

**DOSSIER CONCERNING THE REQUEST TO AMEND ANNEXES V and VI
concerning feed materials, additives/processing aids and certain substances used in animal
nutrition of Commission Regulation (EC) No 889/2008**

Articles 16.3 b of Council Regulation (EC) No 834/2007.

"Where a Member State considers that a product or substance should be added to, or withdrawn from the list referred to in paragraph 1, or that the specifications of use mentioned in subparagraph (a) should be amended, the Member State shall ensure that a dossier giving the reasons for the inclusion, withdrawal or amendments is sent officially to the Commission and to the Member States."

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 |
|------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Orthophosphoric Acid | Used as a preservative to maintain product quality and widely used in dry cat pet food for its contribution to available phosphorus in the body, modulating urinary pH. |

3. Status

Authorization in general agriculture or food processing

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| <p>Historic use</p> <p>Orthophosphoric acid is safe for all animal species when used as a preservative provided that the optimal ratio of Ca:P is maintained. It is considered to be a source of available phosphorus in the diet. Its contribution to the phosphorus supply of animals must be considered when formulating diets. That ability to provide bioavailable phosphorus to the animal makes phosphoric acid an additive which is authorized as a preservative but that has also some nutritional impact. Indeed, it has some urine acidifying properties because it influences the cation/anion balance in the diet with its contribution to phosphorus supply. That's why Phosphoric acid has been historically used as a preservative but at the same time as a urine acidifier in dry cat pet food formulation as it helps to promote a safe urine pH so that the risk to develop struvite urolithiasis is reduced.</p> <p>Regulatory status (EU, national, others) (including expiry dates of authorisation if applicable)</p> |
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REGULATION (EC) No 1831/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 September 2003 on additives for use in animal nutrition

COMMISSION IMPLEMENTING REGULATION (EU) No 1055/2013 of 25 October 2013

4. Identification ¹

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| Common name Phosphoric acid |
| Name(s) of active substance Orthophosphoric acid |
| Other names |
| Trade names N/A |
| CAS2 No. 7664-38-2 |
| IUPAC3 Name Phosphoric acid |
| E.C Additive Identification No 1a338 |
| Other code(s) EINECS number 231-633-2 |

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

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| Geographical relevance (Member States, regions, ...) Relevant in all member states |
| Socio-economic relevance (acreage, turnover, number of stakeholders affected, ...) Without authorization of Phosphoric Acid use in the EU organic Regulation, the formulation of urinary safe organic dry cat food is compromised. It is currently highly difficult to formulate |

¹ To be filled in only when applicable

² Chemical Abstracts Systematic Names

³ International Union of Pure & Applied Chemistry

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| dry organic cat food that promote safe urine pH. All manufacturers producing complete dry cat organic petfood would benefit from its authorization. |
| <p>Sectors affected</p> <p>Dry Cat Organic petfood.</p> |
| <p>Stakeholder engagement/consultation in dossier preparation</p> <p>Submission of this dossier is the result of a joint effort from French petfood manufacturers with the support of French Trade association and endorsement of European trade association (FEDIAF).</p> |
| <p>Market presence: availability (quantity / quality) and origin (local / imported)</p> <p>Global volumes available are huge, shared between Phosphoric acid food grade (with Coca Cola as the main buyer). Pet food industry participates to these volumes but at a much lower level.</p> <p>Biggest producers globally are Morocco, Israel, China, USA.</p> |
| <p>Aspects of international harmonization / market distortion</p> <p>Phosphoric acid is widely used in standard petfood as an authorized preservative and as a urine acidifier. Its absence from the positive list of substances approved in organic feed is compromising the development of organic dry cat products that are safe for cat's urinary tract. This is a major barrier for organic manufacturers to ensure safe cat food that can compete in</p> |

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| terms of nutritional performance with non-organic products. |
| A (possible) authorization leads to amendment(s) in the respective Annex ⁴ |
| Yes |
| <p>Other aspects justifying high priority, such as</p> <ul style="list-style-type: none"> • relevance for the development of a new organic production sector, • addressing of a newly upcoming problem in production or a quarantine organism, • addressing a recent development in agricultural policies, • addressing a new trend in consumer preferences/nutritional habits or new developments in food technology, • addressing a declared goal of organic farming. <p>Phosphoric Acid authorization in Organic is key for the formulation of safe dry cat food and for the development of Organic petfood sector. The absence of authorized urine acidifying substances in Organic feed puts at risk the health of cats fed with dry organic products that wouldn't promote safe urine pH (risk of formation of struvite urolithiasis). A lack of authorization at EU level could damage the current growing market of Organic petfood in France and in Europe.</p> |

6. Characterisation ⁵

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| Chemical formula/composition of active substance |
| H ₃ PO ₄ |
| Concentration of active substance |
| (67 %-85,7 %) w/w (aqueous solution) |
| If preparation, other components |
| Physical properties |
| Orthophosphoric acid has a molecular weight of 97.99 and a molecular formula H ₃ PO ₄ . It is a water miscible liquid, characterised by a high solubility in water (750–850 g/L) with dissociation constants of pKa1 2.12, pKa2 7.21, and pKa3 12.67. |

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 ..."

⁵ To be filled in only when applicable

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| Origin, inputs and production method of the active substance |
| Orthophosphoric acid is manufactured by two main processes, the wet process and the electrothermal process. In the wet process phosphate rock is digested with sulphuric, nitric or hydrochloric acids. The phosphoric acid is separated from the insoluble slurry by filtration. This process could, however, leave in the acid variable amounts of inorganic impurities that are removed through a solvent extraction purification process to produce the food-grade additive. In the electrothermal process, the phosphate rock, coke and silica are heated in an electric resistance furnace to more than 1 100 °C. The elemental phosphorus is then oxidised to P ₄ O ₁₀ and then hydrated. This process leads to a high-purity orthophosphoric acid. Only arsenic needs to be removed with an additional purification step. |
| Method(s) of analysis |
| For the determination of orthophosphoric acid in the feed additive: titration with sodium hydroxide. |

7. Specification of use

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| Material/additive category |
| Technological additives |
| Material/additive functional group |
| Preservatives |
| Species groups |
| Cat and Dog |
| Minimum or maximum rate according to species group (if appropriate) |
| As the maximum tolerable content of dietary phosphorus for all animal species is well known, setting a maximum content for the additive is not considered necessary. |
| Method of application |
| Added as such in a pet food product |

8. Reasons for the inclusion, withdrawal or amendments,

Specify in which Annex the inclusion , withdrawal or amendments is requested

V ☐ VI ☒

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| Explain the need for the proposed feed material or additive change |
| Preserve the quality of the product until the end of its shelf-life. Formulating organic complete petfood is highly challenging given the limited choice in organic ingredients that narrow the ability to formulate complete, balanced and safe petfood. Especially, the lack of authorization of substances that can modulate urine pH in cat (such as sulfur amino acids like Methionine or Cysteine and other additives having acidifying properties) is compromising the likelihood to have on the market safe dry organic catfood that promote a healthy urinary tract in cats. |
| What alternative solutions are currently authorised or possible? |
| Urine acidifying substances such as synthetic sulfur amino acids, sodium bisulphate or Ammonium Chloride are not currently authorized in Organic regulation. |
| Is there any traditional use or precedents in organic production? |

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| None |
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9. Consistency with objectives and principles of organic production

Please use the check list 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.

10. Impact

Environment

In feed formulation, the phosphorus from the acid will be treated as any other phosphorous source and will therefore not add to the total dietary phosphorus content. The use of orthophosphoric acid in animal nutrition is therefore not expected to pose an additional risk for the environment.

Animal health and welfare

Essential to maintain a healthy urine pH in cats fed with complete dry organic pet food.

Orthophosphoric acid is safe for the target animals when used as a preservative provided that the optimal ratio of Ca:P is maintained.

Deposition of orthophosphoric acid in the target animals' tissues/products is not expected as the phosphorus from orthophosphoric acid enters the phosphate pool of the animal. Consequently, the use of orthophosphoric acid as an additive in animal nutrition would not give rise to concern for the consumers of animal products.

Human health

Orthophosphoric acid is a bulk industrial chemical and the hazards for those handling this substance are well known. It must be labelled as corrosive to the skin and eyes and should be considered as equally hazardous to the respiratory tract (respiratory sensitiser). These hazards are reflected in the material safety data and appropriate protective measures are recommended.

Food quality and authenticity

As orthophosphoric acid is used in food as a preservative and its function in feed it is essentially the same as that in food, no further demonstration of efficacy is necessary. On top of that, its essential role as urine acidifier makes it a key substance to formulate safe dry cat food.

11. Other aspects

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| Various aspects, further remarks |
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12. Annexes

13. References

- 1-Scientific Opinion on the safety and efficacy of orthophosphoric acid for all animal species. EFSA Journal 2013;11(1):3043
- 2-Evaluation of sodium bisulphate and phosphoric acid as urine acidifiers for cats. J. Spears, C Grieshop and G. Fahey. *Arch. Anim. Nutr.*, October 2003, Vol. 57(5), pp. 389 – 398

Annex A

CHECKLIST FOR CONSISTENCY

with objectives and principles of organic production with reference to specific articles in the organic regulations

| Criterion | Specific articles in Reg. 834/2007 | Yes/No/ Not applicable | Brief qualification |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|------------------------|---------------------------------------------------------------|
| Exclude the use of GMOs and products produced from or by GMOs | Art. 9 Art. 4(a)(iii) | Yes | |
| Is it a synthetic amino acid ? | Art. 14 (1) (d) (v) | No | |
| Is it a growth promoter? | Art. 14 (1) (d) (v) | No | |
| 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 3 (c) | N/A | |
| Aim at producing products of high quality | Art. 3(b) | Yes | Preservative and safe urine pH promoter |
| Is it natural (not chemically synthesised)? | Art. 4(b) and (c) Art. 16(2)(e) (ii) | No | |
| Their use is necessary for sustained production and essential for its intended use, and general and specific criteria has been evaluated | Art. 16(2)(a)(e) | Yes | |
| Does it have nutritional value? | Art 14(1)(d)(ii) | Yes | Yes given its ability to positively influence urine pH in cat |
| Is it a natural milk replacer? | Art. 14 (1) (d) (vi) | No | |
| Is it of agricultural origin? | Art. 5 (k) Art. 14 (1) (d) (iv) | No | |
| Is it produced organically? | Art. 14 (1) (d) (i) and (iv) | No | |
| Is it land-based/using natural internal resources? | Art. 4 (a) and (b) Art. 5 (g) | No | |
| Is it aquaculture which complies | Art. 5 (o) | No | |

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| with the principle of sustainable fisheries/using natural internal resources? | Art. 4 (a) (b) and Art. 5 (g) | | |
| The recycling of wastes and by-products of plant and animal origin as input in plant and livestock production | Art. 5 (c) | N/A | |
| Is it produced internally (primarily from the holding where animals are kept or from other holding in the same region? | Art. 14(1) (d) (i) | N/A | |
| Does it affect the permanent access to pasture ? | Art. 14 (1) (d) (iii) | N/A | |
| Does it restrict the use of additives and processing aids? | Art. 7 (b) | No | |
| Is it species appropriate? | Art. 16.2(e)(i) | Yes | Cat |
| Does it have negative environmental impacts? | Art. 3 (a) (i) and Art. 4 (c) (iii) | No | |
| Does it have negative animal health/welfare impacts? | Art. 5 (h) and art. 14 (e) (i) | No | Its absence can have a negative impact on cat's urinary tract health |
| Does it have negative human health impacts? | Art. 3 (b) and (c) | No | |
| Does it involve 'misleading' substances/processes? | Art. 7 (c) and Art. 18 (4) | No | |
| Products and substances to be withdrawn or their use amended/limited | Art .21 (2) | N/A | |
| Others: please specify | | N/A | |