European Consortium of the Organic-Based Fertilizer Industry

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Comments on the draft EU regulation on fertilising products

ECOFI welcomes the Commission's proposal to replace Regulation (EC) 2003/2003 with a regulation that covers the full range of products related to plant nutrition, including organic-based fertilisers and soil improvers. This is a positive step, and ECOFI congratulates the Commission on issuing a strong basis for further discussions and negotiations. Nonetheless, it is complex to prepare a succinct text covering so many product categories, and ECOFI would like to suggest a number of modifications to further improve the text and facilitate its operationalisation.

ECOFI's comments are largely of a technical nature with a view to increasing consistency and clarity or fostering innovation.

Line no.	Commission text	Suggested amendment	Justification
	Article 2		
	[ADD A NEW DEFINITION OF 'MATERIAL']	**'material' means any matter incorporated into a product, including but not limited to substances as defined by Regulation (EC) 1907/2006, and excluding micro-organisms as defined by Annex II of the present regulation.**	• The word "material" is used in many places throughout the draft but is not defined. It is important to distinguish it from the word "substance" – which has a specific definition under REACH Regulation 1907/2006.
	Article 48		
	Member States shall not impede the making available on the market of products which were placed on the market as fertilisers designated "EC fertiliser" in conformity with Regulation (EC) No 2003/2003 before [Publications office, please insert the date of application of this Regulation]. However, Chapter 5 shall apply *mutatis mutandis* to such products.	Member States shall not impede the making available on the market of products which were placed on the market as fertilisers designated "EC fertiliser" in conformity with Regulation (EC) No 2003/2003 before **twelve months after** [Publications office, please insert the date of application of this Regulation]. However, Chapter 5 shall apply *mutatis mutandis* to such products.	• The time foreseen in Article 48 for the transitional period seems unrealistic. Twelve months after the date of application would be more realistic.
	Annex I, Part II		
	[ADD A NEW PARA. 5]	**All percentages refer to fresh mass except where otherwise specified.**	• Defining this parameter in the introductory text of the annex provides greater clarity for its application.
	Annex I, Part II, PFC 1(A)(1)		
	An organic fertiliser shall contain • carbon (C) and	An organic fertiliser shall contain • **organic** carbon (C) and	• To be consistent with the requirements for labelling and tolerances, this text should

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	• nutrients of solely biological origin, excluding material which is fossilized or embedded in geological formations.	• nutrients of solely biological origin, ~~excluding material which is fossilized or embedded in geological formations.~~	specify "organic carbon". • The reference to materials in geological formations makes not sense because it would exclude leonardite, lignite and peat, all of which are common components of organic fertilisers.
	Annex I, Part II, PFC 1(A)(2)		
	Contaminants must not be present in the CE marked fertilising product by more than the following quantities: • Cadmium (Cd) 1,5 mg/kg dry matter, • Hexavalent chromium (Cr VI) 2 mg/kg dry matter, • Mercury (Hg) 1 mg/kg dry matter, • Nickel (Ni) 50 mg/kg dry matter, • Lead (Pb) 120 mg/kg dry matter, and • Biuret (C2H5N3O) 12 g/kg dry matter.	Contaminants must not be present in the CE marked fertilising product by more than the following quantities: **(a) Cadmium (Cd)** **(1) Where the CE marked fertilising product has a total phosphorus (P) content of less than 5 % phosphorus pentoxide (P_2O_5)-equivalent by mass: 3 mg/kg dry matter, or** **(2) Where the CE marked fertilising product has a total phosphorus (P) content of 5 % phosphorus pentoxide (P_2O_5)-equivalent or more by mass:** • **As of [Publications office, please insert the date of application of this Regulation]: 60 mg/kg phosphorus pentoxide (P_2O_5),** • **As of [Publications office, please insert the date occurring three years after the date of application of this Regulation]: 40 mg/kg phosphorus pentoxide (P_2O_5), and** • **As of [Publications office, please insert the date occurring twelve years after the date of application of this Regulation]: 20 mg/kg phosphorus pentoxide (P_2O_5),** (b) Hexavalent chromium (Cr VI) 2 mg/kg dry matter, (c) Mercury (Hg) 1 mg/kg dry matter, (d) Nickel (Ni) 50 mg/kg dry matter, (e) Lead (Pb) 120 mg/kg dry matter, and ~~Biuret (C2H5N3O) 12 g/kg dry matter.~~	• The Cd limits for organic fertilizers and organic soil improvers (Annex I, Part II, PFC 3(A)(2)) seem to be backwards from a safety perspective. OSI are more likely to be applied in greater quantities; therefore if either of the two categories should have lower limits to prevent soil loading, it should be organic soil improvers. • Furthermore, to ensure fair competition among product types, it is recommended to align the Cadmium limits for organic-based products with the limits stated for inorganic fertilisers (PFC 1(C)). • Biuret should be deleted because it is not naturally occurring in organic fertilizers. It is related to the presence of urea.
	Annex I, Part II, PFC 1(A)(3-4)		
	3. Salmonella spp. shall be absent in a 25 g sample of the CE marked fertilising product.	[REPLACE THESE 2 PARAGRAPHS WITH A NEW PARA. 3} **When the CE-marked fertilising product contains an animal by-product as defined in Regulation (EC) 1069/2009, the**	• ECOFI's proposed wording is consistent with reflects how the requirements under Reg. (EC) 1069/2009 are applied.

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	4. None of the two following types of bacteria shall be present in the CE marked fertilising product in a concentration of more than 1000 CFU/g fresh mass: (a) Escherichia coli, or (b) Enterococcaceae. This shall be demonstrated by measuring the presence of at least one of those two types of bacteria.	**manufacturer must demonstrate that the product meets the following criteria:** **1. No Salmonella species in 25 g sample and ≤1000 CFU E. Coli / g product; or** **2. No Salmonella species in 25 g sample and ≤1000 CFU Enterococcaceae / g product**	• The wording in the Commission's current proposal is unclear and opens the door for Notified Bodies to require tests for both E. Coli and Enterococcaceae.
	Annex I, Part II, PFC 1(A)(I)(1)		
	A solid organic fertiliser shall contain 40% or more dry matter by mass.	1. A solid organic fertiliser shall **be an organic fertiliser which is neither in suspension nor in solution within the meaning of PFC 1(A)(II) in this Annex.**	• This rewording would align the definition of solid organic fertilisers with that used for inorganic fertilisers, thus simplifying the text.
	Annex I, Part II, PFC 1(A)(I)(2)		
	The CE marked fertilising product shall contain at least one of the following declared nutrients in the minimum quantities stated: • 2,5% by mass of total nitrogen (N), • 2% by mass of total phosphorus pentoxide (P_2O_5), or • 2% by mass of total potassium oxide (K_2O).	The CE marked fertilising product shall contain at least one of the following declared nutrients in the minimum quantities stated: • 2,5% by mass of total nitrogen (N), **or** • 2% by mass of total phosphorus pentoxide (P_2O_5), or • 2% by mass of total potassium oxide (K_2O).	• Adding "or" clarifies that nitrogen is optional.
	Annex I, Part II, PFC 1(A)(II)(1)		
	1. A liquid organic fertiliser shall contain less than 40% dry matter.	1. A liquid organic fertiliser **shall be an organic fertiliser in suspension or in solution, where:** • **a suspension means a two-phase dispersion in which solid particles are maintained in suspension in the liquid phase, and** • **a solution means a liquid that is free of solid particles.**	• This rewording would align the definition of liquid organic fertilisers with that used for inorganic fertilisers, thus simplifying the text.

Line no.	Commission text	Suggested amendment	Justification
	Annex I, Part II, PFC 1(A)(II)(2)		
	The CE marked fertilising product shall contain at least one of the following declared nutrients in the minimum quantities stated: • 2% by mass of total nitrogen (N), • 1% by mass of total phosphorus pentoxide (P_2O_5), or • 2% by mass of total potassium oxide (K_2O)..	The CE marked fertilising product shall contain at least one of the following declared nutrients in the minimum quantities stated: • 2% by mass of total nitrogen (N), **or** • 1% by mass of total phosphorus pentoxide (P_2O_5), or • 2% by mass of total potassium oxide (K_2O)..	• Adding "or" clarifies that nitrogen is optional.
	Annex I, Part II, PFC 1(B)(1)		
	An organo-mineral fertiliser shall be a co-formulation of • one or more inorganic fertilisers, as specified in PFC 1(C) below, and • a material containing – organic carbon (C) and – nutrients of solely biological origin, excluding material which is fossilized or embedded in geological formations.	An organo-mineral fertiliser shall be a co-formulation of • one or more inorganic fertilisers, as specified in PFC 1(C) below, and • **one or more materials** containing – organic carbon (C) and – nutrients of solely biological origin, ~~excluding material which is fossilized or embedded in geological formations.~~	• The text should be clearer that a single product may contain more than one organic material. • The reference to materials in geological formations makes not sense because it would exclude leonardite, lignite and peat, all of which are common components of organo-mineral fertilisers.
	Annex I, Part II, PFC 1(B)(4-5)		
	4. Salmonella spp. shall be absent in a 25 g sample of the CE marked fertilising product. 5. None of the two following types of bacteria shall be present in the CE marked fertilising product in a concentration of more than 1000 CFU/g fresh mass: (a) Escherichia coli, or	[REPLACE THESE 2 PARAGRAPHS WITH A NEW PARA. 3} **When the CE-marked fertilising product contains an animal by-product as defined in Regulation (EC) 1069/2009, the manufacturer must demonstrate that the product meets the following criteria:** **1. No Salmonella species in 25 g sample and ≤1000 CFU E. Coli / g product; or** **2. No Salmonella species in 25 g sample and ≤1000 CFU**	• ECOFI's proposed wording is consistent with reflects how the requirements under Reg. (EC) 1069/2009 are applied. • The wording in the Commission's current proposal is unclear and opens the door for Notified Bodies to require tests for both E. Coli and Enterococcaceae.

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	(b) Enterococcaceae. This shall be demonstrated by measuring the presence of at least one of those two types of bacteria.	**Enterococcaceae / g product**	
	Annex I, Part II, PFC 1(B)(I)(1)		
	A solid organo-mineral fertiliser shall contain 60% or more dry matter by mass.	A solid organo-mineral fertiliser shall **be an organo-mineral fertiliser which is neither in suspension nor in solution within the meaning of PFC 1(B)(II) in this Annex.**	• This rewording would align the definition of solid organo-mineral fertilisers with that used for inorganic fertilisers, thus simplifying the text.
	Annex I, Part II, PFC 1(B)(I)(2)		
	The CE marked fertilising product shall contain at least one of the following declared nutrients in the minimum quantities stated: • 2,5 % by mass of total nitrogen (N), out of which 1 % by mass of the CE marked fertilising product shall be organic nitrogen (N), or • 2 % by mass of total phosphorus pentoxide (P_2O_5), or • 2 % by mass of total potassium oxide (K_2O).	The CE marked fertilising product shall contain at least 2,5 % by mass of total nitrogen (N), out of which 1 % by mass of the CE marked fertilising product shall be organic nitrogen (N), **and one or both of the following declared nutrients in the minimum quantities stated:** • 2 % by mass of total phosphorus pentoxide (P_2O_5), or • 2 % by mass of total potassium oxide (K_2O).	• Without organic N, there are no nutrients in an organic chemical form that can be tested during market surveillance. i.e. It is impossible to have a P, K, or PK organo-mineral fertilizer. Such a product would, by definition, be an inorganic fertilizer.
	Annex I, Part II, PFC 1(B)(I)(4)		
	In the CE marked fertilising product, each unit shall contain the organic matter and the nutrients in their declared content.	In the CE marked fertilising product, each unit shall contain **organic carbon and all the declared nutrients in their declared content. A unit refers to one of the component pieces of product such as granules, pellets, etc.**	• It is impossible to guarantee the exact proportions of the contents in each unit of the product. A metaphor may help explain why: two batches of chocolate chip cookie dough may contain exactly the same proportions of ingredients, but the proportions in each cookie will be variable. A similar process occurs with the distribution of the inorganic fertiliser units within the organic matter that flows around

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			them in the extrusion process and fills in the gaps between the pieces of organic fertiliser in each unit of the organo-mineral fertiliser.
	Annex I, Part II, PFC 1(B)(I)(5)		
	[INSERT A NEW SUB-PARAGRAPH (5.)	**When urea is used as a raw material biuret must not be present by more than 12 mg/kg.**	• Limits for biuret in solid organo-mineral fertilizers should be aligned with those for inorganic fertilizers, since the urea incorporated into the organo-mineral fertilizer is the likely source.
	Annex I, Part II, PFC 1(B)(II)(1)		
	1. A liquid organo-mineral fertiliser shall contain less than 60 % dry matter by mass.	1. A liquid organo-mineral fertiliser **shall be an organo-mineral fertiliser in suspension or in solution, where:** • **a suspension means a two-phase dispersion in which solid particles are maintained in suspension in the liquid phase, and** • **a solution means a liquid that is free of solid particles.**	• This rewording would align the definition of liquid organo-mineral fertilisers with that used for inorganic fertilisers, thus simplifying the text.
	Annex I, Part II, PFC 1(B)(II)(2)		
	The CE marked fertilising product shall contain at least one of the following declared nutrients in the minimum quantities stated: • 2 % by mass of total nitrogen (N), out of which 0,5 % by mass of the CE marked fertilising product shall be organic nitrogen (N), or • 2 % by mass of total phosphorus pentoxide (P_2O_5), or 2 % by mass of total potassium oxide (K_2O).	The CE marked fertilising product shall contain at least 2 % by mass of total nitrogen (N), out of which 0,5 % by mass of the CE marked fertilising product shall be organic nitrogen (N), **and one or both of the following declared nutrients in the minimum quantities stated:** • 2 % by mass of total phosphorus pentoxide (P_2O_5), or • 2 % by mass of total potassium oxide (K_2O).	• Without organic N, there are no nutrients in an organic chemical form that can be tested during market surveillance. i.e. It is impossible to have a P, K, or PK organo-mineral fertilizer. Such a product would, by definition, be an inorganic fertilizer.
	Annex I, Part II, PFC 1(B)(II)(4)		
	[INSERT A NEW SUB-PARAGRAPH (5.)	**When urea is used as a raw material biuret must not be present by more than 2 mg/kg.**	• Biuret is extremely phytotoxic and should be strictly limited in foliar organo-mineral fertilizers.

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	Annex I, Part II, PFC 1(C)		
	An inorganic fertiliser shall be a fertiliser other than an organic or organo-mineral fertiliser. • 2,5 % by mass of total nitrogen (N), out of which 1 % by mass of the CE marked fertilising product shall be organic nitrogen (N), or • 2 % by mass of total phosphorus pentoxide (P_2O_5), or • 2 % by mass of total potassium oxide (K_2O).	An inorganic fertiliser shall be a fertiliser other than an organic or organo-mineral fertiliser **and shall contain no carbon**.	• Without this addition, organo-mineral fertilizers that have too little carbon to meet the requirements for PFC 1(B) would qualify to be inorganic fertilizers, which would be misleading.
	Annex I, Part II, PFC 3(A)		
	A soil improver shall be a CE marked fertilising product aimed at being added to the soil for the purpose of maintaining, improving or protecting the physical or chemical properties, the structure or the biological activity of soil.	A soil improver shall be a CE marked fertilising product aimed at being added to the soil **in situ** for the purpose of maintaining, improving or protecting the physical **and/or** chemical **and/or biological** properties**, with the exception of liming materials or micro-organisms. 'Mulch' means a type of soil improver used as protective covering placed around plants on the topsoil whose specific functions are to prevent the loss of moisture, control weed growth, and reduce soil erosion.**	• Most of these proposed changes are to align the definition with the one used in Commission Decision (EU) 2015/2099 of 18 November 2015. • The reference to micro-organisms is necessary to prevent microbial biostimulants from being placed on the market masked as soil improvers in order to avoid the stricter requirements for biostimulants.
	Annex I, Part II, PFC 3(A)(1)		
	An organic soil improver shall consist exclusively of material of solely biological origin, excluding material which is fossilized or embedded in geological formations.	• **An organic soil improver** means a soil improver containing carbonaceous materials whose main function is to increase soil organic matter content. 'Organic mulch' means mulch containing carbonaceous materials derived from biomass. ~~.shall consist exclusively of material of solely biological origin, excluding material which is fossilized or embedded in geological formations.~~	• These proposed changes are to align the definition with the one used in Commission Decision (EU) 2015/2099 of 18 November 2015. • The reference to materials in geological formations makes no sense because it would exclude leonardite, lignite and peat, all of which are common components of organic soil improvers.

Line no.	Commission text	Suggested amendment	Justification
	Annex I, Part II, PFC 3(A)(3)		
	When the CE-marked fertilising product contains an animal by-product as defined in Regulation (EC) 1069/2009 (a) Salmonella spp. shall be absent in a 25 g sample of the CE marked fertilising product. (b) None of the two following types of bacteria shall be present in the CE marked fertilising product in a concentration of more than 1000 CFU/g fresh mass: • Escherichia coli, or • Enterococcaceae. This shall be demonstrated by measuring the presence of at least one of those two types of bacteria.	[REPLACE THESE 2 PARAGRAPHS WITH A NEW PARA. 3} **When the CE-marked fertilising product contains an animal by-product as defined in Regulation (EC) 1069/2009, the manufacturer must demonstrate that the product meets the following criteria:** **1. No Salmonella species in 25 g sample and ≤1000 CFU E. Coli / g product; or** **2. No Salmonella species in 25 g sample and ≤1000 CFU Enterococcaceae / g product**	• ECOFI's proposed wording is consistent with reflects how the requirements under Reg. (EC) 1069/2009 are applied. • The wording in the Commission's current proposal is unclear and opens the door for Notified Bodies to require tests for both E. Coli and Enterococcaceae.
	Annex II, Part II, CMC 2		
	1. A CE marked fertilising product may contain plants, plant parts or plant extracts having undergone no other processing than cutting, grinding, centrifugation, pressing, drying, freeze-drying or extraction with water. 2. For the purpose of paragraph 1, plants are understood to include algae and exclude blue-green algae.	1. A CE marked fertilising product may contain plants, plant parts or plant extracts having undergone **only physical, mechanical or biochemical processing. The process may include further concentration, purification and/or blending, provided that the chemical nature of the components is not intentionally modified/altered by chemical and/or microbial processes.** 2. For the purpose of paragraph 1, plants are understood to include algae and exclude blue-green algae. **3. Other plant extracts and materials other than those specified in CMC 2 as well as components structurally similar and functionally identical to components found in plants would fall into CMC 1.**	• These modifications would ensure that a wide range of plant extracts, lignosulfonates and barks from the paper milling industry, cakes from oilseed processing and other useful plant derivatives (such as plant hydrolysates) may be incorporated into fertilising products with appropriate requirements. • Replacing the detailed list of processing by generic processes, ensures that no eligible processes are unintentionally deleted. This proposal would also treatments such as enzymatic hydrolysis, which is exempted from REACH obligations, but excluded from the exemptions mentioned in CMC 1.
	Annex II, Part II, CMC 3(1)(c)		
	Living or dead organisms or parts	~~Living or d~~**D**ead organisms or parts thereof, which are	• Allowing living organisms to be included in

Line no.	Commission text	Suggested amendment	Justification
	thereof, which are unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which are extracted from air by any means, except • the organic fraction of mixed municipal household waste separated through mechanical, physicochemical, biological and/or manual treatment, • sewage sludge, industrial sludge or dredging sludge, and • animal by-products of category 1 according to Regulation (EC) No 1069/2009;	unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which are extracted from air by any means, except • the organic fraction of mixed municipal household waste separated through mechanical, physicochemical, biological and/or manual treatment, • sewage sludge, industrial sludge or dredging sludge, and animal by-products of category 1 according to Regulation (EC) No 1069/2009;	compost would provide a loophole by which micro-organisms that do not qualify for use under CMC 7 could be incorporated in products with much lower safety requirements.
	Annex II, Part II, CMC 3(1)(d, 2nd bullet point)		
	• the total concentration of all additives does not exceed 5 % of the total input material weight; or	• the total concentration of all additives does not exceed 5 % of the total input material weight **before the mix**; or	• Concentrations could be artificially diluted by the mix.
	Annex II, Part II, CMC 3(6)(a, 2nd bullet point)		
	• Criterion: maximum 25 mmol O/kg organic matter/h; or	• Criterion: maximum **50** mmol O/kg organic matter/h; or	• It's not clear why the value is different here than for CMC 5, so we propose aligning the values at 50.
	Annex II, Part II, CMC 5(3)(a)		
	Thermophilic anaerobic digestion at 55°C during at least 24h and a hydraulic retention time of at least 20 days;	Thermophilic anaerobic digestion at 55°C during at least 24h and a hydraulic retention time of at least 20 days, **followed by an analysis to verify that the digestion process successfully destroyed the pathogens**;	• At this low temperature for such a short digestion period, it is possible for some pathogens to survive and to subsequently multiply during the retention period. It is critical to verify the absence of pathogens at the end of

Line no.	Commission text	Suggested amendment	Justification
			the retention period.
	Annex II, Part II, CMC 6 - designation		
	FOOD INDUSTRY BY-PRODUCTS	FOOD **CHAIN** BY-PRODUCTS	• The positive list in CMC 6 currently excludes many materials coming from the food chain that are allowed in food, feed and soil applications
	Annex II, Part II, CMC 6		
	[ADD A SUB-PARAGRAPH 1(d)	**Any other material or substance that has been approved for use in food or animal feed or cosmetology or pharmacy, including food chain industrial by-products with the exception of animal by-products within the meaning of Regulation (EC) 1069/2009, provided that there is no known safety, health or hygiene issue associated with that substance or material.**	• The positive list in CMC 6 currently excludes many materials coming from the food chain that are allowed in food, feed and soil applications. • This new paragraph would allow for materials like yeast from food chain fermentation processes to be used, but exclude spoiled food from being allowed since it could introduce pathogens.
	Annex II, Part II, CMC 7		
	A CE marked fertilising product may contain micro-organisms, including dead or empty-cell micro-organisms and non-harmful residual elements of the media on which they were produced, which • have undergone no other processing than drying or freeze-drying and • are listed in the table below: - Azotobacter spp. - Mycorrhizal fungi - Rhizobium spp. - Azospirillum spp.	**1.** Micro-organisms, including dead or empty-cell micro-organisms and non-harmful residual elements of the media on which they were produced **may be incorporated into a CE marked fertilising product if they are listed in the table below:** • ~~have undergone no other processing than drying or freeze-drying and~~ *- Azotobacter spp.* *- Mycorrhizal fungi* ***- Rhizobia*** *- Azospirillum spp.* **-- Subject to appropriate data protection and data licensing requirements, any microorganism (or consortium of microorganisms) that is allowed by EU regulation to be incorporated into a 'foodstuff' as defined in Article 2 of Regulation (EC) No 178/2002 or that is allowed to be used in the processing of any such foodstuff, including cultures that are considered to be 'traditional food ingredients' within the meaning of Regulation (EC) No 178/2002 of the European Parliament and of the Council;**	• The proposed definition of micro-organisms omits a large number of techniques and processes currently used to produce microbial products. Furthermore, such a restrictive listing of production processes does not favour innovation. As long as safety and quality is ensured, there should be no reason to limit the scope of the category on the basis of production process. Therefore we suggest deleting the first bullet point. • 'Rhizobium spp.' does not accurately reflect the group of organisms that appear to be intended, which includes Bradyrhizobium or Sinorhizobium species are technically not included in this group. • The brief positive list of micro-organisms in the Commission's proposal does not reflect the wide variety of micro-organisms already incorporated into organic-based fertilizers today, let alone all of the strains and consortia

Line no.	Commission text	Suggested amendment	Justification
		-- Subject to appropriate data protection and data licensing requirements, any microorganism (or consortium of microorganisms) that is included in the European Union Register of Feed Additives pursuant to Regulation (EC) 1831/2003; **-- Subject to appropriate data protection and data licensing requirements, any microorganism (or consortium of microorganisms) that has been approved as a plant protection active ingredient under Regulation (EC) 1107/2009 or as a biocide under Regulation (EU) 528/2012;** **-- Subject to appropriate data protection and data licensing requirements, any microorganism (or consortium of microorganisms) that is listed as a biopesticide active ingredient by the United States Environmental Protection Agency;** **-- Any microorganism (or consortium of microorganisms) that has been evaluated as being safe for use as a biostimulant using relevant common specifications or harmonised standards adopted in accordance with Regulation (EU) 1025/2012 of the European Parliament and of the Council that detail acceptable thresholds and analytical methods for safety criteria including those outlined in Article 42 of the present regulation.**	that will be selected in the future. • The Commission's proposal implies that any company that has screened and selected new micro-organisms would have to accept that knowledge will be transformed into a public good and inscribed in the positive list of micro-organisms available to any manufacturer for use. This would essentially force companies to transfer the benefit of their privately funded research to their competitors, thus undermining fair competition and innovation. This is yet another example of European institutions failing to offer a comparable framework to biology-based and chemistry-based technologies (REACH provides evaluation of substances with data protection and licensing provisions). This is a lost opportunity to address the disequilibrium between the evaluation of chemical and biological products and to put in place the right framework conditions for the bioeconomy to flourish. • Foreseeing the use of standardized thresholds and analytical methods for the evaluation of new microbial components would correct one of the major weaknesses of the proposed legislation: the failure to foresee an innovation-friendly way for new microbial components to be evaluated and new products brought to market. At the same time, such an approach to evaluation would be consistent with the New Legislative Framework. • The change of wording at the beginning of the paragraph accommodates the small amounts of safe micro-organisms that are naturally occurring in most organic materials without

Line no.	Commission text	Suggested amendment	Justification
			opening the door for the abusive incorporation of non-listed micro-organism. Without this change, all organic materials would have to be completely sterilised, greatly raising costs and discouraging the re-use of organic materials and thus reducing the potential for nutrient recycling. However, unless such naturally occurring micro-organisms are included in the list, no claims can be made as a result of their presence.
	Annex II, Part II, CMC 11		
	[TABLE IS CURRENTLY BLANK]		• ECOFI welcomes the Commission's willingness to enlarge the list of animal by-products that have reached the end point in manufacturing in the spirit of the Circular Economy. It is essential that this general intent be operationalised by DG SANTE and the Member States through the examination and approval of additional processes for the transformation of animal by-products that have demonstrated their safety and effectiveness at national level. • ECOFI intends to submit several such processes for approval in the near future and urges the European Commission and Member States to evaluate the applications in the shortest time period possible so that more animal by-products may be revalorised into organic-based EC-marked fertilisers and soil improvers as soon as the new regulation goes into effect
	Annex III, Part 1, [ADD A NEW PARA. 4]		
	[ADD A NEW PARA. 4]	**Where the CE marked fertilising product is allowed to be used in organic agriculture according to Regulation (EC) 889/2008, it shall carry the phrase "allowed in organic farming in accordance with EC regulation n°889/2008."**	• Such labelling requirements are as important as those related to the Animal By-Products Regulation and therefore should be specifically mentioned in this list, rather than falling under the 'other information elements' of paragraph 7.

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	Annex III, Part 1,		
	[ADD A NEW PARA. 9]	**The content of other micronutrients may be declared as a percentage of the fertiliser by mass.**	• The presence of micronutrients is often a great added value to farmers.
	Annex III, Part 2, PFC 1(A)(b)		
	the declared nutrients magnesium (Mg), calcium (Ca), sulphur (S) or sodium (Na), by their chemical symbols in the order Mg-Ca-S-Na;	**When they are present in amounts >than 1%,** the declared nutrients magnesium (Mg), calcium (Ca), sulphur (S) or sodium (Na), by their chemical symbols in the order Mg-Ca-S-Na;	• Amounts of these nutrients below the proposed threshold are negligible, yet the costs of analysis would be considerable. Requiring analysis and declaration below this threshold would be a disproportionate burden on industry. • Furthermore, the regulation should specify whether the declarations concern elemental or complex forms of each nutrient.
	Annex III, Part 2, PFC 1(B)(b)		
	the declared nutrients magnesium (Mg), calcium (Ca), sulphur (S) or sodium (Na), by their chemical symbols in the order Mg-Ca-S-Na;	**When they are present in amounts >than 1%,** the declared nutrients magnesium (Mg), calcium (Ca), sulphur (S) or sodium (Na), by their chemical symbols in the order Mg-Ca-S-Na;	• Amounts of these nutrients below the proposed threshold are negligible, yet the costs of analysis would be considerable. Requiring analysis and declaration below this threshold would be a disproportionate burden on industry. • Furthermore, the regulation should specify whether the declarations concern elemental or complex forms of each nutrient.
	Annex III, Part 2, PFC 1(B)(d)		
	[INSERT A NEW BULLET POINT]	**Total copper (Cu) and zinc (Zn), if above 200 and 600 mg/kg dry matter respectively;**	• These nutrients can become toxic at high dosages.
	Annex III, Part 2, PFC 1(B)		
	[INSERT A NEW SUB-PARAGRAPH (f)]	**If biuret content is <0,2%, the phrase "poor in biuret" may be added;** **If chloride content is <2%, the phrase "poor in chloride" may be added;**	• These substances are phytotoxic above these thresholds.
	Annex III, Part 2, PFC 1(B)(I), header of the right-hand column of the table		
	Intended for horticultural use	**Other uses**	• The proposed header is too restrictive

Line no.	Commission text	Suggested amendment	Justification
			compared to actual use.
	Annex III, Part 2, PFC 3		
	The following parameters shall be declared in the following order, and expressed as a percentage of the CE marked fertilising product by mass: – Dry matter; – Organic carbon (C) content; – Total nitrogen (N) content; – Total phosphorus pentoxide (P_2O5) content; – Total potassium oxide (K_2O) content; – Total copper (Cu) and zinc (Zn) content, if above 200 and 600 mg/kg dry matter respectively; and – pH.	The following parameters shall be declared in the following order, and expressed as a percentage of the CE marked fertilising product by mass: – Dry matter; – Organic carbon (C) content; ~~– Total nitrogen (N) content;~~ – ~~Total phosphorus pentoxide (P_2O5) content;~~ ~~– Total potassium oxide (K_2O) content;~~ – Total copper (Cu) and zinc (Zn) content, if above 200 and 600 mg/kg dry matter respectively; and ~~– pH~~.	• Either an upper limit for nutrient content should be added to PFC 3 or it should not be allowed for producers to declare their nutrient content to prevent manufacturers avoiding the (currently stricter) requirements for organic fertilisers. For example, it would be possible for someone to sell an organic fertiliser with a high cadmium content as an organic soil improver; this is inconsistent from the perspective of protecting consumers and the environment, especially since soil improvers are applied in larger amounts than organic fertilisers. • The lower declaration threshold for nutrients should be 1%. Amounts of these nutrients below the proposed threshold are negligible, yet the costs of analysis would be considerable. Requiring analysis and declaration below this threshold would be a disproportionate burden on industry. • Information about the pH value of organic soil improvers provides no value to farmers.
	Annex III, Part 2, PFC 7		
	{ADD A NEW PARAGRAPH]	**The blend shall be described in terms that inform the farmer which PFCs it contains and make it clear whether nutrient proportions were determined before or after mixture.**	• Depending on the proportions of a mixed product, the proportion of nutrients relative to the mass/volume of the final product may be diluted. Labelling requirements should specify how to manage such an issue, depending on the case, for example: • "Contains Organic fertiliser 5-5-5 and a biostimulant", which makes it clear that the proportions are reported before the mix because the biostimulant will bring a negligible amount of additional nutrients; or

Line no.	Commission text	Suggested amendment	Justification
			• "Contains Organic fertiliser and an organic soil improver: 3-3-3", which makes it clear that the proportions are reported after the mix because the combination would significantly modify the proportions.
	Annex III, Part 3, PFC 1(A)		
	[SPECIFY WHICH ANALYTICAL METHODS MUST BE USED]		• These tolerances seem meaningless without reference to a specific analytical method.
	Annex III, Part 3, PFC 1(B)		
	N, P_2O_5, K_2O ± 25% of the declared content of the nutrient forms present up to a maximum of 2 percentage point in absolute terms MgO, CaO, SO_3 ± 25% of the declared content of those nutrients up to a maximum of 1,5 percentage points in absolute terms.	N, P_2O_5, K_2O ± 25% of the declared content **of each** of the nutrient forms present up to a maximum of 2 percentage point in absolute terms MgO, CaO, SO_3 ± 25% of the declared content **of each** of those nutrients up to a maximum of 1,5 percentage points in absolute terms.	• It's not clear if the tolerance of ±25% applies to each nutrient or to the sum of the three nutrients in each group. This proposed change assumes it is for each nutrient separately.
	Annex III, Part 3, PFC 3		
	Granulometry: ± 10 % relative deviation applicable to the declared percentage of material passing a specific sieve.	~~Granulometry: ± 10 % relative deviation applicable to the declared percentage of material passing a specific sieve.~~	• Since this is not a labelling requirement for this PFC, there is no need for a tolerance.
	Annex III, Part 3, PFC 7		
		[ADD A NEW PARAGRAPH EXPLAINING WHETHER TOLERANCES ARE APPLIED BEFORE OR AFTER THE BLEND.]	• How are manufacturers expected to manage tolerances in products that are subject to different tolerances for the same component (e.g. N content in fertilisers and soil improvers)? Are the tolerances applied before mixing? If so, how can they be used in market surveillance?

Comments on some translation problems in some non-English versions of the draft regulation

- Throughout the draft, care must be taken with the non-English translations that the word substance – which has a specific definition under Regulation 1907/2006 -- not be substituted for the word “material”. This is currently the case in many places in French and Italian, among other languages and could pose problems for subsequent application of the regulation.
- The current French translation suggests “fertilisant” as the translation of “fertilising product”. A more appropriate translation would “produit fertilisant” since “fertilisant” alone is generally used as an umbrella term covering organic and inorganic fertilisers.
- In the French version, the numbering under Article 38 does not start at 1 but continues the numbering of the sub-paragraphs from the previous Article 37. (What should be points 1 and 2 are points 9 and 10). This should be corrected in the final version to avoid misunderstandings when different language versions are cross-referenced.
- The French and Italian translations of PFC 1(B) should be corrected because they do not specify that it must be a “co-formulation”. For the French, we propose "Un engrais organo-minéral est une co-formulation de". For Italian, we suggest saying “un concime organo-minerale è una co-formulazione di” instead.
- The second bullet point of PFC 1(B) should be corrected in the Italian translation where the equivalent of “substance” has been substituted for material. This is problematic because of the specific definition of “substance” under the REACH regulation. Many of the materials used in organic-based fertilisers are outside the scope of REACH.
- The Italian translation of Annex II, Part II, CMC 2 contains a translation error where “pressing” is rendered as “pressione”, which means “pressure”. “Pressatura” should be used.
- Annex III, Part I, para. 4: There is a problem of translation in French: "manure" is rendered as "fumier" when it should be "lisier" in accordance with the ABP regulation.
- Annex III, Part 2, PFC1(B)(d): In the Italian version, “water soluble phosphorus pentoxide” is literally translated as “idrosolubile” when the correct technical term is “solubile in acqua”.
- Annex IV, Part I, header 1, para. 2: There is an error in the French translation, which says “CMC” instead of “PFC”.
- There is an error in the Italian version of Annex IV, Part 1, header 3, point 1(c) which says that CMC 11 relates to food by-products and not to animal by-products.
- Annex IV, Part I, header 4, para. 1: add “instead of the procedure specified above.”