check:

- What is understood by '**no change in the nature**' of each fertilising product (Q7.13)

7.4 Specimen of the label or leaflet

A specimen of the label or the leaflet, or both, referred to in Article 6(7) of the FPR containing the information required in accordance with Annex III of the FPR should be included in the technical documentation. More information on the labelling can be found in the Guidance on the labelling of EU fertilising products. That guidance also contains clear examples of product labels for each PFC.

For blends it is advised but not mandatory to also include the labels or leaflets of the blend's component EU fertilising products in the technical documentation.

FAQ

See the FAQ document on the FPR to check:

- Why it is advisable to **keep the labelling information** of component EU fertilising products for conformity assessment (Q9.7)

7.5 Examinations to demonstrate compliance

For PFC 7 fertilising product blend, the manufacturer does not have to test the conformity of the EU fertilising products used in the blend. As only CE marked products can be used in the blend, the manufacturer can assume that the conformity has been verified and the products are compliant with the prerequisites of the FPR.

fulfils the conditions under two of the PFCs 1 to 6 (including relevant requirements of Annex II and Annex III) and which has followed the conformity assessment for both product function categories.

For the fertilising product blends, the following requirements are given.

Related provision	Regulation extract	
PFC 7 specific requirements		
Annex I PFC 7 1	A blend must contain at least two EU fertilising products, or a product that fulfils the conditions under two of the PFCs 1 tot 6 and has followed conformity assessment for both PFCs (functional blend).	List of EU fertilising products in the blend with the EU Declarations of Conformity.
Annex I PFC 7 2	Blending does not change the nature of the product. Storage and usage of the blend do not have a negative effect on human, animal, or plant health or safety, or the environment.	Test, calculations, or statements to demonstrate that the blend does not behave differently compared to the situation where the component fertilising products are used separately.
Annex I PFC 7 2a	When the blend contains an inhibitor (PFC 5 product) or inhibiting compound (CMC 1), the blend meets the reduction thresholds set for PFC 5 or CMC 1 at the level of the blend.	Calculations to demonstrate that the blend meets threshold levels.
Annex I PFC 7 3	The manufacturer asserts that the blend conforms to the FPR.	Draws up the EU declaration of conformity (DoC) for the blend and possses the component EU fertilising products.
General PFC requirements		
Annex III I.1.8	Additional claims by the manufacturer.	Measurement of verifiable factors to support additional claims on product.
Annex IV MODULE A/A1/B/D1 2.2 k	If the total chromium content in the product exceeds 200 mg kg^{-1} dry matter.	Information specifying the source and exact quantity of total chromium (Cr).

Blending EU fertilising products to produce a PFC 7 product may not change the nature of each component fertilising product or have an adverse effect on human, animal or plant health, safety, or on the environment under reasonably foreseeable conditions of storage or use of the blend.

When there is no doubt that blending does not change the nature of the component fertilising products and does not have any adverse effects during storage or use, the manufacturer of the blend (the blender) should include in the technical documentation a declaration or a reference to technical or scientific knowledge showing that blending did not change the nature of the component products or cause adverse effects during storage or use of the blend. Where such an effect on the nature of the component fertiliser products cannot be assumed, the manufacturer of the blend has to demonstrate compliance with the results of calculations, examinations, testing, or trials.

An EU fertilising product blend containing 28 % or more by mass of nitrogen (N) from an EU fertilising product belonging to PFC 1(C) (I)(a)(i-ii)(A), the fertiliser product blend checks for oil retention and detonation resistance, following the specifications in Annex IV, part II to the FPR, under Module A1 point 4 must be demonstrated by a test report.

A blend which contains an inhibiting compound must contain the inhibiting compound in a concentration such that the reduction rates set out for PFC 5 and inhibiting compounds (CMC 1 point 4) are achieved for the blend. To demonstrate compliance with the reduction rates, a calculation should be included in the technical documentation which demonstrates that the concentration of the inhibiting compound in the blend is still within the range of concentrations that ensures the achievement of the reduction rates in the conditions referred to in PFC 5 and respectively in point 4 of CMC 1 at the level of the blend.

In case the blender does not have information about the content of total chromium and its origin in the component EU fertilising products, then tests on total chromium content should be carried out before mixing the component EU fertilising products so that, if the level exceeds 200 mg/kg dry matter of the blend, the blender can identify which of the component EU fertilising products is the origin of the chromium in the blend.

RESOURCES

More information of the Notified Bodies on
- accreditation of testing laboratories,
- the validity of test reports in time,
- the core criteria for laboratories and subcontracting of laboratories,
- acceptance of test reports using internal testing methods, national methods, CEN/ISO standards, or peer-reviewed studies
- ring test participation of laboratories

can be found in the document **Criteria for accepting test reports** of the Coordination Group of NoBos, available in the library on the CIRCABC page of the Commission expert group on fertilising products.

FAQ

See the FAQ document on the FPR to check:
- What is a **chemical change in a natural substance**? Q8.11
- What **must manufacturers chec**k during the conformity assessment of a blend? (Q10.8)
- What are the **obligations of the blender**, including examples of blends where no change in the nature of the component EU fertilising products occurs (Q7.16)
- When should the **requirements for pathogens** in fertilising product blends be checked? (Q7.16)
- What are the **consequences of regrowth of pathogens** in normal conditions during storage or in the distribution chain? (Q7.19)
- What **tolerances** apply to a fertilising product blend? (Q9.12)
- Whether **the nutrient content of the blend** have to be tested as such by the blender or can be calculated on paper? (Q9.12)
- Is **accreditation of the laboratory used** for testing mandatory or advisable? (Q10.4)

- Whether it is mandatory to use the **harmonised standards** (Q10.3)
- How to do conformity assessment when **harmonised standards** are not adopted (Q10.3)

7.6 Test reports

All test reports for tests that were performed to demonstrate that blending does not change the nature of the component fertilising products and does not have any adverse effects during storage must be included in the technical documentation.

Note: the conformity of the component EU fertilising products, including the specific requirements on component materials materials have been already included in the technical documentation of the component EU fertilising products and do not need to be verified again in the blend. Hence, test reports on these component EU fertilising products do not have to be included in the technical documentation of the blend.

7.7 List of standards or specifications

The technical documentation must include a list of standards and specifications which have been used to demonstrate compliance of the product and its components with the relevant requirements of part 2 of Annex I to the FPR and of part 2 of Annex II to the FPR. In the event of partly applied harmonised standards or common specifications, clearly state which part was used.

Only the standards used by the blender to prove compliance of the blend, need to be included in this list. The standards that have been used to demonstrate the conformity of the component EU fertilising products do not have to be included in the list of standards of the blend.

A list of standards and specifications which may be used for each requirement can be found in PART IV of this guidance.

Besides harmonised standards, the references of which have been published in the Official Journal of the EU, other relevant specifications or standards can be applied. In that case, the manufacturer must show that the testing methods in these standards are reliable and reproducible.

RESOURCE

More information of the Notified Bodies on acceptance of test reports using internal testing methods, national methods, CEN/ISO standards, or peer-reviewed studies can be found in the document **Criteria for accepting test reports** of the Coordination Group of NoBos, available in the library on the CIRCABC page of the Commission expert group on fertilising products.

FAQ

See the FAQ document on the FPR to check:

- Whether it is mandatory to use the **harmonised standards** (Q10.3)
- Is there a **list of approved laboratories** to check the conformity with various requirements, such as contaminant content? (Q 10.4)
- How to do conformity assessment when **harmonised standards** are not adopted (Q10.3)

7.8 List of suggested documents

It is suggested to include at least the following documents in the technical documentation:

a. A general description of the product including the PFC designation and intended use.
b. The EU Declaration of Conformity (EU DoC) of the EU fertilising products in the blend
c. Drawings, schemes, descriptions, and/or explanations required for understanding the blending process of the EU fertilising product blend.
d. A specimen of the label or leaflet of the blend, and preferably also those of the component EU fertilising products.
e. A list of standards used in the conformity assessment procedure which also indicates for which requirement each standard was used. This only concerns standards used in the assessment of the blend, not those used in the assessment of the component products.
f. Results of calculations and examinations to prove that there is no change in the nature of the component fertilising products (for instance, references to technical or scientific knowledge showing that the manufacturing process used cannot lead to a chemical reaction).
g. Test reports for tests performed with the objective referred to in the previous point.
h. Where the EU fertilising product contains total chromium (Cr) above 200 mg/kg, information about the maximum quantity and exact source of total chromium (Cr).
i. Documents in support of any additional claims.

A. PFC Detailed list of all the relevant contents for the TD

The following table lists the requirements for each PFC as described in Annex I to the FPR. Besides listing the requirements, the tables also suggest a method or document with which to demonstrate compliance with each criterium.

In part I of Annex I to the FPR the following product function categories (PFCs) are designated:

PFC 1. Fertiliser
- A. Organic fertiliser
  - I. Solid organic fertiliser
  - II. Liquid organic fertiliser
- B. Organo-mineral fertiliser
  - I. Solid organo-mineral fertiliser
  - II. Liquid organo-mineral fertiliser
- C. Inorganic fertiliser
  - I. Inorganic macronutrient fertiliser including sub-categories
    - a. Solid inorganic macronutrient fertiliser
      - i. Straight solid inorganic macronutrient fertiliser
      - A. Straight solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content
      - ii. Compound solid inorganic macronutrient fertiliser
      - A. Compound solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content
    - b. Liquid inorganic macronutrient fertiliser
      - i. Straight liquid inorganic macronutrient fertiliser
      - ii. Compound liquid inorganic macronutrient fertiliser
  - II. Inorganic micronutrient fertiliser including sub-categories
    - a. Straight inorganic micronutrient fertiliser
    - b. Compound inorganic micronutrient fertiliser

PFC 2. Liming material

PFC 3. Soil improver
- A. Organic soil improver
- B. Inorganic soil improver

PFC 4. Growing medium

PFC 5. Inhibitor
- A. Nitrification inhibitor
- B. Denitrification inhibitor
- C. Urease inhibitor

PFC 6. Plant biostimulant
- A. Microbial plant biostimulant
- B. Non-microbial plant biostimulant

PFC 7. Fertilising product blend

Detailed overview of requirements on per product function category and suggested documentation

Note on Test report: Where compliance with a given requirement (such as the absence of a given contaminant) follows certainly and uncontestably from the nature or manufacturing process of an EU fertilising product, that compliance can be presumed in the conformity assessment procedure without verification (such as Test report), at the responsibility of the manufacturer (ANNEX I PART II. 4, FPR). In that case, a statement from the manufacturer in which the compliance is explained and motivated should be added to the technical documentation.

Provision	PFC level	Provision summary	Suggested documention
PFC 1 Fertilisers			
Annex I PFC 1	PFC 1	A PFC 1 product is intended to supply nutrients to plants or mushrooms	Product description
PFC 1 A Organic fertilisers			
Annex I PFC 1 (A) 1	PFC 1 A	Contains organic carbon of biological origin	Component description
Annex I PFC 1 (A) 1	PFC 1 A	Contains nutrients of biological origin	Component description
Annex I PFC 1 (A) 2 and 3	PFC 1 A	Product may not exceed content limits for Cd, Cr VI, Hg, Ni, Pb, As, biuret ($C_2H_5N_3O_2$), Cu, Zn	Test report
Annex I PFC 1 (A) 4	PFC 1 A	Pathogens in the product cannot exceed limits (*Salmonella* spp., *Escherichia coli* or *Enterococcaceae*)	Test report
Annex I PFC 1 (A)(I) 1	PFC 1 A I	The product is solid	Self-evident
Annex I PFC 1 (A)(I) 2	PFC 1 A I	Must contain N, P, and or K with certain minimum contents	Test report
Annex I PFC 1 (A)(I) 3	PFC 1 A I	The organic C content must be >=15% by mass	Test report
Annex I PFC 1(A)(II) 1	PFC 1 A II	A liquid fertiliser must be liquid	Self-evident
Annex I PFC 1(A)(II) 2	PFC 1 A II	Must contain N, P, and or K with certain minimum contents	Test report
Annex I PFC 1(A)(II) 3	PFC 1 A II	The organic C content must be >=5% by mass	Test report

Provision	PFC level	Provision summary	Suggested documention
PFC 1 B Organo-mineral fertilisers			
Annex I PFC 1(B) 1	PFC 1 B	An organo-mineral fertiliser must contain an inorganic fertiliser as specified in PFC 1 (C) and at least one material containing organic carbon and nutrients of solely biological origin (including peat, leonardite and lignite)	List of components/ingredients
Annex I PFC 1(B) 2	PFC 1 B	The ammonium nitrate content must be <16%	Test report
Annex I PFC 1(B) 3 & 4 & 5	PFC 1 B	The product cannot exceed thresholds for contamination with Cd, Cr VI, Hg, Ni, Pb, As, biuret (C2H5N3O2), Cu, Zn, and pathogens	Test report
Annex I PFC 1(B)(I) 1	PFC 1 B I	The product is solid	Self-evident
Annex I PFC 1(B)(I) 2	PFC 1 B I	Must contain N, P, and or K with certain minimum contents	Test report
Annex I PFC 1 (B)(I) 3	PFC 1 B I	the organic C content must be >=5 by mass	Test report
Annex I PFC1 (B)(I) 4	PFC 1 B I	Each physical unit of fertiliser shall contain organic carbon and all declared nutrients in their declared content.	Product description and a description of the manufacturing process
Annex I PFC1 (B)(II) 1	PFC 1 B II	A liquid fertiliser must be liquid	Self-evident
Annex I PFC1 (B)(II) 2	PFC 1 B II	Must contain N, P, and or K with certain minimum contents	Test report
Annex I PFC1 (B)(II) 3	PFC 1 B II	the organic C content must be >=3 by mass	Test report
PFC 1 C Inorganic fertilisers			
Annex I PFC (C) 1	PFC 1 C	An inorganic fertiliser is a fertiliser which is not an organic- or organo mineral fertiliser	Product description
Annex I PFC (C) 2	PFC 1 C	The product may not exceed thresholds for pathogens if it contains certain amounts of organic C	If the organic carbon content >1% by mass. Either a description of the origin of the organic carbon to show it does not need to pass the pathogen criteria or an analysis report to prove that is passes the criteria for pathogens
Annex I PFC (C)(I) 1	PFC 1 C I	Must contain N, P, K, Ca, Mg, Na, and or S	Product description

Provision	PFC level	Provision summary	Suggested documention
Annex I PFC (C)(I) 2 & 3	PFC 1 C I	Must not exceed limits for Cd, Cr VI, Hg, Ni, Pb, As, biuret (C2H5N3O2), perchlorate (ClO2), Cu, and Zn	Test report
Annex I PFC 1(C)(I)(a)	PFC 1 C I a	The product is solid	Self-evident
Annex I PFC 1(C)(I)(a)(i) 1& 2	PFC 1 C I a i	The product contains at least minimum amounts of N, P, K, Ca, Mg, Na, or S OR one of N, P, K and one of Ca, Mg, Na, or S. For a total of at least 18%	Test report
Annex I PFC 1(C)(I)(a)(ii) 1 & 2	PFC 1 C I a ii	The product contains at least minimum amounts of at least two of N, P, K or at least two of Ca, Mg, Na, and S. For a total of at least 18%. Total Na content (Na2O) must be <= 40% by mass	Test report
Annex I PFC 1(C)(I)(a)(i-ii)(A) 1	PFC 1 C I a i-ii A	Must contain >= 28% by mass of ammonium nitrate (NH4NO3)	Test report
Annex I PFC 1(C)(I)(a)(i-ii)(A) 2	PFC 1 C I a i-ii A	No compounds in the product react with ammonium nitrate	Product description
Annex I PFC 1(C)(I)(a)(i-ii)(A) 3	PFC 1 C I a i-ii A	The product is only made available in packaged form. The seal or opening must be visibly and irreparably damaged upon opening.	A description of the packaging
Annex I PFC 1(C)(I)(a)(i-ii)(A) 4	PFC 1 C I a i-ii A	The product is save with regards to oil retention	Test report on oil retention test under the supervision of a NoBo
Annex I PFC 1(C)(I)(a)(i-ii)(A) 5	PFC 1 C I a i-ii A	The product is save with regards to detonation	Test report on detonation test under the supervision of a NoBo
Annex I PFC 1(C)(I)(a)(i-ii)(A) 6	PFC 1 C I a i-ii A	The product is save with regards to combustible material content	Test report
Annex I PFC 1(C)(I)(a)(i-ii)(A) 7	PFC 1 C I a i-ii A	A solution of 10 g of a straight or compound solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content in 100 ml of water must have a pH of at least 4,5.	Test report
Annex I PFC 1(C)(I)(a)(i-ii)(A) 8	PFC 1 C I a i-ii A	The product may not contain more than a given fraction of fine particles	Sieve analysis report
Annex I PFC 1(C)(I)(a)(i-ii)(A) 9	PFC 1 C I a i-ii A	The product does not exceed limits for Cu and Cl content.	Test report
Annex I PFC 1(C)(I)(b)	PFC 1 C I b	A liquid fertiliser must be liquid	Self-evident

Provision	PFC level	Provision summary	Suggested documention
Annex I PFC 1(C)(I)(b)(i) 1	PFC 1 C I b i	The product contains at least minimum amounts of N, P, K, Ca, Mg, Na, or S OR one of N, P, K and one of Ca, Mg, Na, or S. For a total of at least 7%. Sodium content not exceeding a threshold.	Test report
Annex I PFC 1(C)(I)(b)(ii) 1	PFC 1 C I b ii	The product contains at least minimum amounts of at least two of N, P, K or at least two of Ca, Mg, Na, and S. For a total of at least 7%. Sodium content not exceeding a threshold.	Test report
Annex I PFC1(C)(II) 1	PFC 1 C II	Supplies B, Co, Cu, Fe, Mn, Mo, or Zn to plants or Mushrooms	Test report
Annex I PFC1(C)(II) 2	PFC 1 C II	The product must be packaged	Description of the packaging
Annex I PFC1(C)(II)	PFC 1 C II	The product cannot exceed limits for contaminants in relation to the micronutrient content for As, Cd, Pb, Hg, Ni	Test report
Annex I PFC 1(C)(II)(a) 1	PFC 1 C II a	Must only have one declared micronutrient	Test report
Annex I PFC 1(C)(II)(a) 2	PFC 1 C II a	The product meets the description and criteria of one typology given in the table under this clause Annex I PFC1(C)(II)(a) 2	Product description and Test report
Annex I PFC 1(C)(II)(b) 1	PFC 1 C II b	Contains at least two declared micronutrients	Product label or description
Annex I PFC 1(C)(II)(b) 2	PFC 1 C II b	The product contains at least 2% by mass micronutrients when liquid or at least 5% when solid	Test report
PFC 2 Liming materials			
Annex I PFC2 1	PFC 2	The product is aimed at correcting soil acidity by containing a liming material limited to oxides, hydroxides, carbonates and silicates of Ca and Mg	Product description and test report
Annex I PFC2 2&3	PFC 2	Must not exceed limits for Cd, Cr VI, Hg, Ni, Pb, As, Cu, Zn	Test report
Annex I PFC2 4 a	PFC 2	Liming materials must have a minimum neutralising value of 15 (equivalent CaO) or 9 (equivalent HO-)	Test report

Provision	PFC level	Provision summary	Suggested documention
Annex I PFC2 4 b	PFC 2	Liming materials must have a minimum reactivity of 10% (determined with hydrochloric acid test) or 50% after 6 months (incubation test)	Test report
Annex I PFC2 4 c	PFC 2	Liming materials must have a minimum grain size where at least 70% is smaller than 1 mm except for burnt limes, granulated liming material, and chalk.	Sieve analysis report
PFC 3 Soil improvers			
Annex I PFC3	PFC 3	The function of a soil improver is to maintain, improve or protect the physical or chemical properties, structure, or biological activity of the soil.	Product description
Annex I PFC3 A 1	PFC 3 A	An organic soil improver shall consist of material 95 % of which is of solely biological origin.	Component description
Annex I PFC3 A 2 & 3 & 4	PFC 3 A	Must not exceed limits for Cd, Cr VI, Hg, Ni, Pb, As, Cu, Zn, and pathogens	Test report
Annex I PFC3 A 5	PFC 3 A	An organic soil improver shall contain 20 % or more dry matter.	Test report
Annex I PFC3 A 6	PFC 3 A	Organic carbon (C org) content in an organic soil improver shall be at least 7,5 % by mass.	Test report
Annex I PFC3 B 2	PFC 3 B	Must not exceed limits for Cd, Cr VI, Hg, Ni, Pb, As, Cu, Zn, and pathogens	Test report
PFC 4 Growing media			
Annex I PFC 4 1	PFC 4	The product is a growing medium for plants, mushrooms, or algae	Product description
Annex I PFC 4 2	PFC 4	Must not exceed limits for Cd, Cr VI, Hg, Ni, Pb, As, Cu, Zn, and pathogens	Test report
PFC 5 Inhibitors			
Annex I PFC 5	PFC 5	An inhibitor improves nutrient release patterns by delaying or stopping the activity of specific groups of micro-organisms or enzymes	Product description

Provision	PFC level	Provision summary	Suggested documention
Annex I PFC 5 A 1	PFC 5 A	A nitrification inhibitor inhibits the conversion of NH3 to NO2	Test report
Annex I PFC 5 A 2	PFC 5 A	The product decreases the rate of ammoniacal nitrogen oxidation during 14 days after application	Test report
Annex I PFC 5 B 1 & 2	PFC 5 B	The product decreases or blocks the conversion of nitrate to N2 without affecting the oxidation of ammoniacal nitrogen.	Test report
Annex I PFC 5 C 1 & 2	PFC 5 C	The product shows a 20% reduction in hydrolysation of urea compared to an untreated control.	Test report
PFC 6 Plant biostimulants			
Annex I PFC 6 1	PFC 6	The product has at least one of the described functions.	Literature review, field trials, lab trials, and or pot trials.
Annex I PFC 6 2 & 3	PFC 6	Must not exceed limits for Cd, Cr VI, Hg, Ni, Pb, As, Cu, Zn	Test report
Annex I PFC 6 4	PFC 6	The label must specify to which plants the claimed functions apply	Label specimen
PFC 6 A 1	PFC 6 A	The product contains a least one of the allowed micro-organisms	List of components
PFC 6 A 2	PFC 6 A	The product does not exceed limits for pathogens	Test report
PFC 6 A 3	PFC 6 A	When liquid, the pH must be optimal for the contained micro-organisms	Test report
PFC 6 B 2	PFC 6 B	The product does not exceed limits for pathogens	Test report
PFC 7 Fertilising product blends			
Annex I PFC 7 1	PFC 7	A blend must contain at least two CE fertilising products	List of component EU fertilising products
Annex I PFC 7 2	PFC 7	Blending does not change the nature of the product. Storage and usage of the blend does not have a negative effect on human, animal, or plant health or safety or the environment.	Test, calculations, or statements to demonstrate that the blend does not behave differently compared to the situation where the component fertilising products are used separately.

Provision	PFC level	Provision summary	Suggested documention
Annex I PFC 7 2a	PFC 7	When the blend contains an inhibitor, the inhibitor is present in such a quantity that the blend meets the reduction thresholds set for inhibitors	Calculations to demonstrate that the blended product is inhibited within the range referred to in the requirements for PFC 5.
Annex I PFC 7 3	PFC 7	The manufacturer asserts that the blend conforms to the FPR	EU declaration of conformity (DoC) of the component products
Annex IV Part I point 3	PFC 7	A blend containing 28% or more of of nitrogen from a PFC 1 C I a i-ii (A) product, the blend is save with regards to oil retention	Test report on oil retention test under the supervision of a NoBo
Annex IV Part I point 3	PFC 7	A blend containing 28% or more of of nitrogen from a PFC 1 C I a i-ii (A) product, the blend is save with regards to detonation	Test report on detonation test under the supervision of a NoBo

Part III

CMC

Contents

Component material categories

DESIGNATION OF CMCs (Annex II Part I to the FPR consolidated16.03.2023)

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 within the meaning of Regulation (EC) No 1069/2009

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

CMC 12: Precipitated phosphate salts and derivates

CMC 13: Thermal oxidation materials and derivates

CMC 14: Pyrolysis and gasification materials

CMC 15: Recovered high purity materials

1 CMC 1 Virgin material substances and mixtures

Component material category (CMC) 1, comprises virgin material substances and mixtures. By-products and waste are non-virgin materials and do not belong to CMC 1. Furthermore, almost all CMC 1 components must have a REACH registration for use in fertilising products. This chapter first lists the requirements and FPR provisions that apply to CMC 1 materials. Components that act as chelating, complexing agents, or inhibiting agents are subject to additional requirements.

Related provision	Provision summary	Suggested documents
Annex II CMC 1 1	A CMC 1 material is a substance or mixture. A restrictive list of materials is excluded from CMC 1.	Component description
Annex II CMC 1 2	The material has a REACH registration with information provided by Annexes VI, VII, and VIII to REACH and a chemical safety report as described in Article 14 of REACH.	REACH documentation
Annex II CMC 1 3	Any substance intended to enhance long term plant availability of micronutrients must be a chelating- or complexing agent and comply with a set of specific criteria.	Component description, description of its chemical structure reports on product stability
Annex II CMC 1 4	When a CMC 1 material is intended to improve nutrient release patterns, it must be either a nitrification, denitrification, or urease inhibiting compound and must meet specific criteria.	Component description, analysis reports on inhibiting functioning, and evidence that the product has sufficient inhibiting compound and the required form of nitrogen.

1.1 General description of virgin substances and mixtures

A description of the material and its origin or production process should demonstrate that the material is a virgin substance or mixture and does not belong to the excluded categories of materials.

Some substances or mixtures could be defined as either a product or as a by-product, depending on the production process that they result from. As CMC 1 excludes by-products —which belong in CMC 11— information on the origin and the manufacturing process of the substance or mixture should be included in the technical documentation to demonstrate that the material is indeed a virgin material belonging to CMC1.

RESOURCES

Substances (chemicals and compounds) and **mixtures** (mixtures or solutions or two or more substances) are defined under the REACH regulation (Regulation (EC) No 1907/2006), a link to the consolidated version can be found here. Detailed information and guidance on substances and substance identity can be found on the ECHA website on Substance identification and in the Guidance on identification and naming of substances under REACH and CLP.

Waste and **by-products** are defined in the Waste Framework Directive 2008/98/EC; a link to the consolidated version can be found here. More background on the distinction between waste and non-waste can be found here and in the Commission notice on technical guidance on the classification of waste (2018/C124/01).

Animal by-products and derived products are defined in the Animal By-Product Regulation (EC) No 1069/2009; a link to the consolidated version can be found here. More information on **animal by-products** can be found here and on the websites of the national competent authorities, listed here.

More information and guidance on what constitutes a **polymer** can be found in the Guidance for monomers and polymers on the ECHA website.

FAQ

See the FAQ document on the FPR to check:

- If CMC 1 **applies to plants** (Q8.3)
- What does polymer mean (Q 8.8)
- What constitutes a **biodegradable or soluble polymer** (Q8.9)
- If CMC 1 covers **precursors and additives** used for the production of the component materials (Q8.13)
- If **impurities** are considered as CMC 1 components (Q8.17)
- If CMC 1 covers **ammonium sulphate from caprolactam or coke oven production** (Q8.10)
- How to demonstrate the conformity of **materials that are obtained from third parties**, and provide information on **origin and manufacturing** (Q10.13)

1.2 REACH registration obligation

Compliance with the REACH registration requirement can be demonstrated with the REACH registration number of the substance. A REACH registration number is composed as 01-XXXXXXXXXX-XX-XXXX. For the first two digits, the combination 01 indicates the substance is registered. The last 4 digits of the registration number show the manufacturer's identification. The registration number should preferably include the four digits indicating the manufacturer's registration.

Compliance with the chemical safety assessment requirement for the use as a fertilising product can be demonstrated by the indication of the Product category PC12 'Fertilisers' in the Registration file and on the compiled MSDS that is provided by the supplier. See the text box Resources & FAQ in case no SDS is provided.

If a material is covered by one of the registration obligation exemptions provided for by CMC 1. point 2, the description of the material should include an explicit reference to the applicable REACH Annex IV or V, with the EINECS No, the substance name/group, and the CAS No as listed.

RESOURCE

Substances (chemicals and compounds) and **mixtures** (mixtures or solutions or two or more substances) are defined under the REACH regulation (Regulation (EC) No 1907/2006), a link to the consolidated version can be found here. Detailed information and guidance on substances and substance identity can be found on the ECHA website on Substance

identification and in the Guidance on identification and naming of substances under REACH and CLP.

More information and guidance on the **registration of substances** can be found on the ECHA website on Registration and in the REACH Guidance on registration.

Information on **the exemption from the obligation to register provided by Annex V** to REACH can be found in Guidance to Annex V.

Information on the **chemical safety assessment** can be found in the information REACH Guidance on information requirements and chemical safety assessment.

Guidance can be found at the REACH for fertilizers platform, created by Fertilizers Europe, with specific **tools for both the REACH registrants of fertiliser substances and the fertilizer manufacturers**. This website includes the Fertilizers Environmental Exposure (FEE) tool for the environmental exposure assessment, taking into account the local scenario for direct emissions to soil and surface water.

Resolution on 'What would be considered **sufficient evidence to verify compliance with REACH**?' can be found in the CLARIFICATIONS & RESOLUTIONS DOCUMENT by the Notified Bodies, under Folder 7 of the Coordination Group of Notified Bodies within the CIRCABC page for the Commission Expert Group on Fertilising Products. This also covers the case where a **third-party supplier does not provide the REACH registration number or the PC12 mentioned on the SDS.**

FAQ

See the **FAQ document on the FPR** to check:

- If **substances, whose annual market volume is below one tonne**, have to be registered under REACH with a Chemical Safety Report for the purpose of the FPR (Q 8.4)
- **How to register** substances under REACH for the purpose of the FPR (Q 8.5)
- **Who has to register** under REACH? (Q 8.6)
- Do **monomers of a CMC 1 or CMC 11 polymer** have to have a REACH registration in accordance with the FPR? (Q 8.10)
- How to demonstrate the REACH registration and chemical safety report for **component materials that are obtained from third parties** (Q 10.13)
- Whether **substances already registered, exported and then imported into the EU** have to be registered if used in EU fertilising products(Q 8.7)
- Whether **raw minerals** -like phosphate rock- need to be REACH registered (8.12)
- Do **the precursors or reactants** used to produce a CMC 1 component material need to be REACH registered with a chemical safety report covering the use as a fertilising product (Q8.10)
- Do **technical additives** that are used in fertilising products for processing and handling need to be REACH registered with a chemical safety report covering their use in fertilising products (Q 8.12)
- Does the obligation for REACH registration in CMC 1 apply to **preservative agents** incorporated in fertilising products that are already approved under the Biocidal Products Regulation? (Q 8.11)
- A substance or mixture belonging to CMC 1 may contain **detectable traces of unreacted ingredients or processing agents**. Should these **impurities** be separately considered as components of the final composition of a fertilising product? (Q8.14)

1.3 Chelating and complexing compounds

Additional requirements are in place for substances that are added to fertilising products as chelating agents or complexing agents. The functioning as a chelating or complexing agent must be clearly indicated in the component's description.

The description should also include sufficient information to ascertain compliance with the criteria on the molecular composition or structure of the agent. This can be demonstrated with the molecular

formula and the image of the chelating or complexing substance, which is part of the REACH registration.

1.4 Inhibiting compounds

Additional requirements are in place for substances that are inhibiting compounds. Inhibiting compounds can be either a **nitrification**, **denitrification**, or **urease inhibiting compound**. The inhibiting function of a component should be included in the description of the material, specifying which process is inhibited. The functioning of the inhibiting compound should be demonstrated with reports on the relevant tests demonstrating that the required reduction in emissions is achievable with the compound.

1.5 Overview of documentation

The list below summarises the documents that could be included in the technical documentation for CMC 1 components. Note that not each document listed here necessarily must be included and that the documents may be combined.

1. A description of the component including its origin or manufacturing process to support that the component is not a by-product or waste.
2. The REACH registration number (preferably including manufacturer digits) and manufacturer's MSDS with the mention of the use as fertiliser.
3. For chelating agents and complexing agents:
    a. a description of the chemical structure of the component
    b. a report on the stability of the component
4. For inhibiting compounds: documents such as test reports demonstrating that the required reduction in emissions is achievable with the compound.

2 CMC 2 Plants, plant parts or plant extracts

Component material category (CMC) 2, comprises plants, plant parts, and plant extracts. A CMC 2 material must comply with two criteria, the first relates to the nature of the material, the second to the processing that the material underwent.

Related provision	Provision summary	Suggested documents
Annex II CMC 2	CMC 2 materials are plants, plant parts or plant extracts, including mushrooms and algae.	Description of the nature of the material.
Annex II CMC 2	The material has undergone no or only certain methods of processing as specified on a limited list.	Description of processing of material and process schemes.

2.1 Plants, parts and extracts

Materials of CMC 2 can be plants, plant parts, or plant extracts, including mushrooms and algae but not blue-green algae (cyanobacteria) that have undergone no or only certain methods of processing.

Compliance with the first criterion can be demonstrated with a description of the nature of the material.

Compliance with the second criterion can be demonstrated by describing the processing of the material.

RESOURCES

The **EU rules on plant health** (Regulation (EU) 2016/2031) and **invasive species** (Regulation (EU) No 1143/2014) apply to plants in CMC 2 and should be considered by the manufacturer. Regulation (EU) 2016/2031 on protective measures against pests of plants, link to consolidated version here, and invasive species (Regulation (EU) No 1143/2014 on prevention and management of the introduction and spread of invasive alien species, link to the consolidated version here).

Waste, biowaste and **by-products** are defined in the Waste Framework Directive 2008/98/EC; a link to the consolidated version can be found here.

FAQ

See the FAQ document on the FPR to check:

- If CMC 2 covers **micro-algae** (Q8.20)
- If CMC 2 covers **blue-green algae (cyanobacteria)** (Q8.23)
- If CMC 2 covers **seaweed extracted with alkaline solution** (Q8.24)
- How to treat **impurities** in CMC 2 materials (Q 8.21)
- Whether a component material belonging to CMC 2 can be a **waste or by-product** (Q 8.22)

- Does a material obtained via **infusion of plants or plant parts at 100 degrees Celsius** followed by sieving belong to CMCs 2 or 6? (Q 8.25)

2.2 Overview of documentation

The documents that could be included in the technical documentation for CMC 2 components:

1. Documentation describing the nature or origin of the material and all processing that the material underwent.

3 CMC 3 Compost

Component material category (CMC) 3 comprises compost. The criteria for CMC 3 compost relate to five aspects of the material:

1. the input materials of the composting process
2. the plant in which the composting takes place
3. the temperature and time of the aerobic composting process
4. thresholds of contaminants in the material
5. the stability of the compost material

Related provision	Provision summary	Suggested documents
Annex II CMC 3 1	A CMC 3 material is a compost obtained through aerobic composting of exclusively one or more input materials from a limited list of materials, or additives with REACH registration set out in point 2 in CMC 1.	Description of the input materials and for additives, documentation of REACH registration. If the compost contains materials which have previously been composted or digested, proof that this material does not contain more than 6 mg kg^{-1} dry matter of PAH_{16}.
Annex II CMC 3 1a	Certain Animal by-products of Category 2 or Category 3 materials as well as materials derived thereof, may be used as input for composting if an end point has been determined and will be reached before placing the product on the market	Description of the input material. Documentation that the end point has been determined and will be reached before the EU fertilising product containing the component material is placed on the market.
Annex II CMC 3 2	The compost is produced in a plant where production lines for processing of allowed, and not allowed input materials are clearly separated. Input and output materials are physically separated at all times.	A written description and a diagram of the composting process, where each treatment, storage vessel, and area is clearly identified.
Annex II CMC 3 3	The compost is produced with one of the prescribed temperature-time profiles.	Description of the composting process
Annex II CMC 3 4	The compost must meet criteria for maximum PAH_{16}, glass, metal, and plastic contents.	Test reports.
Annex II CMC 3 5	The compost must meet criteria for stability.	Test reports.

3.1 Compost input materials

Compliance with the input material criteria can be demonstrated with a description of the input material themselves. For most materials, a description of the origin of the input material is required.

For bio-waste, the description should indicate whether it contains animal by-products (‘catering waste’ such as separately collected municipal waste) or not (non-food plant waste such as garden waste).

For input materials which have previously been composted or anaerobically digested, a test report or producer declaration to demonstrate that PAH_{16} content is below the threshold level.

For additives, the intended purpose should be described. The description should also include a calculation to show that the total percentage of additives in the material does not exceed 5% of the total input material by weight.

RESOURCES

Bio-waste and **separate collection** are defined in the Waste Framework Directive 2008/98/EC; a link to the consolidated version can be found here.

The definition of '**catering waste**' to distinguish the bio-waste that is considered an animal by-product can be found in Annex I Definitions of the Animal by-product implementing regulation (EU) No 142/2011; a link to the consolidated version here.

Animal by-products and derived products are defined in the Animal by-product regulation (EC) No 1069/2009; a link to the consolidated version can be found here. More information on **animal by-products** can be found here and on the websites of the national competent authorities, listed here**.**

Also, see the Commission Delegated Regulation (EU) 2023/1605 on **determining end points in the manufacturing chain** here.

FAQ

See the FAQ document on the FPR to check:

- How to treat **impurities** in CMC 3 materials (Q8.21)
- Whether a compost that does not meet **national end-of-waste criteria** can be used as CMC 3 compost (Q8.26)
- Whether **plants or plant parts** can be used as an input material for CMC 3 compost (Q 8.27)
- Can **bio-waste containing animal by-products** be used as input material in compost or digestate? (Q 8.30)
- Can products derived from **animal by-products** be used as input material for CMC 3 compost (Q8.31)
- Whether **bio-refinery outputs** can be considered as input material 'living or dead organisms' for CMC 3 compost (Q 8.29)
- What is meant by **sewage sludge, industrial sludge and dredging sludge** (Q8.32)
- Can sludges that are allowed in the context of **the ECOLABEL decision** be used as input material for CMC 3 composts (Q8.32)
- How to demonstrate the **conformity of composts that are obtained from third parties** (Q10.13 and Q10.19)

3.2 REACH registration for additives

Compliance with the REACH registration requirement for additives can be demonstrated with the REACH registration number of the substance. A REACH registration number is composed as 01-XXXXXXXXXX-XX-XXXX. For the first two digits, the combination 01 indicates the substance is registered. The last 4 digits of the registration number show the manufacturer's identification. The registration number should preferably include the four digits indicating the manufacturer's registration.

Compliance with the chemical safety assessment requirement for the use as a fertilising product can be demonstrated by the indication of the Product category PC12 'Fertilisers' in the Registration file and on the compiled MSDS that is provided by the supplier. See the text box Resources & FAQ in case no SDS is provided.

If an additive is covered by one of the registration obligation exemptions provided for by CMC 1. point 2, which also applies to this CMC, the description of the additive should include an explicit reference to

applicable REACH Annex IV or V, with the EINECS No, the substance name/group, and the CAS No as listed.

RESOURCES

Substances (chemicals and compounds) and **mixtures** (mixtures or solutions or two or more substances) are defined under the REACH regulation (Regulation (EC) No 1907/2006), a link to the consolidated version can be found here. Detailed information and guidance on substances and substance identity can be found on the ECHA website on Substance identification and in the Guidance on identification and naming of substances under REACH and CLP.

More information and guidance on the **registration of substances** can be found on the ECHA website on Registration and in the REACH Guidance on registration.

Information on **the exemption from the obligation to register provided by Annex V** to REACH can be found in Guidance to Annex V.

Information on the **chemical safety assessment** can be found in the information REACH Guidance on information requirements and chemical safety assessment.

Guidance can be found at the REACH for fertilizers platform, created by Fertilizers Europe, with specific **tools for both the REACH registrants of fertiliser substances and the fertilizer manufacturers**. This website includes the Fertilizers Environmental Exposure (FEE) tool for the environmental exposure assessment, taking into account the local scenario for direct emissions to soil and surface water.

Resolution on 'What would be considered **sufficient evidence to verify compliance with REACH**?' can be found in the CLARIFICATIONS & RESOLUTIONS DOCUMENT by the Notified Bodies, under Folder 7 of the Coordination Group of Notified Bodies within the CIRCABC page for the Commission Expert Group on Fertilising Products. This also covers the case where a **third-party supplier does not provide the REACH registration number or the PC12 mentioned on the SDS.**

FAQ

See the FAQ document on the FPR to check:

- Do **technical additives** that are used in composting need to be REACH registered with a chemical safety report covering their use in a fertilising product (Q 8.15).
- If **substances, whose annual market volume is below one tonne**, have to be registered under REACH with a Chemical Safety Report for the purpose of the FPR (Q 8.4)
- **How to register** substances under REACH for the purpose of the FPR (Q 8.5)
- **Who has to register** under REACH? (Q 8.6)
- How to demonstrate the **REACH registration and chemical safety report for component materials that are obtained from third parties** (Q10.13)
- Whether substances **already registered, exported and then imported into the EU** have to be registered if used in EU fertilising products(Q 8.7)

3.3 Compost derived from Animal by-products

Compliance with the requirements for the compost derived from animal by-products can be shown with the commercial document from the compost producer indicating that the compost is produced in a plant that is approved by the national competent authority, demonstrated by an approval certificate. The approval certificate should clearly indicate that the plant is approved in the EU to produce the compost with the end point in the manufacturing chain for organic fertilisers and soil improvers in accordance with conditions of Delegated Regulation (EU) 2023/1605 on end points for fertilisers.

The approval certificate also contains a unique approval number, which is linked to Section XII 'Establishments or plants manufacturing organic fertilisers or soil improvers' on the national lists of

approved ABP establishments. The approved plants for the manufacturing of organic fertilisers or soil improvers should have the Remark 'End point in the manufacturing chain'.

ESOURCES

Animal by-products and derived products are defined in the Animal by-product regulation (EC) No 1069/2009; a link to the consolidated version can be found here. More information on **animal by-products** can be found here and on the websites of the national competent authorities, listed here.

Conditions for compost derived from animal by-products to reach the **End points in the manufacturing chain** are determined in Delegated Regulation (EU) 2023/1605 on End points for fertilisers; a link can be found here. A link to the consolidated version of Implementing Regulation (EU) No 142/2011 with the criteria can be found here.

A list of the websites with **contact details of the national competent authorities** and a **list of the approved APB establishments** per EU member state can be found here. More information on **animal by-products** can be found here.

FAQ

See the FAQ document on the FPR to check:

- *In preparation*

3.4 Requirements for the production plant

Compliance with the criteria for the composting plant can be demonstrated with a detailed description of the composting plant. This description must include descriptions of the production lines and clarify how it is ensured that input materials that are allowed for the production of CMC 3 materials are separated at all times from materials that are excluded. From the description, it must also become clear how input and output materials are physically separated. A diagram of the composting process where each treatment, storage vessel, and area is clearly identified must be included.

3.5 Process conditions

Compliance with the criteria for the process condition should be demonstrated with a written description of the composting process. From the description it should be evident that the aerobic composting process consists of controlled decomposition of biodegradable materials, is predominantly aerobic and allows the development of temperatures suitable for thermophilic bacteria as a result of biologically produced heat. The temperature and time trajectory should be evident as well as how is ensured that all parts of each batch are regularly and thoroughly moved or forced ventilated.

3.6 Contaminants

A CMC 3 material may not contain more than 6 mg kg^{-1} dry matter of PAH_{16}. This should be demonstrated with a test report.

Furthermore, a CMC 3 material may not contain more than 3 g/kg dry matter of macroscopic impurities larger than 2 mm in the form of glass, metal, or plastic. Taken together, the content of these macroscopic impurities may not exceed 5 mg kg^{-1} dry matter.

Note: From 16 July 2026, the presence of plastics above 2 mm must be no more than 2,5 g/kg dry matter. By 16 July 2029, the limit value of 2,5 g/kg dry matter for plastics above 2 mm must be re-assessed to take into account the progress in separated bio-waste collection.

Having samples of the materials analysed on these compounds and summing their totals is the most straightforward method to demonstrate compliance.

3.7 Stability

Compliance with the requirement for stability can be shown with a test report for the suitable testing method: the oxygen uptake rate or the self-heating factor.

3.8 Overview of documentation

The list below summarises the documents that could be included in the technical documentation for CMC 3 materials.

1. A document or documents describing the origin of the compost's input material(s), how they are collected, how they were processed if at all, and what their purpose is if they are added as composting additives.
2. For components included as composting additives: the REACH registration number (preferably including manufacturer digits) and manufacturer's MSDS with the mention of the use as fertiliser.
3. Where additives are used: calculation showing that the total concentration of all additives in the compost does not exceed 5% of the total input material by weight.
4. For compost obtained from animal by-products, a commercial document that the material has been produced in a plant in the EU that has been approved for the production of organic fertilisers and soil improvers that reach an end point in the manufacturing chain, and the approval certificate with the mentioning of the endpoint processing from the national competent authority for that plant.
5. A document describing the composting plant, including as diagram of the digestion process where each treatment, storage vessel, and area is clearly identified.
6. A document describing the composting process. The temperature and time trajectory should be evident as well as how is ensured that all parts of each batch are regularly and thoroughly moved or forced ventilated.
7. Reports on analyses of the PAH_{16} content of the material.
8. Report on contamination with macroscopic impurities.
9. Calculations on the total amount of macroscopic impurities.
10. Report of an analysis of the oxygen uptake rate or self-heating factor.

4 CMC 4 Fresh crop digestate

Component material category (CMC) 4 comprises fresh crop digestate. The criteria for CMC 4 relate to:

- The origin of the input material.
- The plant in which the digestion took place.
- The digestion process.
- Post-digestion-processing.
- Material stability.

Related provision	Provision summary	Suggested documents
Annex II CMC 4 1	A CMC 4 material is digestate from anaerobic digestion of plant or plant parts grown for biogas production, or additives with REACH registration set out in point 2 in CMC 1.	Description of the input materials and for additives, documents on REACH registration.
Annex II CMC 4 2	The digestate is produced in a plant where production lines for processing allowed and forbidden input materials are clearly separated. Input and output materials are physically separated at all times.	Description of the digestion plant and storage.
Annex II CMC 4 3, 3a, 3b, 3c	The digestion process must follow one of the given temperature-time profiles and may undergo certain -processing methods.	Description of the digestion process and additional processing.
Annex II CMC 4 4	Digestate (fractions) must meet criteria for stability.	Test reports.

4.1 Digestion input materials

Compliance with the input material criteria can be demonstrated with a description of the input materials.

For additives, the intended purpose should be described. The description should also include a calculation to show that the total percentage of additives in the material does not exceed 5% of the total input material by weight.

FAQ

See the FAQ document on the FPR to check:

- How to treat **impurities** in CMC 4 materials (Q 8.21)
- Whether a digestate that does not meet **national end-of-waste criteria** can be used as CMC 4 digestate (by analogy to CMC 5 digestates Q8.26)
- How to demonstrate the conformity of digestates that are **obtained from third parties** (Q10.13 and Q10.19)

4.2 REACH registration for additives

Compliance with the REACH registration requirement for additives can be demonstrated with the REACH registration number of the substance. A REACH registration number is composed as 01-XXXXXXXXXX-XX-XXXX. For the first two digits, the combination 01 indicates the substance is registered. The last 4 digits of the registration number show the manufacturer's identification. The registration number should preferably include the four digits indicating the manufacturer's registration.

Compliance with the chemical safety assessment requirement for the use as a fertilising product can be demonstrated by the indication of the Product category PC12 'Fertilisers' in the Registration file and on the compiled MSDS that is provided by the supplier. See the text box Resources & FAQ in case no SDS is provided.

If an additive is covered by one of the registration obligation exemptions provided for by CMC 1 point 2, which also applies to this CMC, the description of the additive should include an explicit reference to applicable REACH Annex IV or V, with the EINECS No, the substance name/group, and the CAS No as listed.

RESOURCES

Substances (chemicals and compounds) and **mixtures** (mixtures or solutions or two or more substances) are defined under the REACH regulation (Regulation (EC) No 1907/2006), a link to the consolidated version can be found here. Detailed information and guidance on substances and substance identity can be found on the ECHA website on Substance identification and in the Guidance on identification and naming of substances under REACH and CLP.

More information and guidance on the **registration of substances** can be found on the ECHA website on Registration and in the REACH Guidance on registration.

Information on **the exemption from the obligation to register provided by Annex V** to REACH can be found in Guidance to Annex V.

Information on the **chemical safety assessment** can be found in the information REACH Guidance on information requirements and chemical safety assessment.

Guidance can be found at the REACH for fertilizers platform, created by Fertilizers Europe, with specific **tools for both the REACH registrants of fertiliser substances and the fertilizer manufacturers**. This website includes the Fertilizers Environmental Exposure (FEE) tool for the environmental exposure assessment, taking into account the local scenario for direct emissions to soil and surface water.

Resolution on 'What would be considered **sufficient evidence to verify compliance with REACH**?' can be found in the CLARIFICATIONS & RESOLUTIONS DOCUMENT by the Notified Bodies, under Folder 7 of the Coordination Group of Notified Bodies within the CIRCABC page for the Commission Expert Group on Fertilising Products. This also covers the case where a **third-party supplier does not provide the REACH registration number or the PC12 mentioned on the SDS.**

FAQ

See the FAQ document on the FPR to check:

- Do **technical additives** that are used in b**iogas production** need to be REACH registered with a chemical safety report covering the use as fertilising product (Q 8.15)
- If substances, which **annual market volume is below one tonne**, have to be registered under REACH with a Chemical Safety Report for the purpose of the FPR (Q 8.4)
- **How to register** substances under REACH for the purpose of the FPR (Q 8.5)
- **Who has to register** under REACH? (Q 8.6)
- How to demonstrate the **REACH registration and chemical safety report for component materials that are obtained from third parties** (Q10.13)
- Whether substances **already registered, exported and then imported into the EU** have to be registered if used in EU fertilising products(Q 8.7)

4.3 Requirements to the production plant

Compliance with the criteria for the digestion plant can be demonstrated by a detailed description of the digestion plant. This description must include descriptions of the production lines and clarify how it is ensured that input materials that are allowed for the production of CMC 4 materials are separated at all times from materials that are excluded. From the description, it must also become clear how input and output materials are physically separated.

4.4 Digestion process and other processing

Compliance with the criteria for the process condition should be demonstrated with a written description of the digestion process. From the description, it should be evident that the anaerobic digestion process complies with the conditions set for CMC 4 materials. The temperature and time trajectory should be evident as well as how it is ensured that all parts of each batch are regularly and thoroughly moved and turned in order to ensure correct sanitation and homogeneity of the material. A diagram of the digestion production process, where each treatment, storage vessel and area is clearly identified should be included.

Where the digestion is separated in a solid and liquid fraction or has undergone other post-processing methods, this should also be included in the description.

Where additives are used in post-processing the intended purpose should be described. This description should also include a calculation to show that the total percentage of additives in the material does not exceed 5% of the total input material by weight.

FAQ

See the FAQ document on the FPR to check:

- What **post-processes** are allowed for digestate (Q8.28)

4.5 Stability criteria

Compliance with the requirement for stability can be shown with a test report for the relevant stability criteria: the oxygen uptake rate or the residual biogas potential.

4.6 Overview of documentation

The list below summarises the documents that could be included in the technical documentation for CMC 4 materials. Note that not each document listed here necessarily must be included and that the documents may be combined.

1. A document or documents describing the origin of the digestate's input material(s), how they are collected, how they were processed if at all, and for additives, what their purpose is.
2. A document describing the digestion plant, including drawings or schemes illustrating the different production lines and storage facilities.
3. A document describing the digestion process with special attention to the temperature and duration of digestion and where relevant, a description of the pasteurisation or composting.
4. Report of an analysis of the oxygen uptake rate or the residual biogas potential. If the oxygen uptake rate is used, it should be clear from other documents, the report itself, self-evident, or

evident based on the input materials, that the digestate material does not have more than 20% particles larger than 10 mm.

5. For all additives added during digestion or post-processing: The REACH registration number (preferably including manufacturer digits) and manufacturer's MSDS with the mention of the use as fertiliser.

5 CMC 5 Digestate other than fresh crop digestate

Component material category (CMC) 5, comprises digestate other than fresh crop digestate. The criteria for CMC 5 relate to:

- The origin of the input material
- The plant in which the digestion took place
- The digestion process
- Post digestion processing
- Contaminants
- Material stability

Related provision	Provision summary	Suggested documents
Annex II CMC 5 1	A CMC 5 material is a digestate obtained through anaerobic digestion of exclusively one or more materials from a limited list of materials, or additives with REACH registration set out in point 2 in CMC 1.	Description of the material and for additives documentation of REACH registration.
Annex II CMC 5 1a	Certain Animal by-products of Category 2 or Category 3 materials as well as materials derived thereof, may be used as input for digestion if an end point has been determined and will be reached before placing the product on the market.	Description of the input material. Documentation that the end point has been determined and will be reached before the EU fertilising product containing the component material is placed on the market.
Annex II CMC 5 2	The digestate is produced in a plant where production lines for processing materials which are allowed, and other input materials are clearly separated. Input and output materials are physically separated at all times.	A description and a diagram of the digestion process, where each treatment, storage vessel and area is clearly identified.
Annex II CMC 5 3, 3a, 3b, 3c, 3d	The digestate is produced with one of the described temperature-time profiles and may undergo certain additional processing.	Description of the manufacturing process.
Annex II CMC 5 4	The digestate must meet criteria for maximum PAH16.	Test report.
Annex II CMC 5 5	The digestate must meet criteria for maximum glass, metal, and plastic contents.	Test report
Annex II CMC 5 6	Digestate (fractions) must meet criteria for stability.	Test report on the oxygen uptake rate or residual biogas potential.

5.1 Digestion input materials

A CMC 5 material is a digestate obtained by the anaerobic digestion of exclusively one or several of the input materials listed under CMC 5.

Compliance with the input material criteria can be demonstrated with a description of the input material themselves. For most materials, a description of the origin of the input material is required.

For bio-waste, the description should indicate whether it contains an animal by-product ('catering waste' such as separately collected municipal waste) or not (non-food plant waste such as garden waste).

For input materials which have previously been composted or digested, lab reports on the PAH_{16} contents must be included in the technical documentation.

For additives, the intended purpose should be described. The description should also include a calculation to show that the total percentage of additives in the material does not exceed 5% of the total input material by weight.

RESOURCES

Bio-waste and **separate collection** are defined in the Waste Framework Directive 2008/98/EC; a link to the consolidated version can be found here.

The definition of '**catering waste**' to distinguish the bio-waste that is considered an animal by-product can be found in Annex I Definitions of the Animal by-product Implementing Regulation (EU) No 142/2011; a link to the consolidated version here.

Animal by-products and derived products are defined in the Animal by-product regulation (EC) No 1069/2009; a link to the consolidated version can be found here. More information on **animal by-products** can be found here and on the websites of the national competent authorities, listed here. Also, see the Commission Delegated Regulation (EU) 2023/1605 on **determining end points in the manufacturing chain** here.

FAQ

See the FAQ document on the FPR to check:

- How to treat **impurities** in CMC 5 materials (Q 8.21)
- Whether a digestate that does not meet **national end-of-waste criteria** can be used as CMC 5 digestate (Q 8.26)
- Whether **plants or plant parts** can be used as an input material (Q 8.27)
- What post-processes are allowed for digestate (Q 8.28)
- Are manufacturers allowed to use **bio-waste containing animal by-products** as input material in compost or digestate (Q8.30)
- Can products derived from **animal by-products** be used as input material for CMC 5 digestates (Q8.31)
- Whether **bio-refinery outputs** can be considered as input material 'living or dead organisms' for CMC 5 digestate (Q 8.29)
- What is meant by **sewage sludge, industrial sludge, and dredging sludge** (Q 8.32)
- Can sludges that are allowed in the context of the **ECOLABEL decision** be used as input material for CMC 5 composts (Q 8.32)
- How to demonstrate the conformity of digestates that are **obtained from third parties** (Q 10.13 and Q 10.19)

5.2 REACH registration for additives

Compliance with the REACH registration requirement for additives can be demonstrated with the REACH registration number of the substance. A REACH registration number is composed as 01-XXXXXXXXXX-XX-XXXX. For the first two digits, the combination 01 indicates the substance is

registered. The last 4 digits of the registration number show the manufacturer's identification. The registration number should preferably include the four digits indicating the manufacturer's registration.

Compliance with the chemical safety assessment requirement for the use as a fertilising product can be demonstrated by the indication of the Product category PC12 'Fertilisers' in the Registration file and on the compiled MSDS that is provided by the supplier. See the text box Resources & FAQ in case no SDS is provided.

If an additive is covered by one of the registration obligation exemptions provided for by CMC 1. point 2, which also applies to this CMC, the description of the additive should include an explicit reference to applicable REACH Annex IV or V, with the EINECS No, the substance name/group, and the CAS No as listed.

RESOURCES

Substances (chemicals and compounds) and **mixtures** (mixtures or solutions or two or more substances) are defined under the REACH regulation (Regulation (EC) No 1907/2006), a link to the consolidated version can be found here. Detailed information and guidance on substances and substance identity can be found on the ECHA website on Substance identification and in the Guidance on identification and naming of substances under REACH and CLP.

More information and guidance on the **registration of substances** can be found on the ECHA website on Registration and in the REACH Guidance on registration.

Information on **the exemption from the obligation to register provided by Annex V** to REACH can be found in Guidance to Annex V.

Information on the **chemical safety assessment** can be found in the information REACH Guidance on information requirements and chemical safety assessment.

Guidance can be found at the REACH for fertilizers platform, created by Fertilizers Europe, with specific **tools for both the REACH registrants of fertiliser substances and the fertilizer manufacturers**. This website includes the Fertilizers Environmental Exposure (FEE) tool for the environmental exposure assessment, taking into account the local scenario for direct emissions to soil and surface water.

Resolution on 'What would be considered **sufficient evidence to verify compliance with REACH**?' can be found in the CLARIFICATIONS & RESOLUTIONS DOCUMENT by the Notified Bodies, under Folder 7 of the Coordination Group of Notified Bodies within the CIRCABC page for the Commission Expert Group on Fertilising Products. This also covers the case where a **third-party supplier does not provide the REACH registration number or the PC12 mentioned on the SDS.**

FAQ

See the FAQ document on the FPR to check:

- Do **technical additives** that are used in digestion need to be REACH registered with a chemical safety report covering their use as fertilising products (Q 8.15)
- How to demonstrate the **REACH registration and chemical safety report for component materials that are obtained from third parties** (Q10.13)
- If substances, **whose annual market volume is below one tonne**, have to be registered under REACH with a Chemical Safety Report for the purpose of the FPR (Q 8.4)
- **How to register** substances under REACH for the purpose of the FPR (Q 8.5)
- **Who has** to register under REACH? (Q 8.6)
- Whether substances **already registered, exported and then imported into the EU** have to be registered if used in EU fertilising products(Q 8.7)

5.3 Digestate derived from Animal by-products

Compliance with the requirements for digestates derived from animal by-products can be shown with the commercial document from the digestate producer indicating that the digestate is produced in a plant that is approved by the national competent authority, demonstrated by an approval certificate. The approval certificate should clearly indicate that the plant is approved in the EU to produce compost with the end point in the manufacturing chain for organic fertilisers and soil improvers in accordance with conditions of Delegated Regulation (EU) 2023/1605 on end points for fertilisers.

The approval certificate also contains a unique approval number, which is linked to Section XII 'Establishments or plants manufacturing organic fertilisers or soil improvers' on the national lists of approved ABP establishments. The approved plants for the manufacturing of organic fertilisers or soil improvers should have the Remark 'End point in the manufacturing chain'.

RESOURCES

Animal by-products and derived products are defined in the Animal by-product Regulation (EC) **No** 1069/2009; a link to the consolidated version can be found here. More information on **animal by-products** can be found here and on the websites of the national competent authorities, listed here.

Conditions for digestates derived from animal by-products to reach the E**nd points in the manufacturing chain** are determined in Delegated Regulation (EU) 2023/1605 on End points for fertilisers; a link can be found here. A link to the consolidated version of Implementing Regulation (EU) No 142/2011 with the criteria here.

A list of the websites with **contact details of the national competent authorities** and a **list of the approved APB establishments** per EU member state can be found here. More information on **animal by-products** can be found here.

FAQ

See the FAQ document on the FPR to check:

- *In preparation*

5.4 Requirements to the production plant

Compliance with the criteria for the digestion plant can be demonstrated by a detailed description of the digestion plant. This description must include descriptions of the production lines and clarify how it is ensured that input materials that are allowed for the production of CMC 5 materials are separated at all times from materials that are excluded. From the description, it must also become clear how input and output materials are physically separated. A diagram of the digestion process where each treatment, storage vessel, and area is clearly identified must be included.

5.5 Process conditions

Compliance with the criteria for the process condition should be demonstrated with a written description of the digestion process. From the description, it should be evident that the anaerobic digestion process complies with conditions set for CMC 5 materials. The temperature and time trajectory should be evident as well as how it is ensured that all parts of each batch are regularly and thoroughly moved and turned in order to ensure the correct sanitation and homogeneity of the material.

Where the digestion is separated in a solid and liquid fraction or has undergone other post-processing methods this should also be included in the description of the digestion process.

Where additives are used in post-processing the intended purpose should be described. The description should also include a calculation to show that the total percentage of additives in the material does not exceed 5% of the total input material by weight.

FAQ

See the FAQ document on the FPR to check:

- What **post-processes** are allowed for digestate (Q8.28)

5.6 Contaminants

Compliance with the requirements on the content of PAH_{16} and macroscopic impurities can be shown with in the form of glass, metal, or plastic can be demonstrated with a test report.

5.7 Stability criteria

Compliance with the requirement for stability can be shown with a test report for the suitable stability criteria: the oxygen uptake rate or the residual biogas potential.

5.8 Overview of documentation

The list below summarises the documents that could be included in the technical documentation for CMC 5 materials. Note that not each document listed here necessarily must be included and that the documents may be combined.

1. A document or documents describing the origin of the digestate's input material(s), how they were processed if at all, and what their purpose is if they are added as digestion additives.
2. For components included as composting additives: the REACH registration number (preferably including manufacturer digits) and manufacturer's MSDS with the mention of the use as fertiliser.
3. Calculation showing that the total concentration of all additives in the digestate does not exceed 5% of the total input material by weight.
4. For digestate obtained from animal by-products, commercial document that the material has been produced in a plant that has been approved for production of organic fertilisers and soil improvers that reach an end point in the manufacturing chain, including the approval certificate from the national competent authority for that plant.
5. A document describing the digestion plant, including as diagram of the digestion process where each treatment, storage vessel, and area is clearly identified.
6. A document describing the digestion process. From the description of the digestion process, the temperature and time trajectory should be evident as well as how is ensured that all parts of each batch are regularly and thoroughly moved or turned to ensure the correct sanitation and homogeneity.
7. Reports on analyses of PAH_{16} content of the material.
8. Reports on contamination with macroscopic impurities in the input materials and a calculation of the impurities in the final material. Or a report on macroscopic impurities in the final material.
9. Report of an analysis of the oxygen uptake rate or residual biogas potential. If the oxygen uptake rate is used, it should be clear from other documents, the report itself, self-evident, or evident

based on the input materials, that the digestate does not have more than 20% particles larger than 10 mm.

6 CMC 6 Food industry by-products

Component material category (CMC) 6, comprises food industry by-products. Material eligible as CMC 6 must be listed and must have a REACH registration with a designation for use in fertilising products.

Related provision	Provision summary	Suggested documents
Annex II CMC 6 1	A CMC 6 food industry by-product is a material belonging to a limited list of by-products.	Description of input material and origin
Annex II CMC 6.2	The by-product shall comply with the REACH requirements set out in point 2 in CMC 1.	REACH documentation

6.1 Food industry by-products

Food industry by-products in CMC 6 are materials belonging to the limited list of materials under CMC 6. A description of the material and its origin or production process should demonstrate that the material is a food industry by-product belonging to the restricted list under CMC 6.

RESOURCES

Waste and **by-products** are defined in the Waste Framework Directive 2008/98/EC; a link to the consolidated version can be found here.

More background on the distinction between waste and non-waste can be found here and in the Commission notice on technical guidance on the classification of waste (2018/C124/01).

FAQ

See the FAQ document on the FPR to check:

- How to demonstrate the **conformity of by-products that are obtained from third parties** (Q 10.13 and Q 10.19)

6.2 REACH registration obligation

Compliance with the REACH registration requirement can be demonstrated with the REACH registration number of the substance. A REACH registration number is composed as 01-XXXXXXXXXX-XX-XXXX. For the first two digits, the combination 01 indicates the substance is registered. The last 4 digits of the registration number show the manufacturer's identification. The registration number should preferably include the four digits indicating the manufacturer's registration.

Compliance with the chemical safety assessment requirement for the use as a fertilising product can be demonstrated by the indication of the Product category PC12 'Fertilisers' in the Registration file and on the compiled MSDS that is provided by the supplier. See the text box Resources & FAQ in case no SDS is provided.

If a substance is covered by one of the registration obligation exemptions provided for by CMC 1 point 2, which also applies to this CMC, the description of the substance should include an explicit reference to applicable REACH Annex IV or V, with the EINECS No, the substance name/group, and the CAS No as listed.

RESOURCES

Substances (chemicals and compounds) and **mixtures** (mixtures or solutions or two or more substances) are defined under the REACH regulation (Regulation (EC) No 1907/2006), a link to the consolidated version can be found here. Detailed information and guidance on substances and substance identity can be found on the ECHA website on Substance identification and in the Guidance on identification and naming of substances under REACH and CLP.

More information and guidance on the **registration of substances** can be found on the ECHA website on Registration and in the REACH Guidance on registration.

Information on **the exemption from the obligation to register provided by Annex V** to REACH can be found in Guidance to Annex V.

Information on the **chemical safety assessment** can be found in the information REACH Guidance on information requirements and chemical safety assessment.

Guidance can be found at the REACH for fertilizers platform, created by Fertilizers Europe, with specific **tools for both the REACH registrants of fertiliser substances and the fertilizer manufacturers**. This website includes the Fertilizers Environmental Exposure (FEE) tool for the environmental exposure assessment, taking into account the local scenario for direct emissions to soil and surface water.

Resolution on 'What would be considered **sufficient evidence to verify compliance with REACH**?' can be found in the CLARIFICATIONS & RESOLUTIONS DOCUMENT by the Notified Bodies, under Folder 7 of the Coordination Group of Notified Bodies within the CIRCABC page for the Commission Expert Group on Fertilising Products. This also covers the case where a **third-party supplier does not provide the REACH registration number or the PC12 mentioned on the SDS.**

FAQ

See the FAQ document on the FPR to check:

- How to demonstrate the **REACH registration and chemical safety report for component materials that are obtained from third parties** (Q10.13)
- If substances, whose **annual market volume is below one tonne**, have to be registered under REACH with a Chemical Safety Report for the purpose of the FPR (Q 8.4)
- **How to register** substances under REACH for the purpose of the FPR (Q 8.5)
- **Who has to register** under REACH? (Q 8.6)
- Whether **substances already registered, exported and then imported into the EU** have to be registered if used in EU fertilising products(Q 8.7)

6.3 Overview of documentation

1. A description of the origin and processing of a CMC 6 material should suffice in demonstrating compliance with the list of allowed materials.
2. The REACH registration number (preferably including manufacturer digits) and manufacturer's MSDS mentioning the use as fertiliser.

7 CMC 7 Micro-organisms

Component material category (CMC) 7 comprises micro-organisms that may be used in PFC 6(A) Microbial plant biostimulants.

Related provision	Provision summary	Suggested documents
Annex II CMC 7	A CMC 7 micro-organism is a micro-organism, including dead or empty-cell micro-organisms and non-harmful residual elements of the media on which they were produced, which belongs to a limited list of species.	Documentation of the genus, species and strain.
	Micro-organisms may have undergone no or only certain processing.	A description of any processing the material underwent.

7.1 Micro-organisms

Compliance with the criteria can be demonstrated with a description of the component, its contents, and the production process of the material. The material may contain micro-organisms, dead or empty-cell micro-organisms, and non-harmful residual elements of their growing medium. This includes the name of the microorganism and the taxonomic classification of the microorganism: genus, species, strain.

RESOURCES

A resolution of the NoBos on **whether mycorrhizal and bacterial strain(s) from non-European soils** are to be acceptable as a component material(s) of an EU fertilising product can be found in the NoBo PFC 6 Guidance document. That Guidance contains clarifications and resolutions and can be found under the folder of the Coordination Group of Notified Bodies within the CIRCABC page of the Commission Expert Group on Fertilising Products.

FAQ

See the FAQ document on the FPR to check:

- How to treat **impurities** in CMC 8 materials (Q 8.21)

7.2 Overview of documentation

A document with a description of the component including the name and the taxonomic classification of the microorganism: genus, species, strain. This document must also include a description of any processing the material underwent.

8 CMC 8 Nutrient polymers

Component material category (CMC) 8, comprises polymers which degrade into nutrients. Strict criteria apply to CMC 8 polymers with regards to their origin, solubility, and degradation products.

The following requirements apply to CMC 8 materials which are discussed in more detail below.

Related provision	Provision summary	Suggested documents
ANNEX II CMC 8 1	A CMC 8 Nutrient polymer is a polymer which is made up of monomers which comply with the REACH criteria in points 1 and 2 of CMC 1. The purpose of polymerisation must be the controlled release of nutrients from at least one of the monomer substances.	A description of the component and documentation on REACH registration for monomers
ANNEX II CMC 8 2	The component must meet solubility criteria in a phosphate buffer solution with a pH of 7.5 at 100 °C.	Test results on solubility.
ANNEX II CMC 8 3	The polymers must degrade to nothing but ammonia, water and carbon dioxide.	A description of the chemical structure of the polymer and how it degrades.
ANNEX II CMC 8 4	The component may not contain more than 600 ppm of formaldehyde	Test reports.

8.1 Nutrient polymer

A description of the monomers and their origin or production process should demonstrate that the polymer is a virgin substance and does not belong to the excluded categories of materials.

Some substances could be defined as either a product or as a by-product, depending on the production process that they result from. As CMC 1 excludes by-products (which belong in CMC 11) information on the origin and the manufacturing process of the substance should be included in the technical documentation to demonstrate that the material is indeed a virgin material belonging to CMC1.

To demonstrate compliance with the criterion on the controlled release, the description should indicate the purpose of the polymer as the controlled release of nutrients from at least one of the monomer substances.

Resource

More information and guidance on what constitutes a **polymer** can be found in the Guidance for monomers and polymers on the ECHA website.

FAQ

See the FAQ document on the FPR to check:

- How to treat **impurities** in CMC 8 materials (Q 8.21)
- What does **polymer** mean (Q 8.8)
- What constitutes a **biodegradable or soluble polymer** (Q8.9)
- How to demonstrate the **conformity of materials that are obtained from third parties** (Q 10.13 and Q 10.19)

8.2 REACH registration obligation

Compliance with the REACH registration requirement for the constituting monomers can be demonstrated with the REACH registration number of the monomer. A REACH registration number is composed as 01-XXXXXXXXXX-XX-XXXX. For the first two digits, the combination 01 indicates the substance is registered. The last 4 digits of the registration number show the manufacturer's identification. The registration number should preferably include the four digits indicating the substance manufacturer registration.

Compliance with the chemical safety assessment requirement for the use as a fertilising product can be demonstrated by the indication of the Product category PC12 'Fertilisers' in the Registration file and on the compiled MSDS that is provided by the supplier. See the text box Resources & FAQ in case no SDS is provided.

If a material is covered by one of the registration obligation exemptions provided for by CMC 1. point 2, the description of the material should include an explicit reference to applicable REACH Annex IV or V, with the EINECS No, the substance name/group, and the CAS No as listed.

RESOURCES

Substances (chemicals and compounds) and **mixtures** (mixtures or solutions or two or more substances) are defined under the REACH regulation (Regulation (EC) No 1907/2006), a link to the consolidated version can be found here. Detailed information and guidance on substances and substance identity can be found on the ECHA website on Substance identification and in the Guidance on identification and naming of substances under REACH and CLP.

More information and guidance on the **registration of substances** can be found on the ECHA website on Registration and in the REACH Guidance on registration.

Information on **the exemption from the obligation to register provided by Annex V** to REACH can be found in Guidance to Annex V.

Information on the **chemical safety assessment** can be found in the information REACH Guidance on information requirements and chemical safety assessment.

Guidance can be found at the REACH for fertilizers platform, created by Fertilizers Europe, with specific **tools for both the REACH registrants of fertiliser substances and the fertilizer manufacturers**. This website includes the Fertilizers Environmental Exposure (FEE) tool for the environmental exposure assessment, taking into account the local scenario for direct emissions to soil and surface water.

Resolution on 'What would be considered **sufficient evidence to verify compliance with REACH**?' can be found in the CLARIFICATIONS & RESOLUTIONS DOCUMENT by the Notified

Bodies, under Folder 7 of the Coordination Group of Notified Bodies within the CIRCABC page for the Commission Expert Group on Fertilising Products. This also covers the case where a **third-party supplier does not provide the REACH registration number or the PC12 mentioned on the SDS.**

FAQ

See the FAQ document on the FPR to check:

- How to demonstrate the **REACH registration and chemical safety report for component materials that are obtained from third parties** (Q10.13)
- If substances, whose **annual market volume is below one tonne**, have to be registered under REACH with a Chemical Safety Report for the purpose of the FPR (Q 8.4)
- **How to register** substances under REACH for the purpose of the FPR (Q 8.5)
- **Who has to register** under REACH? (Q 8.6)
- Whether **substances already registered, exported and then imported into the EU** have to be registered if used in EU fertilising products(Q 8.7)

8.3 Solubility, degradation products and contaminants

Compliance with the solubility in a phosphate buffer solution can be demonstrated with a test report.

Compliance with the degradation criterion can be demonstrated by describing the chemical structure of the polymer or its monomers and describing the degradation to ammonia (NH_3), water (H_2O), and carbon dioxide (CO_2).

Compliance with the criterion on formaldehyde can be demonstrated by a test report.

8.4 Overview of documentation

The list below summarises the documents that could be included in the technical documentation for CMC 8 materials. Note that not each document listed here necessarily must be included and that the documents may be combined.

1. Description of the polymer and the monomers that it is made up of and its function.
2. A description of the degradation products, this can be combined with a description of the polymer and its monomers.
3. Test results on solubility.
4. Testing report on the formaldehyde content.
5. The REACH registration number (preferably including manufacturer digits) and manufacturer's MSDS with the mention of the use as fertiliser for each monomer in the material.

9 CMC 9 Polymers other than nutrient polymers

Component material category (CMC) 9 comprises polymers other than nutrient polymers. Criteria are in place regarding the component's function and environmental safety.

Related provision	Provision summary	Suggested documents
Annex II CMC 9.1	CMC 9 polymers have the purpose as coating agent, to increase water retention capacity or wettability, or act as a binding agent for PFC 4	Description of polymer substance and function
Annex II CMC 9.2	[Placeholder]	
Annex II CMC 9.3	Toxicity testing	Test reports

9.1 Polymers other than nutrient polymers

Polymers other than nutrient polymers should have the following purpose:

a. to control the water penetration into nutrient particles and thus the release of nutrients (in which case the polymer is commonly referred to as a 'coating agent'),
b. to increase the water retention capacity or wettability of the EU fertilising product,
c. to bind material in an EU fertilising product belonging to PFC 4 (growing medium).

Compliance should be shown in a general description in which the purpose of the CMC 9 component is given.

Resource

More information and guidance on what constitutes a **polymer** can be found in the Guidance for monomers and polymers on the ECHA website.

FAQ

See the FAQ document on the FPR to check:

- How to treat **impurities** in CMC 9 materials (Q 8.21)
- What does **polymer** mean (Q 8.8)
- What constitutes a **biodegradable or soluble polymer** (Q8.9)
- How to demonstrate the **conformity of materials that are obtained from third parties** (Q 10.13 and Q 10.19)

9.2 Degradability criteria

[placeholder]

9.3 Toxicity

Polymers added to control water penetration or increase water retention of the product (a and b listed above) and their degradation must pass a plant growth acute toxicity test, an earthworm acute toxicity test, and a nitrification inhibition test with soil micro-organisms.

Compliance with the criteria can be demonstrated with a test report where the test results meet the experimental conditions specified under CMC 9.3 of Annex II to the FPR.

9.4 Overview of documentation

The list below summarises the documents that could be included in the technical documentation for CMC 9 materials.

1. A description of the component including its purpose in the product.
2. For polymers added to control water penetration or increase water retention of the product,
   - a report demonstrating biodegradability
   - a test report on the plant growth acute toxicity test.
   - a test report on the earthworm acute toxicity test.
   - a test report on the nitrification inhibition test with soil micro-organisms.

10 CMC 10 Products derived from ABP

Component material category (CMC) 10, comprises derived products within the meaning of the Animal By-products Regulation which have reached an endpoint in the manufacturing chain for fertilisers. These materials are to be mentioned in a table, which will need to be established by a delegated act.

Related provision	Provision summary	Suggested documents
Annex II CMC 10	An EU fertilising product may contain certain derived products within the meaning of Regulation (EC) No 1069/2009 that have reached the endpoint in the manufacturing chain as determined in accordance with EC Regulation EC 1069/2009, and which are listed under CMC 10	Placeholder

10.1 Animal by-product derived products

[placeholder]

10.2 Endpoint for derived products

RESOURCES

Animal by-products and derived products are defined in the Animal By-Products Regulation (EC) **No** 1069/2009; a link to the consolidated version can be found here. More information on **animal by-products** can be found here and on the websites of the national competent authorities, listed here.

The conditions for certain animal by-products, such as **manure,** to reach the E**nd points in the manufacturing chain** are determined in Delegated Regulation (EU) 2023/1605 on End points for fertilisers; a link can be found here. A link to the consolidated version of Implementing Regulation (EU) No 142/2011 is here.

A list of the websites with **contact details of the national competent authorities** and a **list of the approved ABP establishments** per EU member state can be found here. More information on **animal by-products** can be found here.

FAQ

See the FAQ document on the FPR to check:

- *In preparation*

11 CMC 11 By-products

Component material category (CMC) 11 comprises by-products within the meaning of directive 2008/98/EC (Waste Framework Directive; WFD). The criteria for CMC 11 materials are laid down in Annex II of the FPR which defines the by-products which may be categorised as CMC 11 and lays down requirements for REACH registration. The detailed criteria for agronomic efficiency and safety for the use of by-products in EU fertilising products are laid down in is delegated regulation (EU) 2022/973[1].

Related provision	Provision summary	Suggested documents
ANNEX II CMC 11 1	A CMC 11 material is a by-product within the meaning of the Directive 2008/98/EC, with exception of restricted list of materials.	Description of the component, and documentation to demonstrate that it meets the conditions for by-product
ANNEX II CMC 11 2	The CMC 11 by-product shall comply with the REACH requirements set out in point 2 in CMC 1.	Proof of REACH registration with the corresponding documents.
(EU)2022/973 Art 1 1	CMC 11 materials may be certain very pure salts or mixtures thereof from certain production processes with a purity of at least 95%, and that are used to provide nutrients or improve nutrition efficiency. These very pure salts or mixtures thereof must meet criteria for C-carbon, PAC and PCDD/PCDF EU Fertilising products containing these very pure salts or mixtures thereof must meet criteria for total chromium (Cr) and thallium (Tl) content.	Description of the production process. Test reports on salt content or constituting elements followed by calculations to contents of salts. Test reports. Test reports.
(EU)2022/973 Art 1 2	CMC 11 materials that are used as technical additives have the role of improving the agronomic efficiency or safety of use of an EU fertilising product, and make up maximum 5% by mass of that product. These materials must meet the criteria for PAH_{16} and PCDD/PCDF content	Material description including role, percentage Test reports.
(EU)2022/973 Art 2 1	CMC 11 by-products may be materials belonging to a limited list of materials.	Description of the component and process where appropriate
(EU)2022/973 Art 2 2	By-products of residues from the processing of sedimentary phosphate ore must not have a radioactivity exceeding 1 kBq kg^{-1}. EU fertilising products containing certain by-products belonging to the limited list of Art 2 1	Test reports on the material's radioactivity and contents of total chromium, thallium and vanadium if applicable, where appropriate.

[1] *Commission Delegated Regulation (EU) 2022/973 of 14 March 2022. supplementing Regulation (EU) 2019/1009 of the European Parliament and of the Council by laying down criteria on agronomic efficiency and safety for the use of by-products in EU fertilising products.*

	must meet criteria on total chromium (Cr), thallium (Tl), and vanadium (V) contents.	
EU/2022/973 Art 4	EU fertilising products containing certain by-products belonging to the limited list of Art 2 1 must indicate selenium (Se) content or chloride (Cl) content under certain conditions.	Test reports, where appropriate.

11.1 By-products

For by-products of CMC 11, the technical documentation should contain the technical and administrative evidence that the by-products comply with the national measures transposing Article 5(1) of Directive 2008/98/EC (Waste Framework Directive; WFD) and, where applicable, implementing acts referred to in Article 5(2) or national measures adopted under Article 5(3) of that Directive.

The article 5.1 of the WFD defines the conditions under which a substance is considered a by-product and not waste. The technical documentation should refer to the national regulations of the MS in which these conditions are implemented, as the WFD does not apply directly. A document should be included that clarifies how the material fulfils the conditions for by-products, including a description of the material and the production process.

The article 5.2 of the WFD refers to EU implementing acts to establish detailed criteria on the application of the conditions for by-product to specific substances or objects. However, no EU implementing acts for materials eligible for the FPR have been adopted yet.

The article 5.3 refers to national law establishing detailed criteria on the application of the conditions for by-product to specific substances or objects. Where the material in CMC 11 is covered by these national criteria, a document should be included that clarifies how the material fulfils the detailed criteria for this by-product in the national law, with reference to the corresponding national rules.

RESOURCES

The criteria for By-products are defined in the Waste Framework Directive 2008/98/EC; a link to the consolidated version can be found here. More background on the **distinction between waste and non-waste** can be found here and in the Commission notice on technical guidance on the classification of waste (2018/C124/01).

A list of **national transpositions** of the Waste Framework Directive by member states can be found here.

The definition **of Animal by-products and derived products** are set out in the Animal By-product Regulation (EC) No 1069/2009; a link to the consolidated version can be found here. More information on **animal by-products** can be found here and on the websites of the national competent authorities, listed here.

The **criteria for CMC 11 by-product materials** are laid down in the **Delegated Regulation (EU)2022/973** laying down criteria on agronomic efficiency and safety for the use of by-products in EU fertilising products. A link can be found here.

More information and guidance on what constitutes a **polymer** can be found in the Guidance for monomers and polymers on the ECHA website.

FAQ

See the FAQ document on the FPR to check:

- If **impurities** are considered as components (Q8.17)
- What does **polymer** mean (Q 8.8)
- What constitutes a **biodegradable or soluble polymer** (Q8.9)
- If CMC 11 covers **ammonium sulphate from caprolactam or coke oven** production (Q8.19)

- How to demonstrate the **conformity of materials that are obtained from third parties** (Q 10.13 and Q 10.19)

11.2 REACH registration obligation

Compliance with the REACH registration requirement can be demonstrated with the REACH registration number of the substance. A REACH registration number is composed as 01-XXXXXXXXXX-XX-XXXX. For the first two digits, the combination 01 indicates the substance is registered. The last 4 digits of the registration number show the manufacturer's identification. The registration number should preferably include the four digits indicating the manufacturer's registration.

Compliance with the chemical safety assessment requirement for the use as a fertilising product can be demonstrated by the indication of the Product category PC12 'Fertilisers' in the Registration file and on the compiled MSDS that is provided by the supplier. See the text box Resources & FAQ in case no MSDS is provided.

If a substance is covered by one of the registration obligation exemptions provided for by Annex II Part II CMC 1. point 2, which also applies to this CMC, the description of the substance should include an explicit reference to applicable REACH Annex IV or V, with the EINECS No, the substance name/group, and the CAS No as listed.

RESOURCES

Substances (chemicals and compounds) and **mixtures** (mixtures or solutions or two or more substances) are defined under the REACH regulation (Regulation (EC) No 1907/2006), a link to the consolidated version can be found here. Detailed information and guidance on substances and substance identity can be found on the ECHA website on Substance identification and in the Guidance on identification and naming of substances under REACH and CLP.

More information and guidance on the **registration of substances** can be found on the ECHA website on Registration and in the REACH Guidance on registration.

Information on **the exemption from the obligation to register provided by Annex V** to REACH can be found in Guidance to Annex V.

Information on the **chemical safety assessment** can be found in the information REACH Guidance on information requirements and chemical safety assessment.

Guidance can be found at the REACH for fertilizers platform, created by Fertilizers Europe, with specific **tools for both the REACH registrants of fertiliser substances and the fertilizer manufacturers**. This website includes the Fertilizers Environmental Exposure (FEE) tool for the environmental exposure assessment, taking into account the local scenario for direct emissions to soil and surface water.

Resolution on 'What would be considered **sufficient evidence to verify compliance with REACH**?' can be found in the CLARIFICATIONS & RESOLUTIONS DOCUMENT by the Notified Bodies, under Folder 7 of the Coordination Group of Notified Bodies within the CIRCABC page for the Commission Expert Group on Fertilising Products. This also covers the case where a **third-party supplier does not provide the REACH registration number or the PC12 mentioned on the SDS.**

FAQ

See the FAQ document on the FPR to check:

- How to demonstrate the **REACH registration and chemical safety report for component materials that are obtained from third parties** (Q10.13)
- Do **monomers of a CMC 1 or CMC 11 polymer** have to have a REACH registration in accordance with the FPR? (Q 8.10)

- If substances, whose **annual market volume is below one tonne**, have to be registered under REACH with a Chemical Safety Report for the purpose of the FPR (Q 8.4)
- **How to register** substances under REACH for the purpose of the FPR (Q 8.5)
- **Who** has to register under REACH? (Q 8.6)
- Whether **substances already registered, exported and then imported into the EU** have to be registered if used in EU fertilising products(Q 8.7)
- Do **technical additives** that are used in fertilising products for processing and handling need to be REACH registered with a chemical safety report covering use as fertilising products (Q 8.15)

11.3 Criteria for by-products

A description of the material and its function must be given in the technical documentation to determine which criteria apply to the material.

Note that some criteria apply on the level of the CMC Where compliance with a given requirement follows certainly and uncontestably from the nature or manufacturing process of the by-product or the EU fertilising product containing the by-product, compliance may be presumed without verification at the responsibility of the manufacturer. If compliance is presumed, include a statement that this is the case in the technical documentation.

Criteria for certain salts used to provide nutrients or improve efficiency

A written description demonstrating that the pure salt by-product material is aimed to provide nutrients or improve efficiency. Compliance with the criteria for by-product salts can be demonstrated with a description of the production plant, demonstrating that the by-product is produced as an integrated part of the production process. A diagram of the production process, where each treatment is identified should be included.

Compliance with the content criteria can be demonstrated by test reports on:

a. the dry matter content of the constituting elements of the ammonium salts, sulphate salts, phosphate salts, elemental sulphur, calcium carbonate or calcium oxide, and calculations to demonstrate the resulting content of salts on dry matter base.
b. Test reports on the organic carbon, PAH_{16}, and PCDD/PCDF,
c. Test reports on total chromium (Cr), and thallium (Tl) contents in the EU fertilising product
d. Reports on selenium (Se) and chloride (Cl^-) contents

Criteria for by-products used as additives

A written description demonstrating that the by-products are aimed to be used as technical additives which have the role of improving the agronomic efficiency or safety of use of the product. Compliance with the criteria of by-product salts can be demonstrated by a description of the production plant, demonstrating that the by-product is produced as an integrated part of the production process. A diagram or scheme of the production process, where each treatment is identified should be included.

Compliance with the content criteria can be demonstrated by test reports on PAH_{16} and PCDD/PDCF contents.

Compliance with the limit on the total content of all additives can be shown by calculations on the percentage of additives in the EU fertilising product.

Criteria for certain by-products belong to limited list

The technical documentation should include written description demonstrating that the by-products belong to the limited list of by-products that are produced from the mentioned processes and complying with the specific conditions thereof.

Compliance with limits of certain contaminants or risks can be demonstrated with test reports on radioactivity, contents of thallium (Tl), vanadium (V), total chromium (Cr), selenium (Se), and chlorine (Cl^-)

11.4 Overview of documentation

The list below summarises the documents that could be included in the technical documentation for CMC 11 materials. Note that not each document listed here necessarily must be included and that the documents may be combined.

1. A description of the by-product including its function, demonstrating that the product fulfils the conditions for by-products, including a reference to national law in which the conditions and criteria are laid down. and a reference to an EU implementing act or national detailed criteria which define by-product criteria.
2. If the by-product is a very pure salt or mixture thereof aimed at providing nutrients:
    a. A description of the production process from which the by-product originates. From this description, it must be clear that the material is produced as an integral part of a production process that does not use animal by-products as input materials.
    b. Test report on the dry matter content of the constituting elements of the ammonium salts, sulphate salts, phosphate salts, elemental sulphur, calcium carbonate or calcium oxide, calculations on the percentage of salts in the material on dry matter base.
    c. Test reports on the organic carbon, PAH_{16}, and PCDD/PCDF, total chromium (Cr), and thallium (Tl) contents.
    d. Test reports on selenium (Se) and chloride (Cl^-) contents.
3. If the by-product is included as a technical additive:
    a. A description of the function of the additive with regard to agronomic efficiency and/or safety of the EU fertilising product
    b. Test reports on the PAH_{16}, and PCDD/PCDF contents
    c. Calculations showing that the total concentration of technical additives is lower than 5% by mass,
4. For specific materials listed under article 2.1 of the delegated regulation, where applicable:
    a. Written description demonstrating that the by-product belongs to the limited list of by-products and complies with conditions therein.
    b. Test reports on radioactivity, contents of thallium (Tl), vanadium (V), total chromium (Cr), selenium (Se), and chlorine (Cl^-) where appropriate.
5. The REACH registration number (preferably including manufacturer digits) and manufacturer's SDS mentioning the use as fertiliser.

12 CMC 12 Precipitated phosphate salts and derivates

Component material category (CMC) 12, comprises precipitated phosphate salts and derivates. The FPR sets requirements on the input materials to produce precipitated phosphate salts, the reactor in which the precipitation takes place, its contents of P_2O_5, organic carbon content, aluminium and iron contents, impurities, the production plant, and pathogens in EU fertilising products containing CMC 12 materials.

Related provision	Provision summary	Suggested documents
ANNEX II CMC 12 1	A CMC 12 material is a precipitated phosphate salt obtained through precipitation from one or more input materials belonging to limited list, or derivatives processed by certain methods, which may have undergone certain processing.	Description of the component, the origin of the input materials, and the processing of the input materials.
ANNEX II CMC 12 2	Precipitation must take place under controlled conditions, using only uncontaminated input materials.	Description of the reactor where precipitation takes place.
ANNEX II CMC 12 3	The component must have a minimum P_2O_5 content and not exceed maximum contents of organic C and macroscopic impurities.	Test reports
ANNEX II CMC 12 4-5	Derivatives from precipitated phosphate salts may be used as a CMC 12 material if processed under certain conditions, using precipitated phosphate salts complying with points 1, 2, and 3 above.	Description of the chemical process
ANNEX II CMC 12 6	Animal by-products of categories 2 and 3 as well as derived products thereof may be used to produce precipitated phosphate salts and derivates if an end point in the manufacturing chain has been determined.	[placeholder]
ANNEX II CMC 12 7	Precipitation must take place in a plant where the input materials are kept separated from other material streams.	Description of the plant and a diagram of the process, where each treatment, storage vessel, and area is clearly identified.
Annex II CMC 12 8	The EU fertilising product containing CMC 12 material must meet criteria with regard to pathogen content, even when not required in PFC description.	Test reports
ANNEX II CMC 12 9	EU fertilising products containing CMC 12 materials recovered from municipal wastewater treatment plants must additionally meet the criteria for contamination with certain other pathogens.	Test reports

ANNEX II CMC 12 11	The precipitated phosphate salts or derivates recovered from wastewater or sewage sludge from municipal wastewater treatment plants must meet the criterion for PAH_{16} contamination.	Test reports
ANNEX II CMC 12 12	The precipitated phosphate salts or derivates may not contain more than 10% aluminium and iron on dry weight basis combined.	Test reports
ANNEX II CMC 12 13	The precipitated phosphate salts or derivates must meet REACH registration criteria	REACH documentation
ANNEX II CMC 12 14	Dry matter determination of samples must be done with vacuum drying at 40 °C to avoid loss of crystal-bound water.	Specification of the methods used to determine dry matter of the component

12.1 Precipitated phosphate salts input materials

The technical documentation must include a description of input materials that are used in the recovery of the precipitated phosphate salt, to demonstrate that they belong to one of the allowed input materials and meet specifications.

The technical documentation must include information on the processing and temperature of the input materials, demonstrating that these belong to one of the listed processes and the temperature trajectory for CMC input materials.

RESOURCES

Waste, bio-waste, by-products, mixed municipal waste and **separate collection** and are defined in the Waste Framework Directive 2008/98/EC; a link to the consolidated version can be found here. More background on the Distinction between waste and non-waste can be found here and in the Commission notice on technical guidance on the classification of waste (2018/C124/01).

Animal by-products and derived products are defined in the Animal By-product Regulation (EC) 1069/2009; a link to the consolidated version can be found here. More information on **animal by-products** can be found here and on the websites of the national competent authorities, listed here.

Processing residues from bioethanol and biodiesel are defined in the Directive 2009/28/EU. A link to the last consolidated version can be found here.

Substances (chemicals and compounds) and **mixtures** (mixtures or solutions or two or more substances) are defined in the REACH Regulation (EC) No 1907/2006, a link to the consolidated version can be found here. Detailed information and guidance on substances and substance identity can be found on the ECHA website on Substance identification and in the Guidance on identification and naming of substances under REACH and CLP.

FAQ

See the FAQ document on the FPR to check:

- What is meant by **sewage sludge, industrial sludge and dredging sludge** (Q8.32)
- Do the **limit values for pathogens** in precipitated phosphate salts belonging to CMC 12 apply at the level of the component material or of the product (Q8.34)
- What is meant by '**controlled conditions in a reactor**' in CMC 12, precipitated phosphate salts (Q8.35)
- How to demonstrate the conformity of **components that are obtained from third parties** (Q10.13 and Q10.19)

12.2 Production plant and reactor

Compliance with the criteria for the precipitation reactor and plant can be demonstrated by a detailed description of the reactor (an identifiable unit, tank, or installation in which the precipitation process takes place) and the plant. Where appropriate, detail the chemical reactions generated during the precipitation process. From the description, it must also become clear how input and output materials in the plant are physically separated and how it is ensured that input materials that are allowed for the recovery of CMC 12 materials are separated at all times from materials not allowed. A diagram of the precipitation process, where each treatment, storage vessel and area is clearly identified must be included.

Include calculations, schemes and/or diagrams, specifying the details and conditions (temperature, duration, etc.) of each step of the manufacturing process.

12.3 Component criteria

Compliance with the criteria for minimum P_2O_5 and maximum organic C on dry matter basis can be shown by a test report.

Reports of analyses and/or tests which show the amount of macroscopic impurities to be below the thresholds on weight by weight basis.

12.4 Derivates of precipitated phosphate salts

A CMC 12 component may also be derivates from precipitated phosphate salts produced through one or more chemical manufacturing steps that react precipitated phosphate salts with substances and mixtures -listed as input material under CMC 12 point 1- that are consumed in, or used for, chemical processing. The manufacturing process of a derivate must be executed such as to modify the chemical composition of the precipitated phosphate salts.

The processes and materials used should be detailed in the description of the processing conditions under 12.1 Precipitated phosphate salts.

12.5 Animal by-products and derived products as input material

No end-point criteria have been defined for precipitated salts derived from animal by-products. [placeholder]

12.6 Pathogens

For EU fertilising products containing CMC 12 materials, criteria on pathogen limits apply. Compliance can be shown by a test report on the final product, or by a description demonstrating of the material and production process demonstrating that the product contains solely CMC 12 materials and all biogenic input materials or the salts, have undergone pressure sterilisation, pasteurisation, or hygienisation.

12.7 Content of Al and Fe

The sum of aluminium (Al) and iron (Fe) in precipitated phosphate salts or derivates shall not exceed 10 % of the dry matter of the precipitated phosphate salts or the derivates. Compliance can be shown by a test report.

12.8 REACH registration obligation

Compliance with the REACH registration requirement can be demonstrated with the REACH registration number of the substance. A REACH registration number is composed as 01-XXXXXXXXXX-XX-XXXX. For the first two digits, the combination 01 indicates the substance is registered. The last 4 digits of the registration number show the manufacturer's identification. The registration number should preferably include the four digits indicating the manufacturer's registration.

In the case of precipitated phosphate salts and derivates recovered in the European Union, this REACH registration obligation is fulfilled if the producer can demonstrate that the material is the same (within the meaning of point (d)(i) of Article 2(7) of Regulation (EC) No 1907/2006) as a substance registered with a dossier containing the information indicated above, and if the SDS information is available to the fertilising product manufacturer (within the meaning of point (d)(ii) of Article 2(7) of Regulation (EC) No 1907/2006).

Compliance with the chemical safety assessment requirement for the use as a fertilising product can be demonstrated by the indication of the Product category PC12 'Fertilisers' in the Registration file and on the compiled MSDS that is provided by the supplier. See the text box Resources & FAQ in case no SDS is provided.

RESOURCES

Substances (chemicals and compounds) and **mixtures** (mixtures or solutions or two or more substances) are defined under the REACH regulation (Regulation (EC) No 1907/2006), a link to the consolidated version can be found here. Detailed information and guidance on substances and substance identity can be found on the ECHA website on Substance identification and in the Guidance on identification and naming of substances under REACH and CLP.

Information on the REACH obligations for **recovered substances** can be found in REACH Guidance to Waste and recovered substances.

Information on the **chemical safety assessment** can be found in the information REACH Guidance on information requirements and chemical safety assessment.

Guidance can be found at the REACH for fertilizers platform, created by Fertilizers Europe, with specific **tools for both the REACH registrants of fertiliser substances and the fertilizer manufacturers**. This website includes the Fertilizers Environmental Exposure (FEE) tool for the environmental exposure assessment, taking into account the local scenario for direct emissions to soil and surface water.

Resolution on 'What would be considered **sufficient evidence to verify compliance with REACH**?' can be found in the CLARIFICATIONS & RESOLUTIONS DOCUMENT by the Notified Bodies, under Folder 7 of the Coordination Group of Notified Bodies within the CIRCABC page for the Commission Expert Group on Fertilising Products. This also covers the case where a **third-party supplier does not provide the REACH registration number or the PC12 mentioned on the SDS.**

FAQ

See the FAQ document on the FPR to check:

- Is it possible for the manufacturers of EU fertilising products to **rely on the REACH registration done by other operators for a recovered substance**? (Q 8.16)
- How to demonstrate the **REACH registration and chemical safety report for component materials that are obtained from third parties** (Q10.13)
- If substances, whose **annual market volume is below one tonne**, have to be registered under REACH with a Chemical Safety Report for the purpose of the FPR (Q 8.4)
- **How to register** substances under REACH for the purpose of the FPR (Q 8.5)
- **Who** has to register under REACH? (Q 8.6)
- Whether substances **already registered, exported and then imported** into the EU have to be registered if used in EU fertilising products(Q 8.7)

12.9 Overview of documentation

The list below summarises the documents that could be included in the technical documentation for CMC 12 materials. Note that not each document listed here necessarily must be included and that the documents may be combined.

1. A description of the material including the precipitation input materials, their origin, and how they are processed.
2. A detailed description of the production process, the production lines, and for derivates how they are chemically modified.
3. A detailed description of the production plant which clarifies how different materials streams are kept separated as well as how input and output materials are kept separated.
4. Analysis reports on the contents of P_2O_5, organic carbon (C_{org}), aluminium (Al), and iron (Fe).
5. Calculation of the sum of aluminium and iron contents.
6. Reports and calculations on the content of macroscopic impurities.
7. For precipitated phosphate salts produced from wastewater or sludge: analysis reports on the PAH_{16} and PCDD/PCDF contents.
8. A report on the pathogen contents unless the product is suitably hygienised. Demonstrating hygienisation can be included in the description of the input materials, their processing, a separate document, or a description of all processing steps.
9. The REACH registration number (preferably including manufacturer digits) and manufacturer's MSDS mentioning the use as fertiliser.

13 CMC 13 Thermal oxidation materials and derivates

Component material category (CMC) 13, comprises thermal oxidation materials and derivates. The FPR sets requirements on the input materials, the production plan and processing, contaminants, and impurities. A REACH obligation is set forward.

Related provision	Provision summary	Suggested documents
ANNEX II CMC 13 1	A CMC 13 thermal oxidation material is obtained through thermochemical conversion under non-oxygen-limiting conditions of one or more input materials belonging to a limited list.	Description of the thermal oxidation material and its input materials.
ANNEX II CMC 13 2	Animal by-products of categories 2 and 3 and products derived thereof may also be used as input materials for thermal oxidation if an end point has been determined and will be reached before placing the product on the market.	Description of the input material. Documentation that the end point has been determined and will be reached before the EU fertilising product containing the component material is placed on the market.
ANNEX II CMC 13 3	The thermal conversion must take place under certain conditions, with a specific time-temperature criteria for the resulting gas depending on the input materials.	Description of the thermal oxidation process and conditions.
ANNEX II CMC 13 4	The thermal conversion shall take place in incineration or combustion chamber, using uncontaminated input materials. Input material must be kept separate from other material streams and physical contact between input and output materials must be avoided. The organic C content of the resulting slags and ashes must meet criterion on content.	Description of the incineration or combustion chamber, and diagram of the process, where each treatment, storage vessel, and area is clearly identified. Test report.
ANNEX II CMC 13 5	The thermal oxidation materials must be ashes or slags and must meet the criteria for PAH_{16} and PCDD/PCDF content	Test report.
ANNEX II CMC 13 6	Derivatives from thermal oxidation products may be used as a CMC 13 material if the manufacturing process is of a specific nature using certain input materials, and which is executed to intentionally modify the chemical composition of the thermal oxidation products. Restrictions on mixing or reacting are set for thermal oxidation materials that display hazardous properties. Removal or transformation of hazardous properties in these materials must be demonstrated using a mass balance approach.	Description of the manufacturing process and all input materials used. Test results and hazardous waste calculations.

ANNEX II CMC 13 7	EU fertilising products containing thermal oxidation materials or derivatives must meet criteria for vanadium content and, depending on the input material, must also meet criteria for chromium, thallium, and/or chlorine.	Description of the input materials, and test results on the EU fertilising product.
ANNEX II CMC 13 8	The thermal oxidation products or derivates must comply with the REACH requirements set out in point 2 in CMC 1.	REACH documentation

13.1 Thermal oxidation input materials

To demonstrate that a thermal oxidation input material of the CMC 13 material belongs to the limited list of input materials, a description of the input material must be included in the technical documentation. This description must sufficiently describe the nature and origin of the input material(s).

RESOURCES

Waste, bio-waste, separate collection and **by-products** are defined in the Waste Framework Directive 2008/98/EC; a link to the consolidated version can be found here. More background on the Distinction between waste and non-waste can be found here and in the Commission notice on technical guidance on the classification of waste (2018/C124/01).

Processing residues from bioethanol and biodiesel are defined in Directive 2009/28/EU. A link to the last consolidated version can be found here.

Substances (chemicals and compounds) and **mixtures** (mixtures or solutions or two or more substances) are defined under the REACH Regulation (EC) No 1907/2006, a link to the consolidated version can be found here. Detailed information and guidance on substances and substance identity can be found on the ECHA website on Substance identification and in the Guidance on identification and naming of substances under REACH and CLP.

FAQ

See the FAQ document on the FPR to check:

- What is meant by **sewage sludge, industrial sludge and dredging sludge** (Q8.27)
- How to demonstrate the conformity of components that are **obtained from third parties** (Q10.13 and Q10.19)

13.2 Animal by-products and derived products thereof as input material

Compliance with the requirements for the thermal oxidation materials derived from animal by-products can be shown with the commercial document from the producer indicating that the thermal oxidation material is produced in a plant that is approved by the national competent authority, demonstrated by an approval certificate. The approval certificate should clearly indicate that the plant is approved in the EU to produce the ashes with the end point in the manufacturing chain for organic fertilisers and soil improvers in accordance with conditions of Delegated Regulation (EU) 2023/1605 on end points for fertilisers.

The approval certificate also contains a unique approval number, which is linked to Section XII ‘Establishments or plants manufacturing organic fertilisers or soil improvers’ on the national lists of approved ABP establishments. The approved plants for the manufacturing of organic fertilisers or soil improvers should have the remark ‘End point in the manufacturing chain’.

RESOURCES

Animal by-products and derived products are defined in the Animal By-Products Regulation (EC) **No** 1069/2009; a link to the consolidated version can be found here. More information on **animal by-products** can be found here and on the websites of the national competent authorities, listed here.

Conditions for **thermal oxidation materials/ashes** derived from animal by-products to reach the **End points in the manufacturing chain** are determined in Delegated Regulation (EU) 2023/1605 on End points for fertilisers; a link can be found here. A link to the consolidated version of Implementing Regulation (EU) No 142/2001 with the criteria here.

A list of the websites with **contact details of the national competent authorities** and a **list of the approved ABP establishments** per EU member state can be found here. More information on **animal by-products** can be found here.

FAQ

See the FAQ document on the FPR to check:

- *In preparation*

13.3 Thermal oxidation process and plant

To demonstrate that the thermal oxidation installation and the plant where thermal oxidation takes place comply with the FPR, the technical dossier should include a detailed description of the thermal oxidation process, the installation, and the plant. Important points that should be clear from the description are the temperature and time of the thermal oxidation, how allowed and unallowed input materials are always kept separate within the plant, and how input and output materials are kept separate. A diagram of the processing and thermal oxidation process, where each treatment, storage vessel and area are clearly identified, must be included.

13.4 Contents and contaminants

Compliance with the criteria on maximum contents can be demonstrated by including test reports on the contents of the thermal oxidation products, the derivatives or the EU fertilising product.

On CMC level

For organic carbon (C_{org}) and PCDD/PCDF the test report on the contents of the ashes or slags should be included.

On PFC level

Depending on the input materials for thermal oxidation: test reports on the thallium (Tl), vanadium (V), and chlorine (Cl^-) contents of the EU fertilising product should be included.

For EU fertilising products containing thermal oxidation materials that display one or more of the hazardous properties listed in Annex III to Directive 2008/98/EC, test reports on hazardous properties, and the result of calculations on the removal or transformation of hazardous properties during the production process, using mass balance approach on the incorporation rate as described under Annex IV, part IV, Module D1 point 2.(ga) must be inclu

RE-SOURCE

Hazardous properties and **limit values** are defined in the Waste Framework Directive 2008/98/EC; a link to the consolidated version can be found here.

13.5 REACH registration obligation

Compliance with the REACH registration requirement can be demonstrated with the REACH registration number of the substance. A REACH registration number is composed as 01-XXXXXXXXXX-XX-XXXX. For the first two digits, the combination 01 indicates the substance is registered. The last 4 digits of the registration number show the manufacturer's identification. The registration number should preferably include the four digits indicating the manufacturer's registration.

In the case of thermal oxidation materials and derivates recovered in the European Union, the condition on REACH registration is fulfilled if the producer can demonstrate that the material is the same (within the meaning of point (d)(i) of Article 2(7) of Regulation (EC) No 1907/2006) as a substance registered with a dossier containing the information indicated above, and if the SDS information is available to the fertilising product manufacturer (within the meaning of point (d)(ii) of Article 2(7) of Regulation (EC) No 1907/2006).

Compliance with the chemical safety assessment requirement for the use as a fertilising product can be demonstrated by the indication of the Product category PC12 'Fertilisers' in the Registration file and on the compiled MSDS that is provided by the supplier. See the text box Resources & FAQ in case no SDS is provided.

RESOURCES

Substances (chemicals and compounds) and **mixtures** (mixtures or solutions or two or more substances) are defined under the REACH regulation (Regulation (EC) No 1907/2006), a link to the consolidated version can be found here. Detailed information and guidance on substances and substance identity can be found on the ECHA website on Substance identification and in the Guidance on identification and naming of substances under REACH and CLP.

Information on the REACH obligations for **recovered substances** can be found in REACH Guidance to Waste and recovered substances.

Information on the **chemical safety assessment** can be found in the information REACH Guidance on information requirements and chemical safety assessment.

Guidance can be found at the REACH for fertilizers platform, created by Fertilizers Europe, with specific **tools for both the REACH registrants of fertiliser substances and the fertilizer manufacturers**. This website includes the Fertilizers Environmental Exposure (FEE) tool for the environmental exposure assessment, taking into account the local scenario for direct emissions to soil and surface water.

Resolution on 'What would be considered **sufficient evidence to verify compliance with REACH**?' can be found in the CLARIFICATIONS & RESOLUTIONS DOCUMENT by the Notified Bodies, under Folder 7 of the Coordination Group of Notified Bodies within the CIRCABC page for the Commission Expert Group on Fertilising Products. This also covers the case where a **third-party supplier does not provide the REACH registration number or the PC12 mentioned on the SDS.**

FAQ

See the FAQ document on the FPR to check:

- Is it possible for the manufacturers of EU fertilising products to **rely on the REACH registration done by other operators for a recovered substance**? (Q 8.16)
- How to demonstrate the **REACH registration and chemical safety report for component materials that are obtained from third parties** (Q10.13)
- If substances, whose **annual market volume is below one tonne**, have to be registered under REACH with a Chemical Safety Report for the purpose of the FPR (Q 8.4)
- **How to register** substances under REACH for the purpose of the FPR (Q 8.5)
- **Who** has to register under REACH? (Q 8.6)
- Whether substances **already registered, exported and then imported** into the EU have to be registered if used in EU fertilising products(Q 8.7)

13.6 Overview of documentation

The list below summarises the documents that could be included in the technical documentation for CMC 13 materials. Note that not each document listed here necessarily must be included and that the documents may be combined.

1. A description of the material including description(s) of the input material(s), their origin, and how they are processed
2. For thermal oxidation input materials which are animal by-products, proof that the material has reached an end point in the manufacturing chain.
3. A detailed description of the production process, the production lines, and for derivates how they are chemically modified.
4. A detailed description of the production plant which clarifies how different materials streams are kept separated as well as how input and output materials are kept separated.
5. Analysis reports on the organic carbon (C_{org}), PAH_{16}, and PCDD/PCDF contents of the material
6. Depending on the input materials for thermal oxidation: test results on the thallium (Tl), vanadium (V), and chlorine (Cl^-) contents of the EU fertilising product.
7. The REACH registration number (preferably including manufacturer digits) and manufacturer's SDS mentioning the use as fertiliser.

14 CMC 14 Pyrolysis and gasification materials

Component material category (CMC) 14 comprises pyrolysis and gasification materials.

The table below lists all requirements for EU fertilising products containing CMC 14 components and the components themselves. In the following paragraphs, these requirements are discussed in more detail.

Related provision	Provision summary	Suggested documents
ANNEX II CMC 14 1	A CMC 14 pyrolysis or gasification material is obtained through thermochemical conversion under oxygen-limiting conditions of input materials included in a limited list.	Description of the input material and any processing it underwent.
ANNEX II CMC 14 2	During pyrolysis or gasification, a temperature of at least 180 °C must be reached for at least 2 seconds. Contact between input and output materials must be avoided at all times. The reactor itself may only process input materials which are not contaminated with other materials	Description of the conversion process including how the input and output materials are kept separated from each other.
ANNEX II CMC 14 3	Limits are defined for the H/C_{org} ratio and contents of PAH_{16} and PCDD/PCDF	Test reports
ANNEX II CMC 14 4	Input material for gasification or pyrolysis may contain animal by-products and derived products of category 2 and category 3 if an end point in the manufacturing chain has been determined and reached before placing the product on the market.	Description of the material and any processing it underwent. As well as proof that the product has reached an end point in the manufacturing chain once placed onto the market.
ANNEX II CMC 14 5	Production lines where a CMC 14 material is produced must be clearly separated from production lines where input materials which are not allowed for CMC 14, are processed.	Description of the plant and diagram of the process, where each treatment, storage vessel, and area is clearly identified.
ANNEX II CMC 14 6	Fertilising products must meet criteria for chlorine contents if they contain CMC 14 components. They must also meet thallium content criteria if they contain more than 5% pyrolysis and gasification additives on fresh weight basis.	Test report
ANNEX II CMC 14 7	The thermal pyrolysis or gasification product must comply with the REACH requirements set out in point 2 in CMC 1.	REACH documentation

14.1 Input materials

To demonstrate that the input material(s) of CMC 14 material belong to the limited list of input materials, a detailed description of the inputs to the pyrolysis or gasification process, including the nature and origin of all materials as well as all processing that the input material underwent should be given.

RESOURCES

Waste, bio-waste, separate collection, and **by-products** are defined in the Waste Framework Directive 2008/98/EC; a link to the consolidated version can be found here. More background on the Distinction between waste and non-waste can be found here and in the Commission notice on technical guidance on the classification of waste (2018/C124/01).

Animal by-products and derived products are defined in the Animal By-Products Regulation (EC) No 1069/2009; a link to the consolidated version can be found here. More information on **animal by-products** can be found here and on the websites of the national competent authorities, listed here.

Processing residues from bioethanol and biodiesel are defined in Directive 2009/28/EU. A link to the last consolidated version can be found here.

Substances (chemicals and compounds)and **mixtures** (mixtures or solutions or two or more substances)are defined under the REACH Regulation (EC) No 1907/2006, a link to the consolidated version can be found here. Detailed information and guidance on substances and substance identity can be found on the ECHA website on Substance identification and in the Guidance on identification and naming of substances under REACH and CLP.

FAQ

See the FAQ document on the FPR to check:

- What is meant by **sewage sludge, industrial sludge and dredging sludge** (Q8.27)
- How to demonstrate the conformity of components that are **obtained from third parties** (Q10.13 and Q10.19)

14.2 Pyrolysis or gasification process and plant

To demonstrate that the thermochemical conversion installation and the plant where thermochemical conversion takes place comply, the technical dossier should include a detailed description of the thermochemical conversion process, installation, and the plant. Important points that should be clear from the description are the temperature and time of the thermal oxidation, how allowed and unallowed input materials are always kept separated within the plant, and how input and output materials are kept separated. Include drawings and/or schemes to aid in comprehending the plant and processes. A diagram of the processing and pyrolysis or gasification process, where each treatment, storage vessel and area are clearly identified, must be included.

14.3 Contents and contaminants

Most criteria on contents and contaminants for CMC 14 components apply on the component level. However, there are also several criteria stemming from this CMC for which compliance must be demonstrated on the product level.

On CMC level

Compliance can be demonstrated by test reports on the organic carbon (C_{org}), the ratio of organic carbon to hydrogen, and PAH_{16} and PCDD/PCDF contents of the material.

On PFC level

Depending on additives used in the production of the pyrolysis or gasification material: report on the thallium (Tl) of the EU fertilising product.

Regardless of the used additives and input materials, a test report on the chlorine (Cl^-) content of the EU fertilising product should be included.

14.4 Animal by-products and derived thereof as input material

Pyrolysis and gasification materials obtained through precipitation from Category 2 or Category 3 materials or derived products thereof, could be used provided that the end point in the manufacturing chain has been determined in accordance with Article 5(2), third subparagraph, of Regulation (EC) No 1069/2009.

No end-point criteria have yet been defined for pyrolysis and gasification materials from animal by-products. [placeholder]

14.5 REACH registration obligation

Compliance with the REACH registration requirement can be demonstrated with the REACH registration number of the substance. A REACH registration number is composed as 01-XXXXXXXXXX-XX-XXXX. For the first two digits, the combination 01 indicates the substance is registered. The last 4 digits of the registration number show the manufacturer's identification. The registration number should preferably include the four digits indicating the manufacturer's registration.

In the case of pyrolysis and gasification materials recovered in the European Union, this condition is fulfilled if the producer can demonstrate that the material is the same (within the meaning of point (d)(i) of Article 2(7) of Regulation (EC) No 1907/2006) as a substance registered with a dossier containing the information indicated above, and if the SDS information is available to the fertilising product manufacturer (within the meaning of point (d)(ii) of Article 2(7) of Regulation (EC) No 1907/2006).

Compliance with the chemical safety assessment requirement for the use as a fertilising product can be demonstrated by the indication of the Product category PC12 'Fertilisers' in the Registration file and on the compiled MSDS that is provided by the supplier. See the text box Resources & FAQ in case no SDS is provided.

RESOURCES

Substances (chemicals and compounds) and **mixtures** (mixtures or solutions or two or more substances) are defined under the REACH regulation (Regulation (EC) No 1907/2006), a link to the consolidated version can be found here. Detailed information and guidance on substances and substance identity can be found on the ECHA website on Substance identification and in the Guidance on identification and naming of substances under REACH and CLP.

Information on the REACH obligations for **recovered substances** can be found in REACH Guidance to Waste and recovered substances.

Information on the **chemical safety assessment** can be found in the information REACH Guidance on information requirements and chemical safety assessment.

Guidance can be found at the REACH for fertilizers platform, created by Fertilizers Europe, with specific **tools for both the REACH registrants of fertiliser substances and the fertilizer manufacturers**. This website includes the Fertilizers Environmental Exposure (FEE) tool for the environmental exposure assessment, taking into account the local scenario for direct emissions to soil and surface water.

Resolution on 'What would be considered **sufficient evidence to verify compliance with REACH**?' can be found in the CLARIFICATIONS & RESOLUTIONS DOCUMENT by the Notified

Bodies, under Folder 7 of the Coordination Group of Notified Bodies within the CIRCABC page for the Commission Expert Group on Fertilising Products. This also covers the case where a **third-party supplier does not provide the REACH registration number or the PC12 mentioned on the SDS.**

FAQ

See the FAQ document on the FPR to check:

- Is it possible for the manufacturers of EU fertilising products to **rely on the REACH registration done by other operators for a recovered substance**? (Q 8.16)
- How to demonstrate the **REACH registration and chemical safety report for component materials that are obtained from third parties** (Q10.13)
- If **substances, of which the annual market volume is below one tonn**e, have to be registered under REACH with a Chemical Safety Report for the purpose of the FPR (Q 8.4)
- **How to register** substances under REACH for the purpose of the FPR (Q 8.5)
- **Who has to register** under REACH? (Q 8.6)
- Whether **substances already registered, exported and then imported into the EU** have to be registered if used in EU fertilising products (Q 8.7)

14.6 Overview of documentation

The list below summarises the documents that could be included in the technical documentation for CMC 14 materials. Note that not each document listed here necessarily must be included and that the documents may be combined.

1. A description of the material including description(s) of the input material(s), their origin, and how they are processed
2. A detailed description of the production process, and the production lines,
3. A detailed description of the production plant which clarifies how different materials streams are kept separated as well as how input and output materials are kept separated.
4. Analysis reports on the organic carbon (C_{org}), the ratio of organic carbon to hydrogen, PAH_{16} and PCDD/PCDF contents of the material
5. Depending on the amount of additives used in the production of the pyrolysis or gasification material: report on the thallium (Tl) of the EU fertilising product
6. Report on the chlorine (Cl^-) content of the EU fertilising product
7. The REACH registration number (preferably including manufacturer digits) and manufacturer's MSDS with the mention of the use as fertiliser.

15 CMC 15 Recovered high purity materials

Component material category (CMC) 15, comprises recovered high purity materials.

Related provision	Provision summary	Suggested documents
ANNEX II CMC 15 1	A CMC 15 material may be a recovered ammonium-, sulphate-, or phosphate salt, elemental sulphur, calcium carbonate, calcium oxide, or mixtures thereof with a purity of at least 95%.	Description of the material, test reports on salts or constituting elements followed by calculations to salt content
ANNEX II CMC 15 2	A CMC 15 material may only be recovered from production processes using substances and mixtures except animal by-products, and from gas purification of off-gases derived from a limited list of input materials and facilities.	Description of the input material and its origin, and diagram of the production or recovery process, where each treatment, storage vessel and area is clearly identified.
ANNEX II CMC 15 3	A CMC 15 material must not contain more than 0.5% C_{org} on dry matter basis.	Test report
ANNEX II CMC 15 4	The component must meet criteria for PAH_{16} and PCDD/PCDF contents.	Test report
defined	Fertilising products must meet criteria for chlorine and thallium contents if they contain CMC 15 components.	Test report
ANNEX II CMC 15 7	EU fertilising products containing CMC 15 material obtained from the purification of off-gasses, must meet criteria for pathogens.	Test report
ANNEX II CMC 15 9	Where high purity materials are stored improperly, they may be used if they are manufactured at most 36 months before the signing the EU declaration of conformity.	Description of the storage facilities of the component and the manufacturing date of the high purity material (if stored unprotected from precipitation and sunlight).
ANNEX II CMC 15 10	The thermal pyrolysis or gasification product must comply with the REACH requirements set out in point 2 in CMC 1.	REACH documentation

15.1 Recovered high purity material

A recovered high purity material is ammonium salt, sulphate salt, phosphate salt, elemental sulphur, calcium carbonate or calcium oxide, or mixtures thereof, of a purity of at least 95 % dry matter of the material. Purity can be demonstrated with test reports on the contents of the salts or the constituting elements followed by a calculation to the salt.

Compliance with the requirement on the input materials and production or recovery processes should be demonstrated by a description of the material and the production or recovery process,

demonstrating in sufficient detail that the high purity material is recovered from waste that is generated from:

a. a production process that uses as input materials substances and mixtures other than animal by-products or derived products within the scope of the Animal By-Product Regulation
b. a gas purification or emission control process designed to remove nutrients from off-gases.

A diagram of the production or recovery process, where each treatment, storage vessel and area is clearly identified, must be included.

RESOURCES

Substances (chemicals and compounds)and **mixtures** (mixtures or solutions or two or more substances) are defined under the REACH Regulation (EC) No 1907/2006, a link to the consolidated version can be found here. Detailed information and guidance on substances and substance identity can be found on the ECHA website on Substance identification and in the Guidance on identification and naming of substances under REACH and CLP.

Waste, bio-waste, separate collection, and **by-products** are defined in the Waste Framework Directive 2008/98/EC; a link to the consolidated version can be found here. More background on the Distinction between waste and non-waste can be found here and in the Commission notice on technical guidance on the classification of waste (2018/C124/01).

Animal by-products and derived products are defined in the Animal by-product Regulation (EC) No 1069/2009; a link to the consolidated version can be found here. More information on **animal by-products** can be found here and on the websites of the national competent authorities, listed here.

Urban waste water and **domestic waste** water are defined in Directive 91/271/EEC of 21 May 1991 concerning urban wastewater treatment.

Hazardous properties are described in Annex III of Waste Framework Directive 2008/98/EC; a link to the consolidated version can be found here.

Fuel input to **waste co-incineration plants** is defined in Directive 2010/75/EU on industrial emissions

FAQ

See the FAQ document on the FPR to check:

- What is meant by **sewage sludge, industrial sludge and dredging sludge** (Q8.27)
- How to demonstrate the **conformity of components that are obtained from third parties** (Q10.13 and Q10.19)
- Are **high purity materials out of off-gases generated** by manure-derived products within the scope of the Animal By-Products Regulation? (Q 8.36)

15.2 Contents and contaminants

Most criteria on contents and contaminants for CMC 15 components apply on the component level. However, there are also several criteria for which compliance must be demonstrated on the product level.

On CMC level

Compliance with the criteria on organic carbon (C_{org}) content, the contents of PAH_{16} and PCDD/PCDF[2] kg^{-1} can be demonstrated with a test report.

[2] *Sum of 2,3,7,8-TCDD, 1,2,3,7,8-PeCDD; 1,2,3,4,7,8-HxCDD; 1,2,3,6,7,8-HxCDD; 1,2,3,7,8,9-HxCDD; 1,2,3,4,6,7,8-HpCDD; OCDD; 2,3,7,8-TCDF; 1,2,3,7,8-PeCDF; 2,3,4,7,8-PeCDF; 1,2,3,4,7,8-HxCDF; 1,2,3,6,7,8-HxCDF; 1,2,3,7,8,9-HxCDF; 2,3,4,6,7,8-HxCDF; 1,2,3,4,6,7,8-HpCDF; 1,2,3,4,7,8,9-HpCDF; and OCDF*

On PFC level

An EU fertilising product containing a CMC 15 component must not contain more than 400 mg kg^{-1} dry matter of total chromium (Cr) and not more than 2 mg kg^{-1} dry matter of thallium (Tl).

Test reports can be used to demonstrate compliance with the limits on total chromium and thallium on product level.

Compliance with the limits on *Salmonella* spp., *Escherichia coli*, and or *Enterococcaceae* -whether in place by virtue of the product's PFC or the product containing a CMC 15 material- must be verified via testing. No testing on pathogens or processing is required when an EU fertilising product consists of solely high purity materials obtained from off-gasses derived from an incineration process, as demonstrated by the process description.

Where the high purity material or all of the biogenic input materials used, are not tested on pathogens, a written description and process scheme demonstrating that the material has undergone pressure sterilisation or processing in a pasteurisation or hygienisation unit should be included. Time-temperature trajectories have to be described.

15.3 Storage

Compliance with the storage condition can be demonstrated by a description and scheme of the storage conditions.

For compliance with the storage period the record-keeping should show the date of production of a batch and the date of signing the EU declaration of conformity for the respective EU fertilising product in which the batch was used.

15.4 REACH registration obligation

Compliance with the REACH registration requirement can be demonstrated with the REACH registration number of the substance. A REACH registration number is composed as 01-XXXXXXXXXX-XX-XXXX. For the first two digits, the combination 01 indicates the substance is registered. The last 4 digits of the registration number show the manufacturer's identification. The registration number should preferably include the four digits indicating the manufacturer's registration.

In the case of high purity recovered in the European Union, this condition is fulfilled if the producer can demonstrate that the material is the same (within the meaning of point (d)(i) of Article 2(7) of Regulation (EC) No 1907/2006) as a substance registered with a dossier containing the information indicated above, and if the SDS information is available to the fertilising product manufacturer (within the meaning of point (d)(ii) of Article 2(7) of Regulation (EC) No 1907/2006).

Compliance with the chemical safety assessment requirement for the use as a fertilising product can be demonstrated by the indication of the Product category PC12 'Fertilisers' in the Registration file and on the compiled MSDS that is provided by the supplier. See the text box Resources & FAQ in case no SDS is provided.

RESOURCES

Substances (chemicals and compounds) and **mixtures** (mixtures or solutions or two or more substances) are defined under the REACH regulation (Regulation (EC) No 1907/2006), a link to the consolidated version can be found here. Detailed information and guidance on substances and substance identity can be found on the ECHA website on Substance identification and in the Guidance on identification and naming of substances under REACH and CLP.

Information on the REACH obligations for **recovered substances** can be found in REACH Guidance to Waste and recovered substances.

Information on the **chemical safety assessment** can be found in the information REACH Guidance on information requirements and chemical safety assessment.

Guidance can be found at the REACH for fertilizers platform, created by Fertilizers Europe, with specific **tools for both the REACH registrants of fertiliser substances and the fertilizer manufacturers**. This website includes the Fertilizers Environmental Exposure (FEE) tool for the environmental exposure assessment, taking into account the local scenario for direct emissions to soil and surface water.

Resolution on 'What would be considered **sufficient evidence to verify compliance with REACH**?' can be found in the CLARIFICATIONS & RESOLUTIONS DOCUMENT by the Notified Bodies, under Folder 7 of the Coordination Group of Notified Bodies within the CIRCABC page for the Commission Expert Group on Fertilising Products. This also covers the case where a **third-party supplier does not provide the REACH registration number or the PC12 mentioned on the SDS.**

FAQ

See the FAQ document on the FPR to check:

- Is it possible for the manufacturers of EU fertilising products to **rely on the REACH registration done by other operators for a recovered substance**? (Q 8.16)
- How to demonstrate the **REACH registration and chemical safety report for component materials that are obtained from third parties** (Q10.13)
- If substances, whose **annual market volume is below one tonne**, have to be registered under REACH with a Chemical Safety Report for the purpose of the FPR (Q 8.4)
- **How to register** substances under REACH for the purpose of the FPR (Q 8.5)
- **Who** has to register under REACH? (Q 8.6)
- Whether substances **already registered, exported and then imported into the EU** have to be registered if used in EU fertilising products(Q 8.7)

15.5 Overview of documentation

The list below summarises the documents that could be included in the technical documentation for CMC 15 materials. Note that not each document listed here necessarily must be included and that the documents may be combined.

1. A description of the material including description(s) of the input material(s), their origin, and how they are processed.
2. A description of the composition of the material.
3. A description of the production process.
4. Analysis reports on the organic carbon (C_{org}), PAH_{16} and PCDD/PCDF contents of the material.
5. Report on the total chromium (Cr) and thallium (Tl) content of the EU fertilising product.
6. Report on the pathogen contents of the EU fertilising product or proof that the input materials have been treated in such a way that demonstrating compliance with pathogen criteria is no longer required.
7. The REACH registration number (preferably including manufacturer digits) and manufacturer's MSDS with the mention of the use as fertiliser.

Part V

IT- tool: fpr-td-gen

1.1 The IT-tool fpr-tc-gen

Finding out what needs to be included in the Technical Documentation can be laborious. NMI has developed a tool which distils the information of technical study on the elaboration of the technical documentation: the **fpr-td-gen** package. The package helps to determine what needs to be included in the TD based on a minimum set of questions. After answering all questions, the user gets a checklist of all elements that must be present in the TD for the conformity assessment procedure.

1.2 Technical information on IT tool fpr-td-gen

NMI implemented the first version of fpr-td-gen tool as an open-source package on April 15th2024. The package provides the logic and the content, but no user interface (UI). The package does not store or sent data to an external party and can be used freely under the EUPL-1.2 license.

The fpr-gen-td package makes it possible to easily extend existing (internal) applications, with a dynamic task list for providing technical documentation for an EU fertiliser product. Implementation of the packages requires no knowledge of the FPR. The package offers 4 functions to go through the different steps of the package. The output of the tool is a task list with everything that needs to be included in the technical documentation to demonstrate that the product and its components comply with the regulation.

The fpr-gen-td package is written in JavaScript/TypeScript and published on npm where it is available free of charge. The package stores all data only locally, does not share with third parties, does not require an internet connection, and can therefore be used offline. The code is public and can be viewed[1] on GitHub. Currently, both English and Dutch are supported, and it can easily be expanded with support for the other 22 official languages of the European Union.

The full documentation of the package can be found @nmi-agro/fpr-td-gen[2], which also contains the installation command, the instructions for usage and information on settings and contributions.

[1] https://github.com/AgroCares/fpr-td-gen
[2] https://agrocares.github.io/fpr-td-gen/

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