DOSSIER CONCERNING THE REQUEST TO AMEND ANNEX II TO COMMISSION IMPLEMENTING REGULATION 1165/2021[1]

Fertilisers, soil conditioners and nutrients referred to in Article 24 (1)(b) of Regulation (EU) No 848/2018[2] 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"Where a Member State considers that a product or substance should be added to or withdrawn from the lists of authorised products and substances referred to in paragraphs 1 and 2, or that the specifications of use referred to in the production rules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

Nature of the request	☒ Inclusion ☐ Deletion ☐ 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
SOIL CONDITIONER FROM DIGESTATE – CATTLE MANURE	Stable odourless solid product with high fibre and carbon content (~12% organic matter) and also nutrients, suitable for consumers as potting/gardening soil and for farmers as a soil conditioner on agricultural land.

3. Status

Authorization in general agriculture or food processing

Historic use: digestate or processed digestate has been generally used in agriculture by spreading it on agricultural land as source of organic matter and nutrients and to improve the general characteristics of agricultural soil.

[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

Regulatory status (EU, national, others) (including expiry dates of authorisation if applicable): Category of fertilising product under EU reg. 2019/1009: FPC 3.A – organic soil conditioner composed of CMC 5 – Digestate other than fresh crop digestate.

4. Identification[3]

Identification of substance, terminology, synonyms

Chemical name(s): organic amendment / soil improver
Other names: stable organic matter, solid fraction of digestate, biogas digestate, Acidogenic digestate; Methanogenic digestate, Anaerobically digested manure;
Trade name: Organic soil improver from dairy slurry
CAS code (Chemical Abstracts Systematic Names): Not identified
Other code(s)

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

Geographical relevance (Member States, regions, …): Carbon content with potential to increase carbon stocks in soils, feed their microbiota and ultimately improve soils' quality and health. Contains other valuable nutrients (macro, meso and micro-nutrients) in lower concentration, relatively high in phosphorus, normally slowly released, which could be additionally removed by an additional process of acidification and precipitation if needed.
Socio-economic relevance (acreage, turnover, number of stakeholders affected, …): diversification of potential revenues for livestock farmers and new and recycled nutrient sources for agricultural and fertilising companies to be used in their formulations. Additionally, digestate is produced from the anaerobic digestion of cattle slurry, diversifying potential energy source in a farm and making it self-sustainable energetically, making the farm, therefore, less dependent on external energy sources.
Sectors affected: livestock sector, agricultural sector and industrial sector (fertilizing industry)
Stakeholder engagement/consultation in dossier preparation Farmers in the dairy farming region Achterhoek in the Netherlands and farmer organisations such as ZLTO/LTO are involved and positive.
Market presence: availability (quantity / quality) and origin (local / imported) For an actual average farm it could represent 10% of the volume of (digested) manure, for example for dairy livestock farms. The product originates from relatively simple solid-liquid separation technologies like a screw press, drum filter, belt press or centrifuge press, with generally low cost and energy of treatment. In countries like Netherlands, Germany, Belgium and Denmark these installations are becoming common practise, so are the products derived.
Aspects of international harmonization / market distortion In United States, digestate obtained from manure is the second greatest source, after digestate obtained from sewage sludge. Concentrated animal feeding operations (CAFOs) are regulated

[3] To be filled in only when applicable

as point sources of pollution by the EPA [40 CFR 412]. In most of the States anaerobic digesters on CAFOs are required to meet all federal, state and local regulations, including Best Management Practices for the application of manure [40 CFR 412.4]. Anaerobic digestate made of manure feedstocks does not appear on the National List of Non-synthetic substances prohibited for use in organic crop production published by the National Organic Standards Board of United States. Therefore, Manure-based digestate could be authorised if processing requirements are met (§205.203(c)(2)).

In the case of Japan, the Japanese Agricultural Standard for Organic Products of Plant Origin lists a number of authorised fertilising products in its Appended Table 1 "Fertilizers and soil improvement substances". In the list of authorised substances, substances derived from fermented, dried or calcined manure (derived from manure of livestock and poultry) as well as methane fermentation digestive juices in which manure is specifically mentioned as an authorised feedstock are mentioned.

A (possible) authorization leads to amendment(s) in the respective Annex[4]

Origin of the digested manure should be amended, currently factory farming not authorised, but lacks clarification on the definition of the term.

Other aspects justifying high priority, such as:

It is primarily used to cycle organic matter, and also provides macro, meso, and micronutrients. In this regard, organic matter and particularly highly stable carbon can be integrated into agricultural soils which is expected to significantly increase the soils' health and ultimately increase carbon stocks significantly contributing to the climate action.

In countries like Netherlands, Germany, Belgium and Denmark solid-liquid separation installations are becoming common practise, and so the products. Therefore, availability of these kind of processed organic amendments is expected to increase.

• other

6. Characterisation

Raw materials, methods of manufacture

Composition/ingredients:

Digested cattle slurry:

- Organic carbon: 126 g/kg fresh matter
- Total nitrogen: 6.5 g/kg fresh matter
- Total phosphorous: 2.4 g/kg fresh matter
- Total potassium: 5.0 g/kg fresh matter
- Dry matter: 260 g/kg fresh matter.

Relevant nutrients and trace elements content:

- S: 1.4 g/kg fresh matter

[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 …"

- Ca: 4.4 g/kg fresh matter
- Mg: 2.1 g/kg fresh matter
- Na: 0.8 g/kg fresh matter
- Mn: 521 mg/kg dry matter
- Zn: 277 mg/ kg dry matter
- Cu: 154 mg/kg dry matter

Other trace elements and pathogens:

- Ni: 5.2 mg/kg dry matter
- Pb: <5 mg/kg dry matter
- Cr: 6.6 mg/kg dry matter
- Cr VI: not available
- Hg: <0.05 mg/kg dry matter
- As: <1 mg/kg dry matter
- Cd: <0.4 mg/kg dry matter
- Fe: 2.4 g/kg dry matter
- Salmonella spp.: Not detected in 25 g of sample
- E.Coli: 9,500 CFU/g. (Colony Forming Units)

Basic physical properties: Solid fibrous material with basic pH 8.4 and 0.5 g/cm3 density

Solubility

According to the agronomic tests performed (soil incubations, pot tests and field tests) release of available nutrients is relatively slow in soil

Origin of raw materials, production methods: Anaerobic digestor working at reactor temperatures between 35 and 37ºC. The effective capacity of digester is 650m3 and the residence time 90 days on average. The digestor treats all the cattle slurry produced in the dairy farm plus other co-substrates (feed residues, solid stable manure, etc.). Digestate is separated in a solid and liquid fraction with a conventional separation system, in this case a screw press using electricity

7. Specification of use

Agronomic use

Fertiliser or soil conditioner:

organic soil conditioner with low concentration of nutrients mainly in organic form

Application method:

integration into agricultural soil, mainly arable crops, fodder maize or natural grass land, can be in a two-step process, first application above ground and then plowing under within some hours

Dosage:

Ideally the dosage would dependent on the current soil carbon content, cultivation system type, other fertilizers and residual effect of previous fertilisation, etc. Following the recommendation done by one of the national agricultural laboratories Eurofins, dosage would range from roughly 0 to 3,000 kg in terms of effective organic matter (=EOM), so the effective part of the organic matter. However, in practice, the dosing would depend on maximum applicable nitrogen and in the case of some countries such as the Netherlands, additional national phosphorus application limits linked to soil status/type and crop type would determine the application dose
Stage of plant development: Soil preparation before sowing
Physiological effect, mode of action: Nutrient provision for crops and soils, but mainly structural effect for soil quality and fertility

8. Reasons for the inclusion, withdrawal or amendments

Explain the need for the proposed fertilizer or soil conditioner or nutrient Soil organic carbon levels are under treat, since more and more organic residues and wastes are digested for biogas production or incinerated. Carbon is not stable in soils and have to be replenished. This organic soil conditioner can be a potential product with high value. High in carbon, low in nutrients which are recovered separately in useful products
What alternative solutions are currently authorised or possible? • Biogas digestate containing animal by-products (categorised as category 3 or 2 according to Regulation (EC) No 1069/2009) co-digested with material of plant or animal origin as listed in Annex II of Regulation 2021/1165 are accepted. However, factory farming origin is forbidden. It is not clear what is the criteria to consider a family company and small sized cattle farm of about 60-80 dairy cows as factory farming but most probably and considering the characteristics of the farm Arjan Prinsen Farm (producer) can be categorised out of that definition. Cows are largest part of the year outside in the field, that is also a requirement set by the milk cooperative for which milk is produced. In the Netherlands the organisation responsible of authorising manure derived fertilisers (SKAL, see https://www.skal.nl/ in Dutch) in organic farming authorised 30% from non-organic agriculture source, specifically from cattle, goats, sheep and horse. In this case, the requirement is that the animals have pasture or an outdoor area, or a partially littered floor. Manure from veal calves and solid manure from free-range pigs are also only permitted under these conditions. Arjan Prinsen Farm meets those conditions
Is there any traditional use or precedents in organic production? Only digestate from manure from farms under organic farming

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)	Y	Tested and demonstrated in pot and field trials
High level of biodiversity	Art. 4(c) and (i); Art 6(a)	Not applicable	Not assessed, but expected to promote soil biodiversity by the addition of organic carbon
Makes responsible use of energy and the natural resources, such as water, soil, organic matter and air	Art. 3(a)(iii)	Y	Soil conditioner obtained after anaerobic digestion permitting the generation of heat and electricity from the co-generation engine implemented at the farm. The farm is potentially energetically self-sufficient.
Aim at producing products of high quality	Art. 5(d)	Y	Agricultural performance equivalent to other conventional organic fertilizing products (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)

Criteria	Specific articles in Regulation (EU) 848/2018	Fulfilled? Yes / no / not applicable	Brief qualification
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)	Y	Crops tested: grass, maize, potatoes and root crops in general
Use living organisms and mechanical production methods	Art. 5(f)(i)	N	Produced after the biological transformation of cattle manure with agricultural residues through anaerobic digestion and subsequent solid liquid separation
Limited to natural or naturally-derived substances	Art. 5(g)(ii)	Y	Produced from digested cattle manure using feed residues as co-substrate
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)	Not applicable	

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)	Y	Potential contamination to groundwater and atmosphere assessed. Better performing in terms of emissions than the conventional fertilisation strategies used (mineral fertiliser fertilization)
The corresponding use is authorised in general agriculture […]	Art. 9 (3)	Y	Full accepted in the Netherlands and other countries. With application requirements for best agronomic and environmental performance
Their use is necessary for sustained production and essential for its intended use	Art. 24(3)(a)	Y	Cycling organic matter is important in arable farming and dairy farming
All products and substances shall be of plant, animal, microbial or mineral origin …	Art. 24(3)(b)	Y	Animal manure based and not addition of chemicals
… 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)	Not applicable	
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)	Not applicable	
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)	Not applicable	

Criteria	Specific articles in Regulation (EU) 848/2018	Fulfilled? Yes / no / not applicable	Brief qualification
Products and substances to be withdrawn or their use amended/ limited	Art. 24(7)	No	
Others: please specify			

References:

Environmental Protection Agency (2003) 40 CFR Part 412 —Concentrated Animal Feeding Operations (CAFO) point source category. https://www.ecfr.gov/current/title-40/part-412

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 205.203 Soil fertility and crop nutrient management practice standard. https://www.ecfr.gov/current/title-7/section-205.203