Bio-based Fertilising Products: Quality, safety and alignment with EU Regulation

A Joint Position Paper of the 5 RUR08 Sister projects

1. Bio-based Fertilisers Definition – need to reach a consensus.

European research programs put a large emphasis on recovering nutrients from residual waste, resulting in the production of fertilising products from up-cycled or transformed material. Moreover, the Fertilising Products Regulation (EU) 2019/1009, is applicable since July 2022 and aims to establish harmonized rules for placing fertilising products on an open EU market.

The term Bio-Based Fertiliser (BBF) is already being used in R&D publications as well as in many R&D projects funded in Horizon 2020 or Horizon Europe. In fact, the Working Programmes of the main EU funding schemes, are specifically mentioning the term Bio-based fertilisers. However, in terms of regulation and official definitions there is no clear framework telling on what exactly a Bio-based fertiliser is. *Annex 1* of this document presents the different definitions that some of the sister projects funded under the RUR-08 topic (LEX4BIO, FERTIMANURE, SEA2LAND, RUSTICA and WALNUT) have proposed in the framework of their initiatives.

The non-consolidated definition of the term Bio-based fertiliser has led to confusion at the European level, encompassing both scientific and legal dimensions. Consequently, efforts are underway to reach a consensus for defining "Bio-based fertilisers". As examples led by the five RUR-08 sister projects we have the following: (i) FERTIMANURE organized a round table in a conference to discuss with relevant stakeholders working on manure valorisation what should be considered as a "BBF"; (ii) WALNUT has developed the WALNUT Lexicon [1] to harmonize the term "bio-based fertiliser" and other relevant terms related to nutrient recovery from secondary sources. This Lexicon was also presented in one of the webinars organized by the ESNI Community [2]; (iii) LEX4BIO and FERTIMANURE actively participated in the initiative led by the European Sustainable Phosphorus Platform to jointly define the term BBF [3].

However, despite the different efforts made, a joint agreement and harmonization have yet not been reached.

2. Demonstrating the efficient agronomic quality and performance and the safe use of Bio-based fertilisers recovered from different secondary nutrient rich streams.

The comprehensive agronomic assessment of the BBFs must consider the variable physicochemical properties of the side streams used to produce BBFs, as well as the different climatic and soil conditions across the EU. For evaluating the agronomic efficiency of BBFs (the nutrient response relative to mineral fertiliser and conventional fertilisation strategies) in different crops, growing and soil conditions more than 35 field trials and 40 greenhouse/pot tests were performed in the framework of the different sister projects. This ensures that deviations in agronomic efficiency between sites are due to different climatic, crop management and soil conditions. However, due to the limited duration of the projects, the field tests covered as maximum 2 growing seasons in each of the projects.

Summary tables with the results already available of the agronomic trials performed by the sister projects are shown in the Annex of the document. In summary, the assessments made allow us to conclude that BBFs are able to compete in terms of quality with conventional fertilising products, offering similar crop yields and similar environmental performance in terms of emissions (soil, water and atmosphere). However, this requires BBF application rates to be appropriately adjusted to crop N and P needs, assuring a relatively high fertiliser efficiency, and with precautions to prevent potential gaseous losses [4].

Ensuring food safety, human health and environmental protection are as vital as good agronomic performance for ensuring wider acceptance of BBFs to replace mineral fertilisers. Therefore, it is important to assess various risks related to their use. Crucial in this respect is an assessment of the potential introduction of pollution into the soil and crops, which may ultimately find its way into the human diet. In addition, potential adverse influences on the soil environment itself must be considered. To address these issues, LEX4BIO studied the potential of introducing persistent organic pollutants (POPS), plastics, phthalate plasticizers, pesticides, pharmaceuticals (including antibiotics) and heavy metals via the agricultural application of the BBFs selected in the project. In addition, they performed an ecotoxicological and human exposure risk assessments, and assessed the potential of inducing antibiotic resistance in the soil via application of BBFs obtained from different sources ([5], [6], [7]). Moreover, a critical revision of available ecotoxicological methods to assess the toxicity of BBF was also completed [8]. The lack of harmonized assessment methodologies for pollutant of emerging concern in BBFs is also a relevant challenge.

3. How BBFs could cover EU fertilisers needs?

Nitrogen and phosphorus are the main nutrients restricting crop growth worldwide. While excess use of N fertilisation largely results in environmental losses, excess use of P fertilisation also increases soil P stocks, called “legacy P”. Production of synthetic N fertilisers is an energy intensive process and its production and use accounts for 5% of global greenhouse gas emissions [9], whereas P is a finite natural resource with very limited mineable deposits in the EU, and only global reserves for a few centuries of supply at current consumption rates. Optimizing the use of N- and P-BBFs could reduce the European dependency on imported mineral fertilisers and reduce emissions into the environment.

The quantification of the nutrient content of relevant nutrient-rich side-streams (NRSS) accumulating in the EU indicated that that N requirements in agriculture cannot be covered only by N available from NRSS and an additional supplementation with mineral N is still necessary.

Intensive animal production and associated import of animal feed has created regions with a significant surplus of P and consequently increased soil P status. It is estimated that 72% of the EU´s cropland and 57% of grasslands have such a high P status that P fertilisation does not provide any yield responses [10]. Based on these findings, most of the European demand (86%) for P fertilisation can be covered by recycling P from food processing, manure, wastewater, and municipal solid waste.

4. Regulatory restrictions for using Bio-based fertilisers.

The need for a fundamental reorientation of EU agriculture and EU food systems is driven by their strong dependency towards imported inputs, such as fertilisers. The Green Deal and the newly reformed Common Agricultural Policy aim to facilitate actions proposed towards safe and sustainable food systems, and BBFs obtained from recycled materials present a huge opportunity in this regard. The policy framework is one of the key drivers of the transition towards sustainable adoption of BBFs, and the Fertilising Products Regulation revision has opened the door to market creation for such products. Nonetheless, the practical implementation in the local/national context and the actual adoption are still restricted by other relevant EU legislation (e.g., Nitrates

Directive, animal by-product regulation, Waste framework directive). A common/joint vision is completely needed to define market-relevant pathways for BBFs.

The EU Fertilising Products Regulation (FPR) (Regulation EU 2019/1009) opens the European market for BBFs. The FPR is a regulatory tool providing harmonised rules for placing on the market CE- labelled biobased Fertilising Products allowing free movement in a single EU market, and list those materials used as feedstocks that are allowed in fertiliser and plant bio-stimulant products. A highly relevant point for the development of bio-based fertilisers, concerns the use of animal by-products, waste and side streams. The requirements of CE-labelled fertilisers are often different to national legislation in member states. Therefore, it needs to be thoroughly assessed which feedstocks, valorisation routes and value chains are possible at the European and/or national level, and which are not.

In this framework, a relevant aspect of the new FPR (Article 19) is that CE-labelled products obtained from secondary materials are no longer considered as a waste (Directive 2008/98/EC): EU End-of-Waste status. This End-of-Waste status applies only once the final EU fertilising product is CE-label certified and does not apply to the input materials used in its production (CMCs). In addition, CE-marked BBFs recovered from animal by-products (e.g. manure, slaughterhouse waste, fisheries and aquaculture waste) can under certain conditions reach the end-point in the animal by-product manufacturing chain (Regulation (EC) No 1069/2009) (Delegated Act Act 2023-1605 and others pending). Safety aspect is essential and therefore, in both cases, the end-of waste or end-point of the manufacturing chain of side streams are reached by applying the authorized transformation steps which guarantee the sanitization of the product before they re-enter in the food production-chain.

Animal by-products, including manure, can be used and recycled in such a way that risks to public and animal health arising from those products are prevented and minimised. If manure-derived products are treated in such a way that they do not pose any risk for the safety of the food and feed chain, an 'end point in the manufacturing chain' can be declared. The end point products from manure treatment can then be used as a fertiliser under the scope of the FPR and/or national fertiliser regulations. The products that reached the end-point will then be outside the scope of the Regulation (EC) No 1069/2009 and can be handled without the restrictions and requirements that are imposed on handling, transport and use of animal by-products.

However, several regulatory barriers still exist that are hampering the market uptake of bio-based fertilisers. Currently the European Commission is already working on better defining the scope and materials to be included in different CMCs, by the publication of different consultations and the performance of technical studies. The entities involved in the 5 RUR08 sister projects have been actively involved in contributing to the different consultations. However, with the present position papers, we aim to summarise the main aspects identified that should be considered and clarified by the European Commission to promote the entrance of BBFs in the EU fertilisers market:

- Nitrogen recovered from secondary sources (including manure) do not pose an increased risk for nitrate leaching or adverse environmental effects as compared to mineral N fertilisers if N application is restrained to the same as the optimum mineral reference. In this regard, it should be excluded from the 170 kg N/ha limit that is posed on manure application following the Nitrates Directive.

- Recently the JRC published a draft for *"Technical proposals for processed manure as a component material for EU Fertilising Products" [11]*. Some transformation criteria are proposed for manure to reach the end-point in the manufacturing chain, including a list of technological processes allowed for such purpose. However, the transformation of the manure with one of the sanitation methods mentioned in the Annex IV of EU 142/2011 is still required (treatment at 70ºC for at least 1h is the most common) to reach the end point according to 1069/2009. Other technological processes could be feasible to reach this same objective and should be further evaluated to be included as authorised options to reach the end-point.
- Sludges obtained in agroindustrial wastewater treatment plants (slaughterhouse, dairy industry, aquaculture, etc.) are not specifically mentioned in the animal by-products regulation (Regulation (EC) No 1069/2009), leading to confusion for their further valorisation as fertilising products. A more detailed classification of industrial sludges is needed for matching the potential recovered products with a specific CMC under the Regulation EU 2019/1009 (FPR).

5. Specific Suggestions to policy makers

Based on the different aspects discussed in this position paper, the 5 RUR08 sister projects (LEX4BIO, FERTIMANURE, SEA2LAND, RUSTICA and WALNUT) strongly believe that bio-based fertilising products can be key to guarantee major future fertilisation needs of European agricultural production and have a significant contribution to future food security. In this regard, and based on the results obtained in our projects, our suggestions are the following:

Need to reach a global consensus on the definition of Bio-based fertiliser to be used at different levels: innovation, industry and legislation.

From the conclusions obtained in the different discussions and initiatives, our recommendation is that the "Bio-based fertiliser" definition should consider: (i) BBFs should be products derived from biomass (material of biological origin excluding material embedded in geological formations and/or fossilized, as defined in CEN European Standard EN 16575); (ii) raw nutrient rich streams should not be considered a BBF; (iii) a BBF should have a minimum nutrient content; (iv) storability and stability are important factors to be considered; (v) BBFs should have low heavy metal contents (within the limits established by the regulation) and should be free from organic contaminants (e.g. pharmaceuticals or pathogens).

Moreover, from the conclusions of the workshop organised by ESPP on January 2024 (ESPP's meeting on Defining "Bio-Based Fertilisers" and FPR "solely biological origin), where LEX4BIO and FERTIMANURE actively participated, the following next steps, which are supported by the sister projects, were highlighted:

- It is needed to continue working with stakeholders and researchers to look for consensus around a clear definition.
- The European Commission has to add specification of the term "bio-based" into the EU Fertilising Products Regulation labelling (Annex III).
- It is needed to engage with CEN and request that CEN prepare and adopt an EU standard defining "bio-based" content for nutrients (in fertilisers and in other applications) and a methodology for measuring this.

- It is needed to work on defining incentives and policies to support uptake of bio-based fertilisers and recycled nutrients.

Need to have funding for the performance of long-term field trials.

For ensuring optimal use of nutrients in changing climatic conditions, long-term field trials are needed to validate the agronomic efficiency, especially of bio-based fertilisers due to their heterogenous composition and different nutrient release pattern compared to conventional synthetic fertilisers. This is especially needed now when CE-labeled fertilisers can be marketed across the EU. Long-term field trials also ensure better evaluation of critical soil P status and requirement for P fertilisation, as well as determination of accumulated residual N supply capacity from earlier years application of organic-N rich BBFs.

Need to define and approve harmonized methodologies to assess pollutants of emerging concern in Bio-based fertilisers.

Harmonized methodologies for pollutants are needed to ensure food and feed safety, and both soil and human health. The methodologies for simultaneous quantification of multiple known, and emerging, pollutants in complex matrices, as well as the ecotoxicological assessments developed within LEX4BIO form a starting point for this. However, further research is needed to further test, consolidate and certify these methodologies to be considered as part of the harmonised standards that are currently under development by CEN and which are expected to be published in 2024 and in 2025.

Need to consider and approve other proven transformation stages to reach end-of-waste and end-point in the manufacturing chain of certain side streams

Other processing technologies, such as pyrolysis, incineration in a rural context with lower temperatures than the ones specified, or even membrane processes have demonstrated the potential for pathogens removal. With an adequate treatment train using these technologies (and others) it is feasible to obtain bio-based fertilisers from animal manure that are accomplishing the quality and safety requirements of the FPR, without the need for an additional sanitation step. In this regard, it is needed that EFSA can evaluate and give opinion about additional technological processes to be then included in the Annex IV of EU 142/2011.

Need to distinguish between industrial sludges from different origins.

The sludges generated in the transformation processes of the agroindustrial wastewater treatment plants present adequate quality and safety aspects. Therefore, we highly believe that BBFs derived from this kind of side stream do not pose an increased risk when reintroducing them in the food-chain. Currently, the FPR is referring to “industrial sludge”, being a very wide term and without any specific classification. Moreover, the animal by-products regulation (Regulation (EC) No 1069/2009) is not mentioning the sludges produced in the biological treatment of the agroindustrial wastewaters. Not being able to effectively valorise this kind of feedstock due to the lack of clear definitions, can limit the implementation of the circular economy of the mentioned agroindustrial sectors.

6. References and Relevant Documents

[1] WaLNUT, 2023. D4.1 Good experimental practice protocol. https://walnutproject.eu/wp-content/uploads/2023/11/Attachment_0-11.pdf

[2] https://www.biorefine.eu/nutrient-recycling/

[3] https://www.phosphorusplatform.eu/calendar/2-uncategorised/2455-defining-bio-based-fertilisers-and-fpr-solely-biological-origin

[4] Wester-Larsen L., Müller-Stöver D.S., Salo T., Jensen L.S. (2022) Potential ammonia volatilization from 39 different novel biobased fertilizers on the European market – A laboratory study using 5 European soils. Journal of Environmental Management 323, 116249 https://doi.org/10.1016/j.jenvman.2022.116249

[5] Dong, Y., Das, S., Parsons, J.R., Praetorius, A., de Rijke, E., Helmus, R., Slootweg, J.C., Jansen, B. 2023. Simultaneous detection of pesticides and pharmaceuticals in three types of bio-based fertilizers by an improved QuEChERS method coupled with UHPLC-q-ToF-MS/MS. Journal of Hazardous Materials 458, 131992. https://doi.org/10.1016/j.jhazmat.2023.131992

[6] Das, S., Helmus, R., Dong, Y., Beijer, S., Praetorius, A., Parsons, J.R., Jansen, B. 2023. Organic contaminants in bio-based fertilizer treated soil: Target and suspect screening approaches. Chemosphere 337, 139261. https://doi.org/10.1016/j.chemosphere.2023.139261

[7] Estoppey, N., Castro, G., Slinde, G.A., Hansen, C.B., Loseth, M.E., Krahn, K.M., Demmer, V., Svenni, J., Thi Tran, T.-V.-A., Asimakopoulos, A.G., Arp, H.P.H., Cornelisssen, G. Exposure assessment of plastics, phthalate plasticizers and their transformation products in diverse bio-based fertilizers. Science of The Total Environment 918, 170501. https://doi.org/10.1016/j.scitotenv.2024.170501

[8] Albert, S., Bloem, E. 2023. Ecotoxicological methods to evaluate the toxicity of bio-based fertilizer application to agricultural soils – A review**,** Science of The Total Environment 879, 163076. https://doi.org/10.1016/j.scitotenv.2023.163076

[9] Gao, Y., Cabrera-Serrenho, A. 2023. Greenhouse gas emissions from nitrogen fertilizers could be reduced by up to one-fifth of current levels by 2050 with combined interventions. Nat Food 4, 170–178 (2023). https://doi.org/10.1038/s43016-023-00698-w

[10] Recena, R., García-López, A.M., Quintero, J.M., Skyttä, A., Ylivainio, K., Santner, J., Buenemann, E., Delgado, A. 2022. Assessing the ase dons demand in European agricultural soils ase don the Olsen method. Journal of Cleaner Production 379, 134749. https://doi.org/10.1016/j.jclepro.2022.134749

[11] *JRC_REPORT_DRAFT_CMC 10.DOCX (https://circabc.europa.eu/ui/group/36ec94c7-575b-44dc-a6e9-4ace02907f2f/library/49bba9a9-241c-4d1a-9baf-90d9cf83e4bc/details)*

ANNEX. Complementary information for justification of the statements made in the position paper.

A.1. BBFs definitions proposed by the sister projects

Project	Proposed definition
LEX4BIO	Biobased fertilisers (BBFs) can be defined as materials or products derived from biomaterials (plant, animal or microbial origin, often wastes, residues or side-streams from agriculture, industry or society) with a content of bioavailable plant nutrients suitable to serve as a fertiliser for crops (Wester-Larsen et al. 2022)
FERTIMANURE	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 biomass-related resources 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".
RUSTICA	Definition of RBBF (**RUSTICA bio-based fertiliser**): RBBF relies technologically on several RUSTICA technologies and composting and is made up of at least two of the RUSTICA building blocks. According to RUSTICA, the definition of a bio-based fertiliser should: • Be as broad as possible to cover as much bio-based materials or biomass as possible in order to ensure a solid and sufficient raw material base (in terms of quality and quantity) in Europe and beyond since biomass is a valuable but limited global resource. • Include more traditional and well introduced bio-based fertilisers, such as digestate, compost, manure, and slurry to ensure a broad acceptance of farms, fertiliser producers etc. and their associations. • Avoid the requirements of "transformation" from a natural available fertiliser (e.g. manure) into a processed fertiliser and subsequent definitions and parameters thereto since the spectrum of deployments and markets will become more limited. • Offer novel options for farmers in terms of economic and ecological advantages but not belittle or compete with common available fertilisers entailed with crop or animal production in farms. • Clearly express the differences to biofertilisers which are defined in some countries (e.g. Colombia) and under use in European Policy (e.g. Farm to Fork Strategy) and keep an eye on the global situation and developments. • Be in line and tailored to the current legal fertiliser terminology and categories under use at EU and national level (e.g., organic, organo-mineral and inorganic fertiliser) to accelerate the political and legal process of incorporation.

	• Meet the requirements of already established and well recognized standards on the term "bio-based" (e.g. bio-based EN 16575 : 2014). • Take into account that patents and other IP exist on bio-based and biofertilisers.
WALNUT	**Proposed definition from WALNUT project:** Fertiliser derived from biomass using the nutrient recovery and re-use technologies (physical, thermal, chemical and/or biological, excluding anaerobic digestion and composting*) to up concentrate nutrients from the initially treated biomass and hence improve its nutrient efficiency. *Anaerobic digestion and composting are excluded as they do not aim to up concentrate nutrients. Therefore, digestate, manure and compost fall under organic fertilisers and not biobased fertilisers. On the other hand, mechanical separation aims to up concentrate nutrients, and hence liquid fractions of manure and digestate are considered as BBFs.

A.2. Summary results of agronomic performance tests

The tables below summarize the agronomic performance of the BBFs tested in different sister projects (those that are available in March 2024).

Sister project: FERTIMANURE	
List of BBFs tested *(not listing all the details, only the type of product)*	• *Mineral fertilisers: Ammonium-based fertilisers: ammonium sulphate, ammonium nitrate and ammonium water; and phosphorus-based fertilisers: phosphorus-rich ashes and phosphoric acid* • *Organo-mineral fertilisers: nutrient (NPK) rich concentrate, K-rich liquid fertiliser* • *Organic fertiliser: P rich fertiliser* • *Organic amendments: soil conditioner, phosphorus and potassium rich biochars from different feedstocks and technologies, biodried organic amendment* • *Amino acid- based biostimulants* • *More added-value products: on- farm and centralised TMFs, biologically activated BBFs*
Type of agronomic performance tests developed	*10 pot trials, 14 field trial locations (ES, BE, NL, FR), pot tests for biostimulant effect over hydric and saline stresses, and soil incubations for nutrient release.*
Crops tested	*Potato, rye grass, winter wheat, tomato, spinach, cabbage, maize, lettuce, sugar beet, grass*
Main conclusions on agronomic performance	• *Agronomic performance of the BBFs equals the yields with mineral and conventional fertilisation strategies.* • *The use of biostimulant can increase crop resistance to stress conditions (hydric and saline stress).*
Main conclusions on environmental performance	• *Tested BBFs do not differ from synthetic counterparts in regard to nitrate residue, showing even a lower risk of nitrate leaching in some cases.* • *The GHG emissions are also similar, except for N_2O which emissions are lower using BBFs.*

Sister project: LEX4BIO	
List of BBFs tested *(not listing all the details, only the type of product)*	*<u>Both N- and P-BBFs</u>* Selection of wide range of BBFs to cover PFC/CMC categories as widely as possible, including 42 N-BBFs and 41 P-BBFs BBFs were either already on the market or in the development stage at a relatively high TRL
Type of agronomic performance tests developed	Pot trials in five locations (FI, AT, CH, FR, ES, DE) and field trials in 8 locations (FI, DE, DK, AT, HU, CH, FR, ES) for determining agronomic efficiencies of BBFs for both N and P. Laboratory incubation trials conducted for determining N mineralization and potential for gaseous (ammonia) losses. A rainfall simulation assay was used for estimating the P leaching risk. A soil-plant-atmosphere simulation model (Daisy) was applied for six different European agronomic typologies to estimate BBF vs. mineral N leaching risk.
Crops tested	*Spring barley, winter wheat, spring wheat, maize, sunflower, ryegrass*
Main conclusions on agronomic performance	Agronomic efficiency of N-BBFs in the year of application was an average NFRV 71% across sites and crops, somewhat lower for surface application (in growing winter wheat) than for incorporation (prior to seeding spring crop). For most N-BBFs, there was a clear residual NFRV in the year after application, but not significantly higher than for the mineral N reference. Agronomic efficiency of P-BBFs were equal to mineral counterparts in the field trials. Chemical composition of P-BBFs determined agronomic efficiency in greenhouse trials.
Main conclusions on environmental performance	Leaching losses of P after application of P-BBFs were similar or lower than from conventional mineral P fertiliser. Potential ammonia volatilisation varied greatly between the biobased fertilisers, both in terms of the maximum and the temporal dynamics of ammonia volatilization – ammonia loss risk is higher for many BBFs than for mineral N fertiliser. Digestates showed high initial ammonia volatilisation rate; all other BBF showed a delay (varying duration) in ammonia volatilization dynamics. Potential ammonia volatilisation was effectively reduced by soil incorporation compared to surface application, and the risk of ammonia volatilisation also varied with soil type, clay soils < sandy soils. The N leaching risk of N-BBFs was similar to or lower than for conventional mineral N fertiliser, as long as total N application rates were kept similar; if farmers apply more N-BBF to compensate for lower agronomic efficiency, this leads to higher N leaching losses. Very limited number of pesticides and pharmaceuticals was found in the BBFs, all in concentrations below the EU limits. Studied BBFs did not pose a risk of enriching antibiotic resistance in the soil.