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Technical proposals for processed manure as a component material for EU Fertilising Products

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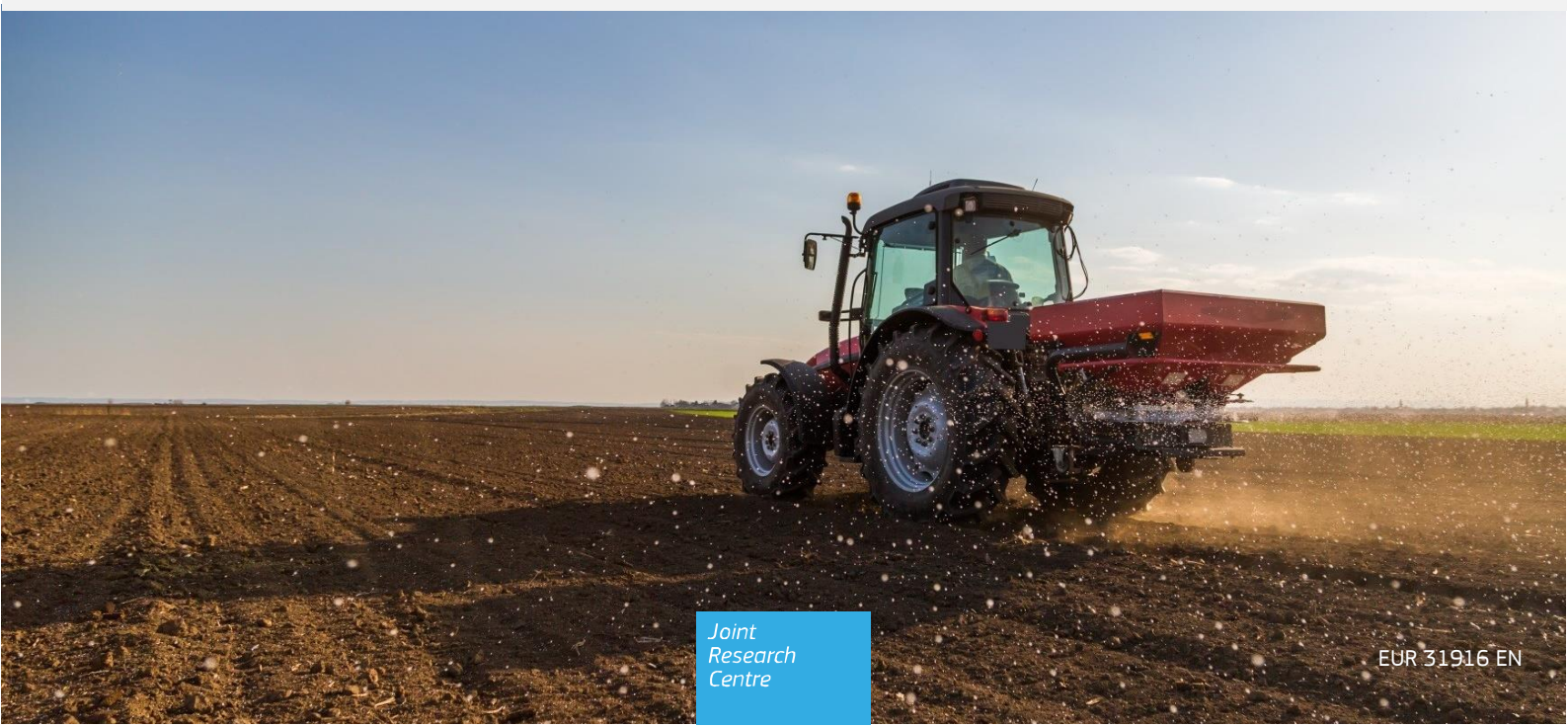

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Contents

Abstract

The Fertilising Products Regulation (EU) 2019/1009 lays down rules on the making available on the market of EU fertilising products. The European Commission may, under certain conditions, adopt delegated acts for new to add products derived from animal by-products within the meaning of Regulation (EC) No 1069/2009. This JRC report develops and brings forward evidence-based criteria proposals for processed manure considering aspects beyond those to prevent and minimise risks to public and animal health as per Regulation (EU) 2023/1605. The criteria proposals describe technical criteria to ensure that EU Fertilising Products containing processed manure (i) have a demonstrated agronomic efficiency, (ii) do not cause risks to the environment and/or human health, and (iii) can be expected to be subject to significant trade on the EU market. The criteria proposals form the technical basis to adopt a delegated Regulation to amend and introduce the requirements for processed manure when used as a component for EU Fertilising Products.

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Executive summary

Policy context

Regulation (EU) 2019/1009 ("the Fertilising Product Regulation", FPR) lays down common rules on safety, quality and labelling requirements for EU fertilising products.

The JRC has been requested by DG GROW to develop rules and technical criteria to enable the placing on the market of EU fertilising products containing processed manure:

(a) which have the potential to be the subject of significant trade on the internal market, and

(b) for which there is scientific evidence that they:

  (i) do not present a risk to human, animal or plant health, to safety or to the environment, and

  (ii) ensure agronomic efficiency.

Findings

Processed manure that has reached the end point in the manufacturing chain pursuant Article 5(2) of Regulation (EC) No 1069/2009 may require further processing to limit the spreading of viable weeds seeds that survive the digestive tract of livestock animals, and/or to ensure a minimal stability when used as a fertilising product component.

Processing steps are commonly applied, either before or after the hygienisation step, to transform raw manure into processed manure suitable to be used as a component for high-quality fertilising products. Additives may be used during manure processing.

On occasion, polycyclic aromatic hydrocarbons (PAH) may be present in processed manure in levels that cause risks to human health and the environment. In addition, proper storage conditions may be required for processed manure, for instance to minimise odour nuisance before land applications.

End-users of processed manure may benefit from labelling information on the material's potential to release ammonia and on certain herbicide residues that may affect susceptible crops.

It is possible to put forward technical criteria for processed manure as a component material for EU fertilising products to ensure compliance with Article 42(1) of the FPR as outlined above.

Recommendations

In addition to fulfilling the conditions in Article 3(d) of Delegated Regulation (EU) 2023/1605, the following technical criteria are proposed for CMC 10 (Part II of Annex II to Regulation (EU) 2019/1009):

1.1 An EU fertilising product may contain processed manure only if it was treated to reach an end point according to Regulation (EC) No 1069/2009 at the latest 36 months before signing the EU declaration of conformity for the respective product and the material underwent additional processing so that at least one of the following conditions is met:

a. at least 90 % by dry mass of the material can pass through a sieve with a mesh of 0,25 mm;

b. the material has been granulated under pressure, pelletised, dried at temperatures higher than 100°C or has undergone any equivalent process that ensures that the content of viable weed seeds and plant propagules in the processed manure is no more than 3 units/l; or

c. the material fulfills at least one of the stability criteria set out in point 5 of CMC 3.

1.2 The material referred to in point 1.1 may undergo one or more of the following additional processes:

a. the processing methods referred to in CMC 2;

b. biological treatment involving nitrification and denitrification;

c. mechanical separation of the solid and liquid fractions;

d. processes to recover nutrients and/or organic carbon, without the intention to otherwise modify the material;

e. chemical processing to modify the pH without the intention to otherwise modify the material;

f. physical processing to remove water and to transform the material into powder, granules or pellets, without the intention to otherwise modify the material.

1.3 Additives needed in the processing referred to in points 1.1 and 1.2 may be used provided that:

a. the additive complies with the requirement set out in point 2 of CMC 1;

b. the concentration of the additives needed in each of the processes does not exceed 5 % of the weight of the processed manure or fraction used as input in the respective process.

1.4 The processed manure shall contain no more than 6 mg/kg dry matter of PAH16.*

1.5 The processed manure to be used as component material in an EU fertilising product shall be stored in a way that protects it against precipitation and direct sunlight.

2. Where compliance with the requirement set out in point 1.4 follows certainly and uncontestably from the nature or the processing of the component material or the manufacturing process of the EU fertilising product, such compliance may be presumed in the conformity assessment procedure without verification (such as testing), under the responsibility of the manufacturer.'

** Sum of naphthalene, acenaphthylene, acenaphthene, fluorene, phenanthrene, anthracene, fluoranthene, pyrene, benzo[a]anthracene, chrysene, benzo[b]fluoranthene, benzo[k]fluoranthene, benzo[a]pyrene, indeno[1,2,3-cd]pyrene, dibenzo[a,h]anthracene and benzo[ghi]perylene.'.*

In addition, labelling requirements for processed manure are suggested. Particularly, it is proposed to add the following points to Part I of Annex III to Regulation (EU) 2019/1009:

Where an EU fertilising product contains processed manure as referred to in Part II, CMC 10, of Annex II, information about the possible air quality impacts of the release of ammonia from the product's use and an invitation to users to apply appropriate remediation measures shall be included on the label.

Where an EU fertilising product contains processed manure as referred to in Part II, CMC 10, of Annex II, the following warning shall be included on the label 'This product may contain aminopyralid or clopyralid and must not be used for the production of plants susceptible to these substances, such as beans, clover, lentils, peas, salat, sunflowers and tomatoes. This product must be used in such a manner as to avoid leading to the exceedance of the maximum residue levels for food or feed set in accordance with Regulation (EC) 396/2005', or a similar warning. Such a warning is not needed for EU fertilising products containing processed manure with no more than 50 µg aminopyralid or clopyralid/kg dry matter.

Related and future work

The findings and recommendations of this report may be used by DG GROW to amend Regulation (EU) 2019/1009 ("the Fertilising Product regulation", FPR) and include processed manure as a component material. According to Article 42(5) of the FPR, the Commission may supplement Annex II, Annex IV in relation to Component Material Category (CMC) 10 by laying down criteria for the use of *derived products within the meaning of Regulation (EC) No 1069/2009* [1]in EU fertilising products.

Quick guide

The JRC developed this report based on the assessment of techno-scientific literature and consensus building with the Commission's Expert Group on Fertilising Products. Taking into account the principles of technical expertise, transparency and neutrality, the JRC has collected, analysed and reported information to assess proposed processed manure against pre-established criteria on material safety, agronomic efficiency and potential for trade on the EU market.

[1] These include animal by-products for which an end point in the manufacturing chain has been determined in accordance with Article 5(2) of Regulation (EC) No 1069/2009. The Commission shall assess such derived products with respect to relevant aspects not taken into account for the purpose of determining an end point in the manufacturing chain in accordance with Regulation (EC) No 1069/2009. If that assessment concludes that the criteria in point (b) of paragraph 1 of this Article are fulfilled, the Commission shall adopt delegated acts pursuant to paragraph 1 of this Article to include those materials in the table in component material category 10 in Part II of Annex II to this Regulation without undue delay whenever such an end point is determined.

1 Introduction

1.1 The EU Fertilising Products Regulation

Regulation (EU) 2019/1009 on the making available on the market of EU fertilising products sets out rules for EU fertilising products carrying the CE marking. The Regulation sets out requirements for (i) maximum levels of contaminants and pathogens, (ii) minimum content of nutrients and other relevant characteristics depending on the category of the product, (iii) labelling and (iv) the testing of the conformity of EU fertilising products.

As acknowledged in the Communication on 'ensuring availability and affordability of fertilisers[2]', further progress is required in promoting green and circular alternatives to natural gas and mined raw materials for fertiliser production. Opening the European Union (EU) single market to high-quality fertilising products which previously had not been covered by harmonisation rules, such as processed manure, contributes to this objective.

1.2 Component Material Category 10 – Derived products within the meaning of Regulation (EC) No 1069/2009

Within the meaning of Regulation (EC) No 1069/2009, 'derived products' means products obtained from one or more treatments, transformations or steps of processing of animal by-products[3]. Derived products having reached the end point in the manufacturing chain of certain organic fertilisers and soil improvers, will no longer be subject to the requirements of Regulation (EC) No 1069/2009 and will fall only within the scope of Regulation (EU) 2019/1009.

Commission Delegated Regulation (EU) 2023/1605 sets out the requirements as regards the determination of end points in the manufacturing chain of certain organic fertilisers and soil improvers. Article 3(d) indicates that processed manure shall be considered as having reached the end point as organic fertilisers and soil improvers when fulfilling the requirements set out in Chapter I, Section 2, points (a), (b), (d) and (e), of Annex XI to Regulation (EU) No 142/2011 (BOX 1).

[2] https://agriculture.ec.europa.eu/common-agricultural-policy/agri-food-supply-chain/ensuring-availability-and-affordability-fertilisers_en

[3] In turn defined in the Regulation as "entire bodies or parts of animals, products of animal origin or other products obtained from animals, which are not intended for human consumption, including oocytes, embryos and semen".

BOX 1. requirements set out in Chapter I, Section 2, points (a), (b), (d) and (e), of Annex XI to Regulation (EU) No 142/2011

The placing on the market of processed manure, derived products from processed manure and guano from bats shall be subject to the following conditions, in addition to the consent of the Member State of destination referred to in Article 48(1) of Regulation (EC) No 1069/2009:

(a) They must come from a plant for derived products for uses outside the feed chain or from a biogas or a composting plant or from a plant for the manufacturing of organic fertilisers or soil improvers.

(b) They shall have been subjected to a heat treatment process of at least 70 °C for at least 60 minutes and they shall have been subjected to reduction in spore-forming bacteria and toxin formation, where they are identified as a relevant hazard.

(d) Representative samples of the manure taken during or immediately after processing at the plant in order to monitor the process must comply with the following standards:

Escherichia coli: n = 5, c = 5, m = 0, M = 1 000 in 1 g;

or Enterococcaceae: n = 5, c = 5, m = 0, M = 1 000 in 1 g;

and

Representative samples of the manure taken during or on withdrawal from storage at the plant of production or the biogas or composting plant must comply with the following standards:

Salmonella: absence in 25 g: n = 5; c = 0; m = 0; M = 0

where:

n = number of samples to be tested;

m = threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all samples does not exceed m;

M = maximum value for the number of bacteria; the result is considered unsatisfactory if the number of bacteria in one or more samples is M or more; and

c = number of samples the bacterial count of which may be between m and M, the sample still being considered acceptable if the bacterial count of the other samples is m or less.

Processed manure or processed manure products not complying with the standards in this point shall be regarded as unprocessed;

(e) They must be stored in such a way that once processed contamination or secondary infection and dampness is minimised. They must therefore be stored in:

(i) well-sealed and insulated silos or properly constructed storage sheds; or

(ii) properly sealed packs, such as plastic bags or 'big bags'.

The Commission shall assess such derived products with respect to relevant aspects not taken into account for the purpose of determining an end point in the manufacturing chain in accordance with Regulation (EC) No 1069/2009. In line with Article 42, delegated acts may adapt the Regulation (EU) 2019/1009 to technical progress and in view of facilitating internal market access and free movement for EU fertilising products:

a) which have the potential to be the subject of significant trade on the internal market, and;

b) for which there is scientific evidence that they:

(i) do not present a risk to human, animal or plant health, to safety or to the environment, and

(ii) ensure agronomic efficiency.

When adopting delegated acts which introduce new contaminant limit values in Annex I, the Commission shall take into account scientific opinions of the European Food Safety Authority, the European Chemicals Agency or the Commission's Joint Research Centre, as relevant.

1.3 JRC mandate

To assess the compliance of the specific candidate material "processed manure" under CMC 10 "Derived products within the meaning of Regulation (EC) No 1069/2009" with the criteria outlined above, DG GROW has requested support from DG JRC to provide recommendations. The JRC will assess risks not taken into account in the determination of the end points in the manufacturing chain based on the assessments already performed by the European Food Safety Authority (EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), 2021), in accordance with Article 42(5) of the FPR.

2 Scope

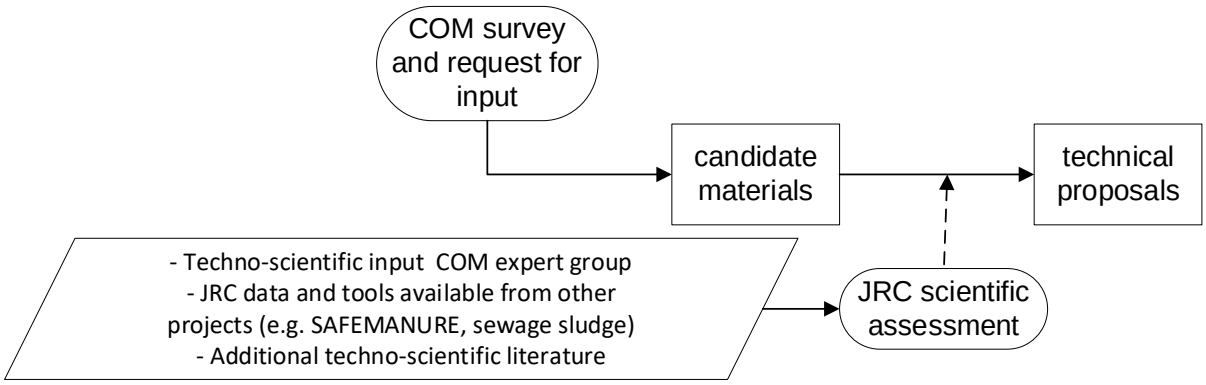
The scope of this project involves processed manure which fulfils the following requirements set out in Section 2, Chapter I, of Annex XI of Regulation (EU) No 142/2011 (BOX 1).

“Frass”, according to Commission Regulation (EU) 2021/1925 defined as “a mixture of excrements derived from farmed insects, the feeding substrate, parts of farmed insects, dead eggs and with a content of dead farmed insects of not more than 5 % in volume and not more than 3 % in weight” falls outside the scope of this project.

In addition, processed manure subject to a precipitation process (CMC 12), thermal oxidation process (CMC 13) or pyrolysis or gasification process (CMC 14) falls outside the scope of this project.

3 Methodology

Figure 1: Schematic overview of the methodology applied to develop technical criteria proposals for "processed manure" under Component Material Category 10 (Derived products within the meaning of Regulation (EC) No 1069/2009) in Annex II of the EU Fertilising Products Regulation (EU) 1009/2019



Source: own work.

The process was initiated with two requests from the Commission services to the Commission expert group on fertilising products to flag candidate materials for CMC 10. These process steps that transform "manure[4]" into "processed manure" compliant with requirements set out in Section 2, Chapter I, of Annex XI of Regulation (EU) No 142/2011 were inventoried, as well as possible concerns in relation to the agronomic efficiency and contaminants. Tools and data available from prior work on processed manure (Huygens et al., 2020) and other biogenic materials (e.g. Huygens et al., 2022) was taken into consideration during this assessment. During the scientific assessment, this information was studied and concerns identified by stakeholders and/or techno-scientific literature were investigated. Draft criteria proposals have been revised iteratively to account for feedback from the Commission Expert Group on Fertilising Products and Commission services. The final result of this process is a set of criteria proposals and recommendations that can be used to develop a delegated Regulation amending the FPR.

[4] According to Commission Regulation (EC) No 1069/2009 on laying down health rules as regards animal by-products and derived products not intended for human consumption, 'manure' means any excrement and/or urine of farmed animals other than farmed fish, with or without litter.

4 Candidate materials and their process description

Manure processing often involves stand-alone or combined transformation processes, including "pre-treatment", "main process steps" and "post-processing steps". It is noted that composting and anaerobic digestion are the most common manure processing techniques and that manure that has undergone one of both processes is already covered under other Component Material Classes (CMCs) that allow manure as an input material (CMC 3 (compost) and 5 (digestate other than energy crop digestate)).

Solid-liquid and nutrient-organic matter separation methods are common manure processing techniques that can be applied before or after subjecting manure fractions to a hygienisation treatment step. These methods may involve physical (e.g. sieves, filter press, centrifuge) or chemical methods (e.g. coagulation, flocculation, precipitation). The solid and/or liquid fraction can then be subject to further treatment.

Based on direct stakeholder feedback in response to the survey launched by the Commission, experts indicated that candidate materials that classify as "processed manure" involve, in addition to the sterilisation step, manure that is thermal and bio-dried, or aerated (e.g. ground aeration with a controlled temperature rise). Additional consultation of literature on manure processing (Foged et al., 2011) further indicated that additional manure processing steps may involve acidification and liming of manure and vermi-composting (manured decomposed by worms).

Processed manure is commonly post-processed by pelletising/granulation, grinding, shredding, powdering, concentration methods (e.g. filtration, reverse osmosis) and/or applying additives. Such processes make it easier for handling (storage, transport), mixing with other Component Material Categories, application on the field while as well reducing manure erosion losses. Approaches for the granulation of manure streams include mixer-dryer granulation, disc pelletizing, drum granulation, and extrusion (FEECO, 2022). In order to granulate a material, large particles will need to be removed or ground (FEECO, 2022). Grinding manure can help to speed up manure stabilisation by increasing the surface area of the material, and increasing the nutrient release potential after field application.

It is noted that the scope of CMC 3, 5, 10, 12, 13, and 14 now covers the complete spectrum of processed manure materials resulting from documented manure processing techniques in the EU by Foged et al. (2011).

5 Assessment on potential to be the subject of significant trade on the internal market

Manure is often used close the livestock farms where it is generated due to its high moisture content and limited nutrient density. Manure processing involves a set of physico-chemical and/or chemical transformation processes that are performed for reasons of material hygienisation, drying, granulation and/or material separation for improved handling (section 4). Therefore, processed manure may be subject to trade, e.g. from regions with a high nutrient density (e.g. the Netherlands, Belgium, Germany) to regions characterised by soils having a nutrient deficient status. For instance, in the Netherlands, more than one-fifth of the pig manure (equivalent to >50 kilotonnes of phosphate annually) is exported outside the country (The World Bank, 2017). Exports take place, amongst others, as dried, pelletised processed manure. Such exports of processed manure are thus effectively taking place with a view to address local nutrient surplus, and show the potential for significant trade on the international market of processed manure.

6 Assessment of risks to human, animal or plant health, to safety or to the environment

6.1 Weed seeds and plant propagules

Weed seeds can pass through the digestive tracts of livestock animals in viable form (Larney and Blackshaw, 2003). The presence of weed seeds and plant propagules in manure can lead to the establishment of new weed populations in fields where the manure is applied; this issue may be particularly important when dealing with processed manure that is traded internationally as a component of EU fertilising products. Even when manure storage or drying at room temperatures has taken place, seeds contained in processed manure may be reactivated after dormancy[5] when applied on wet soils. Hence, managing weed seeds in manure is crucial to prevent the unintended spread of viable weeds, ensuring sustainable and productive agriculture (Modderman, 2022).

It is noted that the minimal default thermal treatment (70°C for 1 hour) may only moderately reduce the survival of weed seeds (Modderman, 2022). Weed seeds exhibit remarkable resilience when it comes to survival and persistence. Unlike pathogens, which can be more susceptible to various environmental factors, weed seeds have developed mechanisms that allow them to withstand adverse conditions and remain viable for extended periods (Walsh et al., 2013). Weed seeds also have a greater size than pathogens. An average size of seeds of common weeds exceeds 0.25 mm (Dvorak and Krejcir, 1974; Smutny and Kren, 2002), for which sterilisation is more difficult to achieve.

Certain EU Member States, such as Austria, have criteria on viable weed seeds and plant propagules in fertilising materials (e.g. max. 3 units/litre), similar to the value of 2 units/litre for viable weed seeds and plant propagules as proposed in the EU Ecolabel for soil improvers and growing media[6].

It is noted that many manure processing techniques involve treatment steps that may cause the destruction viable weed seeds. For instance, powdering and grinding techniques (often a first step in a granulation process), pressure granulation, and drying manure at high moisture content >100°C in humid media such as manure, will partially destroy viable weed seeds (Bloemhard et al., 1992; Zamora and Olivarez, 1994; Larney and Blackshaw, 2003; Dahlquist et al., 2007; EFSA Panel on Contaminants in the Food Chain (CONTAM) et al., 2023). The execution of such treatment may therefore act as an alternative to measuring weed seeds and plant propagules.

The Commission Expert Group on Fertilising Products also confirmed the relationship between stability and weed seed content, and indicated that stable processed manure is not a vector for the spreading of viable weed seeds. Limited data on the stability of processed manure (e.g. oxygen uptake rate) is available in techno-scientific literature or from the industry. Organic fertilisers are generally considered stable when they have a low rate or degree of organic matter decomposition, and when they are able to maintain their nutrient content over time (Mukai and Oyanagi, 2021). Stability criteria for aerobically dried or (partially) composed manure are given in point 5 of CMC 3 of the FPR.

[5] Seed dormancy refers to a quiescent state in which viable seeds remain alive but do not germinate under favorable conditions.

[6] Commission Decision (EU) 2022/1244 of 13 July 2022 establishing the EU Ecolabel criteria for growing media and soil improvers (notified under document C(2022) 4758) (Text with EEA relevance)

Overall, it is proposed to ensure an acceptable content of viable weed seeds and plant propagules by requiring that EU fertilising products may contain processed manure on condition that at least one of the following conditions is met:

a. at least 90 % by dry mass of the material can pass through a sieve with a mesh of 0.25 mm;

b. the material has been granulated under pressure, pelletised, dried at temperatures higher than 100°C or has undergone any equivalent process that ensures that the content of viable weed seeds and plant propagules in the processed manure is no more than 3 units/l; or

c. the material fulfills at least one of the stability criteria set out in point 5 of CMC 3.

6.2 Veterinary drug residues and antimicrobial resistance genes

6.2.1 Scientific assessment

The scientific evaluation and proposals for this section are based on the scientific assessment performed in the year 2020 on processed manure as part of the so-called SAFEMANURE or RENURE JRC project (Huygens et al., 2020). The text and information base is further complemented with recent relevant literature.

The available evidence indicates that veterinary drug residues, particularly tetracyclines, are widely used and found in manure (Wohde et al., 2016; Conde-Cid et al., 2018). Upon manure application on soils, these compounds may accumulate in the soil, enter the food chain, and be transported to surface water bodies. These processes are determined by degradation, adsorption/desorption and transport processes (Fernández-Calviño et al., 2015; Liu et al., 2017; Zhou et al., 2017). Drug residues may cause toxicity to soil and aquatic organisms in the environment, particularly due to the long residence time of some veterinary drugs (e.g. tetracyclines) (Boleas et al., 2005; Cycon et al., 2019; Fekadu et al., 2019).

Antibiotics may accumulate in soil over time when input rates exceed dissipation rates. In soil, these substances may then affect the structure and function of bacterial communities and the development and spread of antimicrobial resistance genes and associated mobile genetic elements. Manure is also one of the main sources of antimicrobial resistance (Boelee et al., 2019). Antimicrobial resistance defines the ability of certain microorganisms to resist antimicrobial (including antibiotic) treatments. It is generally agreed that the excessive, and especially preventative, use of antibiotics on farm animals has been a major factor in bringing about antimicrobial resistance, although part arises also from human use (Review on Antimicrobial Resistance, 2015).

Increased temperature treatments (including pasteurisation) cause partial antibiotic removal (Sara et al., 2013; Van Epps and Blaney, 2016). Pasteurisation plays an important role in degrading tetracyclines during manure processing, probably attributed to the sustained increase in the system temperature (Wallace et al., 2018). However, a 70°C treatment does not result in a complete removal of the antibiotics. Antimicrobial resistant bacteria are, similar to their non-resistant counter equivalents, not heat-resistant (James et al., 2021). Heat treatments and sterilisation may be effective in causing cell lysis and thus the inactivation of antimicrobial resistant bacteria (James et al., 2021). The evidence as to whether viable antimicrobial resistance genes may persist after such heat treatments is sparse, and also whether these genes can be transferred to other bacteria. Whilst the published evidence is limited, the studies identified provide some evidence that genes may

partially be damaged following heat treatments (James et al., 2021). This may be important given that processed manure may otherwise cause the spreading of antimicrobial resistant bacteria and genes when transported on the internal market. In sum, the available scientific evidence indicates that a heat and sterilisation treatment (>70°C for 60 minutes) may partially remove veterinary drug residues and antimicrobial resistance genes, whereas antimicrobial resistant bacteria will be killed.

Processed manure will not fully replace unprocessed manure, but will rather act as a supplement to the locally generated manure following long-distance transport. Unprocessed manure will continue to be spread, in line with the minimum requirements outlined in the Animal By-Products Regulation (EC (No) 1069/2009) and the Nitrates Directive (91/676/EEC). Evidence exists that soil biodiversity profiles are subject to strong modifications when exogenous substances (e.g. antibiotics in manure) are applied to soils, but that adding supplementary veterinary drug residues upon an already adulterated soil environment has limited effects on soil microbial community structures (Zheng et al., 2020). At the wider, regional scale, manure processing will reduce inputs of unprocessed manure and veterinary drugs into the environment. It will thus be effective in decreasing the overall residual antibiotic load relative to the current business-as-usual scenario of landspreading manure in unprocessed form on soils.

6.2.2 Legal framework and EU policies on human and veterinary pharmaceuticals in the environment

European Union legislation on medicinal products[7] is the primary means for ensuring the quality, safety and efficacy of pharmaceuticals for use in humans and animals, and their safety for the environment. Veterinary medicinal products should be authorised, and its quality, safety and efficacy be demonstrated. An environmental risk assessment is now mandatory for all applications for a marketing authorisation for human and veterinary medicinal products. Hence, EU legislation on veterinary medicinal products sets standards of quality, safety and efficacy for veterinary medicinal products in order to meet common concerns as regards the protection of public and animal health and of the environment. With the aim of contributing to the fight against antimicrobial resistance, the recently adopted Regulation (EU) 2019/6 on veterinary medicinal products (applicable as of 2022) introduces further measures to limit the use of antimicrobials, which should result in an overall reduction of the used and therefore excreted quantities and is expected to lessen their environmental impact.

Additionally, the European Commission Communication on the EU Strategic Approach to Pharmaceuticals in the Environment[8] outlines a set of actions:

- Increase awareness and promote prudent use of pharmaceuticals;
- Support the development of pharmaceuticals intrinsically less harmful for the environment and promote greener manufacturing;

[7] Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC, OJ L 4, 7.1.2019, p.43, and Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311, 28.11.2001, p.67, as amended

[8] available at

https://ec.europa.eu/environment/water/water-dangersub/pdf/strategic_approach_pharmaceuticals_env.PDF

- Improve environmental risk assessment and its review;
- Reduce wastage and improve the management of waste;
- Expand environmental monitoring;
- Fill other knowledge gaps through research on e.g.:
    - the eco-toxicity and environmental fate of pharmaceuticals,
    - the links between the presence of antimicrobials in the environment and the development and spread of antimicrobial resistance; and
    - Cost-effective methods for reducing the presence of pharmaceuticals including antimicrobials in slurry and manure.

Finally, policies are in place that limit the application rate of manure and processed manure, such as the Nitrates Directive. EU Fertilising products containing processed manure will continue to be subject to these policies and associated application rate limits.

At present, no international standards are available for the quantification of antibiotics in manure or processed manure.

6.2.3 Criteria proposals

At first, targeted legislation that regulates the placing on the market of veterinary drugs is in place, and the procedural requirements involve an environmental risk assessment.

Secondly, setting a requirement that contains limit values for one or more veterinary drug residues would be challenging given the wide variety of substances used, and the absence of international standards to measure concentration levels for each of these compounds in processed manure.

Thirdly, it would not be coherent with the provisions of other CMCs that contain requirements for materials of a very similar nature (and likely containing similar levels of drug residues and antimicrobial resistance genes), particularly manure-derived compost (CMC 3) and digestate (CMC 5).

Fourthly, evidence indicates that supplementary human health and/or environmental risks from the land application of processed manure relative to a business-as-usual scenario of the (local) landspreading of (mostly unprocessed) manure are not suggested. On the contrary, it is indicated that relative to unprocessed manure, manure processing may help to partially reduce toxicity to soil and water organisms and limit the prevalence of antimicrobial resistance bacteria and their genes in the environment. Further research is required to better understand the absolute risks from the spreading of processed manure containing certain levels of drug residues and antimicrobial genes to the environment.

For all these reasons, no additional criteria requirements are proposed for veterinary drug residues and/or antimicrobial resistance genes in processed manure.

6.3 Metal and metalloids

Metal and metalloid inputs from livestock manure are heavily influenced by the quantities of copper (Cu) and zinc (Zn) added to animal feed as a growth promotor. Copper and Zinc are micronutrients, but their presence in soil in excess can contaminate soils and the food chain. In the Fertilising Products Regulation (EU) 2019/1009, limit values for Cu and Zn have been laid down for different Product Function Categories, including soil improvers and (organic) fertilisers. Hence, no supplementary

requirements are required at CMC level. Our assessment has not identified risks from other metals or metalloids present in processed manure.

6.4 Biological pathogens

The process requirements to meet the end point in the manufacturing chain (point (b) and (d), Section 2, Chapter I, of Annex XI of Regulation (EU) No 142/2011) are sufficient to limit environmental and health risks from biological pathogens to an acceptable level. No additional requirements are proposed.

6.5 Air quality contaminants

Processed manure may be rich in ammonium and have a high pH, conditions that may favour ammonia emissions to air (Huygens et al., 2020). Emissions of ammonia from the agricultural sector continue to rise, posing a challenge for EU Member States in meeting EU air quality standards and emission ceilings, according to the European Environment Agency (European Environment Agency, 2019).

Good management practice guidelines to reduce NH_3 emissions are described in the sectoral reference document on best environmental management practices and benchmarks of excellence for the agriculture sector (European Commission, 2018) and the Best Available Techniques (BAT) Reference Document for the Intensive Rearing of Poultry or Pigs (Giner Santonja et al., 2017). Also the guidance document for preventing and abating ammonia emissions from agricultural sources, submitted by the co-chairs of the Task Force on Reactive Nitrogen (Economic Commission for Europe, 2014) contains a description of abatement techniques to limit NH_3 emissions resulting from the land application of ammonia-rich fertilisers and manure-derived materials. Essentially, techniques rely on either physically trapping the formed NH_3 or converting volatile NH_3 to non-volatile NH_4 to prevent volatilisation (Sigurdarson et al., 2018).

In order to promote the use of such abatement techniques, a labelling requirement is proposed as follows:

> *"Where an EU fertilising product contains processed manure as referred to in Part II, CMC 10, of Annex II, information about the possible air quality impacts of the release of ammonia from the product's use and an invitation to users to apply appropriate remediation measures shall be included on the label."*

6.6 Material storage

Manure can be released in the environment as spills in case subject to environmentally unsound storage practices, causing undesirable nutrient and odour pollution in the local environment (Marques-dos-Santos et al., 2023). This holds particularly true in case processed manure is not stored under proper conditions (e.g. storage without protection from precipitation). It is proposed to add criteria to ensure best practices in relation to storage as follows:

- *"An EU fertilising product may contain processed manure only if it was treated to reach an end point according to Regulation (EC) No 1069/2009 at the latest 36 months before signing the EU declaration of conformity for the respective product".*
- *"The processed manure to be used as component material in an EU fertilising product shall be stored in a way that protects it against precipitation and direct sunlight."*

6.7 Polycyclic aromatic hydrocarbons (PAH)

Manure may contain PAH (Adánez-Rubio et al., 2021), and long-term fertilisation with manure has been shown to potentially increase the accumulation of these persistent organic pollutants (Krzebietke et al., 2020; Mackiewicz-Walec and Krzebietke, 2020). Hence, it is proposed to align the criteria on PAH with those for other CMCs, as follows:

> *"Processed manure shall contain no more than 6 mg/kg dry matter of PAH_{16}"*

Upon discussing this criterion with the Commission's expert group on fertilising products, it was flagged that PAH should in principle not be present in concentration levels exceeding 6 mg/kg dry matter and that the testing may further increase administrative burdens and compliance costs for producers. However, limited data are available to confirm this statement. Therefore, it is proposed to add a criterion that manufacturers may, under their responsibility, omit testing when they are certain that concentration levels are below the limit value proposed:

> *"Where compliance with the requirement set out in point 1.4 follows certainly and uncontestably from the nature or the processing of the component material or the manufacturing process of the EU fertilising product, such compliance may be presumed in the conformity assessment procedure without verification (such as testing), under the responsibility of the manufacturer."*

6.8 Macroscopic impurities

No observations on macroscopic impurities > 2 mm of glass, metal or plastics have been documented for manure as these are not normally present in feed. It is noted that impurities observed in (composts derived from) bio-waste (Saveyn and Eder, 2014) are likely originating from other feedstocks, such as food waste (Porterfield et al., 2023). Hence, no criterion on macroscopic impurities has been proposed.

7 Assessment on agronomic efficiency

7.1 Agronomic value of processed manure

Processed manure typically contains nutrients and organic matter, two fundamentals of a fertile soil. Manure and processed manure are some of the main nutrient inputs to EU soils (Leip et al., 2015; Grizzetti et al., 2023). The agronomic value of certain processed manure materials is further described in Foged et al. (2011) and Wageningen Livestock Research (2019). Hence, the agronomic value of processed manure is well recognised, particularly in nutrient-poor regions and/or soils of low organic matter content.

7.2 Pyridine herbicide residues

Over 450 different active pesticide substances are approved in the EU[9]. Some pesticides such as clopyralid and aminopyralid can remain active in hay, grass clippings, and manure for an unusually long time (Janíková-Bandžuchová et al., 2015; Watanabe et al., 2019). Such pyridine herbicides have a history of reported incidents due to their presence in fertilising materials in the EU and the US (Fløistad, 2020; EPA, 2021).

An expert of the Commission working group on Fertilising Products also raised concerns on the potential presence of herbicide residues, particularly clopyralid. In a recent measurement campaign on processed manure samples, particularly clopyralid and aminopyralid showed high concentrations, up to 1.2 mg kg^{-1} (FOR Fritidsodlingens Riksorganisation, 2022; Almvik, 2023). These herbicide residues detected in pelleted livestock manure may originate from straw that was previously sprayed with the herbicide (Almvik, 2023). Another source could be straw and grass used as feed that contains pyralids. This is because clopyralid in feed almost totally ends up in the urine and manure produced by the animal (Almvik, 2023). The Norwegian Food Safety Authority Regulation has indicated that for fertilisers marketed as suitable for use on sensitive crops, actions will be undertaken "if the recommended use leads to a content of more than 1 µg/kg of aminopyralid or clopyralid, individually or in combination in a soil/culture medium." The actions are then evaluated on an ad-hoc basis, but may include e.g. a request for additional product documentation, labelling and even potentially a ban of such products.

Clopyralid proved to be stable under pasteurisation and sterilisation conditions (European Food Safety Authority et al., 2018). Moreover, clopyralid and other pyralid herbicides may be persistent in manure, particularly when sterilised, because the degradation of these compounds mainly occurs through microbial pathways, e.g. following well-executed composting and digestion processes (Blewett et al., 2005; EFSA, 2009; Taylor et al., 2010; WRAP, 2010). Nevertheless, the compounds typically do not accumulate in (aerobic) soils and is biodegradable in the short- to mid-term in soils (<60 days) (USDA Forest Service, 1999; Tomco et al., 2016; European Food Safety Authority et al., 2018). Hence, processed manure may temporarily introduce phytotoxicity to susceptible plant species at very low concentration levels (e.g. beans and clover, that can withstand less than 1 µg/kg in the soil (Almvik, 2023)).

[9] https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/start/screen/active-substances (search performed on 09/06/2023)

At the same time, it is noted that a recent risk assessment by EFSA concluded that "the short-term and long-term intake of residues resulting from the use of clopyralid according to the reported agricultural practices is unlikely to present a risk to consumer health provided that risk mitigation measures are in place to avoid clopyralid residues in rotational and/or succeeding crops" (EFSA (European Food Safety Authority) et al., 2021). In line with this observation, Commission Regulation (EU) 2021/1191[10] has now extended the approval of the active substance clopyralid until 30 September 2036. Similarly, aminopyralid has been approved for use until 30 December 2024 as per Regulation (EU) No 2018/155, based on older EFSA risk assessments (EFSA, 2009).

The EU maximum residue levels for clopyralid and aminopyralid are set at values from 0.01 mg kg^{-1} to 0.05 mg kg^{-1} fresh matter (Annex III of Regulation (EC) No 396/2005, Regulation (EU) 2021/1807, and Regulation (EU) 2021/1841, thus at levels that are a factor 10 to 50 greater than soil concentrations that may cause harm to the most susceptible plants. However, the addition of manure to soils will dilute the concentrations with an expected minimum factor of 70-420 (assuming that manure is applied at an application rate of 10 tonnes ha^{-1} yr^{-1}; thus adding 10 tonnes dry matter of manure to about 700-4200 tonnes of soil (5-30 cm mixing depth, bulk density of 1400 kg m^{-3}). Hence, it seems that the application of processed manure that contains not more than (the rounded value of) 50 µg/kg dry matter can be considered safe to ensure agronomic efficiency in all situations, including when applied on sensitive crops and will not lead to the exceedance of maximum levels for food and feed grown on these manure-amended soils.

At the same time, it is noted that concentrations measurements for aminopyralid or clopyralid are expensive (due to analytical methods required, e.g. liquid chromatography/tandem mass spectrometry). Therefore, it is desirable to omit testing by default, though producers of EU fertilising products could optionally be allowed to confirm the concentration of aminopyralid or clopyralid to levels below those of concern. As such, the labelling requirement would not be necessary.

In sum, a labelling requirement for maximum residue levels of clopyralid and aminopyralid in EU fertilising products is proposed as follows:

> *"Where an EU fertilising product contains processed manure as referred to in Part II, CMC 10, of Annex II, the following warning shall be included on the label 'This product may contain aminopyralid or clopyralid and must not be used for the production of plants susceptible to these substances, such as beans, clover, lentils, peas, salat, sunflowers and tomatoes. This product must be used in such a manner as to avoid leading to the exceedance of the maximum residue levels for food or feed set in accordance with Regulation (EC) 396/2005', or a similar warning. Such a warning is not needed for EU fertilising products containing processed manure with no more than 50 µg aminopyralid or clopyralid/kg dry matter."*

[10] Commission Implementing Regulation (EU) 2021/1191 of 19 July 2021 renewing the approval of the active substance clopyralid in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Text with EEA relevance). Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2021.258.01.0037.01.ENG

8 Pre- and post-processing

As described in section 4, the transformation of processed manure to an EU Fertilising product may contain a combination of steps (e.g. solid-liquid separation, drying, pelletising) that may occur either before or after the sterilisation process. Pressures and temperatures observed for steam sterilisation and/or granulation processes typically do not exceed 160°C and 5 bar. Higher pressures and/or temperatures may induce a risk of formation of undesirable and non-evaluated volatile and/or persistent organic compounds by maintaining water in a liquid state ("hydrothermal carbonisation") or introducing temperatures that may lead to the formation of PAHs and PCDD/F. Such transformation processes have been evaluated by the JRC previously when assessing candidate materials for CMC 13 and 14 (Huygens et al., 2019).

It is proposed to indicate that supplementary manure processing techniques may take place, and list technical and economical techniques of a high readiness level that are at present applied on-the-ground. This involves separation techniques, chemical and biological processes to modify or recover nutrient and carbon-rich manure fractions, techniques that modify the pH of the manure (e.g. to reduce ammonia emissions upon field application), and any other physical processes to improve the handling of the (processed) manure.

The proposed provisions are inspired by those outlined in Regulation (EU) 2022/1519[11] and provisions applicable by other CMCs in the Fertilising Products Regulation, as follows:

> *"An EU* fertilising *product may contain processed manure that may undergo one or more of the following additional processes:*
>
> - *the processing methods referred to in CMC 2;*
> - *biological treatment involving nitrification and denitrification;*
> - *mechanical separation of the solid and liquid fractions;*
> - *processes to recover nutrients and/or organic carbon, without the intention to otherwise modify the material;*
> - *chemical processing to modify the pH without the intention to otherwise modify the material;*
> - *physical processing to remove water and to transform the material into powder, granules or pellets, without the intention to otherwise modify the material."*

[11] Regulation (EU) 2022/1519 as regards the requirements applicable to EU fertilising products containing inhibiting compounds and the post processing of digestate.

9 Additives

The processing steps that are required to transform raw manure into processed manure, e.g. to improve handling, remove viable weeds, and undertake pre- and post-processing may require the use of additives in the CMC production process. Similar to other CMCs (e.g. compost listed under CMC 3), it is proposed to enable a maximum of 5% of the weight of the processed manure or fraction used as input in the respective process, as well as compliance with a REACH registration (Regulation (EC) No 1907/2006). Hence, the criterion proposed is the following:

> *"Additives needed in the processing referred to in points 1.1 and 1.2 may be used provided that:*
> *a. the additive complies with the requirement set out in point 2 of CMC 1;*
> *b. the concentration of the additives needed in each of the processes does not exceed 5 % of the weight of the processed manure or fraction used as input in the respective process."*

10 Conclusion

The animal by-product “processed manure” shows a potential for trade on the internal market, mainly with a view to facilitate the long-distance transport of nutrient- or organic-matter rich fractions. This may help to address nutrient-excess in livestock intense EU regions. The processing of manure (minimum 70°C for 60 minutes) will additionally sanitise the manure and limit as such biological pathogens. Supplementary criteria for viable weed seeds and plant propagules, PAH and good storage management are proposed and a description of post-processing techniques for processed manure is put forward. Furthermore, a labelling requirement to limit emissions from processed manure and for clopyralid and aminopyralid substances unintentionally present in processed manure that exceed a concentration threshold is proposed to ensure agronomic efficiency as well as to minimise environmental and health risks from processed manure placed on the market.

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List of abbreviations and definitions

Abbreviations	Definitions
BAT	Best Available Techniques
CMC	Component Material Category
FPR	Fertilising Product regulation
JRC	Joint Research Centre
PAH	Polycyclic Aromatic Hydrocarbons

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