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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. All relevant documents can be found on the CircABC page of the group.

This is a revised version of the document updated on 6 April 2023 and includes additional answers and changes to existing ones, as endorsed by the Group on 24 October 2022.

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 questions 7.1, 8.1 and 10.1.

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 and totally 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. Therefore, fertilising products containing substances or microorganisms which are authorised active substances in accordance to the PPPR could be under the scope of the FPR and will not necessarily classify as plant protection products.

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. Thus, some substances or microorganisms with a known pesticide effect can also be used in a different way, typically at a lower dosage, to obtain a fertilising or biostiEBIC: This sentence does not

add much, and it actually makes the interpretation more confusing by now referring to "intrinsic property", while the term used for the component is "effect"

mulant effect. In such case, the product/formulation containing this substance or microorganism can fall under the scope of the FPR if the manufacturer can explain and account for, why at the proposed use instructions, the product complies to the conditions of the FPR and, , does not have a pesticide function.

Function is described in Article 2 of the PPPR and refers to products used to protect plants against harmful organisms, to influence the life processes of plants, such as substances influencing their growth, other than as a nutrient or a plant biostimulants, to destroy or prevent the growth of undesired plants or parts of plants. This does not mean that a substance or a microorganism does not possess any intrinsic pesticide property.

For products containing just one substance, the function or the effect is to be determined based on the use instructions provided by the manufacturer. For instance, copper may be placed on the market as an EU fertilising product (PFC 1(C)(II) inorganic micronutrient fertiliser) if the function or the effect of the product – as used in accordance with the use instructions – is that of remediating copper deficiency in certain soils, and not a plant protection function/effect. This is true even though copper might have a pesticidal effect when used in higher application rates, as long as that higher application rate is not described on the label or any other product information.

Products with a pesticide or plant protection function or effect remain outside the scope of the FPR even if they also have a plant biostimulant function (meaning a fertilising product function). The possibility of declaring any additional fertilising function to the plant protection one is to be assessed under the PPPR and the national rules on fertilising products.

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 8.26 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 II to Regulation (EU) 2021/1165. These products can be either harmonised products (marketed in accordance with the EU rules) or non-harmonised products (marketed under the national legislation). Some categories of products have to comply with the limit-values for contaminants as laid down in the FPR to be accepted in organic farming, even if they are non-harmonised products.
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 II to Regulation (EU) 2021/1165.

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 POPs Regulation apply to EU fertilising products?

Yes. This implies that, where for a given persistent organic pollutant ('POP') there is no limit value in the FPR, the limit value in the POPs Regulation must be respected. By contrast, where there is a stricter limit value in the FPR itself, that stricter limit value of the FPR must be respected, which also entails compliance with the less strict limit value of the POPs Regulation.

The POPs Regulation lays down the general rules applicable to all products containing persistent organic pollutants (POP). The POPs Regulation lays down no exception for fertilising products, so its provisions fully apply to such products.

Given the particularity of fertilising products, which are directly applied to soils, the FPR lays down stricter requirements for POPs, when deem appropriate (for example, the FPR imposes limits values for PAH_{16} in certain component materials, while the POPs Regulation itself does not lay down a limit value for these pollutants, but a general obligation to reduce their release).

1.8 Do waste rules apply to EU fertilising products or to their component materials? When does a component material recovered from waste reach end-of-waste status?

Waste rules may apply to component materials using waste as input.
The FPR lays down end-of-waste criteria to allow the recovery of materials from certain waste streams. The EU end-of-waste status is reached the moment the manufacturer signs the EU declaration of conformity of the EU fertilising product containing such a material.
This means that:

- During the production of the component material itself (during the composting) and all the subsequent stages until the signature of the EU declaration of conformity (such as, where relevant, transport of compost to the EU fertilising product manufacturer, storage, performing the conformity assessment or packaging) the component material has not reach end-of-waste status based on the FPR and the waste rules may be applicable. A component material may reach national end-of-waste status based on national criteria adopted in accordance with the Waste Framework Directive. This implies that the waste rules will no longer apply in the Member State where the criteria apply. It does not necessarily imply that the end-of-waste status will be recognised by other Member States (so, waste rules might still be applicable if the material is transported to another Member State).

- From the moment the EU declaration of conformity is signed and the product is CE-marked, the component material reaches end-of-waste status in accordance with the FPR, the waste rules no longer apply and the product moves freely in the internal market.

<u>Example 1:</u>

- Company A incinerates sewage sludge, and supplies the resulting ash, which respects criteria defined in CMC 13, to company B;
- Company B processes the ash to phosphoric acid (a derivate as defined in CMC 13) and supplies the phosphoric acid to a company C;
- Company C processes the phosphoric acid to an inorganic fertiliser respecting the criteria of PFC 1.

The FPR does not confer EU end-of-waste status to the ash, nor to the phosphoric acid, but only to the EU fertilising product produced by company C, and as of the moment where the EU declaration of conformity is signed.
In some EU countries, the ash or for the phosphoric acid may reach national end-of-waste status based on national rules. In this case:

- If the situation is confined in that EU country, then the ash or the phosphoric acid can be transported (without crossing national borders) without waste traceability, and the company C does not need an operating permit enabling to take waste as an input;
- If company C is in a different EU country than company B, or company B from company A and the ash or phosphoric acid with national end-of-waste status is transported to a different EU country, then these materials may revert to waste status

when crossing the national border, depending on the waste rules applicable in the new country.

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

No. The FPR does not change the rules applicable under the Nitrates Directive.
The FPR lays down the conditions for the manufacture and making available on the market of EU fertilising products. If a 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.

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.

3.2 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.

3.3 What are the obligations of manufacturers when they believe that one of their products poses a risk?

[1] See section 2.3 of the 'Blue Guide' on the implementation of EU products rules 2022
[2] See section 2.3 of the 'Blue Guide' on the implementation of EU products rules 2022

The FPR lays down an obligation for manufacturers to inform immediately the competent national authorities when they consider or have reason to believe that an EU fertilising product, which they have placed on the market, presents a risk.
This obligation applies in the following conditions:

- The manufacturer has already placed a product on the market – this does not concern products in various stages of the production;
- The product placed on the market presents a risk to human, animal or plant health, to safety or to the environment. The risk may be created during storage, transport or use of the product. It is enough if the risk exists; there is no need that the human, animal or plant health, the safety or the environment have been already affected.

The obligation of notifying the competent authorities from the EU country where the product has been made available on the market applies in addition to the obligation to take any corrective measures necessary to eliminate the risk.

3.4 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 solely under its name or trademark becomes automatically the manufacturer for the purposes of the FPR. Therefore it takes the entire responsibility for the conformity assessment (design and production) of the product, even if this has been actually done by somebody else. Furthermore the company must be in the possession of all documentation and certificates necessary to demonstrate the conformity of the product, which in practical terms means possessing the technical documentation. The documents proving compliance of the products with the FPR do not need to be under its name.

If a company repackaging a product adds on it its own brand but clearly indicates its role by mentioning 'packaged/repackaged by' and keeps the information concerning the manufacturer on the label, then this company does not claim the role of a manufacturer and therefore has the obligations of an importer or distributor, depending on its role in the supply chain.

3.5 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.

Distributors may have the same obligations as manufacturers if they place an EU fertilising product on the market under their name or trademark (see question 3.4) or modify an EU fertilising product already placed on the market in such a way that compliance with the FPR may be affected.

Where distributors package or repackage an EU fertilising product, but do not place the product on the market on their own name, then they have to add their name, registered trade name or registered trade mark and postal address preceded by the words ‘packaged by’ or ‘repackaged by’; and keep a specimen of the original leaflet at the disposal of the market surveillance authorities for 5 years after having made the EU fertilising product available on the market.

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 be performed only by notified bodies under the Regulation.

The list of conformity assessment bodies notified under the FPR is available in the NANDO database.

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 an EU country 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 an EU country.
The procedure to be followed has to be laid down in national legislation, in compliance with the rules included in the FPR.
The NANDO database contains the information related to the notifying authorities and the national procedures for the notification of conformity assessment bodies under the FPR.

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 When a notified body subcontracts the services of a laboratory, does this laboratory have to be accredited for standard 17025?

No.
Where a notified body subcontracts specific tasks connected with conformity assessment, it must ensure that the subcontractor meets the requirements set out in Article 24 FPR, which also cover the technical capacity to perform the specific tasks. Compliance with the EN ISO/IEC 17000 series of standards entails a presumption of conformity of the subcontractor with most of the requirements, as is the case with the notified body itself.
Notified bodies have the obligation to keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor.
For more details on subcontracting by a notified body, see The Blue Guide, page 85.

5.6 How does the Commission ensure the coordination and cooperation between notified bodied for the purposes of the FPR?

The Commission ensures that coordination and cooperation between notified bodies are organised in the Coordination group of notified bodies for EU fertilising products. This group deals with technical and procedural questions relating to conformity assessment under Modules A1, B and D1, in order to ensure a uniform application of the FPR.
All the notified bodies, as well as conformity assessment bodies interested in a notification under the FPR participate in the work of the group.
Documents endorsed by the group are made publically available here.

5.7 Do manufacturers have to revert to a notified body established in the same EU country where they are registered or where they produce the products?

No. Manufacturers may choose freely the services of any of the notified bodies established in one of the EU countries and listed in the NANDO database[3], irrespective of where the products are produced or where the manufacturers have their registered office.

6. Transitional period

6.1 When will the FPR start to apply?

The FPR fully applies as of 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 (ABPR) and the Plant Protection Products Regulation (PPPR)
- 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 Regulation (EC) No 2003/2003?

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

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

from the transitional rule in the FPR, not to merely for the type or series to which an individual product belongs.[4]

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.[5] An offer or agreement concluded before the stage of manufacture has been finalised cannot be considered as placing on the market[6]. The transfer does not necessarily require the physical handover of the product, and it can be based on any type of legal instrument.[7]
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.[8]

Two interpretations have been discussed as regards EC Fertilisers produced in third countries before 16 July 2022 and:

- there is a contract signed before that date for supply in the EU,
- the products are stored in that third country for the purpose of supply in the EU and
- the delivery date of the products is after 16 July 2022.

Some national authorities share the view that as long as there is incontestable evidence that the products have been produced and the contract has been signed before 16 July 2022, then the moment the EC Fertilisers physically enter the EU is not decisive and these products are covered by the transitional provision.

Other national authorities have a more restrictive interpretation, as their market surveillance authority cannot check the activity of the economic operator established in a third country.

In the view of the Commission services, in this scenario the products are stored for the purpose of supply and so they have already been placed on the market in accordance with Regulation (EC) No 2003/2003 before 16 July 2022. The Commission services encourage

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4 See by analogy section 2.3 of the 'Blue Guide' on the implementation of EU products rules 2022. 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.

5 Idem.

6 Idem.

7 Idem.

8 See by analogy section 2.5 of the 'Blue Guide' on the implementation of EU products rules 2022. 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.

national authorities to apply this interpretation. In response to the concerns regarding market surveillance, it should be recalled that this is a transitional arrangement, with limited effects in time.
Economic operators are advised to get in contact with national authorities, who are primarily responsible for the correct implementation of the EU law, in order to verify how they interpret the transitional rules in this respect [the list of national authorities responsible for fertilisers is available at the following link https://ec.europa.eu/docsroom/documents/44015].
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.
FPR will not allow an economic operator 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. However, if such a fertiliser may be lawfully placed on the market in one or more Member States by virtue of national rules, it may also be allowed in other Member States by virtue of mutual recognition.

6.3 Is it only distributors that are allowed, after 16 July 2022, to make available on the market products designated 'EC fertilisers' under Regulation (EC) No 2003/2003?

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 question 6.2).
It is true that recital 70 of the FPR refers only to distributors, and not to any other economic operators.
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. 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' have been placed on the market before 16 July 2022?

The burden of proof in this respect is 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) No 2003/2003 before 16 July 2022.

6.5 Are manufacturers allowed to start the conformity assessment of their products before the application date of the FPR?

Yes. In particular, before 16 July 2022, the date of application of the FPR, manufacturers may:

- start producing fertilising products;
- start the conformity assessment procedure and, where appropriate, contact a notified body and have the relevant certificates issued;
- do any preparatory acts (including printing labels with CE-mark on them), so that they are ready to 'place products on the market' (*i.e.* supply them) as of the application date.

6.6 Can manufacturers use packaging, formerly used for EC Fertilisers placed on the market under Regulation 2003/2003, for EU fertilising products placed on the market in accordance with FPR after 16 July 2022?

Yes, if the manufacturers ensure that the packaging will be labelled in accordance with the FPR.

The FPR contains no transitional arrangements concerning pre-existent EC Fertilisers packaging. Therefore, nothing prevents manufacturers from continuing to use these bags for EU fertilising products and it is even advisable to do so, to avoid packaging waste.

The EU fertilising product packaged in an EC Fertiliser bag will have to be labelled in accordance with the FPR. So, all the labelling requirements in the FPR have to be affixed to the packaging.

6.7 Can manufacturers place blends of EC Fertilisers, where the EC fertilisers are produced in accordance with Regulation 2003/2003 before 16 July 2022, on the market after 16 July 2022 with "EC fertiliser" mentioned on the blend?

Yes. 'Blended fertilisers' are defined in EC Fertilisers Regulation as fertilisers obtained by dry mixing of several fertilisers, with no chemical reaction. As long as all the fertilisers used in the blend are EC fertilisers, compliant with Regulation (EC) No 2003/2003, produced and placed on the market before 16 July 2022, the mere mixing of these products will not result in the production of new materials.

Therefore, the resulting blends are to be considered as being covered by the transitional arrangements in the FPR and may continue to be made available on the market after 16 July 2022, until the stocks are finished.

For more details, see question 6.2 on placing on the market.

6.8 Can bulk EC Fertilisers, placed on the market in accordance with Regulation 2003/2003 before 16 July 2022, be packaged and supplied further with "EC fertiliser" mentioned on the package after that date?

Yes, those bulk products may be packaged and supplied further with "EC fertiliser" mentioned on the package after 16 July 2022, provided that the product itself is not changed. By contrast, changes in the composition of the product would imply a new conformity assessment and would result with a new Fertiliser, which can no longer be placed on the market by virtue of Regulation 2003/2003 after 16 July 2022.

6.9 If an EC fertilizer was marketed with a trade name under Regulation (EC) No 2003/2003, is it possible to maintain this trade name for an EU fertilising product placed on the market after 16 July 2022 in accordance with FPR?

Yes. Nothing prevents EC Fertilisers manufacturers from continuing to market their products under the same trade name, provided that they comply with the relevant requirements in the FPR.

6.10 Can a product produced after 16 July 2022 in accordance with the rules of Regulation (EC) No 2003/2003, which does not comply with the rules of FPR, be placed on the market in the EU?

Yes, under two conditions:

First, this must be allowed in the Member State where the product is placed on the market, explicitly or implicitly,

- under that Member State's national legislation, or
- based on mutual recognition in that Member State of the product lawfully placed on the market in another Member State.

Second, the product must not bear the CE mark or mention "EC fertiliser". That is because it is not covered by the rules of either Regulation 2003/2003 or FPR, and should therefore not circulate in Member States relying on those rules for the safety and efficiency of fertilising products.

7. Annex I to the FPR – Product Function Categories (PFCs)

7.1 What is the product function category 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 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 Does organic carbon from methylene urea, isobutylidene urea and crotonylidene urea count when determining if an inorganic fertiliser has less than 1 % organic carbon?

In accordance with point 2 in PFC I(C) in Part II of Annex I, the requirement concerning pathogens do not apply to inorganic fertilisers with up to 1% organic carbon, other than organic carbon from: chelating and complexing agents, inhibitors, coating agents, urea and calcium cyanamide. Similarly to urea, urea derivates such as methylene urea, isobutylidene urea and crotonylidene urea, do not contain organic carbon of biological origin. Therefore, the organic carbon contained in urea derivates is not to be counted towards the limit-value of organic carbon of 1%.

Following the same approach, such inorganic fertilisers may be labelled as 'mineral fertilisers' in the conditions laid down in point 4 in PFC I in Part II of Annex III.

7.6 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).

7.7 Do 'nutrients of solely biological origin' include nutrients from bioidentical, but synthesised amino acids?

No.

According to the FPR, both the organic fertilisers and organic soil improvers contain only nutrients and organic carbon of biological origin. The same applies to the organic moiety of organo-mineral fertilisers. In those product categories, the notion of 'biological origin' is put in contrast to the notions of fossilised materials, mineral materials or nutrients contained in chemically synthesised substances or mixtures.

In this respect, materials of biological origin are materials that are contained in, extracted from or produced by living or dead organisms or parts thereof. When it comes to extraction,

the material coming from living or dead organisms should not be broken down to single and simple chemical substances where the link with the organism is lost.
So, to provide examples: amino acids extracted from seaweeds contain nitrogen (N) of biological origin, whilst this is not the case for amino acids that are chemically synthesised.

7.8 May manufacturers place on the market organo-mineral or inorganic phosphate fertilisers that do not comply with the solubility requirements of mineral fertilisers?

Yes. Phosphate fertilisers (both inorganic and organo-mineral ones) may be CE-marked (subject to the requirements in the FPR, including minimum phosphorus content), without any minimum phosphorus solubility requirements.
Based on the FPR, an inorganic fertiliser may be labelled as a mineral fertiliser when it complies with additional requirements regarding, in this case, the phosphorus solubility (at least 40% water solubility or 75 % neutral ammonium citrate solubility or (for soft rock phosphate only) 55% solubility in formic acid). If phosphorus does not meet any of these solubility requirements, the product cannot be labelled as a mineral fertiliser in accordance with point 4 in PFC 1, Part II of Annex III, but it can still be placed on the market as an organo-mineral or inorganic fertiliser (PFC 1(B) or 1(C) in Annex I).

7.9 Can a micronutrient solution fertiliser contain just one form of a straight micronutrient inorganic fertiliser?

Yes.
The FPR lays down an exhaustive list of typologies of micronutrient fertilisers. These various typologies have been drafted in such a way as to include in a general manner the specific types of EC fertilisers already covered by Regulation (EC) No 2003/2003.
One of the typologies listed in the FPR is:

Micronutrient solution fertiliser	An aqueous solution of different forms of a straight inorganic micronutrient fertiliser	2 % by mass of a micronutrient solution fertiliser shall consist of a water-soluble micronutrient

While the Regulation refers to 'different forms' of micronutrient fertiliser, the intention is not to exclude micronutrient fertilisers containing just one form (for instance, micronutrient in oxide form), but rather to allow several forms (for instance, micronutrients both in oxide and salt form).

7.10 How to classify products with inhibitors?

Manufacturers have the possibility to place on the market inhibiting compounds in:

- Inhibitors, as products belonging to PFC 5;
- Fertilisers, as products belonging to PFC 1 with an inhibiting substance as component material [CMC 1, point 1(4)];
- Blends of EU fertilising products referred to above.

An inhibiting substance referred to in CMC 1, point 4 cannot be used as a component material in an inhibitor, as point 4 in CMC 1 covers only substances which improve the nutrient

release pattern of a specific EU fertilising product. A product belonging to PFC 5 may contain a material belonging to CMC 1, point 1.

7.11 How to prove compliance with the requirement for bioavailable nickel, inorganic arsenic or hexavalent chromium?

To prove the compliance with the limit value for bioavailable nickel in certain growing media, manufacturers have the possibility to choose between:

- Using a testing method which determines only the bioavailable content;
- Using a testing method determining the total nickel content, as long as the result of the test shows a content below the limit value for the bioavailable content. In such a case, the manufacturer can safely assume that their product complies with the limit value for bioavailable nickel.

The same logic applies for requirements concerning the content of inorganic arsenic or hexavalent chromium. If a test report concerning the total arsenic or chromium shows a content below the limit value for the inorganic arsenic or hexavalent chromium, then the manufacturer can assume the compliance with the latter requirements without having to determine the exact content of inorganic arsenic or hexavalent chromium.

7.12 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.

7.13 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.

Examples:

- 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.
- mixing an ammonium nitrate fertiliser with high nitrogen content with other EU fertilising product in a blend: even if the blend no longer has at least 28% by mass of nitrogen out of the ammonium nitrate fertiliser of high nitrogen content and Module A will apply to the blend, this is not a change in nature of the component EU fertilising products. This is valid for all nutrients, which will be expressed on the label as % by mass out of the blend.
- mixing a solid EU fertilising product and a liquid one is allowed as long as there is no change in the chemical composition of the component EU fertilising products (as long as there are no chemical reactions facilitated by the content of water).
- mixing a fertiliser composed of substances with microorganisms: the nature of the component EU fertilising products is not changed as long as the microorganisms are not metabolising the substances.
- changes in the forms of nutrients, as described in question 9.2, as long as they are not produced by the blending itself, but are a natural evolution in time of those nutrients (like it would happen in nature).

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.

7.14 Can a fertilising product blend contain another fertilising product blend?

No.

A fertilising product blend may contain EU fertilising products belonging to PFCs 1 to 6. It is not possible to mix fertilising product blends to obtain a new fertilising product blend.

This means that, even in case of a functional blend to be mixed with a different fertilising product, the blender will have to rely on the conformity assessment of each single EU fertilising product belonging to PFC 1-6. This will ensure that the blender will be in a position to:

- Assess if the blending will change the nature of any of the component EU fertilising products belonging to PFC 1-6;
- Will include in the technical documentation the EU declaration of conformity of all EU fertilising products belonging to PFC 1-6, even if part of them are already marketed as a blend;

Will label the product by including all the labelling requirements of the component EU fertilising products belonging to PFC 1-6, by reference to the (new) blend.

7.15 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.

7.16 When should the requirements *for pathogens in fertilising product blends be checked? What are the consequences of regrowth of pathogens in normal conditions during storage or in the distribution chain?*

The FPR sets out limit-values for various pathogens such as *Salmonella*, *E. coli* and *Enterococcaceae* for all products that contain organic carbon belonging to PFCs 1 to 6. These requirements are laid down as a parameter to evaluate the effectiveness of the sanitation during the manufacturing process of a fertilising product.
The compliance with these requirements should be tested before placing an EU fertilising product belonging to PFCs 1 to 6 on the market.
There are situations where, given the unique characteristics of organic soil improvers and growing media, it cannot be excluded that when mixing such products with fertilisers, in a fertilising product blend (PFC 7), favourable conditions for the regrowth of *E. coli* and *Enterococcaceae*, may be created.
Even if the component materials themselves or the EU fertilising products when tested before being placed on the market and being mixed in the blend meet the microbiological requirements of the FPR, when these are mixed together, favourable conditions for regrowth of such pathogens are sometimes created (presence of organic matter, optimum oxygen contents, humidity or pH).
This does not necessarily mean that the fertilising product blend would automatically no longer be a compliant EU fertilising product.
In accordance with the FPR:

- Manufacturers have an obligation to draw up an EU declaration of conformity **before placing the product on the market**. This declaration states that the fulfilment of the requirements in the Regulation has been demonstrated (before placing the product on the market) (see Articles 6(2) and 16(1) FPR). These declarations are filled in for the component EU fertilising products in the blend, after checking the pathogens content in the respective products.
- Blending must not have an adverse effect on human, animal or plant health, on safety, or on the environment, **under reasonably foreseeable conditions of storage** of the fertilising product blend. This obligation does not imply no regrowth of pathogens at all, but that this regrowth should not make the products unsafe (Annex I, Part II, PFC 7). The manufacturer of a fertilising product blend will rely on the conformity assessment already done for the component EU fertilising products for all the

requirements laid down in the FPR for those products. The manufacturer of a fertilising product blend would normally not check again these requirements in the blend itself. However, knowing the risk of regrowth of pathogens, the manufacturer of the blend should mix the component fertilising products as close as possible to the delivery.

- The limit values for pathogens in the FPR are strict and it is reasonable to assume that complying with these strict limits at the moment of testing before placing the product on the market would ensure the safety of the product afterwards until they are used, under normal conditions.
- Both importers and distributors have an obligation to ensure that the storage and transport conditions do not jeopardise the compliance of the EU fertilising product with the requirement in the FPR (Articles 8(5) and 9(3) FPR).
- Nothing in the FPR seems to imply that unavoidable increases of pathogens in some products (like blends of growing medium and fertiliser) even despite reasonable storage measures taken would automatically imply that the product is no longer compliant and trigger the responsibility of the manufacturer.

The existing practice consists in testing materials for pathogens immediately after production in order to quickly identify potential issues in the manufacturing process. Given the provisions mentioned above, nothing in the FPR opposes this practice. Nevertheless, market surveillance authorities may check fertilising product blends already placed on the market in particular if they have a suspicion that the products become unsafe following the excessive regrowth of pathogens caused, for instance, by improper storage conditions. For the reasons explained above, regrowth of pathogens in these particular products should not lead to the conclusion that the products are no longer safe.

8. Annex II to the FPR – Component Material Categories (CMCs)

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 15 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
12. Precipitated phosphate salts and derivates
13. Thermal oxidation materials and derivates

14. Pyrolysis and gasification materials

15. Recovered high purity materials

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 the 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 the 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 Does CMC 1 apply to plants?

CMC 1 applies to substances and mixtures within the meaning of REACH Regulation (point 1 of Article 3 and point 2 of Article 3 of Regulation (EC) No 1907/2006 respectively).

Substance means a chemical element and its compounds. The term substance includes both substances obtained by a manufacturing process (for example, magnesia) and substances in their natural state (e.g. phosphate rock). The term substance also includes any additive necessary to preserve its stability and impurities where these are part of its manufacturing process but excludes any solvent which can be separated without affecting the stability of the substance or changing its composition. Detailed guidance on substances and substance identity can be found in the Guidance on identification and naming of substances under REACH and CLP. A mixture is composed of two or more substances.

For the purpose of chemical complexity vs. homogeneity, REACH categorises substances into well-defined substances and substances of unknown or variable composition (UVCB).

UVCB substances may cover biological materials or chemical and mineral substances with poorly defined, complex or variable composition (such as essential oils, natural pigments, or peat).

So, whole plants as living or dead organisms are not substances covered by CMC 1, but CMC 1 may cover substances, extracts, parts derived from plants (where a change in chemical composition occurred).

Additional examples:

- Materials not covered by CMC 1: whole living or unprocessed dead organisms (e.g. yeast, freeze-dried bacteria) or parts thereof (e.g. body parts, blood, branches, leaves, flowers) (see also ECHA Guidance for Annex V).

Materials which may be covered by CMC 1: chemical extracts from plants or micro-organisms, materials from chemical or enzymatic hydrolysis processes (e.g., protein hydrolysates, mixtures of polypeptides, peptides and/or amino acids issued from thermal, chemical and/or enzymatic hydrolysis of vegetal and/or microbial raw materials), materials derived from petroleum or other materials of biological origin which are fossilized or embedded in geological formations.

8.4 Do substances, *which annual market volume is below one tonne, have to be registered under REACH with a Chemical Safety Report for the purpose of the FPR?*

Yes, unless they belong to a CMC where no REACH registration is required. In CMCs where such a registration is required, they are covered by registration obligation exemptions in accordance with the FPR. The registration dossiers should comply with the requirements of Annex VI, VII and VIII. It should also contain a Chemical Safety Report justifying a safe use of the substance considered as a (part of a) fertilising product.

The Fertilising Products Regulation requires in point 2 of CMC 1 that all substances are registered under REACH unless exempted by virtue of the last paragraph of point 2 of CMC 1. Even though, in accordance with the REACH Regulation, a substance has to be registered only when it is manufactured or imported above one tonne, that requirement of FPR applies for substances to be used in EU fertilising products even below one tonne. This is regardless to their concentration in the component material or the fertilising product. This only applies to substances intentionally added, as such or in a mixture, by the manufacturer of the fertilising product.

This is a safety requirement. It implies that the risks associated with the use of that substance in soils or on plants have been assessed.

8.5 How to register substances under REACH for the purpose of the FPR?

For the purpose of the Fertilising Products Regulation, a registration dossier should be prepared containing as a minimum the following pieces of information set out in:

- Annex VI of REACH on the information to be submitted for general registration purposes;
- Annex VII of REACH on standard information requirements for substances manufactured or imported in quantities of one tonne or more; and
- Annex VIII of REACH on standard information requirements for substances manufactured or imported in quantities of ten tonnes or more.

The dossier also has to contain a chemical safety report pursuant to Article 14 REACH covering the use as a fertilising product [see question 8.4 for more details].

Thus, to comply with the requirement in the FPR, the substance has to be registered with the same information required under REACH for substances manufactured or imported at ten tonnes or more per year, even if these substances are manufactured or imported below this threshold.

Where the actual quantities of substances in EU fertilising products regulated by the FPR are higher than 100 tonnes, the additional information requirements laid down in the REACH Regulation apply directly by virtue of that regulation.

If a substance above 100 tonnes is exempted from registration under REACH, but has to be registered for the purpose of the FPR, the REACH registration will have to satisfy the conditions in the FPR (similar to substance between 10 to 100 tonnes).

For more details on REACH registration in general, follow this link: Guidance on REACH registration- ECHA (europa.eu)

8.6 Who has to register under REACH?

In accordance with the Fertilising Products Regulation, it is the responsibility of the manufacturer of EU fertilising products to prove that their products comply with all the requirements. This does not necessarily mean that the manufacturers of EU fertilising products have to register themselves the component substances under REACH.

In most cases, the substances they use in fertilising products should have already been registered under REACH by their suppliers (manufacturers/ importers of these substances) in order to comply with their REACH obligations.

In cases where the substance is registered at the 10-100 tonnage band or higher, the information required by REACH Annexes VI, VII and VIII should have already been included, and the use of the substance as a fertilising product should have already been reported in the accompanying chemical safety report. In such cases, the manufacturers of the EU fertilising products can rely on the existing registrations submitted by their suppliers.

In cases where the substance is registered under REACH at the 1-10 tonnage band, the manufacturers of the EU fertilising product can request their suppliers to update their registrations with the relevant information needed to comply with their obligations under the Fertilising Products Regulation.

In cases where the substance is not registered under REACH because it is imported or manufactured in quantities of less than 1 tonne or is exempted from the REACH registration requirement, the FPR manufacturers should request their suppliers of the substance to submit a REACH registration dossier containing the minimum information identified in question 8.4.

REACH provisions on joint submission of data by multiple registrants, sharing information, providing information in the supply chain or adding the use as a fertilising product by downstream users remain applicable.

For more details on REACH registration in general, follow this link: Guidance on REACH registration - ECHA (europa.eu)

8.7 Do substances already registered, exported and then imported into the EU have to be registered if used in EU fertilising products?

No, provided that the pre-existing registration meets the conditions requested under the FPR (see question 8.5) and the conditions in Article 2(7)(c) REACH are met meaning that:

a. the substance being re-imported is the same as the exported substance and
b. the manufacturer of the EU fertilising products has been provided with the information relating the exported substance in the conditions in Articles 31-32 REACH.

For more details see Section 2.2.3.6 of the Guidance on REACH registration.

8.8 What is a biodegradable or soluble polymer (CMCs 1 or 11)?

In accordance with the FPR, manufacturers may use biodegradable or soluble polymers in EU fertilising products as materials belonging to CMCs 1 or 11. For now, the FPR does not define biodegradability criteria for such polymers. As regards solubility, specific criteria are laid down in the Regulation.

The manufacturer may use any relevant international, European or national standard to prove the biodegradability potential of the polymers used or that it meets the solubility requirements.

Once the ongoing work on the REACH restriction on microplastics is finalised, it will be considered if to introduce more detailed biodegradability criteria in the FPR to align its provision with the general requirements under REACH.

8.9 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 mixtures. 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.

8.10 If a material belonging to CMC 1 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 the FPR? Is it the precursors or the reaction product that need to correspond with such requirements?

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 substance or mixture will be produced. This final substance or mixture will be part of the composition of the EU fertilising product, so only this one needs to comply with the provisions of CMC 1 and the requirements of the corresponding PFC.

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 material belonging to 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.

Following the same logic, whenever an 'additive' reacts with a substance, the additive has to be considered, together with the said substance, as a precursors; in any event, by virtue of the REACH Regulation itself, it needs to be registered under REACH unless exempted or considered a constituent part of the reacted substance.

Similarly, it is the product in its final composition that need to respect all thresholds in relation to macro- or micro- nutrients content or contaminants content relevant to the claimed product function category.

For example, in the case of the production of an inorganic micronutrient fertiliser, iron sulphate, zinc sulphate and boric acid are added to the chemical process. The reaction products, at the end of the manufacturing process, will be part of the EU fertilising product's composition. So, when the manufacturer will assess the compliance of this micronutrient fertiliser to the FPR rules related to the minimum micronutrients content (specified in PFC 1(C)(II)), he/she will need to analyse the product in its final composition. If these limits are not reached therein, the product does not fulfil the requirements for the respective PFC, even if the precursors' content in micronutrients complied with the same limits.

8.11 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 (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.

8.12 Do technical additives belonging to, for instance, CMC 1, have to be REACH registered with a dossier containing a chemical safety report covering the use as fertilising products, given that they are not themselves fertilising products?

Yes.
The FPR requires substances belonging to CMC 1 to be REACH registered with a Chemical Safety Report covering the use *as* a fertilising product. In the case of substances or mixtures that are used as technical additives in EU fertilising products, the same rules apply, although these additives are not used *as* fertilising products but *in* fertilising products for processing or handling purposes.
Taking into consideration recital (26) of the FPR, it is clear that the intention of the legislator was to impose REACH registration of substances and mixtures in fertilising products (e.g. technical additives) not only covering the use for processing or handling, but also the use on arable soil or crops, since that would correspond with the actual exposures to those additives. The main purpose of this requirement of the FPR is to ensure that, when assessing the safety of the said substances or mixtures, the fact that they would end up in direct contact with soil or crops as components of fertilising products is assessed.
In fact, the REACH registration requirement, including the safety report covering the use *as* a fertilising product, is also provided for composting and digestion additives (CMCs 3 to 5), while it is obvious that these additives are not fertilising products themselves, similarly to the other technical additives which may be used *in* fertilising products.

8.13 Is it possible for the manufacturers of EU fertilising products to rely on the REACH registration done by other operators for a recovered substance?

Yes, under certain conditions.

Article 2(7)(d) REACH lays down the situations when a substance, on its own, in mixtures or in articles, recovered from waste in the territory of the Union, is exempted from the registration obligations. According to this Article, operators 'recovering' such a substance do not have to submit their own REACH registration dossier if certain conditions are met:

(1) the substance has already been registered by another operator;
(2) the recovery operator can demonstrate that the recovered substance is the same as the one already registered; and
(3) the information to be communicated through the supply chain in accordance with Articles 31 or 32 REACH is available to the establishment undertaking the recovery of the substance.

The requirement for REACH registration in the FRP is considered fulfilled if operators are recovering a substance from a waste stream and have not themselves submitted a REACH dossier to ECHA because they are relying on the registration done by another operator.
The registration previously done by the other operator has to fulfil the conditions specified in the relevant provision in the FPR, meaning to cover the use of the substance or mixture as a fertilising product.

8.14 A substance or mixture belonging to CMC 1 may contain detectable traces of unreacted ingredients or processing agents. Should these impurities be separately considered as components of the final composition of fertilising product?

Having in mind the common industrial practices, it is evident that the substances and mixtures belonging to CMC 1 present in the final composition of an EU fertilising product cannot be 100% pure. Thus, irrespectively of the actual industrial process followed, component materials belonging to CMC 1 in a fertilising product are expected to contain detectable traces of impurities.
The FPR refers to the REACH definition of 'a substance'. A substance is defined under Article 3(1) of REACH as 'a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition'.
Following the substance definition, impurities are part of the substance composition. The Guidance for identification and naming of substances under REACH and CLP (p.15) defines an impurity as 'an unintended constituent present in a substance as manufactured. It may originate from the starting materials or be the result of secondary or incomplete reactions during the manufacture process. While it is present in the final substance it was not intentionally added'.
Impurities should not be considered as substances on their own, but should be dealt within the context of the relevant substance they are part of in the REACH registration.

8.15 How to comply with the REACH registration obligations in case of substances which evolve over time?

Some substances may evolve over time, especially when in contact with soil. In most of cases, the transformation is an expected and desired outcome.

REACH Regulation exempts from the registration substances which result from a chemical reaction that occurs incidentally to exposure of another substance to environmental factors.
For instance, some additives degrade to a metabolite due to exposure to environmental factors or storing conditions or in connection with the end use of the EU fertilising product. The metabolite as such would not be covered by the extended REACH registration requirement imposed by the FPR.

8.16 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 and the safety and agronomic efficiency criteria laid down in Regulation (EU) 2022/973.

8.17 Does CMC 2 cover micro-algae?

Yes. For the purpose of CMC 2, algae are included in the definition of plants. This covers both micro and macro algae, except cyanobacteria.

8.18 How to treat impurities in CMCs 2, 3, 4, 5, 7, 8 and 9, where no REACH registration is required?

As mentioned in question 8.14, there are no pure materials and it is to be expected to find impurities in component materials (unintended constituents present in the material).
In some CMCs, there are specific provisions regarding some impurities (such as maximum limit values for macroscopic impurities in compost). In such cases, those limit values have to be respected. In addition, the safety criteria in Annex I are also to be taken into account.
There are also CMCs where some materials are excluded expressly. For instance, CMC 2 excludes blue-green algae (cyanobacteria) and, therefore, such materials cannot be present in any detectable quantity as impurities either.
Finally, there are CMCs where there are no references to impurities at all. In such cases, the level of any impurities in the component materials has to be assessed taken into account the need for the product to remain safe and agronomically efficient. In accordance with Article 4(2) FPR, for any aspects not covered by Annex I or II, EU fertilising products have to not present a risk to human, animal or plant health, to safety or to the environment.
If the presence of impurities in detectable quantities must have been known to the manufacturer (such as significant level of plastics in CMC 2), he or she is not using the material as described in the CMC, and the product is not compliant. Furthermore, if an unknown impurity poses a risk to, for instance, the environment, the product may be compliant, but both the EU countries and the Commission have the possibility to react and

take the appropriate measures in accordance with Articles 38-41 FPR. In addition, if needed, the Annexes to the FPR could also be amended to adopt generally applicable measures to deal with such risks.
In addition, the FPR applies without prejudice to Regulation (EU) 2019/1021 on persistent organic pollutants[9].

8.19 Can a component material belonging to CMC 2 be waste or by-product?

Yes.
CMC 2 (Plants, plant parts or plant extracts) does not exclude explicitly waste or by-products within the meaning of Directive 2008/98/EC. Therefore, fruits and vegetables peelings or tree bark, which are part of bio-waste, may be used in an EU fertilising product in the conditions laid down in CMC 2 meaning:

- They contain only pure plants, plant parts or plant extracts and
- have been subject only to the exhaustive list of processing methods mentioned therein or are not processed at all.

In addition to the safety requirement in Annex I to the Fertilising Products Regulation (the maximum limit-values for contaminants and pathogens), the EU rules on plant health[10] and invasive species[11] apply.
If such a component material containing waste is used in an EU fertilising product which successfully passes the conformity assessment procedures laid down in the FPR, the said waste reaches end-of-waste status from the moment the manufacturer signs the EU declaration of conformity.

8.20 Can manufacturers use blue green algae (cyanobacteria) in EU fertilising products?

No, except certain extracts under specific conditions.
Blue green algae (cyanobacteria) are excluded from CMC 2.
CMC 1 covers virgin material substances and mixtures, within the meaning of the REACH Regulation. So, blue green algae (cyanobacteria) are not covered by that CMC either. It is nevertheless possible to cover extracts of blue green algae except the extracts that:

- are waste or by-products within the meaning of the WFD
- or have reached end-of-waste status based on national rules.

The provision regarding the REACH registration will apply to those extracts.
Blue green algae (cyanobacteria) are not covered by the exhaustive list of food industry by-products in CMC 6.

[9] OJ L 169, 25.6.2019, p. 45.
[10] Regulation (EU) 2016/2031 of the European Parliament of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC (OJ L 317, 23.11.2016, p. 4).
[11] Regulation (EU) No 1143/2014 of the European Parliament and of the Council of 22 October 2014 on the prevention and management of the introduction and spread of invasive alien species (OJ L 317, 4.11.2014, p. 35).

8.21 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 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 excluded from the scope of CMC 1.
For more details on waste in CMC 2, see question 8.19.

8.22 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 CMCs 3 or 5 may be placed on the market in any EU country.
The end-of-waste criteria in CMCs 3 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.

8.23 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.

8.24 What post-processes are allowed for digestate (CMCs 4 and 5)?

Digestate may be post-processed only in the conditions laid down in CMCs 4 and 5. Three categories of post-processes are mentioned therein:

- the mechanical separation of the solid/liquid fraction, which could be done via processes such as:

    - filtration, ultra-, nano- or other membrane filtration, including under pressure or vacuum;
    - gravitational separation, such as settling or flotation (including air bubble flotation, centrifugation).
- the recovery of nitrogen or phosphorus by, for example:
    - ammonia stripping (e.g. by increasing pH by adding e.g. caustic soda, bubbling air through the digestate, increasing the temperature, decreasing the pressure (vacuum), gas membrane separation) followed by nitrogen recovery;
    - adsorption / ion-exchange;
    - precipitation
- the dewatering, by processes such as:
    - drying by standing, atmospheric drying, using air or hot air, or by using solar radiation, belt dryers, push-turn, fluid bed, and drum dryers;
    - concentration of the liquid fraction;
    - freeze drying;
    - reverse osmosis and membrane concentration;
    - vacuum evaporation

All such processes are allowed provided that they lead only to the changes inherent to mechanical separation, nutrient recovery or dewatering, without the intention to otherwise chemically modify the digestate or the fraction.

8.25 Do 'living or dead organisms' as input materials in CMCs 3 and 5 cover bio-refinery outputs?

It depends on the bio-refinery processes.
Living or dead organisms may be used as input materials in CMCs 3 or 5 only if they are unprocessed or have been subject only to one of the processes included in the exhaustive list defined for CMC 3 and CMC 5 in Annex II to the FPR. The list of processes ensures that the living or dead organisms are not chemically modified.
Thus, if the bio-refinery is using only mechanical processing of plant materials (e.g. pressing of orange juice or olive oil), then the remaining plant parts may be used as input materials for compost or digestate covered by CMC 3 and CMC 5 respectively. If heat is used for a second extraction, then this would exclude the material from the use as input material as the process is not included in the exhaustive list of processes.

8.26 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.
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 CMC 10 in Annex II to the FPR.

8.27 What do sewage sludge, industrial sludge and dredging sludge mean?

CMCs 3 (compost) and 5 (digestate other than fresh crop digestate) allow as input materials living or dead organisms except 'sewage sludge', 'industrial sludge' and 'dredging sludge'.
These notions are not defined in the FPR.
The notion of 'sludge' is defined in the Sewage Sludge Directive[12] as follows:
'sludge' means:

(i) residual sludge from sewage plants treating domestic or urban waste waters and from other sewage plants treating waste waters of a composition similar to domestic and urban waste waters;
(ii) residual sludge from septic tanks and other similar installations for the treatment of sewage;
(iii) residual sludge from sewage plants other than those referred to in (i) and (ii).'

The notions 'industrial sludge' and 'dredging sludge' used in the FPR are not defined as such in the Sewage Sludge Directive and therefore they should be understood in the usual meaning of the terms.
'Industrial sludge' covers the residual sludge from plants treating industrial waste water, including from agro-food industry. During the negotiations for the adoption of the Fertilising Products Regulation, the European Parliament proposed to allow as input in compost and digestate 'non-consumable food residues, fodder and plantations linked to agrofuels'. The European Commission explained to the co-legislators that the risks from agro-fuel industry sludge have not been assessed (in particular if plant protection products or biocides are present) and this may negatively affect the composting/digestion process. This amendment has not been included by the European Parliament and the Council in the Regulation.
The fact that certain types of sludge are allowed in the context of the ECOLABEL Decision for growing media and soil improvers does not mean that they may also be used as input materials under the FPR.

[12] Council Directive 86/278/EEC of 12 June 1986 on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture, OJ L 181, 4.7.1986, p. 6.

8.28 Can microbial plant biostimulants contain other component materials than those belonging to CMC 7?

Yes. A microbial plant biostimulant may contain any other component material, as long as there is no intentional chemical reaction between those component materials and the microorganisms in CMC 7.
However, the microorganisms listed in CMC 7 may be used only in a microbial plant biostimulant. This is very important because the safety criteria for PFC 6(B) are specifically adapted to the microorganisms listed in CMC 7.

8.29 Are high purity materials out of off-gases generated by manure derived products within the scope of the Animal by-products Regulation?

No.

Off-gases from manure are not animal by-products or derived products within the scope of the Animal by-products Regulation, as defined in Article 2 of that Regulation[13].

Therefore, the recovered high purity materials out of such off-gases are not within the scope of the said Regulation either and no end-point in the manufacturing chain has to be determined under the animal by-products rules for the use of such materials in EU fertilising products.

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 Does the obligation to declare on the label all ingredients above 5% mean also that the manufacturer should consider only ingredients above 5% when performing the conformity assessment procedure?

No. All materials present into an EU fertilising products, irrespective of their concentration in the product have to belong to a component material category. For example, additives which represent 2% by mass of the product have to fit into a component material category even if they are not declared on the label. The manufacturer will draw a technical documentation including details on all component materials.

[13] 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)

9.3 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 inorganic 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.

9.4 Are manufacturers allowed to declare nutrients content in a plant biostimulant?

No.
Plant biostimulants have to fulfil their function irrespective of their nutrient content.
Fertilisers are the only PFC the main function of which is to provide plants with nutrients. The content of nutrients in fertilisers may be declared only where they are present in the EU fertilising product in the minimum quantity specified in Annex I for the relevant PFC. If nitrogen (N) or phosphorus (P) are not declared nutrients, the content of nitrogen (N) or phosphorus pentoxide (P_2O_5) is nevertheless indicated if above 0,5 % by mass.
The FPR expressly provides for the declaration of nutrients also in other PFC in a limited number of cases (CaO and MgO in liming materials, P and N in soil improvers). There are no such provisions for plant biostimulants.
Last but not least, the information on the label should not be misleading. Adding nutrients on a plant biostimulants label could create the false impression that the product fulfils the function of a fertiliser, even though the conformity assessment for PFC 1 was not performed.
Nutrients may be declared when the manufacturer places the product on the market as a fertilising product blend (of a fertiliser and a plant biostimulant). For more details, see question 9.6.

9.5 What has to be included in the use instructions of inhibitors?

The manufacturers of inhibitors (belonging to PFC 5) have to include on the label use instructions, which will ensure that the product will be used in such a way that the inhibitor will produce the expected result.
As an example, the following information has to be included on the label:

‘Use instructions: this product may be mixed with fertilisers containing nitrogen, 50% of which is urea; mix between 2,25 to 4,50 % of product by mass of the total urea nitrogen’

9.6 How to declare the nutrients content in blends composed of a fertiliser and a plant biostimulant?

In the case of blends composed of a fertiliser and a plant biostimulant, the declaration of the nutrients content is only relevant to the fertiliser and the manufacturer has to follow the product specific labelling provisions and the adjacent tolerances.
There are two possible situations:

1. A manufacturer produces a plant extracted protein. The manufacturer claims two functions for this material (functional blend): it is a blend (PFC 7) composed of a fertiliser covered by PCF 1(A) and a plant biostimulant covered by PFC 6(B).

In this case, the manufacturer may declare the total nutrients content present in the material and he/she needs to follow the tolerance rules that apply for fertilisers covered by PCF 1(A).

2. A manufacturer mixes two different EU fertilising products: a liquid inorganic macronutrient fertiliser (covered by PFC 1(C)(I)(b)) and a plant biostimulant (covered by PFC 6(B)). The plant biostimulant may also naturally contain some nutrients, however these nutrients cannot be declared.

The manufacturer of this blend will declare on the blend’s label:

- the nutrients content in the fertiliser expressed in relation to the fertilising product blend;
- the concentration of the plant biostimulant in the blend expressed as g/kg or g/l at 20 degrees Celsius.

The manufacturer also has to be in possession of the EU declaration of conformity of the component EU fertilising products. It is advisable to add information in the technical documentation of the blend concerning the nutrient content of the fertiliser contained therein. In general, the manufacturer of a blend will be in possession of all the labelling information for all the component fertilising products contained in the blend. It is strongly advisable to add all that information in the technical documentation of the blend, since this can constitute useful evidence in compliance checks.
In this way, during a subsequent compliance check of the blend, it could be easily determined if the nutrient content has been declared correctly. The fact that the tolerances for the declaration of nutrients in the fertiliser would not be respected in the case of the blend itself is not relevant. These tolerances are set out for the declaration of nutrients in fertilisers, and not in the blend.

9.7 When nitrogen is not a declared nutrient, but is present above the 0,5 limit in a fertiliser, what are the forms of nitrogen which have to be declared?

Annex II, Part II, PFC 1, point 2 FPR requests manufacturers to label the content of nitrogen when it is present in a fertiliser above 0,5 % by mass. This requirement has been introduced by the Council during the negotiations on the FPR due to environmental concerns. To ensure the correct implementation of the Nitrates Directive, professional users have to know if

fertilisers contain nitrogen and phosphorus, even if the primary aim of the product is not the provision of these nutrients.
For the purpose of that Directive, 'fertiliser' means any substance containing a nitrogen compound or nitrogen compounds utilized on land to enhance growth of vegetation. 'Nitrogen compound' is defined as any nitrogen-containing substance except for gaseous molecular nitrogen.
Therefore, the manufacturers have the obligation to declare any substances concerning nitrogen and not only for forms of nitrogen listed in the FPR when nitrogen is a declared nutrient.

9.8 What is the purpose of the maximum residue limits (MRL) labelling requirement and when is it applicable?

The FPR in the form adopted in June 2019 set out rules for EU fertilising products containing a substance with maximum residue limit values for food and feed laid down in accordance with EU rules[14]. The manufacturer was obliged to provide use instructions to ensure that the intended use of the EU fertilising product would not lead to the exceedance of the maximum limit values for food and feed. In addition, the manufacturer had to include in the technical documentation the results of calculations that proved compliance with that obligation.
In the discussions on how to implement this obligation, it has become clear that it is impossible for manufacturers to comply therewith, thus preventing agronomic efficient, safe, and already widely traded fertilising products from passing the conformity assessment and accessing the single market.
The amendments introduced by Commission Delegated Regulation (EU) 2021/1768[15] follow the same objective of avoiding the exceedance of the MRLs in crops, but the obligations provided therein are more proportionate and implementable.
To ensure a fair balance of the burden, the newly introduced labelling requirement does not apply to any EU fertilising product containing substances with a defined MRL. The purpose is to address the specific risks of the commercialisation as fertilising products of crops that cannot be placed on the market as food and feed as they do not comply with MRL. For crops non-complaint with MRL, it is important to avoid their disposal as waste and to reintroduce

[14] Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food, OJ L 37, 13.2.1993, p. 1.
Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC, OJ L 70, 16.3.2005, p. 1.
Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council, OJ L 152, 16.6.2009, p. 11.
Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed - Council statement, OJ L 140, 30.5.2002, p. 10.
[15] Commission Delegated Regulation (EU) 2021/1768 of 23 June 2021 amending, for the purpose of its adaptation to technical progress, Annexes I, II, III and IV to Regulation (EU) 2019/1009 of the European Parliament and of the Council laying down rules on the making available on the market of EU fertilising products, OJ L 356, 8.10.2021, p. 8.

them in the economy, in this case as fertilising products. However, it is equally important to avoid that the resulting crops would also be non-compliant. Therefore, farmers who use fertilising products out of non-compliant crops should be warned and be in a position to take all measures to avoid that their own crop will be affected.

The labelling requirement applies to EU fertilising products complying with the following two cumulative conditions:

1. They contain a component material which, if placed on the market as food or feed, would have been subject to:
    a. maximum residue limits established pursuant to Regulation (EC) No 470/2009 or Regulation (EU) No 1831/2003[16];
    b. maximum residue levels set in accordance with Regulation (EC) No 396/2005 or
    c. maximum levels established pursuant to Regulation (EEC) 315/93 or Directive 2002/32/EC.

    The list of EU rules laying down the various MRL is exhaustive. If, for instance, there are limits for feed additives for the safety of the animals, this is not relevant for the application of the labelling requirement.

    Such component materials could be, for instance, carrots or wheat straw crops, with the MRL exceeded, which could be used as CMC 2 in a soil improver. It does not cover the situation where these materials would be used as input materials for a CMC like compost.
2. that component material contains a substance in exceedance of (one of) the corresponding limit value(s).

    It is necessary that the MRL is exceeded in the component material and not in the final EU fertilising product because, the intention is to address those materials which can no longer be marketed as food or feed and are redirected towards the production of fertilising products.

    It is possible that one and the same substance has various MRLs. In such a case, it is enough if any of the MRLs are exceeded for the application of the labelling requirement.

    It is not relevant if the said substance has already a maximum limit value laid down in Annex I to the FPR. There might be cases where there is both an MRL and a maximum limit in Annex I. However, these limits follow different objectives. The limit values in Annex I are mandatory and no fertilising product may be placed on the market exceeding those limits. The MRLs are laid down for food and feed and may be stricter than the limit values in Annex I, given that food and feed have a direct impact on human health. The fertilising product may contain a component material exceeding the MRL and still be marketed. However, the label should contain the necessary information, even if the said substance is well below the limit in Annex I.

If the two conditions are fulfilled, the manufacturers have the obligation:

[16] Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition, OJ L 268, 18.10.2003, p. 29.

1. to indicate the maximum concentration of that substance in the EU fertilising product (not in the component material, but in the final product); and
2. to include on the label a warning that the EU fertilising product must not be used in such a manner as to risk leading to the exceedance of that limit in food or feed; the warning may be drafted along the following lines:

'This product contains [the concentration] % by mass of [the substance with the MRL exceeded]. Make sure that the use of the product is not leading to the exceedance of the maximum limit of this substance/these substances in the crop'.

9.9 Where can manufacturers find information on maximum residues limits?

In the EU pesticides data base, manufacturers may find information on pesticide residues and the *MRLs that apply for such residues in food products*. The data-base offers the possibility to select a particular pesticide residue in specific food products and find the current or historical MRLs that legally apply. Manufacturers can also download data on MRLs.
For more information, follow this link:
https://ec.europa.eu/food/plants/pesticides/eu-pesticides-database_en
For contaminants in food, each contaminant has a dedicated webpage with links to the relevant regulations at the following link:
https://ec.europa.eu/food/safety/chemical-safety/contaminants_en#further-information
For feed additives, the relevant information is available in the European Union Register of Feed Additives at the following link:
https://ec.europa.eu/food/safety/animal-feed/feed-additives/eu-register_en
For pharmacologically active substances (MedVet) and some excipients, Regulation (EU) No 37/2010 sets MRLs in foodstuffs of animal origin (most recent consolidated version available at the time these FAQs were finalised):
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02010R0037-20210506

9.10 How should chelating and complexing agents be labelled?

The FPR as adopted in 2019 required the declaration of the percentage of each micronutrient chelated by each chelating agent and of each micronutrient complexed by each complexing agent, as applicable.
Products with micronutrients may contain a mixture of chelating agents, or complexing agents, or both. In such cases, the analytical methods available cannot support the determination of the exact percentage of each micronutrient chelated or complexed by each individual agent.
Thus, the FPR has been amended to allow the manufacturer to comply with these labelling requirements, thereby facilitating their access to the single market.
Where the declared micronutrients are chelated by chelating agent(s) or complexed by complexing agent(s), the following information has to be provided on the label:

1. One of the following qualifiers:
    a. 'chelated by [name of the chelating agent(s) or its(their) abbreviation]' or
    b. 'complexed by [name of the complexing agent(s) or its(their) abbreviation]' or

c. ‘chelated by [name of the chelating agent(s) or its(their) abbreviation] and complexed by [name of the complexing agent(s) or its (their) abbreviation]’

and

2. the amount of chelated/complexed micronutrient(s) as % by mass.

Where the declared micronutrients are chelated by chelating agent(s), the pH range guaranteeing acceptable stability has also to be indicated.

So, to provide an example, in the section provided information on nutrients it could be indicated:

‘9 % water soluble iron (Fe) chelated by EDTA and EDDHA, pH range guaranteeing acceptable stability 3-6.5’

The manufacturer may opt to provide more detailed information, when available, such as:

‘3 % water soluble iron (Fe) chelated by EDTA, pH range guaranteeing acceptable stability 1.5-6.5

6% water soluble iron (Fe) chelated by EDDHA, pH range guaranteeing acceptable stability 3-10’.

9.11 What tolerance applies when declaring the total nitrogen in organo-mineral and inorganic macronutrient fertilisers?

The FPR lays down tolerances only for the various forms of nitrogen (such as nitric or ammoniacal nitrogen), and not for the total nitrogen.

The total nitrogen is the sum of the various forms of nitrogen declared for the relevant fertilisers. Therefore, as the variation of the components of the total nitrogen are regulated, the variation of the total nitrogen itself will also be limited in practice.

For instance, an inorganic macronutrient fertiliser has:

Parameter	**Declared on the label**	**Actual content**	**Deviation**
nitrate N	5%	4%	**-20%** (complies with difference of 1,5 percentage points in absolute terms)
ammoniacal N	7%	5,6 %	**-20%** (complies with the difference of 1,5 percentage points in absolute terms)
total N	12%	9,6 %	Which also gives a **-20%** deviation

9.12 What tolerances apply to a fertilising product blend?

All the labelling requirements applicable to all component EU fertilising products apply to the fertilising product blend, and are to be expressed in relation to the final fertilising product blend.

The FPR lays down tolerances specific for blends only for the quantity and for the concentration of each plant biostimulant in the blend.

For all the other elements to be included on the label of a blend, there are no tolerances. Nevertheless, by limiting the deviation of various parameters in the component EU fertilising products, the deviations in the fertilising product blend will also be limited, in practice.

As an example:

- When declaring the nutrient in a fertiliser (PFC 1), the tolerances in Annex III, Part III apply: if, on the label, there is 5% of a form of nitrogen, the existing tolerance rules allow for a deviation from 4% to 6%. These differences may be justified by slight differences from a batch to another and by the methods applied to determine the nutrient, which could have their own errors.
- Once such a fertiliser is mixed with another one in a blend, then the blender will calculate on paper the content of the nutrient in the final blend (following the same example, if the fertiliser is 50% of the blend, then the label will have 2.5 % of nutrient; given the tolerances applicable to the fertiliser, the deviations in the blend would vary between 2 to 3%).

The content of nutrient in the blend will not be tested as such by the blender. There are no minimum concentrations of nutrients in blends either. This is part of the conformity assessment of the component fertiliser itself (which is a separate conformity assessment, done before the blend is manufactured).

Once the blend is placed on the market, a market surveillance authority may test the content of nutrient in the blend and find that the actual content is 2,25% of the blend. The market surveillance will also do the calculation and see that the blender used indeed compliant EU fertilising products when manufacturing the blend, because the component EU fertilising products had a content of nutrient within the limits as provided by the tolerances in Annex III, Part III.

There might be situations where a market surveillance authority will not reach a clear conclusion on paper – but then, in case of doubts on the compliance of the component EU fertilising products, it is up to the market surveillance authority to investigate more if need be.

10. Annex IV - Conformity assessment

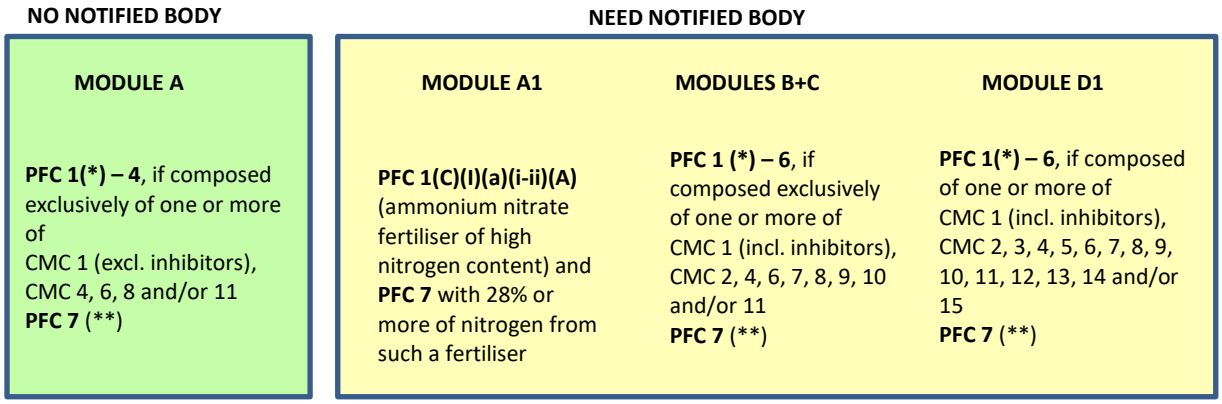
10.1 What conformity assessment procedure do the manufacturers have to follow?

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 types 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:



(*) 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.

For more details, see this table.

10.2 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.

10.3 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.

10.4 Is there a list of approved laboratories to check the conformity with various requirements, such as contaminant content?

No. Contrary to the Regulation on EC Fertilisers, the FPR no longer refers to a list of approved laboratories.

The manufacturers perform the conformity assessment under their responsibility (with or without the involvement of a notified body, depending on the products – see question 10.1). Irrespective of the type of conformity assessment followed, the manufacturers will have to test the products themselves or will choose freely the laboratory which will perform tests on their behalf.
It is recommended to perform the relevant tests by using a laboratory which is accredited for Standard 17025. Details on laboratories accredited are published on the website of the national accreditation body in each EU country.
The contact details, including web-sites, of all national accreditation bodies, are available here: EUROPA - European Commission - Growth - Regulatory policy - NANDO

10.5 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.
For the specific situation of Module D1, see question 10.19.

10.6 What do manufacturers test during conformity assessment procedure in Module D1 for materials recovered from waste?

When requesting the approval of the quality control system, the manufacturer will provide the notified bodies, among others:

- all relevant information for the EU fertilising product category envisaged,
- the documentation concerning the quality system,
- the technical documentation of all EU fertilising products.

In the technical documentation, the manufacturer will include test reports proving the compliance of the EU fertilising product with all the relevant requirements or, where applicable, will explain why conformity may be assumed under his/her responsibility, in accordance with point 4 in Part I of Annex I to the Fertilising Products Regulation.

During the manufacturing process, the manufacturer will test samples of the relevant component materials concerned, with the regularity indicated in sub-points f and fa in point 5.1.3.1 in Module D1, in Part II of Annex IV to the FPR. The frequency varies depending on the volume of input materials and the previous testing reports.

10.7 What do notified bodies test during audits of a quality assurance system in Module D1 for component materials recovered from waste?

During regular audits, the notified bodies will take samples of the output materials (the component materials out of recovered waste). The notified bodies may test EU fertilising products during unexpected audits, if found necessary.

10.8 What must manufacturers check during the conformity assessment of a blend?

The starting point of the conformity assessment of a blend is that the component EU fertilising products have already passed successfully a conformity assessment procedure.
Blenders have to check that the blending of the component EU fertilising products does not change the nature of the fertilising products [see question 7.13 for more information]. Blenders do not have to check again all the requirements of the component EU fertilising products.
The scope of the conformity assessment of the blend remains unchanged even if the manufacturer decides to rely on a notified body to perform the conformity assessment (and thus to follow Modules D1 or B). The notified body will not check the conformity assessment of the component EU fertilising products, irrespective of whether they have been assessed via a conformity assessment procedure involving a notified body.

10.9 What conformity assessment procedure is to be followed for a blend containing an ammonium nitrate fertiliser of high nitrogen content?

It depends on the share of nitrogen from ammonium nitrate fertilisers of high nitrogen content in the blend.
Module A1 must be used for a fertilising product blend containing 28 % or more by mass of nitrogen (N) from an ammonium nitrate fertiliser of high nitrogen content.
If the content is below 28% in the blend, then the manufacturer of the blend may apply any conformity assessment procedure.

10.10 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.

10.11 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.

10.12 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.[17]

10.13 How should the manufacturer perform the conformity assessment of component materials belonging to, for instance, CMC 1, bought from third parties and provide information about their origin or manufacturing?

Manufacturers may use in the production of the EU fertilising products substances or mixtures belonging to CMC 1 bought from third parties. Even if this is the case, the manufacturers of the EU fertilising product bear the whole responsibility for placing products on the market which are compliant with the Regulation and should therefore obtain the information required for the conformity assessment from their suppliers.
In particular, several ready-made mixtures of additives used in the production of fertilising products are often supplied by operators not involved in the subsequent production of the fertilising products.
Given that the substances constituting such mixtures are "virgin material substances", the mixtures could be covered by CMC 1 of Annex II to the FPR, if the substances are REACH registered as specified in the relevant provisions of point 2 of CMC 1.
In such cases, for complying with relevant provisions of Annex IV to the FPR, the manufacturers should have in their possession at least the information that they will have by virtue of REACH.
Article 31 REACH requires suppliers of substances or mixtures to provide the recipients with a safety data sheet, where the substance or the mixture meets the criteria for classification

[17] See section 7.4 of the 'Blue Guide' on the implementation of EU products rules 2022.

under Regulation 1272/2008 (CLP), the substance is a PBT[18] or vPvB[19], or included in the candidate list established in accordance with Article 59(1) REACH. The safety data sheet must contain the product identifier as per Article 18 CLP and, in the case of mixtures, the product identifiers, the concentration or concentration ranges and the classifications for at least all substances meeting the conditions of point 3.2.1 or 3.2.2 of Annex II to REACH.
Furthermore, the supplier should provide a description of the origin and the manufacturing process of the mixture which at least allows the fertilising product manufacturer to guarantee that the criteria of CMC 1 are met (e.g. none of the substances in the mixture is waste or any of the other types of material excluded from CMC 1).
Ultimately the fertilising product manufacturers are responsible for the product's conformity with the FPR. Therefore, it is advisable for them to include in the supply contract a contractual liability for the accuracy of that guarantee, as well as a commitment by the supplier to collaborate with competent national authorities upon reasoned request (mirroring his or her own duty in Article 6(9) FPR).

10.14 What does the technical documentation of a blend has to contain?

The minimum content of the technical documentation as laid down in point 2.2 in each Module has to take into account the scope of the conformity assessment procedure of blends, as explained in question 10.8.

Thus, the technical documentation of the blend has to specify the applicable requirements for PFC 7 and cover, as far as relevant for the assessment, the design, manufacture and intended use of the fertilising product blend.

Out of the minimum list in point 2.2 in the Modules in Part II of Annex IV to the FPR, the parts cut through are not considered relevant for blends and in green the meaning of certain relevant requirements is further explained:

(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,
(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,
(d) drawings, schemes, descriptions and explanations necessary for the understanding of the manufacturing process of the EU fertilising product (meaning the blend), ~~and, in relation to compost belonging to CMC 3 or digestate belonging to CMC 5, as defined in Annex II, a written description and a diagram of the production process, where each treatment, storage vessel and area is clearly identified,~~

[18] Persistent, bioaccumulative and toxic

[19] Very persistent and very bioaccumulative

(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, (meaning the blend; it is advisable to also include the labels of the component EU fertilising products)

(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 will specify the parts which have been applied, [again this concerns only those tests done by the blender to prove that there is no change in nature; the standards used for the component EU fertilising products are listed in the EU declaration of conformity of the respective product]

(g) results of calculations made, examinations carried out, etc. to prove that there is no change in nature (for instance, references to technical or scientific knowledge showing that the manufacturing process described in point d cannot lead to a chemical reaction).

(h) test reports, for tests performed with the objective referred to in the previous point

(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,~~

(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~~

(k) where the EU fertilising product contains total chromium (Cr) above 200 mg/kg, information about the maximum quantity and exact source of total chromium (Cr). In case the blender does not have information about the content of total chromium and its origin in the component EU fertilising products, then tests on total chromium content should be carried out before mixing the component EU fertilising products so that, if the level exceeds 200 mg/kg dry matter of the blend, to be able to identify which of the component EU fertilising products is the origin of the chromium in the blend.

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

10.15 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.

10.16 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.

10.17 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 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. The coordination group of notified bodies agreed that certificates should be issued with a validity of up to 5 years.
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.

10.18 What does Module D1 mean?

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

10.19 How can manufacturers comply with the requirements in Module D1 if they buy the component materials (compost for instance) and do not produce them themselves?

Module D1 is a conformity assessment procedure which implies, among others, that the manufacturer:

- operates an approved quality system for production, final product inspection and testing of the EU fertilising products concerned and
- is subject to surveillance by a notified body.

Manufacturers buying (part of the) component materials for the production of an EU fertilising product are bound by the same obligations. Therefore, they have to make sure that in their contractual relationship with the supplier they will include the relevant stipulations, which will allow them to fulfil these obligations.

Thus, the manufacturer of the EU fertilising product needs to agree with the compost producer that the notified body who is taking care of the conformity assessment for the EU fertilising product will also audit the quality assurance system of the compost producer as part of the conformity assessment process. A notified body may agree to rely upon the audit performed by other notified body to the same supplier, if relevant. However, the notified body of the manufacturer of the EU fertilising product is responsible for the whole conformity assessment, including the tasks covering the activity of the supplier.

If the manufacturer produces various types of EU fertilising products containing the same component material out of recovered waste but in combination with other materials, in various concentrations, he/she has the possibility to cover with the same quality assurance system the production of all the relevant products. Nevertheless, some steps in the conformity assessment are specific to each product (such as drafting the technical documentation). Therefore, the manufacturer will have to draft separate technical documentations and make them all available to the notified body.

10.20 The reports of what types of accidents or incidents should be included in the quality management documentation in Module D1?

The quality management documentation has to include reports on all accidents or incidents that occur to the site, their known or suspected causes and actions taken (point 5.1.4.1(i) in Module D1 in Annex IV to the FPR). Given the general formulation in the provision, all types of accidents and incidents should be documented (environmental, safety, health, working accidents).