Legislation on recycling-derived fertilising products: changes, chances and challenges

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Summary and conclusions

Within the circular economy ambitions of the European Commission, a new Regulation for fertilising products has come into force on 16th July 2022. The scope of this regulation has been extended to include organic fertilisers, soil improvers and growing media and biostimulants for plants. It is intended to open the internal EU market to organic and recycling derived fertilising products.

In the underlying report the changes, chances and challenges of the new legislative framework for the marketing and use of organic and recycling-derived fertilising (RDF) products are discussed.

The focus in this study has been on those organic and recycling derived products and materials that have been considered in the NWE interreg project ReNu2Farm. These include struvites, ashes, composts, digestates, liquid N-products derived from manure treatment and ammonium salts recovered from off-gasses.

Changes for the RDF products:

On 16th July 2022 the Fertilising product regulation (FPR) replaced the EC 2003/2003 on mineral fertilisers. The scope of the FPR has been extended in comparison with EC 2003/2003, because it includes organic fertilisers, soil improvers and growing media and biostimulants for plants.

The extensive list of specific fertiliser types in EC 2003/2003 is replaced by Product Function Categories (PFCs) with specific criteria. Additionally, criteria on safety for health and environment were introduced. The FPR confers an explicit end-of waste for recycling derived EU fertiliser products with CE marking. A fertilising product compliant to the FPR may exclusively be composed of materials belonging to one of the component material categories (CMCs). The FPR includes several CMCs for secondary raw materials, including struvites, ashes, composts, products derived from animal by-products with an end point, and ammonium salts recovered from off-gasses.

The legislative structure of the FPR and the responsibilities of the different stakeholders have changed compared to the EC2003/2003.

The FPR introduces more comprehensive labelling requirements for the different EU fertilising products, and these may differ between PFC and the CMC materials used.

The FPR introduces conformity assessment obligations for producers. Four conformity assessment modules are described with varying degree of control be in proportion to the level of risk involved and the level of safety required for the different PFC products and CMC materials.

Chances arising from the FPR

The FPR is considered as a big step forward as it provides access to the market in all EU countries for fertilising products derived from waste, residues, and organic matter. It creates a level playing field for producers of fertilising products compared to producers of chemical fertilisers.

The CE marking and end-of-waste status will change perception and increase acceptance of RDF products by end-users. The CE marking provides assurance for safe and reliable products, whereas waste products are associated with risks and contaminations. Enabling the market entry for organic and recycling-derived products will not only stimulate the circular economy and decrease the loss of nutrients, but also increase the independency of the EU from a geopolitical point of view. The CE marking of RDF products will also contribute to the international acceptance of recycling-derived fertilisers as quality products.

Challenges for further implementation:

RDF materials that meet all criteria of one CMC are still considered as a waste product till the moment that they are brought on the market as an EU-fertilising product with the CE marking. This involves an administrative, logistic and financial hurdle that significantly hampers the uptake of the RDF materials as component materials in the fertiliser market chain.

The waste status of the RDF materials proves to be even more problematic because of the differences in national approaches to the waste, end-of-waste, and by-product status in the different EU countries. The approaches to recognise end-of waste (EoW) or by-product status differ between EU countries. Many EU countries do not confer a national end-of-waste status at all, so that producers do have no other option then the 'self-declaration of EoW' which does not provide any assurance that this will be accepted by the responsible authorities. Stakeholders are also faced by the lack of transparency on the regulations, requirements and status of the waste or waste derived products in the different countries of the EU. Because of these differences there is no level playing field for the producers in different EU countries.

The FPR does provide a framework to use materials that are derived from animal by-products (ABP) in the production of EU-fertilising products. However, no ABP or derived products have been defined yet in CMC 10 or for the use in the composting or digestion processes of CMC 3 and CMC 5. A concept proposal for a supplementary regulation for the definition of the required 'end points' has been brought forward for feedback by the DG SANTE-EFSA. Several points of feedback were given from the ReNu2farm project:

- The draft text on the definition of end-points for certain products derived from ABP does not define whether the end point determination only applies to products

that will be regulated under the scope of the Regulation (EU) 2019/1009 or also to products that are regulated under the national fertiliser regulations.

- Under the prescribed requirement in Annex V chapter II of the draft supplementary regulation, a derogation on the pasteurisation requirements for certain biogas plants is granted. This derogation is however not excluded or addressed in the draft text of the Supplementing regulation. Therefore, it is not clear from the draft text on the end point for digestates that only pasteurised digestates are considered for the determination of end points.
- For the compost of source separated municipal biowaste the requirement to use only the *harmonised* EU processing standards proves very difficult to achieve. Compost and digestates which have been transformed in approved plants using alternative parameters that were authorised by the competent authority are excluded from the determination of end points. It is strongly recommended that the compost and digestates that are produced with national authorised treatments should be added for the definition of end points.

Not all composts and digestates are going to be brought to the market as a CE marked EU fertilising products. Therefore, at the national level, the marketing and use of these composts as an organic fertiliser or soil improver should be regulated by the inclusion of composts in national fertiliser regulations to stimulate the circulate economy at national level. Policy makers at the national level should be aware that the regulation of compost and digestates as a fertilising product without CE marking remains of importance.

Ashes from the incineration or combustion of (poultry) manure are already brought to the market as fertilisers or fertiliser components. It is not clear yet how the determination of an end-point in the manufacturing chain for ashes will influence the legal status of the product. The end-point in the manufacturing chain for OS/FI could be interpretated as a declaration of product status. Following that line of reasoning, the ashes would not be a waste product.

One of the recovered materials of manure treatment is ammonium salt (in the form of either ammonium nitrate or ammonium sulphate). These ammonium salts are within the scope of CMC 15 Recovered high purity materials. However, disputes on the legal status of these ammonium salts are seriously hindering the marketing of these very pure ammonium salts as fertilisers. Under the FPR, the salts are to be considered as a pure product recovered from off-gasses (CMC15). Following a strict interpretation of the definition of 'manure' in the Nitrates Directive, the salts are considered as manure and consequently as ABP. The manure status limits the use of the product to 170kg N in nitrate vulnerable zones, and hence the market perspective. The ABP status is requiring registrations and controls for all stakeholders. This restricts the market uptake because of the imposed administrative, logistic, and financial hurdles. No end-point for the ABP

status can be defined however as under the ABP regulation the ammonium salts do not fit the definition of animal by-products or manure. This proves to be a real Catch 22.

Manure-derived high-quality N-products that do not pose an increased risk for nitrate leaching or other adverse environmental effects compared to synthetic N fertilisers should be excluded from the 170 kg N ha^{-1} limit that is posed on manure application in the Nitrate Vulnerable zones following the Nitrate Directive. The JRC-EC has evaluated several manure-derived products within the SAFEMANURE/ReNure research project. The major outcome was that, following a set of criteria, certain manure-derived fertilising products can be used as replacement of chemically produced nitrogen fertilisers without increasing risks for nitrate leaching. The use of these recovered N products as synthetic fertiliser replacements products fits within the framework of the circular economy action plan of the European Commission and will strengthen the independence of the EU with regards to natural gas and fertilisers.

Considering that the Regulation is already in force, the lack of published EU-harmonised EU standards by CEN is problematic. Because, stakeholders are reluctant to make investments for methods without the assurance that these will be accepted. Routine laboratories for the analyses of fertilising products do not yet offer standard packages for the analysis of the different fertilising products or component materials.

Most EU countries are late to implement the FPR and provide information targeted at the regional stakeholders on the consequences and changes arising from the FPR.

The accreditation of notified bodies (NoBo) is limited to ten parties (Feb 2023). Only two of those can certify EU fertilising products with RDF-materials.

The EU legislation does offer the option to regulate the national marketing of fertilising products without CE marking by national legislation on fertilising products. This will remain to be of importance for RDF products that do not fully comply with all prerequisites of the FPR and for products that are not within the scope of the FPR because of their small regional market. Policy makers should be aware that even with the inclusion of certain RDF products in the FPR the national legislations on fertilisers remain relevant.

Recycling-derived fertilising products are treated inconsistently in the national legislations of member states within NW Europe. Also, the national regulations on fertilising products are implemented in an inconsistent way between the different countries.

Transparency on the legislative framework on fertilising products would also be useful for policy makers, market surveyance authorities and other decision makers and certification institutions. It will provide more insight in the regulatory options for the legislation of certain fertilising products, a more efficient implementation and could contribute to the creation of a level playing field.

The specifications and rules on the labelling are difficult to understand in detail and producers find it difficult to obtain an overview of relevant specifications for their product. The EC has developed a guideline showing how to interpretate the different specification. The guidelines also contain template examples for the different PFCs.

Producers also struggle with the requirements for the Technical Documentation to prove conformity of their products with the FPR. The EC has launched a study for the development of a guidance for the elaboration of the Technical Documentation.

The conformity assessment module D1 requires the involvement of a NoBo. For the EU fertilising products containing RDF components (CMCs 3, 5,12, 13, 14, and 15) the NoBo will have to audit every single production location on a yearly basis and take samples for analysis. For small production plants this may not be economically feasible. The national fertiliser legislation will remain of importance to bring products from small plants to the market.

For ABP-derived components it should be made explicitly clear that the surveyance by the national surveyance authorities under the scope of the ABP regulations 1069/2009 and 142/2011 would be sufficient for the conformity assessment of the module D1.

1 Introduction

The objective of the NWE-Interreg project ReNu2Farm is to increase the use and production of recycled nitrogen (N), phosphorus (P) and potassium (K) for fertilisers in Northwest Europe (NWE). The main essential plant nutrients are N, P and K which are mostly combined in so called mineral NPK-fertilisers. Anually, 5,400Gg of N, 400Gg of P and 6,000Gg K as mineral fertiliser used in the combined NWE countries.

Fertiliser production in the EU is dependent on imported raw materials (P, K) and energy (N). Each year about 2,392 Gg of P is imported into the EU-27, mostly in the form of mined rock phosphate or animal feed. A large part of the P ends as sewage sludge which is eitherlandfilled or incinerated without further valorisation of the ashes. This is a waste of a valuable resource because rock phosphate is a finite resource. The dependence on imported gas for the production of synthetic N-fertilisers makes the EU vulnerable to distortions in the geopolitical situation.

Within the scope of sustainable agriculture and a circular, biobased economy, it is crucial to find ways to reduce quantities of non-recycled nutrients like N, P, and K and to decrease the dependency on energy and nutrient imports. In the NWE Interreg project ReNu2Farm, we considered sewage sludge, food waste, and animal manure as potential sources of nutrients for the production of recycling-derived fertilisers.

The trade and use of recycling-derived fertilisers that are derived from various waste and (animal) by-product streams is limited for several reasons hampering the development of the market for bio-based fertilisers. An important barrier is the legal status of the fertilisers. Because the products are often produced from waste or from animal by-products, the end products are legally still considered as waste or animal by-products as well. For that reason, it is not allowed or difficult to trade these products between EU countries as a fertilising product.

Within the ReNu2farm project, the legal barriers for the trade of organic and recycling derived fertilising products have been analysed (overview in Van Schöll & Postma 2022a). In addition, the country specific requirements for transfrontier transport and use of recycling-derived fertilisers in Northwest Europe were evaluated (Van Schöll & Postma 2022b). The additional prerequisites for fertiliser management and consequences for the use of recycling-derived fertilisers were discussed by Postma & van Schöll 2022.

Within the circular economy ambitions of the European Commission, a new Regulation for fertilising products (FPR) has come into force on July 16th, 2022. The scope of this regulation has been extended to include organic fertilisers, soil improvers and growing

media and biostimulants for plants. It is intended to open the internal EU market to organic and recycling derived fertilising products.

In the underlying report the changes, oppertunities, and challenges of the new legislative framework for the marketing and use of organic and recycling-derived fertilising (RDF) products are discussed.

The focus in this study has been on those organic and recycling derived products and materials that have been considered in the NWE interreg project ReNu2Farm. These include struvites, ashes, composts, digestates, liquid N-products derived from manure treatment, and ammonium salts recovered from off-gasses.

2 Changes legal status RDF under FPR

Change: FPR has replaced Regulation EC 2003/2003 on mineral fertilisers.

On 16th July 2022 the Fertilising product regulation replaced the EC 2003/2003 on mineral fertilisers. The FPR is one of the pillars of the circular economy package of the European commission.

The EU regulation 2019/1009 Fertilising product regulation (FPR) aims at 'facilitating the recognition of organic and waste-based fertilisers in the single market and thus encourage the recycling of bio-nutrients as fertilising products in the circular economy'. When strict rules for the safe recovery of nutrients into secondary raw materials are fulfilled, those raw materials may be used as a component of CE-marked fertilising products. The consequence is that RDF products can become an EU fertilising product, if they meet the criteria for raw materials, production process, agricultural effectivity, and contaminants.

Change: The scope of the FPR has been extended to include organic fertilisers, soil improvers and growing media and biostimulants for plants.

To accommodate the extended scope of the FPR the structure of the regulation differs from that of EC 2003/2003. The extensive list of specific fertiliser types in EC 2003/2003 is replaced by function categories with specific criteria. In Annex I of the FPR the following product function categories (PFC) are designated:

1. Fertiliser
    - A. Organic fertiliser
        - I. Solid organic fertiliser
        - II. Liquid organic fertiliser
    - B. Organo-mineral fertiliser
        - I. Solid organo-mineral fertiliser
        - II. Liquid organo-mineral fertiliser
    - C. Inorganic fertiliser
        - I. Inorganic macronutrient fertiliser including sub-categories
        - II. Inorganic micronutrient fertiliser including sub-categories
2. Liming material
3. Soil improver
    - A. Organic soil improver
    - B. Inorganic soil improver
4. Growing medium
5. Agronomic additive
    - A. Inhibitor
        - I. Nitrification inhibitor

II. Urease inhibitor
B. Chelating agent
C. Complexing agent
6. Plant biostimulant
A. Microbial plant biostimulant
B. Non-microbial plant biostimulant
7. Fertilising product blend

In the second part of Annex I of the FPR, the requirements with respect to the PFCs have been formulated. These includes minimum contents for fertilising products (e.g. nutrients, organic matter, or neutralising value).

Change: criteria on safety for health and environment are introduced.

A new aspect in comparison with the outgoing EC regulation 2003/2003 is that, in addition to criteria for minimal contents of fertilising substances, criteria have been formulated for maximum allowed contents of heavy metals, organic-micropollutants, pathogens, undesired substances (e.g., plastic, glass), and decomposability of polymers. The requirements differ between the PFCs and CMCs.

Change: explicit end-of waste for recycling derived EU fertiliser products are introduced.

If a fertilising product with CE marking is produced from a waste material the product will automatically have reached an end-of-waste status (Article 19). The waste-derived fertilising product will therefore no longer be subjected to the requirements and restrictions of the Waste Framework directive and the Waste Shipment Regulation. Instead, it can be brought to the free internal market of the EU under the scope of the FPR without any restrictions or requirements at the national level.

Change: inclusion of secondary raw materials as components

The materials used for the production of fertilising products mentioned before, have to be clean and safe. For that reason, CMCs have been defined for materials that may be used for the production of the fertilising products. In addition to the eleven CMCs defined in the original text of the FPR, four CMC have been defined on RDF materials: CMC 12 including struvites, CMC 13 including ashes, CMC 14 including biochars, and CMC 15 for pure materials recovered from waste, including ammonium salts from off-gasses of manure or manure treatment.

The CMCs that are designated in Annex II of the FPR are:

1. Virgin material substances and mixtures;
2. Non-processed or mechanically processed plants, plant parts or plant extracts;
3. Compost;
4. Fresh crop digestate;
5. Other digestate than fresh 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 Regulation (EC) No 1069/2009 (Animal by-products Regulation);
11. By-products within the meaning of Directive 2008/98/EC (Waste Framework Directive);
12. Precipitated phosphate salts or derivates (including struvites)
13. Thermal oxidation materials or derivates (including ashes)
14. Pyrolysis or gasification materials.
15. Pure materials recovered from waste

In the second part of Annex II of the FPR, the specific requirements with respect to the different CMCs have been formulated. The requirements differ between the CMCs depending on material characteristics and risks. In most cases it gives a precise description of the requirements of the starting materials that may be used, the way it is produced and processed, the maximum allowed contents of potential contaminants that are not regulated at the PFC level, and/or the minimum requirements of other quality characteristics. For certain CMC materials, a REACH registration is required.

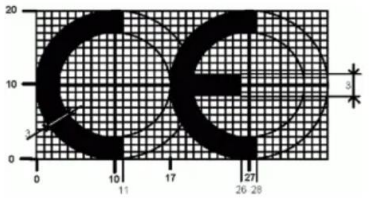
Recycling-derived or waste products that belong to one of the CMCs do not get an end-of-waste status. Only the final EU fertilising product with CE marking will obtain the end-of-waste status.

Change: the legislative structure of the FPR and the responsibilities of the different stakeholders have changed compared to the EC2003/2003.

The basis of the FPR is European horizontal legislation, which implies that there are obligations for the supply of information and there is a connection with other regulations about the control of environmental risks, like the Regulation on Animal By-Products (EC 1069/2009 and 142/2011) the Waste Framework Directive 2008/98/EC and EC Regulation 1907/2006 (REACH) on registration, evaluation, authorisation, and restriction on chemicals.

The FPR has been drafted in line with the New Legislative Approach of the European commission. The goal of the new legislative approach is to improve the internal market and strengthen the conditions for placing a wide range of products with on the EU market. It also introduces measures that aim to improve market surveillance and boost the quality of conformity assessments. Therefore, national market surveyance authorities have to be appointed. Furthermore, notified bodies (NoBo's) for the certification of CE marked

products have to be accredited. The New Legislative Apporach also regulates the use of CE marking.



Change: Labelling requirements.

Under the scope of the FPR, more information on the product function, contents, components, and use has to be mentioned on the label. The labelling requirements for the different fertilising products are given in Annex III of the FPR and differ depending on which PFC a product belongs to and which CMC materials were used for its production.

Change: conformity assessment obligations for producers

Producers of EU fertilising products have to demonstrate that their EU fertilising products made available on the market comply with the requirements of the Regulation. Also, the competent authorities in the different countries of the EU need harmonised standards and instructions for the verification of the EU fertilising products. The assessment procedures should be in proportion to the level of risk involved and the level of safety required.
In Articles 13-41 and Annex IV of the EU Fertilising Products Regulation 2019/1009 it is described how the conformity assessment procedures with respect to EU Fertilising products will be organised.

Four types of conformity assessment procedures are distinguished:

NO NOTIFIED BODY	NEED NOTIFIED BODY		
MODULE A	**MODULE A1**	**MODULES B+C**	**MODULE D1**
PFC 1(*) – 4, if composed exclusively of one or more of CMC 1 (excl. inhibitors), CMC 4, 6, 7, 8 and/or 11 **PFC 7** (**)	**PFC 1(C)(I)(a)(i-ii)(A)** (ammonium nitrate fertiliser of high nitrogen content) and **PFC 7** with 28% or more of nitrogen from such a fertiliser	**PFC 1 (*) – 6**, if composed exclusively of one or more of CMC 1 (incl. inhibitors), CMC 2, 4, 6, 7, 8, 9, 10 and/or 11 **PFC 7** (**)	**PFC 1(*) – 6**, if composed of one or more of CMC 1 (incl. inhibitors), CMC 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14 and/or 15 **PFC 7** (**)

(*) 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.

PFC's containing a recycling derived products fall under the scope of the Module D1, which includes certification of the production process and auditing by a NoBo.

3 Chances for RDF products

Chance: the FPR is a big step forwards access to EU market for fertilising products derived from waste, residues, and organic matter.

The legal base of recycling-derived materials as a valuable component for fertilising products in the EU ensures market access for RDF products in all EU countries. Especially in EU countries that do not regulate the marketing and use of RDF products in the national legislative framework for fertilisers and waste this will open the market for RDF products.

Access to the internal EU market will facilitate the development of marketing chains between regions with surplus of organic matter and nutrients and regions with a demand for nutrients and organic matter.

Chance: creation of level playing field for producers of fertilising products.

The FPR confers the end-of-waste status to fertilising products containing recycling-derived components. This offers a unique opportunity for RDF fertilising products to enter the internal EU market without all the requirements and obligations from the Waste Framework Directive[1] (WFD 2018/851) and the Waste Shipment regulation (1013/2006)[2].

The end-of-waste status creates a level playing field between synthetic fertilisers and recycling-derived fertilisers.

Chance: change perception and increase acceptance of RDF products by end-users.

End users are reluctant to accept RDF products that have the waste status because of their perceived risks with regards to contaminations and pathogens. The FPR has strict requirements for the quality and contaminants in the CE marked products. For recycling derived fertilising products, the certification and control by an independent party (a NoBo) will offer the end users the assurance that the RDF products with CE marking meet requirements for contaminants and pathogens and are therefore safe to use.

Chance: promoting the circular economy, increasing the self-reliance of the EU.

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[1] *Directive (EU) 2018/851 of the European Parliament and of the Council of 30 May 2018 amending Directive 2008/98/EC on Waste*

[2] *Regulation (EC) no 1013/2006 of the European Parliament and of the Council of 14 June 2006 on shipments of waste.*

Enabling market entry for organic and recycling-derived products will not only stimulate the circular economy and decrease the loss of nutrients but also increase the independency of the EU with regards to plant nutrients (which are derived from phosphate rock, animal feed, and natural gas).

Chance: international acceptance of recycling-derived fertilisers as quality products.

The EU product standards are internationally recognised as strong and reliable. This has been experienced by producers of organic fertilisers derived from manure and other animal by-products that are regulated under the EU regulations on animal by-products.

Using the CE marking for recycling-derived fertilising product may increase the awareness and acceptance of these products internationally. This may open up the international market for the CE-marked RDF products. It may also stimulate countries outside the EU to adopt regulations and standards for the recycling of their waste and residue products as fertilising products.

4 Challenges on Legal status of RDFs

4.1 Waste status of certain CMC materials

Change: The FPR provides an end-of-waste status for EU-fertilising products that are brought to the market with an CE-marking.

Chance: This offers a unique opportunity for RDF products to enter the internal EU market without all the requirements and obligations from the Waste Framework Directive[3] (WFD 2018/851) and the Waste Shipment regulation (1013/2006)[4]. The CE-marking is also expected to change the perception of the RDF products from being perceived as hazardous waste to a save and high quality product.

Challenge: RDF materials that meet the CMC criteria of the FPR are still considered as waste products till the moment that they are brought on the market as an EU-fertilising product with the CE marking.

Not all producers of RDF materials aim to bring the CMC material on the market as an EU fertilising product themselves. These materials are recovered during processes such as thermal oxidation of manure or biowaste (ashes) or sewage treatment processes (struvite). The CMC materials are not the main aim of the process, and the producers do not aim to position themselves, or to function as, fertiliser producers. The CMC materials are sold to fertiliser producers for use in fertilising products. As a CMC material product however, it will have to be stored, handled, and transported in compliance with requirements of the waste framework directives regulation. Any transporter, intermediate, and subsequent handler will have to be registered and approved as a waste handling facility. Also, contracts will have to involve financial guarantees. This involves an administrative, logistic, and financial hurdle that significantly hampers the uptake of the RDF component materials in the fertiliser market chain.

The EC has launched a study by the JRC to identify a list of priority waste or by-products streams, and to derive the most suitable candidate streams for which to develop further EU-wide end-of-waste or by-product criteria (Orveillon et al. 2022). The CMC materials recovered from wastewater and sewage sludge, such as ammonium salts and

[3] *Directive (EU) 2018/851 of the European Parliament and of the Council of 30 May 2018 amending Directive 2008/98/EC on Waste*

[4] *Regulation (EC) no 1013/2006 of the European Parliament and of the Council of 14 June 2006 on shipments of waste.*

phosphorus, were considered as candidates but were not ranked as a priority stream. Hence, no EU-wide end-of-waste criteria will be developed for RDF materials such as struvite, ashes and ammonium salts.

Challenge: there is no agreement between member-states on determining when waste ceases to be waste

The waste status of RDF materials proves to be even more problematic because of the differences in national approaches to the waste, end-of-waste and by-product status in the different EU countries. Differences in the national implementation of the waste regulations and criteria may lead to real or assumed market distortions of the EU internal market for secondary raw materials, legal uncertainty as well as disputes over shipments of waste and non-waste. This was concluded by a study launched by the EC DG environment (2020) to analyse the barriers and drivers for the use and recovery of secondary raw materials classified as waste or by products.

The EC study (2020) concluded that there were no Union-wide end-of-waste (EoW) criteria, the EU countries may decide at national level whether certain waste has ceased to be waste or qualifies as a by-product, either by binding national criteria or by single case decisions.

It was also concluded that approaches to recognise EoW or by-product status differ between EU countries. This is in particular the case in single-case decision-making. In some EU countries a designated institution such as the Environment Ministry or the Environment Agency is responsible for deciding whether EoW of by product status is applicable or not. In other countries local or regional authorities take such decisions, or alternatively, the responsibility is with the industry to self-declare EoW, with random ex-post inspections carried out by the enforcement authorities. Many EU countries do not confer a national end-of-waste status at all, so that producers do have no other option then the 'self-declaration of EoW' which does not provide any assurance that this will be followed by authorities.

Because of these differences there is no level playing field for the producers in the different EU countries.

Challenge: Stakeholders face a lack of transparency on the regulations, requirements and status of the waste or waste derived products in the different countries of the EU.

National criteria on the end-of-waste will have to be notified to the European Commission and are published under the EU's Technical Regulation Information System (TRIS). Single case decisions do not need to be notified to the European Commission and cannot be found in the TRIS database. For by-products (BP), there are no binding Union-wide criteria

and the national authorities are not required to provide information on any national criterium or on single-case decisions to the European Commission.

The TRIS database is a step towards transparency but it does not provide the information or transparency needed by producers. This can be shown for compost. Legally binding national legislation on compost that is mentioned in TRIS are the criteria for compost in a bylaw under the Austrian Waste Management Law or criteria for compost produced from biodegradable waste, digestate resulting from biofuel production, sewage sludge resulting from sewage treatment established in Estonia. However, the end-of waste status of compost under the Belgium regulations is not obvious in TRIS, as this was notified under more general regulations on waste (different for Flanders and Wallonia). In the Netherlands, the use of compost and struvite as a fertiliser or soil improver is regulated under the Fertiliser Act, but this does not confer a legal end-of-waste status on the compost and is not mentioned in TRIS at all.

In fact, the Dutch government does not confer national end-of-waste declarations, but only gives a legal opinion on the status of waste, end-of-waste or by-products. These do however not provide assurance to producers as this is not legally binding. A legal opinion has been given for certain production locations of struvite and compost and for certain marketing chains of the ashes of poultry manure. This will lift the requirements for involved parties on handling, storage or using waste, but does not give any guarantee that the opinion will be followed by the local authorizing bodies or by the national authorities of other EU countries.

4.2 ABP-derived products in CMC 3,5, and10: End point ABP

Change: The FPR does provide a framework to use materials that are derived from animal by-products (ABP) in the production of EU-fertilising products. These will fall under CMC 10 or may be used to produce CMC 3 compost or CMC 5 digestates. These ABP material are required to have reached an 'end point in the manufacturing chain' by which they are excluded from the scope of the regulation EC 1069/2009 on ABP.

Chance: under the FPR the free internal EU market is open to the trade of products that are (partly) composed of materials derived from the treatment of animal by-products (ABP) without all the restrictions and obligations of the animal by product regulations (ABPR: EC 1069/2009 and EU 142/2001).

Challenge: However, no ABP-derived products have been defined yet in the CMC 10 or for the use in the composting or digestion process of CMC 3 and CMC 5. A concept proposal for a supplementary regulation for the definition of certain end points has been

brought forwards for feedback by the DG SANTE-EFSA. The initiative will supplement the Regulation (EC) No 1069/2009 on ABP with conditions to enable certain fertilisers containing animal by-products to be placed on the market without the need for further controls.

The marketing and use of ABP as organic fertilisers and soil improvers is currently regulated at the national level by the national fertiliser regulations for non-harmonised fertilising products. The Regulation (EC) No 1069/2009 of the European Parliament and of the Council lays down public and animal health rules for animal by-products and derived products to prevent and minimise risks to public and animal health arising from those products, and in particular to protect the safety of the food and feed chain. The public and animal health rules regards the safe treatment, and the processing or transformation of animal by-products into derived products. The Regulation (EC) 1069/2009 also specifies (Article 32) which ABP products can be used as an organic fertiliser/soil improver (OF/SI).

The concept proposal for the supplementary regulation defines end points for certain derived products referred to in Article 32. The end point in the manufacturing chain of animal by products sets conditions to ensure the animal and public health safety. Products with an end point may be placed on the market without animal health restrictions and can brought under the scope of the FPR.

Derived products included for the definition of an end point are amongst others:

- ashes from categories 2 and 3 (including manure)
- biogas digestion residues (in effect digestate)
- compost
- processed manure and processed insect frass

These products must comply with the harmonised EU processing standards and transformation parameters as defined in the annexes of the implementation regulation EU 142/2011 on ABP.

Challenge: For the compost of source separated municipal biowaste the requirement to use only the *harmonised* EU processing standards proves very difficult to achieve. Source-separated municipal biowaste is considered as an ABP category 3 as it may contain animal by-products. Therefore the composting process has to be in accordance with the processing standards of the EU142/2011. The derived compost is defined as can be used as an OF/SI according to the article 32 of the (EC) 1069/2009.

The EU harmonised treatment parameters (time-temperature parameters 1hour – 70°C and the 12mm particle size threshold) are difficult to achieve in the composting process

that uses biowaste as a feedstock. Under the ABPR's other parameters[5] may be used as an alternative to the harmonised treatment parameters. These treatments have to be authorised by the national competent authorities following validation rules of the ABPR. Producers have to prove that the same guarantees on safety for use and absence of pathogens are given as for the harmonised parameters. Under the scope of the ABPR, compost produced with these alternative treatment parameters can be handled and brought to the EU market with the same requirements as compost treated with the harmonised treatment parameters.

Compost and digestates which have been transformed in approved plants using alternative parameters that were authorised by the competent authority (so called national authorised treatments) are excluded from the determination of end points, but there is no apparent reason or motivation for this exclusion. Therefore this exclusion seems unjustified. It is strongly recommended that the compost and digestates that are produced using national authorised treatments (Annex V Chapter section 2) should be added in the article 3.b and 3.c of the supplementing Regulation, or to give a motivation why these products should remain subject to the prerequisites of Regulation (EU) 1069/1009.

Challenge: The national fertiliser regulations will remain of importance for the marketing of compost that do not comply with the treatment parameters required for the determination of end points. These composts and digestates will continue to fall under the scope of the regulation 1069/2009 animal by-product. Composts derived from municipal biowaste collection falls under the scope of the EC1069/2009 ABP as a category 3 material. It contains the kitchen waste and comparable biowaste that contains residues of animal products, which at this point are not be intended any more for human consumption. Most composting plants use non-harmonised treatment parameters that have been authorised by the national authorities in compliance with the requirements of the ABP regulation EU142/2011 Annex V). In this case, putting on the market and use of these composts as a fertiliser or soil improve is regulated by national fertiliser regulations.

Composting of municipal biowaste is important in the ambitions of the circular economy and waste recycling. Currently most compost facilities do not produce according to the EU-harmonised treatment parameters. Conversion of existing plants is not feasible and not necessary as the compost produced is safe to use. Also, not all compost producers intend to produce for the EU market. Therefore, at the national level, the marketing and of these composts as an organic fertiliser or soil improver should be regulated by the inclusion in the national fertiliser regulations to stimulate the circulate economy at

[5] *According to Annex V of Regulation (EU) 142/2011 Section 2, point 4,'Operators may place on the market digestion residues and compost, which have been produced according to parameters which have been authorised by the competent authority*

regional level. Policy makers at the national level should be aware that the regulation of compost and digestates as a fertilising product without CE marking remains of importance.

Challenge: From the draft text for the Supplementing Regulation, it is not clear that the end point only applies to pasteurized biogas digestion residues. Biogas plants that use manure as a feedstock commonly do not have a pasteurization/hygienisation unit, using a derogation[6] on the obligation for the pasteurisation of 'safe manure' biogas plants. The derogation on pasteurization of biogas digestion residues of 'safe' manure seems justified as the transformation does not add to the pathogen risk and it would be unreasonable to impose restrictions on the digestate that do not apply to the manure that it is derived from. The 'safe' manure and derived digestate can be used for spreading on land but not for transfrontier transport to other EU countries.

Challenge: The EU Regulations EU 1069/2009 and EU 142/2011 are complex texts which contain specific terminology and definitions and many cross-references. The same might be said for the draft text of the supplementing Regulation which refers to specific articles and annex texts in these regulations. Under the prescribed requirement in Annex V chapter II, a derogation for the pasteurisation requirements for biogas plants using 'safe manure' is granted under section 1.2.d with reference to Article 13(f) of Regulation (EC) No 1069/2009.

This derogation is however not excluded or addressed in the draft text of the Supplementing regulation. Therefore, it is not clear from the draft text on the end point for digestates that only pasteurised digestates are considered for the determination of end points. As the text is very difficult to understand and interpretate, this will undoubtedly lead to confusion and discussion between the producers and authorities. As a recommendation, the text should be written more clearly, without the cross-references and should not be open to different interpretations.

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[6] *The derogations on the pasteurisation obligation of 'safe manure' biogas plants:.*

Section 1 of Chapter I of Annex V of EU 142/2011 "1.2. By way of derogation from point 1, a pasteurisation /hygienisation unit shall not be mandatory for biogas plants that transform only:" …

> *"(d) animal by-products which may be applied to land without processing in accordance with Article 13(f) of Regulation (EC) No 1069/2009 and with this Regulation, if the competent authority does not consider them to present a risk of spreading any serious transmissible disease to humans or animals;"*

The referred Article 13(f) of Regulation (EC) No 1069/2009 reads:

> *Article 13 Disposal and use of Category 2 material"*
> *"Category 2 material shall be:" …*
> *"(f) applied to land without processing, in the case of manure, " … " which the competent authority does not consider to present a risk for the spread of any serious transmissible disease"*

Challenge: Ashes from the incineration or combustion of (poultry) manure are already brought to the market as fertilisers or fertiliser components. The ashes have the legal status of waste, and as such do not come under the scope or the ABPR. The legal status of the ashes as a waste or end-of waste has been proven to be a hurdle which required considerable efforts from both the ash producer as the receiving parties. It is not clear yet how the determination of an end-point in the manufacturing chain for ashes will influence the legal status of the product. The end-point in the manufacturing chain for OS/FI could be interpretated as a declaration of product status. Following that line of reasoning, the ashes would not be a waste product and could be handled and brought to the market as a product without the requirements and prerequisites of the waste regulations.

Challenge: The draft text on the definition of end-points for certain ABP-derived products does not define whether the end point determination only applies to products that will be regulated under the scope of the Regulation (EU) 2019/1009 or also to products that are regulated under the national fertiliser regulations. The marketing and use of ABP as organic fertilisers and soil improvers is currently regulated at the national level by the national fertiliser regulations for non-harmonised fertilising products.

Th draft text does not regulate the legal base for the subsequent use of the end-point products, and hence there is no prerequisite to bring the derived product under the scope of Regulation (EU) 2019/1009 for harmonised fertilising products. This seems to imply that these derived products with an end-point can also be regulated as organic fertiliser or soil improver under the national fertiliser regulations without the prerequisites of the Regulation (EU) 1069/2009 of the FPR.

To avoid confusion or different interpretations of the meaning of the text, it is recommended that the text of the supplementing Regulation is reworded to make it unequivocally clear whether (1) the use of the derived products with end point is limited to the use as organic fertilisers and soil improvers under the scope of the (EU 2019/1009, or, whether (2) these end point products can also be used under the scope of national fertiliser regulations.

Once the feedback has been considered and the final proposal adopted by the European Commission (expected in first quarter of 2023) it will be submitted to the Council and the European Parliament. The Council and EU Parliament can suggest amendments to the proposed regulation. Once the Council and the Parliament agree on the final proposal, it is adopted.

After the adoption of the Regulation on End points, an amendment to the FPR has to be made to include the derived products in the CMC 10. The DG GROW Fertiliser expert

committee is already working on a concept proposal for these amendments, based on the concept texts on the regulation by DG SANTE.

4.3 Legal status of Ammonium salts

Change: One of the recovered materials of manure treatment is ammonium salt (in the form of either ammonium nitrate or ammonium sulphate). These ammonium salts are within the scope of CMC 15 Recovered high purity materials.

The CMC 15 RECOVERED HIGH PURITY MATERIALS includes:
"recovered high purity material, which is ammonium salt, sulphate salt, phosphate salt, elemental sulphur, calcium carbonate or calcium oxide, or mixtures thereof, of a purity of at least 95 % dry matter of the material. The high purity material shall be recovered from waste generated from:" …

"(b) a gas purification or emission control process designed to remove nutrients from off-gases derived from one or more of the following input materials and facilities:".

"(viii) manure within the meaning of Article 3, point 20, of Regulation (EC) No 1069/2009 or derived products thereof; or

(ix) livestock housing facilities."

Chance: their recycling of secondary nitrogen will contribute to the circular economy and the geopolitical independence of the EU.

Challenge: In some EU countries, the ammonium salts derived from manure or manure treatment facilities are still considered as manure and or animal by-products (ABP). The legal status of manure and/or ABP limits market uptake as it poses a complex set of prerequisites on transport, handling and storage of the products (laid down in EC 1069/2009 and 142/2011) and requires registration, approval, control and certification of all facilities, vehicles and actors along the market chain. This forms a logistical and administrative burden that further complicated and hinders the market entry and acceptance of the products. The different interpretation on the legal status of the ammonium salts between member states also causes an unfair and uneven playing field for producers in the different countries.

The different interpretations on the legal status of the ammonium salts are the result of the different definitions for animal manure.
In the EC Nitrate Directive manure is defined as:
" *'livestock manure': means waste products excreted by livestock or a mixture of litter and waste products excreted by livestock, even in processed form*."

In a rigid interpretation this definition would stretch to any product that has any component originating from manure. Thus, as the ammonium recovered from the off-gasses of manure or manure treatment originates from manure the recovered ammonium salts would also be defined as livestock manure and hence also as an ABP.

The addition 'even in processed form' is reasonable and justified when this is intended towards manure-derived products with characteristics that pose the same risks for the contamination of waters as the unprocessed manure. However, conferring the status of livestock manure to products that are chemically equivalent to synthetically produced equivalent products, such as ammonium salts, is unreasonable and unjustified.

Conferring the legal status of livestock manure-ABP to high purity recovered ammonium salts does not contribute to the goals of the Nitrate Directive to protect water quality: ammonium salts recovered from off-gases of manure and manure-treatment processes were evaluated by the EC-JRC as equivalent to chemical fertilisers and as a safe material to be exempted from the threshold of 170 kg N in the form of livestock manure per hectare application under the Nitrate directive. There is no need and no justification to confer the status of manure and/or animal by-product to the recovered high purity ammonium salts.

Defining the ammonium salts derived from off-gases as processed manure and of as ABP also opposes the EU regulations on animal by-products. In the Regulation on animal by-products EC 1069/2009 manure and animal by-products are defined as:
" *'manure' means any excrement and/or urine of farmed animals other than farmed fish, with or without litter;*
and
" *'animal by-products' means entire bodies or parts of animals, products of animal origin or other products obtained from animals, which are not intended for human consumption, including oocytes, embryos and semen*"

These definitions do not seem to include the recovered high purity ammonium salts. In the opinion of DG SANTE, responsible for the EC 1069/2009, off-gasses are emissions and not manure or animal by-products. As such they do not fall within the scope of the regulation on animal by-products EC 1069/1009No I069/2009.

The ammonium salts recovered from the off-gasses of manure or manure treatment processes are not included in the Supplementing Regulation for the definition of certain end points (in prep,. DG SANTE). As the ammonium salts are not covered by the definitions of manure or animal by-products, they are not in the scope of the regulation and cannot be given an endpoint within the regulation.

For the use of the ammonium salts as a CMC 15 material in the FPR no declaration of end point is needed. This is underlined by the Commission Expert group on Fertilising Products in their FAQ [4]: *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. 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."*

There seems to be no legal base to consider the recovered high purity ammonium salts as a manure or animal by-products. This difference in interpretation of the legal status of the ammonium salts as an either a processed ABP or a recovered product has consequences that will not be solved by the implementation of the ReNure criteria or the inclusion in FPR CMC 15!

Unambiguous definition by the European commission on the legal status of ammonium salts recovered from air purification of the off-gases generated by manure or manure treatment processes is needed to ensure a coherent interpretation and to provide a fair level playing field between the different EU countries. The different branches of the EC **(**DG ENVIR, DG GROW and DG SANTE) need to align on the statement that the ammonium salts derived from off-gases of manure or manure treatment processes are not animal by-products or manure.

4.4 ReNure implementation

Change: Innovative manure treatment processes have been developed in regions with a manure surplus. In some regions, the high load of N in the form of manure caused water pollution. The establishment of threshold loads of manure to be applied by the Nitrate Directive has driven the innovations in the manure treatment technologies. This has led to several high quality N products that could be seen as equivalent to synthetically derived nitrogen fertilisers. The use of these recovered N products as synthetic fertiliser replacements products fits within the framework of the circular economy action plan of the European Commission.

Chance: Within the Circular economy action plan the focus is laid on the use of recovered nutrients. For nitrogen, this has been strengthened by the high gas prices and the war between Russia and Ukraine, which highlighted the need for geopolitical independence of the EU. Manure-derived high quality N-products that do not pose an increased risk for nitrate leaching or other adverse environmental effects compared to synthetic N fertilisers should be excluded from the 170 kg N ha^{-1} limit that is posed on manure application in the Nitrate Vulnerable zones following the Nitrate Directive.

Challenge: The JRC-EC has evaluated a number of manure-derived products within the SAFEMANURE/ReNure research project. Major outcome was that, following a set of criteria, certain manure-derived fertilising products can be used as replacement of chemically produced nitrogen fertilisers without increasing risks for nitrate leaching. As the technologies are developed, installations ready to produce, and farmers are in need for nitrogen fertilisers, and the EU needs to decrease the energy need for fertiliser production, the implementation of the ReNure criteria should be accelerated.

5 Challenges on implementation

5.1 Harmonised standards FPR

Change: Under the FPR producers have to prove that their products comply with the requirements set in the relevant PFC and CMCs for their product. These requirements deal with the function claims and environmental criteria. The FPR regulates the development of a set of harmonised EU standards that can be used to show compliance. These EU harmonised norms are developed by the CEN and will be published in the Official Journal of the EU, which creates so-called 'the presumption of conformity. Producers may also use other standards for the it can be equally shown that these are adequate to prove compliance.

Chance: The harmonised EU standards give the producers the assurance that market surveyance authorities in the different member states and NoBos will accept the test reports of the laboratories. At the same time, the FPR also provides the opportunity to use other quality standards that are more common for industry or in specific countries or that are otherwise preferably.

Challenge: Considering that the Regulation is already in force the lack of published EU-harmonised EU standards by CEN is problematic. The lack of EU-harmonised standards required fertiliser companies with in-house laboratories and commercial laboratories to invest in development of analytical measurements for fertiliser contents, contaminants, and pathogens without the assurance whether these analytical measurements will be accepted as an EU harmonised standard or equivalent. Currently, CEN has published Technical Specifications for certain PFC and CMC requirements. These technical specification were presented as a 'concept' for the EU-harmonised standards and are used as such by producers and NoBos. They do however not offer the assurance of acceptance.

Routine laboratories for the analyses of fertilising products do not yet offer standard packages for the analysis of the different fertilising products or component materials. It will be up to the producers to find laboratories offering the analytical methods that will be deemed acceptable by the market surveyance authorities and NoBos. Most producers do not have the in-house knowledge on the different analytical methods. Also, not all the analytical measure in the CEN technical specifications are offered by routine laboratories.

The EC DG-GROW responsible for the FPR has launched a study for the development of guidelines for the Technical Documentation. This will include a list of standards that can

be used to show compliance with the requirements with the FPR. This list will include the harmonised EU-standards, but also other standards that can be used.

- Standard list of CEN/Technical Specifications (TS), existing standards (International, European or national), other reliable and reproducible testing methods which may be used to assess the conformity of products with the relevant requirements of the FPR.
- Each TS, standard or method will be clearly correlated to one or more of the FPR requirements, the assessment of which it supports.
- It will be clearly indicated if a non-harmonised standard or method is supported by the NoBo's or market surveillance authorities.
- A list of references to other national or international standards or testing methods commonly used in the EU that may have a potential to be included in the standard list.

This list should be seen as a living document, which may be used to create a common understanding between all stakeholders. It will also avoid duplication of the efforts that stakeholders make to show the suitability of the non-harmonised standards.

5.2 FPR implementation at the national level

Change: The FPR sets out responsibilities and obligations for the different operators involved in the conformity assessment following the provisions of the new legislative framework. The EU countries have to appoint market surveyance authorities.

The market surveillance authorities have to survey:

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

For the market surveyance authorities, the extension of the scope to new product categories and the introduction of the conformity assessment procedures and harmonized standards implies a more diverse group of products and more complex procedures compared to the survey of EC-fertilisers under EC 2003/2003.

Chance: The appointment of market surveyance authorities and the founding of an EU body for the market surveyance authorities will improve the consistency, transparency and efficiency of the market surveyance in the different EU countries.

Challenge: The implementation of the FPR at the national level is behind schedule. Some EU countries still have to appoint market surveillance authorities for the control of EU fertilising product and the appointment of NoBos.

Challenge: Parallel to the late implementation of the FPR, information targeted at the stakeholders in the marketing chain of fertilising products at the national level on the changes, chances and consequences arising from the FPR has been scarce.

Most EU countries did not seem to have a communication strategy or awareness campaign to inform producers or potential NoBos. This has been felt especially by the producers of the new FPR products and new CMC materials such as the producers of products containing recycling-derived CMC materials. These are often small or medium enterprises (SME) that do not have the inhouse capacity to follow and interpretate the legislative changes and do not have the financial means for consultancies.

5.3 Limited number of NoBos for RDF products

Change: The FPR has introduced Notified Bodies (NoBo) as a new stakeholder in the fertilising product manufacturing chain. Te NoBos are independent bodies that are accredited to evaluate and certify EU fertilising products with the CE marking.

Notified bodies have to assess:

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

Chance: by the certification of certain products or production processes the conformity and quality of the EU fertilising products can be ensured. By accrediting independent certification bodies that all have to follow the same set of rules from the FPR a coherent and quality assessment throughout the EU will be established. This ensures a level playing field.

Challenge: Products containing components from the CMC 3 Compost, CMC 5 Digestate, CMC 12 Struvite, CMC 13 Ashes, CMC 14 Biochars and CMC 15 High purity materials recovered from waste or animal by-products have to be certified with the conformity module D1. This requires certification by a Notified Bodies (NoBo).

Notified Bodies are listed on the NANDO website[7] (New Approach Notified and Designated Organisations). On 16th July 2022 three NoBos were registered. Currently (Feb 2023) there are ten registered NoBos. Not all NoBos are covering all modules and all CMCs, as can be seen in the Table 5-1. Of the ten NoBos, only three are registered to certify EU fertilising products with components in CMC 3 and 5, and only two of those are also registered for the certification of products with components from CMCs 12, 13, 14, 15.

Table 5-1 Accredited Notified Bodies (NoBo's) for the EU 2019/1009, Modules and CMC's as indicated (source: NANDO website, d.d. 22/02/2023). Last column shows which CMC for recovered materials are covered in the certification are covered (only Module D1 relevant)

NoBo name	**Country**	**Module**			**RDF-CMC's covered**
		A1	**B**	**D1**	**In Module D1**
CerTrust Kft.	Hungary	x	x	x	CMC 3-5-12-13-14-15
TUV AUSTRIA HELLAS LTD	Greece	x	x	x	CMC 3-5-12-13-14-15
POLSKIE CENTRUM BADAN CERTYFIKACJI S.A.	Poland	x	x	x	CMC 3-5
Kiwa VERIN B.V.	Netherlands			x	none
LATVIAN CERTIFICATION CENTRE (LATSERT)	Latvia		x		*
TNO Defense, Security and Safety	Netherlands				*
EMCI Register and EFCI Register	Netherlands		x		*
Inspectorate Estonia AS	Estonia	x			*
Instytut Nadzoru Technicznego	Poland	x			*
LABORATORIO OFICIAL JOSE MARIA DE MADARIAGA	Spain	x			*

** EU fertilising products containing recycled or recovered materials (CMC 3-5-12-13-14-15) can only be certified under the conformity Module D1*

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

5.4 No transparency on national fertiliser regulations

Change: The FPR has broadened the scope for the marketing of EU fertilising products containing RDF materials with significant EU market perspective and for which sufficient scientific data is available to show the agricultural value and environmental safety.

Chance: Fertilising products that are not intended for the EU market but that have a regional market should however not be excluded from the market. Therefore, the EU legislation does offer the option to regulate the national marketing of fertilising products without CE marking by national legislation on fertilising products. Producers do have the option to either bring their products to the market as an EU fertilising product with CE marking by complying the FPR or as a fertilising product without CE marking by complying to the national fertiliser regulations.

Challenge: Not all RDF materials or products are within the scope of FPR.

The option for national regulations could apply to products that are recovered in small volumes for which the costs and requirements for the conformity assessment module D1 (required for EU fertilising products containing CMC 3, 5, 12, 13, 14, or 15) are not economically feasible.

The option to bring fertilising products to the market by complying with national legislation is also important for materials and products that are derived from new innovative recovering methods that are not covered by one of the CMC definitions. These will have to prove themselves before an EU market introduction. The regulation of these products at the national level will also provide the opportunity to establish the required database on agronomical functioning and environmental safety.

Challenge: The national fertiliser legislation will remain of importance to bring RDF products to the market. Policy makers should be aware that even with the inclusion of certain RDF products in the FPR the national legislation on fertilisers remains relevant.

Challenge: There is no level playing field for the producers of RDF products outside the scope of the FPR in the different countries of the EU. Recycling-derived fertilising products are treated inconsistent in the national legislations of member states within NW Europe, amongst others in the following ways:

- Procedures for the authorisation of waste or by-products as fertiliser are often not clear and strongly differ between countries;
- In some countries, recycling-derived fertilisers are authorised by defining a generic category with criteria in the regulations, while in other countries the same products undergo a case-by-case authorisation, that is applicable only to the

specific product from a specific waste stream / site / process and/or a specific producer;
- Criteria for contaminants like heavy metals are different between countries, so that a specific RDF product may meet the criteria for heavy metals in one country and not in another country;
- The fertiliser status and end-of-waste status are of relevance. In some countries, the end-of-waste status is supplied as soon as a product receives a fertiliser status, but in other countries that is not the case.

As a result, specific RDF products may have a fertiliser status in one country and a waste status in another country.

In general, it requires a lot of administrative work and good knowledge of the authorisation procedures to bring RDF products to the market by complying to the national regulations. This hampers the recycling of nutrients from waste, because it hinders:

- the use of RDF materials as secondary raw material in fertiliser production,
- the marketing and use as a fertiliser product in different countries.
- the use as a component for blending,
- cross-border transport between countries in the EU.

Challenge: Fertiliser products that are brought to the market by complying to the national regulations can be brought to the market in other EU countries by applying to the mutual recognition principle. In that case, the producers may still be required to show that their fertilising products do comply with the criteria on environmental safety set in the regulation of the receiving country. The prerequisites of the EU regulation on Mutual recognition are interpreted differently by the member countries within NW Europe. In practice most countries prescribe the regular procedure for the authorisation of fertilisers, even if a fertiliser product has a fertiliser status in another member state.

Challenge: The national regulations on fertilising products are implemented in an inconsistent way between the different countries. As there is no overview or database of the national legislation on fertilising products, producers have trouble to find the regulatory requirements their products have to comply with under the mutual recognition principle. This lack of transparency is a barrier to the cross-border marketing of fertilisers that are not in the scope of the FPR.

Transparency on the legislative framework on fertilising products would also be useful for policy makers, market surveyance authorities and other decision makers and certification institutions. It will provide more insight in the regulatory options for the legislation of certain fertilising products, a more efficient implementation and could contribute to the creation of a fair level playing field.

6 Challenges for producers

6.1 FPR Requirements for labelling and documentation

Change: The FPR contains specification for the labelling (Annex III) and the conformity assessment procedure (Annex IV) of EU fertilising products with CE marking. Annex III contain rules on the product function and components and on the concentration of nutrients. Annex IV describes the conformity assessment modules that have to be followed for the different product and component categories.

Chance: The obligations on the labelling information give the end-consumers the same information on the products throughout the EU. Also, the labelling rules on product functioning and restriction on other claims that cannot be proven will help consumers to evaluate the products better. The rules on conformity ensure that CE marked products are in accordance with the labelling information and provides a control on the compliance with the prerequisites of the FPR.

Challenge: the specifications and rules on the labelling are difficult to understand in detail and producers find it difficult to obtain the overview of relevant specifications for their product. In response an extensive Guideline[8] for the labelling of EU fertilising products has been developed (Communication 2021/C 119/01). The guideline provides answers to questions on how to interpretate the different specifications and also give examples on how to formulate the different requirements. The guidelines also contain template examples for the different PFCs.

The guideline on labelling is clear but still complex and too extensive for some producers. Especially the SME producers required more ready-made instructions tailored to their product. The Dutch association of fertiliser producers, Meststoffen Nederland, has published concise instruction leaflets[9] per fertilising product category (in Dutch) in addition to the Guideline form the EC.

Challenge: Producers are also struggling with the requirements for the Technical Documentation (TD) to prove the conformity of their products. The TD is the compilation

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

[9] *https://www.meststoffennederland.nl/dossiers/regelgeving/productie-en-distributie/etikettering*

of all information that producers have to show the compliance of their product and components used with the prerequisites of the FPR.

The common elements of TD are

- general description of the product, claimed function and corresponding PFC, intended use;
- component materials, their CMCs, origin or manufacturing process;
- if the product contains by-products - evidence for compliance with criteria and requirements of Dir 2008/98/EC;
- drawings, schemes, descriptions and explanations of the manufacturing process;
- list of harmonized technical norms, specifications and/or other relevant technical specifications applied;
- results of calculations, examinations, etc.;
- test reports;
- a specimen of the label and/or the leaflet, containing the required labelling;
- if total Cr> 200 mg/kg - maximum quantity and exact source.

While the information required for some elements is self-explanatory, for other elements the kind of documentation and the level of detail needed is less clear.

In response to the producers' requests, the EC has launched a study for the development of a guidance for the elaboration of the Technical Documentation. This Guidance document should provide producers with a tailored template detailing the information required for a specific PFC product containing specific CMC materials, which documents have to be compiled, which tests and standards can be used. It will also document a common understanding of the requirements set by the FPR and ensure a smooth transition and uniform implementation.

The Guidance is expected to be finalised December 2023 and will also include an IT-tool. The IT tool will allow users to generate personalized templates in all EU languages, with specifications dedicated to specific product and components requirements.

6.2 Conformity requirements Module D1

Change: EU fertilising products that contain components derived from waste fall under the strictest conformity assessment module D1. This includes a control of the production process of the fertilising products and the waste-derived components.

Chance: The control and certification of the waste derived product will ensure the quality and safety of the products. This will stimulate their perception and acceptance as high

quality trusted products, whereas waste products are often associated with risks and contaminations.

Challenge: The conformity assessment module D1 requires the involvement of a NoBo. For the EU fertilising products containing RDF components (CMC3, 5, 12, 13, 14, 15) the NoBo will have to audit every single production location on a yearly basis and take and analyse samples. Many RDF materials are recovered individual plants which are too small to make the conformity assessment economically feasible. This is the case for struvites that are recovered at sewage treatment plants, for the recovered ammonium salts and for many compost and digestion plants. As a result, the RDF materials are not going to be used for the production of EU fertilising products with the CE marking. The national fertiliser legislation will remain of importance to bring these products to the market. Policy makers should be aware that even with the inclusion of certain RDF products in the FPR the national legislation on fertilisers remains relevant.

Challenge: Components that are derived from animal by-product (CMC 3, 5, 10) are already controlled under the ABP regulations (EC)1069/1009 and (EU)142/2011. For these components it should be made explicitly clear that the surveyance is by the national surveyance authorities under the scope of the ABP regulations 1069/2009 and 142/2011 would be sufficient for the conformity assessment of the module D1.

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