FERTIMANURE

Innovative nutrient recovery from secondary sources – Production of high-added value **FERTI**lisers from animal **MANURE**

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D1.3. REPORT ON THE **BBF REGULATORY FRAMEWORK** IN THE **EU** & **CELAC** COUNTRIES

FERTIMANURE

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Deliverable

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Preface

This deliverable is part of the European project FERTIMANURE funded by the H2020 programme (project number 862849). The project FERTIMANURE aims to develop, integrate, test and validate innovative nutrient management strategies so as to efficiently recover and reuse nutrients and other products with agronomic value from manure, to ultimately obtain reliable and safe fertilisers that can compete in the EU fertiliser market.

This deliverable detail the work performed in Task 1.3 Policy and legislation Assessment as part of WP1 of the FERTIMANURE project. The task was led by ELO, and the preparation of the Deliverable counted with active participation of all project partners, mainly from LEITAT (WP1 coordinator) and UVIC (project coordinator). The main aim of this task was to assess the regulatory framework that has an effect on the FERTIMANURE products at European level, national level and also in the CELAC countries participating in the project: Argentina and Chile.

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Summary

FERTIMANURE project is willing to have a direct impact on reducing the high dependence that EU is currently having on external sources for the supply of key fertilisers used in agriculture. This will be achieved by developing and accessing innovative technological approaches for the production of homogeneous and standardized fertiliser products from organic origin (BBFs and TMFs) in a more sustainable way. To achieve this ambitious goal, the project will need to work and provide relevant data to overcome different barriers that may hamper its final impact and real implementation. Some identified barriers that may affect FERTIMANURE's market success of the obtained end-products are: the acceptance of the obtained products, as they are produced from non-typical source; technological innovation yields, related to the introduction of innovative process and technologies; and also, a relevant barrier will be the regulatory framework to the use and bring to the market the obtained products.

In this regard, the deliverable looks at the current and the impending regulation to provide a complete picture of how the EU and participating Member States regulates certain fertilising products with special attention to the legislation relevant for processed biobased materials derived from manure. In this way, the deliverable includes: (a) Analysis of main EU regulation impacting on FERTIMANURE results where new Fertilisers Regulation, Regulation (EC) 2019/1009 (also referred to as Fertiliser Products Regulation - FPR) is analysed in detail due to its relevance within the project; (b) Analysis of organic farming regulatory framework; (c) Assessment of regulation framework on the countries where the 5 on-farm pilots are installed: France, Spain, Belgium, Germany, and the Netherlands; and (d) Analysis of fertilisers regulation framework in Argentina and Chile (participating CELAC countries).

Besides, this deliverable is completed by the comparison of the currently on-going fertilisers regulation (Regulation 2003/2003) with the new regulatory framework entering into force in July 2022 (Regulation 2019/1009). Moreover, an assessment of the 19 BBFs produced in FERTIMANURE and their feasibility according the new FPR and the Member States regulations has been performed.

This deliver establishes the framework and the basis for FERTIMANURE project to work towards providing clear evidence-based information regarding the quality and performance of the different end-products obtained to assure their market uptake.

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List of Abbreviations

ABP	Animal by-products
BBF	Bio-based Fertiliser
CE	Conformité Européenne
CMCs	Component material category(ies)
DG	Directorate-General
DüG	Düngegesetz
DüMG	Düngemittelgesetz
DüV	Düngeverordnung
EBIC	European Biostimulants Industry Council
EC	European Commission
EoW	End-of-waste
EU	European Union
FPR	Fertilisers Products Regulation
N	Nitrogen
NVZ	Nitrate Vulnerable zone
P	Phosphorus
TMF	Tailor-made Fertiliser

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1. Introduction

As populations increase and climate change become more apparent, it is essential to promote sustainable agriculture worldwide to reduce greenhouse gas emissions efficiently. Hence, there is a need for more sustainable nutrient management, which will be essential to food security and improving water quality globally. This has become increasingly more important in European Union (EU) policies.

Nitrogen (N) and phosphorus (P) losses to inland and coastal waters cause eutrophication, leading to hypoxic conditions in aquatic ecosystems. In the EU, legislation has been put to reduce nutrient losses from urban and rural areas to achieve all water bodies' “good ecological status”, as stated in the Water Framework Directive and Nitrate Directive. Further reduction in the nutrient load will require more focus on nutrient losses from agricultural areas. Part of those losses is related to the sub-optimal use of organic waste, particularly manure. As animal husbandry farms have become more prominent, the manure is more concentrated in the landscape, which has often led to nutrient overapplication on fields close to where manure is produced and stored. This fact increases the risk for more significant losses of both N and P to water bodies from those areas, and estimating nutrient budgets at various scales is considered an essential component of efforts to reduce those losses.

Additionally, even though N, P, potassium (K), secondary nutrients and micronutrients are essential inputs to ensure high yields in agriculture, many farms are dependent on nutrient sources that are not renewable. This includes synthetic N fertilisers produced using fossil fuels to fix atmospheric N into crop available N13 and P fertilisers produced from geopolitically concentrated phosphate rock deposits. However, the need for agricultural specialisation, urbanisation and synthetic fertilisers' availability has contributed to less efficient recycling and a heavy dependency on synthetic fertilisers.

In this framework, fertilisers are among products in respect of which strict rules may be necessary due to legitimate concerns about health, environment, and quality. Finding ways to utilize nutrient-rich organic waste better will be an essential part of sustainable nutrient management in the EU.

Regulation (EC) No. 2003/2003 has harmonised the EU mineral fertilisers market. However, the European Commission envisages a replacement of the currently valid Regulation (EC) No. 2003/2003, expanding its scope to secondary raw material based, i.e. recovered and bio-based fertilising products. In this way, the previously applicable Regulation (EC) No. 2003/2003 will be repealed with effect from 16 July 2022 and replaced by the new Regulation (EU) No. 2019/1009.

The (EC) 2019/1009 regulation will change the way manufacturers, importers, and distributors achieve Conformité Européenne (CE) certification and their products' labelling requirements. The new regulation will increase the market within the EU by enabling products such as bio-stimulants, organic fertilisers, and organo-mineral fertilisers to be bought and sold if they meet the environmental and safety standards.

This report aims to analyse the European/national legislative framework concerning to FERTIMANURE project. FERTIMANURE focuses on developing production methods and the scaling-up of biobased fertilisers (BBFs) derived from livestock manure. Therefore, this analysis is essential to understand the relating legislative framework which will guide how products are produced and marketed.

In this way, the report describes main European directives impacting the project, being Nitrate Directive, ABP regulation and fertiliser regulation. An analysis of the new Regulation No. 2019/1009 and its main differences from Regulation (EC) No. 2003/2003 is performed. Organic

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farming regulation framework is also analysed. Besides, a legislative analysis at FERTIMANURE's regions level, as well as in Argentina and Chile is addressed.

2. Methodologies and Organisation

The scope of the study is focused on evaluating the regulation framework which mainly impacts Fertimanure's results. Particular attention was paid to fertilisers regulations. In this way, the analysis was framed covering the following aspects:

a) European regulatory framework: Analysis of main regulation impacting on Fertimanure's results including Organic farming regulations. Fertilisers Regulation is analysed in more detail due to its importance within the project. Main difference between old and new fertilisers regulations are addressed.

b) National regulations: analysis of national regulations at Fertimanure's countries level. Partners from 5 Member States have contributed to this task by providing legislation information on the Member States selected as case studies (France, Spain, Belgium, Germany, and the Netherlands).

c) Analysis of CELAC Countries regulations: Analysis of fertilisers regulation framework in Argentina and Chile.

d) Analysis of the 19 BBF's of FERTIMANURE in relation to the fertiliser's regulation as well as a matrix of the feasibility of the 19 BBF's in each of the covered countries

In this sense, a comparative and policy research method was used for this deliverable. The former allowed the identification of the differences between legislative frameworks and the latter to identify the implication on FERTIMANURE.

Data collection was completed using EU legislative documents and local legislative and regulatory documentation. This information was analysed through the lens of FERTIMANURE to draw conclusions and implications for the project. Literature analysis provided the foundation to form policy recommendations.

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PART A: European regulatory framework

Legislation of the European Union consists of policies, regulations and directives which govern fertilizers marketing and nutrient use.

The European Union (EU) regulations regarding nutrients provide guidance and legislation over a broad spectrum, including marketable nutrients and their use in crop and livestock farming, animal manure and organic waste treatment, water and air pollution, the treatment of food waste, wastewater treatment plants and end-of-waste as well as secondary raw materials (The RISE Foundation, 2016). Table 1 summarises the EU legislation and guidance related to fertilisers and use of manure.

Table 1. Main EU Regulation impacting to nutrient flows and management in the EU

Category	EU legislation
General strategies	➢ Bioeconomy strategies ➢ Circular economy strategy
Fertilizers manufacture and trade	➢ CRM-Critical raw material list ➢ Fertilisers regulation: Regulation EC 2019/1009 derogating Regulation EC 2003/2003 ➢ Registration, Evaluation, Authorisation and Restriction of chemicals (REACH) EC 1907/2006
Animal manure and organic wastes	➢ Regulation (EI) 1069/2009 (Animal by - products regulation) ➢ Waste framework directive (91/689/EEC)
Nutrient use and management in crop and livestock production	➢ Nitrate Directive (91/676/ECC) ➢ Sludge Directive 86/278/ECC ➢ Water framework Directive (200/60/EC)
Food safety	➢ General Food Law Regulation EC (178/2002)

As follows, European policies and regulation impacting FERTIMANURE project scope are described:

The Bioeconomy Strategy

The Bioeconomy strategy[1] was launched and adopted the 13th of February of 2012, and it addresses the production of renewable biological resources and their conversion into vital products and bio-energy. The strategy aims to focus Europe's common efforts in response to increasing populations, depletion of natural resources, impacts of increasing environmental pressures and climate change. Its main purpose is to streamline existing policy approaches in this area. It is structured around three pillars: i) investments in research, innovation and skills, ii) reinforced policy interaction and stakeholder engagement, iii) enhancement of markets and competitiveness. The Bioeconomy Strategy manifests itself in dedicated research and innovation strategies and topics, including research projects which may come out of the nutrient recovery and recycling activities.

[1] A sustainable bioeconomy for Europe: Strengthening the connection between economy, society and the environment: updated bioeconomy . strategyfile:///C:/Users/cfabregat/Downloads/KI0418806ENN.en.pdf

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Circular Economy Package

Circular Economy Package[2] has been adopted in December 2015 to help European businesses and consumers to engage in a transition to a stronger and more circular economy where resources are used in a more sustainable way. The proposed actions contribute to "closing the loop" of product lifecycles through greater recycling and re-use and bring benefits for both the environment and the economy. The plans aim at extracting the maximum value and use from all raw materials, products and waste, fostering energy savings and reducing greenhouse gas emissions.

3. European regulation

3.1 Overview

More sustainable nutrient management is essential to food security to improve water quality globally and the sustainable use of nutrient resources. This dual importance has come to the forefront of European Union (EU) policies. First, nitrogen (N) and phosphorus (P) losses to inland and coastal waters cause eutrophication, leading to hypoxic conditions in aquatic ecosystems. In the EU, legislation has been created to reduce nutrient losses from urban and rural areas to achieve all water bodies' "good ecological status". **The Nitrates Directive (91/676/EEC)[3]** aims to protect water quality from pollution caused by agricultural sources and to promote the use of good farming practices.

Historically, animal (manure) and human excreta recycling to supply crops with nutrients was an ordinary and necessary agricultural practice. However, the need for agricultural specialisation, urbanisation and synthetic fertilisers' availability has contributed to less efficient recycling and a heavy dependency on synthetic fertilisers. Finding ways to better utilize nutrient-rich organic waste (manure) will be an essential part for a sustainable nutrient management in the EU. The Animal By-product (ABP) **regulation (EC) No 1069/2009[4]** lays down health rules regarding these animal by-products and derived products not intended for human consumption.

In EU regulation, products used to improve plant growth are referred to as "fertilising products". Nitrogen, phosphorous and potassium are the most common fertilisers used to improve plant growth. As the world population continues to rise, the use of fertilisers has also risen due to the higher crop yields they facilitate. However, there have also been concerns regarding the security of the supply and their impact on the environment. In 2003, Regulation (EC) No 2003/2003[5] came into force and aimed to ensure an internal market for free trade of fertilisers. This regulation did harmonise the EU market for fertilisers and liming materials; however, the main focus was on mineral fertilisers and lacked regulation on any new types of fertilisers.

[2] A new Circular Economy Action Plan COM(2020) 98 final.
https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1583933814386&uri=COM:2020:98:FIN
[3] Council Directive 91/676/EEC of 12 December 1991 concerning the protection of waters against pollution caused by nitrates from agricultural sources.
https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:31991L0676&from=EN
[4] REGULATION (EC) No 1069/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009
https://eur-lex.europa.eu/eli/reg/2009/1069/2019-12-14
[5] Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers
https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32003R2003

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The new facultative Fertilising Products Regulation (FPR) **Regulation EU 2019/1009**[6] was published in the EU Official Journal in June 2019 and will come into force on 17th July 2022. Moreover, Nitrate Directive, ABP Regulation and particularly Fertilizers Regulation are the main regulations impacting to project and are described in more detail, as follows.

3.2 Summary of Nitrate Directive 91/676/EEC

To reduce the nitrogen pressure from agriculture to groundwaters and surface waters, the Nitrates Directive, was adopted in 1991 by the European Commission. The aim of this directive is to sustainably protect ground and surface waters from pollution with nitrogen (nitrate) originated in agricultural fertilising practices.

The Directives require Member States to identify Nitrate Vulnerable Zones-NVZ (article 3) and must adopt action Programmes (Nitrate Action Programmes -NAP) related to vulnerable zones that include the monitoring of specific species that farmers must implement (article 5).

NVZ are regions with nitrate concentrations in the groundwater over 50 mg/L. In general, these NVZs are regions with high animal densities (large organic and mineral N inputs) or intensive arable crop production (large inputs through mineral N). Specific action programmes have to be implemented in these NVZs to reduce N pressures and thus nitrate concentrations in water bodies. An important element in the directive is the reporting every 4 years on the monitoring of ground- and surface-water quality. For the purpose of designating and revising the designation of vulnerable zones, Member States shall monitor the nitrate concentration in freshwaters (article 3)

An action programme may relate to all vulnerable zones in the territory of a Member State or, where the Member State considers it appropriate, different programmes may be established for different vulnerable zones or parts of zones. Action programmes shall consider an (a) available scientific and technical data, mainly with reference to respective nitrogen contributions originating from agricultural and other sources; as well as (b) environmental conditions in the relevant regions of the Member State concerned.

Action programmes shall be implemented within four years of their establishment and shall consist of (a) the measures indicated in the Annex III of the directive or of (b) those measures which Member States have prescribed in the code(s) of good agricultural practice established in accordance with Article 4, except those which have been superseded by the measures in Annex III.

In this way, Action programme measures are required to promote best practice in the use and storage of fertiliser and manure by 4 key measures:

- **a)** Limiting inorganic N fertiliser application to crop requirements:
- **b)** Limiting organic manure applications.
- **c)** Seasonal restrictions on the application of slurry, manure sand sludge on sandy and shallow soils.
- **d)** Maintenance of farm records that encompass cropping, livestock numbers and fertiliser management.

In this way, action programmes have to include a set of measures laid down in the Directive, relating to, for example, periods when fertilisation is prohibited, minimum storage capacity for livestock manure, and rules to control the spread of nutrients near water or on slopes, to reduce

[6] REGULATION (EU) 2019/1009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 June 2019. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32019R1009

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the risk of contamination. In particular, limitation of the land application of fertilizers, consistent with good agricultural practice, considers the characteristics of the vulnerable zone concerned including, (a) soil conditions (soil type and slope); (b) climatic conditions, rainfall and irrigation; and (c) land use and agricultural practices[7].

In addition, these measures will ensure that, for each farm or livestock unit, the amount of organic nitrogen applied to the land each year, including by the animals' excreta themselves, shall not exceed a specified amount per hectare. The specified amount per hectare is 170 kg N. However, Member States may allow amounts up to 210 kg N for the first four-year action programme and they may fix different amounts from those referred to above during and after the first four-year action programme.

3.3 Summary Regulation (EC) No 1069/2009

Regulation (EC) 1069/2009 and Commission Regulation (EU) 142/2011[8] are the framework within all handling, collecting, processing and trading of animal by-products take place. The main principles are safe sourcing, safe treatment and safe end uses. This is achieved by traceability and risk-based measures to process and use the raw material and the products. Together, they provide: • the definition of ABP • categories for ABP, (categories 1, 2 and 3) • permitted options for disposal or future use of ABP • the staining of ABP • the storage and labelling of ABP • the restriction of the movement of ABP which requires staining • the service of legal notices for the disposal of ABP or for cleaning and disinfection of vehicles, containers or establishments

By definition: 'animal by-product' means entire bodies or parts of animals, products of animal origin or other products obtained from animals, which are not intended for human consumption (Article 3). The legislation will divide all ABP into 3 different categories, depending on their potential risk (article 8,9 and 10):

- **Category 1 material** is defined in Article 8 Regulation (EC) 1069/2009.as the category showing the highest risk, and consists principally of material that is considered a TSE risk, such as Specified Risk Material (SRM) - those parts of an animal considered most likely to harbour a disease such as BSE, for example bovine spinal cord. Pet animals, zoo and circus animals and experimental animals are also classified as category 1 material due to the level of veterinary drugs and residues they may contain. Wild animals may also be classified as category 1 material when they are suspected of carrying a disease communicable to humans or animals. Catering waste from means of international transport (catering waste which has come from outside the EU) is also category 1.
- **Category 2 material** is defined in Article 9 of Regulation (EC) 1069/2009 as the category showing high-medium risk. it includes fallen stock, manure and digestive tract content. Category 2 is also the default status of any animal by-product not defined in Regulation (EC) 1069/2009 as either category 1 or category 3 material.

[7] The limitation has to be based on a balance between the foreseeable nitrogen requirements of the crops as well as the nitrogen supply to the crops from the soil and from fertilization , corresponding to the amount of nitrogen present in the soil at the moment when the crop starts to use it to a significant degree (outstanding amounts at the end of winter), the supply of nitrogen through the net mineralization of the reserves of organic nitrogen in the soil, - additions of nitrogen compounds from livestock manure, and the additions of nitrogen compounds from chemical and other fertilizers

[8] COMMISSION REGULATION (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2011.054.01.0001.01.ENG

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- **Category 3 material** is defined in Article 10 of Regulation (EC) 1069/2009 and it is considered as low risk material. It includes parts of animals selected as adequate for human consumption in a slaughterhouse, but which are not intended for consumption. Category 3 also includes products of animal origin, or foodstuffs containing products of animal origin which are no longer intended for human consumption for commercial reasons or due to manufacturing or packaging defects or other defects that do not pose a risk to public or animal health.

The category will determine which options are available to use or dispose the animal by-products. The routes available for this disposal and use are listed in articles 12, 13 and 14 of Regulation (EC) 1069/2009. The detailed rules on use and disposal are found in the implementing Regulation (EU) 142/2011. Table 2 shows the permitted uses/disposal routes for each category.

Table 2. Permitted uses/disposal routes for each category of animal by-products according to ABP regulation

Disposal/use route	Category 1	Category 2	Category 3
Disposed of as a waste for incineration	✓	✓	✓
Co-incineration and pressure sterilisation to the required standard followed by disposal in an approved landfill	✓	✓	✓
Burial	✓ in an approved landfill	✓ following pressure sterilisation	Not considered
Used as fuel for combustion	✓	✓	✓
Used in the manufacture of derived products	✓	✓	✓
land spread following a risk assessment by the competent authority	*x*	✓ Manure, digestive tract, milk and milk products	✓ Raw milk and colostrum
Landfill disposal following processing	*x*	*x*	✓
Processed as animal or pet food, fertilizer or land improver	*x*	*x*	✓
Production of biogas	*x*	*x*	✓

All stages of the ABP chain must be registered or approved by the competent authorities and specific processing methods are laid down in order to guarantee safe usage or destruction. Producers of ABPs and derived products must comply with the legislation from the manufacturing

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chain's start to end. This affects BBFs and TMFs to be used as fertilisers as they have to reach the last stage to have the CE mark. Derived products that comply with other pieces of EU legislation can be sold when they reach the manufacturing chain.

3.4 Summary of Regulation (EC) No 2019/1009

On June 5th 2019, the European Parliament and the Council of the European Union approved the new regulation for EU Fertilising Products (Regulation (EU) 2019/1009). The Regulation (EC) No 2003/2003 will be withdrawn on July 16, 2022 (European Parliament, Council of the European Union, 2019). The new Regulation of fertilising products replacing the Regulation (EC) 2003/2003 has been conceived as the first deliverable of the Circular Economy Package. By its holistic approach, including virgin and recycled materials from mineral and organic resources and by its "built-in" end-of-waste 18 status for compliant products, it fully reflects the circular thinking.

This will significantly change the way manufacturers, importers, and distributors can reach Conformité Européenne (CE) for free trade of fertilising products certification and the requirements regarding labelling of the products. The Regulation (EU 2003/2003 does not cover 'national fertilisers' being fertilising products that Member States market by their national legislation. The new regulation includes the opening of the single market for bio-based fertilisers and tailormade fertilising products. This will reduce barriers in place and encourage the production of new and innovative fertiliser products from organic materials and inorganic secondary raw materials. The new regulation will also have strict guidelines on the labelling requirements of all EU fertiliser products to encourage harmonisation among products being traded within the EU (European Parliament, Council of the European Union, 2019).

The diagram below from Fertilisers Europe shows how the regulations differ for inorganic fertilising products.

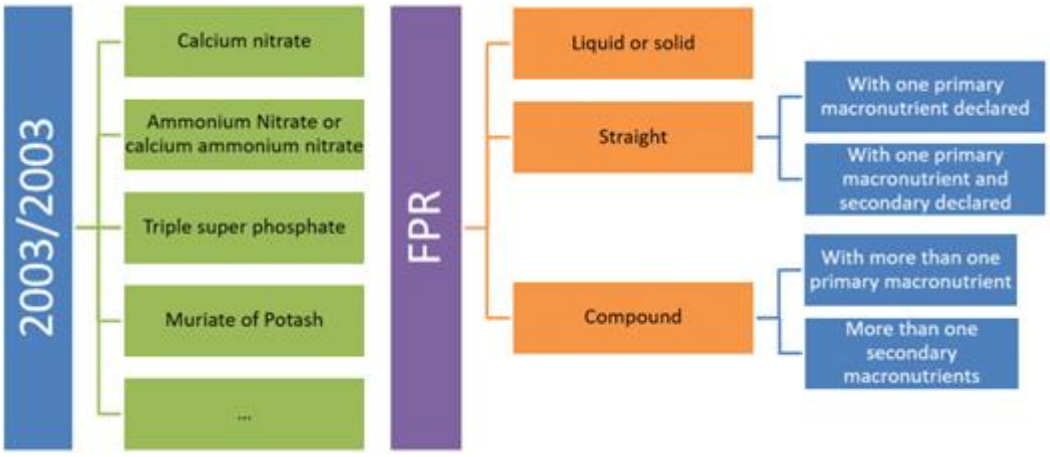

Figure 1. EU Fertilizing Product Regulation Source: Fertilisers Europe, 2019

For the first time, the harmonised product categories include not only mineral/inorganic fertilisers but also organic and, in particular, recycled products used for fertilisation, so that their CE marking is possible. The advantage, is the associated presumption of conformity and thus free marketability throughout the EU. The new EU Fertiliser Regulation does not apply to animal by-products and plant protection products, because harmonised special rules already exist for these products (EC Regulations No 1069/2009 and No 1107/2009). As follows, main aspects of this new Fertilisers Regulation are summarized:

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3.4.1 Scope

The new Fertiliser Regulation (FPR), Regulation (EU) 1009/2019 replaces (EC) No 2003/2003 by July 17, 2022. This regulation will apply directly to all Member States. The replacement of the current regulation (Regulation (EC) No 2003/2003) is seen by the European Commission as an expansion of its scope to cover secondary raw material-based products, i.e., recovered and bio-based fertilising (BBF) products.

MAIN ASPECTS OF NEW REGULATION (EU) 2019/1009

• It opens the single market for fertilising products which are not currently covered by harmonisation rules, such as organic* and organo-mineral* fertilisers, soil improvers*, inhibitors*, plant biostimulants, growing media or blends.
• It lays down common rules on safety, quality and labelling requirements for fertilising products.
• It introduces limits for toxic contaminants for the first time. This will guarantee a high level of soil protection and reduce health and environmental risks while allowing producers to adapt their manufacturing process to comply with the new limits.
• It maintains optional harmonisation, as it does not prevent non-harmonised fertilising products from being made available on the internal market in accordance with national law and the general free-movement rules.

Regulation (EU) 2019/1009 defines seven Product Function Categories (PFCs): Fertilizers, liming materials, soil improvers, growing media, inhibitors and plant biostimulants as well as blends of those PFCs.

1. **PCF 1: Fertilisers:** A fertiliser shall be an EU fertilising product the function of which is to provide nutrients to plants or mushrooms. Fertilizers are classified into Organic fertiliser, Organo mineral fertiliser and Inorganic fertiliser (see Table 3)

2. **PCF 2: Liming material:** A liming material shall be an EU fertilising product the function of which is to correct soil acidity.

3. **PCF 3 Soil improver:** An organic soil improver shall consist of material 95 % of which is of solely biological origin. An organic soil improver may contain peat, leonardite and lignite, but no other material which is fossilized or embedded in geological formations. Soil improvers are classified into organic soil improver and inorganic (see Table 3)

4. **PCF 4 Growing medium:** A growing medium shall be an EU fertilising product other than soil in situ, the function of which is for plants or mushrooms to grow in.

5. **PCF 5 Inhibitor:** An inhibitor shall be an EU fertilising product the function of which is to improve the nutrient release patterns of a product providing plants with nutrients by delaying or stopping the activity of specific groups of micro-organisms or enzymes. Inhibitors are classified into nitrification inhibitor, denitrification inhibitor and urease inhibitor.

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6. **PCF 6 Plant bioestimulants:** A plant biostimulant shall be an EU fertilising product the function of which is to stimulate plant nutrition processes independently of the product's nutrient content with the sole aim of improving one or more of the following characteristics of the plant or the plant rhizosphere: nutrient use efficiency, tolerance to abiotic stress, quality traits or confined nutrients in the soil or rhizosphere. Plant biostimulants are classified into microbial plant biostimulants and non-microbial plant biostimulants (see Table 3)

7. **PCF 7 Fertilizing product blend** A fertilising product blend shall be an EU fertilising product composed of two or more EU fertilising products of PFC 1 to PFC 6 for which the compliance with the requirements of this Regulation of each component EU fertilising product in the blend has been demonstrated in accordance with the conformity assessment procedure applicable to that component EU fertilising product.

In addition, component material categories (CMC) are introduced, whose specific requirements must be met when EU fertilising products are placed on the market (Article 4(1) b) of the new EU Fertiliser Regulation). In accordance with Annex II to the Regulation, an EU fertilising product shall consist solely of component materials complying with the requirements of the CMCs listed in this Annex. The new regulation does not apply to animal by-products or derived products which are subject to the requirements of Regulation (EC) No 1069/2009 when made available on the market, neither plant protection products covered by the scope of Regulation (EC) No 1107/2009 (see summary).

The rules apply to the design, manufacture and placing on the market of EU fertilising products. The regulation does not apply to the use or the mode of application of the EU fertilising products.

The FPR will exist in parallel to national legislation and mutual recognition as it is only creating an optional harmonization. In this way, the new regulation (FPR) will not replace any national legislation already in place, although the Member States may alter their current national legislation due to the new Fertilising Product Regulation. The new EU regulation is facultative: the manufacturer chooses which regulation will be followed: EC/2019/1009 or national regulations for quality of fertilising products. A CE marked fertilising product has free trade within each EU Member State. The purpose of the new regulation is to create increased harmonisation on free trade of fertilising products between the Member States, and so it will be the manufacturer's decision whether or not the product requires the CE mark. Without the CE mark, a product will not be permitted on the EU internal market; however, this will not impact their ability to trade on the national market or other European markets based on mutual recognition for fertilisers with regular production. In order to allow companies to be ready for the implementation of the FRP, there is a three-year delay between publishing and implementing the regulation.

3.4.2 Product requirements

The new regulation states that to comply, an EU fertilising product must meet several requirements set out in Annex I, II and III of the regulation. The requirements in Annex I include details on the claimed function of the product and the mode of action. Requirements are set by each product category (PCF).

In cases where the product contains a substance for which there are maximum values regulated, the product must comply with additional regulations such as Council Regulation (EEC) No 315/93.

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Annex II covers component material category(ies) and states that “an EU fertilising product shall consist solely of component materials complying with the requirements for one or more of the component material category(ies) (CMCs) listed in this Annex”. These CMCs include but are not limited to virgin material substances and mixtures, fresh crop digestate, polymers (nutrient and other), and by-products within the meaning of Directive 2008/98/EC. Many details are laid out in Annex III of the regulation that sets out the product's requirements for labelling. These requirements cover the product's claimed function, the product's mass or volume, instructions for the intended use (application rates, timing, and frequency), and storage recommendations. Any relevant information regarding managing risk to human, animal or plant health is also required on the labelling. The regulation also states that the product's labelling shall not claim that it is ‘sustainable’ or ‘environmentally friendly’ unless the product complies with legislation or standards that permit it to do so. The Commission aims to publish a document guiding manufacturers and market surveillance authorities regarding label requirements. The document will also include clear information and examples regarding the visual appearance of the requirements. This will be published by 16 July 2020 (European Parliament, Council of the European Union. 2019).

Any aspects of EU fertilisers that are not covered in Annex I or II must not present a risk to human, animal or plant health or the environment's safety.

In the following tables (table 1 to 4), PCF categories and subcategories as well as main related requirement according to Annex I and II of the regulation are indicated.

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Table 3. Fertilizer category and subcategories. Main product requirements according to annex I and II of Regulation EU 2019/1009

PCF Category and subcategories	Requirements
PCF 1. Fertiliser: A fertiliser shall be an EU fertilising product the function of which is to provide nutrients to plants or mushrooms.	
A. Organic fertiliser: An organic fertiliser shall contain organic carnon and nutrients of solely biological origin	Contaminants limits values: Cd:1,5mg/kg dry matter, CrVI: 2 mg/Kg dry matter, Hg:1m/g dry matter, Ni:50 mg/Kg dry matter, Pb:120 mg/kg dry matter As 40 mg/kg dry matter. Pathogens: Salmonella sp: limit:absence in 25g o 25 ml *Escherichia coli or Enterococcaceae:* limit 1000UFC/g or mL
Solid organic fertiliser: A solid organic fertiliser shall be in solid form, and it shall contain at least one of the following declared primary nutrients: nitrogen (N), phosphorus pentoxide (P2O5) or potassium oxide (K2O).	A solid organic fertiliser shall be in solid form. A solid organic fertiliser shall contain at least one of the following declared primary nutrients: nitrogen (N), phosphorus pentoxide (P2O5) or potassium oxide (K2O). Requierement of nutrient content is indicated in the annex II of the regulation
Liquid organic fertiliser: A liquid organic fertiliser shall be in liquid form, and it shall contain at least one of the following declared primary nutrients: nitrogen (N), phosphorus pentoxide (P2O5) or potassium oxide (K2O).	A liquid organic fertiliser shall be in liquid form. A liquid organic fertiliser shall contain at least one of the following declared primary nutrients: nitrogen (N), phosphorus pentoxide (P2O5) or potassium oxide (K2O). Requierement of nutrient content is indicated in the annex II of the regulation
B. Organo-mineral fertiliser: An organo-mineral fertiliser shall be a co-formulation of one or more inorganic fertilisers, as specified in PFC 1(C), and one or more materials containing: organic carbon and nutrient of solely biological origin.	An organo-mineral fertiliser shall be a co-formulation of: (a) one or more inorganic fertilisers, as specified in PFC 1(C), and (b) one or more materials containing: organic carbon (Corg); and nutrients of solely biological origin. An organo-mineral fertiliser may contain peat, leonardite and lignite, but no other material which is fossilized or embedded in geological formations. Where one or more of the inorganic fertilisers in the co-formulation is a straight or compound solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content, an organo-mineral fertiliser shall not contain 16 % or more by mass of nitrogen (N) as a result of ammonium nitrate (NH_4NO_3). Contaminants in an organo-mineral fertiliser must not exceed the limits indicated in the annex II. Pathogens limits: Salmonella sp:absence in 25g o 25 ml *Escherichia coli* or Enterococcaceae: 1000UFC/g or mL
Solid organo-mineral fertiliser: A solid organo-mineral fertiliser shall be in solid form and it shall contain at least one of the following declared primary nutrients: nitrogen (N), phosphorus pentoxide (P_2O_5) or potassium oxide (K_2O).	A solid organo-mineral fertiliser shall be in solid form. A solid organo-mineral fertiliser shall contain at least one of the following declared primary nutrients: nitrogen (N), phosphorus pentoxide (P2O5) or potassium oxide (K_2O). Requirement of nutrient content is indicated in the annex II of the regulation.

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Liquid organo-mineral fertiliser: A liquid organo-mineral fertiliser shall be in liquid form and it shall contain at least one of the following declared primary nutrients: nitrogen (N), phosphorus pentoxide (P_2O_5) or potassium oxide (K_2O).	A liquid organo-mineral fertiliser shall be in liquid form. A liquid organo-mineral fertiliser shall contain at least one of the following declared primary nutrients: nitrogen (N), phosphorus pentoxide (P2O5) or potassium oxide (K_2O). Requirement of nutrient content is indicated in the annex II of the regulation.
C. Inorganic fertiliser: An inorganic fertiliser shall be a fertiliser containing or releasing nutrients in a mineral form, other than an organic or organo-mineral fertiliser.	An inorganic fertiliser contains more than 1 % by mass of organic carbon (Corg), other than organic carbon (Corg) from: chelating or complexing agents referred to in point 3 of component material category (CMC) 1 in Part II of Annex II, nitrification inhibitors, denitrification inhibitors or urease inhibitors referred to in point 4 of CMC 1 in Part II of Annex II, coating agents referred to in point 1(a) of CMC 9 in Part II of Annex II, urea (CH_4N_2O), or calcium cyanamide (CaCN2). Pathogens: *Salmonella* sp: limit:absence in 25g o 25 ml *Escherichia coli* or Enterococcaceae: limit 1000UFC/g or mL
Inorganic macronutrient fertiliser: An inorganic macronutrient fertiliser shall be aimed at providing plants or mushrooms with one or more of the following macronutrients: primary macronutrients: nitrogen (N), phosphorus (P) or potassium (K), and secondary macronutrients: calcium (Ca), magnesium (Mg), sodium (Na) or sulphur (S).	An inorganic macronutrient fertiliser shall be aimed at providing plants or mushrooms with one or more of the following macronutrients: (a) primary macronutrients: nitrogen (N), phosphorus (P) or potassium (K), (b) secondary macronutrients: calcium (Ca), magnesium (Mg), sodium (Na) or sulphur (S). Contaminants in an inorganic macronutrient fertiliser must not exceed the limits indicated in the Annex II
Solid inorganic macronutrient fertiliser	A straight or compound solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content shall be ammonium nitrate (NH4NO3)-based and contain 28 % or more by mass of nitrogen (N) as a result of ammonium nitrate (NH4NO3). Any matter other than ammonium nitrate (NH4NO3) shall be inert towards ammonium nitrate (NH4NO3). A straight or compound solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content shall be made available to the end-user only in packaged form.
Liquid inorganic macronutrient fertiliser	Organic macronutrient fertiliser shall be in liquid form.
Inorganic micronutrient fertiliser: An inorganic micronutrient fertiliser shall be an inorganic fertiliser other than an inorganic macronutrient fertiliser aimed at providing plants or mushrooms with one or more of the following micronutrients: boron (B), cobalt (Co), copper (Cu), iron (Fe), manganese (Mn), molybdenum (Mo) or zinc (Zn).	Inorganic micronutrient fertilisers shall be made available to the end-user only in packaged form. Contaminants in an inorganic micronutrient fertiliser must not exceed the following limit values: As 100mg/Kg, Cd 200 mg/Kg, Pb 600mg/kg, Hg 100 mg/Kg, Ni 2000 mg/Kg. (Limit values of contaminants expressed in mg, in relation to the total micronutrient content expressed in kg (mg/kg of total micronutrient content, which means boron (B), cobalt (Co), copper (Cu), iron (Fe), manganese (Mn), molybdenum (Mo) and zinc (Zn))

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Table 4. Liming material, soil improver and growing medium category and subcategories. Main product requirements according to annex I and II of Regulation EU 2019/1009

PCF Category and subcategories		Requirements
PFC 2. Liming material: A liming material shall be an EU fertilising product the function of which is to correct soil acidity		
A liming material shall contain oxides, hydroxides, carbonates or silicates of the nutrients calcium (Ca) or magnesium (Mg). Contaminants in a liming material must not exceed the limits indicated in the Annex II of the regulation		
PCF 3. Soil improver: An organic soil improver shall consist of material 95 % of which is of solely biological origin. An organic soil improver may contain peat, leonardite and lignite, but no other material which is fossilized or embedded in geological formations		
	A. Organic soil improver: An organic soil improver shall consist of material 95 % of which is of solely biological origin. An organic soil improver may contain peat, leonardite and lignite, but no other material which is fossilized or embedded in geological formations.	Contaminants in organic soil improver must not exceed the following limit values: Cd:2mg/kg dry matter, CrVI: 2 mg/Kg dry matter, Hg:1m/g dry matter, Ni:90 mg/Kg dry matter, Pb:120 mg/kg dry matter As 40 mg/kg dry matter. The copper (Cu) content must not exceed 300 mg/kg dry matter, and the zinc (Zn) content must not exceed 800 mg/kg dry matter. Pathogens limits: Salmonella sp: absence in 25g o 25 ml, *E. Coli* or Enterococcaceae: 1000UFC/g or mL. An organic soil improver shall contain 20 % or more dry matter. Organic carbon (Corg) content in an organic soil improver shall be at least 7,5 % by mass.
	B. Inorganic soil improver: An inorganic soil improver shall be a soil improver other than an organic soil improver.	Contaminants in inorganic soil improver must not exceed the following limit values: Cd:1.5mg/kg dry matter, CrVI: 2 mg/Kg dry matter, Hg:1m/g dry matter, Ni:100 mg/Kg dry matter, Pb:120 mg/kg dry matter As 40 mg/kg dry matter. The copper (Cu) content must not exceed 300 mg/kg dry matter, and the zinc (Zn) content in must not exceed 800 mg/kg dry matte
PCF 4. Growing medium. A growing medium shall be an EU fertilising product other than soil in situ, the function of which is for plants or mushrooms to grow in. Plants includes algae		Contaminants in growing medium must not exceed the limits indicated in the Annex II of the Regulation Pathogens limits: Salmonella sp: absence in 25g o 25 ml , Escherichia coli or Enterococcaceae: 1000UFC/g or mL

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Table 5. Inhibitor and plant biostimulant category and subcategories. Main product requirements according to annex I and II of Regulation EU 2019/1009

PCF Category and subcategories	Requirements
PCF 5. Inhibitor: An inhibitor shall be an EU fertilising product the function of which is to improve the nutrient release patterns of a product providing plants with nutrients by delaying or stopping the activity of specific groups of micro-organisms or enzymes. Inhibitors are classified into nitrification inhibitor, denitrification inhibitor and urease inhibitor.	
A. Nitrification inhibitor: A nitrification inhibitor shall inhibit the biological oxidation of ammoniacal nitrogen (NH_3-N) to nitrite nitrogen (NO_2^-), thus slowing nitrate nitrogen (NO_3^-) formation.	The ammoniacal nitrogen (NH_3-N) oxidation rate shall be measured by:(a) ammoniacal nitrogen (NH_3-N) disappearance, or (b) the sum of nitrite nitrogen (NO_2^-) and nitrate nitrogen (NO_3^-) production with respect to time. Compared to a control sample where the nitrification inhibitor has not been added, a soil sample containing the nitrification inhibitor shall show a 20 % reduction in ammoniacal nitrogen (NH_3-N) oxidation rate based on an analysis carried out 14 days after application at the 95 % confidence level.
B. Denitrification inhibitor: A denitrification inhibitor shall inhibit the formation of nitrous oxide (N_2O) by slowing down or blocking the conversion of nitrate (NO_3^-) to dinitrogen (N_2) without influencing the nitrification process	Compared to a control sample where the denitrification inhibitor has not been added, an in vitro test containing the denitrification inhibitor shall show a 20 % reduction in rate of the release of nitrous oxide (N_2O) based on an analysis carried out 14 days after application at the 95 % confidence level.
C. Urease inhibitor: A urease inhibitor shall inhibit hydrolytic action on urea (CH_4N_2O) by the urease enzyme, primarily targeted to reduce ammonia volatilisation.	Compared to a control sample where the urease inhibitor has not been added, an in vitro test containing the urease inhibitor shall show a 20 % reduction in the rate of hydrolysis of urea (CH_4N_2O) based on an analysis carried out 14 days after application at the 95 % confidence level
PCF 6. Plant biostimulant: A plant biostimulant shall be an EU fertilising product the function of which is to stimulate plant nutrition processes independently of the product's nutrient content with the sole aim of improving one or more of the following characteristics of the plant or the plant rhizosphere: nutrient use efficiency, tolerance to abiotic stress, quality traits or confined nutrients in the soil or rhizosphere.	Contaminants in a plant biostimulant must not exceed the limits indicated in the Annex II of the Regulation. The plant biostimulant shall have the effects that are claimed on the label for the plants specified thereon.
A. Microbial plant biostimulant: A microbial plant biostimulant shall consist of a micro-organism or a consortium of micro-organisms: *Azotobacte*r spp. Mycorrhizal fungi *Rhizobium* spp. *Azospirillum* spp.	Pathogens in a microbial plant biostimulant must not exceed the following limits: *Salmonella* spp: Absence in 25 g or 25 ml. *Escherichia coli*:Absence in 1 g or 1 ml. *Listeria monocytogenes*:Absence in 25 g or 25 ml. *Vibrio* spp.:Absence in 25 g or 25 ml.*Shigella* spp.:Absence in 25 g or 25 mL. *Staphylococcus aureus:*Absence in 25 g or 25 ml. Enterococcaceae:10 CFU/g.Anaerobic plate count unless the microbial plant biostimulant is an aerobic bacterium:10^5 CFU/g or ml.Yeast and mould count unless the microbial plant biostimulant is a fungus: 1 000 CFU/g or ml
B. Non-microbial plant biostimulant: A non-microbial plant biostimulant shall be a plant biostimulant other than a microbial plant biostimulant.	Pathogens in a non-microbial plant biostimulant must not exceed the following limits: *Salmonella* sp: absence in 25g o 25 mL *Escherichia coli* or Enterococcaceae: 1000UFC/g or mL

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Table 6 Fertilising product blend category. Main product requirements according to annex I and II of Regulation EU 2019/1009

PCF Category and subcategories	Requirements
PCF 7. Fertilising product blend: A fertilising product blend shall be an EU fertilising product composed of two or more EU fertilising products of PFC 1 to PFC 6 for which the compliance with the requirements of this Regulation of each component EU fertilising product in the blend has been demonstrated in accordance with the conformity assessment procedure applicable to that component EU fertilising product	The manufacturer of the blend shall assess the conformity of the blend with the requirements set out in points 1 and 2 of this PFC, ensure the blend's compliance with the labelling requirements laid down in Annex III, and assume responsibility pursuant to Article 16(4) of the Regulation 2019/1009 for the compliance of the blend with the requirements of the Regulation by:(a) drawing up an EU declaration of conformity for the fertilising product blend in accordance with Article 6(2) of the Regulation, and (b)being in possession of the EU declaration of conformity of each of the component EU fertilising products.

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3.4.3 Economic operators' obligations

The new EU Fertiliser Regulation introduces the term "economic operator", which includes manufacturers, authorised representatives, importers and distributors (see Article 2(15) of the new EU Fertiliser Regulation) and defines their responsibilities and obligations in detail (Articles 6-12 of the new EU Fertiliser Regulation).

Manufacturer' means a person who manufactures an EU fertilising product or has an EU fertilising product designed or manufactured and markets that EU fertilising product under his or her name or trademark (Article 2(11) of the new EU Fertiliser Regulation).

In this way, according to article 6, **manufacturers' obligations** of fertilising products require manufacturers to ensure they have been designed and manufactured in a way that meets the requirements mentioned above and set out in Annex I and II of the regulation. It is also the manufacturer's responsibility to provide technical documentation and ensure any relevant assessment procedures are carried out. Only once a conformity assessment procedure has been demonstrated may manufacturers draw up an EU declaration of conformity and affix the CE marking. All technical documentation and the EU declaration of conformity relating to a product must be kept by manufacturers for a minimum of 5 years from when the product is placed on the market. If requested, the manufacturers are granted permission to make copies of the declaration available to other economic operators.

Manufacturers may carry out sample testing of the fertilising products once available on the market to investigate and, if necessary, recall any non-conforming EU fertilising products to ensure all distributors are informed of any such monitoring. In order to ensure this can be done effectively, it is the manufacturer's responsibility to ensure the packaging of the products displays a type number and batch number or method of identification. If the product(s) are supplied out of the packaging, a document must accompany the product detailing all the required information. In order to further increase the traceability of the product, manufacturers are required to include their name, registered trading number or trademark, and a postal address on the packaging of the product.

A manufacturer may, by a written mandate, appoint an **authorised representative**. An authorised representative shall (a) keep the EU declaration of conformity and the technical documentation at the disposal of national market surveillance authorities for 5 years after the EU fertilising product covered by those documents has been placed on the market; (b) to provide, further to a reasoned request from a competent national authority, all the information and documentation necessary to demonstrate the conformity of an EU fertilising product; and (c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by EU fertilising products covered by the authorised representative's mandate.

Importers and **distributors** are other economic operators which are not considered to be manufacturers. 'Importer' means any natural or legal person established within the Union who places an EU fertilising product from a third country on the Union market; 'Distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes an EU fertilising product available on the market. The obligations for importers and distributors are comprehensively regulated in respective Articles 8 and 9 of the new EU Fertiliser Regulation. The central idea is that only compliant EU fertilising products may be placed on the market.

Importers' obligations require the importer to ensure that only compliant EU fertilising products are place on the market. Before placing an EU fertilising products on the market, importers shall ensure that the manufacturer has completed the conformity assessment procedure (according to Article 15) and drawn up the technical documentation required by this legislation to accompany the product. In addition, the importer must indicate their name, registered trade name or

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trademark and postal address on the product's packaging for traceability purposes. The importer's responsibility is to ensure that the product is handled correctly whilst under their care to avoid altering the product's compliance with this regulation. Where an importer considers that an EU fertilising product is not in conformity with this Regulation, the importer shall not place the EU fertilising product on the market until it has been brought into conformity. Furthermore, where the EU fertilising product presents a risk to human, animal or plant health, to safety or to the environment, the importer shall inform the manufacturer and the market surveillance authorities to that effect. In this way, the importers are responsible for taking immediate corrective measures if any products are non-compliant with the regulations. Importers must keep the technical documentation and the EU declaration of conformity for five years after the EU fertilising product covered by those documents has been placed on the market. If requested, the manufacturers are granted permission to make copies of the declaration available to other economic operators.

Distributors' obligations require the distributor to ensure that any EU fertilising product made available on the market has the accompanying documentation. This includes batch numbers, trademarks and technical documentation as detailed in the summary of Articles 6 and 8. This information must be provided in a language that the end-user understands. Distributors also hold a responsibility to withhold a product from the market if they consider or have reason to believe a fertilising product does not conform with the requirements of this regulation. Suppose there is a risk to human, animal, or plant health and/or safety or the environment, the distributor must inform the manufacturer or importer of such risk and notify the market surveillance authorities. If the product has already been made available on the market at the time of concern, the distributor must take corrective measures to bring the product in line with conformity. Should the product need to be withdrawn or recalled, it is the responsibility of the distributor to do so.

Distributors must also ensure storage or transport conditions of the EU fertiliser product do not jeopardise its compliance with the requirements of this regulation. If there is concern or reason to believe a product presents a risk to the health and safety of humans, animals, plants and/or the environment, immediate action must be taken to inform the relevant authorities of the Member States in which the product is available on the market. This includes providing details of any non-compliance and any corrective measures taken or to be taken. If requested to do so, distributors must provide their national authority with all information and documentation necessary to demonstrate the conformity of the fertilising product. The distributor must cooperate with any action taken to eliminate risks presented by the product they have distributed.

However, if these importer/distributors act as manufacturers of a product by marketing it under their own trademark, although they did not manufacture it themselves, or if they make changes to the product which may affect its conformity, these operators (importers/distributors) are also subject to the far-reaching manufacturer obligations (Article 11 of the new EU Fertiliser Regulation).

Economic operators should take these obligations seriously and set up appropriate internal compliance systems to ensure and monitor their observance. Otherwise, not only civil law actions, but also administrative and possibly even criminal sanctions may be imposed. In addition, Packaging and repackaging obligations are set in article 12, These regulations require the importers and distributors to ensure their name, registered name or registered trademark are clearly stated on the packaging and the postal address where the product was packaged or repackaged. The address must be preceded with a statement indicating whether the product has been packaged or repackaged. Importers and distributors, as with manufacturers, must also ensure they keep any technical documentation and EU declaration of conformity relating to a product for a minimum of 5 years from the point at which the product is placed on the market.

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3.4.4 Marketing, CE marking and traceability

Only fertilisers that comply with this regulation may be made available on the EU market (article 5). If they are in conformity with the harmonised safety, quality and labelling requirements regulated in this new regulation, they can be sold freely throughout the EU and may no longer be hindered by product-related national measures and regulations, which is now expressly stipulated (Article 3 of the new Fertiliser Regulation).thus, no Member State may demand additional marking elements for such EU fertilising products based on its national regulations, nor may national regulations result in EU fertilising products having to be changed in their composition. The new EU Fertiliser Regulation thus pursues a model of optional harmonisation, which gives enterprises a certain freedom of choice.

Within this framework, an “EU fertilising product” has to be CE marked when made available on the market (Article 2 (2) of the new EU Fertiliser Regulation). In this way, according to article 17, The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008. The CE marking should be affixed by the manufacturer to the product (on each individual package or on the accompanying document in the case of unpackaged products) if the product complies with the requirements of the Regulation. The CE marking may only be used if the conformity assessment procedure within the meaning of Article 15 in con-junction with Annex IV of the new EU Fertiliser Regulation has been successfully completed.

Products that are allowed to be CE marked may be freely traded in the EU, which is an enormous advantage for enterprises operating throughout the EU.

A new obligation for all economic operators is that they must ensure the traceability of the EU fertilisers they market: they must be able to inform market surveillance authorities from whom they have purchased a specific EU fertilising product and to whom they have supplied it (Article 12 of the new EU fertiliser regulation). The new EU fertiliser regulation introduces in Article 38 a special procedure at national level for handling EU fertilising products which present a risk. In this way, evaluations in line with the requirements of this regulation may be carried out when any market surveillance authorities have sufficient reason to believe any EU fertilising product does pose a risk to the health and/or safety of humans, animals, plants or the environment. Corrective action is required to take place within a reasonable period outlined by the market surveillance authorities depending on the level of risk presented. The corrective action may require the product to be withdrawn or recalled from the market.

If the non-compliance is thought not to be restricted to a national territory, the Commission and the other Member States must be informed of the evaluation results and any required action as a result.

This procedure also includes a coordination mechanism between EU Member States and the Commission for non-compliant EU fertilising products marketed throughout the EU. Besides, in order to increase transparency and to reduce processing time, the new EU fertiliser regulation requires improving the safeguard procedure, with the view to making it more efficient and drawing on the expertise available in Member States (Article 40 of the new EU fertiliser regulation).

3.4.5. End of waste status

The Regulation defines criteria for which material is considered waste, as defined in Directive 2008/98/EC, can cease to be wasted, if contained in a compliant EU fertilising product. It means

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that If an (organic) fertiliser bears the CE marking, it no longer constitutes waste (for the definition of waste see Directive 2008/98/EC). This arises from Article 19 of the new EU fertiliser regulation.

The new EU fertiliser regulation now covers organic fertilisers that are manufactured, among other things, from recycled biodegradable waste from the food industry or from non-animal agricultural by-products. In this sense, the individual components (biodegradable waste) used for the manufacture of the finished product are not yet affected by the end-of-waste status, so they continue to constitute waste. In such cases, the recovery operation under this Regulation shall be performed before the material ceases to be waste, and the material shall be considered to comply with the conditions laid down in Article 6 of that Directive and therefore to have ceased to be waste from the moment that the EU declaration of conformity was drawn up.

3.4.6 Notification of conformity assessment bodies

According to Articles 20-36, the Commission and the other Member States must be notified of anyone that has been authorised to carry out third-party conformity assessment tasks. Subsidiaries or subcontractors may only undertake tasks connected with conformity assessments if the client agrees to it.

The Member States must have a designated party responsible for setting up and executing any procedures necessary when assessing and notifying conformity assessment bodies. The notifying authority must take full responsibility for the tasks performed by the designated body. There must be no conflict of interest within the notifying authority about the conformity assessment bodies. The impartiality and objectivity of the notifying authority must also be safeguarded, and the confidentiality of the information the notifying authority obtains.

A conformity assessment body must be a legal personality and be independent of the organisation or the EU fertilising products it assesses. This means that they are not involved in the design, manufacturing, or distribution of fertilising products to maintain the independence of judgement concerning conformity assessment activities. A conformity assessment body must perform the technical and administrative tasks associated with the conformity assessment activities in a way that is suitable to ensure access to all necessary equipment or facilities.

Member States are obliged to make the Commission aware of any changes made to the notifying authority, making this information publicly available. Any doubts expressed by the Commission or brought to the attention of the Commission regarding the competence of a notified body must be thoroughly investigated. If requested by the Commission, the Member State must provide all information relating to the body concerned. The Commission will notify the relevant Member State of their conclusion, and appropriate action will be taken. It is presumed that if a conformity assessment body demonstrates conformity with the Official Journal of the European Union, then this conformity will reach the requirements set out in Article 24 of chapter IV.

The Commission will assign a single identification number to a notified body even where the body is notified under several Union acts. The list of these bodies will be made publicly available by the Commission, who must be made aware of any changes to ensure the list is kept up to date. Changes that the Commission must be aware of include cases where a notifying authority no longer meets the requirements laid out in Article 24 and/or a failure by the notifying authority to fulfil its obligations. The action taken following these changes depends on the severity of the failure but can result in the notifying authority being restricted, suspended, or withdrawn. The

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Commission and the Member States must be immediately informed. The files of the body that are restricted/suspended/withdrawn must either be processed by an alternative notifying body or kept available for the responsible notifying and market surveillance authorities at their request.

Any unnecessary economic burdens associated with conformity assessments must be avoided. If a notified body finds a manufacturer has not met technical specifications, they can demand the manufacturer in question to take appropriate action prior to a decision of approval being made. If the notifying body discovers an EU fertilising product does not comply, but approval has already been granted, the body holds the right to suspend or withdraw the approval until corrective action is taken.

There must be an appeals procedure for the notified bodies should they object to the decision. Notified bodies must inform the notifying authority if any certificate or approval decision is refused, suspended, or withdrawn. Any circumstances that affect the conditions under which a certificate or approval decision is granted must also be brought to the attention of the notifying authority. The notifying authority must be aware of any information received from market surveillance authorities regarding the conformity assessment activities. When requested, any conformity assessment activities carried out, including cross-border activities and subcontracting, must also be made available to the notifying authority.

The Commission will ensure coordination and cooperation between all bodies notified in this regulation. In the case of group work, all notified bodies must participate directly or through a designated representative.

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3.5 Organic farming

3.5.1. Introduction

The area under organic farming in Europe has increased by almost 66% in the last 10 years - from 8.3 million hectares in 2009 to 13.8 million hectares in 2019. Organic farming currently accounts for 8.5% of the EU's total 'utilised agricultural area'. The maintenance of soil fertility in this production method is paramount: as no manufactured fertilizers are authorised, organic farmers try to work in closed nutriment circuits as much as possible.

Currently, in Europe, there is a broad consensus on the importance and the key role of organic production and consumption. In that sense, on 25th of March 2021, the Commission presented an action plan for the development of organic production. In its Farm to Fork Strategy and the Biodiversity Strategy, the Commission has defined the objective of **'at least 25% of the EU's agricultural land under organic farming and a significant increase in organic aquaculture by 2030'**, and this is why the Commission is putting forward this action plan. The Action Plan for the development of organic production builds up on the action plan for the period 2014-2020, which already addressed some of the problems identified by the review of the EU organic policy that resulted in the adoption of **Regulation (EU) 2018/848** on organic farming.

Organic agriculture is a farming system that sustains the health of soils, plants, animals, ecosystems and people whilst contributing to long-term food security. The maintenance of soil fertility in this production method is paramount: as no manufactured fertilizers are authorised, organic farmers try to work in closed nutriment circuits as much as possible. In that sense, external inputs accepted to be used in organic farming are selected based on a strict set of criteria, with the aim to exclude any inputs that may cause issues related to environmental, human and animal toxicity, or may be in contradiction to the traditions of the sector and/or expectations by organic farmers and consumers.

As a result, only a small number of fertilizing products are allowed to be used in organic production. Specifically, the permitted fertilisers are the ones listed in the Annex I of the **Regulation (EU) 2021/1165**.

Regarding the consideration of organic farming at member state level, The Commission encourages Member States to develop national organic action plans to increase their national share of organic farming. There are significant differences between Member States regarding the share of agricultural land currently under organic farming, ranging from 0.5% to over 25%. The national organic action plans will complement the national CAP strategic plans, by setting out measures that go beyond agriculture and what is offered under the CAP.

The main regulations are explained in the following sections, being focused on those aspects that are relevant in the framework of FERTIMANURE project.

3.5.2 Regulation (EU) 2018/848

On 1st January 2022 the new EU Regulation 2018/848 on organic production and labelling of organic products has entered into force, repealing Council Regulation (EC) No 834/2007. The new regulation was already adopted in 2018 and was initially foreseen to enter into force in January 2021. However, due to the COVID-19 pandemic, the application was delayed for 1 year.

The simpler and more harmonized approach of the new Organic Regulation could allow the sector to grow even faster and offer more protection to consumers. Main changes and additions to this new regulation are related with: 1) New definitions (such as preventive measures, precautionary

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measures or non-compliance); 2) New products (the new regulation has been expanded with new production groups); 3) Labelling (considers specific provisions on the labeling of organic products aiming to protect the interests of both, economic operators and consumers); 4) Organic production logo of the European Union; 5) Obligations and actions in the event of suspicion of non-compliance (the new regulation lays down how an operator and/or control body should act in case of suspicion of non-compliance with the regulations).

The Articles on this regulation that have an effect on FERTIMANURE products are Article 24 and 31. Main aspects to be considered during the project execution are summarized below.

Article 24, *Authorisation of products and substances for use in organic production*

The Commission may authorise certain products and substances for use in organic production, and shall include any such authorised products and substances in restrictive lists, for the following purposes:

(a) as active substances to be used in plant protection products; (b) *as fertilisers, soil conditioners and nutrients*; (c) as non-organic feed material of plant, algal, animal or yeast origin or as feed material of microbial or mineral origin; (d) as feed additives and processing aids; (e) as products for the cleaning and disinfection of ponds, cages, tanks, raceways, buildings or installations used for animal production; (f) as products for the cleaning and disinfection of buildings and installations used for plant production, including for storage on an agricultural holding; (g) as products for cleaning and disinfection in processing and storage facilities

The authorisation of the products and substances referred to in the previous paragraph for use in organic production, and specifically referring to the fertilisers, soil conditioners and nutrients, shall be subject to the principles laid down in Chapter II and to the following criteria, which shall be evaluated as a whole: (a) they are essential for sustained production and for the use for which they are intended; (b) all of the products and substances concerned are of plant, algal, animal, microbial or mineral origin, except in cases where products or substances from such sources are not available in sufficient quantities or qualities or where alternatives are not available; (c) their use is essential for building or maintaining the fertility of the soil or to fulfil specific nutritional requirements of crops, or for specific soil-conditioning purposes.

The Commission is empowered to adopt delegated acts in accordance with Article 54 amending paragraphs 3 and 4 of this Article by adding further criteria for the authorisation of products and substances referred to in paragraphs 1 and 2 of this Article for use in organic production in general, and in the production of processed organic food in particular, as well as further criteria for the withdrawal of such authorisations, or by amending those added criteria.

Where a Member State considers that a product or substance should be added to or withdrawn from the lists of authorised products and substances referred to in paragraphs 1 and 2, or that the specifications of use referred to in the production rules should be amended, it shall ensure that a dossier giving the reasons for the inclusion, withdrawal or other amendments is officially sent to the Commission and to the other Member States and is made publicly available, subject to Union and national legislation on data protection.

Article 31, *Labelling of products and substances used in crop production*

Notwithstanding the scope of this Regulation as set out in Article 2 (1), products and substances used in plant protection products or as fertilisers, soil conditioners or nutrients that have been

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authorised in accordance with Articles 9 and 24 may bear a reference indicating that those products or substances have been authorised for use in organic production in accordance with this Regulation.

3.5.3 Regulation (EU) 2021/1165

Being the Regulation (EU) 2018/848 the main regulatory framework affecting the organic production, for the specific case of FERTIMANURE project, the main regulation to be considered is the Regulation (EU) 2021/116, authorising certain products and substances for use in organic production and establishing their lists.

As stated in *Article 11, the Regulation (EU) 2021/116 is repealing the Regulation (EC) No 889/2008.*

Also, as considered in *Article 13, this Regulation shall apply from 1 January 2022. However, Article 5 (Products for cleaning and disinfection) (1), (2) and (3) and Article 7 (Non-organic agricultural ingredients to be used for the production of processed organic food) shall apply from 1 January 2024.* Neither Article 5 nor Article 7 are affecting FERTIMANURE outputs, so the project shall consider that all the related Articles in this regulation are entering into force since 1 January 2022.

Main sections of this regulation that shall be considered are Article 2 and Annex II, which are detailed below.

Article 2. *Fertilisers, soil conditioners and nutrients*

For the purposes of point (b) of Article 24(1) of Regulation (EU) 2018/848, only the products and substances listed in Annex II to this Regulation may be used in organic production as fertilisers, soil conditioners and nutrients for plant nutrition, litter improvement and enrichment or algae cultivation or husbandry environment of aquaculture animals, provided that they are compliant with the relevant provisions of Union law, in particular with Regulation (EC) No 2003/2003 of the European Parliament and of the Council, the relevant applicable Articles of Regulation (EU) 2019/1009 of the European Parliament and of the Council, Regulation No 1069/2009 of the European Parliament and of the Council and Commission Regulation (EU) No 142/2011 and, where applicable, in accordance with national provisions based on Union law.

Annex II of the Regulation is presenting the authorized fertilisers, soil conditioners and nutrients referred in the Article 24 of the Regulation (EU) 2018/848. The content of this Annex is key to evaluate the possible feasibility of FERTIMANURE end-products for being used in organic farming.

Fertilisers, soil conditioners and nutrients listed in Annex II may be used in organic production, provided that they are compliant with:

- The relevant Union and national legislations on fertilising products, in particular, where applicable, Regulation (EC) No 2003/2003 and Regulation (EU) 2019/1009;
- Union legislation on animal by-products, in particular Regulation (EC) No 1069/2009 and Regulation (EU) No 142/2011, in particular Annexes V and XI.

In accordance with point 1.9.6 of Part I of Annex II to Regulation (EU) 2018/848, preparations of micro-organisms may be used to improve the overall condition of the soil or to improve the availability of nutrients in the soil or in the crops.

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They may only be used according to the specifications and restrictions of use of those respective Union and national legislations. More restrictive conditions for use in organic production are specified in the right column of the tables shown in the Annex.

Table 7 List of authorized fertilisers, soil conditioners and nutrients (Annex II). Only the ones affecting FERTIMANURE have been listed.

Name **Compound products or products containing only materials listed hereunder**	**Description, specific conditions and limits**
Farmyard manure	product comprising a mixture of animal excrements and vegetable matter (animal bedding and feed material) factory farming origin forbidden
Dried farmyard manure and dehydrated poultry manure	factory farming origin forbidden
Composted animal excrements, including poultry manure and composted farmyard manure included	factory farming origin forbidden
Liquid animal excrements	use after controlled fermentation and/or appropriate dilution factory farming origin forbidden
Biogas digestate containing animal by-products co-digested with material of plant or animal origin as listed in this Annex	animal by-products (including by-products of wild animals) of category 3 and digestive tract content of category 2 (categories as defined in Regulation (EC) No 1069/2009) factory farming origin forbidden the processes have to be in accordance with Regulation (EU) No 142/2011 not to be applied to edible parts of the crop
Algae and algae products	as far as directly obtained by: (i) physical processes including dehydration, freezing and grinding (ii) extraction with water or aqueous acid and/or alkaline solution (iii) fermentation only from organic or collected in a sustainable way in accordance with point 2.4 of Part III of Annex II to Regulation (EU) 2018/848
Biochar – pyrolysis product made from a wide variety of organic materials of plant origin and applied as a soil conditioner	only from plant materials, when treated after harvest only with products included in Annex I until 15 July 2022: maximum value of 4 mg polycyclic aromatic hydrocarbons (PAHs) per kg dry matter (DM) from 16 July 2022, the relevant limits for contaminants set in Regulation (EU) 2019/1009 apply

3.5.4 Analysis of the FERTIMANURE outputs on the organic farming context

To achieve the ambitious target of 25% of agricultural area under organic farming and a significant increase in organic aquaculture by 2030 as outlined in the Farm to Fork and the biodiversity strategies, it is necessary to provide the organic sector with tools that will create the conditions that can trigger the change in EU agriculture and aquaculture towards the high-quality standards that EU consumers value.

FERTIMANURE project is willing to contribute to the challenge established by the commission on achieving the goal that 25% of farmland should be under organic agriculture by 2030 by providing

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synthesized technical guidance on the way forward for assuring adequate fertilizer supply for organic agriculture.

In terms of product quality, the main parameters to be considered are those indicated by the EU Regulation 2019/1009 (see section 3.4). FERTIMANURE is already considering this regulation for assessing the quality of the fertilising products produced. Currently, the main limitation of FERTIMANURE products to be accepted to be used for organic farming is that manure coming from factory farming origin is forbidden.

The EU livestock sector is the largest in the world. Meat, milk and eggs make up 40% of the EU's agricultural value and it accounts for 48% of total EU agricultural activity, with an estimated €130bn output value annually and creates employment for almost 30 million people. It is estimated that total farm livestock population in Europe excrete around 1400 Mt of manure annually. Total N and P excreted by livestock in the EU27 are estimated at 7-9 Mt N/year and 1.8 Mt P/year. Moreover, the trends are not expected to change during the following years. EU meat production is expected to reach 47.5 million tonnes by 2030, and global meat consumption is estimated to increase by an average of 1% per year between 2017 and 2030.

Moreover, it is also important to consider the types of farms to produce this high amount of meat that is demanded. Very large farms now account for 72.2% of all the animals being reared in the EU. In the Benelux countries and Denmark, more than 90% of animals are reared on very large farms.

Considering the scenario of the livestock sector, it may seem complicated that FERTIMANURE products could be accepted to be used for organic farming. However, the project would like to change the paradigm about the nutrients coming from animal manure, demonstrating that FERTIMANURE BBFs are not manure anymore.

The definition of BBF in FERTIMANURE is the following: Bio-based Fertilizers (BBFs) are fertilising products or a component to be used in the production of (Tailor-Made) Fertilisers that are derived from biomass-related resources. The BBFs of FERTIMANURE are "obtained through a physical, thermal/thermo-chemical, chemical, and/or biological processes for the treatment of manure or digestate that result into a change in composition due to a change in concentration of nutrients and their ratios compared to the input material(s) in order to get better marketable products providing farmers with nutrients of sufficient quality".

In the framework of FERTIMANURE, the following relevant data will be obtained to provide policy relevant information to demonstrate that FERTIMANURE BBFs can fulfil the quality requirements needed for organic farming:

- Complete sustainability assessment of the processes and products
- Quality and safety check of the 19 BBFs in line with the new regulation
- Thorough evaluation of antibiotic resistance genes and their dynamics when the BBFs are applied
- FERTIMANURE products will be compared with raw manure and with other commercial fertilising products.

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4. Member State level regulation

This section detail national regulations impacting project results by Member States involved in the FERTIMANURE project.

4.1 Spain

The Spanish pilot is located in Osona, within the province of Barcelona (Catalonia). This pilot combines two separate treatment trains for the treatment of solid or liquid streams derived from raw pig slurry. As a first pre-treatment step, a solid/liquid separation unit is installed to obtain different flows of the raw material. In a very brief way, the solid fraction and the liquid fraction of the slurry continue various treatments until five BBF are obtained: biodried solid fraction, phosphoric acid, ammonium salts, concentrate rich in nutrients and algae-based biostimulants.

The current regulation in Spain on fertilisers is the Royal Decree 506/2013, of June 28, on fertilizer products which complements the Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers, and will be repealed by Regulation (EU) 2019/1009 of the European Parliament and of the Council. The Royal Decree covers the organic fertilisers and amendments not included in the EU Regulation, so it has been a very interesting law for some treatment by-products in Spain, such as several types of compost.

In Spain it is not allowed to put on the market fertiliser products that are not included in any of the types of Annex I of Regulation (CE) No. 2003/2003, of the European Parliament and of the Council, of October 13, 2003, or in any of the types of Annex I of this Royal Decree, and that do not meet the quality and other requirements provided for in this royal decree.

The products that can be used as fertilisers or amendments in agriculture and gardening are included in Annex I, and divided into the following groups:

Group 1. Inorganic fertilisers.
Group 2. Organic fertilisers.
Group 3. Organo-mineral fertilisers.
Group 4. Other fertilizers and special products.
Group 5. Limestone amendments.
Group 6. Organic amendments.
Group 7. Other amendments.

Considering the five sub products obtained from the train treatment, in general, it is difficult to comprise them in any existing category in the currently Royal Decree. In some cases, the characteristics of the product are similar to the requirements in the category however, the category is only focus for products with synthetic origin, thus, within group 1, or as a result of the mixing of fertilisers of organic origin with fertilisers of mineral origin (group 3).

However, the Royal Decree allows the inclusion of new products, either from the same government or from the proposal of the manufactures or their associations. In some cases, the new products should meet several conditions, such as they must ensure that they provide nutrients or improve the properties of the soil, they must have methodologies for sampling, analysis and testing to verify their composition and quality, also they must demonstrate that they do not produce harmful effects for health or the environment.

The products must be evaluated by an expert committee also the relevant competent administrations must be informed of their manufacture and the effects on human health and the environment.

The following are the different groups and categories of the Royal Decree where the 5 sub products obtained could be located, considering that they would hardly meet the exact requirements, due to any of the circumstances described in the previous paragraphs.

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4.2 France

The French pilot focuses on technologies (pyrolysis and N-stripping) able to produce BBFs from pig/cattle/poultry manures. The objective is to treat manure sources directly on their production sites, with the possibility of using bio-based fertilisers (BBFs) on the same site. The main technology innovations are testing on-farm mobile units for pyrolysis (on solid biomasses like poultry manures) and stripping (directly on liquid phases of slurries or after preliminary step of methanisation). Two units will be tested in Brittany and Grand-Est, two leading French agricultural regions. The pilot has 3 main technologies: dry anaerobic digester (mineralization of organic matter with biogas production), the pyrolysis unit (final stabilization of organic matter), and the stripping unit (recovery of ammonia from liquids waste - digestate, sludgeslurry). In such a way that the BBFs produced from French pilots are biochar, ammonium sulfatesulphate and liquid K fertilizer.

According to the current regulations in Europe, so in France, France, Regulation 1774/20021069/2009 of the European Parliament and of the Council establishes the health standards relating to animal by-products not intended for human consumption. Animal products not intended for human consumption (pet food, feed of ruminant and non-ruminant cattle, or for fertilizers and crop substrates), must also be accompanied by a declaration of compliance with EU regulation 999/200.

At national level, in France the fertilizer products are based on Article L255-2 of the Rural code and maritime fishing, ; Chapter V, title V, title II: launch on the market and use of the fertilizing materials, the additives for fertilizing materials and supports of media. : Placing on the market and use of fertilizing materials, adjuvants for fertilizing materials and growing media (Articles L255-1 to L255-18) and more specifically, marketing is governed by the articles L255-1 to L255-4 (Amended by LAW n°2020-1508 of December 3, 2020 - art. 31).

According to the rural code L255-2 fertilising materials and growth media can be put on the market, or be imported and distributed, even for free, provided they have been granted authorisation prior to that marketing, import or distribution. Although the authorisation can be provisional.

Pursuant to Article L.255-2 of the Rural Code, fertilising materials and growing media may be marketed, imported, distributed or even transferred free of charge in France, provided they have been subject to approval or a temporary sales authorisation (APV) or import authorisation. To market these types of products in France, an assessment file must be sent to the regulated products department of the “Agence nationale de sécurité sanitaire de l’alimentation, de l’environnement et du travail”: ANSES (National Health Safety Agency for Food, Environment, and work) formerly AFSSA [Agence française de Sécurité Sanitaire des Aliments]). In this case, the person responsible for marketing must send a technical file to the ANSES for the product’s harmlessness for humans, animals and their environment, and its effectiveness when used in prescribed or normal conditions, to be verified.

Nevertheless, according to Article L255-5 - Amended by Ordinance No. 2019-1110 of October 30, 2019 - art. 4.

The following are exempted from the obligations provided for in Articles L. 255-2 to L. 255-4:

1° Fertilizing materials, adjuvants for fertilizing materials and growing media that comply with a standard made mandatory by an order issued on the basis of decree no. 2009-697 of 16 June 2009 relating to standardization taken for application of Law No. 41-1987 of May 24, 1941 relating to national standardization;

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2° Fertilizing materials, adjuvants for fertilizing materials and growing media that comply with a European Union regulation that does not require an authorization to be issued by a Member State prior to their placing on the market or that hinders that a restriction be placed on their placing on the market and their use;

3° Fertilizers, their adjuvants as well as growing media that comply with national specifications approved by regulation guaranteeing their effectiveness and harmlessness;

4° Natural substances for biostimulant use authorized in accordance with the specific procedure provided for in the second paragraph of Article L. 253-1;

5° Waste, residues or effluents from the facilities defined in Articles L. 214-1 and L. 511-1 of the Environmental Code, the disposal or dumping of which on agricultural land as fertilizing materials is the subject to a spreading plan guaranteeing the absence of harmful effects on human and animal health and on the environment;

6° Raw organic materials or growing media of natural origin, delivered as they are or mixed together, obtained from natural materials without chemical treatment and constituting by-products of agricultural exploitation or non-agricultural establishment for the breeding or maintenance of animals when they are transferred directly, free of charge or against payment, by the operator or the person in charge of the establishment;

7° Fertilizers, adjuvants for fertilizing materials or growing media stored or circulating on the national territory which are not intended to be used there, nor to be put on the market there.

The implementation of Nitrate Directive results in the establishment of national action programs (PAN) governing the use of nitrogen fertilizers and promoting appropriate management of agricultural land in areas said to be vulnerable to pollution by nitrates of agricultural origin. The decree of January 10, 2001 (amended by the decree of May 30, 2005 and the amended order of March 6, 2001), which transposes the directive with regard to the implementation of PAN (Repealed by Decree No. 2007-397 of March 22, 2007 relating to the regulatory part of the Environmental Code).

In summary, each French department concerned by a vulnerable zone draws up a program of actions (based on PAN and adapted to local soils and crops) setting out the prescriptions aimed at correcting the practices that generate the most pollution that all farmers in the corresponding vulnerable zone must respect. This program is reviewed every four years based on the results of a monitoring program assessing their effectiveness. It is built in consultation with all the actors concerned, on the basis of a local diagnosis. The main measures relate to:

- Limit at 170 kg of organic nitrogen per spreadable hectare;
- Indication of maximal use of organic nitrogen by crops;
- the prohibition of spreading at certain times and depending on the state of the soil and its slope;
- Mandatory keeping of a provisional manure plan and a record book;
- Practices per farm concerned, in order to check the balance of nitrogen fertilization;
- Setting up sufficient storage capacity to comply with the manure plan;
- The obligation to install cover crops that trap nitrates;
- The obligation to install grass strips along watercourses.

There is no direct regulation of maximum phosphorus use on crops. But, the French water Framework Directive aims to achieve good water status. It requires achieving low phosphorus concentrations in water and reducing eutrophication phenomena. This directive is implemented

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via the master plans for water development and management (SDAGE), which identify the actions to be implemented to preserve and restore water quality.

Moreover, local regulations apply depending on local issues, where problems related to agricultural phosphorus have been identified. Local regulations on agricultural phosphorus are mainly defined within the framework of the SDAGE.

Agricultural activities are also subject to compliance with technical requirements, which fall under two possible categories of regulations: the departmental health regulations and the system of installations classified for the protection of the environment (ICPE).

- The departmental health regulations enact technical rules of hygiene, health and safety, not contained in the other texts. Specific to each territory, the departments can therefore adapt them to the local context. For example, the department “Vendée” has chosen to include a ceiling for the spreading of phosphorus limited to 100kg/ha/year.

At the national level, the nomenclature of ICPEs subjects agricultural activities to an obligation to declare, register or authorize with the prefect according to the importance of the risks or pollution that they can generate. The ministerial decrees of December 27, 2013 setting the requirements applicable to certain ICPEs lay down the principle that "the quantities spread of raw or treated livestock manure are adapted so as to ensure the supply of useful elements to the soil and crops without exceeding their needs and their export capacities considering the contributions of any kind that they can receive by elsewhere

4.3 Belgium

For Belgium, the region of Flanders is seen as ‘a virtual pilot’ that produces fragmented sources of ammonium salts (i.e. ammonium nitrate, ammonium sulphate from stripping and/or scrubbing, and ammonium water from evaporation process) that could be used in centralised chemical processing facility. As nutrient content in recovered ammonium salts is variable, depending on the type of the installation and the load of ammonia (i.e. recovery of ammonia during the mechanical separation of digestate and/or manure, from animal stables, from composting units, stripping/scrubbing of liquid fraction of digestate and/or manure), the aim is to perform monitoring campaign to identify the degree of nutrient variability in these products, and for this purpose they will be collected from different farms. In order to provide information on mass and energy balances (WP2), only one farm is going to be used as ‘a hardware’ for in-depth data collection, and choice was made to use DETRICON stripping/scrubbing installation. For the first two years of the project (2020 and 2021), DETRICON pilot in Gistel was monitored. At this farm, animal manure (horse manure, solid fraction of pig manure and pig manure) and food waste are treated via an anaerobic digestion. The digestate (and sometimes animal manure; both sent to the same receiving pit) is mechanically separated into liquid fraction and solid fraction, and liquid fraction is subsequently subjected to stripping/scrubbing DETRICON pilot, resulting in ammonium nitrate. Based on the insights gained during the optimization testes, it was decided to build a second pilot plant. The second pilot was pretested and demonstrated to interested farmers at the Flemish research institute INAGRO, subsequently transported and installed at piggery farm in Hooglede. The new stripping/scrubbing pilot is expected to treat yearly 25,000 tonnes of liquid fraction of manure and will be monitored from 2022 onwards, in the framework of WP2 of FERTIMANURE. The farm in Hooglede, treats only animal manure, which is mechanically separated into solid and liquid fraction of manure. The liquid fraction of manure is subjected to DETRICON stripping/scrubbing pilot, resulting in ammonium sulphate.

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According to (EC) 2003/2003, ammonium salts are recognized as 'EC fertilizer' (category C1 n°1, with C1: straight fluid fertilizers and n°1: nitrogen fertilizing solution) if the N content is at least 15%. Whereas the ammonium nitrate from stripping/scrubbing from the installations in Flanders, meets the 15 % requirement (because of the use of nitric acid), this is not the case for the ammonium sulphate which is currently mostly produced by air washing ammonia rich air from animal stables. In the new Fertiliser Products Regulation (EC 2019/1009) regulation, active from mid July 2022, a fertilizing product is defined by its product function category (PFC, type of product/fertilizer) and the component material category (CMC, allowed input materials). Ammonium salts correspond to the Product Fertilizer Category (PFC) C.I. (b) (i) Straight liquid inorganic macronutrient fertilizer if the N-concentration > 5 %. Both, produced in Flanders, ammonium nitrate and -sulphate meet that N-content. The same case is for the ammonium water.

At the Belgian national level, the Royal Decree of 28th January, 2013 includes the regulations on the marketing and use of fertilizers, soil amendments, cultivation substrates, sewage sludge and to any product to which a specific effect to promote plant production is attributed (referred to as "products" in this Royal Decree). It is thus a product regulation, defining which products can be considered fertilizers, soil improvers and cultivation substrates. These are the main categories of products that are accepted for trade and marketing in Belgium, as listed in annex I of the Royal Decree (28/01/2013). It includes both the fertilizers with CE label, as included in 2003/2003 (and therefore implements this regulation) and nationally accepted fertilizers.

Every fertilizer is detailed by: type, description, requirements and principal capacities and levels to be guaranteed.

CHAPTER I. Fertilisers
- Section I. Fertilisers with CE label
- Section II. Fertilisers that don't have the CE label

CHAPTER II. Fertilisers based on secondary materials
- Section I. Fertilisers from secondary materials with CE label
- Section II. Fertilisers from secondary materials that don't have the CE label

CHAPTER III. Soil improvers
- A. Organic Soil improvers
- B. Physical Soil improvers

CHAPTER IV. Cultivation substrates
- A. Organic cultivation substrates
- B. Anorganic cultivation substrates

CHAPTER V. Fertilizers with micronutrients
- Section I. Fertilisers with CE label
- Section II. Fertilisers that don't have the CE label

CHAPTER VI. Fertilizers for the production of nutrient solutions for hydroponics and substrate cultivation

CHAPTER VII. Related products

CHAPTER VIII. Sewage sludge

Products not occurring in Annex I to the Royal Decree of 28 January 2013 can be placed on the market via a so-called derogation (this is an authorization for fertilizers, soil improvers, growing media and related products). The Minister may authorize national trade in non-Annex I products (pursuant to Article 5) by granting them an exception. The derogation is granted for a period of maximum 5 years and can repeatedly be renewed for a period of maximum 5 years at a time.

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If the product for which a derogation is requested is a byproduct, a waste product or a processed waste product, one also needs an authorization, granted by the Region (in Belgium the 3 regions are: Wallonia, Flanders, Brussels) where the producer is located. In Flanders this authorization is granted through a “raw materials declaration”, granted by OVAM.

For this member state we must also consider that the whole region of Flanders is designated as a nitrate vulnerable zone (NVZ). Therefore, according to article 2(g)[3] of the EU Nitrates Directive (91/676/EEC), all manure, even in processed form, is considered as animal manure and can be applied up to the maximum limit of 170 kg N/ha/year. On Flemish level this is regulated via Manure Decree that regulates the use of fertilizing products. Currently produced ammonium salts from stripping/scrubbing (ammonium sulphate, ammonium nitrate) are considered to be animal manure and as such compete with it for the application on the land. However, ammonium sulphate, recovered from scrubbing ammonia rich air from animal stables, is under derogation which means it is not considered as animal manure and can be used as a replacement for synthetic fertilizers.

Finally, the newly proposed RENURE criteria (not yet implemented) by Joint Research Centre (JRC) state under which criteria manure-derived N fertilizers could be used in NVZ as replacement for synthetic mineral N fertilizers: (i) a total organic carbon:total N (TOC:TN) ratio ≤ 3 or a mineral N:TN ratio ≥ 90%, (ii) the content of copper (Cu) and zinc (Zn) should not exceed respectively 300 mg kg^{-1} DW and 800 mg kg^{-1} DW. Being BBFs in inorganic form, ammonium sulphate, ammonium nitrate and ammonium water might have the potential to be used in future as replacements for synthetic mineral N fertilizers in NVZ. Finally, it should be highlighted that ammonium sulphate, ammonium nitrate and ammonium water should be applied with low-emission techniques: injection or incorporation within 2h from the application are obligatory in Flanders.

4.4 The Netherlands

The pilot plant in this Member State is installed at the Arjan Prinsen Farm (APF), in a small town called Haarlo (Achterhoek region). By applying nutrient recovery technologies of pilot plant digestate dairy slurry is separated into a soil conditioner, producing 3 types of fertilising products: P-rich sludge, ammonium sulphate solution and K-rich liquid fertiliser.

The Fertiliser Act (In Dutch: Meststoffen) regulates free trade of fertilisers and the use of animal manure. All fertilising products derived from animal manure are designated as animal manure as the definition of the Nitrates Directive (EG/91/676) is in force. All fertilising products of APF are thus subjected to regulation of use for animal manure as designated by the Fertiliser Act and its decree and implementation regulation. In force are provisions application standards for nitrogen and phosphorus. For nitrogen the application standards depend of crop, soil type on fertilising product. For phosphorus these standards depend on phosphorus status of the soil. Next the storage capacity of animal manure has to fulfil regulatory requirements. Administrative obligations are in force for farms (agricultural enterprises), manufactures, representatives and distributors. On transport specific regulation is in force as well as on manure processing. Livestock numbers are regulated.

Both manufacturer and fertilising product with quantities require a form of RVO registration (RVO (*Rijksdienst voor Ondernemend Nederland* – Netherlands Enterprise Agency)). There is no specific Dutch legislation for the quality of fertilising products based on animal manure but the total content of nitrogen and phosphate (as P_2O_5) for each batch that is transport must be based on measurement based on designated analytical methods.

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The whole Netherland's country is designated as a vulnerable nitrate zone. Therefore, it must also comply with the regulations of the EU Nitrates Directive (91/676/CEE),
The current legislation is defined in the Six Action Plan Nitrates Directives (2018-2021). The maximum application standard for manure and digestate is 170 kg N per ha, in line with the value mentioned in the Nitrates Directive. The amount that can be applied is based on the total nitrogen content of manure digestate or other organic products. The Netherlands has a derogation for dairy farms with more than 80% grassland. They can apply higher manure/digestate application rates on grassland: 230 kg N as manure per ha on sandy soils and 250 kg N as manure per ha on clay soils.

Furthermore, total nitrogen application standards (manure/digestate/organic plus mineral fertilisers) for different crop-soil combinations have been set as a maximum nitrogen application. For this calculation, the effectiveness of the nitrogen must be taken into account. The effectiveness is defined for different types of products in terms of Nitrogen Fertiliser Replacement Value (NFRV).

Besides the N application standards for manure and N total (manure + fertiliser), application standards are also defined for phosphate. The phosphate application standards depend on the soil phosphorus status and crop type. In principle, the phosphorus status of all soils is assumed to be high. If the farmer can prove (by certified sampling and laboratory tests) that the status is lower than high, he can apply more phosphate in that field. If the soil phosphorus status is neutral, the phosphate application rate is 95 kg P_2O_5 per ha for grassland and 70 kg P_2O_5/ha for arable land.

There is strict legislation regarding when manure and fertiliser can be applied (Rijksdienst voor Ondernemend Nederland). This legislation identifies what type of fertiliser can be applied during a set period. These periods not only depend on the amount of fertiliser being applied but also the type of soil they are being applied to.

4.5 Germany

The German pilot is located at the facilities of Fraunhofer UMSICHT in the municipality of Sulzbach-Rosenberg

The German legal regulation concerning the application of fertilisers consists of the Fertiliser Law (Düngemittelgesetz (DüMG). The purpose of the law is to regulate the nutrient supply to plants, maintain or improve soil fertility, avoid any risks to human's or animal's health, ensure sustainable and resource-efficient use of nutrients and implement regulations from the EU concerning the issues as mentioned earlier. In order to enforce the Fertilising Law, two ordinances are applied i) Fertilisation Ordinance (Düngeverordnung (DüV)) and ii) Fertiliser Ordinance (Düngemittelverordnung (DüMV)). The Fertiliser Act (Düngegesetz (DüG)) stipulates the following: (a) fertiliser is to be used solely following good agricultural practice; (b) fertilisers are to be compatible with the type, quantity and timeline related nutritional needs of the plants in question; and (c) fertiliser use is to consider available soil nutrients, the organic substances in the soil, and local and cultivation related conditions (Umweltbundesamt, 2019).
The Fertilisation Ordinances regulate the application of fertilisers. The objective is to balance the nutrient supply by the farmer and nutrient demand by the crops. For manure application, for example, thresholds for nitrogen are applied. A nitrogen load on arable land must not exceed 170 kg N/Hectares (ha). In addition, the time for the application is restricted. After the harvest of the main crop until January 31st, it is prohibited to spread out manure to the fields. For phosphorus,

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no general threshold exists. To determine the right amount for supply, the phosphorus content in soil has to be analysed and balanced with the crops demand.

Although there are notable differences between plant protection products and plant strengtheners in Germany, they are covered under the plant protection law. Products categorised as plant aid agents (Pflanzenhilfsmittel) and soil improvers (Bodenhilfsstoffe) are covered by the Fertiliser Law (Düngemittelgesetz (DüMG)).

The legal basis for the production, buying and selling, and use of fertilisers, soil improvers, plant aid agents (Pflanzenhilfsmittel) and growth media is the Fertiliser Law (Düngegesetz - DüG) and the respective Fertiliser Regulation (Düngemittelverordnung (DüMV)). The Fertiliser Regulation establishes the requirements for commercialising fertilisers. They only have to be used according to good agricultural practice (GAP) and must be adapted to the plant's needs in terms of type, amount and required time of a specific nutrient. When using fertilisers, the nutrients present in the soil must be considered (European Biostimulants Industry Council, 2019). The surface water quality requirements are also specified in the regulation. The distribution regulation (Verbringungsverordnung) regulates transport, delivery and placement on the market and related intermediate markets of industrial fertilisers. Plant strengtheners are considered substances and mixes, including microorganisms intended to maintain plant health in general and are not considered plant protection products. However, plant strengtheners can protect plants from non-parasitic impairments and are not governed by the German Fertiliser Law (DüG). Soil improvers are substances without any significant nutrient or microorganism content that aim to influence the soil's biological, chemical, or physical properties to improve growth conditions for the crops or promote symbiotic assimilation of nitrogen. Plant aid agents are also substances without significant nutrient content; however, they are intended to act chemically or biologically on plants to achieve a plant-structural, production-technical, or use-technical benefit. Plant aid agents are considered separate from plant strengtheners and are covered by the Fertiliser Regulation (DüMV). Each fertilising product has to match one out of three categories or one of the listed types of fertilisers.

1) Requirements regarding nutrient content and plant availability of nutrients have to be met.
2) Thresholds for heavy metals and organic pollutant content are listed in **¡Error! No se encuentra el origen de la referencia.** have to be complied with.
3) Only educts or raw materials listed in the corresponding regulation DüMV may be used for the production of fertilisers, soil improvers and plant growth substrates.

Table 8 Thresholds for pollutants in accordance with German Fertiliser Ordinance (DüMV)

Parameter	Unit*	Threshold
Arsenic	mg/kg (DM)	40
Lead	mg/kg (DM)	150
Cadmium1	mg/kg (DM)	1.5
Chromium (total)2	mg/kg (DM)	300
Chromium (CrVI)	mg/kg (DM)	2
Nickel	mg/kg (DM)	80

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Mercury	mg/kg (DM)	1.0
Thallium	mg/kg (DM)	1.0
Perfluorinated tensides	mg/kg (DM)	0.1
Sum of dioxins and dl-PCB (WHO-TEQ 2005)3	ng(kg (DM)	30

[1]above 5 % P_2O_5, the threshold for Cd is 50 mg/kg P_2O_5 [2]labeling requirement only

[3]not applied for manure and digestate from biogas plants (without organic waste) *DM refers to dry matter

In **¡Error! No se encuentra el origen de la referencia.** the requirements for the fertilising products obtained from the pilot plants within this project are listed.

Table 9 Fertilising products and their requirements

Fertilising product	Category in DüMV	Minimum content	Main Components/Educts
Ammonium nitrate	Nitrogen fertiliser	20% N	N (total), NH4-N, NO3-N
Ammonium phosphate	Mineral multi-nutrient fertiliser	3% N[2], 5% P_2O_5[3]	
Ammonium sulphate	Nitrogen fertiliser	20% N	N (total), NH4-N
Ammonium sulfate solution	Nitrogen fertiliser	5% N, 6% S	NH4-N, S (water soluble)
Ammonium water[1]	-	-	-
Biochar	Plant growth medium	80% C	Wood, Lignite, Leonardit or Xylith
Biostimulants[1]	-	-	-
P-rich organic amendment, Nutrient-rich concentrate, Soil conditioner, Dried organic P-rich fertiliser	Organic fertiliser (single nutrient)	3%	Manure solid or liquid
	Organic fertiliser (multi-nutrients)	1% N, 0.3% P_2O_5, 0.5 K_2O	Manure solid or liquid
	organo-mineral fertiliser (single nutrient)	3%	Manure solid or liquid
	organo-mineral fertiliser (multi- nutrient)	1.5% N, 0.5% P_2O_5, 1.0 K_2O	Manure solid or liquid
Phosphoric acid[4]	-	-	-

[1]Not listed

[2]N-Species: N (total), NH4-N, NO3-N and ureic nitrogen

[3]Water soluble phosphate, neutral ammonium citrate soluble phosphate as well as water and neutral ammonium citrate soluble phosphate

[4]Listed as digestion agent for raw phosphate and therefore an educt* for fertiliser production

*substance that has been extracted from a mixture as opposed to a product created by a chemical reaction

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Manure itself is a raw material and used for the production of organic and organo-mineral fertilisers. Both the solid part and the liquid phase of the manure can be used for this purpose. The resulting products are fertilisers with a combination of N, P and K or they contain only one macronutrient. The requirements for the respective products are listed in **¡Error! No se encuentra el origen de la referencia.**.

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5. Discussion

5.1 New paradigm of new fertiliser Regulation EU 2019/1009, main differences from old Regulation EU 2003/2003

Before new fertiliser Regulation come into force, regulation (EC) No 2003/2003 partially harmonised the conditions for making fertilisers available on the internal market. However, it **exclusively covered fertilisers from mined or chemically produced inorganic materials.** For this reason, a large patchwork of complicated and partially very different national provisions of fertiliser legislation has existed up to know to cover other kind of fertilisers than mineral ones, such as fertiliser produced from side stream wastes or by mixtures of organic and inorganic raw materials.

The new Regulation allows the CE making of not only mineral/inorganic fertilisers but also organic and, in particular, recycled products used for fertilisation. It abolishes the well-known fertiliser types and replaces them with new product function categories (PFC). In accordance with Annex II to the Regulation, an EU fertilising product shall consist solely of component materials complying with the requirements of the CMCs “component material categories” listed in this Annex.

With the new Regulation, if fertilisers are in conformity with the harmonised safety, quality and labelling requirements, they can be sold freely throughout the EU and may no longer be hindered by product-related national measures and regulations. Obligations of economic operator are well stablished in the new Regulations and in contrast to the previous Regulation (EC) No 2003/2003, other economic operators such as importers and distributors are not deemed to be manufacturers from the outset.

In this way, the new regulation shows greats advantaged to the farmers in comparison with the old fertiliser regulation. In this way, the new FRP makes it easier for producers of organic and recovered fertilisers to sell with harmonized quality standards for all types of fertilizing material that can be traded across the EU. In this way, the new FRP contributes to circular economy while boosting the organic and biobased waste fertilisers and promotes increased use of recycled materials for producing fertilisers.

Besides, farmers have more choice to reduced health and environmental risk for consumers. In this sense, the new Regulation guarantee the safety of the fertilisers establishing clear rules about toxic elements, and organic contaminants. For example, the new Regulation stablishes cadmium limits for each PFC that will fully guarantee a high level of soil protection and reduce health risks.

In this way, although the most remarkable change between 2003 and 2019 is the harmonisation of alternative fertiliser products, changes in requirements, market, obligations of manufacturers, importers and distributors, packaging, and compliance, among others, resulted in a new set of regulations to be followed.

As follows, a summary of main remarkable changes is addressed, comparing both legislations packages.

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Scope

Regulation EC 2003/2003	Regulation EU 2019/1009
This Regulation shall apply to products which are placed on the market as fertilisers designated 'EC fertiliser' (Article 1)	The Regulation applies to EU fertilising products. This Regulation does not apply to animal by products and plant protection products (Article 1)
The 2003 regulation covers five types of fertilisers listed in Annex I of the regulation, namely: A. Inorganic straight primary nutrient fertilisers B. Inorganic compound nutrient fertilisers C. Inorganic fluid fertilisers D. Inorganic secondary nutrient fertilisers E. Inorganic micro-nutrient fertilisers F. Liming material	Seven Product Function Categories (PFCs) are covered: Fertilizers, liming materials, soil improvers, growing media, inhibitors and plant biostimulants as well as blends of those PFCs. In addition, component material categories (CMC) are introduced, whose specific requirements must be met when EU fertilising products are placed on the market (Article 4(1) b) -Annex I)
Fertiliser definition: 'Fertiliser' means material, the main function of which is to provide nutrients for plants (Article 2)	Fertiliser definition: fertilising product' means a substance, mixture, micro- organism or any other material, applied or intended to be applied on plants or their rhizosphere or on mushrooms or their mycosphere, or intended to constitute the rhizosphere or mycosphere, either on its own or mixed with another material, for the purpose of providing the plants or mushrooms with nutrient or improving their nutrition efficiency (Article 2)

Comments and observations:

The replacement of the Regulation (EC) No 2003/2003 for the new Fertiliser Regulation EU 2019/1009 expands its scope to recovered and bio-based fertilising products. In this sense, noticeable changes in the 2019 Annex I include the inclusion of organic fertilisers, organo-minerals, inorganic fertilisers, liming materials, soil improvers, inhibitors, biostimulants and fertiliser products blends.

In this way, the new regulation also encourages circular farming and so the distribution and importing of raw materials will now also be possible on the free market providing their fertilising products meet the standards of regulation (EC) 2019/1009.

Requirements

Regulation EC 2003/2003	Regulation EU 2019/1009
A type of fertiliser may only consider EC fertiliser if: (a) it provides nutrients in an effective manner; (b) relevant sampling, analysis, and if required, test methods are being provided. (c) under normal conditions of use it does not adversely affect human, animal, or plant health, or the environment. (Article 14)	An EU fertilising product shall: (a) meet the requirements set out in Annex I for the relevant product function category; (b) meet the requirements set out in Annex II for the relevant component material category or categories; and (c) be labelled in accordance with the labelling requirements set out in Annex III (Article 4)
For each product listed in Annex 1 of the regulation, the legislation details the minimum and maximum levels of nutrient content and the legal expression of these nutrients: • Declaration of Calcium, magnesium, sodium, and sulphur. • Statement of minimum quantities for these nutrients (Article 17, 18)	The requirements in Annex I include details on the claimed function of the product and the mode of action. Requirements are set by each product category (PCF). Annex II covers component material category(ies) and states that "an EU fertilising product shall consist solely of component materials complying with the requirements for one or more of the component material category(ies) (CMCs) listed in this Annex

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Comments and observations:

Regulation (EC) No 2003 only covered characteristics such as specific nutrient levels in the final product. The 2019 regulation will go beyond this and cover input materials as well as end characteristics. There will also be maximum limits set on the level of elements such as cadmium (a heavy metal found in phosphate) and other contaminants. There are no criteria for contaminants in Regulation 2003.

If compiled, requirements from Annex I (both 2003 and 2019), the fertiliser can be designed with "EC" letters, allowing it to be sold throughout the EU. This designation guarantees minimum nutrient content and safety. Further legislation must be analysed (e.g. packaging, waste directives, chemical registration, etc.).

Manufacturing and Marketing aspects

Regulation EC 2003/2003	Regulation EU 2019/1009
EC fertilisers could freely circulate (Article 5) Regulation specifically states to indicate nutrient, secondary nutrient and micro-nutrient content in marketable fertilisers (Article 6) The manufacturer shall be established within the Community and shall be responsible for the conformity of the 'EC fertiliser' (Article 4) Manufacturers must keep records that make it possible to trace a fertiliser while it is on the market and for a further 2 years thereafter. Responsibilities of Manufacturer: (a)ensure rules in annex III (ammonium nitrate) (Article 26) (b) Ensure traceability of ammonium nitrate fertilisers (Article 26) ¨(c) Ensure that fertilisers put on the market has passed the test of resistance (Article 27) Specific statements for packaging and labelling are indicated: Certain basic information, such as the manufacturer's contact details and the fertiliser's main properties, must appear on packages, labelling and accompanying documents. (Articles 9-12 and Annex IV)	EU fertilising products shall only be made available on the market if they comply with 2019 Regulation (Article 5) In this way, 2019 Regulation states: "The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008." The 2019 regulation states the rules and conditions when affixing the CE marking. A new term "economic operator", which includes manufacturers, authorised representatives, importers, and distributors (see Article 2(15)) is introduced The regulation states the specific definition and obligations for each economic operator: Manufacturer (Article 6), "authorised representative" (Article 7), importers (Article 8), distributors (Article 9). Article 10 sets that importers and distributors that can be considered as manufactures shall be covered by Article 6. It introduces a new obligation for all economic operators aimed at ensuring the traceability of the EU fertilisers they market (Article 12). General provisions on market surveillance are detailed from Article 16 to Article 29 Specific statements for packaging (Article 11) and for CE marking (Article 17, 18) are indicated

Comments and observations:

Both legislative packages apply to products which are placed on the market designated as "EC fertiliser". Guidelines to obtain conformity must be followed in both legislations. Contents from the fertiliser should be expressed by the Member States. A new section of market surveillance is included in the 2019 regulation.

The new Regulation opens the single market for fertilising products which are not currently covered by harmonisation rules of 2003 Regulation, such as organic and organo-mineral, fertilisers, soil improvers, inhibitors, plant biostimulants, growing media or blends.
This harmonisation, however, could be optional in the sense that Member States will be able to continue implementing their own additional national regulation. In this framework, the existing EU rules do not affect the so-called 'national fertilisers' placed on the market of the Member States in accordance with national legislation. Some Member States have very detailed national rules whereas others do not. Producers can

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choose to market a fertiliser as 'EC fertiliser' or as 'national fertilisers´. In this way, if the manufacturer wishes to benefit from free circulation on the market, they will be required to demonstrate the product meets the standards set by the regulation in order to bear the CE marking. However, any product that does not bear the CE marking will maintain rights to circulate within the national market. In the same way, Regulation (EC) No 2003/2003 does not prevent non-harmonised fertilisers from being made available on the internal market in accordance with national law.

New 2019 Regulation states clear obligation for economic operators, such as verifying whether the manufacturer has provided the necessary documentation and information. They must also ensure that storage and transport conditions do not compromise the compatibility of EU fertilising products with the new EU Fertiliser Regulation as long as the products fall within their area of responsibility. In contrast to the previous Regulation (EC) No 2003/2003, other economic operators such as importers and distributors are not deemed to be manufacturers from the outset. However, if they decide to act as manufacturers of a product by marketing it under their own name/trademark, although they did not manufacture or produce it themselves, or if they make changes to the product which may affect its conformity, these operators (importers/distributors) are also subject to the far-reaching manufacturer obligations (Article 10 of the new EU Fertiliser Regulation).

Safety, risk issues

Regulation EC 2003/2003	Regulation EU 2019/1009
The regulation states the prohibition of products marketing if heaths and environmental risks are suspicious. Analysis at Member state level (Article 15) Responsibilities of Manufacturer: (a)ensure rules in annex III (ammonium nitrate) (Article 26) (b) Ensure traceability of ammonium nitrate fertilisers (Article 26) ¨(c) Ensure that fertilisers put on the market has passed the test of resistance (Article 27)	The new regulation sets limits values for contaminants and heavy metals (annex II) The regulation states specifics obligation for each economic operator in case they suspect that a EU fertilising product presents a risk to human, animal or plant health, to safety or to the environment: • Manufacturer's obligations (Article 6) • Importer's obligations (Article 8) • Distributor's obligations (Article 9)

Comments and observations:

The standard of dealing with EU fertilising products that present a risk to the health and/or safety of humans, animals, plants or the environment in regulation 2019/1009 closely mirror those of the 2003 regulation. The 2019 regulation offers more detail in terms of the procedure for dealing with the product presenting the risk but the end result is the same. It introduces limits for toxic contaminants for the first time. This will guarantee a high level of soil protection and reduce health and environmental risks while allowing producers to adapt their manufacturing process to comply with the new limits.

Both legislation documents encourage operators to take immediate measures and notify competent authorities to act promptly. However, regulation (EC) No 2003/2003 do not offer a clear framework to address new concerns, such as environmental and material safety concerns in inorganic fertilisers. The new regulation at EU level not only sets (uniform) limit values for contaminants and heavy metals in EU fertilising products (toxic contaminants such as cadmium in phosphate fertilisers). The new Regulation will provide strict rules on safety and quality requirements for all fertilisers to be traded freely across the EU. Producers will need to demonstrate that their products meet those requirements before affixing the CE mark

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Conformity assessment

Regulation EC 2003/2003	Regulation EU 2019/1009
EC fertilisers may subject to official control measures (Article 29)- Responsible member state	EU fertilising products shall be presumed to be in conformity with the requirements set out in Annexes I, II and III covered by those standards or parts thereof (Article 13) Tests for verifying the conformity of EU fertilising products with the requirements set out in Annexes I, II and III shall be performed in a reliable and reproducible manner (Article 13) Conformity assessment and EU declaration of conformity (Article 15, 16) Conformity assessment and notification bodies (Article 20 to 36) Market surveillance, control of EU fertilising products and safeguard procedure are state in Article 37 to 41)

Comments and observations:

In contrast to 2003 Regulation, an additional actor in the new FPR will be the Notified Bodies, which are considered as a conformity assessment body officially designated by the national authority to carry out the procedures for conformity assessment within the meaning of the FPR. All the Notified Bodies will be listed in a public database on the internet (called NANDO). The market and local competition are both determining the price range as much as the work performed. Market surveillance authorities shall inform the relevant notified body accordingly where they find that the EU fertilising product does not comply with the requirements laid down in this Regulation.

Environmental aspects: End of waste/ biodegradability

Regulation EC 2003/2003	Regulation EU 2019/1009
Nothing addressed	The Regulation defines criteria for which material is considered waste, as defined in Directive 2008/98/EC, can cease to be wasted (Article 19) The regulation states "By 16 July 2024, the Commission will carry out a review in order to assess the possibility of determining biodegradability criteria of mulch films, and the possibility of incorporating them into component material category 9 in Part II of Annex II."

Comments and observations:

The category of waste appears for the first time on the legislation package. As intended, the promotion of waste-based fertilisers is prominent.

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5.2 Matrix of feasibility of FERTIMANURE products

A matrix of feasibility of the BBFs obtained in FERTIMANURE was built according to the selected member state regulations. This matrix of feasibility includes specific feasibility in terms of operational and technical aspects, economic aspects, specific regulatory aspects and the overall feasibility expected for each BBF in selected countries.

To simplify the feasibility matrix of the FERTIMANURE BBFs, BBFs of same type obtained in different pilots were gathered into different categories (Table 10).

A summary of the mentioned aspects considered in the overall feasibility of the BBFs obtained per each country selected is given in the next tables (Table 11 Matrix of feasibility of ammonium sulphate solution

-Table 23).

Table 10 Categories of BBFs evaluated in the matrix of feasibility

BBF		**BBF category**	**Type**
1	NL- AS	Ammonium sulphate solution/ ammonium salts	Liquid mineral N fertilised
9	ES- AM		
11	DE - AS		
15	BE - AS		
18	FR - AS		
14	BE- AN	Ammonium nitrate	
16	BE-AW	Ammonium water	
8	ES-PA	Phosphorus (ashes)	Solid P fertiliser
13	DE-AP	Ammonium phosphate on perlite (solid)	Solid mineral NP fertilised
2	NL- LK	Liquid K- fertiliser	Liquid organic K fertiliser
19	FR- LK		
3	NL-SC	Soil conditioner	Organic soil amendment
7	ES-DSC	Bio-dried solid fraction	
12	DE- BC	Biochar	
17	FR - BC		
4	NL-WP	Wet organic P-rich fertiliser	Solid organic P fertiliser
5	NL- DP	90% Dried organic P rich fertiliser (calc)	
6	ES-NC	Nutrient-rich concentrate	Liquid organic NPK fertiliser
10	ES-AA	AA-based biostimulants	Biostimulant

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Table 11 Matrix of feasibility of ammonium sulphate solution

BBF: Ammonium sulphate solution. Pilot producing BBF: NL, ES, DE, BE, FR	
PFC/ CMC Category (Regulation EU 2019/1009) in which it could tentatively fit: Product Fertilizer Category (PFC) 1 C.I. (b) (i) Straight liquid inorganic macronutrient fertilizer; expected Component Material Categories (CMC) 10 derived products within the meaning of Reg. (EC) No. 1069/2009, or CMC 15 Recovered high purity materials.	
Implementation feasibility in Belgium	Product **currently** regarded as **animal manure**, however, if **RENURE** is **accepted** and ammonium sulphate can be used as **substitute for mineral fertiliser**, then **operational and economic benefit can be expected**. Ammonium sulphate from air stripping can be used as mineral fertilizer replacement in Flanders and it is already in the market. For RENURE products 1-2 years might be needed for the acceptance of proposed criteria and their translation in the national legislation – once legal procedures are finalized, then the product can be marketed. **Main barrier:** needs to be **classified as RENURE** product.
Implementation feasibility in France	Product **already in the market,** thus, **economic feasibility** is positive. There is **no operational or technical barrier** if product is coming from **gas washing**. Legally it can be **classified as NF U42-001-1/A1** product provided that N content is between 3 and 15%. **Main barrier: no barriers identified so far.**
Implementation feasibility in the Netherlands	Product **currently** regarded as **animal manure**, however, if **RENURE** is **accepted** as **substitute for mineral fertiliser** and not considered in nitrates directive as N supply it can be both **operational an economic benefit**. For RENURE products 1-2 years to arrive the market are estimated. **Main barrier:** needs to be **classified as RENURE** product.
Implementation feasibility in Spain	Equivalent products are **already in the market**, although the appropriateness of the feedstock (animal manure) can hinder reaching the market, social acceptance and certification as fertilising product (**Group 06, Nitrogenous mineral fertiliser** according to the Spanish Royal Decree 506/2013), which can take up to 2-3 years in Spain. Regarding operational and technical issues, **technologies** for its production are already in the market in Spain and **technical feasibility** was demonstrated. **Infrastructure** in Spain exists but **not** usually implemented **in farms**.
Implementation feasibility in Germany	Product **already in the market.** Has to be from only **one raw material** (according to Appendix 2 Table 6.1 of DüMV 2012) using concentrated sulphuric acid (technical grade) or $CaSO_4$. There has to be a **minimum content of 5 % nitrogen and 6 % sulphur** (water-soluble). The pH value must be marked. In case of a pH value < 4.0 additional note for proper use: "Not suitable for foliar not suitable for foliar fertilization" There are **no operational or technical barriers**.

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Table 12 Matrix of feasibility of soil conditioner

BBF: Soil conditioner. Pilot producing BBF: NL	
PFC/ CMC Category (Regulation EU 2019/1009) in which it could tentatively fit: Product Fertilizer Category (PFC) 1 (A)(I) Solid organic fertiliser; PFC 3(A) Organic soil improver; PFC 4 Growing medium; Expected Component Material Categories (CMC) 5 digestate other than fresh crop digestate or CMC 10 derived products within the meaning of Reg. (EC) No. 1069/2009.	
Implementation feasibility in Belgium	Product **currently** regarded as **animal manure** but it does **not present legal restrictions** so far. **Operationally and technically** feasible. **Profitable** product, it is normally sold or exported. **Main barrier: no barrier so far although is still considered manure.**
Implementation feasibility in France	Product **already in the market,** thus, **economic feasibility** is positive. Legally it can be **classified as NF U44-051** or **NF U42-001-3** product. **Main barrier: no barriers identified so far.**
Implementation feasibility in the Netherlands	Product **already in the market,** thus, **economic feasibility** is positive. There are no technical, operative or legal issues. **Main barrier: no barriers identified so far.**
Implementation feasibility in Spain	Although digestate is already **being used as organic amendment** in agricultural crops, it is **not** considered a **product with added value** and its N content is accounted in the fertilising plans (management dependent on organic N). In economic terms, **economic feasibility** of the implementation of anaerobic digestor **depend** on its treatment **capacity**. So far, in **Catalonian** region there are only **few installations** treating animal manure. Centralised treatment plans can be a potential solution. Product could be **legally categorised** as an **organic amendment** from animal manure according to the Royal Decree 506/2013. **Main barrier: still considered manure, few installations available on farm, significant economic investment required.**
Implementation feasibility in Germany	**Possible** when used properly and **safely**, do not damage the fertility of the soil, the health of humans, animals and crops and do not endanger the natural balance. Compliance with limit values is important (Annex 2 Table 1.4 Column 4 of DüMV 2012). Substances may not be placed on the market as soil additives or plant aids if content of total nutrients in the dry matter of more than (1.5% (N), 0.5% (P_2O_5), 0.75% (K_2O), 0.3% (S), 0.07% (Cu), 0.5% (Zn). Alternatively, in the case of basic constituents, a value of more than 30 per cent, expressed as CaO, is achieved. In addition, it is not possible if application recommendations based on the product would lead to an application of more than 50 kilograms of N, 30 kilograms of P_2O_5, 50 kilograms of K_2O, 500 kilograms of CaO or 15 kilograms of S per hectare in a single application. Different products **already in the market**. Could be **economic feasible** if prices can compete with existing products. **Main barrier: no barriers identified so far.**

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Table 13 Matrix of feasibility of wet organic P-rich fertiliser

BBF: Wet organic P-rich fertiliser. Pilot producing BBF: NL	
PFC/ CMC Category (Regulation EU 2019/1009) in which it could tentatively fit: Product Fertilizer Category (PFC) 1 (A)(I) Solid organic fertiliser; PFC 3(A) Organic soil improver; PFC 4 Growing medium; Expected Component Material Categories (CMC) 5 digestate other than fresh crop digestate or CMC 10 derived products within the meaning of Reg. (EC) No. 1069/2009.	
Implementation feasibility in Belgium	Soils in Belgium are normally already rich in phosphorus (**P surplus**) and thus, this product is expected to face **operational and economic limitations (cannot be applied in the crops nearby)**. **Depending** on the **market** and its **exportability** it **could be profitable**. **Main barrier: must be exported.**
Implementation feasibility in France	No information on the feasibility of product
Implementation feasibility in the Netherlands	Although it could be **marketable**, **product quality** needs to be **improved**. Also, currently, there is **national P surplus** and product could only be exported, although **economic feasibility for exportation** is **negative**. **Main barrier: must be exported and could not be economically feasible considering its current quality.**
Implementation feasibility in Spain	Product could be accepted as **organic amendment from animal origin** according to Spanish regulation (Royal Decree 506/2013) and it could be **marketable**. However, its product quality **limits** its **exportability** and **profitability**. It should be used in the crops nearby. **Main barrier: limited exportability and profitability.**
Implementation feasibility in Germany	May not be possible in Germany since no phosphates other than those listed in Table 4 of Appendix 2 (DüMV 2012) have to be used. Expected **economic feasibility is positive** since phosphate fertilizer sales have risen by 23 percent to 247 766 metric tons in 2021. NP fertilizers rose by almost 45 % to 151 479 metric tons (Industrieverband Agrar annual report 2020/2021). Import of P-rich fertiliser could be feasible in Germany. **Main barrier: limited input materials**, transport cost due to wetness, competition with products produced in Germany

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Table 14 Matrix of feasibility of dried P-rich fertiliser

BBF: Dried P-rich fertiliser. Pilot producing BBF: NL	
PFC/ CMC Category (Regulation EU 2019/1009) in which it could tentatively fit: Product Fertilizer Category (PFC) 1 (A)(I) Solid organic fertiliser; PFC 3(A) Organic soil improver; PFC 4 Growing medium. Expected Component Material Categories (CMC) 5 digestate other than fresh crop digestate or CMC 10 derived products within the meaning of Reg. (EC) No. 1069/2009.	
Implementation feasibility in Belgium	Soils in Belgium are normally already rich in phosphorus (**P surplus**) and thus, this product is expected to face **operational and economic limitations (cannot be applied in the crops nearby)**. **Depending** on the **market** and its **exportability** it **could be profitable**. **Main barrier: must be exported.**
Implementation feasibility in France	No information on the feasibility of product
Implementation feasibility in the Netherlands	Theoretically it could be **marketable**, but **drying step** still **to be implemented**. Also, currently, there is **national P surplus** and product could only be exported, although **economic feasibility for exportation** is **negative**. **Main barrier: must be exported.**
Implementation feasibility in Spain	Product could be accepted as **organic amendment from animal origin** according to Spanish regulation (Royal Decree 506/2013) and it could be **marketable**. However, its product quality **limits** its **exportability** and **profitability**. It should be used in the crops nearby. **Main barrier: limited exportability and profitability.**
Implementation feasibility in Germany	May not be possible in Germany since no phosphates other than those listed in Table 4 of Appendix 2 (DüMV 2012) have to be used. Rising interest in P-fertilisers in Germany if it meets standards of the DüMV it **could be economically feasible.** **Main barrier: Competition with products produced in Germany, transport cost**

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Table 15 Matrix of feasibility of liquid K-fertiliser

BBF: Liquid K- fertiliser. Pilot producing BBF: NL, FR	
PFC/ CMC Category (Regulation EU 2019/1009) in which it could tentatively fit: Product Fertilizer Category (PFC) 1 (A)(II) liquid organic fertiliser. Expected Component Material Categories (CMC) 5 digestate other than fresh crop digestate or CMC 10 derived products within the meaning of Reg. (EC) No. 1069/2009.	
Implementation feasibility in Belgium	Product **currently** regarded as **animal manure,** but it does **not present legal restrictions** so far. **Operationally and technically** feasible. **Economically feasible** if used in own land. **Main barrier: no barrier so far although is still considered manure.**
Implementation feasibility in France	**Operationally and technically** feasible but technology needs to be **adapted** for the **feedstock**. **Economically feasible** if used in own land. The only **legal requirement** is the **spreading plan** on agricultural lands. **Main barrier: economically feasible** only if **used in own land,** which **requires a spreading plan.**
Implementation feasibility in the Netherlands	It does **not present operational, legal restrictions** so far. **Economically feasible** if used in own land. **Main barrier: no barriers identified so far.**
Implementation feasibility in Spain	**Operationally and technically** feasible. Equivalent products are already in the market so **timeline to achieve the market** should be **minimum**. In legislative terms, although there is a category for **potassium rich solutions** in the Spanish regulation, this category **does not include organic solutions** and in the category for organic fertilisers there is no liquid organic fertiliser. **Main barrier: limited ability** to **fit** in the **categories** established **Spanish regulation**.
Implementation feasibility in Germany	**No legal restrictions** for the product. Two categories identified: 1.3.2 (Appendix 1 (to § 1 No. 11, § 3 Para. 1, § 6 Para. 3, § 8 Para. 3 and 4)) **Potassium fertilizer-solution** with a **minimum content of 20 % K_2O**, essential composition Potassium hydroxide, potassium formate and 1.3.3 Potassium sulphate-solution with a minimum content of 6% K_2O and 6% S, essential composition: potassium sulphate; sulfuric acid. Could be **economically feasible** as manufacturing has **better environmental performance than mining alternative** (KCl in Germany obtained through mining). **Main barrier: Transport costs high (liquid) must compete with price of KCl (most important K-fertiliser in Germany)**

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Table 16. Matrix of feasibility of nutrient rich concentrate

BBF: Nutrient rich concentrate. Pilot producing BBF: ES	
PFC/ CMC Category (Regulation EU 2019/1009) in which it could tentatively fit: Product Fertilizer Category (PFC) 1 (A)(II) liquid organic fertiliser; Expected Component Material Categories (CMC) 10 derived products within the meaning of Reg. (EC) No. 1069/2009 or CMC 15 Recovered high purity materials.	
Implementation feasibility in Belgium	Equivalent products are available obtained from membrane filtration. **Operational and technical feasibility** via **freezing** technology should be **demonstrated**, marketability and economic feasibility would depend on that. **Market demand** of this kind of product **might be limited**. Product **should be classified** as **RENURE** product. **Main barrier**: **Operational, technical and economic feasibility** of technology must be **demonstrated**. Product needs to be **classified as RENURE** product.
Implementation feasibility in France	No information on the feasibility of product
Implementation feasibility in the Netherlands	Product **currently** regarded as **animal manure**, however, if **RENURE** is **accepted** as **substitute for mineral fertiliser** and not considered in nitrates directive as N supply it can be both **operational an economic benefit**. Still, **product quality should be improved**. For RENURE products 1-2 years to arrive the market are estimated. **Main barrier:** needs to be **classified as RENURE** product.
Implementation feasibility in Spain	**Operationally and technically feasible** (replicable, robust and versatile technology) with **no deep training** of workers needed. Manure **pre-treatment** (S/L separation technology) should be guaranteed and its availability in Spanish farms is **very limited**. Technology can be applied with or without previous membrane-based technology step provided that equipment and operational parameters are adapted. Currently **limited economic feasibility** due to the **current infrastructure** available (significative investment required). Also, **product quality should be improved.** In legislative terms, although there is a category for **NPK solutions** in the Spanish regulation, this category **does not include organic solutions** and in the category for organic fertilisers there is no liquid organic fertiliser. Main barrier**: unavailable pre-treatment**
Implementation feasibility in Germany	**Operationally** and **technically feasible** if it meets the specifications for organic and organic-mineral fertilizers in Germany. Data has to be presented if it can compete with traditional fertilisers (NPK-fertilisers) regarding in field performance and price. If quality is below existing fertilisers, it will be **not economically** feasible. **Main barrier: unavailable pre-treatment**

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Table 17. Matrix of feasibility of biodried solid fraction

BBF: Biodried solid fraction. Pilot producing BBF: ES	
PFC/ CMC Category (Regulation EU 2019/1009) in which it could tentatively fit: Product Fertilizer Category (PFC) 1 (A)(I) Solid organic fertiliser; PFC 3(A) Organic soil improver; PFC 4 Growing medium; Expected CMC 3 Compost or CMC 10 derived products within the meaning of Reg. (EC) No. 1069/2009.	
Implementation feasibility in Belgium	**Operational feasibility** for composting exists but **not for biodrying**. Marketability will **depend on the market demand**, it could be **profitable** if product is sold/exported. **Main barrier: operational feasibility** of **biodrying not demonstrated**
Implementation feasibility in France	No information on the feasibility of product
Implementation feasibility in the Netherlands	There are **no technical, operative or legal issues** detected. It could have a **value** if **applied in arable land**. **Main barrier: no barriers identified so far.**
Implementation feasibility in Spain	**Operationally and technically feasible** (robust and easy to implement). **No deep training** of workers would be required. There is **infrastructure available** (composting) that could be **easily adapted**. **Economic feasibility** seems to be **positive** if a market niche exists. Legally, product could be **categorized as an organic amendment** from animal origin if **sanitisation** is guaranteed. **Main barrier: no barriers identified so far.**
Implementation feasibility in Germany	**Operationally** and **technically feasible** if it meets the specifications of DüMV 2012 § 3 Approval of fertilizer types. Product could be categorized as an organic amendment if limit values are not exceeded (Annex 2 Table 1.4 Column 4 of DüMV 2012) Could be economically feasible if it can compete with existing products that are already in the market. **Main barrier: has to be exported (transportation cost)**

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Table 18. Matrix of feasibility of phosphorus rich ashes

BBF: Phosphorus rich ashes. Pilot producing BBF: ES	
PFC/ CMC Category (Regulation EU 2019/1009) in which it could tentatively fit: Product Fertilizer Category (PFC) C.I. (a) (i) Straight solid inorganic macronutrient fertilizer (in the case of phosphorus rich ashes) PFC) C.I. (b) (i) Straight liquid inorganic macronutrient fertilizer (in the case of phosphoric acid); expected Component Material Categories (CMC) 10 derived products within the meaning of Reg. (EC) No. 1069/2009 or CMC 13 thermal oxidation materials and derivatives.	
Implementation feasibility in Belgium	**Operational and technical feasibility** only demonstrated in **pilot installations** aiming for **scientific research**. **Flemish legislation** does **not accept combustion** of **manure** as a suitable processing due to carbon loss. Also, **regulation concerning emission gases** during combustion are very **strict** and **very difficult** to comply with at **farm level**. **Economic** feasibility would **depend** on its **permission**. Finally, **the use of final product** would be limited due to strict P application limits and export of P ashes would be needed. **Main barrier: legal restrictions** for **combustion** of **manure** and **very strict rules** for **combustion emissions**. Also, P ashes would need to be exported.
Implementation feasibility in France	**No technical or operational issues** detected so far. Economic benefits might be limited just to the **management of ash flows**. Legally it can be **classified as NF U42-001-1.** **Main barriers: no barriers identified so far** although **production changes** would be **recommended**.
Implementation feasibility in the Netherlands	Theoretically it could be **operationally and technically feasible,** but from **dried product** which needs **improvement**. Also, currently, there is **national P surplus** and product could only be exported, although **economic feasibility for exportation** is **negative**. **Main barrier: must be exported.**
Implementation feasibility in Spain	**Operationally** and **technically feasible** in **commercial biomass boilers** if operational parameters are **adapted** (user-friendly, robust and replicable technology). **Technical feasibility** of **phosphorus extraction** from ash has been **demonstrated** and requires further **technification of workers**. In **economic** terms, **benefits** are expected due to **energy recovery** from manure although **economic feasibility** of **phosphorus extraction** from ash could be **limited** (product price might be not able to overcome the production costs), **limiting** also its **marketability**. **No category** identified in **Spanish regulation** for **ash** but there is a **category** for **phosphoric acid** (extracted phosphorus) **Main barrier: No** fertilising product **category identified** for **ashes**. **Economic feasibility** might be **limited** for **phosphoric acid** obtained from P extraction from ash.
Implementation feasibility in Germany	**Operationally** and **technically feasible** in Germany regarding DüMV 2012 □ 6.2 Phosphate fertilizers according to Annex 1 point 1.2.9 and 6.2.2 Incineration of substances of animal origin. Has to meet Phosphate fertilizer specifications. Increasing interest in phosphate fertilizers in Germany in 2021 and often sources of phosphate fossil nature. Product not yet in the market but interest is high could be **economically feasible.** **Main barrier: must be exported.**

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Table 19. Matrix of feasibility of AA-based biostimulants

BBF: AA- based biostimulants. Pilot producing BBF: ES	
PFC/ CMC Category (Regulation EU 2019/1009) in which it could tentatively fit: Product Fertilizer Category (PFC) 6(B): non-microbial plant biostimulant; Expected Component Material Categories (CMC) 10 derived products within the meaning of Reg. (EC) No. 1069/2009.	
Implementation feasibility in Belgium	**Economic feasibility** seems to be **low** as no category is identified in the regulations in the Belgium. **Main barrier: no category identified for the product.**
Implementation feasibility in France	**Equivalent products** are already in the **market**. **Operationally** and **technically feasible** but for its commercialization **specific documentation** for its **authorization** is needed ("authorisation de mise en marché") and it can take up to **2 years to reach** the **market**. **Main barrier: no barriers identified so far.**
Implementation feasibility in the Netherlands	There are **no technical or operative issues** detected. Economic feasibility seems to be low as no category is identified in the regulations in the Netherlands. **Main barrier: no category identified for the product.**
Implementation feasibility in Spain	**Technology** is already in the **market** and **equivalent products** already exist. Infrastructure in farms does not exist and technologies would require **high technification** of workers (constant monitoring and specific equipment required). In **economic** terms, **operational costs** are expected to be high (energy demand, reagents, and specific equipment) although the use of **manure-based permeate** as **cultivation media** might make it **competitive if compared to conventional biostimulant production** processes. **Legally**, product would fit in the Spanish fertilising products' regulation in the **category** of special products as **amino-acid solution** (Group 4.01. Aminoacids) (RD 506/2013). **Main barrier**: **economic feasibility** could be **limited** due to high operational demand.
Implementation feasibility in Germany	**Equivalent products** are already in the **market**. **Operationally** and **technically feasible** have to meet the requirements of the German fertilizer regulation (DüMV). Some companies advertise novel biologicals for crop protection and management (few products in the market). **High interest in biostimulants** due to rising fertilizer prices therefore product could be **economically feasible.** **Main barrier: no barriers identified so far.**

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Table 20. Matrix of feasibility of biochar

BBF: Biochar. Pilot producing BBF: FR, DE	
PFC/ CMC Category (Regulation EU 2019/1009) in which it could tentatively fit: Product Fertilizer Category (PFC) 3 (A) Organic soil improver; expected Component Material Categories (CMC) 10 derived products within the meaning of Reg. (EC) No. 1069/2009; or CMC 14 Pyrolysis and gasification materials.	
Implementation feasibility in Belgium	**Operational and technical feasibility** only demonstrated in **pilot installations** aiming for **scientific research**. **Flemish legislation** does **not accept combustion** of **manure** as a suitable processing due to carbon loss. Also, **regulation concerning emission gases** during combustion are very **strict** and **very difficult** to comply with at **farm level**. **Economic** feasibility would **depend** on its **permission**. **Main barrier: legal restrictions** for **combustion** of **manure** and **very strict rules** for **combustion emissions**.
Implementation feasibility in France	**Operationally** and **technically feasible** provided that **technology** is **adapted** to **feedstock**. Its commercialization **specific documentation** (evaluated by the French sanitary security agency, ANSES) for its **authorization** is needed ("authorisation de mise en marché") and it can take up to **2 years to reach** the **market**. Currently there is no real market in France for its use for agricultural purposes, mainly due to its high cost (600€/t). **Main barrier: limited market in France**.
Implementation feasibility in the Netherlands	There are **no technical, operative or legal issues** detected. It could have a **value** if **applied in arable land and open horticulture**. **Main barrier: no barriers identified so far.**
Implementation feasibility in Spain	**Operationally** and **technically feasible** technology although limited to **pilot or research installations**. There is **no full installation** in farms. Equivalent product already exist and **economic feasibility would depend** on the **avoided costs** due o the **internal use** of the **products** rather than its selling. **High investment costs** can be expected limiting its economic feasibility. Product could be accepted as an **organic amendment** from animal origin in Spanish regulation. **Main barrier: economic feasibility** could be **limited** due to **high investment costs**.
Implementation feasibility in Germany	**Operationally** and **technically feasible** also in big quantities (500 kg/h feed rate). Threshold values for soil additives have to be complied with. Substances may not be placed on the market as soil additives or plant aids if content of total nutrients in the dry matter of more than (1.5% (N), 0.5% (P_2O_5), 0.75% (K_2O), 0.3% (S), 0.07% (Cu), 0.5% (Zn). Alternatively, in the case of basic constituents, a value of more than 30 per cent, expressed as CaO, is achieved. In addition, it is not possible if application recommendations based on the product would lead to an application of more than 50 kilograms of N, 30 kilograms of P_2O_5, 50 kilograms of K_2O, 500 kilograms of CaO or 15 kilograms of S per hectare in a single application. If **low production** prices are achieved and the additional **valorisation of feedstocks** are **accepted**, it will be **economically feasible** in Germany. I**ncreasing interest** in the topic in Germany with **start-ups focusing on biochar production**. **Main barrier: no barriers identified so far.**

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Table 21. Matrix of feasibility of ammonium phosphate on perlite

BBF: Ammonium phosphate on perlite. Pilot producing BBF: DE	
PFC/ CMC Category (Regulation EU 2019/1009) in which it could tentatively fit: Product Fertilizer Category (PFC) C.I. (a) (i) Straight solid inorganic macronutrient fertilizer; expected Component Material Categories (CMC) 10 derived products within the meaning of Reg. (EC) No. 1069/2009, or CMC 12 precipitated phosphate salts and derivatives; or CMC 15 Recovered nitrogen products	
Implementation feasibility in Belgium	There is **national P surplus** and product could only be exported, although **economic feasibility for exportation** is **negative**. **Main barrier: must be exported.**
Implementation feasibility in France	**Operationally** and **technically feasible. A specific documentation** (evaluated by the French sanitary security agency, ANSES) for its **authorization** is needed ("authorisation de mise en marché") and it can take up to **3 years to reach** the **market**.
Implementation feasibility in the Netherlands	There are **no technical, operative or legal issues** detected. Also, currently, there is **national P surplus** and product could only be exported, although **economic feasibility for exportation** is **negative**. **Main barrier: must be exported.**
Implementation feasibility in Spain	Feasibility of similar products (apatite on zeolites) produced with urban wastewater streams has been demonstrated. However, the **appropriateness** of the **feedstock** (animal manure) can hinder reaching the **market, social acceptance** and **certification** as fertilising product. In the regulatory framework there is a **category** in the Spanish Fertilising regulation (506/2013) for **perlite (group 7),** however it does not consider the added value given by its phosphorus content. **Main barrier: no barriers identified so far.**
Implementation feasibility in Germany	**Operationally** and **technically feasible** although process has to be optimized. Transport cost will be low due to production of solid material. Phosphate fertilizer sales have risen by 23 percent to 247 766 metric tons in 2021. NP fertilizers rose by almost 45 % to 151 479 metric tons (Industrieverband Agrar annual report 2020/2021). Import of P-rich fertiliser could be feasible in Germany. With optimized process conditions it will be **economically feasible** but it **must compete with traditional MAP fertilisers**. **Main barrier: optimization of process**

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Table 22. Matrix of feasibility of ammonium nitrate

BBF: Ammonium nitrate. Pilot producing BBF: BE, FR	
PFC/ CMC Category (Regulation EU 2019/1009) in which it could tentatively fit: Product Fertilizer Category (PFC) 1 C.I. (b) (i) Straight liquid inorganic macronutrient fertilizer; expected Component Material Categories (CMC) 10 derived products within the meaning of Reg. (EC) No. 1069/2009, or CMC 15 Recovered high purity materials	
Implementation feasibility in Belgium	Product **currently** regarded as **animal manure**, however, if **RENURE** is **accepted** and ammonium nitrate can be used as **substitute for mineral fertiliser**, then **operational and economic benefit can be expected**. For RENURE products 1-2 years might be needed for the acceptance of proposed criteria and their translation in the national legislation – once legal procedures are finalized, then the product can be marketed. **Main barrier:** needs to be **classified as RENURE** product.
Implementation feasibility in France	**Product already in the market,** thus, **economic feasibility** is **positive. Besides the adaptation to specific feedstock t**here is **no** major **operational or technical barrier if product is coming from gas washing. Legally it can be classified as NF U42-001-1/A1 product provided that N content is between 3 and 15%.** **Main barrier: no barriers identified so far.**
Implementation feasibility in the Netherlands	There are **no technical, operative or legal issues** detected. **Product is already in the market, and it has a very high value** thus, **economic feasibility** is **positive.** **Main barrier: no barriers identified so far.**
Implementation feasibility in Spain	Equivalent products are **already in the market**, although the appropriateness of the feedstock (animal manure) can hinder reaching the market, social acceptance and certification as fertilising product (**Group 06, Nitrogenous mineral fertiliser** according to the Spanish Royal Decree 506/2013), which can take up to 2-3 years in Spain. Regarding operational and technical issues, **technologies** for its production are already in the market in Spain and **technical feasibility** was demonstrated. **Infrastructure** in Spain exists but **not** usually implemented **in farms**.
Implementation feasibility in Germany	**Already in the market** as **mineral mono-nutrient fertilizer**. Has to have **minimum content of 20% N**. If the fertilizer contains more than 28% nitrogen, it may only be supplied to the user in closed packages. Leaching of nitrate to the ground water is a problem in Germany (17 % of the measuring points are above the threshold) therefore the interest of nitrate containing fertilisers is drastically decreasing. **Might be not economically feasible**. **Main barrier: no barriers identified so far** but **storage might be problematic** due to danger of explosion.

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Table 23. Matrix of feasibility of ammonium water

BBF: Ammonium water. Pilot producing BBF: BE, FR	
PFC/ CMC Category (Regulation EU 2019/1009) in which it could tentatively fit: Product Fertilizer Category (PFC) 1 C.I. (b) (i) Straight liquid inorganic macronutrient fertilizer; expected Component Material Categories (CMC) 10 derived products within the meaning of Reg. (EC) No. 1069/2009, or CMC 15 Recovered high purity materials	
Implementation feasibility in Belgium	Product is **not applicable on land** and it could **only** be used as **ingredient** mixing it with other BBFs. **Equivalent product** is already in the **market** used in **denox process** (flue gas NOx removal). **Main barrier**: **not applicable** in **agricultural** land.
Implementation feasibility in France	**Product already in the market,** thus, **economic feasibility** is **positive. Besides the adaptation to specific feedstock t**here is **no** major **operational or technical barrier if product is coming from gas washing. Legally it can be classified as NF U42-001-1/A1 product provided that N content is between 3 and 15%.** **Main barrier: no barriers identified so far.**
Implementation feasibility in the Netherlands	If **RENURE** is accepted as **substitute** for **mineral fertiliser** and not considered in nitrates directive as N supply it can be both **operational and economic benefit**. However, still, product quality needs to be improved. For RENURE products 1-2 years to arrive the market are estimated. **Main barrier:** needs to be **classified as RENURE** product.
Implementation feasibility in Spain	**Equivalent products are already in the market,** thus, **economic feasibility** is **positive. Legally** it can be **classified** as **ammonium rich solution** in the Spanish regulation (group 1.1- 01) if ammoniacal nitrogen accounts for the 20% of total N. **Main barrier: no barriers identified so far.**
Implementation feasibility in Germany	No information on the feasibility of product

Legend for the overall feasibility of products

Good	Moderate	Unlikely/Low	Possible if changes are made	Impossible for the listed reasons

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PART B: CELAC regulatory framework

6. Chilean regulation

Chile is located along the southwestern sector of America and has a diverse geography with more than 4,200 km in length, with a maximum width of 375 km and a minimum of 90 km. Of the total of 75.6 million hectares that continental Chile has, 31.6 million hectares are potential for agricultural, livestock and forestry use, including the surface of native forest, however, only 2,123,943 hectares are used due to restrictions both geographical and economic.

Another important issue to mention is that Chile is among the ten countries with the lowest levels of subsidies to the agricultural sector with 5.6% of the value of agricultural production, one of the lowest among the OECD countries, being 24% in United States, 26% in the European Union and more than 50% in Japan, Korea and other European countries such as Switzerland and Norway. The domestic prices of agricultural products are in line with international prices. The support to farmers is mainly oriented to small farmers and the direct contributions are aimed at improving productivity, competitiveness, recovery of degraded soils and the improvement of irrigation systems. The greatest share of government spending is done on general services related to the inspection and control of irrigation infrastructure and systems to support the development of new knowledge and innovation systems.

Chilean agriculture focuses its development on international markets, which forces producers to obtain high-quality and competitive products. In addition to low government support, Chilean agriculture and agribusiness has been forced to maintain a high degree of technological and management innovation to increase its competitiveness.

As the national market is very small and Chile has a high productive potential in the forestry and agricultural sector, which is great and diversified, a strategy of wide opening to international trade was chosen, unilaterally lowering the tariffs and signing free trade agreements with several countries.

Chile has twenty-eight trade agreements in force with sixty-four countries, distributed around the world, today 94% of exports are made under trade agreements.

Chile has been increasing the added value of agricultural and forestry products. The vast majority of primary exports correspond to the agricultural subsector, especially fresh fruit.

The agricultural policies promoted by the government consider the challenge of competitiveness and, therefore, support increasing investment in innovation, the expansion of efficient irrigation systems, defending the phytosanitary and animal health heritage, and promoting associativity, especially in medium and small producers.

Work has been done on the incorporation of new technologies such as telemetry and renewable energy, along with new practices such as infiltration and aquifer recharge, among other initiatives for the efficient use of resources.

Among the environmental management instruments to strengthen the sustainable management of natural resources, the Clean Production Agreements and the environmental impact assessment system (SEIA) stand out in Chile. Since the Clean Production Agreements began to operate in Chile (1999), a total of 44 agreements have been made in the agri-food sector, which

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include 4,793 companies. The certification of good agricultural practices of the GlobalGAP protocol is also one of the most implemented in the Chilean agri-food sector.

On the other hand, until 2020, the agricultural and forestry sector did not have an adequate regulatory framework for fertilizers to ensure their quality. It was difficult to have enough information for its use and the control by the SAG was not adequate either. The previous regulation started in 1981 (D.L. No. 3,557), which was replaced in 2011 by resolution No. 1035/10. (Ministerio de Agricultura de Chile, 2018). It was very important to regulate the fertilizer market since, according to ODEPA studies, they represent up to 30% of the production costs of some crops. Therefore, a new regulation was required that will update the requirements for its importation, commercialization, possession and distribution, covering not only its components but also other elements that represent a relationship with its quality. In addition, it was necessary to reduce information asymmetries regarding the essential elements for the development of a sustainable activity, and also comply with the different commitments acquired by Chile with the international community, and thus have OECD standard regulations.

The new Law No. 21,349 modified Decree Law No. 3,557, Establishes provisions on agricultural protection, Decree with Force of Law No. R.R.A. 25, of 1963, and Law No. 18,755, Establishes regulations on the Agricultural and Livestock Service, repeals Law No. 16,640 and other provisions. With the new Law No. 21,349, the Chilean regulation on fertilizers and biostimulants is modernized and updated, according to the needs of the productive sector, improving information for the farmer for decision-making, strengthening the powers of the SAG to adequate control and supervision of these inputs, all of which will contribute to the sustainable and competitive development of national agriculture. The Law No. 21,349 will enter into force on September 27, 2022.

6.1 LAW No. 21,349 on Fertilisers and Biostimulants

On June 9, 2021, a new **Law No. 21,349** was approved in Chile, which establishes rules on the composition, labeling and marketing of fertilizers and biostimulants, and which **begins to apply on September 27, 2022**. **Law No. 21,349** and its 4 resolutions (described below) were drafted using as a reference the **Regulation (EU) 2019/1009 of the European Parliament and of the Council**, because it is one of the most complete and updated international regulations.

6.1.1 Scope

This new regulation modernizes and updates the regulation Chilean for fertilizers and biostimulants, improving the information availability that is delivered to farmers who use these products, to support decision-making. The Livestock Agricultural Service (SAG) will be the entity in charge of supervising and ensuring compliance with this law, its regulations and other complementary provisions, and adopting the necessary measures for its application.

In addition, the faculties of SAG will be strengthened for its control and supervision, all of which will contribute to the sustainable and competitive development of national agriculture.

Law No. 21,349 is complemented by **four resolutions** that specifically describe four issues: i) labeling, ii) minimum content of nutritional elements and maximum contaminants, iii) tolerance ranges of laboratory results, and iv) control procedure and sampling of fertilizers and biostimulants. These resolutions have already been drafted and they are in the process of public consultation, which ends on February 7, 2022.

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The SAG gives two years for fertilizers and biostimulants stocks regularization according to the new requirements established by the Law No. 21,349 and its complementary resolutions. New products, whether imported or domestically manufactured, must comply with the all regulation.

For the purposes of this law, among other definitions, the following stand out:

Fertilizer: organic or inorganic material, of natural or synthetic origin. Fertilizers are used to facilitate the growth of plants, increase their yield and improve the quality of crops, some are used to modify the fertility of the soil or its physical, chemical or biological characteristics, or the nutrition of plants to apply them to the foliage. This concept includes amendments and fertilizers. They can also be classified as fertilizers with a heterogeneous composition, this means that they have a non-uniform conformation or combination of elements, or fertilizers with a homogeneous composition, that is, they have a standardized and uniform formulation that can be reproduced with identical characteristics.

Biostimulant: substance or mixture of substances or microorganisms, applicable to seeds, plants or rhizosphere, that stimulate the natural processes of plant nutrition, in order to improve the efficiency in the use of nutrients, tolerance to abiotic stress, quality attributes, or the availability of nutrients immobilized in the soil or in the rhizosphere.

According to the regulation and considering the additional and specific resolutions mentioned, fertilizers are classified into 6 groups and subgroups, which are named below:

GROUP 1. Organic fertilizers: are fertilizers of plant or animal origin that, after being transformed by the activity of microorganisms, result in a product rich in nutrients and organic carbon.

GROUP 2. Inorganic fertilizers classified in four subgroups:

Subgroup a. Inorganic fertilizer composed of a macronutrient.

Subgroup b. Inorganic fertilizer composed of more than one macronutrient.

Subgroup c. Inorganic fertilizer based on micronutrients, c.1.Fertilizer based on a chelated micronutrient.

Subgroup d. Fertilizer based on complexed nutrients.

GROUP 3. Organo-mineral fertilizer: referred to a co-formulation of one or more inorganic fertilizers with an organic fertilizer that provides nutrients for plants.

GROUP 4. Amendments: organic or inorganic compounds capable of modifying, improving or maintaining the physical, chemical or biological properties and characteristics of the soil. Includes two subgroups:

Subgroup a. Organic amendment.

Subgroup b. Inorganic amendment, b.1. Limestone Amendment.

GROUP 5. Substrates enriched with fertilizers.

GROUP 6. Specific action products intended to modify and facilitate soil fertility or its physical, chemical or biological characteristics. The subgroups are:

Subgroup a. Nitrification inhibitor.

Subgroup b. Denitrification inhibitor.

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Subgroup c. Urease inhibitor.

Plant biostimulants are classified into 2 groups: GROUP 1 which are Microbial biostimulants, that are biostimulants composed of a microorganism or group of microorganisms; and GROUP 2 of Non-Microbial biostimulants, which correspond to products that do not contain microorganisms in their composition, among them are considered: amino acids, carboxylic acids, humic and fulvic acids, algae extracts, cassava extracts, vitamins, enzymes, among others.

Considering the feedstocks and the general characteristics of FERTIMANURE's BBFs, most of the products could be categorized into the Group 1, Group 3, and Group 4 subgroup a. Besides, biostimulant obtained in FERTIMANURE belongs to Group 2 (Non-microbial).

6.1.2 Product requirements

As already mentioned, several requirements on the minimum content of nutritional elements and maximum content of contaminants have been established for the product categories above-mentioned in one of the additional resolutions considered in the law No. 21,349.

Table 24 summarizes those requirements established for each of the categories considered in the law. Additionally, the maximum limits for contaminants, pathogens and impurities for each group are detailed in Annex I, tables 1 to 11.

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Table 24. Summary of requirements for each of the cateogries.

Category and subcategories		Requeriments
1. Fertiliser:		
GROUP 1. Organic fertilizers: An organic fertilizer must contain organic carbon (Corg) and nutrients of exclusively organic origin.		An organic fertilizer must contain organic carbon (Corg) and nutrients of exclusively organic origin. Organic fertilizers will contain at least one of the following declared primary nutrients: nitrogen (N), phosphorus pentoxide (P_2O_5) or potassium oxide (K_2O). These nutrients will be present in the following minimum concentrations: · 1% total nitrogen (N), · 1% total phosphorous pentoxide (P_2O_5), or · 1% total potassium oxide (K_2O). · Organic carbon will be present in at least 5%. In case of presenting secondary macronutrients, you must declare them on the label or brochure.
GROUP 2. Inorganic fertilizers: Inorganic fertilizer is that material obtained through extraction or industrial procedures of a physical or chemical nature, whose declared nutrients are presented in mineral form.	**Subgroup a. Inorganic Fertilizer Composed of a Macronutrient.**	Inorganic fertilizers composed of a macronutrient must contain the following minimum concentration: · 5% total nitrogen (N), · 5% total phosphorus pentoxide (P_2O_5), · 3% total potassium oxide (K_2O), · 2% total magnesium oxide (MgO), · 6% total calcium oxide (CaO), · 5% total sulfur trioxide (SO_3), or · 1% total sodium oxide (Na_2O).

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	Subgroup b. Inorganic Fertilizer, Composed of more than one Macronutrient	Inorganic fertilizers composed of more than one macronutrient will contain two or more of the following macronutrients in the following minimum concentrations: · 1.5% of total nitrogen (N), · 1.5% total phosphorus pentoxide (P_2O_5), · 1.5% total potassium oxide (K_2O), · 0.75% total magnesium oxide (MgO), · 0.75% total calcium oxide (CaO), · 0.75% total sulfur trioxide (SO_3), or · 0.5% total sodium oxide (Na_2O).
	Subgroup c. Micronutrient-Based Inorganic Fertilizer	If an inorganic fertilizer contains only one declared micronutrient, this will be found in a minimum content of 2%. -In the case of a fertilizer composed of more than one micronutrient, the minimum content will be obtained from the sum of the concentrations of all the nutrients that make it up and will correspond to a value not less than 2%. The micronutrient-based fertilizer can be found in the form of salt, oxide, hydroxide, in aqueous solution or suspension. -If the declared water-soluble micronutrient is combined with chelating agents, this will represent 5% of the total weight/volume of the fertilizer. At least 50% of the water-soluble micronutrient must be chelated by a chelating agent.
	Subgroup d. Fertilizer based on Complex Nutrients	The declared water-soluble nutrient combined with a complexing agent will represent 5% of the total weight/volume of the fertilizer. · At least 50% of the declared water-soluble nutrient will be complexed by a complexing agent.

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GROUP 3. Organo-mineral fertilizer: An organo-mineral fertilizer is a co-formulation of one or more inorganic fertilizers with an organic fertilizer product whose main function is to provide nutrients for plants.		An organo-mineral fertilizer will contain at least one of the following declared primary nutrients: nitrogen (N), phosphorous pentoxide (P_2O_5) or potassium oxide (K_2O). These nutrients will be present in the following minimum concentrations: · 2% of total nitrogen (N), · 2% total phosphorous pentoxide (P_2O_5), or · 2% total potassium oxide (K_2O). · Organic carbon (C org) will be present in an organo-mineral fertilizer when less than 3%. In case of presenting secondary macronutrients, you must declare them on the label.
GROUP 4. Amendments: Amendments are defined as organic or inorganic matter capable of modifying, improving or protecting the physical, chemical or biological properties and characteristics of the soil.	**Subgroup a. Organic Amendment**	An organic amendment will contain 20% or more dry matter and at least 7.5% organic carbon (C org).
	Subgroup b. Inorganic Amendment	The molecule that performs corrective action, such as calcium oxide (CaO) or magnesium oxide (MgO) must be found in a minimum content of 5%. The following parameters determined in terms of mass of a limestone amendment shall be met: a) minimum neutralizing value: 15 (equivalent of CaO) or 9 (equivalent of HO-), and b) minimum granulometry: at least 70% < 1 mm, except in the case of quicklime, granulated limestone amendment and chalk (ie 70% of the content must be able to pass through a 1mm mesh sieve).

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GROUP 5. Substrates enriched with fertilizers: Substrates enriched with fertilizers are those substrates that are regulated by the Service through Resolution No. 558 of 1999 or another that the Service may issue and that have been enriched with fertilizers. These correspond to a different product of the soil present in situ whose function is to facilitate the anchoring of crops or fungi and allows them to grow and feed on it.		A fertilizer-enriched growing medium should contain at least one of the following declared nutrients: nitrogen (N), phosphorous pentoxide (P_2O_5) or potassium oxide (K_2O), magnesium oxide (MgO), calcium oxide (CaO), sulfur trioxide (SO3), sodium oxide (Na_2O), boron (B), cobalt (Co), copper (Cu), iron (Fe), manganese (Mn), molybdenum (Mo) or zinc (Zn). These nutrients will be present in the following minimum concentrations: · 1% total nitrogen (N), · 1% total phosphorous pentoxide (P_2O_5), or · 1% total potassium oxide (K_2O). · 0.75% total magnesium oxide (MgO), · 0.75% total calcium oxide (CaO), · 0.75% total sulfur trioxide (SO_3), or · 0.5% total sodium oxide (Na_2O). · If a substrate enriched with fertilizers contains exclusively a declared micronutrient, this will be found in a minimum content of 2%. Yes contains more than one, the minimum content will be obtained from the sum of the concentrations of all the micronutrients that make it up and will correspond to a value not less than 2%.
GROUP 6. Specific action products intended to modify and facilitate soil fertility or its physical, chemical or biological characteristics	**Subgroup a. Nitrification Inhibitor**	The performance of nitrification inhibitors will be measured by: a) the disappearance of ammoniacal nitrogen (NH_3-N), or b) by the sum of nitrites (NO_2-) and nitrates (NO_3-) that are produced with respect to time. Compared to a control sample to which the denitrification inhibitor has not been added, a sample with the nitrification inhibitor will show a 20% reduction in the oxidation rate of ammoniacal nitrogen (NH_3 -N) based on analysis performed 14 days after application with a confidence level of 95%.
	Subgroup b. Denitrification Inhibitor	The performance of denitrification inhibitors will be measured by comparing a control sample with a sample to which the denitrification inhibitor has been added. denitrification: The sample with the denitrification inhibitor will show a 20% reduction in the rate of nitrous oxide (N_2O) release based on analysis performed 14 days after application with a 95% confidence level.

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	Subgroup c. Urease inhibitor	The performance of urease inhibitors will be measured by comparing a control sample to a sample to which urease inhibitor has been added: The sample with the urease inhibitor will show a 20% reduction in the rate of hydrolysis of urea (CH_4N_2O) according to an analysis carried out 14 days after application with a confidence level of 95%.
2. Mixtures		
Mixtures: A mixture corresponds to a combination of two or more categories, groups or subgroups of fertilizers and/or biostimulants.		The mixture must comply with the nutrient content of the category (group/subgroup) component of the mixture that presents the lowest value. In the case of physical mixtures (heterogeneous), it must comply with the nutrient content of each of the fertilizers and biostimulants that compose it, as appropriate.

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6.2 Sanitary and phytosanitary requirements for fertilizing products (DS 16 /1963; DS 1150/2000)

In addition, fertilizers and biostimulants that are also composed of by-products of animal origin, humus, compost, enriched substrates or other fertilizers or biostimulants of organic origin, must be in order with the sanitary or phytosanitary requirements established by the other competent Divisions of the SAG (DS 16 /1963; DS 1150/2000) governed by the WTO Agreement and its Annexes and, in particular, the Agreement on the Application of Sanitary and Phytosanitary Measures)[9].

The SAG, through a well-founded resolution, must restrict or prohibit the import, manufacture, formulation, production, distribution, possession and marketing of fertilizers and biostimulants that constitute a risk to human, animal or plant health, and must maintain a public and updated file. with the detail of prohibited and restricted fertilizers and biostimulants. The SAG, through a resolution, will determine the information on prohibited and restricted fertilizers and biostimulants that the aforementioned file must contain.

The law establishes that there will be a Single National Registry, in which the producers, manufacturers, formulators, marketers, packers, importers and exporters of fertilizers and biostimulants, and those persons who, in the exercise of their activity, use them for purposes other than agricultural use, in accordance with the conditions and requirements established in the regulations.

In terms of composition and labeling, the law provides that packaged fertilizers and biostimulants must inform on their labels the percentage composition of the nutrient elements, when applicable, or other components, impurities or contaminants, as well as the quality parameters of their content and it is ideal form of use. In particular, they must indicate the solubility of the compound and granulometry, as appropriate, the origin and manufacturer, the date of import or date of manufacture or production in the country and the batch of the product, whether national or imported.

6.3 Law No. 20,089 Chilean Organic farming legislation

In relation to the use of fertilizers for organic agriculture, the **Law No. 20,089** related to the National Certification System for Organic Agricultural Products (2006) should be considered. This law aims to ensure and certify that organic products are produced, processed, packaged and handled in accordance with the standards of this law and its regulations. Also, the SAG is the competent authority to oversee compliance with this law and its complementary regulations.

The Chilean law of organic agriculture (Law No. 20,089/2006) indicates that the use of fertilizers must tend to maintain or increase soil fertility using a series of strategies such as incorporation of composted manure, use of green manures, establishment of rotations of crops and carry out a minimum tillage of the soil (DS No.17 SAG/2011).

By-products of livestock farming, such as composted manure, may be used in accordance with the criteria established in Annex A of this Law. The List 1 of Annex A indicates that the use of composted, dry, liquid, semi-liquid manure is permitted but the origin of intensive farming is prohibited.

[9] WTO Agreements series: Sanitary and Phytosanitary Measures

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To obtain the authorization of inputs for use in organic agriculture before the SAG, it must be ensured that the active substances treated by physical, chemical, biological/enzymatic and/or microbial processes and their substances (reagents or solvents) do not produce impurities that cause adverse effects, adverse human health, animals or the environment.

In the case of fertilizers and biostimulants authorized for use in organic agriculture, mentioned condition must be indicated on the label.

7. Argentinian regulation

Argentina is basically an agro-exporting country developing its economy based on the wealth of its natural resources. In Argentina until 1990, large areas of cereal and oilseed crops remained without carrying out a systematic fertilization plan to replenish the export of nutrients, this was done at the expense of the Pampean Region and Northwest (NOA) soils natural wealth. In 1996, the process of agricultural intensification began, basically based on soybean monoculture (soybeanization process). Thus, negative balances were registered in these soils in some macro and micronutrients, and it was necessary to reverse this situation. The current negative nutrient balances in some regions put the soil/plant relationship at risk, compromise the quality (fertility) of the soil, affect crop yields and severely threaten the sustainability of production systems. Fertilization is essential to sustain production, to maintain soil potential and guarantee food security.

In this context, the country has been enacting general specific legislation on the environmental issue since the new National Constitution (CN, 1994). Thus, Art. 41 of the CN establishes that *"It is the responsibility of the Nation to dictate the norms that contain the" minimum budgets "of protection, and to the provinces, those necessary to complement them, without the former altering the local jurisdictions"*. In this context, at the national level there are 10 laws of minimum budgets. Among them, for FERTIMANURE 3 of them are remarkable as they approach the issues in this context: i) Law 25,675 on the General Law of the Environment, ii) Law 25,688 on the Regime of Environmental Management of Water and iii) Law 25,831 on the Regime of Free Access to Environmental Public Information. In this general framework are located the specific laws described in next specific sections.

Regarding fertilizing products, inorganic fertilizers consumption in Argentina, in the year 2000 was 1.75 Mt and, in 2019 and 2020, 5.3 Mt, according to the Rosario Cereal Exchange. In both 2019 and 2020, this import of fertilizers meant an outlay of foreign exchange of about US$1.1 billion.

Since 2020, several efforts were being made to promote the enactment of the Law for the Promotion of the Use of Fertilizers in Extensive Crops in Argentina, which would allow the additional deduction in the annual settlement of Income Tax between 50% and 100% of the deductible amount for expenses for such supplies. Actually, it is not yet legislated. However, it is necessary to rebuild the current richest soil fertility, which run the risk of degradation.

Additionally, Argentina developed the legal framework related to its organic production system back in the 90ies by creating the Organic Production Control System. The qualification system of such control aims to be equivalent to the EU standards and it is roughly ruled by the National organic Law 25.127 and its modifications or complementary resolutions (Fuchshofen et al., 2017). The certification of the products under organic farming system are given Argencert S.A., Food

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Safety S.A., Letis S.A. and OIA S.A. (Organización Internacional Agropecuaria) and approved and supervised by SENASA. Overall, it can be stated that offer 75K hectares (Ha) crops are produced under organic production system while organic farming consists of almost 3 million of hectares.

7.1 National Law of Minimum Budgets for the Sustainable Management of Intensive and Concentrated Animal Production Systems (SICPA)

Since the end of 2020, Argentina has in parliamentary process the first national regulatory framework for livestock waste. Thus, it defines them appropriately and regulates their management and handling to protect the country's natural resources. The Honorable Chamber of Deputies of the Nation is in the process of promulgating the National Law of Minimum Budgets for the Sustainable Management of Intensive and Concentrated Animal Production Systems (SICPA). Intensive and Concentrated Animal Production Systems (SICPA) are understood as the procedures and / or activities aimed at the intensive production of animals, their products and by-products (meat, eggs, milk, hides, skins, feathers, hair, wool, etc. .), including aquatic animals, from a certain scale of production to be determined in the regulations of this law and developed in establishments where the process of feeding the animals is carried out directly, and where the waste, residues and effluents generated on the farm are concentrated.

Articles 3 and 22 are relevant to the FERTIMANURE Project and deal, the first one, on the treatment of effluents and waste. They indicate where and how adequate systems for permanent and sustainable treatment of effluents and residues should be available, through methods approved by the Enforcement Authority, in order to avoid all types of runoff, leaching or direct overturning, considering their adequate end provision.

Art 22 promotes agreements for training and scientific research, technological development and innovation. The Enforcement Authority will endeavor to sign agreements with the provinces, universities, institutes and research and development centers, with the Institute of Agricultural Technology (INTA), with the National Service of Agrifood Health and Quality (SENASA) and with other related organizations. , public or private, in order to coordinate their institutional participation for the dictation of training and / or updating courses and for the implementation of programs and projects of scientific research, technological development and innovation that allow to improve the techniques and procedures applicable to all the stages and processes of the Intensive and Concentrated Animal Production Systems (SICPA).

This Framework Law is an enormous advance for Argentina and an opportunity to promote projects such as FERTIMANURE and is in direct relationship with the provisions of the General Environmental Law (Law 25,675). In this way, by establishing this basic regulatory framework for environmental protection, the recovery of waste and effluents is being promoted at the national level and it is urged that the provincial governments complete it with their specific regulations, according to the natural and social conditions of each territory.

7.2 Law of Inspection of Fertilizers and Amendments (Law 20,466)

This law emanates from MINAGRI and control is carried out by SENASA, as explained in WP1 Deliverable 1.2, of the Argentine Report of FERTIMANURE project. In this context, it should be highlighted that all BBF's and TMF's products generated by FERTIMANURE and that are intended

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to be introduced for commercialization in Argentina, must be strictly governed by this Law on the Control of Fertilizers and Amendments, trying to consider the main articles that they are mentioned here below.

7.2.1 Scope

The Law specifies in its Article 1 that it regulates the production, import, export, possession, fractionation, distribution and sale of fertilizers and amendments, throughout the territory of the Republic, in order to assure the user of goodness and quality guaranteed of the same.

In Art. 3 it makes it clear that there must be an enforcement agency that will keep a register in which all those natural or legal persons who prepare, import, export, divide, sell and / or distribute fertilizers or amendments must be registered.

In Articles 4 and 8.- It is clearly specified that all fertilizers and amendments that are prepared, imported, divided, destined for sale or export, must be previously authorized by SENASA for the sole purpose of certifying their suitability for use as a fertilizer or amendment. In addition, they are responsible before the law for the accuracy of the declared contents and not to exceed the technical tolerances established by the regulations. In Art. 5 °. The products exhibited for sale must bear a printed label, written in Spanish and all the required information visible for reading. Art. 9 empowers SENASA to take samples to verify if what has been declared matches those that are being marketed.

It should be clarified also that this law was published in 1973 and it was complemented or modified in 19 posterior laws. Regulatory Decrees (DR) 4830/73 and 1624/80 are remarkable in this sense since some important modifications substituting some articles of Law 20,466 are established in them.

At this point, it is noteworthy that among the mentioned modifications, Regulatory Decree 1624/80 incorporates biological fertilizers for the first time within the regulations and defines them in its Article 3 as follows: "Biological fertilizers or biofertilizers are those that contain a microorganism or several as the main component, on a support and they are classified into two large groups according to their biostimulant action":

> 4.1- Nitrogen and/or phosphorus fixing bacteria.
>
> 4.2-Growth promoters (PGPR). As active ingredients in biological fertilizer formulations with growth-promoting activity, we find bacteria and fungi.

7.3 Resolution

7.3.1 Scope

This resolution generates and extends Law 20,466 to improve the regulation of the Regulation for the Registration of Fertilizers, Amendments, Substrates, Conditioners, Protectors and Raw Materials in the Argentine Republic and delegates the Enforcement Authority to SENASA.

In article I the law establishes the categorization of fertilising products in the Argentinian market together with the characteristics required for a fertiliser under each category to permit their registration.

In general terms, the fertilizing product categories considered in this law are the following:

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1) Fertilisers:

A – Inorganic fertiliser

B – Organo-mineral fertiliser

C - Organic fertiliser

D - Biologic fertiliser

E – Aminoacid based fertiliser

F – Fertilising products based on blood/bones/hoof flour

G – Physical mixtures

2) Amendments:

A – Inorganic amendment

B – Organic amendment

C - Biologic amendment

3) Growing media

4) Plant protective products

5) Soil conditioner:

A – Inorganic soil conditioner

B – Biologic soil conditioner

6) Products for pre-inoculation

7) Pre-inoculated products

Additionally, in Article 3 of the law, the National Registries of Laboratories for Biological Products, Pre-inoculating Plants and Mixing Plants (solid and liquid chemicals, organic, chemical-organic) are created, within the framework of the National Registry of Fertilizers, Amendments, Substrates , Conditioners, Protectors and Raw Materials dependent on the Directorate of Agrochemicals and Biologicals, of the National Directorate of Agrochemicals, Veterinary Products and Food of the National Service of Health and Food Quality (SENASA).

Art. 7 approves the type of registration form for biological products listed as Annex V, which is part of this resolution. Art. 8 and 9 approve the form for the registration of substrates (Annex VI) and inoculated products (Annex VII). Art. 10 and 11 Through Annex VIII and IX, approve the - product suitability forms and - the form for the certification of free sale of fertilizers, amendments, substrates, conditioners, protectants and raw materials.

It is important to highlight that the national or imported bagged merchandise that is in transit must have an identification where the generic name of the product is stated, which must remain attached to the pallet or container during the entire transport until its arrival at the warehouse (Art.

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14). Said identification must have the necessary strength to withstand wetting and stowage (plastic labels, stamps, stickers, etc.). Once in deposit, the individual identification of the product must be carried out with an approved label in accordance with the provisions of this resolution, if it is not already identified.

Very important to consider the prohibition of subsection 5- regarding the importation, for health reasons, of organic matter from manure or non-sterilized manure. Sterilization must be certified by the sanitary or phytosanitary authority of the country of origin, indicating the method used.

7.3.2 Product requirements

As already mentioned, several requirements on the minimum content of nutritional elements and maximum content of contaminants have been established for the product categories above-mentioned in the annex I of Resolution 264/2011, chapter 3.

The description and specific requirements for each of the categories mentioned are summarised in Table 25. Additionally, the maximum limits for contaminants, pathogens and impurities for each group are detailed in annex II, tables 12 and 13.

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Table 25. Summary of the fertilising product categories requirements in Argentinean regulation.

Product Category and subcategories		Requirements
1. Fertiliser:		
A. Inorganic fertiliser: An inorganic fertiliser shall contain a minimum Nitrogen-phosphorus-potassium content never lower than 12% (as a sum)		Complete information of N, P and K speciation, pH shall be required for the registration of product. Specific particle size distribution through granulometry is required for each form of fertiliser (granulated, on pearls or powder). Density and solubility shall be required for liquid fertilisers for foliar application. Contents of heavy metals might be required. Fertilisers based on ammonium nitrate shall be registered according to the decree 306/07 of national weapon registration. For compound fertilisers (NPK), except for treatments for seeds, a minimum content of the following elements shall be required: Ca (1%), Mg (0.5%), S (1%), Bo (0.02%), Cl (0.1%), Co (0.0005%), Cu (0.05%); Fe (0.1%), Mn (0.05%), Mo (0.0005%), Zn (0.05%), Na (0.1%).
	Solid inorganic fertiliser:	Granulometry for granulated fertilisers or in pearl: 80% in fraction 0.84-3.36mm and <2% in fraction <0.84mm. Granulometry for fertilisers in powder: 80% in fraction 0.07-0.50mm and <2% in fraction <0.07mm. For solid foliar fertilisers a biuret content <0.06% shall be required. Foliar fertilisers shall not contain Cr (VI) and free chlorine.
	Liquid inorganic fertiliser:	For liquid foliar fertilisers a biuret content <0.04% shall be required. Foliar fertilisers shall not contain Cr (VI) and free chlorine.
B. Organo-mineral fertiliser: An organo-mineral fertiliser shall contain a minimum content of primary macronutrients never lower than 12% (as a sum) and an organic matter content never lower than 15% (fresh basis) for solid products and 8% (fresh basis) for liquid products.		Those fertilising products containing secondary elements or micronutrients a minimum content of the following elements shall be required: Ca (1%), Mg (0.5%), S (1%), Bo (0.02%), Cl (0.1%), Co (0.0005%), Cu (0.05%); Fe (0.1%), Mn (0.05%), Mo (0.0005%), Zn (0.05%), Na (0.1%).

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C. Organic fertiliser: An organic fertiliser shall contain a minimum content of primary macronutrients never lower than 6% (as a sum) and a C/N below 20/1.	The content (in percentage of product) of the organic materials used for the product formulation shall be specified. Complete information of N, P and K speciation, organic matter, ash content, moisture content, C/N, content of humic and fulvic acids, pH shall be required for the registration of product. Density and solubility shall be required for liquid fertilisers for foliar application. Contents of heavy metals might be required. For those products including organic materials from animal origin sanitisation of product shall be guaranteed by pathogens limits: Salmonella sp:<1 in 4g (dry weight) and faecal coliforms: 1000UFC/g (dry weight). Organic fertilisers shall not contain Cr (VI) and free chlorine.
D. Biologic fertiliser: A biologic fertiliser shall contain one or various microorganisms and principal component.	Safety of products should be guaranteed and in the case of non-traditional strains, strain identification via PCR shall be required for its registration. Expiration of product shall be 6-18 months. Specific requirements for products based on Rhizobium and Bradyrhizombium: 1 x 10^8 cfu/ml or g at expiration date and nodulation yield >80%. Specific requirements for products based on Azospirillum: 1 x 10^7 cfu/ml or g at expiration date.
E. Aminoacid based fertiliser: aminoacids shall be in L-form	Extraction process/methodology and feedstocks of vegetal or animal origin used in the production of the process shall be specified. Specification of analytical methodology and aminogram shall be provided. Those products enriched with chemicals or organic materials should comply with the categories B and C.
F. Fertilising products based on blood/bones/hoof flour:	Products should comply with the categories B and C. Certificate of the provision of feedstocks shall be provided and annually renewed.

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G. Physical mixtures (inorganic. Organo-mineral or organic):	Products should comply with the categories A, B and C in each case. Granulometry for granulated fertilisers: 80% in fraction 0.84-3.36mm and <2% in fraction <0.84mm. Granulometry for fertilisers in powder: 80% in fraction 0.07-0.50mm and <2% in fraction <0.07mm. For those products containing organic or organo-mineral ingredients the content (in percentage of product) of the organic materials used for the product formulation shall be specified. For those products including organic materials from animal origin sanitisation of product shall be guaranteed by pathogens limits: Salmonella sp:<1 in 4g (dry weight) and faecal coliforms: 1000UFC/g (dry weight).

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2) Soil amendments		
A. Inorganic soil amendments		Content (in percentage of product) of the inorganic compounds used for the product formulation shall be specified. Granulometry for granulated amendments or in pearls: 80% in fraction 0.84-3.36mm and <2% in fraction <0.84mm. Granulometry for fertilisers in powder: 80% in fraction 0.074-0.50mm and <2% in fraction >0.84mm and <2% in fraction <0.071mm. Contents of heavy metals might be required. For calcium sulphate based products, specific requirements of products are the following: 85%
B. Organic soil amendments		
	Compost	Content (in percentage of product) of the feedstocks used for the product formulation shall be specified. Complete information of organic matter, ash content, moisture content, C/N, content of humic and fulvic acids, pH, electrical conductivity (for products with CE>4mS/cm restriction of use shall be required), total nitrogen content shall be required for the registration of product. Sanitisation of product shall be guaranteed by pathogens limits: Salmonella sp:<1 in 4g (dry weight) and faecal coliforms: <1000UFC/g (dry weight), helminth ova <1 egg/4 g (dry weight). Contaminants limits values: Cd:3mg/kg dry matter, Cr: 270 mg/Kg dry matter, Hg:5m/g dry matter, Ni:120 mg/Kg dry matter, Pb:150 mg/kg dry matter, Cu:450 mg/kg dry matter, Zn:1100 mg/kg dry matter.
	Vermi-compounds	Content (in percentage of product) of the feedstocks used for the product formulation shall be specified. Complete information of organic matter, ash content, moisture content (must be <45%), C/N, pH (must be in the range of 6.8-7.2), electrical conductivity shall be required for the registration of product. Sanitisation of product shall be guaranteed by pathogens limits: Salmonella sp.:<1 in 4g (dry weight) and faecal coliforms: <1000UFC/g (dry weight), helminth ova <1 egg/4 g (dry weight). Contaminants limits values: Cd:3mg/kg dry matter, Cr: 270 mg/Kg

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		dry matter, Hg:5m/g dry matter, Ni:120 mg/Kg dry matter, Pb:150 mg/kg dry matter, Cu:450 mg/kg dry matter, Zn:1100 mg/kg dry matter.
	Peat	Complete information of organic matter, ash content, moisture content, pH, electrical conductivity (must be < 1.5mS/cm) shall be required for the registration of product. 4 peat products are classified according to their pH: • Acid peat with pH 3-5 • Moderately acid peat with pH 5-6 • Neutral peat with pH 6-7.5 • Alkaline peat with pH > 7.5 3 types of peat are classified according to their morphology: black peat, white peat, mixed peat. Specific granulometry fractions are required for the different type of fibres present in the peat.
C. Biologic soil amendments: A biologic amendment shall contain one or various microorganisms in the production process of compost and are able to enhance the decomposition of organic matter in the soil.		Complete information of genus and species, certification of the strain provision, identification of the strain via PCR or similar, methodology of analysis and indications for its use shall be required for the registration of product.
3) Growing media: defined as any solid material not defined as soil, either natural, mineral or organic or synthetic that might be used in a container alone or in mixture allowing the attachment of plant roots.		
Growing media		Complete information and limits on the following parameters shall be provided and guaranteed for their registration: moisture content (must be 40-55%), ash content, organic matter content, granulometry (80% in fraction 2-5mm), water holding capacity, pH (must be 5.8-6.3), presence of pathogens (coliforms, salmonella, helminth ova, etc.). They must not contain any plant propagules or inert material (glass, metals, plastic, etc.).
4) Plant protective products: defined as those products that when applied are able to protect the seed/plant from other microorganisms that might be present in biological fertiliser.		
Plant protective products		Complete information on the laboratory analysis conducted, specific seeds and inoculum targeted by the products, methodology of analysis and indications for its use.

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5) Soil conditioner:	
Inorganic: defined as those mineral substances able to positively change the agronomic efficiency by improving the physic-chemical properties of a soil, crop and/or a product.	Qualitative and quantitative composition shall be provided in the product specifications for product registration. Bibliographic information on the active substance shall be facilitated.
Biologic: defined as substances that contain microorganisms that are able to positively change the agronomic efficiency by improving the physic-chemical properties of a soil, crop and/or a product.	Complete information of genus and species, certification of the strain provision, identification of the strain via PCR or similar, methodology of analysis and indications for its use shall be required for the registration of product.
6) Products for pre-inoculation: defined as those products that when are applied to a certain seed are able to maintain the viability of the microorganisms present in an inoculum for a certain period of time.	
Products for pre-inoculation	The information required for its registration is the following: complete composition of the product, viability of inoculum in the seed, methodology of analysis and indications for its use. Also, for laboratory analysis seed and inoculum shall be facilitated.
7) Pre-inoculated products	
Pre-inoculated products	The information required for its registration is the following: information of the microorganism (inscription number of inoculum in SENASA), conditions for its storage, equipment and process followed during production, inscription number in SENASA in the case of fungicide/pesticide. For coated seeds, the compounds included in the coating shall be specified.

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7.4 Joint Resolution 01/2019 on COMPOST and 19/19 on Digestate from SENASA Enforcement Agency 'Ministry of Agriculture, Livestock and Fisheries of the Nation' (MINAGRI)

Besides the regulation already mentioned, although not directly on fertilizing products, the laws establishing the rules for the use of compost and digestates may be also important to be considered in the framework of Argentina for the products obtained in FERTIMANURE project.

In this context, protected by the precepts of the General Environmental Law No. 25,675, some specific laws were established: i) the Law of Integral Management of Household Waste No. 25,916, ii) the Law of Integral Management of Urban Solid Waste No. 25916/2003 (ENGIRSU), and iii) the Law of Integral Management of Industrial Waste and Service Activities No. 25,612.

In one hand, given the greater demand for the compost product, it was necessary to update and expand the requirements and controls for the marketing of compost and on these foundations. Thus, the Normative Framework of National Reference for Production, Record and Application of Compost was responsible on developing, as a result of the inter-institutional agreement, the Joint Resolution 1/2019 on Compost.

This law aims to recognise composting as a simple, economical and highly efficient technology for the recovery of organic waste from feedstocks including also those resulting from the productive activity of the agricultural and agro-industrial sector, thus manure would be also considered in this law. Also, this rule establishes the requirements on the characteristics of composts, considering content of nutrients and toxic pollutants, and microbial, stability and maturity criteria (annex II, tables 14 to 18). Finally, it classifies compost into different categories.

In the other hand, with the same legal grounds as Resolution 01/19 on compost, Resolution 19/19 on digestate was formulated. The aim of this resolution was *"to promote the agronomic valorization of the digest due to its nutrient content and other intrinsic properties that make it potentially beneficial for soils and crops, protecting the health of people, animals and the environment"*. By means of this resolution, the technical aspects for the elaboration and application of the by-products that are generated in the anaerobic biodigesters were established (annex II, table 19). Besides that, the resolution determines the quality parameters that must be satisfied in the digestate, as well as the requirements and restrictions for its application. It should be highlighted that currently, in Argentina, digestate cannot be marketed and must be disposed of within the establishments where they were generated.

8. Conclusions

- The European Union (EU) regulations regarding nutrients provide guidance and legislation over a broad spectrum, including marketable nutrients and their use in crop and livestock farming, animal manure and organic waste treatment, water and air pollution, the treatment of food waste, wastewater treatment plants and end-of-waste as well as secondary raw materials. **Nitrate Directive, ABP Regulation and particularly Fertilizers Regulation are the main regulations impacting to project**

- **Nitrate Directive sets the rules 91/676/EEC** to sustainably protect ground and surface waters from pollution with nitrogen (nitrate) originating from agriculture.

- ABP regulation, Regulation (EC) 1069/2009 sets the rules for handling, collecting, processing and trading of animal by-products, defining ABP categories. Manure is classified into category 2.

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- In EU regulation, products used to improve plant growth are referred to as “fertilising products” Nitrogen, phosphorous and potassium are the most common fertilisers used to improve plant growth. In 2003, Fertilisers **Regulation (EC) No 2003/2003** came into force and aimed to ensure an internal market for free trade of fertilisers.

- **The Regulation (EC) 2003/2003 will be repealed by the Regulation (EU) 2019/1009** to **allow harmonisation between the Member States** by having a compliance criterion that sets out the safety and quality specifications required for a product to be on the free market.

- The new fertiliser **Regulation (EU) 2019/1009** improve several aspects from the old Regulation 2003/2003. The most remarkable change between 2003 and 2019 is the harmonisation of alternative fertiliser products (including not only mineral/inorganic fertilisers but also soil improvers, inhibitors, plant biostimulants, growing media or blends), however other important changes in requirements, market, obligations of manufacturers, importers and distributors, packaging, and compliance, among others, are also set.

- **National regulatory framework** for each Fertimanure’ participating countries is addressed showing specific regulations and rules for each country. National legislation within the Member States covers fertilisers that, until now, were not covered under EU fertilizer Regulation.

- The 2019/1009 regulation is intended to bridge the gaps between EU and national legislation. While the many Member States can continue to enforce their existing national legislation, the 2019/1009 regulation could reduce the need for additional national legislation and an increased harmonisation across the EU.

- In Chile, the proposals made by Decree-Law 3557 on fertilisers which are in its first constitutional process of the Chamber of Deputies, give the SAG more extraordinary powers to inspect and control the quality of fertilisers throughout the entire marketing process. Having relevant product information on the packaging will allow farmers to decide when purchasing fertilisers to yield the best results and therefore have better quality fertilisers and labels with the necessary technical information available.

- Law No. 21,349 and its four resolutions in Chile were drafted using Regulation (EU) 2019/1009 of the European Parliament and of the Council as a reference. According to that regulation, the BBFs fertilizers developed by Fertimanure could be marketed in compliance with the regulations on organic fertilizers and organic biostimulants. Besides, the BBFs could enter the Chilean market of organic agriculture, however, the restriction of prohibition of the use of fertilizers from manure from intensive farming should be considered.

- In Argentina, the national legal framework is generic regarding environmental impact. No general regulations at the national or provincial level exist when it comes to managing intensive animal production, and there is no law concerning the handling of excreta and slurry. Municipal regulations dictate the rules for the authorisation of livestock activities. The framework laws in process (SICPA) and the one already enacted (Climate Change) allow for national ordering of the management and handling of livestock excreta and are a very important advance in this matter for Argentina. Based on this legislation, it is being possible to stimulate producers and companies in the agricultural sector to make a valuation of animal excreta, mainly, using technologies such as composting and / or anaerobic digestion and include them within the framework of the law.

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- Sometimes a disparity of normative criteria is generated within the same province in Argentina due to the fact that there is an overlap of regulations between different national and provincial organisms. It would be necessary to join efforts to achieve points of agreement or coincidence.

- The Regulations on Fertilizers and Amendments and the creation of the 2 key standards for the recycling of Livestock Waste Resolutions 01/19 and 19/19) are rapidly contributing to stimulate producers and companies to make investments to use and / or sell by-products valued for reinjected in the rural sector. Argentina is including in its new legislation and generating public policies to strongly stimulate the recycling of livestock excreta.

- Overall, In Argentina, FERTIMANURE project has great possibilities to introduce its technologies to reconvert these residues and livestock effluents into inorganic fertilizers and amendments. Moreover, it shows a huge opportunity to register and commercialize its products, namely, BBF's and TMF's, and seem to have potential for a huge demand ahead of it in agro-ecological and other organic crops. Besides, there seems to be a business opportunity niche for the FERTIMANURE Project, through the possibility of installing pilot plant models such as those that are being successfully developed in the EU.

- The need for sustainable agriculture is becoming more apparent due to climate change, and therefore a shift to sustainable and better-quality fertilisers is needed. These new laws and regulations in the EU, Argentina and Chile, where specific toxic contaminants are banned and proper labelling of products is mandatory, will enable farmers to make better-informed decisions on which fertilisers to use on their land.

9. Recommendations

This deliver establishes the framework and the basis for FERTIMANURE project to work towards providing clear evidence-based information regarding the quality and performance of the different end-products obtained to assure their market uptake.

The regulations analysed in this Deliverable harmonises standards for the fertilisers produced from organic or secondary raw materials in Europe and in the CELAC regions participating in the project, establishing the limits for a range of contaminants contained in fertilising products. According to the new FPR, EU fertilising products bearing the “CE marking” will have to fulfil certain requirements to benefit from free circulation in the EU's global market. These requirements will include obligatory maximum contaminant levels, the use of defined component material categories and labelling requirements. Those fertilising products that do not bear the CE marking will still have the possibility of placing them on their national market, that is why this Deliverable has also provide an analysis of Member State regulations and a matrix of feasibility of the 19 FERTIMANURE BBFs considering both, national and EU markets.

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Annexes

ANNEX I- CHILEAN REGULATION

Below are shown the maximum limits for contaminants and impurities according to Regulation that establishes minimum content of elements nutritional, and maximum content of contaminant elements in fertilizers and biostimulants and repeals resolutions that indicates (Regulation of LAW No. 21,349).

GROUP 1. Organic fertilizers

Table 26. Pathogens level

PARAMETER		PROCESS	LIMIT VALUE
I.	*Salmonella sp.*	uninformed	Absence in 25 g or 25 ml
II.	*Escherichia coli*	uninformed	1000 CFU in 1 g or 1 ml
III.	Fecal coliforms	uninformed	< 1.000 MPN per g, on dry base
IV.	Variable helminth eggs (1)	uninformed	< 1 in 4 g, on dry base

(1): It will only be required for materials whose composition contains by-products of origin

Table 27. Maximum limits for contaminants and impurities

Contaminants	Total content in mg/kg or ppm
Cd	1,5
Cr	70
Cr hexavalent	2
Hg	1
Ni	50
Pb	120

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As	30
Cu	300
Zn	800

GROUP 2. Inorganic fertilizers

Table 28. Maximum limits for contaminants and impurities

Contaminants	**Total content in mg/kg or ppm**
Cd (P_2O_5 > 5%)	3
Cd (P_2O_5 5,1% to 10%)	10
Cd (P_2O_5 10,1% to 20%)	20
Cd (P_2O_5 20,1% to 30%)	30
Cd (P_2O_5 30,1% to 40%)	40
Cd (P_2O_5 40,1% to 50%)	50
Cd (P_2O_5 > 50%)	60
Cr	70
Cr hexavalent	2
Hg	1
Ni	100
Pb	120
As	40
Cu	600
Zn	1500

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GROUP 3. Organo-mineral fertilizers

Table 29. Pathogens level

PARAMETER		PROCESS	LIMIT VALUE
I.	*Salmonella sp.*	uninformed	Absence in 25 g or 25 ml
II.	*Escherichia coli*	uninformed	1000 CFU in 1 g or 1 ml

Table 30. Maximum limits for contaminants and impurities

Contaminants	Total content in mg/kg or ppm
Cd (P_2O_5 > 5%)	3
Cd (P_2O_5 5,1% to 10%)	10
Cd (P_2O_5 10,1% to 20%)	20
Cd (P_2O_5 20,1% to 30%)	30
Cd (P_2O_5 30,1% to 40%)	40
Cd (P_2O_5 40,1% to 50%)	50
Cd (P2O5 > 50%)	60
Cr	70
Cr hexavalent	2
Hg	1
Ni	100
Pb	120
As	40
Cu	600
Zn	1500

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GROUP 4. Amendments

Table 31. Pathogens level for organic amendments

PARAMETER		PROCESS	LIMIT VALUE
I.	*Salmonella sp.*	uninformed	Absence in 25 g or 25 ml
II.	*Escherichia coli*	uninformed	1000 CFU in 1 g or 1 ml
III.	Fecal coliforms	uninformed	< 1.000 MPN per g, on dry base
IV.	Variable helminth eggs (1)	uninformed	< 1 in 4 g, on dry base

Table 32. Maximum limits for contaminants and impurities

Contaminants	Total content in mg/kg or ppm
Cd	2
Cr	70
Cr hexavalent	2
Hg	1
Ni	100
Pb	120
As	30
Cu	300
Zn	800

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Table 33. Maximum limits for contaminants and impurities

Contaminants	Total content in mg/kg or ppm
Cd (P_2O_5 > 5%)	3
Cd (P_2O_5 5,1% to 10%)	10
Cd (P_2O_5 10,1% to 20%)	20
Cd (P_2O_5 20,1% to 30%)	30
Cd (P_2O_5 30,1% to 40%)	40
Cd (P_2O_5 40,1% to 50%)	50
Cd (P_2O_5 > 50%)	60
Cr	70
Cr hexavalent	2
Hg	1
Ni	100
Pb	120
As	30
Cu	600
Zn	1500

Biostimulants

Table 34. Pathogens level for Microbial Plant Biostimulant

PARAMETER		PROCESS	LIMIT VALUE
I.	*Salmonella spp.*	uninformed	Absence in 25 g or 25 ml
II.	*Escherichia coli*	uninformed	1000 CFU in 1 g or 1 ml
III.	*Listeria monocitogenes*	uninformed	Absence in 25 g or 25 ml

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IV.	*Vibrio spp.*	uninformed	Absence in 25 g or 25 ml
V.	*Shigella spp.*	uninformed	Absence in 25 g or 25 ml
VI.	*Staphylococcusaureus*	uninformed	Absence in 25 g or 25 ml
VII.	*Enterococos*	uninformed	10 CFU/g
VIII.	*Recuento anaeróbico de placas, salvo que el bioestimulante microbiano sea una bacteria aerobia.*	uninformed	10^5 CFU/g o ml
IX.	*Recuento de levaduras y mohos, salvo que el bioestimulante microbiano sea un hongo.*	uninformed	1000 CFU/g o ml

Table 35. Pathogens level for Non-Microbial Plant Biostimulant

PARAMETER		**PROCESS**	**LIMIT VALUE**
I.	*Salmonella sp.*	uninformed	Absence in 25 g or 25 ml
II.	*Escherichia coli*	uninformed	1000 CFU in 1 g or 1 ml

Table 36. Maximum limits for contaminants and impurities

Contaminants	**Total content in mg/kg or ppm**
Cd	1,5

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Cr	70
Cr hexavalent	2
Hg	1
Ni	50
Pb	120
As	40
Cu	600
Zn	800

Mixtures

The mixture must not exceed the content of contaminants and impurities of the category of the component of the mixture that presents the highest value. In the case of physical mixtures (heterogeneous), it must not exceed the content of contaminants and impurities of each of the fertilizers and biostimulants that compose it.

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ANNEX II- ARGENTINA LEGISLATION

Table 37. Minimum content of micronutrients in compound fertilisers

Element	Minimum content on compound fertilisers (in %)
Calcium	1.0%
Magnesium	0.5%
Sulphur	1.0%
Boron	0.02%
Clorine	0.1%
Cobalt	0.0005%
Copper	0.05%
Iron	0.1%
Manganese	0.0005%
Zink	0.05%
Sodium	0.1%

Table 38. Maximum limits for contaminants and impurities in compost

Contaminants	Total content in mg/kg or ppm
Cd	3
Cr	270
Hg	5
Ni	120
Pb	150
Cu	450
Zn	1100

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JOINT RESOLUTION 1/19 (COMPOST). Enforcement Agency MINAGRI-SENASA

Table 39. Pathogens level

PARAMETER	PROCESS	LIMIT VALUE
I. Fecal coliforms	Open systems ≥55°C,15 days with at least 5 volts	<1000 NMP per gram of compost, on a dry basis
II. Salmonella sp.	≥ 55°C, 3 consecutive days with coverage that ensures temperature on the surface of the battery	<1 NMP/ 4 grams of compost on dry basis;
III. Ascaris lumbricoides	Closed systems ≥ 60°, 7 days	< 1 viable egg of Ascaris in 4g of compost on dry base

For the compost where the process can be certified, it is required to comply with I) or I) and not II). In the case of compost where the process cannot be certified, it is required to comply with I), I I) and III).

Table 40. Stability and maturity indicators

Stability indicators (At least one indicator of each group should be measured)		
INDICATOR		**VALUE**
Group I	Water soluble C (CSA)	< 10 g/kg
	CSA/N total	≤ 0.7
Group II	CO_2 production	< 120 mg of CO_2 /kg.h
	Solvita Test	≥ 5 for CO_2
	Static Respirometric Index (SRI)	≤ 0.5 mg O_2/g MO.h
	Dynamic Respirometric Index (IRD)	≤ 1 mg O_2/g MO.h
Maturity indicators (At least two indicators should be measured, one of which should be the germination index)		
Ammonium ($N\text{-}NH_4^+$)		< 400 mg $N\text{-}NH_4^+$/kg

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Ammonium ratio: nitrate (N-NH $^{+/N-NO}$)	< 0.3
Germination rate using two species	> 60% (perennial or annual ryegrass, tomato, radish, barley, wheat, lettuce, or watercress (*Lepidium sativum)*
Solvita Test	≥ 4 for NH_3

Table 41. Quality parameters

PARAMETERS	**COMPOST CLASS A**	**COMPOST CLASS B**
pH	5.0 – 8.5	
Odours	No unpleasant odours	
Humidity (H%)	< 60	
Electrical Conductivity (EC dS/m)	<4	<6
C/N ratio (%)	≤20	< 30
Organic matter (MO %)	≥20	
Potentially toxic elements (mg/kg DM)		
Cadmium	1.5	3
Copper	150	450
Total Chrome	100	270
Mercury	0.7	5
Nickel	30	120
Lead	100	150
Zinc	300	1100
Arsenic	15	30

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Table 42. Quantity of inert materials ≤ 16mm allowed in compost

MATERIAL	DIMENSION (mm)	QUANTITY (% DM)
Flexible plastics and/or films	>4	≤5
Stones and/or soil clods	>4	≤5
Glass and/or metals and/or rubber and/or hard plastics	≥2	≤0.5

a) Inert materials of a size greater than 16 mm are not allowed in any kind of compost.

b) For all classes of compost, the tolerance of impurities of size less than or equal to 16 mm must not exceed the values indicated in Table No. 4.

Table 43. Recommended limit values for the amounts of EPT that can be introduced into soils annually (kg/ha. Year) and maximum load allowed in 10 years (kg/ha)

TOXIC ELEMENTS	LIMIT VALUE (kg/ha.year)	MAXIMUM LOAD ALLOWED (kg/ha)
Cadmium	0.15	0.5
Copper	12	40
Chrome	3	10
Mercury	0.1	0.3
Nickel	3	10
Lead	15	50
Zinc	30	100
Arsenic	0.5	1.8

The ANNUAL DOSE OF EPT LOAD to be added to a soil is calculated according to the concentration of EPT in compost and the limit value of EPT (Table No. 6), according to the following procedure:

a) The content of EPT in the compost to be applied is analysed;

b) The ANNUAL EFA LOAD DOSE to be added for each of the elements is calculated using the following formula: **DACE = (NL x 1,000) / C**

Where:

DACE: Annual Load Dose of EPT on a dry weight basis expressed in Tn/ha.year

LV (limit value): Amount of PTEs for compound "n" expressed in kg/ha.year (Table 6) C: Concentration of element "n" in compost expressed in mg/kg (dry matter basis) 1,000: Conversion factor

c) The ANNUAL EFA LOAD DOSE to be applied is the lowest of those calculated in the previous stage;

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d) To calculate the REAL DOSE OF COMPOST (at its natural humidity) to be applied, the ANNUAL DOSE OF EPT LOAD must be converted to dry base considering the humidity content of the compost to be used according to the following formula:

DRC = (DACE x 100) / MS

Where:

DRC: Royal Dose of Compost in Tn/ha.year

DACE: Annual Load Dose of EPT dry weight base

MS: Percentage of dry matter in the compost to be used

Joint Resolution 19/19 (Anaerobic Digests). Enforcement Agency 'Ministerio de Ambiente y Desarrollo Sustentable (MAyDS)'

Table 44. Concentration of Potentially Toxic Elements in Soils for digestate application

PARAMETER	REFERENCE VALUE (mg/kg DM)	
	pH<7	pH >7
Arsenic	15	20
Cadmium	1	3
Zinc	150	450
Copper	50	210
Total Chrome	100	150
Mercury	1	1.5
Nickel	30	112
Lead	50	300

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References

1. Kübler-Ross, E. (with Byock, I.). (2014). *On death & dying: What the dying have to teach doctors, nurses, clergy & their own families* (50th anniversary ed.). Scribner. (Original work published 1969)

2. Lyons, D. (2009, June 15). Don't 'iTune' us: It's geeks versus writers. Guess who's winning. *Newsweek*, 153(24), 27.

3. A sustainable bioeconomy for Europe: Strengthening the connection between economy, society and the environment: updated bioeconomy.

4. A new Circular Economy Action Plan COM(2020) 98 final. https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1583933814386&uri=COM:2020:98:FIN

5. Council Directive 91/676/EEC of 12 December 1991 concerning the protection of waters against pollution caused by nitrates from agricultural sources. https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:31991L0676&from=EN

6. REGULATION (EC) No 1069/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009. https://eur-lex.europa.eu/eli/reg/2009/1069/2019-12-14

7. Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers. https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32003R2003.

8. REGULATION (EU) 2019/1009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 June 2019. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32019R1009

9. COMMISSION REGULATION (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2011.054.01.0001.01.ENG

10. Röld & Partner Changes to harmonize EU fertilizer legislation: The new Regulation (EU) No. 2019/1009 11 november 2020 https://www.roedl.com/insights/life-sciences-law/eu-regulation-20191009-fertiliser-legislation-manufacturer-traceability-enterprise.

11. NUTRIMAN - NUTRIent MANagement and Nutrient Recovery Thematic Network The new fertiliser regulation – consequences for farmers 16 september 2019 . https://nutriman.net/news/new-fertiliser-regulation-consequences-farmers

This project has received funding from
the EU Horizon 2020 Research and Innovation Programme
under grant agreement No. 862849

12. FAO. (2017). *El futuro de la alimentación y la agricultura: tendencias y desafío.*

13. Ministerio de Agricultura de Chile. (2018). *Proyecto que establece normas de composición etiquetado y comercialización de los fertilizantes-Informe de Productividad.*

14. Ministerio del Medio Ambiente. (2016). *Tercera Comunicación Nacional de Chile ante la Convención Marco de las Naciones Unidas sobre Cambio Climático.*

15. Oficina de Estudios y Políticas Agrarias ODEPA. (2019). *Panorama de la Agricultura Chilena.*

16. Fuchshofen, N., Hirsch, D., Brodtmann, L. I., & Terlau, W. (2017). Importance of Organic Agriculture and Food in Argentina: An Explorative Analysis of the Domestic Situation and its Regional Context.

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FERTIMANURE

FERTIMANURE

INNOVATIVE NUTRIENT RECOVERY FROM SECONDARY SOURCES-PRODUCTION OF HIGH-ADDED VALUE FERTILISERS FROM ANIMAL MANURE

PROJECT COORDINATOR

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CONSORTIUM

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Wageningen Environmental Research (The Netherlands)
University of Milan (Italy)
Leitat (Spain)
GreenWin (Belgium)
European Landowners Organisation (Belgium)
IPS Konzalting (Croatia)
Fraunhofer (Germany)
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Prinsen Dairy Company (The Netherlands)
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PROJECT WEBSITE:

https://www.fertimanure.eu

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FERTIMANURE

Brief project summary

The mission of the FERTIMANURE project is to provide innovative solutions (technology, end-products, and business models) that solve real issues, ie the manure challenge, and help farmers with the challenges that they are currently facing. FERTIMANURE will develop, integrate, test and validate innovative nutrient management strategies so as to efficiently recover and reuse nutrients and other products with agronomic value from manure, to ultimately obtain reliable and safe fertilisers that can compete in the EU fertiliser market.

The FERTIMANURE project will cover both technological and nutrient management approaches. The technological side will be addressed with the implementation of 5 innovative & integrated on-farm experimental pilots for nutrient recovery in the most relevant European countries in terms of livestock production (Spain, France, Germany, Belgium, The Netherlands), whereas nutrient management will be addressed through 3 different strategies adapted to mixed and specialised farming systems:

Strategy #1 with on-farm production and use of bio-based fertilisers (BBF)(1) , **Strategy #2** with on-farm BBF production and centralised tailor-made fertilisers (TMF)(2) production, and **Strategy #3** with on-farm TMF production and use.

Definition of Bio-based fertilisers (BBFs): *Bio-based fertilisers (BBFs) are fertilising products or a component to be used in the production of (Tailor-Made) Fertilisers that are derived* ***from biomass-related resources.***

The BBFs of FERTIMANURE are "obtained through a ***physical, thermal/thermo-chemical, chemical, and/or biological processes for the treatment*** *of manure or digestate that result into a change in composition due to a change in concentration of nutrients and their ratios compared to the input material(s) in order to get better marketable products providing farmers with nutrients of sufficient quality".*

However, just separation of manure in a solid and liquid fraction (as first processing step) is excluded. These products are not conceived as a BBF, although they are valuable sources to supply nutrients on agricultural land.

LIST OF BBFs Produced in FERTIMANURE

Number	BBF-code	BBF product description
1	NL-AS	Ammonium sulphate solution
2	NL-LK	Liquid K-fertiliser
3	NL-SC	Soil conditioner
4	NL-WP	Wet organic P-rich fertiliser
5	NL-DP	*90% dried organic P rich fertiliser (calc)*
6	ES-NC	Nutrient-rich concentrate
7	ES-DSC	Bio-dried solid fraction
8	ES-PA	Phosphorous (ashes)
9	ES-AM	Ammonium salts
10	ES-AA	AA-based biostimulants
11	DE-AS	Ammonium sulphate solution (liquid)
12	DE-BC	Biochar (solid)
13	DE-AP	Ammonium phosphate on perlite (solid)

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14	BE-AN	Ammonium nitrate
15	BE-AS	Ammonium sulphate
16	BE-AW	Ammonium water
17	FR-BC	Biochar
18	FR-AS	Ammonium sulphate
19	FR-LK	Liquid K-fertiliser

Definition of Tailor-Made Fertilisers (TMFs): *A tailor-made fertiliser (TMF) is a customized fertiliser that meets with the nutrient requirements of a specific crop by taking into account the soil type, soil fertility status, and growing conditions and fertilisation practises.*

The TMFs obtained in FERTIMANURE are produced from BBFs (produced from manure or digestate and/or other recovered fertilising products that are available) and/or mineral fertilisers (MF) (and/or biostimulants).

Fully crop specific TMFs can be defined and centrally produced assuming e.g. a sufficient nutrient status of a soil type and no additional fertilisation practice.

However, on farm level the soil-crop requirements will be different due to another nutrient status of the soil and the fact that often manure/digestate will be applied on the fields which has to be taken into account as nutrient supplier. Consequently, the composition of the TMF (combination of BBF and MF) that will be used by the farmer can differ from the one produced in a centralised way.

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