

**DOSSIER CONCERNING THE REQUEST TO AMEND ANNEX II
TO COMMISSION IMPLEMENTING REGULATION 1165/2021¹**

**Fertilisers, soil conditioners and nutrients referred to in Article 24 (1)(b) of Regulation
(EU) No 848/2018² to be evaluated for use in EU organic production**

Article 24 (7) of Regulation (EU) No 848/2018:

"Where a Member State considers that a product or substance should be added to or withdrawn from the lists of authorised products and substances referred to in paragraphs 1 and 2, or that the specifications of use referred to in the production rules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

1. General information on the request

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|-----------------------|--|
| Nature of the request | <input checked="" type="checkbox"/> Inclusion <input type="checkbox"/> Deletion <input type="checkbox"/> Change of disposition |
| Request introduced by | [Member State] Contact e-mail: |
| Date | |

Please indicate if the material provided is confidential

2. Requested inclusion/deletion/amendment

| Name of additive / substance | Primary use/conditions |
|----------------------------------|---|
| ALGAE-BASED BIOSTIMULANTS | Enzymatically hydrolysed <i>Scenedesmus spp.</i> microalgae biomass cultured in reclaimed water from pig slurry. Product sold as fertiliser and plant protection products |

3. Status

Authorization in general agriculture or food processing

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| Historic use: |
| Regulatory status (EU, national, others) (including expiry dates of authorisation if applicable): Category of fertilising product under EU reg. 2019/1009: PFC6B. – non microbial biostimulant composed of CMC 1 – Virgin material substances and mixtures |

¹ [EUR-Lex - 32021R1165 - EN - EUR-Lex \(europa.eu\)](#)

² <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R0848&from=EN>

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4. Identification³

Identification of substance, terminology, synonyms

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| Chemical name(s): Aminoacid-based biostimulants |
| Other names: protein hydrolysate |
| Trade name |
| CAS code (Chemical Abstracts Systematic Names): CAS 100209-45-8 |
| Other code(s): Potential product registration as REACH regulation: 309-353-8 (protein hydrolysate, vegetable) |

5. Aspects related to the relevance and priority of the request

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| Geographical relevance (Member States, regions, ...): Biostimulants can help to stimulate plant growth through different mechanisms. Our aminoacid-based biostimulants were demonstrated (in pot tests) to help several crops to face hydric and salinity stress (demonstrated in tomato, spinach and lettuce), which can be particularly relevant in Mediterranean region in which water scarcity is an increasing concern |
| Socio-economic relevance (acreage, turnover, number of stakeholders affected, ...): Demonstrated plant protection effect towards hydric and saline stress conditions in pot test. Diversification of plant protection products that might open a new revenue source for livestock farmers. Field tests did not produce conclusive results and additional tests would be needed to validate the results from mesocosms |
| Sectors affected: livestock sector, agricultural sector and industrial sector (organic fertilizing product industry) |
| Stakeholder engagement/consultation in dossier preparation: public administration involved in the preparation of the dossier (DACC Department of Climate Action, Food and Rural Agenda of the Catalan Government) |
| Market presence: availability (quantity / quality) and origin (local / imported): Most market analysts report that the European biostimulants market accounts for roughly half of the global market. Estimates of the value of the European market range around USD 1.5-2 billion in 2022. (Market Date Forecast, Market and Markets and Dunham Trimmer). The compound annual growth rate (CAGR) reported is 10-12% (European Biostimulants Industry Council, 2023) |
| Aspects of international harmonization / market distortion The National Organic Program of the United States published the guidance document “Materials for Organic Crop Production” and referred as NOP 5034-1. This guide is aimed to be a guidance for organic producers when deciding about the authorised materials to be used in the organic sector, including organic agricultural production. The guide includes a list of materials which are considered non synthetic (natural) and are not required to be included on the National List. There is an specific section regarding aquatic plant products, including algae and algae products that can be extracted with non-synthetic or synthetic materials. Enzymes (endo and exopeptidases) |

³ To be filled in only when applicable

used in the hydrolytic process of algae to extract free aminoacids in biostimulant could be categorized as non-synthetic materials and moreover animal-derived enzymes are authorised as ingredients in or on processed products labelled as “organic” or “made with organic (§ 205.605). Therefore, we do not identify any aspect against authorising the biostimulant in evaluation as fertilising product for crops according to the US rules of organic farming.

Aminoacid-based biostimulants, as such, are not mentioned in the table authorising certain “Fertilizers and soil improvement substances” of the [Japanese Agricultural Standard for Organic Products of Plant Origin](#) (Appended Table 1). However, since biostimulants are algae-derived product they could be categorised as “Substances derived from plants and their residues” in which the only requirement for its authorisation is that the product must not have undergone any chemical treatment. Enzymatic treatment is a fermentative process, and therefore the biostimulant in evaluation could be authorised in the Japanese organic production

A (possible) authorization leads to amendment(s) in the respective Annex⁴

According to the agronomic results obtained, Aminoacid rich biostimulants obtained from microalgae hydrolysis could be included as “*Other low risk substances from plant or animal origin **” in the Annex I Active substances contained in plant protection products authorised for use in organic production. Otherwise, this product could fit in the following categories listed in the Annex II: Hydrolysed proteins of plant origin, Algae and algae products

Other aspects justifying high priority, such as

- Using these biostimulants can help diverse crops to face different stressors (effectivity demonstrated under hydric and saline stress). They could increase plant resistance to stress conditions, limiting the need of other protection products. Also, since biostimulants were also related to better soil nutrient availability, their use could be associated to a less fertilising product need
- Other

6. Characterisation

Raw materials, methods of manufacture

Composition/ingredients: Biostimulants obtained after enzymatic hydrolysis of *Scenedesmus spp.* using 2% endopetidase + 1% exopeptidase. Microalgae were cultivated over reverse osmosis permeate obtained from the liquid fraction of pig slurry (a farm in Catalonia region with a rearing license for 1618 fattening pigs per year).

Biostimulants are composed of 1.5% of total free aminoacids

| Parameter | Value | Parameter | Value |
|-----------|-------|-----------|-------|
|-----------|-------|-----------|-------|

⁴ It should be carefully analysed whether the specific use of a substance is already (implicitly) authorized or not. This is to avoid the following conclusion: "The Group considers that the use of ... is in line with the objectives, criteria and principles of the organic regulation. There is no need for amendment of the specific conditions of Annex ..."

| | | | |
|---|------------------|------------------------------|------------|
| Organic Matter (g/kg fresh matter) | 60.4 ± 1.2 (n=2) | Cu (mg/kg DM) | <0.1 (n=2) |
| Organic C (g/kg fresh matter) | 25.2 ± 0.2 (n=2) | Zn (mg/kg DM) | <0.1 (n=2) |
| Total N (NTK) (g/kg fresh matter) | 4.5 ±0.3 (n=2) | Fe (mg/kg dry matter) | <0.1 (n=2) |
| Total P (g/kg fresh matter) | 40.9 ±0.1 (n=2) | Mn (mg/kg dry matter) | <0.1 (n=2) |
| Total K (g/kg fresh matter) | 1.2 ±0.1 (n=2) | Cd (mg/kg dry matter) | <0.1-(n=2) |
| S (g/kg fresh matter) | 0.37 ±0.03 (n=2) | Ni (mg/kg dry matter) | <0.1 (n=2) |
| Ca (g/kg fresh matter) | <0.1 (n=2) | Pb (mg/kg dry matter) | <0.1 (n=2) |
| Mg (g/kg fresh matter) | < 1 | Cr (mg/kg dry matter) | <0.1-(n=2) |
| Na (g/kg fresh matter) | 0.33 ±0.03 (n=2) | Hg (mg/kg dry matter) | <0.1 (n=2) |
| Protein content (g/kg fresh matter) | 28.3 ±1.8 (n=2) | As (mg/kg dry matter) | <0.1 (n=2) |
| Total free amino acids (g/kg fresh matter) | 13.6 ±1.2 (n=2) | | |

Relevant nutrients and trace elements content: Macro, meso and micronutrient contents as well as heavy metals contents of the aminoacid based biostimulant are reported in the following table

Basic physical properties: liquid biostimulant (0.99 kg/L) with near to neutral pH (pH 7.7)

Solubility

Not measured. The aim of the product is not providing nutrients to the plant.

Origin of raw materials, production methods:

1. First microfiltration (400 nm pore size tubular ceramic membrane) and reverse osmosis (a low rejection polymeric RO membrane working at ~40bar and 50°C) of the liquid fraction of pig slurry to obtain a clean and safe permeate (Rodriguez-Alegre et al., 2023)
2. Reclaimed permeate is then used as culturing media for *Scenedesmus spp.* microalgae in photobioreactor. A commercial inoculum of *Scenedesmus spp.* microalgae (2.2L of inoculum per each L of permeate) is used to inoculate the culturing media. Microalgae cultivation lasts for approximately 1 month, after that period, the remaining nutrients in the permeate are exhausted and microalgae are dewatered through a centrifuge, obtaining 0.63% of the inlet permeate recovered as microalgae paste (in fresh mass) rich in algal protein. The exhausted cultivation media could be used as reclaimed water
3. Enzymatic hydrolysis of dewatered algae biomass. The optimised hydrolysis for the maximum protein solubilisation consisted of the use of 2% DM. exopeptidase and 1% DM. endopeptidase at 50°C for 6h, and then 1% endopeptidase in the aqueous phase at 50°C for 1h. Besides, hydrolysis was maximised when pH was controlled to pH8

7. Specification of use

Agronomic use

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| Fertiliser or soil conditioner: biostimulant |
| Application method: Foliar application |
| Dosage: Depending on amino acids concentration but slightly higher than commercial references (6-10% free aminoacids) |
| Stage of plant development: 3-5 applications following phenological stages of the plant: seedling, vegetating, budding, flowering and ripening, i.e. |
| Physiological effect, mode of action: From the results obtained, it can be concluded that they improved the nutrient availability, nutrient efficiency and crop tolerance to abiotic stress, although the mode of action should be clarified by specific research Since they can increase plant resistance to hydric stress, we could suggest using them in locations with high risk of drought periods, and and/or in crops with high water demand. All in all, aminoacid-based biostimulants could help to optimize the use of water in crops |

8. Reasons for the inclusion, withdrawal or amendments

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| Explain the need for the proposed fertilizer or soil conditioner or nutrient |
| What alternative solutions are currently authorised or possible? Algae and algae products are authorised in organic farming provided that they are treated by (i) physical processes including dehydration, freezing and grinding; (ii) extraction with water or aqueous acid and/or alkaline solution or (iii) fermentation. Enzymatic hydrolysis could fit under these definitions. However, in this case organic origin of the feedstock is compulsory which algae cultured over reclaimed water recovered from the membrane treatment of the liquid fraction of pig slurry does not meet |
| Is there any traditional use or precedents in organic production? Algae and algae products are authorized, including hydrolysed products. Origin of the cultivation media and enzymatic hydrolysis are the specific points to be evaluated for their authorisation |

9. Consistency with objectives and principles of organic production

Please use the checklist in Annex A to this dossier to indicate consistency with objectives and principles of organic production, as well as criteria and general rules, laid down in Council Regulation (EC) 834/2007 Title II and Title III as applicable.

Annex A

CHECKLIST FOR CONSISTENCY
with objectives and principles of organic production with reference to specific articles in
the organic regulation

| Criteria | Specific articles in Regulation (EU) 848/2018 | Fulfilled? Yes / no / not applicable | Brief qualification |
|--|---|---|---|
| Exclude the use of GMOs and products produced from or by GMOs | Art. 3(58)(59)(60); Art. 5(f)(3); Art. 11; Art. 30(4) | Not applicable | |
| Enhances the health of soil, water, plants and animals | Art. 4(b) | Yes | |
| High level of biodiversity | Art. 4(c) and (i); Art 6(a) | | Not tested |
| Makes responsible use of energy and the natural resources, such as water, soil, organic matter and air | Art. 3(a)(iii) | Yes | Biostimulants have been demonstrated to enhance the protection towards hydric stress. They can help using more efficiently the resources such as water, nutrients etc. |
| Aim at producing products of high quality | Art. 5(d) | Yes | Improved agronomic performance under stress conditions (supporting material D2.5 Final - Report on agronomic performance of the obtained BBFs and TMFs in laboratory setting and D2.6 Final - Report on agronomic and Environmental performance in field trial Experiences will be available online in the webpage of FERTIMANURE) |
| Aim at producing a wide variety of foods and other agricultural products.....goods produced by the uses of processes that do not harm the environment, human health, plant health or animal health and welfare | Art. 5 (d) | Yes | |

| Criteria | Specific articles in Regulation (EU) 848/2018 | Fulfilled? Yes / no / not applicable | Brief qualification |
|--|--|---|--|
| Use living organisms and mechanical production methods | Art. 5(f)(i) | Yes | Microalgae <i>Scenedesmus spp.</i> Is cultivated and then enzymatically hydrolysed to obtain biostimulants. Permeate to cultivate algae is obtained by mechanical separation (separation and purification via membrane systems). Algae paste is dewatered via centrifugation before its enzymatic treatment. |
| Limited to natural or naturally-derived substances | Art. 5(g)(ii) | Yes | Endo and exo-proteases are used for the enzymatic hydrolysis, which are normally obtained by fermentative processes |
| For chemically synthesized inputs: appropriate management practices do not exist | Art. 4(c)(i) | Not applicable | |
| For chemically synthesized inputs: organic, natural or naturally-derived alternative substances are not available on the market | Art. 24(5) | Not applicable | |
| For chemically synthesized inputs: use of organic, natural or naturally-derived alternative substances contributes to unacceptable environmental impacts | Art. 24(5) | Not applicable | |
| Maintenance of plant health primarily by preventative measures, such as resistant species/varieties, appropriate crop rotations, cultivation techniques, mechanical and physical methods, thermal processes and the protection of natural enemies of pests | Art. 3(4) | Yes | Plant health is enhanced by promoting the resistance of plant to hydric and saline stress, which are preventative measures |

| Criteria | Specific articles in Regulation (EU) 848/2018 | Fulfilled? Yes / no / not applicable | Brief qualification |
|---|--|---|---|
| All plant production techniques used shall prevent or minimise any contribution to the contamination of the environment | Art. 3(5) | Yes | |
| The corresponding use is authorised in general agriculture [...] | Art. 9 (3) | Yes | In principle, under CMC1 virgin materials as PFC6B: non microbial biostimulant (Reg UE 2019/1009) |
| Their use is necessary for sustained production and essential for its intended use | Art. 24(3)(a) | No | It is not essential but it could reduce the use of other input materials such as plant protection products or fertilising products |
| All products and substances shall be of plant, animal, microbial or mineral origin ... | Art. 24(3)(b) | Yes | |
| ... except where products or substances from such sources are not available in sufficient quantities or qualities or if alternatives are not available | Art. 24(3)(b) | No | |
| Their use is essential for the control of a harmful organism or a particular disease for which other biological, physical or breeding alternatives or cultivation practices or other effective management practices are not available | Art. 24(3)(c)(i) | Yes | It provides protection towards hydric and saline stress. Relevant stressors in areas with water scarcity such as Mediterranean area |
| If products are not of plant, animal, microbial or mineral origin and are not identical to their natural form, they may be authorised only if their conditions for use preclude any direct contact with the edible parts of the crop | Art. 24(3)(c)(ii) | Non applicable | |
| Products and substances to be withdrawn or their use amended/ limited | Art. 24(7) | Non applicable | |
| Others: please specify | | | |

References:

European Biostimulant Industry Council (2023). Economic Overview of the European Biostimulants Market. Retrieved from: <https://biostimulants.eu/highlights/economic-overview-of-the-european-biostimulants-market/>

European Commission (2019). Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003. Official Journal of the European Union 170 (2019) 1–114.

Japanese Agricultural Standard for Organic Products of Plant Origin (Public Notice of the Ministry of Agriculture, Forestry and Fisheries No. 1605 of October 27, 2005)
<https://www.japaneselawtranslation.go.jp/ja/notices/view/133>

United States Department of Agriculture, Agricultural Marketing Service (2000). 7 CFR 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”
<https://www.ecfr.gov/current/title-7/section-205.605>

United States Department of Agriculture, Agricultural Marketing Service, National Organic Program (2016) Guidance Materials for Organic Crop Production (NOP 5034-1) (2016) 1- 24.
<https://www.ams.usda.gov/sites/default/files/media/NOP-5034-1.pdf>

Rodríguez-Alegre, Rubén, et al. "Nutrient recovery and valorisation from pig slurry liquid fraction with membrane technologies." *Science of The Total Environment* 874 (2023): 162548.
<https://doi.org/10.1016/j.scitotenv.2023.162548>

Rodríguez-Alegre, Rubén and Zapata-Jiménez, Julia and Pérez Megías, Laura and Andecochea Saiz, Carlos and Sanchis, Sonia and Pérez-Moya, Montserrat and García-Montaña, Julia and You, Xialei, On-Site Demonstration of Nutrient Recovery from Pig Slurry Liquid Fraction Using Membrane Technologies at Pilot Scale. Available at SSRN:
<https://ssrn.com/abstract=4652832> or <http://dx.doi.org/10.2139/ssrn.4652832>