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Regulation (EU) 2019/1009 – the Fertilising Products Regulation
Frequently Asked Questions

The Frequently Asked Questions (FAQs) document aims in facilitating the implementation of the Fertilising Products Regulation ('FPR') by providing guidance to both national authorities and economic operators. In this regard, this document focuses on issues that could raise difficulties in practice.

The answers in the FAQs document represent the opinion of the Commission services in charge of the FPR, but may not necessarily represent the opinion of the Commission. The document does not constitute any formal commitment on behalf of the Commission. Only the Court of Justice of the European Union can give an authoritative interpretation of the EU legislation.

These answers have been discussed in the Commission expert group on Fertilising Products in the meetings held on 7 November 2019, 25 June and 24 November 2020 and endorsed by the Group on 24 November 2020. All documents concerning these meetings can be found on the CircABC page of the group.

The FAQs is by definition a living document, which will be periodically updated by the Commission services depending on the need.

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Abbreviations:

ABPR Animal By-Products Regulation - Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002, OJ L 300, 14.11.2009, p. 1–33

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

FPR Fertilising Products Regulation - Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003, OJ L 170, 25.6.2019, p. 1–114.

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

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

REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals, establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ L 396, 30.12.2006, p. 1–850.

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

1. The scope of the FPR

1.1 What is a fertilising product?

A fertilising product is:

- a substance, mixture, micro-organism or any other material which:
  - is applied on plants or their rhizosphere or on mushrooms or their mycosphere, or
  - constitutes the rhizosphere or mycosphere, either on its own or mixed with another material

  and
- has as a purpose:
  - to provide plants or mushrooms with nutrient or
  - improve their nutrition efficiency.

Fertilising products include fertilisers (which provide plants with nutrients), but also other categories of products (such as inhibitors, liming materials or growing media).

For more details on the products concerned, see question 7.1.

1.2 What is an EU fertilising product?

An EU fertilising product is a fertilising product which is CE marked when made available on the market.

A manufacturer is allowed to CE mark a fertilising product only if, in accordance with the FPR, it:

- meets the requirements for the relevant product function category (Annex I)
- meets the requirements for the relevant component material category or categories (Annex II)
- is labelled in accordance with the labelling requirements (Annex III); and
- has successfully passed the relevant conformity assessment procedure (Annex IV).

For more details, see the questions 7.1 and 8.1.

1.3 Does the FPR cover fertilising products containing substances or microorganisms which have a pesticide effect, such as copper compounds or calcium cyanamide?

Products that fall under the scope of the PPPR are automatically excluded from the scope of the FPR. But this rule cannot apply directly to substances or microorganisms with a known pesticidal or other plant protection effect. If a fertilising product, which complies with all requirements set in the FPR, happens to contain a substance or microorganism known to have a pesticidal or other plant protection effect, it could still be covered by the FPR, as long as this fertilising product does not have a pesticidal or other plant protection function within the meaning of the PPPR.

Function is described in Article 2 of the PPPR. This does not mean that a substance or a microorganism does not possess any intrinsic pesticide property.

1.4 Are organic fertilisers in the meaning of the ABPR covered by the FPR?

Currently, derived products within the meaning of the ABPR are placed on the market as organic fertilisers, and soil improvers ('OFSI'), in accordance with the provisions laid down in that Regulation. These derived products placed on the market solely under the ABPR are not CE marked.

These ABPR notions differ from the notions of 'organic fertiliser' and 'organic soil improver' in the FPR, where they are defined as product function categories.

A product containing derived products within the meaning of the ABPR:

- may be placed on the market as a national/non-harmonised fertiliser in the conditions set under national legislation and complying with the special requirements in the ABPR
- may in future be placed on the market as an EU fertilising product if the conditions described in question 8.10 are met.

1.5 Is an organic fertiliser or an organic soil improver as set out in the FPR allowed to be used in organic farming production?

An organic fertiliser or an organic soil improver in the meaning of the FPR has a specific definition and needs to comply with all related requirements as set in the provisions of the FPR. This is independent of the acceptance of a fertiliser or soil conditioner for use in organic production.

Fertilisers and soil conditioners that are authorised in organic production are listed in Annex I to Regulation (EC) No 889/2008. These products can be either harmonised products (currently marketed as EC fertilisers) or non-harmonised products (marketed under the national legislation). Annex I to Regulation (EC) No 889/2008 is for the moment referring to certain EC fertilisers types defined in Regulation 2003/2003 and, therefore, it is under revision in order to align it with the FPR.

It is, thus, important to clarify that the term "organic" in PFCs 1(A) and 3(A) should not be understood as related to organic production at all. This being said, it is not excluded that a product can both comply with PFCs 1(A) or 3(A) in the FPR and be listed in Annex I to Regulation (EC) No 889/2008.

1.6 Does the FPR cover fertilising products for seed treatment?

According to the FPR definition, a "fertilising product means a substance, mixture, micro-organism or any other material applied or intended to be applied on plants [...]". Given the fact that a seed corresponds to one of the developmental stages of a plant, being a small embryonic plant, it is understood that a fertilising product applied on seeds follows the FPR definition and thus falls under the scope of this Regulation. Nevertheless, a seed treated with an EU fertilising product cannot be placed in the market as an EU fertilising product. In this specific case, the seed is the intended recipient of the fertilising effect and may not be part of the composition of an EU fertilising product.

1.7 Does the FPR change the rules concerning the use of processed manure under the Nitrates Directive?

No. The FPR lays down the conditions for the manufacture and making available on the market of EU fertilising products. If an EU fertilising product contains processed manure, as defined under the Nitrates Directive, then its use is subject to the requirements of the Nitrates Directive, irrespective of whether or not it is a CE-Marked fertilising product.

The FPR does not change the rules applicable under the Nitrates Directive.

2. Optional harmonisation

2.1 Does the FPR replace the existing national legislations? Can fertilising products still be placed on the market based on national legislation alone?

Contrary to most other products harmonisation measures in Union law, the FPR does not replace national legislations and does not prevent non-harmonised fertilising products from being available on the single market in accordance with national legislations.

Compliance with the harmonised rules as laid down in the FPR remains optional. It is at manufacturers' discretion to decide if:

- to apply the FPR and affix the CE mark to their products; thus, these products move freely in the single market
- to follow the rules laid down at national level in an EU country; if they intend to place their products on the market in another EU country, they have to follow the mutual recognition rules
- or to market the product both under the FPR and the national legislations, provided that the requirements under both sets of rules are met.

2.2 If the fertilising product meets the requirements of national legislation, can the manufacturer indicate reference to national legislation on the label of the CE marked fertilising product?

In principle, a manufacturer is allowed to provide voluntary information other than the mandatory labelling elements defined in the FPR. That also extends to information about compliance with national legislation in EU countries or third countries.

However, there are some restrictions for voluntary information in point 8 of Part I of Annex III to the FPR. *E.g.*, the information must not mislead the user, has to relate to verifiable factors, and must not make unsubstantiated sustainability claims.

2.3 Is it possible that manufacturers market products of one facility under national legislation and also as CE-marked products? Do CE-marked products and national products have to be derived from different production lines, or is it possible to switch between CE-marked and national products from batch to batch?

In principle yes, it is possible to sell the same product formulation both with and without the CE mark, and to use the same production line.

Note, however, that there might be specific rules in the FPR regarding the production lines. For instance, there is a specific rule for compost and digestate: Composting and digestion have to take place in a plant where the production lines are clearly separated from production lines processing any input materials other than those indicated in the exhaustive lists of input materials for CMCs 3, 4 and 5. But as long as the non-CE marked product is derived from the same input materials, nothing in the FPR prevents the manufacturer from using the same production line for EU fertilising products as for non-CE marked products.

3. Manufacturers

3.1 The obligation to keep the declaration of conformity and the technical documentation for 5 years after placing the product on the market

3.1.1 As of which date is this period of 5 years calculated for a production series of identical products?

According to the FPR, manufacturers have to keep the technical documentation and the EU declaration of conformity for 5 years after the respective EU fertilising product has been placed on the market. In this respect, "product" refers to an individual product, and not a product series.[1] In other words, the 5 year period starts counting as from the date that the first batch / package of a production series of an EU fertilising product was made available on the Union market for distribution or use in the course of a commercial activity, but then starts running again each time a new product is placed on the market, and ends only 5 years after the last product in the series has been placed on the market.

3.1.2 How can manufacturers prove that a product was placed on the market more than 5 years ago?

At horizontal level, there is currently no harmonised guidance for market surveillance authorities regarding which evidence to accept in this respect. However, placing a product on the market requires an offer or an agreement between two or more legal or natural persons for the transfer of ownership, possession or any other property right concerning the product in question after the stage of manufacture has taken place[2]. Any documentation demonstrating the transfer of ownership should therefore be kept as proof for placing on the market.

3.2 A company repackages fertilising products already marketed by the original manufacturer, and gives them its own name and logo and then sells on the market. Is this company always considered a manufacturer for the purpose of the FPR? If so, how can it obtain information about the design and production process to carry out the relevant conformity assessment procedure?

Yes, a company which places the product on the market under its name or trademark becomes automatically the manufacturer for the purposes of the FPR. Therefore he or she takes the

[1] See section 2.3 of the 'Blue Guide' on the implementation of EU products rules 2016 (2016/C 272/01; https://ec.europa.eu/docsroom/documents/18027)

[2] See section 2.3 of the 'Blue Guide' on the implementation of EU products rules 2016 (2016/C 272/01; https://ec.europa.eu/docsroom/documents/18027)

entire responsibility for the conformity assessment (design and production) of the product, even if this has been actually done by somebody else. Furthermore he or she must be in the possession of all documentation and certificates necessary to demonstrate the conformity of the product, but these do not need to be under his or her name.

3.3 What traceability elements do manufacturers have to include on the packaging?

Manufacturers have to ensure that the packaging of the EU fertilising products bears a type number or a batch number or any other element to allow their identification. For this purpose, the FPR takes into consideration that economic operators have already in their current practice established different ways of identifying and tracing the products that they make available on the single market and intends to allow them to keep their existent practices.

The traceability obligations are important for market surveillance activities as they allow to easily identify products which are not compliant or present a risk.

4. Distributors

4.1 Does the FPR change the obligations of distributors comparing to the current rules?

According to the FPR provisions, the obligations of distributors of an EU fertilising product change in relation to the rules under Regulation (EC) No 2003/2003.

When distributors make available on the Union market an EU fertilising product, they have the obligation to verify that this product is accompanied by the documents related to labelling requirements as specified in Annex III of the FPR.

The distributors have to ensure that the storage or transport conditions do not jeopardise the compliance with the requirements set out in the FPR.

Distributors have also to take measures if they consider or have reason to believe that an EU fertilising product is not in conformity with FPR. In such cases, they will not make the product available on the market and inform the manufacturer or the importer and the market surveillance authorities thereof if the product presents a risk. If the product has been already made available on the market, distributors have to make sure that corrective measures are taken. In case of a product presenting a risk, they have to immediately inform the competent national authorities.

Following a reasoned request from a competent national authority, the distributor has the obligation to provide all necessary documentation (technical documentation, EU declaration of conformity and any documents related to labelling requirements) in order to demonstrate the conformity of an EU fertilising product with the FPR.

5. Notified Bodies

5.1 What is a notified body?

A notified body is a conformity assessment body which has been notified based on the FPR by an EU country in order to perform specific conformity assessment procedures set out in the Regulation.

Where the Regulation requires the intervention of a third-party in the conformity assessment procedures, such conformity assessment tasks can only be performed by notified bodies under the Regulation.

5.2 What conditions does a conformity assessment body have to fulfil in order to become a notified body under the FPR? Can a private entity be a notified body?

All conditions are laid down in Article 24(2)-(11) of the FPR. In short, the conformity assessment body has to:

- be established under the national law of a Member State and have legal personality;
- be a third party independent of the product/organisation it assesses;
- preserve its confidentiality, objectivity and impartiality to perform assigned conformity assessment activities;
- have the appropriate human resources and infrastructure to perform the assigned activities;
- take out liability insurance for the conformity assessment.

Apart from public conformity assessment bodies, private entities can also receive notification and become notified bodies in accordance with national legislation.

5.3 What procedure does a conformity assessment body have to follow to ask the notification under the FPR?

The notification of conformity assessment bodies, as well as their withdrawal from the list of notified bodies, are the responsibility of the notifying authority in a Member State.

The procedure to be followed has to be laid down in national legislation, in compliance with the rules included in the FPR.

In order to facilitate the preparatory work as regards the designation of notified bodies in Member States, Commission has created the NANDO database. All the information related to the procedure that a conformity assessment body has to follow, in order to apply for a notification in a Member State will be made available in the NANDO database once transmitted by Member States.

The Commission created a dedicated space for the FPR in order to make publicly available information related to: a) the Member States Notifying Authorities, b) the appropriate procedures for the notification of conformity assessment bodies per Member State, c) the procedures for the monitoring of notified bodies, and eventually d) a list of Notified Bodies.

5.4 Does a conformity assessment body have to be able to perform conformity assessment for all types of EU fertilising products in order to become a notified body?

A conformity assessment body has the possibility to apply for notification for certain module or modules, or certain EU fertilising products as long as that body complies with the conditions set in Article 24 of the FPR.

5.5 How is the Commission planning to ensure the coordination and cooperation between notified bodied for the purposes of the FPR?

The Commission will ensure that coordination and cooperation between notified bodies are organised in the form of a sectoral group of notified bodies. This group will deal with technical problems relating to conformity assessment in order to ensure a uniform application of the technical provisions of the FPR.

The group will be established without undue delay after the Commission receives the first notifications by the notifying authorities. All the notified bodies will participate in the work of the group directly or by designated representatives. The group will be free to define its rules of procedure.

6. Transitional period

6.1 When will the FPR start to apply?

The FPR will fully apply from 16 July 2022.

A number of provisions Apply earlier as follows:

- as of 15 July 2019: specific provisions related to:
  - the publication by the Commission of guidance document on labels
  - the empowerment of the Commission to adopt various implementing or delegating acts
  - the amendments to the Animal By-Products Regulation (Regulation 1069/2009) and the Plant Protection Product Regulation (Regulation 1107/2009)
- as of 16 April 2020: all provisions related to the notification of conformity assessment bodies.

For more details, see Article 53 of the FPR.

6.2 After 16 July 2022, is an economic operator allowed to make available on the market products designated "EC Fertilisers" under the current rules?

It depends.

After 16 July 2022, EC fertilisers can still be made available on the market if they 'were placed on the market in conformity with Regulation (EC) No 2003/2003' before that date.

This implies that the product has actually been produced and is already fully compliant with that Regulation before that date. This must be the case for each individual product benefitting from the transitional rule in the FPR, not to merely for the type or series to which an individual product belongs.[3]

[3] See by analogy section 2.3 of the 'Blue Guide' on the implementation of EU products rules 2016 (2016/C 272/01; https://ec.europa.eu/docsroom/documents/18027). Please note, however, that the Blue Guide describes the concept of placing on the market pursuant to the 'New Legislative Framework', which is different from the same concept in Regulation (EC) No 2003/2003.

According to Regulation (EC) No 2003/2003, the date that an EC fertiliser is 'placed on the market' is when the individual product is 1) actually supplied, whether against payment or free of charge, or 2) stored for the purpose of supply, or 3) imported into the customs territory of the EU.

1) Placing on the market through **actual supply** happens at the time of an offer or an agreement (written or verbal) between two or more legal or natural persons for the transfer of ownership, possession or any other right concerning the product in question after the stage of manufacture has taken place.[4] An offer or agreement concluded before the stage of manufacture has been finalised cannot be considered as placing on the market.[5] The transfer does not necessarily require the physical handover of the product, and it can be based on any type of legal instrument.[6]
2) An EC fertiliser may be **stored** in either bulk or packaged form. The "purpose" to supply an EC fertiliser stored before 16 July 2022 becomes obvious when the product is supplied, even if the actual supply, as described in the previous paragraph, occurs only after that date. However, a product can obviously not be stored before it has been produced.
3) The moment of **importation** of an EC fertiliser is the moment when the product is physically brought into the customs territory of the EU. It is unrelated to the customs procedure for the clearance of goods brought into the customs territory, and is not necessarily the same as the moment of release for free circulation.[7]

In conclusion, after 16 July 2022, an economic operator will thus be allowed to make available individual EC fertilisers that

- were already manufactured and compliant with Regulation (EC) No 2003/2003, and
- were already either supplied, stored for the purpose of supply or imported.

Those products can remain on the market until their expiry date.

An economic operator will *not* be allowed to make any individual EC fertiliser available on the market which was *not* supplied, stored for the purpose of supply or imported before 16 July 2022, even if it is in compliance with Regulation (EC) No 2003/2003.

6.3 Is it only distributors that are allowed, after 16 July 2022, to make available on the market products designated "EC fertilisers" under the current rules?

No, pursuant to Article 52 of the FPR this is also possible for any other person making available an 'EC fertiliser' on the market (under the conditions referred to in the previous answer).

It is true that recital 70 of the FPR refers only to distributors, and not to any other economic operators.

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4 Idem.

5 Idem.

6 Idem.

7 See by analogy section 2.4 of the 'Blue Guide' on the implementation of EU products rules 2016 (2016/C 272/01; https://ec.europa.eu/docsroom/documents/18027). Please note, however, that the Blue Guide describes the concept of placing on the market pursuant to the 'New Legislative Framework', which is different from the same concept in Regulation (EC) No 2003/2003.

But it is clear that also other economic operators can have an interest in making available on the market after 16 July 2022 an 'EC fertiliser' placed on the market before that date, *e.g.* an importer having stored the 'EC fertiliser' after the importation, or a manufacturer storing a product previously manufactured by him or her. And Article 52 of the FPR does not explicitly put them in a less favourable position than a distributor, nor is there any objective justification for making such a discrimination.

The reference to distributors in recital 70 must therefore be seen only as an example representing the most plausible scenario covered by Article 52, and not as pre-empting the Article of the rest of its content.

6.4 How can an economic operator prove that fertilisers designated 'EC Fertilisers' under the current rules have been placed on the market before 16 July 2022?

The burden of proof in this respect will be on the economic operator supplying the product.

There is currently no harmonised guidance for market surveillance authorities regarding which evidence to accept in this respect.

If the EC fertiliser was supplied before 16 July 2022, it is advisable to provide documentation demonstrating the transfer of ownership, possession or any other right on the product, for example with a contract of sale or information on the shipping of the product.

If the EC fertiliser was only stored for the purpose of supply before that date, the manufacturer has to ensure proper documentation demonstrating that the product was produced in conformity with Regulation (EC) 2003/2003 before 16 July 2022.

6.5 Before 16 July 2022, is an economic operator allowed to make EU fertilising products available on the market pursuant to the FPR?

No.

EU fertilising products are defined in Article 2(2) of the FPR as fertilising products which are CE marked when made available on the market. Pursuant to Article 30 of Regulation (EC) No 765/2008, CE marking is affixed only to products to which its affixing is provided for by specific EU harmonisation legislation, and must not be affixed to any other product. In other words, fertilising products must not be CE marked as long as no provision in the FPR providing for that is yet applicable. The provision in the FPR providing for affixing the CE marking is Article 18. However, as follows from Article 53 of the FPR, Article 18 is not applicable before 16 July 2022. Therefore, the CE marking must not be affixed to a fertilising product made available on the market before 16 July 2022. Since fertilising products made available on the market at any given point in time before 16 July 2022 can thus not be CE marked at that point in time, they do not qualify as EU fertilising products at that point in time. At that point in time, they therefore fall entirely out of the scope of the FPR.

7. Annex I – Product Function Category (PFC)

7.1 What is the function of an EU fertilising product?

Any EU fertilising product may belong to one of the product function categories predefined in the FPR.

The Regulation lists the following product function categories:

- fertiliser, the function of which is to provide nutrients to plants or mushrooms
- liming material, the function of which is to correct soil acidity
- soil improver, the function of which is to maintain, improve or protect the properties of the soil
- growing medium, the function of which is to provide a material other than soil in situ for plants or mushrooms to grow in
- inhibitor, the function of which is to improve the nutrient release patterns of a fertiliser by delaying or stopping the activity of specific groups of micro-organisms or enzymes
- plant biostimulants, the function of which is to stimulate plant nutrition processes independently of the product's nutrient content with the sole aim of improving nutrient use efficiency, tolerance to abiotic stress, quality traits and/or availability of confined nutrients in the soil or rhizosphere
- fertilising product blend, which is composed of two or more EU fertilising products belonging to one or more of the function categories mentioned before.

EU fertilising products are subject to different safety and quality requirements depending on the function(s) claimed by the manufacturer.

For more details, see question 7.3 and Annex I to the FPR.

7.2 When a product could comply with different product function categories in the FPR, is the manufacturer free to choose the product function for that EU fertilising product?

Yes. In case a product could comply with the requirements of more than one product function categories (PFCs) as set in the FPR, the manufacturers are free to choose to claim the preferred PFC for their product. The manufacturers have the obligation to perform a complete conformity assessment and prove that the product complies with all requirements of the claimed/chosen PFC and relevant component materials.

7.3 May an EU fertilising product belong to two product function categories at the same time?

EU fertilising products may belong to just one product function category, but may have several functions if they belong to product function category 7.

If one single material or one single composition of materials fulfils the conditions under two of the predefined product function categories 1 to 6, as well as the other relevant requirements in Annexes II and III to the FPR, the manufacturer has the possibility to follow the conformity assessment procedure for each product function category and then market the product as a blend (product function category 7). This could for instance be a protein which acts as a plant biostimulant PFC 6(A) and also biodegrades to release nitrogen and phosphorus, PFC 1(A).

Even though the product is a fertilising product blend, it does not necessarily have to mention the word "blend" on the label.

7.4 What is the maximum content of organic carbon (C_{org}) that an inorganic fertiliser may contain?

Inorganic fertilisers are fertilisers that contain or release nutrients in a mineral form, other than organic or organo-mineral fertilisers. In the FPR there are no restrictions as regards the presence of organic matter or organic carbon (C_{org}). Thus, it cannot be excluded that inorganic fertilisers may contain C_{org} and there is no maximum limit for the content set in the FPR. However, for inorganic fertilisers that are labelled as mineral fertilisers the maximum content of C_{org} is 1 %, with some exceptions.

7.5 How to categorise an inorganic fertiliser that contains only secondary nutrients?

A product that only contains secondary macronutrients (calcium (Ca), magnesium (Mg), sodium (Na) or sulphur (S)) is an Inorganic Macronutrient Fertiliser (PFC 1(C)(I)). In order to narrow down the categorisation, there are two options:

a) if this inorganic fertiliser contains **only one** secondary nutrient (Ca or Mg or Na or S) then it could belong to
   - PFC 1(C)(I)(a)(i)- Straight Solid Inorganic Macronutrient Fertiliser (if it is in solid form) or
   - PFC 1(C)(I)(b)(i)- Straight Liquid Inorganic Macronutrient Fertiliser (if it is in liquid form),

   or

b) if this inorganic fertiliser contains **more than one** secondary nutrient (Ca, Mg, Na, S) then it could belong to PFC 1(C)(I)(a)(ii)- Compound Solid Inorganic Macronutrient Fertiliser (if it is in solid form) or PFC 1(C)(I)(b)(ii)- Compound Liquid Inorganic Macronutrient Fertiliser (if it is in liquid form).

7.6 What is a fertilising product blend?

A fertilising product blend is composed of two or more EU fertilising products of PFC 1 to 6.

A blend may contain either:

- Product(s) belonging to different product function categories: for instance, a blend obtained by mixing a fertiliser belonging to PFC 1 and a liming material belonging to PFC 2; this also covers a product comprised of a single material fulfilling the conditions under two of the predefined product function categories 1 to 6, as well as the other relevant requirements in Annexes II and III to the FPR, and for which the manufacturer has previously followed the corresponding conformity assessment procedures;
- products belonging to the same product function category: for instance, a blend obtained by mixing two fertilisers belonging to PFC 1.

Also see question 7.3.

7.7 What are the obligations of a blender under the FPR?

A blender is the manufacturer of the fertilising product blend and should be in the position to guarantee that the blending performed:

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

This implies that, when the farmer or other user applies the blend to the soil, the result should be no different from the result of applying the two component fertilising products simultaneously but separately.

As an example, a mere change of the pH of a component fertilising product in the blend as a result of mixing EU fertilising products with different pH values should not be considered as a change in the nature of the products blended, if the same change of pH would have occurred if the farmer or user would have applied the two component fertilising products simultaneously but separately to the soil. The pH value of a product is calculated by using the logarithmic concentration of hydrogen ions in it. When blending two component products that have different pH values, the resulting product blend will have a pH value that corresponds to the average concentrations of hydrogen ions provided by the two component products.

In addition, the blender has the following obligations:

- to ensure that the blend is compliant with the corresponding labelling requirements laid down in the FPR (Annex III)
- to draw up an EU declaration of conformity for the fertilising product blend
- to have in his/her possession the EU declaration of conformity of each of the component EU fertilising products used when manufacturing the blend.

7.8 Is a blender of two EU fertilising products allowed to place the blend on the market without the CE mark, under national rules?

Yes. There is no restriction in the FPR for the use of EU fertilising products in the production of products outside the scope of the FPR and in conformity with other pieces of legislation.

A blender may use two or more EU fertilising products to produce a blend and decide to place it on a national market following solely the respective national rules.

8. Annex II – Component Material Category (CMC)

8.1 What may EU fertilising products contain/consist of?

EU fertilising products may consist solely of materials complying with the requirements for one or more of the component material categories listed in the FPR.

There are 11 component material categories:

1. Virgin material substances and mixtures
2. Plants, plant parts or plant extracts
3. Compost

4. Fresh crop digestate
5. Digestate other than fresh crop digestate
6. Food industry by-products
7. Micro-organisms
8. Nutrient polymers
9. Polymers other than nutrient polymers
10. Derived products within the meaning of the ABPR
11. By-products within the meaning of the WFD

The FPR lays down different rules for each component material category regarding, for instance, the input materials or the processing methods.

For more details, see Annex II to the FPR.

8.2 How does a manufacturer demonstrate that the product placed on the market consists "solely" of CMCs? Is the manufacturer required to produce a list of all CMCs present in the final product indicating the % of each one?

The manufacturer has to draw up the technical documentation in support of the conformity assessment of his/her fertilising product. The technical documentation, among others, has to contain a list of every component material used in the final product, with reference to its corresponding CMC and information on its origin or its manufacturing process. This list has to contain all the component materials and consequently no other ingredient deliberately incorporated into the fertilising product is expected to be found in the final composition of this fertilising product. This does not concern contaminants as they are not intentionally added.

There is no obligation for the manufacturer to declare the actual percentage of each component material as part of the final product.

8.3 Can a component material fit under two CMCs at the same time (e.g. both CMC 1 (virgin substance) and 11 (by-products within the meaning of WFD), or both CMC 6 (food industry by-products) and 11)? If yes, who decides what CMC to rely on?

There might be some cases where a component material could comply with the requirements for more than one Component Material Categories (CMCs). In those cases, the manufacturer is free to choose the CMC that suits best his or her material and production. The manufacturer has to make sure that his/her material complies with all the requirements as set for the respective CMC.

There are situations where two CMCs are mutually exclusive. A material that falls under the scope of CMC 11 (by-product within the meaning of WFD) is by definition excluded from the scope of CMC 1 (see Annex II, part II, CMC 1, point 1(d)). If a by-product is chemically reacted with another substance, then the resulting material can be eligible for CMC 1, as this CMC does not exclude materials derived from by-products.

However, a food industry by-product that complies with requirements of the CMC 6 could also comply with the requirements set in the CMC 11.

8.4 Is it possible to place on the market in an EU country, EU fertilising products containing compost or digestate even if the compost or digestate therein do not meet the national end-of waste criteria?

Yes.

The FPR is legally binding in all EU countries. Once it is applicable, EU fertilising products containing compost or digestate complying with the requirements of the CMCs 3, 4 or 5 may be placed on the market in any EU country.

The end-of-waste criteria in CMCs 3, 4 and 5, like any harmonisation rules, may be more restrictive than the national legislation in some EU countries or more permissive in others. However, this does not have an impact on placing CE marked products on the market. In the same way, the end-of-waste criteria in the FPR have no influence on placing on national market of compost or digestate complying with the national rules.

8.5 If raw materials taken from earth/ground are used as raw material and remain in unreacted form in the fertilising product, then is it necessary to do a REACH registration for that material for the purpose of compliance with CMC 1?

All materials that are finally contained in an EU fertilising product have to comply with the requirements for at least one of the CMCs. As a result, any raw material that deliberately remains part of the final composition of the EU fertilising product (other than as a trace) must be listed in the technical documentation and must comply with the provisions of one CMC.

For example, phosphate rock may be one of the component materials of an EU fertilising product and may be listed as belonging to CMC 1 as long as it complies with all requirements laid down for virgin material substances and mixture. Furthermore, the phosphate rock does not need to be registered under REACH, because phosphate rock is covered by one of the registration obligation exemptions that are acknowledged by CMC 1.

8.6 Does the obligation for REACH registration in CMC 1 apply for preservative agents incorporated in fertilising products that are already approved under the Biocidal Products Regulation?

The basic principle in the Biocidal Products Regulation (Regulation (EU) 528/2012, hereafter BPR) is that a biocidal product must be authorised before it can be made available on the market or used in the EU. This takes place in two consecutive steps. First, the active substance is evaluated and, provided the criteria are fulfilled, is then approved for a specified product-type. The second step is the authorisation of each product consisting of, containing or generating the approved active substance(s).

In order to approve an active substance, its hazardous properties and possible risks to humans, animals and the environment are thoroughly assessed.

To avoid duplications, such active substances manufactured or imported for use in biocidal products only are considered as being REACH registered, according to Article 15(2) of REACH Regulation.

This concerns both active substances approved (including for use in product-type 6 – preservatives for products during storage), as well as substances listed in Annex II to Regulation 1062/2014 as being under assessment in the programme of review of existing biocidal active substances.

Some fertilising products, especially those in liquid form, may include a biocidal products (mixtures or substances) used as a preservative agent during storage. For the purpose of the FPR, these mixtures or these substances may belong to CMC 1. In such a case, the active substances in these biocidal products are regarded as being registered in REACH exclusively for this use and the requirement in point 2 in CMC 1 is considered as fulfilled, and no REACH registration of the active substance(s) is necessary for the purpose of fulfilling the criteria of CMC 1.

8.7 Can ammonium sulphate as a by-product from caprolactam or coke oven production be classified as a component material belonging to CMC 1 (Virgin material substances and mixtures)?

No. The ammonium sulphate from caprolactam or coke oven production cannot be classified as a component material belonging to CMC 1, since it is a by-product. The appropriate category to cover this ingredient seems to be CMC 11, since it covers by-products that are part of the final composition of an EU fertilising product, under the condition that they fulfil all requirements of that category.

8.8 Does the CMC 2 (Plants, plant parts or plant extracts) include the seaweed extracted with alkaline solution?

Seaweed and seaweed extracts may fall under the scope of CMC 2 as long as they have undergone one of the permitted processes that are listed therein. Since any further treatments are not allowed under this CMC unless specifically mentioned, seaweed treated with, (or materials extracted from seaweed using) alkaline solution, for instance, does not comply with the harmonised rules in CMC 2, but could be covered by the provisions of CMC 1, under the conditions specified for this component category. In case the seaweed used for the alkaline extraction is a waste, then the extract is also a waste (unless it has got national End-of-Waste status) and thus it is excluded from the scope of CMC 1.

8.9 If a CMC 1 ingredient is produced through intentional chemical reaction between two chemical substances ('precursors'), at which point in the manufacturing process must the chemical substance(s) comply with the requirements of CMC 1? Is it the precursors or the reaction product that need to correspond with the conditions in CMC 1?

According to the general provisions of Annex II, the materials that are finally contained in an EU fertilising product have to comply with the requirements for at least one of the CMCs listed in this Annex.

In some cases during the manufacturing process of a CMC 1, different precursors are expected to react with each other following a series of chemical conversions. At the end of the

manufacturing chain, a final chemical substance or mixture of substances will be produced. This final chemical substance or mixture will be part of the composition of the EU fertilising product, so only this needs to comply with the provisions of CMC 1.

For example: Spent sulphuric acid may be a by-product from industry. If it meets all requirements for constituting a by-product according to the WFD (Article 5(1)), it can be directly used as a reactant for the production of a fertiliser under CMC 1. In the latter production process, the sulphuric acid chemically reacts with rock phosphate, dried and granulated to single super phosphate. The sulphuric acid is not directly used as a fertilising product component, so it cannot be considered as a CMC 11 material. It is used as a precursor to react with another substance (phosphate rock) to produce the single super phosphate which will be part of the final composition of the EU fertilising product. For this reason the single super phosphate, in the example case explained above, is eligible to be considered as a material covered by CMC 1.

8.10 Are manufacturers allowed to use derived products from animal by-products, such as processed manure, in EU fertilising products?

The FPR creates the framework for manufacturers to use products derived from animal by-products:

- either as input materials for some component material categories (such as compost and digestate) or
- as a standalone component material belonging to CMC 10.

However, in both cases, there is a precondition: an end point in the manufacturing chain for that derived product (for use in fertilising products) has to be determined under the ABPR.

For the moment, none of these products (processed manure included) have an end point defined under the ABPR. That is because, hitherto, the Commission has not been empowered under the ABPR to define end points for organic fertilisers and soil improvers. The FPR changed that by giving the Commission an empowerment to determine an end point in the manufacturing chain under the ABPR by delegated acts.

The end-point as determined in the ABPR has to be reached by the end of the manufacturing process of the EU fertilising products.

In addition, to use a derived product as a component material, in addition to having the end point determined, the derived product has also to be listed in the corresponding component material category in Annex II to the FPR.

8.11 Are manufacturers allowed to use plant/plant parts grown for the production of biogas in compost or digestate other than fresh crop digestate?

Yes. CMC 3 (Compost) and CMC 5 (Digestate other than fresh crop digestate) have an exhaustive list of the input materials to be used. These lists include living or dead organisms or parts thereof, except:

- the organic fraction of mixed municipal household waste
- sewage sludge, industrial sludge or dredging sludge and

- animal by-products or derived products under certain conditions.

Manufacturers may, therefore, use any plants or plant parts in compost or digestate other than fresh crop digestate.

However, these plants or plant parts have to be unprocessed or processed only with one of the methods allowed in CMC 3 or CMC 5 respectively.

9. Annex III – Labelling requirements

9.1 Can a manufacturer use green or any other coloured pictogram to provide product information on the label of an EU fertilising product?

The FPR does not prohibit the use of green or any other colour as labelling elements. However, a coloured pictogram or statement should have a clear content that should not lead to unsubstantiated product claims or environmental benefits. Any unjustified or unverifiable claim could be misleading and thus this practice is incompatible with the FPR.

9.2 How should a manufacturer label the nutrients content of a fertilising product blend if the content of some forms of the nutrients vary over time, like in the case of blending a growing medium with an inorganic fertiliser?

When labelling a fertilising product blend the manufacturer has to include all labelling requirements that are applicable to the component EU fertilising products.

In some cases, there might be fluctuation of various forms of nutrients in a relative short period of time.

This may happen for instance in case of a blend composed of a growing medium and organic fertiliser. Due to the characteristics of this product, the forms of the nutrients therein evolve like it would happen in nature. The manufacturer should rely on the conformity assessments that were already finalised for the two components (the growing medium and the inorganic fertiliser) and put all relevant information on the label of the blend. Consequently, the manufacturer should declare, for example, information on nutrients content, based on the assessment of the growing medium and information on nutrient content, based on the assessment of the inorganic fertiliser. Any fluctuations in the final concentration of specific forms of nutrients over time are an expected outcome. As the content of the total nutrients remains unchanged, the variations of forms should not raise questions of compliance of the said product with the labelling requirements and the tolerances in the FPR.

9.3 How should users be informed about the presence of materials obtained from manure in organic or organo-mineral fertilisers?

The FPR requires to provide any relevant information on measures recommended to manage risks to human, animal or plant health, to safety or to the environment (point 1 (g) of part 1 of Annex III of the FPR).

Directive 91/676/EEC, concerning protection of waters against pollution caused by nitrates from agricultural sources (Nitrates Directive) sets a maximum amount of nitrogen from livestock manure, including processed manure that can be applied per hectare per year.

To be able to comply with the obligations under the Nitrates Directive, users need to be informed about the amount of nitrogen that has been obtained from manure in the organic and organo-mineral fertiliser. Therefore, when declaring the origin of the organic matter, the manufacturers should declare how much organic nitrogen of animal origin is out of manure, as a percentage of the total organic matter.

10. Annex IV - Conformity assessment

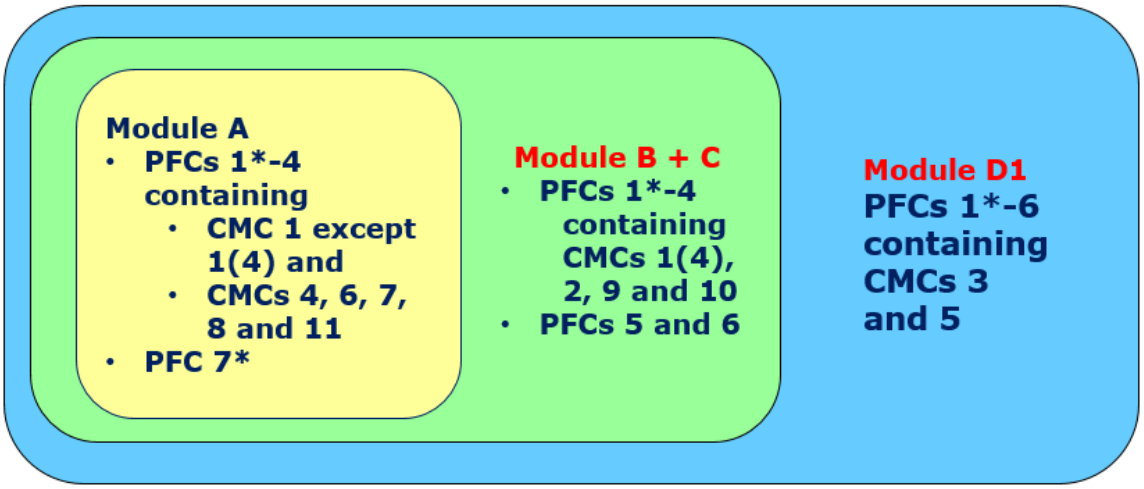
10.1 What conformity assessment procedure do the manufacturers have to follow?

The FPR describes the conformity assessment procedures applicable to different EU fertilising products depending on their product function category (PFC) and their component material category or categories (CMC).

Four type of procedures may apply:

- Module A – internal production control
- Module A1 – internal production control plus supervised product testing
- Module B – EU type examination followed by Module C – conformity to type based on internal production control
- Module D1 – quality assurance of the production process

In short:



* With the exception of ammonium nitrate fertilisers of high nitrogen content to which only Module A1 applies.

Note:

- when Module A may apply to a product, the manufacturer can chose to apply Modules B + C or D1 instead
- when Modules B + C may apply to a product, the manufacturer may choose to apply Module D1 instead
- Module D1 may apply to any EU fertilising products, except ammonium nitrate fertilisers of high nitrogen content.

For more details, see this table.

10.2 Can conformity assessment be done even if harmonised standards are not adopted?

Yes. The FPR lays down mandatory requirements for EU fertilising products which apply independently of any standards.

It is for the manufacturer to prove that the product is compliant with these requirements, by any means. The manufacturer bears full responsibility for the compliance of products placed on the market.

EU fertilising products which are in compliance with a harmonised standard, the reference of which has been published in the *Official Journal of the European Union* for the purpose of the FPR, are presumed to be in compliance with the requirements covered by that standard.

However, using such harmonised standards is not mandatory. The manufacturer may prove compliance with the Regulation by other means, such as different technical specifications. In the latter case, products will not benefit from the presumption of conformity and it will be up to the manufacturer to demonstrate that the products comply with the applicable requirements in the Regulation.

10.3 If a manufacturer subcontracts certain parts of the production process to other company, using the original production process of the manufacturer, is it necessary to do a different conformity assessment?

No. The manufacturer may design and manufacture the product himself/herself or subcontract part/-s of the manufacturing process to another operator. Where subcontracting takes place, the manufacturer must retain the overall control for the product and ensure that he or she receives all the information that is necessary to guarantee the compliance of the product with the applicable requirements and to carry out the conformity assessment procedure. The manufacturer who subcontracts some or all of his or her activities may not, under any circumstances, discharge himself/herself from the responsibilities under the FPR.

Provided that the manufacturing process is not changed, the conformity assessment procedure is not to be repeated if the manufacturer decides to start subcontracting parts of it, but the manufacturer continues to retain overall responsibility for the compliance of the product.

The manufacturer has ultimate responsibility for the conformity of the product to the applicable legal requirements, as far as he/she places the product on the market under his name or trademark. Therefore, he/she needs to carry out the conformity assessment himself/herself or be in the possession of all documentation and certificates necessary to demonstrate the conformity of his/her product.

10.4 Who performs the conformity assessment in case the product is produced by a manufacturer from a third country and imported in the EU?

The conformity assessment procedure is to be followed by manufacturers irrespective of whether they are established in an EU country or a third country.

In case of products produced in a third country, the FPR lays down also obligations for importers.

Importers can place on the market only compliant EU fertilising products. Therefore, the importer needs to ensure that the manufacturer:

- has carried out successfully the appropriate conformity assessment procedure (even if this implies the involvement of a notified body)
- has drawn up the technical documentation, affixed the CE marking,
- has fulfilled his/her traceability obligations and
- accompanied, where relevant, the product by the instructions and safety information in a language easily understood by end-users, as determined by the EU country were the product is marketed.

10.5 What is expected by 'adequate analysis and assessment of the risk(s) to be included in the technical documentation'?

Broadly speaking, the risks of fertilising products are covered by the FPR, in particular Annexes I and II. Therefore, in principle the requirements of the FPR applicable to the product as well as the product's conformity with the relevant requirements in the Regulation must be documented. However, it is also recognised in Article 4(2) that there might be aspects not covered by Annexes I and II. Risks in a specific field are usually known by diligent manufacturers operating in that field, and the technical documentation should identify them and document how they have been addressed.

10.6 Does technical documentation have to be physically available for the inspection, or can it be accessible through digital means?

The technical documentation can be kept and sent to market surveillance authorities either in paper or electronic form.[8]

10.7 What does 'Modules B + C' mean?

The conformity assessment is done broadly speaking in two steps. Firstly, the conformity of the design proposed by the manufacturer is assessed by a notified body under Module B and in case the assessment is positive, the notified body issues an EU-type examination certificate. Secondly, the manufacturer assesses the conformity of the EU fertilising products to the EU-type certificate previously issued (Module C). The manufacturer will then refer to the EU-type certificate in the declaration of conformity for the EU fertilising product.

10.8 What is an EU-type certificate issued by a notified body and what is its expiry date?

The EU-type examination is part of a conformity assessment procedure in which a notified body examines, verifies and attests that the technical design (type) of an EU fertilising

[8] See section 7.2 of the 'Blue Guide' on the implementation of EU products rules 2016 (2016/C 272/01; https://ec.europa.eu/docsroom/documents/18027)

product meets the requirements of the FPR. Where the type meets the requirements that apply to the EU fertilising product concerned, the notified body issues an EU-type examination certificate to the manufacturer.

In the FPR, there is no specific provision regulating the validity period of the EU-type examination certificates. Nevertheless, it is in general considered best practice to limit the validity of EU-type examination certificates to 5-10 years. This will ensure at least a minimum monitoring/reassessment of approved types.

Further to the above, if there is such change in the state of the art that affects the approved type's compliance to the requirements of the FPR, or if the manufacturer makes modifications to the approved type, the certificate has to be revised.

10.9 For ammonium nitrate fertilisers of high nitrogen content, does the manufacturer or the notified body perform the detonation resistance test and the oil retention test?

In order to ensure compliance, manufacturers of ammonium nitrate fertilisers of high nitrogen content must follow the conformity assessment procedure described in Module A1 of Annex IV. The FPR requires that the thermal cycles and tests, namely the detonation resistance test and the oil retention test, are carried out under the responsibility of a notified body chosen by the manufacturer. Therefore, the tests have to be carried out by the notified body itself or by an entity contracted by the notified body to perform such tests. Either way, the notified body maintains the responsibility for performing the tests in accordance with the FPR.

10.10 Can national authorities require that Module D1 is used for a fertilising product that only requires Module A, e.g., an organic fertiliser?

No, national authorities cannot require that the manufacturer uses a conformity assessment module different from that prescribed/allowed by the FPR. The applicability of modules is an integral part of the FPR and has a direct binding legal effect in all EU countries.