

# Technical study on the elaboration of the technical documentation for the FPR

Inception report

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# 1 Introduction

## 1.1 Legislative framework

The new 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 the Regulation (EC) 2003/2003 relating to EC Fertilisers, which applied mainly to traditional inorganic fertilisers out of various raw materials. The FPR extends the scope of the EU rules to include fertilising products out of recovered waste 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 has been drafted in line with the New Legislative Approach of the European Commission. 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 for this approach<sup>1</sup> 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;
- 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 also 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).

The FPR is an optional regulation for bringing fertilising products onto the market in the EU. Besides the FPR, fertilising products may also be brought onto the market via national legislation. 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 mutual recognition. This is however beyond the scope of this document, see the 'Blue Guide' for more information on mutual recognition and market harmonisation.

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<sup>1</sup> Background information and the links the Regulations on the New Legislative Approach can be found at [https://single-market-economy.ec.europa.eu/single-market/goods/new-legislative-framework\\_en](https://single-market-economy.ec.europa.eu/single-market/goods/new-legislative-framework_en)

## 1.2 Stakeholders in conformity assessment

The FPR sets out responsibilities and obligations for the different stakeholders involved in the conformity assessment of fertilising products. It follows the provisions of the new legislative framework, which is still new to many stakeholders.

The **manufacturers** have new obligations in comparison with the repealed regulation EC2003/2003 on mineral fertilisers. Manufacturers will have to:

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

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 harmonized standards implies a more diverse group of products and more complex procedures compared to the survey of EC-fertilisers under EG 2003/2003. Market surveillance authorities have to survey:

- non-compliant products and safeguard procedures,
- formal non-compliance,
- compliant products which present a risk.

The FPR has introduced **Notified Bodies (NoBo)** as a new stakeholder in the fertilising product manufacturing chain. The notified bodies will have to get familiar with fertiliser manufacturing and with the specific requirements imposed by the FPR on the assessment and certification of EU-fertilising products. Notified bodies have to assess:

- product compliance with the requirements of Annex I and Annex II,
- the technical documentation (TD) provided by the producer,
- other requirements following relevant modules from Annex IV.

## 1.3 Guidance document on technical documentation

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 producer 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 requirements, etc.).

The compilation of the technical documentation has proved a difficult task, for both producers that are new to the EU regulations, and for producers of EC-fertilisers under the EC/2003/2003 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 study will also deliver an IT tool to generate personalized templates in all EU languages, with specifications dedicated to specific product and component requirements.

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 will document a common understanding of the requirements set by the FPR and thus ensure a smooth transition and uniform implementation. The stakeholders have different roles and responsibilities in drafting, assessing, and surveying 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 Technical study on the elaboration of the technical documentation**

The guidance document on the elaboration of the technical documentation is intended as a living document. The current technical study will provide a first draft. The guidance document will also serve as the background documentation of the IT tool.

The study contains 5 tasks:

1. Map documents for the development of the guideline
2. Draft general guidelines
3. Development of draft product related guidelines
4. Compilation of a list of standards
5. Development of an IT tool

This inception report provides the main findings of the research in the field of guidance documents for the technical documentation of products (Task 1).

In addition, based on the findings of Task 1, the inception report contains a first draft of the guidelines for the elaboration of technical documentation of products. This first draft contains a detailed table of all the relevant elements/contents, which will serve as the structure for the elaboration of the guidelines (Tasks 2 and 3).

The inception report also includes a timetable of all the consultation activities which will be performed.

## 2 Inventory of documents for the development of guidelines

As a first step in this technical study (Task 1) relevant existing guidelines were mapped. By reviewing previous guidelines, useful features and elements can be identified. Furthermore, features that do not seem to work well can be identified to avoid these in the new guidance document.

The guidance documents that have been studied include guidance documents on EU directives which have been drafted or amended following the new legislative approach. These documents were studied to see how they elaborate on drafting technical documentation.

### 2.1 Guidance documents on other EU legislation

#### 2.1.1 The Blue Guide

The [Blue Guide](#)<sup>2</sup> 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 directives to enable a single open market within the union and how these directives evolved. This gives a good impression of why the NLF was set up and how it works in general. The Blue Guide does not cover the Directive on General Product Safety, the European Union Rapid Information System (RAPEX), motor vehicles, construction products, REACH, food legalisation and food contact materials.

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.

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<sup>2</sup> 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](https://single-market-economy.ec.europa.eu/news/blue-guide-implementation-product-rules-2022-published-2022-06-29_en).



### 2.1.2 Toy safety directive technical documentation guidance document

This guidance document<sup>3</sup> starts with a series of notes describing the intended audience and aim of the document as well as a disclaimer that the document is not legally binding. These notes are followed by a one-page introduction reiterating the relevance of the document and the aims of the Toy Safety Directive 2009/48/EC (TSD). The rest of the document is structured in four parts: the first part concerns technical documentation, the second and third concerning assessments, and the last part concerning chemical requirements.

The structure of part one, on technical documentation, is of interest as this could be used as a blueprint for the guidance document on drafting technical documentation for fertilising products. Part I, section 1 starts by briefly discussing all provisions in the TSD relating to technical documentation. Section 2 is specifically on the technical documentation and generally describes why technical documentation is needed and what is expected of technical documentation. A table is included describing the contents of technical documentation, with related provisions. The first item in the table, '*A detailed description of the design and manufacture...*' is discussed at length in section 3. Section 4 discusses the conformity assessment procedures available under the TSD.

The EU declaration of conformity (EU DoC) is discussed in detail in section 5. Other elements discussed are: addresses of place of manufacture and storage (section 6), copies of documents that the manufacturer has submitted to a NoBo (section 7), test reports which must be in the technical documentation when module A was used (section 8), the EC-type examination certificate which must be in the technical documentation when modules B and C were used (section 9), and safety assessment (section 10).

The Part II of the guidance deals with the mechanical physical, flammability and electrical assessment. Part III deals with the hygiene and radioactivity assessment. Part IV deals with the chemical requirements and safety assessment. These parts are of less interest to the technical study here as they do not relate to the activities that are required for the EU fertilising products.

### 2.1.3 Guidance document on labelling EU fertilising products

This guidance document<sup>4</sup> provides relatively 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 of 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.

The document includes examples of labels for each PFC, with clear instructions and comments. In the example labels, a colour coding is used to communicate whether information is part of the general requirements (blue), a PFC-specific requirement (orange), other obligatory information (black), or an

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<sup>3</sup> Guidance document on the application of Directive 2009/48/EC on the Safety of Toys: Technical documentation.  
<https://ec.europa.eu/docsroom/documents/15985/attachments/1/translations>

<sup>4</sup> 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](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2021.119.01.0001.01.ENG)



indicated nutrient (green) (Figure 2-1). This is a solution to the problem, of how to communicate which information is PFC/CMC specific and which information is true for all EU fertilising products.

Coloured text may, however, be harder to read on a white background and can be hard to understand for colourblind people. As an alternative one could use symbols or labels besides or instead of colours.

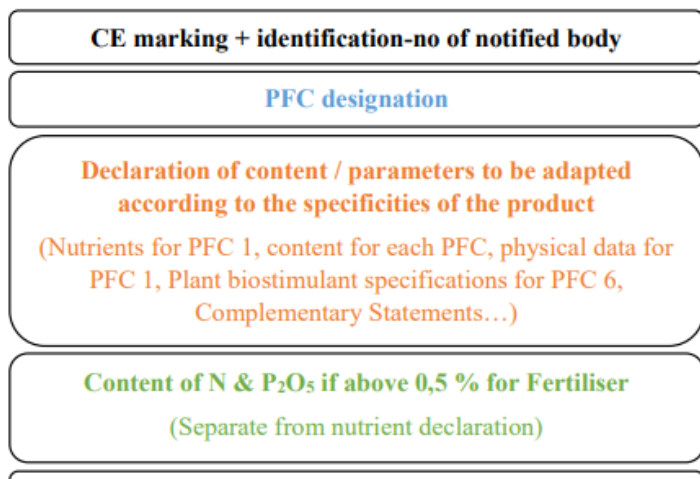


Figure 2-1. Snippet of an illustrative product label in the guidance document on labelling of fertilising products. Colours are used to indicate whether the information is part of the general requirements (blue), a PFC-specific requirement (orange), other obligatory information (black), or an indicated nutrient (green).

## 2.1.4 Guidance documents on EU regulation following new legislative approach

In addition to the FPR and the Directive on the safety of toys, 21 EU directives and regulations have been aligned with, or based on the reference provisions of Decision 768/2008/EC on the Marketing of products<sup>5</sup>. A targeted desk study resulted in the following list of EU guidance documents:

- Guide for the EMCD (Directive 2014/30/EU)
- Guide to the application of the lifts directive 2014/33/EU
- ATEX 2014/34/EU Guidelines
- Low voltage directive 2014/35/EU Guidelines
- PPE Regulation Guidelines, Guide to the application of Regulation (EU) 2016/425 of the European Parliament and of the council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC – 1st Edition-April 2018
- Guide to the Radio Equipment Directive 2014/53/EU (RED guide)
- Guide to application of the Regulation (EU) 2016/424 on cableway installations, edition 1.0-December 2021.

In these guidance documents, the documents that should be included in the technical documentation are often mentioned throughout the guides. If lists of technical documentation elements are given they tend to be of a generic nature. A short description of these guidance documents is given in Annex A.

<sup>5</sup> [https://single-market-economy.ec.europa.eu/single-market/goods/new-legislative-framework\\_en](https://single-market-economy.ec.europa.eu/single-market/goods/new-legislative-framework_en)

## 2.2 Guidelines at national level

The market surveillance of the FPR is implemented at the national level. The national authorities will be the first contact point for economic operators seeking information on the FPR. The national authorities for the FPR do also support the national fertiliser regulations.

At the national level, guidelines developed by member states to support the application of the FPR or the national fertilising products rules can be useful. National guidelines are assessed to the extent that they include examples of good practices in developing the guidelines in support of the FPR.

A recent evaluation of national fertiliser regulations in NW Europe conducted by the NMI (Van Schöll and Postma 2022) has shown that some countries have detailed protocols for the evaluation of national fertilising products and guidance on technical dossiers that have to be compiled, such as the Netherlands and France. In other countries such as Germany and Belgium only general guidelines are available.

A targeted desk study aimed to collect national guidelines via the webpages of the national responsible authorities proved to be laborious and time-consuming. The list of market surveillance authorities for the FPR is extensive, as in some countries several authorities deal with the implementation of the FPR and national regulations (see Annex G). Also, the listed references to the website of the national authorities are mostly very generic (level of Ministry) and not targeted to the relevant department or division dealing with fertilising products. Information on the implementation of the FPR is not always up to date. As a result, not all websites of the responsible authorities could be studied.

During the EU summit of the Organic and organo-mineral fertiliser industries (SOFIE 2023) that was attended by representatives of mayor EU stakeholder associations, several stakeholders confirmed that the national market surveillance authorities are still in the preparation phase for their tasks. Communication to economic operators on the national level is limited and does not include guidance documents on the FPR. On the websites studied, several national authorities responsible for fertiliser legislation still refer to the EG 2003/2003.

**Some general conclusions on the national guidelines for fertilising products** could be drawn:

- The national legislation on fertilising products is regulated via dedicated regulations on fertilisers or included in regulations on plant protection and nutrient product regulations.
- Member states can require the economic operators to register fertilising products, but this is not followed by all member states.
- Registration of fertilising products can be mandatory for all fertilising products, only for certain types of products (typically biostimulants), or for fertiliser types that do not belong to one of the defined fertiliser types or categories.
- Where fertilising products have to be registered, a list with information that has to be provided is generally available. This list is generally self-explanatory.
- In France, the description and requirements for fertilising products are laid down in standards that are not publicly available. Producers have to show compliance with a French standard (NFU) which must be bought from the French Agency for Food, Environmental and Occupational Health & Safety (ANSES). A detailed guidance document is available for the admission of fertilising products that do not comply with one of the NFU standards. The document contains detailed instructions on the measurements that need to be done, with tolerances and the standards to be used.  
<https://www.mesdemarches.agriculture.gouv.fr/demarches/fabrication-ou-distribution-de/commercialiser-un-produit/article/matieres-fertilisantes-et-de>
- The Netherlands provides a protocol for the complicated assessment of fertilising products that consist of or contain residue products. This protocol contains several flow charts as a decision tool, which are concise and informative and easy to understand and follow.

<https://www.rvo.nl/onderwerpen/mest/bewerken/afvalstoffen-reststoffen>.

The **national representatives of the member states are invited to provide feedback on the inception report and provide any relevant information on the guidance documents available.**

National regulations could function as a technical rule under the meaning of the Mutual recognition principle. Member states should notify the EC and other member states of any changes to those national regulations. The notification procedure established by Directive (EU) 2015/1535 is a tool for information, prevention and dialogue in the field of technical regulations on products and Information Society services. Notifications are listed in the Technical Regulation Information System, the **TRIS database**. However, only a limited number of countries have notifications on their national fertiliser regulations, and most often these referred to implementing regulations. This proved a very limited and indirect source of information on guidance documents for national regulations and was not followed through.

Technical rules developed at national level for the evaluation and authorization of fertilising products will also affect the placing on the market of national fertilising products from other member state of the EU. The product contact points could be a source of information. However, information on the targeted desks study generated sufficient results to draw general conclusions on these technical rules and guidance documents.

## 2.3 Guidance documents on other relevant EU legislation

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.

### 2.3.1 EU Guidance documents

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>

### 2.3.2 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/>

### 2.3.3 Guidance documents by industry stakeholders

- REACH for fertilizers: A platform created by Fertilizers Europe, with specific tools for both the REACH registrants of fertilizer 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 1<sup>st</sup> summit.

<https://phosphorusplatform.eu/images/Conference/SOFIE2019/Alessio-Verni-SILC-Fertilizzanti-SOFIE%20ESPP-2019.pdf>

## 2.4 Guidelines developed by industry associations

The industry associations for fertilising products have been active in preparing their members for the FPR. These associations will be consulted on any guidelines or tools or other materials developed at the EU or national level to support economic operators.

The public resources of the European industry associations were consulted for guidance documents on drafting technical documentation for EU fertilising products which these industry associations may have (had) developed as a service to their members. None of the reviewed associations had relevant publicly available documents on the elaboration of the technical documentation. A list of associations whose websites were visited is given in Annex A.

The EU industry associations have expressed interest to be involved in the study and providing feedback and suggestions.

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 producers, *Meststoffen Nederland*, contains instruction leaflets on the labelling of EU fertilising products in compliance with Annex II of the FPR. In the Netherlands, fertiliser producers, especially the SMEs, had trouble using the EU guidance document on labelling of EU fertilising products. The main difficulty was the structure of the document, with information relevant for a specific product type being spread across several chapters. Another difficulty was the use of the legal jargon and references to the articles in the FPR. To overcome these difficulties, *Meststoffen Nederland* has published 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 Dutch*). For producers, this was preferable as they can work with a document that contains all the information for their product category. They don't have to go back and forth in the document and are not troubled with information

that does not apply to their product category. 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>

## 2.5 Lessons learned from guidance documents

By examining the guidelines for product directives that have been aligned with the New Legislative Framework, several commonalities have come to light.

- All guidelines start with a preface or preamble listing the aim of the document, and disclaimers stating that the document is of a general nature, has no legal power, and only relates to the directive concerned.
- A reference to 'The Blue guide' is made.
- The introduction describes the target audience.
- Documents that should be included in the technical documentation are often mentioned throughout the guides. If lists of technical documentation elements are given they tend to be of a generic nature.
- Flow charts prove to be very concise and clear decision-support tools.
- The structure of the document is important. For reference documents, a subject structure with headings following the questions raised is preferable. For instruction documents, a structure in which the information is grouped per product type is preferable.

In general, the examined guidance documents provide a complete and extensive elaboration of obligations and requirements. They serve as a general reference and background document.

For the EU fertilising product manufacturers, especially SMEs, they are deemed too long and complex to be a practical document. Economic operators who need guidance on drawing up technical documentation generally prefer to have the information for their product grouped with hands-on instructions per PFC and CMC.

## 2.6 Structure of the guidance document

In this study the user approach will be used: information is provided in dedicated chapters with hands-on instructions per product category (PFC) and component category. These will serve as building blocks for compiling the technical documentation. Some information that is valid for multiple PFCs or CMCs will be repeated. In this way, producers will only have to read the chapters dedicated to their product and components.

In the proposed structure for the guidance, the document will start with general notes, disclaimers, and an introduction. The introduction will explain its purpose and target audience and mirrors the first section of most EU guidance documents examined under Task 1.

The Guidance document on the Toy Safety Directive (TSD) is taken as a blueprint for the content part. The headers under **content Part I** and **Annex A and B** largely correspond to the guidance document of the TSD. Also, parts of the general texts of that Guidance have been re-used, where necessary with adaptation to the FPR and EU fertilising products.

The structure of the guidance document on TSD could not be followed throughout. The TSD deals with a wide range of products of which the composition, functioning and appearances are not known beforehand. In addition, the production processes and components used are also unlimited. In contrast, the FPR contains a limited and defined list of the type of products (the PFCs) with strict prerequisites on the composition, functioning and appearance. The components used are also limited to materials that comply with strictly defined requirements (the CMCs).

The TSD contains several parts on the safety assessment of mechanical, physical, flammability and electrical hazards, hygiene and radioactivity, and the chemical safety of the toy. The safety assessment is an important part of the TD and of the guidance document and has to be performed by the manufacturer. While the safety assessment of EU fertilising products and their components has been made beforehand. The risks are managed by the detailed descriptions, prerequisites and criteria laid down in Annexes I and II of the FPR on PFC and CMC. The manufacturer proves that the product is safe by demonstrating that the product complies with the PFC and CMC descriptions, prerequisites and criteria. An additional elaborate safety assessment by producers will not be needed.

**Part II** will contain the detailed information per PFC, followed by **Part III** which will contain detailed information per CMC. In **Part IV** the list of standards will be given, with reference to parameters that they can be used for.

In the annexes of the guidance, references to other EU legislation applicable to EU fertilising products or components will be listed (**Annex A**) and other relevant sources of information on EU fertilising products (**Annex B**). Annex A contains a table with the full name of the regulation or directive and a link to summary in EU lex, and, where relevant and available, a link to guidance documents.

# **Guidance document for the elaboration of the TD for EU fertilising products**

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Table with full name, link to summary in EU lex. Where relevant and available, a link to guidance documents
- B. Sources of information on EU fertilising products legislation



# 3 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 Annex I (PFC's);
- ensure compliance with the requirements on components Annex II (CMC's);
- draft a product label according to prerequisites, Annex III (labelling);
- draw up the technical documentation (TD) to demonstrate the conformity of the product to the prerequisites of the FPR;
- carry out the relevant conformity assessment procedure, Annex IV;
- draw up an EU Declaration of Conformity (DoC) and affix the CE marking;
- keep TD and EU DoC for 5 years.

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.

## **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 Article 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.

## 4 Technical documentation

### 4.1 Technical documentation in general

The FPR contains several provisions related to technical documentation. All economic operators have obligations, but the technical documentation is drawn up by the manufacturer, as this is the operator who knows the design, production, and composition (materials and chemicals) 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”.

This obligation for the technical documentation begins when the EU fertilising product 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<sup>6</sup>. 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 toy upon reasoned request.

As a rule, the technical documentation shall contain all relevant data or details of the means 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 Declaration of Conformity signed by the authorised representative, an EC type certificate delivered by a Notified Body, test reports provided by labs, etc.

The FPR requires that the technical documentation is written in one of the official languages of the EU. Upon reasoned request by a Member State's national authority, the manufacturer or importer provides that authority with all the information and documentation necessary to demonstrate conformity of the EU fertilising product with the FPR in a language which can be easily understood by that authority. In order to carry out the conformity assessment procedures requiring third-party verification in a proper

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<sup>6</sup> 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.”

way, the technical documentation should always be in a language understood by the NoBo or in an official language of the Member State where the NoBo is established.

The manufacturer is obliged to provide the documentation and cannot argue that it contains confidential information (e.g. commercial confidentiality). Member State authorities are under the legal obligation to ensure that technical information they collect during market surveillance activities remains confidential, according to the principles laid down in their national legislation. Manufacturers, therefore, have no grounds for fearing that sensitive information they provide to national market surveillance authorities in the context of market surveillance, might be disclosed.

The technical documentation will be unique to an individual EU fertilising product, however much of the content may be repeated across a range of similar EU fertilising products. Generic files are therefore permitted as long as the differences between EU fertilising products and the documents unique to individual EU fertilising products are held.

Technical documentation does not have to be single files 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. It is essential that the history of the product is retained.

## **4.2 Technical documentation**

The technical documentation shall make it possible to assess the conformity, cover the design, manufacture and intended use of the product, and specify the applicable requirements. Compiling technical documentation is a new obligation for the producers of EU fertilising products. The manufacturer shall establish the technical documentation. The technical documentation enables conformity assessment of an EU fertilising product with the relevant requirements.

Annex IV PART II of the FPR gives a description of conformity assessment procedures. The technical documentation shall specify the applicable requirements and when relevant for the assessment also the design, manufacture and intended use of the EU fertilising product.

The general requirements on the technical documentation are given in a template shown in Table I.

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
<b>COMMON ELEMENTS for ALL MODULES</b>		
A general description of the EU fertilising product, the PFC corresponding to the claimed function of the EU fertilising product and a description of the intended use,	A general description of the product	Paragraph 4.3
	The product function category of the product according to its claimed function	Paragraph 4.3
	A description of the intended use	Paragraph 4.3
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 4.4
	For each component, a description of where the component comes from or how it was manufactured	Paragraph 4.4
The EU declarations of conformity for the component EU fertilising products of the fertilising product blend,	Only for fertilising product blends (PFC 7): The declarations of conformity of the component EU fertilising products	Paragraph 4.4
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 4.5
	Text accompanying drawings and schemes required to understand them	Paragraph 4.5
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 4.5
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 4.6
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 4.7
Test reports	Test reports of the measurements and tests done to demonstrate the compliance with the requirements for the PFC and CMCs.	paragraph 4.8
<b>MODULE A, B+C and D1</b>		
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 specifying the source and exact quantity of total chromium (Cr)	paragraph 4.9

MODULE 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 4.8
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 4.12
Modules B+C and D1		
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 is a CMC 11 by-product, proof that the component complies with the agronomic efficiency and safety criteria established for the CMC 11. Where applicable, And with the national measures transposing Article 5(1) of Directive 2008/98/EC...	paragraph 4.10
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 contains components that are derived of Animal by-products: the commercial documents or health certificates as required under the EU regulations on ABP and the evidence for the 'end-point in the manufacturing chain' for that regulations.	paragraph 4.11
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 4.7

### 4.3 General description and designated PFC

**A general description of the EU fertilising product** 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. For example, plant protection functionality falls explicitly outside the scope of fertilising products and can therefore not be a claim for an EU fertilising product.

The claims that are made must be supported by the technical documentation. The effort required to support claims varies between PFCs. It is for example straightforward to demonstrate that a product containing nitrogen in the form of urea supplies nitrogen to plants by a measurement of the N content. For plant biostimulants, on the other hand, the demonstration of the claimed function will typically require results of dedicated field or pot trials or peer-reviewed papers.

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

**A description of the intended use.** The intended use of the product should include application rates, timing, and frequency.

## 4.4 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.

When the product concerns a **fertiliser blend (PFC 7)**, the EU declarations of conformity for the component EU fertilising products of the blend.

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**.

For components that contain or consist of substances that require a REACH registration, the TD should include the **documentation that the substance is registered pursuant to Regulation (EC) No 1907/2006** and Annex II of the FPR. The documentation shall include the material safety data sheet covering the use as a fertilising product.

For the FPR, the REACH registration obligation also applies to substances produced in quantities less than a metric ton per year.

Substances for which a REACH registration is required under REACH or the FPR:

- virgin material substances (CMC 1)
- compost additives (CMC 3)
- digestate additives (CMC 4, CMC 5)
- food industry by-products (CMC 6)
- polymers (CMC 8)
- by-products (CMC 11)
- precipitated phosphate salts and derivatives (CMC 12)
- thermal oxidation materials or derivatives (CMC 13)
- pyrolysis and gasification materials (CMC 14)
- high purity materials (CMC 15)

## 4.5 Information on the manufacturing process

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

**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.



For products **containing or consisting of CMC 13** material, hazardous waste calculations (Module D1) should be included.

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 on the labelling of EU fertilising products. This guidance also contains clear examples of labels for all PFCs.

## 4.6 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 of partly applied harmonised standards or common specifications, 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 hEN 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. These can be assumed to be sufficient to demonstrate compliance with the requirements of Annexes I, II and III. The technical specifications can be obtained from the national EN associations.

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 and in conformity with the harmonised standards or parts thereof.

A list of standards will be compiled as part of this technical study. These will clearly state for which requirements they may be used. This list will contain (if available):

1. hEN Harmonised standards (which are not yet published).
2. CEN technical specifications (which are partly published as a draft for the harmonised standards)
3. Industry standards
4. Other standards

## 4.7 Results of calculations made, examinations carried out, etc.,

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.

## 4.8 Test reports

The results of the calculations made and examinations carried out should be supported by the test reports of the analyses, trials, or reviews carried out on the product and its components to demonstrate conformity with the requirements of Annex I (PFC) and Annex II (CMCs), using the standards or specifications in the list of standards or specifications under section 4.6.

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

For products in **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<sub>4</sub>NO<sub>3</sub>) (Module A1)** test reports of detonation resistance and oil retention tests to demonstrate the compliance with the requirements for the PFC should be included.

For products containing or consisting of **CMC 13 materials (Module D1)**, test should be done 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).

## 4.9 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 should be given.

## 4.10 By-products of CMC 11

Where the EU fertilising product contains or consists of **by-products belonging to CMC 11** (Modules B+C and D1) the following information should be given:

1. Technical and administrative evidence that the by-products comply with the criteria of the CMC 11 (as established by delegated REGULATION<sup>7</sup> (EU) 2022/973 of 14 March 2022).
2. Demonstration that the material complies with the national measures transposing Article 5(1) of the Waste Framework Directive (WFD) on by-products<sup>8</sup>

Article 5(1) of WFD defines the criteria for by-products as:

*Member States shall take appropriate measures to ensure that a substance or object resulting from a production process the primary aim of which is not the production of that substance or object is considered not to be waste, but to be a by-product if the following conditions are met:*

- (a) further use of the substance or object is certain;*
- (b) the substance or object can be used directly without any further processing other than normal industrial practice;*
- (c) the substance or object is produced as an integral part of a production process; and*
- (d) further use is lawful, i.e. the substance or object fulfils all relevant product, environmental and health protection requirements for the specific use and will not lead to overall adverse environmental or human health impacts.*

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<sup>7</sup> 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.

<sup>8</sup> Consolidated text: Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02008L0098-20180705>

In most Member States, these criteria are implemented in national regulations on waste or environmental protection of the environment.

3. Where the material in CMC 11 is covered by an EU implementing act to define by-product criteria for a certain material (art 5.2 WFD) this should be stated with reference in the technical documentation.

Where the material in CMC 11 is covered by national detailed criteria to define by-product criteria for certain materials (art 5.3 of the WFD) this should be stated with reference in the technical documentation.

## 4.11 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 following information should be given:

- the **commercial documents or health certificates** required by the ABPR for the ABPs that are used for the production of OF/SI (Organic fertilisers and Soil improvers as defined in Regulations EC 2009/1069 and EU 142/2011)
- **and** evidence that the derived products have reached the **end point in the manufacturing chain** for OF/SI

## 4.12 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<sub>4</sub>NO<sub>3</sub>)**:

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

## 4.13 EU DoC

Regardless of chosen conformity assessment the manufacturer shall draw up a written EU declaration of conformity (EU DoC) for an EU fertilising product and keep it together with the technical documentation at the disposal of the national authorities for 5 years after the EU fertilising product has been placed on the market.

The template for the EU DoC is given in Annex V of the FPR. This template must be used to draw up the DoC for fertilising products.

# 5 Conformity assessment modules in the FPR

## 5.1 Determination of the applicable Module

There are four conformity assessment modules within the FPR. Which module can be followed for a product depends on the product function and its components (Figure 5-1). The applicability and requirements for each module in the FPR are described in ANNEX IV of 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.

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

\* Except PFC 1(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 PFC 1 (C)(I)(a)(i-ii)(A) (ammonium nitrate fertiliser of high nitrogen content), for which Module A1 is mandatory

Figure 5-1. 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 modules A1, B+C, and D1 require certification by notified bodies. A list of NoBos can be found on the NANDO website<sup>9</sup> of the EC.

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 of the FPR. If a product complies with the criteria of multiple PFCs, the manufacturer may choose a PFC.

Next, for each ingredient/component of the product, one needs to determine to which 'component material category' (CMC) it belongs. The FPR currently has 15 CMCs which are described in ANNEX II

<sup>9</sup> [https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&sort=country&dir\\_id=159361](https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&sort=country&dir_id=159361)

of 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.

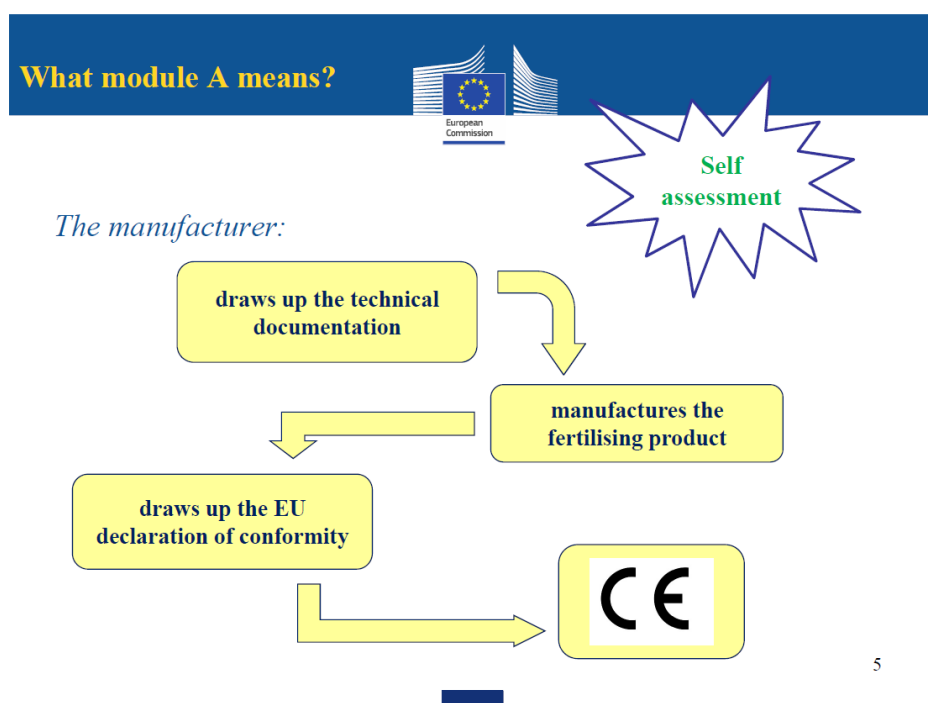
Once the PFC has been determined and all components have been categorised, a conformity assessment procedure can be determined. Within the FPR, the following conformity assessment procedures<sup>10</sup> are available: Module A, Module A1, Module B followed by Module C, and Module D1.

A flow chart to determine the applicable conformity assessment module is given in Figure 5-2.

When several conformity assessment modules are applicable, it is up to the manufacturer to decide which module to use.

## 5.2 MODULE A

Module A is an internal production control. 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 except for inhibiting compounds (CMC 1), 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 in PFC 7.

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

<sup>4</sup> For more general information and background on conformity assessment modules see 'The Blue Guide' on product regulations

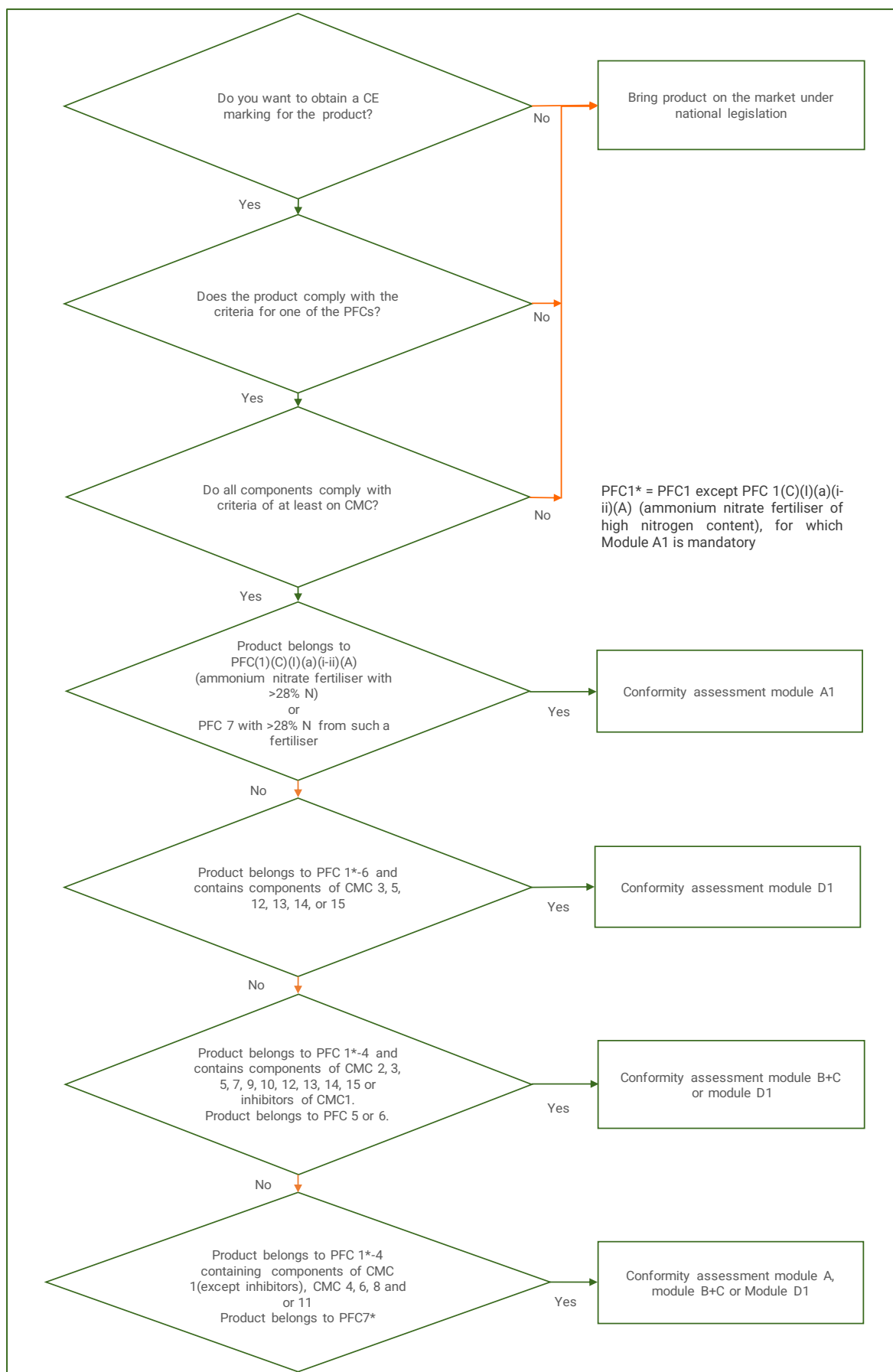
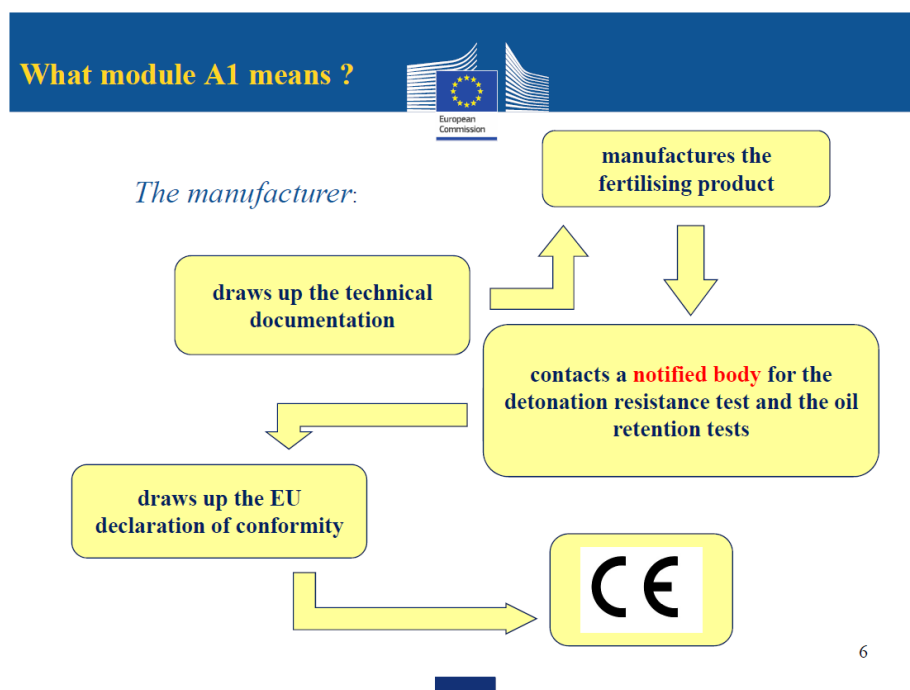


Figure 5-2 Flow chart determining the applicable conformity assessment modules (Annex IV of the FPR).  
 \*Except PFC 1(C)(I)(a)(i-ii)(A) (ammonium nitrate fertiliser of high nitrogen content), for which Module A1 is mandatory

## 5.3 MODULE A1

Module A1 must be used for ammonium nitrate fertilisers and blends with an N content >28% (PFC 1(C)(I)(a)(i-ii)(A)), and PFC 7 containing >28% N from such a fertilising product). This module requires additional testing by 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 as well as thermal cycle tests shall be done periodically on behalf of the manufacturer under the responsibility of the NoBo chosen by the manufacturer.



## 5.4 MODULE B+C

The third procedure is EU-type examination (Module B) followed by conformity to type based on internal production control (Module C).

When MODULE B+C is used as part of the conformity assessment procedure, the manufacturer will send the technical documentation to a NoBo of their choosing as part of the application for EU-type examination. The NoBo will examine this 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.

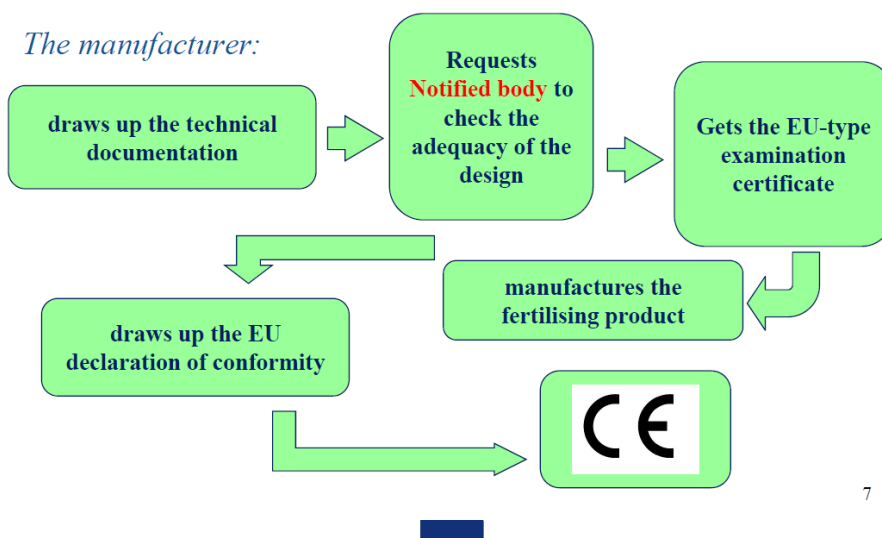
When a manufacturer modifies a product which has an EU-type examination certificate held by a NoBo in such a way that it may affect the conformity, the manufacturer shall then inform the NoBo. Such modifications require additional approval in the form of an addition to the original EU-type examination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



This 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 fertiliser blends (PFC 7) except when they contain a PFC 1(C)(I)(a)(i-ii)(A) fertiliser.

#### What means module B+C?



## 5.5 Module D1

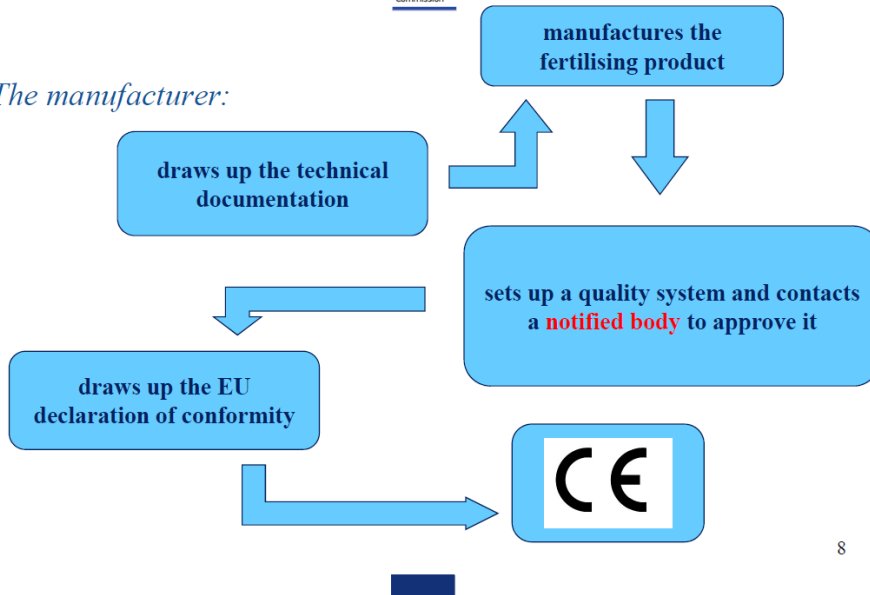
The last procedure is quality assurance of the production process (Module D1).

This module can be chosen for all products except for ammonium nitrate fertilisers with an N content >28% (PFC 1(C)(I)(a)(i-ii)(A)), and fertiliser blends containing such a fertiliser.

## What module D1 means?



*The manufacturer:*



8

## 6 Timeline of consultation activities

The timeline for proposed consultation activities that will be performed within the scope of this study are as follows:

### **18-19 April 2023 Meeting of the commission expert group on fertilising products**

- Presentation of the first results of the technical study as laid down in the inception report
- Invitation for feedback on results and proposed structure of the guidance document
- Introduction to a survey on the standards used by the different stakeholders (task 4)

### **May 2023 consultation on the first draft guidance**

- Gather written contributions from interested stakeholders on the first draft guidance as included in the approved inception report, via a survey, bilateral meetings or any similar way.
- The consultation will provide feedback on the questions if the presented line of work in the study will tackle the problems that the stakeholders encounter and if the approach chosen is seen as an effective way forward.

In addition, NMI will directly **engage most relevant stakeholders during the drafting of the text of specific PFC and CMC** elements that directly apply to them. For instance, Fertilizer Europe on the PFC 1, the EBIC for PFC 6, the ECN for the CMC 3, and the EBA for CMC 4. The EU associations of the economic operators will be consulted as a first point of communication. Stakeholders are seen as points of information, and as the 'problem holders' of the questions and uncertainties that the guidance document is envisaged to address.

### **July 2023 Workshop on the first draft guidelines and draft IT Tool**

- A virtual 3 hours workshop shall be organised to discuss the first draft final guidelines and the draft IT tool, as included in the approved interim report.
- NMI will invite the Members and Observers of the Commission expert group on fertilising products, notified bodies and market surveillance authorities responsible for FPR, as well as other interested stakeholders (such as national associations in the field of fertilising products, and economic operators).

# References

- DG GROW** (2022). *FAQs Related to Regulation (EU) 2019/1009 on Fertilising Products (the 'Fertilising Products Regulation')*. European Commission - DG GROW.
- DG GROW** (2022b) *Conformity assessment under the Fertilising products Regulation. Info session: EU fertilising products. How to CE-mark your product?* 23 May 2022. PPT presentation.
- Van Schöll L & Postma R**, 2022. *Country specific requirements for transfrontier transport and use of recycling derived fertilisers in Northwest Europe*, Nutrient Management Institute BV, Wageningen, Report 1714.N.17-IIIB.

Cover photo: **WH Riechelman** (2022), *Autumn afternoon view over Rhine floodplains near Wageningen*

# Annexes

# A. Reviewed guidance documents

## a. Guidelines at EU level following the new legislative approach

### **Guidelines on the Electromagnetic Compatibility Directive**

The guidance document on the Electromagnetic Compatibility Directive 2014/30/EU (EMCD) is extensive and includes guidance on essential requirements, the obligations of economic operators, conformity assessment for apparatus and fixed installations, market surveillance, and notified bodies. However, only just over a page is devoted to the drafting of technical documentation.

### **Guidance on the application of the lifts directive**

This document gives guidance on the application of the Lifts Directive 2014/33/EU. Many aspects of this directive are covered by this guidance document. There is no chapter specifically on drawing up technical documentation. Yet, the different conformity modules available for lifts are covered in detail.

### **ATEX 2014/34/EU Guidelines**

The guidelines on the ATEX directive (2014/34/EU), concerning equipment used in potentially explosive atmospheres. This guidance document states which documents need to be included in the technical documentation under the headings of the available conformity assessment modules. There is no section devoted specifically to drafting technical documentation.

### **Low Voltage Directive guide**

This guidance document is on the whole directive 2014/35/EU. As such, it discusses every article in the directive and the annexes. Technical documentation is discussed under ANNEX III which discusses the conformity assessment using modules A. Here, a clear list of documents that need to be in the technical documentation is given and includes a general description of the product, conceptual design and manufacturing schemes, descriptions and explanations accompanying the schemes, a list of a list of applied standards, results of calculations, and test reports.

### **PPE regulation guidelines**

This document acts as a guide to the application of Regulation (EU) 2016/425 on personal protective equipment. This guide is on the entire regulation and is thus much more extensive than just drafting technical documentation. It does contain a section specific for technical documentation, namely the one on ANNEX III Technical documentation for PPE. Here the required contents of technical documentation for PPE are listed. Furthermore, some additional remarks on technical documentation specific for the PPE regulation are made.

### **Guide to the Radio Equipment Directive**

The guide on the Radio Equipment Directive 2014/53/EU (RED) covers the whole directive and devotes a modest section to technical documentation under the description of the manufacturer's responsibility. For the general requirements of technical documentation, this guide refers to The Blue Guide.

## **Guide to the application of Regulation (EU) 2016/424 on cableway installations**

Like the other examined guides, this guide covers the entire regulation. About one page is devoted to listing the elements of the technical documentation. For more information, this guide refers to chapter 4.3 of The Blue Guide.

### **b. European industry associations reviewed for existing guidance documents**

The websites of the following associations have been visited in search of guidance documents. Results of the visit are listed after each association.

- EUROPEAN POTASH MANUFACTURERS (APEP) – no guidelines found.
- EBIC- no public guidelines on drafting technical documentation were found.
- ECOFI- no public guidelines on drafting technical documentation were found.
- EUROFEMA- no public guidelines on drafting technical documentation were found.
- EUROPEAN COMPOST NETWORK (ECN) - no public guidelines on drafting technical documentation were found.
- EUROPEAN FERTILIZER BLENDERS ASSOCIATION (EFBA) - no public guidelines on drafting technical documentation were found.
- FERTILISERS EUROPE- no public guidelines on drafting technical documentation were found.
- GROWING MEDIA EUROPE- no public guidelines on drafting technical documentation were found.
- COPA COGECA - no public guidelines on drafting technical documentation were found.
- COCERAL- irrelevant, concerns trading of cereals.
- IMA-EUROPE – irrelevant concerns marketing
- EBA (European Biogas Association) - no public guidelines on drafting technical documentation were found.



## B. Obligations of economic operations on TD and COM

Obligations of manufacturers	Obligations of authorised representatives	Obligations of importers
6. 1. <i>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</i>	7.1. <i>A manufacturer may, by a written mandate, appoint an authorised representative.</i>	8.1. <i>Importers shall place only compliant EU fertilising products on the market.</i>
6.2 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.	The obligations 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.	8.2. 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).
6.3 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.	7.2(a) 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;	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 and ensure that the technical documentation can be made available to those authorities, upon request.

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

7.2.(b) 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; 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.

On request, importers shall make a copy of the EU declaration of conformity available to other economic operators.

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.

## 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.

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	
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	

Products	Applicable procedures	Articles/Annexes	Procedures' applicability limitations
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	
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
			<p>(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).</p> <p>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,</p>
(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:

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

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.



## E. PFC Detailed list of all the relevant elements/contents

Technical documentation must enable someone to assert that a product conforms with the requirements for that product. The requirements differ between PFCs and depend on to which CMC the ingredients belong. The following table lists the requirements for each PFC as described in Annex I of the FPR. The second table lists the requirements for each CMC as laid out in Annex II of the FPR. Besides listing the requirements, the tables also suggest a method or document with which to demonstrate compliance with each criterium.

In Annex I part I of 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

In Annex I part II the description, requirements and criteria are given for each PFC.  
For each FPC product, the elements for every PFC level and sublevel should be included.

Table IV. Overview of requirements for products per product function category and content suggestions for the technical documentation.

clause	PFC level	clause summary	suggested content
<b>PFC 1 Fertilisers</b>			
Annex I PFC 1	PFC 1	A PFC 1 product must be able to supply nutrients to plants or mushrooms	Analysis proofing nutrient contents
<b>PFC 1 A Organic fertilisers</b>			
Annex I PFC 1 (A) 1	PFC 1 A	Contains organic carbon of biological origin	Lab analysis
Annex I PFC 1 (A) 1	PFC 1 A	Contains nutrients of biological origin	Product 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 <sub>2</sub> H <sub>5</sub> N <sub>3</sub> O <sub>2</sub> ), Cu, Zn	Lab analysis
Annex I PFC 1 (A) 4	PFC 1 A	Pathogens in the product cannot exceed limits (Salmonella spp., Escherichia coli or Enterococcaceae)	Lab analysis
Annex I PFC 1 (A)(I) 1	PFC 1 A I	The product is solid	Should be self-evident
Annex I PFC 1 (A)(I) 2	PFC 1 A I	Must contain N, P, and or K with certain minimum contents	Lab analysis
Annex I PFC 1 (A)(I) 3	PFC 1 A I	The organic C content must be >=15% by mass	Lab analysis
Annex I PFC 1(A)(II) 1	PFC 1 A II	A liquid fertiliser must be liquid	Should be self-evident
Annex I PFC 1(A)(II) 2	PFC 1 A II	Must contain N, P, and or K with certain minimum contents	Lab analysis
Annex I PFC 1(A)(II) 3	PFC 1 A II	The organic C content must be >=5% by mass	Lab analysis

clause	PFC level	clause summary	suggested content
<b>PFC 1 B Organo-mineral fertilisers</b>			
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%	Lab analysis
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 (C <sub>2</sub> H <sub>5</sub> N <sub>3</sub> O <sub>2</sub> ), Cu, Zn, and pathogens	Lab analysis
Annex I PFC 1(B)(I) 1	PFC 1 B I	The product is solid	Should be self-evident
Annex I PFC 1(B)(I) 2	PFC 1 B I	Must contain N, P, and or K with certain minimum contents	Lab analysis
Annex I PFC 1 (B)(I) 3	PFC 1 B I	the organic C content must be ≥5 by mass	Lab analysis
Annex I PFC1 (B)(I) 4	PFC 1 B I	Each piece 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	Should be self-evident
Annex I PFC1 (B)(II) 2	PFC 1 B II	Must contain N, P, and or K with certain minimum contents	Lab analysis
Annex I PFC1 (B)(II) 3	PFC 1 B II	the organic C content must be ≥3 by mass	Lab analysis
<b>PFC 1 C Inorganic fertilisers</b>			
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 proof that it 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

clause	PFC level	clause summary	suggested content
Annex I PFC (C)(I) 2 & 3	PFC 1 C I	Must not exceed limits for Cd, Cr VI, Hg, Ni, Pb, As, biuret (C <sub>2</sub> H <sub>5</sub> N <sub>3</sub> O <sub>2</sub> ), perchlorate (ClO <sub>2</sub> ), Cu, and Zn	Lab analysis
Annex I PFC 1(C)(I)(a)	PFC 1 C I a	The product is solid	Should be 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%	Lab analysis
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 (Na <sub>2</sub> O) must be ≤ 40% by mass	Lab analysis
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 (NH <sub>4</sub> NO <sub>3</sub> )	Lab analysis
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	Oil retention test executed by 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	Detonation test by 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	Lab analysis
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.	Proof of the requirement
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.	Lab analysis
Annex I PFC 1(C)(I)(b)	PFC 1 C I b	A liquid fertiliser must be liquid	Should be self-evident

clause	PFC level	clause summary	suggested content
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.	Lab analysis
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.	Lab analysis
Annex I PFC1(C)(II) 1	PFC 1 C II	Supplies B, Co, Cu, Fe, Mn, Mo, or Zn to plants or Mushrooms	Lab analysis
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	Lab analysis
Annex I PFC 1(C)(II)(a) 1	PFC 1 C II a	Must only have one declared micronutrient	Lab analysis
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 lab analysis
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	Lab analysis
<b>PFC 2 Liming materials</b>			
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 lab analysis
Annex I PFC2 2&3	PFC 2	Must not exceed limits for Cd, Cr VI, Hg, Ni, Pb, As, Cu, Zn	lab analysis
Annex I PFC2 4 a	PFC 2	Liming materials must have a minimum neutralising value of 15 (equivalent CaO) or 9 (equivalent HO-)	lab analysis
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)	lab analysis

clause	PFC level	clause summary	suggested content
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.	lab analysis of a sieve test
<b>PFC 3 Soil improvers</b>			
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.	Lab analysis
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	Lab analysis
Annex I PFC3 A 5	PFC 3 A	An organic soil improver shall contain 20 % or more dry matter.	Lab analysis
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.	Lab analysis
Annex I PFC3 B 2	PFC 3 B	Must not exceed limits for Cd, Cr VI, Hg, Ni, Pb, As, Cu, Zn, and pathogens	Lab analysis
<b>PFC 4 Growing media</b>			
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	Lab analysis
<b>PFC 5 Inhibitors</b>			
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
Annex I PFC 5 A 1	PFC 5 A	A nitrification inhibitor inhibits the conversion of NH3 to NO2	Lab analysis
Annex I PFC 5 A 2	PFC 5 A	The product is proven to slow the rate of ammoniacal nitrogen oxidation during 14 days after application	Lab analysis

clause	PFC level	clause summary	suggested content
Annex I PFC 5 B 1 & 2	PFC 5 B	The product is proven to slow or block the conversion of nitrate to N <sub>2</sub> without affecting the oxidation of ammoniacal nitrogen.	Lab analysis
Annex I PFC 5 C 1 & 2	PFC 5 C	The product shows a 20% reduction in hydrolysis of urea compared to an untreated control.	Lab analysis
<b>PFC 6 Plant biostimulants</b>			
Annex I PFC 6 1	PFC 6	The product has at least one of the described functions.	Claims in the product description and claims on the product label. Demonstration of claims must be provided via 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	Lab analysis
Annex I PFC 6 4	PFC 6	The label must specify to which plants the claimed functions apply	Product label
PFC 6 A 1	PFC 6 A	The product contains at 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	Lab analysis
PFC 6 A 3	PFC 6 A	When liquid, the pH must be optimal for the contained micro-organisms	Lab analysis
PFC 6 B 2	PFC 6 B	The product does not exceed limits for pathogens	Lab analysis
<b>PFC 7 Fertilising product blends</b>			
Annex I PFC 7 1	PFC 7	A blend must contain at least two CE fertilising products	List of components
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.	Declaring that the blend does not behave differently compared to the situation where the component fertilisers are used separately.
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.

clause	PFC level	clause summary	suggested content
Annex I PFC 7.3	PFC 7	The manufacturer asserts that the blend conforms to the FPR	EU declaration of conformity (DoC) for the blend and the component products



## F. CMC Detailed list of all the relevant elements/contents

A product belonging to a PFC may solely consist of one or more materials that belong to the CMCs that are designated in Annex II part I.

CMC 1. Virgin material substances and mixes;

CMC 2. Non-processed or mechanically processed plants, plant parts or plant extracts;

CMC 3. Compost;

CMC 4. Energy crop digestate;

CMC 5. Other digestate than energy 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 (Animal by-products Regulation);

CMC 11. By-products within the meaning of Directive 2008/98/EC (Waste Framework Directive);

CMC 12. Precipitated phosphate salts or derivatives (including struvites)

CMC 13. Thermal oxidation materials or derivatives (including ashes)

CMC 14. Pyrolysis or gasification materials.

CMC 15. Pure materials recovered from waste

In Annex II part II of the PFR the description, requirements and criteria are given for each CMC.

These may include requirements on the origin, production or recovery process and parameters, treatment, feedstocks, criteria on contaminants and pathogens and sanitary requirements.

Related clause	suggested content	Clause summary
Annex II CMC 1 1	Description of the material and its origin	A CMC 1 is a substance or <i>mixture not being one of the excluded materials</i>
Annex II CMC 1 2	Proof of REACH registration of the substance or mixture with information provided by Annexes VI, VII, and VIII to REACH and a chemical safety report as described in Article 14 of REACH. For <i>more information on REACH registration see the relevant guidance documents which can be found here: <a href="https://echa.europa.eu/guidance-documents/guidance-on-reach">https://echa.europa.eu/guidance-documents/guidance-on-reach</a>.</i>	Proof of REACH registration of the substance or mixture with information provided by Annexes VI, VII, and VIII to REACH and a chemical safety report as described in Article 14 of REACH.
Annex II CMC 1 3	Description of the molecular structure of the chelating agent. A test report proofing stability for three days in a solution at any indicated pH. <i>A test report proofing stability in water at both pH 6 and 7 for at least 1 day.</i>	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.
Annex II CMC 1 4	Description of the compound	When a CMC 1 material is intended to improve nutrient release patterns, it must be either a nitrification, denitrification, or urease inhibiting compound and meet specific criteria.
Annex II CMC 1 4 a	Experimental evidence illustrating that the required reduction in nitrification rate is achieved when applying the compound to soil	A nitrification inhibiting compound must be proven to reduce the rate of biological oxidation of ammoniacal nitrogen.
Annex II CMC 1 4 b	Experimental evidence illustrating that the required reduction in denitrification rate is achieved when applying the compound to soil without influencing nitrification processes.	A denitrification inhibiting compound must be proven to reduce formation of nitrous oxide in a fertilising product by slowing or blocking conversion of <i>nitrate to dinitrogen without influencing the nitrification process.</i>
Annex II CMC 1 4 c	Experimental evidence demonstrating that the compound reduces hydrolysis of urea by at <i>least 20% compared to a control sample.</i>	A urease inhibiting compound must be proven to reduce urea hydrolysis.
Annex II CMC 2	Description of the component including its origin and the processing which the component underwent.	A complete, part, or extract of plants, mushrooms or algae (excluding cyanobacteria) <i>may only have been processed by cutting, grinding, milling, sieving, sifting, centrifugation, pressing, drying, frost treatment, freeze-drying, extraction with water, supercritical CO2 extraction, or fiberisation at a temperature not higher than 100 °C and without any additives other than water</i>
Annex II CMC 3	Description of the component including its origin and the processing which the component underwent.	A limited number of materials is allowed within CMC 3 and are listed in detail <i>in Annex II CMC 3 articles 1 and 1a</i>

Annex II CMC 3 1	A detailed description of the origin of the materials that went into the composting process. If the compost contains additives (d), include proof of the REACH registration of the additive(s). If the compost contains materials which have previously been composted or digested, proof that this material does not contain more than 6 mg/kg dry matter of PAH16.	A CMC 3 material is a compost obtained through aerobic composting of one or more materials in the following list: (a) separately collected bio-waste, (c) living or dead organisms which are unprocessed or processed in a simple manner excluding organisms from municipal waste, sludge, or animal by-products, (d) composting additives which are REACH registered, do not make up more 5% of the product, and (e) materials listed under (a) or (c) which have previously been digested or composted which do not contain more than 6 mg/kg dry matter of PAH16.
Annex II CMC 3 1a	A description of the compost input material and its origin. Documentation to show that the material has reached an end-point in the manufacturing chain according to Regulation (EC) No 1068/2009.	As an exception to point CMC 3 1, Category 2 or Category 3 materials as well as materials derived thereof, may be used as input for composting if an end point for <i>this material has been determined. In other words, animal-by products that are determined to not be animal by-products any longer, may be used as feedstock for composting.</i>
Annex II CMC 3 2	A written description and a diagram of the composting process, where each treatment, storage vessel and area is clearly identified.	The compost is produced in a plant where production lines for processing allowed and forbidden input materials are clearly separated. <i>Input and output materials are physically separated at all times.</i>
Annex II CMC 3 3	Description of the composting process	The compost is produced with <i>one of the described temperature-time profiles</i>
Annex II CMC 3 4	Analysis of PAH16 contents and macroscopic impurities of the component.	The compost must meet criteria for maximum PAH16, glass, metal, <i>and plastic contents.</i>
Annex II CMC 3 5	Proof compliance with stability criteria with experiments demonstrating <i>the oxygen uptake rate or self heating factor</i>	The compost must meet criteria for stability.
Annex II CMC 4 1	Description of the input materials for digestion. When input materials are (environmental) performance additives, these additives comply with <i>the criteria in point 2 of CMC1 (on REACH registration of substances) and all additives combines shall not exceed 5% by weight of the input materials.</i>	The input materials for digestion must be described and may need to be REACH registered if they are additives.
Annex II CMC 4 2	Description of the plant and the manufacturing process and storage.	The digestate is produced in a plant where production lines for <i>processing allowed and forbidden input materials are clearly separated. Input and output materials are physically separated at all times.</i>
Annex II CMC 4 3	Description of the manufacturing process	The digestion process must follow <i>one of the given temperature-time profiles followed by either hydraulic retention, pasteurisation, or composting.</i>
Annex II CMC 4 3a-d	Description of the processing after digestion.	After digestion, the digestate may be <i>processed but only in a limited number of ways described in points 3a to 3d</i>
Annex II CMC 4 4	Proof of stability of the digestate or digestate fraction(s)	Digestate (fractions) must meet criteria for stability.

Annex II CMC 5 5	Analysis of macroscopic impurities of the component.	The compost must meet criteria for maximum glass, <i>metal</i> , and <i>plastic contents</i> .
Annex II CMC 5 6	Proof of stability of the digestate or digestate fraction(s)	Digestate (fractions) must meet criteria for stability.
Annex II CMC 6 1	Description of the material and the treatments it underwent during processing prior to the material becoming a by-product	The component is one of the following: burnt lime from natural sources, beet or cane molasses, vinasse, <i>distiller grains</i> , <i>plant (parts) or extracts having undergone only heat treatment and/or processing methods listed in CMC2</i> , or <i>lime from drinking water production</i> .
Annex II CMC 6 2	Proof of REACH registration of the substance or mixture with information provided by Annexes VI, VII, and VIII to REACH and a chemical safety report as described in Article 14 of REACH	The material must be REACH registered unless explicitly exempt from REACH registration by the REACH regulation.
ANNEX II CMC 7	Description of the component	Microbial plant biostimulants may <i>contain a limited set of micro-organisms, including dead or empty-cells and non-harmful residues of their growing medium as long as the component has undergone no other processing than drying or freeze-drying</i> .
ANNEX II CMC 8 1	A description of the component and for all its different component monomers: proof of REACH registration of the monomer with information provided by Annexes VI, VII, and VIII to REACH and a chemical safety report as described in Article 14 of REACH	Only polymers made up of monomers that comply with the criteria in points 1 and 2 of CMC 1 are allowed. The purpose of polymerisation must be the controlled release of nutrients from at least one of the monomer substances.
ANNEX II CMC 8 2	Proof of the solubility of the polymers <i>in a phosphate buffer solution with a pH of 7.5 at 100 °C</i>	The component must meet solubility criteria.
ANNEX II CMC 8 3	To be announced	The polymers must <i>degrade to nothing but ammonia, water and carbon dioxide</i>
ANNEX II CMC 8 4	Analysis of formaldehyde content	The component may not <i>contain more than 600ppm formaldehyde</i>
ANNEX II CMC 9 1	A description of the component and its purpose in the product.	Polymers other than nutrient polymers may be used to control water penetration <i>into the nutrient particle of the product, or to increase water retention of the product or to bind growing media (PFC 4)</i>
ANNEX II CMC 9 2	Not yet applicable, see results of the study on biodegradability criteria of polymers expected in 2024.	From July 16th 2026, polymers aimed to control water penetration or water retention of a nutrient particle, <i>must comply with biodegradability criteria</i> .
ANNEX II CMC 9 3	Reports of the plant growth acute toxicity test, earthworm acute toxicity test and nitrification inhibition test which are described in detail in ANNEX II CMC 9 3 a, b and c	Polymers regulating water penetration or wettability of nutrient particles must pass toxicity tests for plant growth and earthworms as well as a nitrification inhibition test.

ANNEX II CMC 10	A description of the component and its origin.	Derived products must have an end point in accordance <i>with the animal by-product regulation and be listed in a table under CMC 10 which has not been drawn up yet.</i>
ANNEX II CMC 11 1	Description of the component	By-products may be used as <i>CMC 11 component if they are not covered by any of the other CMC's</i>
ANNEX II CMC 11 2	Proof of REACH registration of the substance or mixture with information provided <i>by Annexes VI, VII, and VIII to REACH and a chemical safety report as described in Article 14 of REACH</i>	A CMC 11 material is REACH registered unless exempt from REACH registration
ANNEX II CMC 11 3	See criteria from delegated Regulation (EU) 2022/973 below.	Regulation (EU) 2022/973 lays down the criteria for safety <i>and agronomic efficiency of by products which are not explicitly included in CMC's 12, 13, 14, and 15.</i>
Delegated regulation (EU) 2022/973 Article 1 1	Description of the production process, analysis results of organic C, PAH16, and PCDD/PCDF content. As well as analysis results of the fertilising product on total chromium (Cr) and thallium (Tl) contents, unless compliance follows certainly and uncontestably from the nature or manufacturing process of the EU fertilising product.	Components in CMC 11 must have a high purity and low levels of contamination with organic C, PAH16 and PCDD/PCDF. The high purity criteria means that it must contain at least 95% by dry matter of ammonium-, sulphate-, phosphate salts, sulphur, calcium carbonate, calcium oxide, or mixtures of these. <i>Furthermore, products containing such a CMC must meet criteria for total chromium (Cr) and thallium (Tl) content.</i>
Delegated regulation (EU) 2022/973 Article 1 2 a-b	product description including the mass fractions of each component.	When a CMC 11 component is added to a fertilising <i>product as technical additive, they may function as a hardening, binding, filling, or anti-dusting agent. Technical additives may be used to improve the agronomic efficiency or safety of use of the product. A fertilising product shall not contain more than 5% of technical additives by mass.</i>
Delegated regulation (EU) 2022/973 Article 1 2 c-d	Analysis report on PAH16 and PCDD/PDCF contents, unless compliance follows <i>certainly and uncontestably from the nature or manufacturing process of the EU fertilising product.</i>	The component must meet criteria for PAH16 and PCDD/PCDF content

Delegated regulation (EU) 2022/973 Article 2 1	Description of the component	The criteria in Article 1 of CMC 11 do not apply to: (a) mother liquor from the reaction of 5( $\beta$ -methyl-thioethyl)-hydantoin with potassium carbonate in the methionine production process;(b) residues from the processing and purification of minerals and ores, if they contain calcium carbonates, magnesium carbonates, calcium sulphates, magnesium oxide, phosphate salts, and/or water-soluble salts of potassium, magnesium or sodium, in a total content of more than 60 % dry matter of the residues;(c) post-distillation liquid from Solvay process;(d) carbide lime from acetylene production;(e) ferrous slags;(f) substances derived from ore concentrate processing and metal surface treatment that contain at least 2 % by mass of di- or tri-valent transition metal cations (zinc (Zn), copper (Cu), iron (Fe), manganese (Mn) or cobalt (Co)) in solution;(g) humic and fulvic acids from drinking water discolouration.
Delegated regulation (EU) 2022/973 Article 2 2	Analysis report demonstrating the activity of the fertilising product, unless compliance follows certainly and <i>uncontestably from the nature or manufacturing process of the EU fertilising product</i> .	Limits are defined on the radioactivity of fertilising products containing processed sedimentary phosphate ores
Delegated regulation (EU) 2022/973 Article 2 3	Analysis of the total chromium (Cr), thallium (Tl), and vanadium (V) content on dry matter basis, unless compliance follows certainly and <i>uncontestably from the nature or manufacturing process of the EU fertilising product</i> .	Ferrous slags, substances derived from ore processing
Delegated regulation (EU) 2022/973 Article 3	0	Where compliance with a given requirement follows certainly and <i>uncontestably from the nature or manufacturing process of the by-product or of the EU fertilising product containing such a by-product</i> , compliance may be assumed without verification such as a test, at the responsibility of the manufacturer. This applies to the PAH16 and PCDD/PCDF requirements of nutrient providing by-products and technical additives, the total chromium (Cr) and thallium (Tl) requirements for nutrient providing by-products, the radioactivity requirement for products containing processed sedimentary phosphate ores, and the total chromium (Cr), thallium (Tl), and vanadium (V) requirements for ferrous slags and substances derived from ore concentrate processing and metal surface treatments.
Delegated regulation (EU) 2022/973 Article 4 1	Sample of the product label. Analysis of the selenium content. If this exceeds 10 mg/kg dry matter on product basis, the selenium content must be indicated on the product label.	For most by-products which are not used as technical additives, the selenium content of the product must be indicated on the product label if this exceeds 10 mg/kg on dry matter basis.

Delegated regulation (EU) 2022/973 Article 4 2	Sample of the product label. Analysis of the chloride content. If this exceeds 30 g/kg dry matter on product basis, the chloride content must be indicated on the product label. Unless, chloride was added to the fertilising product during the manufacturing process with the intention of producing alkali metal salts or alkaline earth metal salts and information on these salts is provided in accordance with Annex III of the FPR.	For most by-products which are not used as technical additives, the chlorine contents must be indicated on the product label if the product contains more than 30 g/kg chlorine on product basis. Unless chlorine was intentionally added to form alkaline salts (such as potassium, calcium and magnesium chloride).
Delegated regulation (EU) 2022/973 Article 4 3	Sample of the product label	When selenium or chloride content <i>is indicated on the label because they exceed respectively 10 mg/kg and 30 g/kg on dry matter product basis, their declaration(s) must be clearly separated from the nutrient declaration. These indication may be expressed as ranges of values.</i>
Delegated regulation (EU) 2022/973 Article 4 4	Description of the nature of the by-product, its production process and the production process of the fertiliser product.	If the selenium and/or chloride content fall below the limit values and this follows certainly and uncontestably from <i>the nature or manufacturing process of the by-product or the product containing such a by-product, the label may contain no information on these parameters without verification.</i>
ANNEX II CMC 12 1	Description of the component, the origin of the input materials to produce it, and a detailed description of the manufacturing process of the component.	Precipitated phosphate salts can be used as CMC 12 if they are produced from a limited set of input materials with limitation on which processing steps <i>may or must be used.</i>
ANNEX II CMC 12 2	Description of the reactor where precipitation takes place. Including describing other material streams processed at the plant and how <i>these are kept separate from the material for producing CMC 12</i>	precipitation must take place in a plant where the input material can be kept separated from contaminated material streams
ANNEX II CMC 12 3	Lab analysis proofing minimum P2O5 and maximum organic C on dry matter basis. Analysis results proofing that the amount of <i>macroscopic impurities is below the thresholds on weight by weight basis.</i>	The component must have a minimum P2O5 content and not exceed maximum contents of organic C and macroscopic impurities.
ANNEX II CMC 12 4	Description of the production process	Derivatives from precipitated phosphate salts <i>may be used too if they have undergone intentional reaction with a limited set of materials.</i>
ANNEX II CMC 12 5	0	Phosphate salts used to make derivates must comply with points 1, 2, and 3.
ANNEX II CMC 12 6	Description of the component, the origin of the input materials to produce it, and a detailed description of the manufacturing process of the component.	Animal by-product of category 2 and 3 as well as derived products thereof may be used to produce precipitated phosphate salts and derivates if and end <i>point in the manufacturing chain has been determined (it is no longer considered an animal-by-product).</i>
ANNEX II CMC 12 7	Description of the plant where precipitation takes place. Including describing other material streams processed at the plant and how <i>these are kept separate from the material for producing CMC 12</i>	0

CMC 12 8	Analysis reports on pathogens	When the PFC of the product in which a CMC 12 material is used does not have limits for pathogens, the CMC 12 material must meet criteria with regards to pathogen content.
ANNEX II CMC 12 9	Analysis reports on pathogens	Products containing CMC 12 materials must also meet criteria for contamination with <i>Clostridium perfringens</i> and for viable eggs of <i>Ascaris</i> sp.
ANNEX II CMC 12 10	Description of the production processes	The criteria for pathogens do not apply when the product contains solely CMC 12 materials and all biogenic input materials or the salts have undergone pressure sterilisation, pasteurisation, or hygienisation as described in the directive extract.
ANNEX II CMC 12 11	Analysis reports on PAH 16	Salts and derivatives of salts obtained from sewage sludge or municipal wastewater treatment plants must meet criteria for PAH 16 contamination.
ANNEX II CMC 12 12	Lab analysis report on aluminium and iron content on dry matter basis.	Phosphate salts and derivatives may not contain more than 10% aluminium and iron on dry weight basis combined.
ANNEX II CMC 12 13	Proof of REACH registration of the substance or mixture with information provided by Annexes VI, VII, and VIII to REACH and a chemical safety report as described in Article 14 of REACH	The precipitated phosphate salts or derivatives should be REACH registered.
ANNEX II CMC 12 14	Specification of the methods used to determine dry matter of the component	Dry matter determination of samples must be done with vacuum drying at 40 °C to avoid loss of crystal-bound water
ANNEX II CMC 13 1	Description of the component and its input materials	CMC 13 contains thermal oxidation products under non oxygen limited conditions (ashes from combustion) if the input materials are listed in the directive extract.
ANNEX II CMC 13 2	Description of the component and its input materials	Animal by products of category 2 and 3 and products derived thereof may also be used as input materials for thermal oxidation if they have obtained an end-point in the manufacturing chain (they are no longer considered animal-by-products) and they fulfil the conditions in points 3, 4, and 5.
ANNEX II CMC 13 3	Thermal oxidation process description.	The gas resulting from Thermochemical conversion process after the last injection of combustion air must reach a minimum temperature for a minimum amount of time.
ANNEX II CMC 13 4	Description of the incineration or combustion chamber and other materials streams that may be combusted in this chamber. A guarantee that the total organic carbon content of the resulting slag and ashes is less than 3% of the material's dry matter	Contamination of the component must be avoided by keeping it separate from other material streams and separating input and output materials at all times. Furthermore, the organic C content of the resulting slags and ashes cannot exceed 3 % of dry matter.
ANNEX II CMC 13 5	Analysis results of the component slags or ashes of the PAH16 and PCDD/PCDF contents on dry matter basis	The component must meet criteria for PAH16 and PCDD/PCDF content



ANNEX II CMC 13 6	Detailed description of the production process and all input materials used.	Derivates of thermal oxidation products may be used as well, if <i>they have undergone a process to intentionally modify their chemical composition and the manufacturing process is of a specific nature.</i>
ANNEX II CMC 13 7	Description of the input materials, output materials and when needed analyses of chromium, thallium, chlorine, and vanadium content.	The component must meet criteria for vanadium content and depending on the input material must also meet criteria for chromium, thallium, and/or chlorine.
ANNEX II CMC 13 8	Proof of REACH registration of the substance or mixture with information <i>provided by Annexes VI, VII, and VIII to REACH and a chemical safety report as described in Article 14 of REACH</i>	The thermal oxidation products or derivates should be REACH registered.
ANNEX II CMC 14 1	Description of the material and any processing it underwent.	A fertilising product may contain certain products of pyrolysis or <i>gasification obtained through thermochemical conversion under oxygen-limiting conditions.</i>
ANNEX II CMC 14 2	Description of the conversion process including how the input and output materials are kept separated from each other.	During pyrolysis or gasification a temperature of at least 180 °C must be reached for at least 2 seconds. <i>Contact between input and output materials must be avoided at all times. The reactor itself may only process materials streams which are not contaminated.</i>
ANNEX II CMC 14 3	Analysis of the H/Corg content of the dry and ash-free fraction. As well as <i>analysis reports on the PAH16 and PCDD/PCDF contents.</i>	Limits are defined for the H/Corg ratio and contents of PAH16 and PCDD/PCDF
ANNEX II CMC 14 4	Description of the material and any processing it underwent.	Input material for gasification or pyrolysis may contain animal by-products <i>and derived products of category 2 and category 3 if an end-point in the manufacturing chain has been determined and they meet the criteria of points 2 and 3.</i>
ANNEX II CMC 14 5	Description of the plant and the production lines in the plant.	Production lines where a CMC 14 material is produced must be clearly <i>separated from production lines where input materials which are not allowed for CMC 14, are processed.</i>
ANNEX II CMC 14 6	Analysis report of the chlorine and thallium contents on dry matter basis of the product.	Fertilising products must meet criteria for chlorine contents if they contain CMC 14 components. <i>They must also meet thallium content criteria if they contain more than 5% CMC 14 materials on fresh weight basis.</i>
ANNEX II CMC 14 7	Proof of REACH registration of the substance or mixture with information <i>provided by Annexes VI, VII, and VIII to REACH and a chemical safety report as described in Article 14 of REACH</i>	The thermal pyrolysis or gasification product should be REACH registered.
ANNEX II CMC 15 1	Description of the material	A CMC 15 material <i>can be recovered ammonium-, sulphate-, phosphate salt, elemental sulphur, calcium carbonate, calcium oxide, or mixtures thereof if the material has a purity of at least 95%.</i>

ANNEX II CMC 15 2	Description of the material and its origin	A CMC 15 material may only be <i>recovered from production processes that use non animal by-products, and from gas purification of off-gases derived from a limited set of input materials and facilities (including livestock housing, manure, and waste) under the condition that the component does not itself include animal by-products.</i>
ANNEX II CMC 15 3	Analysis report including the organic C content and dry matter content.	A CMC 15 material must not contain more than 0.5% Corg <i>on dry matter basis.</i>
ANNEX II CMC 15 4	Analysis results of the component slags or ashes of the PAH16 and PCDD/PCDF contents on dry matter basis	The component must meet criteria for PAH16 and PCDD/PCDF content
ANNEX II CMC 15 5	Analysis report of the chlorine and thallium contents on dry matter basis of the product.	Fertilising products must meet criteria for chlorine and thallium contents if they contain CMC 15 components.
ANNEX II CMC 15 6	Product description	Where compliance with the requirements for PAH16, PCDD/PCDF, chlorine, and/or thallium content follows certainly and uncontestably from the nature of the recovery process of the component or the manufacturing process of the product, that compliance may be presumed without verification under the responsibility of the manufacturer.
ANNEX II CMC 15 7	Analysis of the product on presence of Salmonella spp, Escherichia coli and Enterococcaceae	If the PFC of the product does not have criteria for pathogens and the CMC 15 material is obtained from the purification of off-gasses, the product must meet criteria for pathogens anyway by virtue of this clause.
ANNEX II CMC 15 8	Lab analysis to demonstrate that the product does not exceed limits for Salmonella spp., Escherichia coli, and Enterococcaceae. OR proof via a description of the production process and facilities that the high purity material or all biogenic material in the product, has undergone <i>either (a) pressure sterilisation to a core temperature of 133°C for at least 20 minutes at least 3 bars whereby the pressure must be produced by the evacuation of all air in the sterilisation chamber and the replacement of the air by steam; (b) processing in a pasteurisation or hygienisation unit that reaches a temperature of 70°C for at least one hour. OR demonstrate that the high purity material is derived from an incineration process defined in Directive 2010/75/EU (Directive on industrial emissions (integrated pollution prevention and control))</i>	Compliance with point 7 must be verified in accordance with point 5.1.3.1 of module D1 unless all biogenic input material of the high purity material have undergone either pressure sterilisation at a given time and temperature or pasteurisation at 70 °C for an hour.
ANNEX II CMC 15 9	Description of the storage facilities of the component and the manufacturing date of the high purity material (if stored unprotected from precipitation and sunlight).	High purity materials that are stored improperly may be used if they are manufactured at most 36 months before signing the EU declaration of conformity.
ANNEX II CMC 15 10	Proof of REACH registration of the substance or mixture with information <i>provided by Annexes VI, VII, and VIII to REACH and a chemical safety report as described in Article 14 of REACH</i>	The thermal pyrolysis or gasification product should be REACH registered.



# G. List of national market surveillance authorities

A list of national market surveillance authorities can be found on the [website](#) EC DG GROW: The implementation of market surveillance in Europe.

The following list is an excerpt (29/3/2023) of the list for the national market surveillance authorities on fertilising products.

## Austria

baes@baes.gv.at  
Tel:+43 5 0555 - 0  
Federal Office for Food Safety -  
www.baes.gv.at  
Spargelfeldstrasse 191, 1220 Vienna - Austria  
*updated Sep.2020*

## Belgium

s1.fertil.pccb@favv-afsca.be  
Tel:+32 2 211 86 15  
Federal Agency for the Safety of the Food Chain  
(FASFC) -  
www.afsca.be  
Boulevard du Jardin Botanique 55, 1000 Brussels -  
Belgium  
*updated Aug.2020*

## Bulgaria

bfsa@bfsa.bg  
Tel:+35929173717; +35929173705 Fax+35929159898  
Bulgarian Food Safety Agency - Plant Protection  
Products, Fertilisers and Control Directorate  
www.bfsa.bg  
15A, Pencho Slaveykov Boulevard, 1000 Sofia -  
Bulgaria  
*updated Sep.2020*

## Croatia

???@dirh.hr  
Tel: +38512375100  
State Inspectorate -  
https://dirh.gov.hr/  
Šubićeva 29, 10000 Zagreb - Croatia  
*updated Aug.2020*

## Cyprus

director@da.moa.gov.cy  
Tel: +357 22408519, +357 22408633  
Fax: 357 22781425,  
+357 22408538  
Ministry of Agriculture, Rural Development and  
Environment - Department of Agriculture  
(Agrochemicals and Feedingstuffs Sector  
www.moa.gov.cy/da

Loukis Akritas Avenue, 1412 Nicosia - Cyprus  
*updated Dec.2022*

## Czech Republic

hnojiva@ukzuz.cz  
Tel:+420543548331, Fax+420257294218  
Central Institute for Supervising and Testing in  
Agriculture - Section of Agricultural Inputs  
www.ukzuz.cz  
Hroznova 2 656 06 Brno - Czech Republic  
*updated Jul.2021*

## Denmark

mail@lbst.dk  
Tel:+4533958000, Fax:+4533958080  
Danish Agricultural Agency -  
https://eng.lbst.dk/about-us/contact/  
Nyropsgade 30, 1780 Copenhagen - Denmark  
*updated Aug.2020*

## Estonia

pta@pta.agri.ee  
Tel:+372 605 1710, Fax:+372 671 2611  
Agriculture and Food Board -  
www.pta.agri.ee  
Teaduse st. 2, 75501 Saku - Estonia  
*updated Sep.2021*  
info@ttja.ee  
Tel:+3726672000, Fax:+3726672001  
Consumer Protection and Technical Regulatory  
Authority - Technical Department (for engines used in  
locomotives)  
www.ttja.ee  
Endla 10a, 10142 Tallinn - Estonia  
*updated Sep.2021*

## Finland

fertilisers@foodauthority.fi  
Tel:+358 29 530 0400  
Finnish Food Authority -  
https://www.ruokavirasto.fi/en/  
P.O. Box 100, FI-00027 Helsinki - Finland  
*updated Aug.2020*

## France

bureau-4c@dgccrf.finances.gouv.fr  
Tel:+33144973067

Ministère de l'Économie, des Finances et de la Relance -  
Direction générale de la concurrence, de la consommation et de la répression des fraudes - Unit 4C  
www.economie.gouv.fr/dgccrf  
Teledoc 223 - 59 boulevard Vincent Auriol - 75703 Paris Cedex 13 - France

*updated Dec.2022*

brmmi.sdqpv.dgal@agriculture.gouv.fr  
Tel:+33149558141, Fax:+33149555949  
Ministère de l'agriculture et de l'alimentation - Sousdirection de la qualité et de la protection des végétaux  
https://agriculture.gouv.fr/  
251 rue de Vaugirard - 75732 Paris Cedex 15 - France

*updated Dec.2022*

#### **Germany**

dr.tobias.hartmann@lwk-saarland.de  
Tel.: +4968268289552  
Landwirtschaftskammer für das Saarland - In der Kolling 310, 66450 Bexbach - Germany  
*updated Apr.2022*  
711@bmel.bund.de  
Tel (central):+49228995290; Direct Tel: +49228995293724  
Fax:+4922899529554262  
Bundesministerium für Ernährung und Landwirtschaft - Referat 711 (Pflanzenbau)  
www.bmel.de  
Rochusstrasse 1, 53123 Bonn - Germany  
*updated Apr.2022*  
biefang@lwk-bremen.de  
Tel.: +4915901605362  
Landwirtschaftskammer Bremen - Düngbehörde  
Johann-Neudörffer-Str. 2,28355 Bremen - Germany  
*updated Apr.2022*  
verkehrs kontrolle@lfl.bayern.de  
Tel: +49816186403637  
Bayerische Landesanstalt für Landwirtschaft (LfL) - Arbeitsgruppe Verkehrs- und Betriebskontrollen  
Am Gereuth 8,85354 Freising - Germany  
*updated Apr.2022*  
holger.burmeister@lvwa.sachsen-anhalt.de  
Tel.: +493455142630  
Landesverwaltungsamt Sachsen-Anhalt - Referat 409 (Agrarwirtschaft, Ländliche Räume, Fischerei, Forstund Jagdhoheit)  
Dessauer Straße 70,06118 Halle (Saale) - Germany  
*updated Apr.2022*  
jan-friedrich.schlimme@lwk-hamburg.de  
Tel.: +494078129134  
Landwirtschaftskammer Hamburg - Düngbehörde  
Brennerhof 121-123,22113 Hamburg - Germany

*updated Apr.2022*

dvk@tllr.thueringen.de  
Tel.: +49361574041263  
Thüringer Landesamt für Landwirtschaft und Ländlichen Raum - Referat 21: Futtermittel- und Marktüberwachung, Düngung und Bodenschutz  
Naumburger Str. 98,07743 Jena - Germany

*updated Apr.2022*

joerg.schaefer@rpks.hessen.de  
sabine.pueschel@rpks.hessen.de  
Tel.: +495611064214  
Regierungspräsidium Kassel - Dezernat 25 Am Alten Stadtschloss 1,34117 Kassel - Germany

*updated Apr.2022*

abt7.lfulg@smekul.sachsen.de  
Tel.: +49352426317210  
Sächsisches Landesamt für Umwelt, Landwirtschaft und Geologie - Referat 72 - Pflanzenbau  
Waldheimer Str. 219,01683 Nossen - Germany

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birgit.blum@lwk-niedersachsen.de  
Tel.: +49441801782  
Landwirtschaftskammer Niedersachsen - Prüfdienste  
Mars-la-Tour-Str. 9,26121 Oldenburg - Germany

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duengemittel-nrw@lanuv.nrw.de  
Tel.: +4923613052293  
Landesamt für Natur, Umwelt und Verbraucherschutz Nordrhein-Westfalen - Fachbereich 88:Futtermittel, Düngemittel, Saatgut  
www.lanuv.nrw.de  
Leibnizstraße 10,45659 Recklinghausen - Germany  
*updated Apr.2022*  
kschlueter@lksh.de  
Tel.: +4943319453344  
Landwirtschaftskammer Schleswig-Holstein - Abt. Pflanzenbau, Pflanzenschutz, Umwelt  
Grüner Kamp 15-17,24768 Rendsburg - Germany  
*updated Apr.2022*

cnawotke@lms-beratung.de  
Tel.: +493812030772  
LMS Agrarberatung GmbH - Zust. Stelle f. landwirtschaftl. Fachrecht und Beratung  
Graf-Lippe-Str. 1,18059 Rostock - Germany  
*updated Apr.2022*  
sabine.henze@rps.bwl.de  
Tel: +4971190413 309  
Regierungspräsidium Stuttgart - Referat 33 "Pflanzliche und tierische Erzeugung"  
Ruppmannstr. 21,70565 Stuttgart - Germany  
*updated Apr.2022*  
marktueberwachung\_duengemittel@lfl.brandenburg.de  
Tel.: +493328436152

Landesamt für Ländliche Entwicklung, Landwirtschaft  
und Flurneuordnung (LELF) des Landes Brandenburg -  
Referat L 2: Ackerbau, Grünland  
Dorfstraße 1, 14513 Teltow- Ruhlsdorf - Germany

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duengung@add.rlp.de

Tel.: +496519494845

Aufsichts- und Dienstleistungsdirektion (ADD) Trier -  
Willy-Brandt-Platz 3, 54290 Trier - Germany

*updated Apr.2022*

#### **Greece**

environment.gcsrl@aade.gr; industrial@gcsrl.gr

Tel:+3021064792645, Fax:+302106441648

Independent Authority for Public Revenue – General  
Chemical State Laboratory (GCSL) - Energy, Industrial  
and Chemical Products Directorate

www.aade.gr/gcsrl

An. Tsocha 16, 11521 Athens - Greece

*updated Feb.2023*

ka6u075@minagric.gr

Tel:+302102124106, +302102128187,

Fax:+302102124137

Ministry of Rural Development and Food - Directorate  
General of Plant Production - Directorate of Inputs for  
Crop Production - Department of Fertilisers

www.minagric.gr

Kapnokoptiriou 6 str. 104 33 Athens - Greece

*updated Feb.2023*

#### **Hungary**

nti@nebih.gov.hu

Tel:+ 3613091011

National Food Chain Safety Office (NFCISO) -  
Directorate

of Plant Protection, Soil Conservation and  
Agrienvironment

https://portal.nebih.gov.hu/

Budaörsi út 141-145, H-I 118 Budapest - Hungary

*updated Jan.2022*

#### **Iceland**

mast@mast.is

Tel:+3545304800

Icelandic Food and Veterinary Authority -  
www.mast.is

Austurvegur 64, IS-800 Selfoss - Iceland

*updated Oct.2021*

#### **Ireland**

feedenquiries@agriculture.gov.ie

Tel:+353 1 5058884, Fax:+35316275955

Department of Agriculture, Food and the Marine -  
Feedingstuffs, Fertilisers, Grain and Poultry Division  
www.gov.ie

Backweston Campus, Administration Building,  
Stacumney Lane,

Celbridge, Co. Kildare - Ireland

*updated Jun.2022*

#### **Italy**

disr5@mpaaf.gov.it

Tel:+390646656090, Fax:+390646656277

Ministry of Agriculture and Forestry - Department of  
the competitive policies in the rural world and the  
quality - Directorate General of competitiveness for  
rural development - DISR V - Plant Production

Via XX settembre 20, 00187 Roma - Italy

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pref4@mpaaf.gov.it

Tel:+390655341668, Fax:+390655341691

Ministry of Agriculture and Forestry - Department of  
Central Inspectorate Quality Protection and Fraud  
Repression of food farming - Central Laboratory of  
Rome

Via del Fornetto 85, 00149 Roma - Italy

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#### **Latvia**

pasts@vaad.gov.lv

Tel:+371 67027406, Fax:+37167185479

State Plant Protection Service -

https://www.vaad.gov.lv

Lielvarde iela 36, 1006 Riga - Latvia

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#### **Liechtenstein**

info.au@llv.li

Tel:+4232366194, Fax:+4232366199

Office of Environmental Protection (AU) -

www.au.llv.li

PO Box 684, 9490 Vaduz - Liechtenstein

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#### **Lithuania**

info@vatzum.lt

Tel:+37052375631, Fax:+37052730233

State Plant Service -

www.vatzum.lt/en/

Ozo Str. 4A, 08200 Vilnius - Lithuania

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#### **Luxembourg**

info@asta.etat.lu

Tel:+352810081-212, Fax:+352810081-333

Service de Chimie de l'Administration des Services  
Techniques de l'Agriculture - Division des  
Laboratoires

www.agriculture.public.lu

BP 75, 9001 Ettelbruck - Luxembourg

*updated Aug.2020*

#### **Malta**

info@mccaa.org.mt

Tel:+35623952000, Fax:+35621242406

Malta Competition and Consumer Affairs Authority -  
Market Surveillance Directorate, Technical  
Regulations

Division

www.mccaa.org.mt

Mizzi House, National Road, Blata l-Bajda, Hamrun,  
HMR 9010 - Malta

*updated Sep.2020*

#### **Netherlands**

secretariaat@nvwa.nl

Tel:+31 88 223 22 33

Netherlands Food and Product Safety Authority

(NVWA) -

<https://www.nvwa.nl>

Catharijnesingel 59, 3511 GG Utrecht - Netherlands

*updated Feb.2022*

#### **Norway**

postmottak@mattilsynet.no

Tel:+4722400000, Fax:+4723216800

Norwegian Food Safety Authority -

[www.mattilsynet.no](http://www.mattilsynet.no)

PO Box 383, 2381 Brumunddal - Norway

*update pending*

#### **Poland**

sekretariat@gios.gov.pl

Tel:+48223692372, Fax:+48228251509

Chief Inspectorate of Environmental Protection -  
Department of Inspection

[www.gios.gov.pl](http://www.gios.gov.pl)

Wawelska Str. 52/54, 00-922 Warsaw - Poland

*updated Aug.2020*

sekretariat@ijhars.gov.pl

Tel:+48226232913, Fax:+48226232998

Agricultural and Food Quality Inspection - Main  
Inspectorate

[www.ijhars.gov.pl/](http://www.ijhars.gov.pl/)

Wspolna Str. 30, 00-930 Warsaw - Poland

*updated Aug.2020*

#### **Portugal**

uno\_msa@asae.pt

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Food and Economic Safety Authority (ASAE) -

UNO/DEPO Unidade Nacional de Operações/Divisão  
de

Estudos e Planeamento Operacional

[www.asae.pt](http://www.asae.pt)

Rua Rodrigo da Fonseca, nº 73; 1269-274 Lisboa -

Portugal

*updated Feb.2023*

arae@madeira.gov.pt

Tel: +351291145120, Fax:+351291215060

Regional Inspectorate for Economic Activities in the  
Madeira (ARAE Madeira) - Direção de Serviços de  
Inspeção

[www.madeira.gov.pt/arae/](http://www.madeira.gov.pt/arae/)

Rua Direita nº 27, 2º; 9050-450 Funchal - Portugal

*updated Feb.2023*

irae@azores.gov.pt

Tel:+351296302270

Regional Inspection of Economic Activities in the  
Azores

(IRAE Açores) - Gabinete Jurídico de Inspeção e das

Contraordenações

[www.iraе.azores.gov.pt](http://www.iraе.azores.gov.pt)

Rua Castilho, nº 21, 9500-042 Ponta Delgada, São

Miguel Açores -

Portugal

*updated Feb.2023*

#### **Romania**

inspectii.central@madr.ro

Tel:+40213078330; Fax:+40213078618

Ministry of Agriculture and Rural Development -

Directorate for Inspections monitoring, Verification  
and

Control

[www.madr.ro](http://www.madr.ro)

Blvd. Carol I, 2-4, 030163 Bucharest - Romania

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#### **Slovakia**

hnojiva@uksup.sk

Tel:+421259880200, +421 259880 411

Central Control and Testing Institute in Agriculture in  
Bratislava -

[www.uksup.sk](http://www.uksup.sk)

Matúškova 21, 833 16 Bratislava - Slovakia

*updated Sep.2020*

#### **Slovenia**

gp.uvhvvr@gov.si

tel:+38659152954, Fax:+38659152959

Administration of the Republic of Slovenija for Food  
safety, Veterinary sector and Plant protection -

[www.uvhvvr.gov.si](http://www.uvhvvr.gov.si)

Dunajska cesta 22, 1000 Ljubljana - Slovenia

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irsko.mko@gov.si

Tel:+38614345700, Fax:+38614345717

Inspectorate of the republic of Slovenia for

agriculture,

forestry, hunting and fisheries - Agriculture

inspection

[www.ikglr.gov.si](http://www.ikglr.gov.si)

Dunajska cesta 58, 1000 Ljubljana - Slovenia

*updated Nov.2022*

#### **Spain**

mpayoevv@mapa.es

Tel:+34913476659

Ministerio de Agricultura, Pesca y Alimentación –

Dirección General de Producciones y Mercados

Agrarios - Subdirección General de Medios de

Producción Agrícolas y Oficina Española de

Variedades

Vegetales

C/ Almagro 33, 28010 Madrid - Spain

*updated Jun.2022*

#### **Sweden**

jordbruksverket@jordbruksverket.se

Tel:+46771223223, Fax:+4636190546

Swedish Board of Agriculture -

www.jordbruksverket.se  
551 82 Jönköping - Sweden

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**Türkiye**

bugem@tarimorman.gov.tr;  
taner.aksoy@tarimorman.gov.tr;  
bahri.gunduz@tarimorman.gov.tr

Tel:+903122588312, Fax:+903122588321  
Ministry of Agriculture and Forest - General  
Directorate for Plant Production  
www.tarimorman.gov.tr/bugem  
Eskişehir Yolu 9th Km Lodumlu / ANKARA - Türkiye  
*updated Feb.2023*





soil for life

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website: [www.nmi-agro.nl](http://www.nmi-agro.nl)