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EU legislation for the registration of new bio-based products: Current challenges and barriers. A case study of products derived from municipal bio-waste for use in the agriculture and chemical industry sectors

Piergiuseppe Morone [a,g], Giulia Borghesi [a], Ilaria Galvagno [b], Elio Padoan [c], Enzo Montoneri [c,*], José Maria Gomez [d], Michalis Koutinas [e], Simone Solaro [f], Federico Boccardo [f]

[a] UnitelmaSapienza University of Rome, Rome, Italy
[b] Acea Pinerolese Industriale Spa, Pinerolo, Italy
[c] Università degli Studi di Torino, Torino, Italy
[d] Biomasa Peninsular, Madrid, Spain
[e] Cyprus University of Technology, Limassol, Cyprus
[f] Hysytech S.r.l, Torino, Italy
[g] Corvinus Institute for Advanced Studies (CIAS), Corvinus University of Budapest, Budapest, Hungary

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ABSTRACT

The present paper analyses current EU legislation governing the production and commercialisation of bio-based products, with a focus on the challenges and regulatory barriers faced by novel bio-based products seeking compliance. The analysis aims to provide a useful tool for manufacturers and/or importers navigating the complex legal landscape associated with the registration of bio-based products derived from various sources and intended for diverse applications. To this end, the analysis is applied to a case study of new bio-based products (NBPs) produced from municipal bio-waste, developed for use in both agricultural and chemical sectors. Although these products are not yet commercially available, they are at an advanced stage of development and nearing market entry. Owing to their multifunctional properties and multipurpose applications, such NBPs may be subject to registration under both the REACH regulation and the Fertilising Products Regulation (FPR). The results show that registration at the EU level provides a significant advantage – namely, market access across all Member States via the CE mark, in line with the Treaty on the Functioning of the European Union and EU regulation on the mutual recognition of goods lawfully marketed in another Member State. In contrast, national-level registration within individual Member States remains significantly more complex and time-consuming. The NBPs case study suggests that EU legislation should be updated to include a dedicated category for multifunctional bio-based products. The collection of more data from more case studies would allow assessing the real impact of national regulatory discrepancies on the industrial scalability and cross-border trade of new multi-functional bio-based products as they become available.

1. Introduction

Bio-based products offer numerous benefits for the economy, society and the environment by addressing some of the most pressing societal challenges, including climate mitigation and adaptation, the transition to a circular and resilient economy, and the development of a greener industrial sector. Moreover, these products [1] strengthen the EU's open strategic autonomy and resilience by reducing reliance on fossil-based resources (e.g., crude oil, natural gas, coal), thereby supporting a shift from the current fossil-based chemical industry to a bio-based alternative driven by bio-refineries. However, this transition is complex and faces several challenges connected to the availability and heterogeneity

* Corresponding author at: Università di Torino – DISAFA, L.go P. Braccini, 2-10095 Grugliasco (TO), Italy.
E-mail addresses: piergiuseppe.morone@unitelmasapienza.it (P. Morone), giulia.borghesi@unitelmasapienza.it (G. Borghesi), ilaria.galvagno@aceapinerolese.it (I. Galvagno), elio.padoan@unito.it (E. Padoan), enzo.montoneri@gmail.com (E. Montoneri), jmgomez@bpeninsular.com (J.M. Gomez), michail.koutinas@cut.ac.cy (M. Koutinas), simone.solaro@hysytech.com (S. Solaro), federico.boccardo@hysytech.com (F. Boccardo).

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of renewable feedstocks, the development of sustainable manufacturing processes and the need for bio-based products to match the performance and cost-efficiency of their fossil-derived counterparts. Moreover, the successful integration of bio-based products into the market is contingent upon the development of EU regulatory frameworks to govern their classification, registration and commercialisation. The present paper presents an in-depth analysis of current EU legislation relevant to bio-based products, identifying key challenges and regulatory barriers that hinder compliance for emerging bio-based products. To illustrate these dynamics, the paper reports a case study of novel products derived from municipal bio-wastes, intended for applications in agricultural and chemical sectors.

1.1. Case study of bio-based feedstock and products

Municipal bio-wastes (MBWs) collected through separate source systems primarily consist of unsorted food waste and green waste from private gardens and public parks. These materials represent one of the most readily available feedstocks for the production of new bio-based products (NBPs), including bio-surfactants (BSs), bio-plastics (BPLs), fertilisers (FTs), biostimulants (BSTs) and agro-chemicals (AGCs). MBW is produced across urban environments worldwide, with production in the EU alone reaching approximately 100 million tonnes per year. Separate source collection is widely implemented across most EU cities [2]. Currently, MBW is processed via anaerobic or aerobic fermentation, producing biogas, anaerobic digestate and compost. However, the economic value of these outputs is insufficient to offset the associated processing costs. As collection and treatment expenses are generally covered by municipal taxation, MBW, along with its digestate and compost, can be considered a negative-cost feedstock [3]. This economic condition creates an opportunity, with the conversion of MBW into value-added chemicals offering a promising route towards the establishment of environmentally sustainable biorefineries capable of generating specialty chemicals, revenue streams and employment. Fig. 1 depicts a clean, low-impact process for converting MBW into NBPs [4]. The process involves the alkaline hydrolysis of fresh and fermented MBW at temperatures ranging from 60 to 90 °C, achieving an NBP yield of approximately 90 %. All products are fully recovered, while excess reagents and process water are recirculated to the hydrolysis reactor. Notably, the process generates no effluents requiring secondary treatment. The estimated processing cost is approximately 0.2 €/kg MBW.

NBPs consist of molecular mixtures ranging in molecular weight from 5 to more than 750 kDa. These molecules contain aliphatic and aromatic carbon moieties substituted with acidic functional groups of varying strength, which form bonds or complexes with the natural mineral elements present in the original MBW. The resulting NBPs exhibit diverse chemical properties and functionalities. NBPs formulated as FT, BST and AGC demonstrate performance that is highly competitive with their commercial counterparts. Specifically, FT- and BST-type

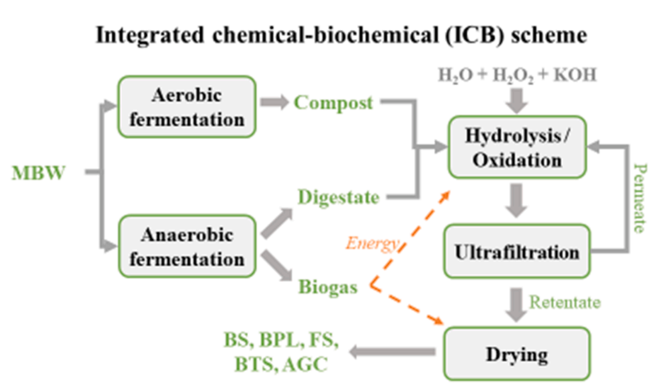

Fig. 1. Schematic representation of the valorisation of MBW as a feedstock for NBP production (modified from [5]).

NBPs, when applied to soil at lower doses than conventional mineral or organic products, enhance plant growth, photosynthetic activity, crop yield and water use efficiency. Additionally, they reduce the leaching of nutrients from soil, thereby mitigating the risk of eutrophication in adjacent aquatic ecosystems. AGC-type NBPs have been shown to inhibit the mycelial growth of several fungal phytopathogens, performing comparably to widely used synthetic fungicidal agents. BS- and BPL-type NBPs exhibit promising properties, albeit with certain limitations. BS-type NPBs, when used as active components in cleaning and dyeing formulations, efficiently remove dirt and regulate dye uptake in textiles. However, their inherent dark colouration can impart a greyish hue to treated fabrics. Ozonisation has been found to enhance the bleaching and surfactant properties of these NBPs, but it also leads to significant degradation, converting a large fraction of the material into compounds with low molecular weight (<5 kDa) with diminished surfactant efficacy. In the case of BPL-type NBPs, composite plastic sheets have been successfully produced from synthetic commercial polymers using melt extrusion. These composites exhibit improved mechanical strength compared to sheets composed solely of synthetic polymers. However, sheets fabricated exclusively from NBPs are not viable due to the high content of mineral elements and condensed aromatic carbon moieties, which confer rigidity and a not-melting property to the material. These findings suggest that mild oxidation is critical for enhancing the properties of both BS- and BPL-type NBPs, while preserving their high molecular weight (≥100 kDa). Recent advancements have also demonstrated promising results through the oxidation of pristine NBPs using catalytic amounts of H_2O_2 in aqueous media.

2. EU policy and regulatory framework: NBP compliance with relevant legislation

The following sections report the regulatory requirements and procedural steps necessary for the registration of NBPs developed by the Italian MBW treatment company Acea Pinerolese, according to the scheme depicted in Fig. 1. These NBPs were produced and analysed as part of the LIFEEBP project (LIFE19 ENV/IT/000004), co-funded by the European Commission. Within this project, ACEA produced several types of NBPs via hydrolysis of various fermented MBWs, including: anaerobic digestate (D) derived from food waste, compost from green waste (CV) and a blended compost (CVD) obtained by mixing digestate (D) with green waste (V) in a 60:40 wt ratio. These feedstocks were subsequently hydrolysed to produce their respective CV- and CVD-type NBPs. The project involved 15 partners across Italy, Greece, Cyprus, Spain and France, all of whom expressed interest in producing, testing and commercialising the NBPs in their respective markets for applications in agricultural and chemical sectors.

The analysis is presented in three main sections. Section 3 describes the NBPs at their current stage of research and development (R&D). Section 4 analyses the most relevant EU policies pertaining to the intended applications of these NBPs, as well as the national regulatory frameworks in the countries involved (i.e., Italy, Spain, Cyprus). This section also explores potential national-level registration categories for fertilisation products, which may differ across Member States. Finally, Section 5 describes the procedural steps required for product registration at both EU and national levels.

3. NBP characterisation and analysis

Table 1 reports the analytical data for the CVD- and CV-type NBPs. These data were generated through collaborative testing conducted across three laboratories: ACEA and the University of Torino (UNITO) in Italy, and Biomasa Peninsular (BPE) in Spain. BPE and ACEA are MBW management companies actively involved in the production and potential commercialisation of NBPs. The data are discussed in Section 4, with reference to product compliance with existing EU and national legislation.

Table 1
NBP analytical data referring to fresh matter (f.m.) and/or dry matter (d.m.).

Analytical laboratory (country)	Biomasa Peninsular (ES)			University of Torino (IT)	
NBP (year)	CVD NBPs (2023)	CVD NBPs (2021)	CV NBPs (2021)	CVD NBPs (2022)	CVD NBPs (2022)
Parameter					
pH	9.5	8.8	8.2	9.5	9.8
Electrical conductivity (μS/cm) (d.m.)	3.9				
Electrical conductivity (μS/cm) (f.m.)	3.9			3.32 mS	2.11 mS
Salinity $_{(meq/100g)}$		278.2	288.7		
Dry matter (%)	74.5	-	-	77.39	37.64
Ash (%)	31.7	28.3	27.9	37.99	33.2
Humidity (%)	25.5	6.9	6.8	22.61	62.36
Humic acids (%) (d.m.)	7.4				
Humic acids (%) (f.m.)	5.5				
Fulvic acids (%) (d.m.)	17.8				
Fulvic acids (%) (f.m.)	13.3				
C from humic and fulvic acids (d.m.)					
Total humic extract (humic acids + fulvic acids) (%) (d.m.)	25.2				
Total humic extract (humic acids + fulvic acids) (%) (f.m.)	18.8				
Total organic matter (%) (d.m.)	68.3	71.7	72.1		
Total organic matter (%) (f.m.)	50.9				
Total organic carbon (%) (d.m.)	39.6	37.5	38.3	35.7	36.2
Total organic carbon (%) (f.m.)	29.5				
Total nitrogen (%) (d.m.)	4.1	4.9	4.0	4.5	4.6
Total nitrogen (%) (f.m.)	3.0				
Organic nitrogen (%) (d.m.)	3.9				
Organic nitrogen (%) (f.m.)	2.9				
P2O5 (%) (d.m.)	4.7	0.8	0.5	5.88	6.13
P2O5 (%) (f.m.)	3.5				
K2O (%) (d.m.)	6.7	4.5	4.3	10.12	9.98
K2O (%) (f.m.)	4.9				
Sum of NPK (d.m.)	15.5			20.5	20.7
Sum of NPK (f.m.)	11.5				
Sum of NP (d.m.)	8.8				
Sum of NP (f.m.)	6.5				
Sum of NK (d.m.)	10.7				
Sum of NK (f.m.)	8.0				
C/N	9.7	7.7	9.5		
Macroscopic impurities (plastic, glass, metal) > 2 mm	< 0.010				
Macroscopic impurities (lithoid inerts) > 5 mm	< 0.010				
Particles able to pass through the 25 mm mesh	< 0.010				
Ca (%)		4.7	6.1	3.9	4.2
Fe (%)		0.9	0.8	1.42	
Mg (%)		0.9	1.1	0.60	0.64
Si (%)		2.5	2.6		
Al (%)		0.6	0.5		
Na (%)		0.2	0.2		
Escherichia coli or enterococcaceae (NMP/g)	< 3				
Salmonella sp. (/25 g)	not detected				
Other					
Heavy metals (mg/kg) (d.m.)					
Zn	687	427	256	548	685
Cu	320	249	202	124	112
Ni	61	97	92	66	67
Cd	3.05	<0.5	<0.5	0.22	nd
Pb	62	99	85	48	59
Hg	0.25	0.3	0.2		
Co				9.19	7.93
Cr VI	not detected			nd	nd
Total Cr	85.3	27	19	62.4	62.7
As				7.40	7.12
Biuret (g/kg d.m)					
PAH_{16}					
Mn				411	485
Mo				0.73	0.53

4. EU policy and regulatory updates, and NBP compliance

As outlined in Section 2, the investigated NBPs are multifunctional materials derived from municipal biowaste, intended for application across agricultural and chemical sectors. Due to their broad functionality and bio-based origin, their registration, industrial-scale production, commercialisation and application must comply with a range of EU regulatory instruments and policy frameworks. The principle regulatory frameworks relevant to these NBPs include: REACH, the Fertilising Products Regulation (FPR), the Common Agriculture Policy (CAP), the Circular Economy Action plan (CEAP) and the Waste Framework Directive (WFD). The following subsections provide a concise overview of each policy and examine the potential regulatory challenges and barriers they pose to the industrial implementation and legal placement of these NBPs on the EU market.

4.1. REACH

Regulation (EC) No 1907/2006 [6] concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) is composed of 15 Titles and 17 Annexes, aimed at ensuring "a high level of protection of human health and the environment" while supporting "alternative (non-animal) methods to assess possible hazardous substances and the free circulation of substances, while promoting competitiveness of the EU chemicals sector" (Art.1). The different Titles establish the procedure to be followed. The required information must be registered in a central database managed by the European Chemicals Agency (ECHA), which plays a key role in evaluating compliance and coordinating the activities of national competent authorities across Member States. Importantly, Member States may provide input and propose amendments to draft decisions issued by ECHA (Art. 51, 59). The Supplementary Material (SM) summarises the most relevant concepts, mainly from Title II (Registration of Substances) and Annex V ("Exemptions from the Obligation to Register in Accordance with Article 2(7)(b)").

For manufacturers and/or importers of products such as NBPs, strategically most significant is the possibility of exemption from registration requirements. Under REACH, substances recovered from waste (e.g. NBPs) fall within the scope of the regulation when the waste is reprocessed (in compliance with the WFD) and used to manufacture a new substance, mixture or article.

Exemptions to registration requirements may apply under the following specific conditions: i.e.,

- if a recovered substance is chemically identical to a substance that has already been registered (see for examples next Section 4.2);
- • compost and digestate as substances exempt from registration, provided they are produced from waste materials in compliance with the WFD. Given that compost and digestate derived from MBW serve as the primary feedstocks for the NBPs described in this case study (Fig. 1), the exemption appears applicable;
- • product-and process-oriented R&D (PPORD), as defined in Article 3.22. This provision is especially applicable to NBPs in close-to-market development phases.

Given that above, CVD-type NBPs may qualify for exemption from REACH registration under multiple provisions of the Reach regulation, as discussed in more details in the Supplementary Material (SM) file Appendix G.

4.2. The fertilising products regulation (FPR) and its impact on reach exemptions

The entry into force of Regulation 2019/1009, commonly known as the FPR [7,8], has significantly influenced the scope and applicability of REACH exemptions. Effective from 16 July 2022, the FPR is a key component of the Circular Economy Action Plan (CEAP), aimed at establishing harmonised rules for the placement of CE-marked fertilising products (including those derived from recycled bio-waste and secondary nutrients) on the EU Single Market, thereby ensuring their free movement across Member States. A manufacturer may only affix the CE mark to a fertilising product if the product complies fully with the provisions of the FPR and its corresponding annexes. Specifically, the product must meet the requirements of the relevant Product Function Categories (PFCs) outlined in Annex I (Fig. 2); the applicable Component Material Categories (CMCs) outlined in Annex II (Fig. 3); the labelling criteria specified in Annex III; and the appropriate conformity assessment procedure outlined in Annex IV. Through this framework, the FPR regulates not only the function and intended use of fertilising products but also the composition and origin of their input materials.

The FPR [7,8] has significantly broadened the scope of the Single Market by allowing access to fertilising products previously excluded from EU harmonisation rules. These include organic and organo-mineral fertilisers, soil improvers, inhibitors, plant biostimulants, growing

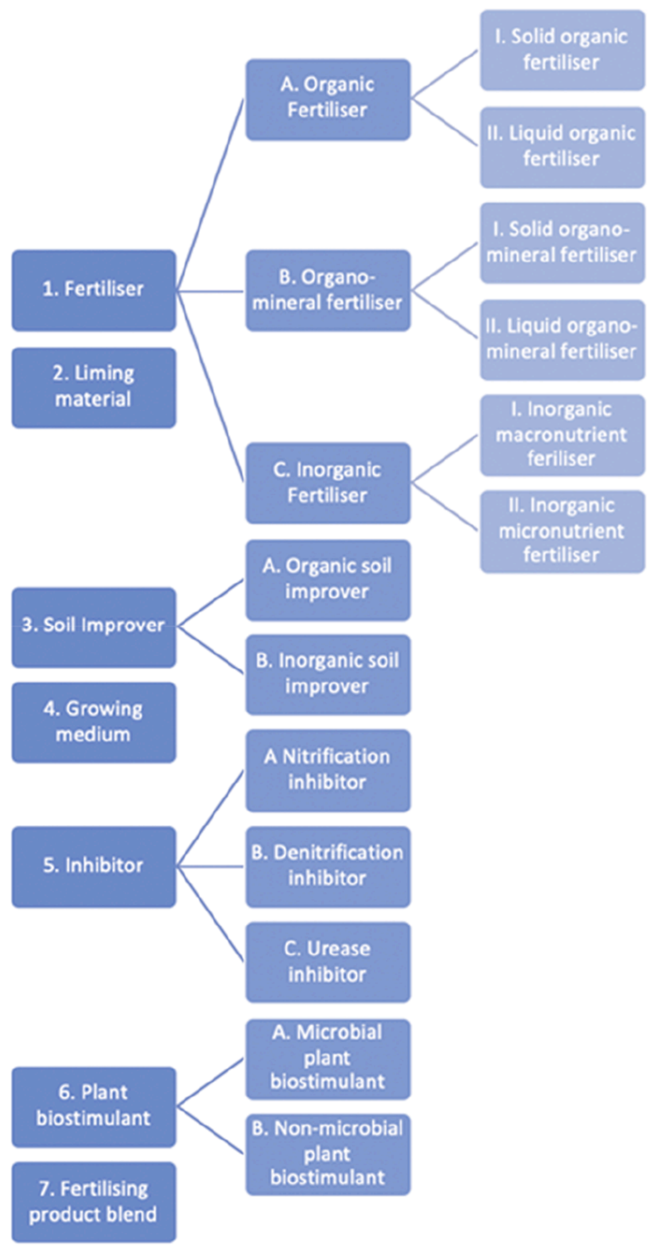

Fig. 2. Product function categories (PFCs).

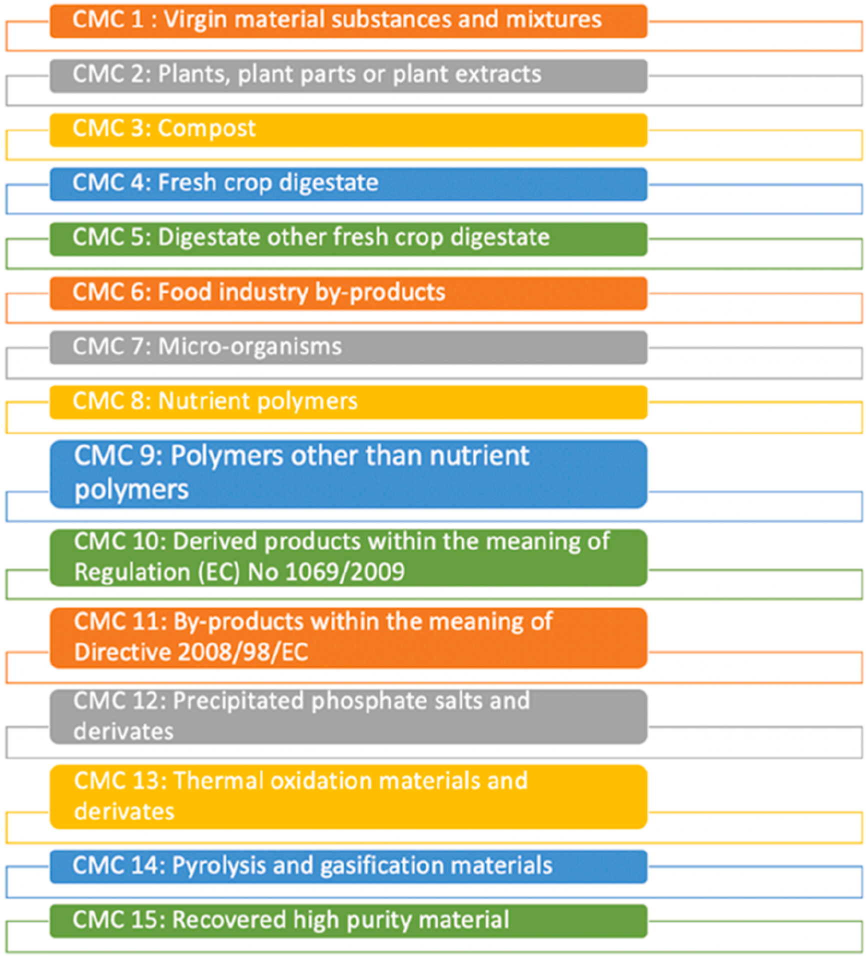

Fig. 3. Component material categories (CMCs).

media and blends. A recent comprehensive review [9] detailed the properties of all NBPs intended for agricultural applications – such as FTs, BSTs and AGCs, as described in Section 1.1. The findings confirmed that these NBPs are well-aligned with several PFCs defined under the FPR: i.e., PFC 1 A and B, PFC 3 A, PFC 4, PFC 6. Detailed classification criteria and product alignment are provided in the SM file Appendix A.

4.2.1. NBP compliance with reach and FPR policies

Published data [9,4] indicate that the industrialisation and commercialisation of NBPs, and the consequent realisation of their associated environmental, economic and social benefits (see Section 5.1), depend far more on compliance with the FPR than with REACH (see also Section 1.1). In this regard, Part II of Annex 1 of the FPR establishes the maximum permissible limits for contaminants and pathogens in EU fertilising products, as well as the minimum nutrients thresholds required for specific PFCs. Table 2 summarises the regulatory requirements for the relevant PFCs to which the NBPs under study may be attributed. At the current stage of NBPs R&D, and with reference to the analytical data reported in Table 1, a preliminary compliance assessment can be made by comparing these values against the threshold limits outlined in Table 2.

For PFCs 6, 3 and 4, it should be noted that no specific requirements are set out in the FPR with respect to parameters such as carbon (C), nitrogen (N), nutrient content (NPK), pH and humidity. Accordingly, the only directly comparable regulatory benchmark relates to heavy metal content. In this regard, nickel (Ni) concentrations in CVD-type NBPs range from 61 to 97 mg/kg, with an average of approximately 77 mg/kg, which slightly exceeds the FPR's threshold of 50 mg/kg. This deviation may be corrected through targeted optimisation of the ultrafiltration step during NBP production (Fig. 1). Moreover, statistical validation may demonstrate that this difference is not significant, providing further support for regulatory acceptability upon refinement.

Given the multifunctionality of the investigated NBPs (Section 1.1), the products may also fall under PFC 7 (Blend), as defined in Annex 1. According to the FPR, a blend is composed of two or more products, all proven to comply with the FPR requirements through the established conformity assessment procedure. Therefore, although a product may formally belong to only one PFC, inclusion under PFC 7 allows it to perform multiple functions. Classification under PFC 7 is potentially advantageous for the product market allocation. However, the requirement to undergo multiple conformity assessment procedures – one for each functional component – may impose significant administrative and economic burdens on manufacturers. For this reason, for NBPs and similar bio-based products composed of complex molecular mixtures obtained from a single biological feedstock, it may be appropriate to introduce a new PFC – tentatively termed a "multifunctional" category – distinct from the current blend classification. Unlike blends, which imply the physical combination of multiple, separately sourced and assessed components, this multifunctional category would accommodate products derived from a single chemical transformation applied to one source material. The formal recognition of such a category would represent a meaningful contribution to EU policy development and regulatory innovation, grounded in the insights gained from NBP R&D efforts.

Table 2
Requirements for select PFCs according to the FPR. Legends as in Table 1. Heavy metal values indicate maximum permissible concentrations.

PARAMETER	FPR 2019/1009				
	PFC1(A) Solid org. fertiliser	*PFC1(B) Org-mineral fertiliser*	*PFC6(B) Non icrobial plan ostimulant*	*PFC3(A) Organic soil improver*	*PFC4 Growing medium*
Total organic carbon (%) (f.m.)	*> 15%*	*> 7,5 %*			
Total nitrogen (%) (d.m.)					
Total nitrogen (%) (f.m.)	*> 1 %*	*> 2 %*			
Organic nitrogen (%) (d.m.)					
Organic nitrogen (%) (f.m.)		*> 0,5 %*			
P_2O_5 (%) (d.m.)					
P_2O_5 (%) (f.m.)	*> 1 %*	*> 2 %*			
K_2O (%) (d.m.)					
K_2O (%) (f.m.)	*> 1 %*	*> 2 %*			
Sum of NPK (d.m.)					
Sum of NPK (f.m.)	*> 4 %*	*> 8 %*			
Escherichia coli or enterococcaceae (CFU/g)	*<1000 CFU/g fresh mass*	*<1000 CFU/g fresh mass*	*<1000 CFU/g fresh mass*	*<1000 CFU/g fresh mass*	*<1000 CFU/g*
Salmonella sp. (CFU/25 g)		*absent*	*absent in 25 g*	*absent in 25 g*	
Other					
Heavy metals (mg/kg) (d.m.)					
Zn	*800*	*1500*	*1500*	*800*	*500*
Cu	*300*	*600*	*600*	*300*	*200*
Ni	*50*	*50*	*50*	*50*	*50*
Cd	*1,5*	*3*	*1,5*	*2*	*1,5*
Pb	*120*	*120*	*120*	*120*	*120*
Hg	*1*	*1*	*1*	*1*	*1*
Co					
Cr VI	*2*	*2*	*2*	*2*	*2*
Total Cr					
As	*40*	*40*	*40*	*40*	*40*
Biuret (g/kg d.m.)	*absent*	*12*	*12 g/kg d.m.*		

4.2.2. Component material categories (CMCs)

Annex II of the FPR is dedicated to the Component Material Categories (CMCs; Fig. 3).As discussed above, PFC 7 (Fig. 2) is defined for fertilising products obtained through the physical blending of multiple components, each compliant with its respective CMC. However, this classification does not appropriately reflect the nature of multifunctional NBPs, which are derived through a single chemical reaction applied to a single biological input (e.g., MBW in the form of anaerobic digestate or compost, as described in Section 1.1). For instance, according to the current FPR, a product physically combining compost and digestate would need to comply with the requirements for CMC 3, and either CMCs 4 or CMC 5. In contrast, the NBPs under investigation are not formed from such mixtures and therefore do not map directly onto multiple CMCs. Under these circumstances, NBPs derived via hydrolysis of compost or digestate should be classified under CMC 10 or CMC 11. Specifically, CMC 10 includes derived products within the meaning of Regulation (EC) 1069/2009, which have reached the end point in the manufacturing chain and are thus considered safe for use. On the other hand, CMC 11, which pertains to by-products, is subject – since 16 July 2022 – to criteria defined by the delegated act referenced in Article 42 of the FPR. This situation, according to Chapter 6 of the FPR, would require to put in force the adoption of the "Delegated Powers and Committee Procedure", by which the EU Commission can amend Annexes I–IV. Such amendments are intended to reflect technical progress and support market access for fertilising products demonstrating significant trade potential that are scientifically verified as safe for human health and the environment, while also ensuring agronomic efficiency. In this context, NBPs registration appears feasible, subject to the Commission's assessment and potential amendment of the relevant annexes, and/or to the introduction of the new "multifunctional" PFC mentioned in paragraph 4.2.1. This would provide a clear basis for such products to qualify for CE marking under the FPR framework (see SM file Appendix B fur further details).

4.3. A controversial issue: Reach exemptions and FPR requirements

As anticipated in Section 4.2, when a fertilising product contains components falling under different CMCs, it must also comply with the corresponding legal requirements established under REACH. Although the FPR does not supersede the application of other legal instruments, including Reg. (EU) 1907/2006 (REACH), certain provisions within the FPR impose registration obligations that extend beyond what REACH alone requires. In particular, the FPR mandates REACH registration for some substances, even when they are produced or marketed in quantities below one tonne per year, which makes them otherwise exempt under REACH. A notable example is provided under CMC 1, as described in Point 2 of CMC 1, Part 2, Annex II of the FPR. In this case, specific materials included under CMC 1 are required to be registered under REACH – as well as the submission of a chemical safety report – despite falling below the standard quantity threshold for registration. As discussed in Section 4.1, this creates a regulatory inconsistency, particularly in the context of multifunctional products such as NBPs (Section 1.1). For instance, a NBP could be marketed exclusively for use as a BS and/or BPL, in which case it might qualify for REACH exemption based on low-volume production (less than one tonne per year).

4.4. The common agricultural policy (CAP)

The CAP (European Union, 2021) is the EU's overarching framework for agricultural development, aimed at supporting farmers, improving productivity, maintaining rural areas and tackling climate change through the promotion of sustainable agricultural practices. The policy is currently governed by three principle regulations (SM file Appendix C): Regulation (EU) 2021/2116, Regulation (EU) 2021/2115 and Regulation (EU) 2021/2117. Among the green initiatives introduced under the reformed CAP, a central role is played by the Eco Schemes, as set out in Regulation (EU) 2021/2115. These schemes are voluntary instruments designed to promote environmentally-friendly farming practices, supported by financial incentives. One area of emphasis is the promotion of organic farming as a model for sustainable agriculture.

For the NBPs case study, particularly relevant is the CAP's strategic emphasis on reducing nutrient losses – particularly nitrogen and phosphorus – by at least 50 % by 2030, as well as its objective to decrease the use of NPK mineral fertiliser, is particularly relevant. Published R&D output [10,9] demonstrates the potential of NBPs to significantly contribute to this goal by improving nutrient retention and efficiency. An important potential contribution of the aimed industrial implementation and commercialisation of NBPs is the promotion of circular economy practices, by advancing a renewable carbon cycle based on the recovery and reuse of organic matter from bio-waste streams. Moreover, given its entirely organic composition, a CV-type NBP obtained from 100 % green compost (Fig. 1) has already been registered in Italy (under the name Florasol V) as fertiliser for both organic (Italian Ministry of Agriculture (MIPAF) registration no 0034,273/21) and conventional agriculture (registration no 0034,272/21). This dual registration aligns with the objectives of the 2021 Action Plan for Organic Production, enabling both farmers and citizens to benefit from the environmental and societal advantages associated with organic farming. See also Section 5.1 at this regard.

4.5. EU circular economy action plan

Another key strategic framework relevant to NBP R&D efforts is the "Circular Economy Action Plan - For a Cleaner and More Competitive Europe" (CEAP), adopted in March 2020 [11]. As a core component of the European Green Deal, the CEAP aims to foster the transition to a sustainable and resource-efficient economy, with a particular emphasis on renewable and bio-based materials. Central to the Plan is the object of achieving "less waste, more value" across the EU. Considering the amount of waste generated from economic activities (approximately 2.5 billion tonnes annually), effective waste management represents a cornerstone of the strategy. A fundamental pillar of the CEAP is the development of a well-functioning EU market for secondary raw materials. Within this framework, NBPs – due to their origin, chemical properties and functional performance – are poised to play a significant role. They enable the valorisation of food and green wastes, converting them into secondary raw materials that can be reintroduced into the soil as fertilisers enriched with recycled nutrients. In this way, the industrial and commercial deployment of NBPs is expected to contribute substantially to the emergence of a virtuous, biowaste-based circular economy. More details are given in the SM file Appendix D.

4.6. Italian legislation

In Italy, the marketing of fertilising products is regulated by Legislative Decree no 75 of 29 April 2010, "Reorganisation and revision of the regulation on fertilisers, in accordance with article 13 of the law of 7 July 2009, n.88," hereinafter referred to as "D.Lgs.75/10" ([12]; Decreto Legislativo 29 aprile 2010). This Decree – alongside its subsequent amendments (available at https://www.normattiva.it/uri-res/N2Ls?urn:nir:stato:decreto.legislativo:2010-04-29;75) – serves as the principle legislative framework governing the placement of products with specific agronomic functions in both the EU and national markets. Following the entry into force of the FPR, it became necessary to revise D.Lgs. 75/10 and implement corresponding measures at the national level. A new legislative decree is currently under development. This Section refers to the most recent update, Decree 12 December 2023, published in the *Gazzetta Ufficiale* on 31 January 2024.

4.6.1. Analysis of product categories and NBP compliance

D.Lgs 75/10 and its subsequent updates outline the current categories of fertilising products and their permitted input materials. In the case of multifunctional NBPs, these include composts derived from green waste (CV) and mixtures of green waste and digestate (CVD). However, the EU and Italian legislations do not account for fertilising products obtained from the chemical hydrolysis of composts. The use of digestate as fertilising product is recognised in various instances within D.Lgs 75/10 – for example, dried vegetable digestate and the solid fraction separated from dried bovine and porcine digestate mixed with bottom ash from the combustion of virgin woody biomass. These are included under the category of NP organic fertilisers. Nonetheless, these products are not equivalent to NBPs, as they differ in terms of their functional properties, input materials and production processes. Thus, the NP organic fertilisers category under D.Lgs 75/10 does not appear to be an appropriate classification for the registration of NBPs.

A similar issue arises with the broader product categories defined under D.Lgs 75/10, such as mixed growing media and mixed soil amendments. The decree defines a growing medium as any material in which plants can grow, other than soils in situ. Despite the fact that the properties of NBPs align with the definitions of growing media and soil improvers (Section 4.2), these categories do not appear suitable for NBPs, primarily due to differences in intended functionality, source materials and production process.

The only category under which CVD-type NBPs could be appropriately registered – in compliance with D.Lgs 75/10 and Decree 12 December 2023 – appears to be that of humic extracts, listed among the activators under the "Products with specific action category." From a functionality standpoint, humic extracts are defined as "products which bring to the soil, to a plant or to a product further substance which help to regulate absorption of nutrients or correct soil physiological weakness." In terms of production, humic extracts are described as products in suspension or solid form obtained through the extraction of soils, fossil materials, fertilisers or organic amendments – substances that have undergone natural humification processes. To qualify as humic extracts, products must meet the following compositional thresholds:

- minimum 30 % organic carbon on a dry matter basis; and
- at least 60 % humified organic carbon relative to total organic carbon (T.U.).

Further criteria apply for use in organic farming, pursuant to EU Reg. 2021/1165 and national legislation. These are detailed in Part 2 of Annex 13 of D.Lgs 75/10 and Decree 12 December 2023. For example:

- humic extracts are permissible in organic farming only if they are extracted using inorganic salts/solutions (excluding ammonia salts) or derived from water purification processes.

Based on the data and information reported in Sections 1.1 and 3, NBPs production may be considered analogous to an accelerated humification process. The composition and effects of NBPs on soil closely resemble those of humic extracts from fossil sources. However, from industrial and commercial perspectives, NBPs offer greater sustainability, as they are sourced from MBWs. Moreover, their demonstrated multifunctionality in both agriculture and chemical sectors represents significant added value compared to currently available commercial humic extracts.

Table 3 compares the compositional thresholds established in D.Lgs 75/10 and Decree 12 December 2023 (Annex 13, Part 2) for mixed soil amendments with the corresponding values observed for the NBPs under investigation. The results indicate that the NBPs comply with the legislative requirements for use in conventional farming, except for the higher content of trace elements compared to the threshold limits established in organic farming. In this context, it should be noted that the maximum permissible levels of trace metals set out in Decree 12

Table 3
Regulatory requirements under D.Lgs 75/10 and Decree 12 December 2023, and compliance of NBPs with established compositional thresholds.

PARAMETER	**NBP average analytical data calculated from Table 1**	**D.Lgs 75/2010, Decree 12 December 2023; conventional farming**	**D.Lgs 75/2010, Decree 12 December 2023; organic farming**
		Mixed soil amendment	**Mixed soil amendment**
Humidity	24.8	< 50%	
C from humic and fulvic acids (d.m.)	> 7 %	>7%	
Total Organic Carbon (%) (d.m.)	37.5	>20%	
Organic Nitrogen % of total N	95	>80%	
C/N	8.5	<25	
Macroscopic impurities (plastic, glass, metal) > 2 mm	< 0.010	< 0.5% d.m	
Macroscopic impurities (lithoid inerts) > 5 mm	< 0.010	< 5% d.m	
*Escherichia coli or enterococcaceae (*NMP/g)	< 3	< 1000 CFU/g per gram of product produced	
Salmonella sp. (/25 g)	Not Detected	Missing in 25 g of product	
Heavy Metals (mg/kg) (d.m.)			
Zn	521	500	200
Cu	201	230	70
Ni	76.6	100	25
Cd	> 0.7	1.5	0.7
Pb	70.6	140	45
Hg	0.25	1.5	0.4
Cr VI	Not Detected	0.5	0
Total Cr	51.3		70

December 2023 are considerably lower than those stipulated in the FPR (Table 2).

4.7. *Spanish legislation*

Annex IV and V of Spanish Regulation "RD 506/2013″ [13] outline the list of biodegradable organic wastes, based on the European Waste Catalogue (EWC), that are authorised for use as components in the production of organic-based fertilising products. For an organic fertiliser to be registered in the Spanish Official Register, the raw materials used must be included in this list. Additionally, the registration requires specification of the weight percentage corresponding to each EWC code used in the formulation. With reference to NBPs production (Fig. 1), Spanish legislation recognises hydrolysates obtained from various municipal biowaste sources or stabilised products, provided they originate from source-separated collection of the organic fraction of municipal solid waste (OFMSW). The following feedstocks are permitted:

- hydrolysates produced directly from OFMSW;
- hydrolysates derived from OFMSW compost;
- hydrolysates obtained from digestate; and
- hydrolysates produced from compost that has undergone prior anaerobic digestion.

For legal compliance and registration in Spain, only raw materials or end-products derived from the source-separated OFMSW corresponding to the following EWC codes are allowed for the production of hydrolysates:

20 01 Fractions separately collected
20 01 08 Biodegradable kitchen & canteen waste
20 02 Residues from gardens and parks
20 02 01 Biodegradable waste
20 03 Other municipal residues
20 3 01 Residues from markets of vegetable or animal origin

Regulation RD 506/2013 also identifies several categories of fertilising products permitted for agricultural use. These product groups vary according to their nitrogen (N), phosphorus (P) and potassium (K) content; the origin of the input waste materials; and the specific manufacturing processes employed. Key examples include:

- 2.01.03 – Organic nitrogen fertiliser from animal or vegetable origin: total $N > 3$ %; C/N ratio < 12.
- 2.03.02 – Organic NPK fertiliser from animal or vegetable origin: $N + K_2O + P_2O_5 > 4$ %; total $N > 3$ %; $P_2O_5 > 3$ %; C/N ratio < 12.
- 2.04.02 – Organic NP fertiliser from animal or vegetable origin: $N + P_2O_5 > 6$ %; total $N > 2$ %; $P_2O_5 > 3$ %; C/N ratio < 12.
- 4.1.03b – Humic acids from organic amendments: Humic acids (%) (f.m.) ≥ 7; total humic extract (humic acids + fulvic acids) (%) (f.m.) ≥ 15;
- 6.01b – Humic organic amendment from animal & vegetable origin: total organic matter > 25 %; moisture content $\langle$ 40 %; total humic extract > 5 %; humic acids > 3 %; C/N ratio < 20.

Based on their production processes and compositional characteristics, the investigated NBPs are most comparable to the category of humic extracts. For example, a typical CVD-type NBPs, analysed on a dry matter basis, shows the following values: total organic matter 47 %, moisture content 14 %, total humic extract 40 % and a C/N ratio of 6.9. To register such "extracted-processed materials" in Spain, it is first necessary to register the original (pristine) materials from which the extracts are derived. As noted in Section 4.4, a comparable product (the CV-type NBP known as Florasol) is currently registered in Italy as an organic fertiliser. Florasol is classified as a hydrolysate of the previously registered green compost product Floraviva V, and features improved solubility compared to its precursor. A similar relationship exists in the case of CVD-type NBPs, which are hydrolysates with enhanced solubility relative to the original CVD compost registered under Italian legislation.

However, the registration of CVD-type NBPs hydrolysates under the Spanish Regulation does not appear feasible. Currently, no products are officially registered under the Spanish category of humic extracts (SM file Appendix E). This is primarily due to the regulatory requirement that all such products must declare minimum nutrient contents – including both "humic acids" and "total humic extract" – expressed on a fresh matter basis. While CVD-type NBPs meet the requirement for total humic extracts (18.8 % vs. the ≥ 15 % threshold), the measured humic acid content (5.5 % fresh matter) falls below the required minimum of 7 %.

Another discrepancy can be observed upon comparing the heavy metals threshold limits set forth in the Spanish (Table 4) and Italian legislation (Table 3). The two legislations list the same heavy metals. However, Table 4 gives three different threshold limits for each metal in five different materials allowed as organic fertilisers or soil improvers, whereas Table 3 listing only two types of fertilisers. Further discrepancy and confusion arise upon comparing materials and threshold limits for trace metals in the FPR (Table 1), and in the Italian and Spanish legislations.

4.8. Cyprus legislation

The primary legal framework for the registration of fertilising products in Cyprus is the "Fertiliser Regulation 2006″ – Law No 31 (I)/ 2006, with particular reference to Article 26. This legislation remained in force until 2022 and set forth requirements and product categories largely aligned with those described in Sections 4.6 and 4.7 for Italy and Spain, respectively. Specifically, the criteria focused on nutrient content, the presence of impurities and limits for heavy metals. At present, however, the available regulatory descriptions of product categories and requirements are insufficiently detailed to enable a comprehensive analysis of the potential registration of CVD-type NBPs under Cypriot law.

4.9. The environmental risk of trace elements

The analysis of the three countries case studies in the above Sections 4.6–4.8 points out that, aside from the discrepancies highlighted among national regulations and the FPR, the presence of trace elements in candidate new products to be registered is matter of high concern. For the NBPs case study, it should be considered that the trace metals present in the product originate from naturally occurring elements in the food waste used as feedstock. Thus, the toxicological risk associated with the NBPs is minimal or negligible, given that these trace elements are already present in food products consumed as part of regular diets. Notably, no heavy metals are introduced during the NBPs production. Nonetheless, the concentration of trace elements in MBW-derived digestates and composts may be higher than that of the original MBW feedstock, by virtue of organic matter mineralisation during fermentation (see Fig. 1). These trace elements are subsequently transferred into the final NBPs product.

Apart from meeting the requirements of the specific product categories, the presence of potential pollutants in NBPs remains an essential consideration. Importantly, the chemical composition of MBW composts, used as pristine material in the NBPs manufacturing process, varies depending on several factors, including the season, geographic origin and method of waste collection. The publication of Sortino et al. [14] addresses the environmental risks causable by the long-term soil accumulation of trace elements in NBPs. These authors report that metals in NBPs are at levels found in quality assured composts (EUC) in use in EU countries, which implies suitability for long term sustainable use of NBPs in soil. The authors experimental plan in real farm operational conditions demonstrates that the amounts of trace elements contributed by CVD NBPs is rather negligible relative to the heavy metal amounts in the starting soil, and that the potential adverse environmental impact of periodically repeated applications of SBO to the same soil should raise no more concern than that contributed by compost materials or other conventional mineral and organic N fertilisers. Nevertheless, for NBPs, the issue represents a potential critical point of attention. This can be managed through the case-by-case optimisation of the NBPs production process, as for example through the membrane ultrafiltration stage depicted in Fig. 1.

5. Procedural steps for product registration at the EU level and in member states

Details regarding the procedures for product registration at both the EU level and within individual Member States are reported in the SM file

Table 4
Requirements of and compliance of NBPs with Spanish Royal Decree 506/2013.

Parameter	Product	Spanish Royal Decree 506/2013				
	CVD NBPs March 2023	2.01.03 Organic N fertiliser from animal or vegetable origin	2.03.02 Organic NPK fertiliser from animal or vegetable origin	2.04.02 Organic NP fertiliser from animal or vegetable origin	4.1.03b Humic acids from organic amendment	6.01b Humic organic amendment from animal & vegetable origin
		Class A		Class B	Class C	
Zn	687	200		500	1000	
Cu	320	70		300	400	
Ni	61	25		90	100	
Cd	3.05	0.7		2	3	
Pb	62	45		150	200	
Hg	0.25	0.4		1,5	2,5	
Cr VI	Not detected	Not detectable by official method				
total Cr	85.3	70		250	300	
As						

Appendix F. In summary, the FPR establishes a common legal framework for placing fertilising products in the EU market. It defines the roles played by key economic operators (i.e., manufacturers and their authorised representatives, importers and distributors) and outlines a number of procedural steps and documentation requirements. It also sets out guiding principles, evaluation criteria and the responsibilities of designated public authorities for the assessment of registration dossiers. In addition, it includes product-specific labelling requirements.

The analysis of the three countries case studies (Sections 46–4.8) and the information presented in the SM file Appendix F reveals a marked lack of harmonisation among Member States' regulatory frameworks. When comparing national registration procedures in countries such as Italy, Spain and Cyprus, clear discrepancies emerge in terms of requirements, procedural steps and the documentation to be submitted to competent authorities. Consequently, the registration of a product in a Member State, other than that in which it is manufactured, often places a disproportionate burden on the manufacturer. By contrast, registration under the FPR – enabling affixation of the CE mark – allows products to be placed directly in the EU Single Market.

5.1. Impact on new products industrial scalability and cross-border trade from lack of consistencies among EU national legislations

The replicability/transferability/full implementation of the NBPs manufacturing process and cross-border product allocation in the EU agriculture and chemical market has been estimated between 1500 and 800,000 €/t [15]. This value is several orders of magnitude higher than the value of the biogas and compost currently produced by the current biowaste treatment plants [16]. Along the economic benefits and contribution to CAP and CEAP (see Sections 4.4 an 4.5), a number of other positive impacts have been estimated for the environment, society and the living EU policy, as for example: a) reducing emissions of ammonia and/or nitrogen oxides from biogas plants processing municipal biowastes and agriculture/zootechnical wastes produced in the rural environment; b) reducing eutrophication caused by the application in soil of conventional biogas digestate containing excess ammonia or of excess mineral fertilisers and leaching of nitrogen nutrients into natural waters; c) lowering CO2 emission by replacing fossil chemicals with NBPs; d) create new jobs; e) establish healthier environment; f) convince citizens that wastes are source of economic, social and environmental benefits, rather than cost; g) include NBPs in EU regulation on fertilisers within CAP PFC3/6 category; h) include NBPs as authorized chemical specialities within REACH Chemicals Policy; i) create the multifunctional PFC (see Sections 4.2.1 and 4.2.2); j) contribute to bio-based products standardization and certification.

The achievement of these expectations depends the industrial scalability of the NBPs manufacturing process and on the product cross-border trade across EU Member States. At the current close-to-market development state of NBPs (see Sections 1.1 and 4.2.1), the realization of the above economic, environmental and social impact is strongly limited by the current discrepancies of EU Member States legislations. Whereas the present paper has highlighted a number of legislative drawbacks, it must be considered that the results of the present paper have been attained in a project co-funded by the European Commission (see acknowledgement), aiming to assess the potential marketability of new bio-based products (NBPs) in Italy, Greece and Cyprus (see Section 2). The reported results are outcomes of a long time R&D work started in 2004, which has involved process and product technology development, and Life cycle environmental (LCA), economic (LCC), regulatory certification (RCA) and social life cycle (S-LCA) assessments. The authors are not aware of other bio-waste derived multifunctional products, which have been studied and developed at close-to-market level as the NBPs. Nonetheless, the project is still a case-study project involving one product type and a rather limited number of EU member countries represented in the project partners' consortium. Under these circumstances, the present paper has a number of limitations. For instance, while the authors highlight the lack of consistency between Italian, Spanish, and Cypriot legislation, a deeper and more reliable analysis should be carried out over a higher number of EU member countries, and over a higher numbers of new bio-based products potentially registrable in the proposed multifunctional Product Function Category (PFC). This approach would allow collecting more data from new case studies and performing more comparative analyses across Member States, in order to assess along-the-way the impact of the national regulatory discrepancies on the industrial scalability and cross-border trade of new bio-based products. This should endorse before the EU Commission the need to update and include the multifunctional PFC in the current legislation.

All above considered, the present paper provides a useful tool for products' manufacturers and/or importers to understand the intricate study matter and deal with the complex legal requirements for the registration of new bio-based products from different sources and for different multiple uses, such as the NBPs. To this end, the NBPs represent a typical example. They are derived from municipal bio-waste for use in different sectors of the agriculture and chemical industries. They are not yet commercially available, although being in close-to-market development state. For their multifunctional properties and multipurpose uses, the NBPs may be registered at EU level under *the Chemicals REACH* and the *Fertilising Products Regulation (FPR)*. The results evidence that registering a product under the EU regulations offers the advantage of including the product on the *Single Market with the CE mark*. In compliance with the *Treaty on the Functioning of the European Union* and the *EU regulation (EU) on the mutual recognition of goods lawfully marketed in another Member State*, the CE marked product can be sold in all Member States. Registration under the regulations of the single EU Member States is much more complex and time-consuming.

The NBPs case study suggests that the EU regulation should be updated, in order to include a new category dedicated to multifunctional bio-based products. It is clear that the NBPs comply with and can contribute to realise all objectives of the CAP, CEAP and WFD EU policies. To do it, the implementation of the NBPs at industrial production and commercialisation level is necessary, but this depends primarily on the compliance of the products with the requirements of FPR and REACH policies. Several drawbacks and hurdles to overcome have been identified at this regard. The introduction of a new PFC in the FPR framework, i.e. the Multifunctional Product Category, seems necessary to remove all controversies for the registration of NBPs and other future similar multifunctional products, easy out their commercialisation, implement their market allocation in the agriculture and chemical industries sectors, and realise the environmental, economic and social benefits set forth by the current EU policy plans.

6. Conclusions

The present analysis confirms that NBPs comply with, and can significantly contribute to, the objectives of key EU policy frameworks, including the CAP, CEAP and WFD. Realising this potential, however, requires the full-scale industrial production and commercial deployment of NBPs. This, in turn, is contingent on their compliance with the regulatory requirements set forth in the FPR and REACH. Several regulatory challenges and barriers to market entry have been identified. In this context, the introduction of a new PFC within the FPR (i.e., a multifunctional product category) appears necessary. Such a category would help resolve current classification ambiguities, facilitate the registration of NBPs and future multifunctional products, and ease their market entry. Moreover, it would support their broader integration into agricultural and chemical sectors, thus helping to deliver the environmental, economic and societal benefits envisioned by current EU policies.

CRediT authorship contribution statement

Piergiuseppe Morone: Writing – review & editing, Writing –

original draft, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Giulia Borghesi:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Ilaria Galvagno:** Writing – review & editing, Writing – original draft, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Elio Padoan:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Enzo Montoneri:** Writing – review & editing, Writing – original draft, Validation, Supervision, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **José Maria Gomez:** Writing – review & editing, Writing – original draft, Resources, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Michalis Koutinas:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Simone Solaro:** Writing – review & editing, Writing – original draft, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Federico Boccardo:** Writing – review & editing, Writing – original draft, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Supplementary materials

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Data availability

Data will be made available on request.

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