

**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"Where a Member State considers that a product or substance should be added to, or withdrawn from the list referred to in paragraph 1, or that the specifications of use mentioned in subparagraph (a) should be amended, the Member State shall ensure that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

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
DL-Methionine	Used as a Nutritional additive to match minimum nutritional requirement in cat and dog complete products. Used in dry cat formulation as a urine acidifier to support safe urine pH.

3. Status

Authorization in general agriculture or food processing

<p>Historic use</p> <p>Used in dog and cat food to reach minimum nutritional requirements. Methionine being an essential amino acid in both species.</p> <p>Methionine is generally the most limiting amino acid in a diet formulated using natural ingredients for cats and is often first or second limiting for dogs. Especially in diets formulated with natural ingredients that are naturally low in methionine and cysteine (e.g. vegetarian and vegan dog diets), the risk of methionine deficient diets is substantial.</p> <p>Since methionine is a methyl group donor, a part of the coenzyme (S-adenosylmethionine) for methyl group transfer, and an amino acid present in proteins, a deficiency of methionine results in a multitude of metabolic aberrations. These include interference with cell replication (defect in methylating RNA and/or DNA) and phospholipid synthesis (causing fatty liver).</p>

Dog:

The removal of methionine from a diet for puppies or adult dogs resulted in an immediate decrease in food intake and severe weight loss. The puppies exhibited dermatitis.

Cat:

Removal of methionine from the diet of kittens and adult cats resulted in body weight loss reported that amongst the essential amino acid deficiencies, the greatest weight loss in kittens (except for arginine deficiency) occurred with a methionine-devoid diet resulted in severe perioral and footpad lesions of young kittens. These clinical signs were similar to that of prolonged protein deficiency, indicating that methionine is most likely the first limiting amino acids when there is a deficiency of crude protein in cats. (NRC 2006)

Regulatory status (EU, national, others) (including expiry dates of authorisation if applicable)
Commission Implementing Regulation (EU) No 469/2013 of 22 May 2013

4. Identification ¹

Common name	DL-methionine, DL-methionine sodium salt, hydroxy analogue of methionine, calcium salt of methionine hydroxy analogue
Name(s) of active substance	DL-Methionine
Other names	N/A
Trade names	N/A
CAS2 No.	DL-methionine: 59-51-8 Sodium DL-methionine, liquid: 41863-30-3 Hydroxy analogue of methionine: 583-91-5 Calcium salt of hydroxy analogue of methionine: 4857-44-7
IUPAC3 Name	2-amino-4-(methylthio)butanoic acid
E.C Additive Identification No	DL-methionine: 3c301 Sodium DL-methionine, liquid: 3c302 Hydroxy analogue of methionine: 3c307 Calcium salt of hydroxy analogue of methionine: 3c308
Other code(s)	

¹ To be filled in only when applicable

² Chemical Abstracts Systematic Names

³ International Union of Pure & Applied Chemistry

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

<p>Geographical relevance (Member States, regions, ...)</p> <p>Relevant in all member states</p>
<p>Socio-economic relevance (acreage, turnover, number of stakeholders affected, ...)</p> <p>Without authorization of DL-Methionine use in the EU organic Regulation, the formulation of complete organic cat and dog food is compromised and might not be delivered to consumers anymore from 01/01/2022.</p>
<p>Sectors affected</p> <p>Dry and Wet Dog and Cat Organic petfood in general and more specifically dry cat food as Methionine has a urine acidifying beneficial effect in cat. More specifically, organic vegetarian and vegan diets for dogs are at the risk of methionine deficiency and need additional DL-methionine to be formulated according to FEDIAF Guidelines.</p>
<p>Stakeholder engagement/consultation in dossier preparation</p> <p>Submission of this dossier is the result of a joint effort from French and Dutch petfood manufacturers with the support of the 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 730.000 tons per year produced by France (60%) and Belgium</p>

(40%).

Aspects of international harmonization / market distortion

DL-Methionine is widely used in standard petfood to fulfil pet's essential nutritional needs. Its absence from the positive list of substances approved in organic feed put organic manufacturers in a situation that will prevent them to compete on the complete petfood market with manufacturers that do noton't produce organic products

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

Yes

Other aspects justifying high priority, such as

- 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.

DL-Methionine authorization in Organic pet food is key for the formulation of complete petfood and for the development of the Organic petfood sector. The absence of urine acidifying substances puts at risk the health of cats fed with dry organic products that wouldn't promote safe urine pH (risk of Feline Lower Urinary Tract Disease development). In addition, organic vegetarian and vegan diets for dogs are at the risk of methionine deficiency. A lack of authorization at EU level will damage the current growing market of Organic petfood in Europe.

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 ..."

6. Characterisation ⁵

Chemical formula/composition of active substance 3c301, 3c307: $C_5H_{11}NO_2S$ 3c302: $(C_5H_{11}NO_2S)_2Na$ 3c308: $(C_5H_{11}NO_2S)_2Ca$
Concentration of active substance DL-methionine: 99% Sodium DL-methionine, liquid: 40% Hydroxy analogue of methionine: 88% Calcium salt of hydroxy analogue of methionine: 84%
If preparation, other components Salts as stated above (Calcium, sodium)
Physical properties Specific weight of DL-methionine is 1.32–1.34g/cm ³ and water solubility 2.9–3.4g/100ml (22–25C).
Origin, inputs and production method of the active substance The products are manufactured by chemical synthesis starting from methyl-thio-propionic aldehyde and hydrogen cyanide in the presence of a catalyst.
Method(s) of analysis DL-methionine, Sodium DL-methionine, liquid: For the determination of methionine in the additives: Ion exchange chromatography coupled with post-column derivatisation and photometric or fluorescence detection (HPLC-UV/FD) - ISO/DIS 17180. For the determination of methionine in premixtures, compound feed, feed materials and water: Ion exchange chromatography coupled with post-column derivatisation and photometric detection (HPLC-UV) - Commission Regulation (EC) No 152/2009 (Annex III, F). Hydroxy analogue of methionine, Calcium salt of hydroxy analogue of methionine: Titrimetry, potentiometric titration followed by oxidation reduction reaction. For the determination of hydroxy analogue of methionine in premixtures, compound feed, feed materials and water: High-Performance Liquid Chromatography and photometric detection (HPLC-UV). : AOAC 999:13 and Reg. (EC) N° 152/2009

7. Specification of use

Material/additive category Nutritional additive
Material/additive functional group Amino acids, their salts and analogs
Species groups Cat and Dog
Minimum or maximum rate according to species group (if appropriate) Minimum:

⁵ To be filled in only when applicable

Dog: 0.35% DM for Early Growth, 0.26% DM for Late Growth and 0.40% DM for adult dog.
 Cat: 0.44% DM for Growth and 0.17% DM for adult cat.
 Maximum (Nutritional):
 Cat: 1.30% DM for Growth

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 ☒

Explain the need for the proposed feed material or additive change

Given the availability of organic raw materials with a better availability of organic vegetal protein vs. animal protein sources, formulating a complete petfood meeting the requirements of omnivorous/carnivorous pets especially in essential amino acids might be difficult. There is a need to supplement the amino acid profile with synthetic forms of the most limiting amino acids (e.g. Methionine, Cysteine, Lysine, Arginine) that are essential in body protein synthesis. To reduce chances of deficiency, a synthetic form of methionine, DL-methionine, is needed when formulating complete and balanced dog and cat diets. On top of that, DL-methionine is also needed in organic pet foods to balance the urinary pH, herewith reducing the chance of formation of urinary crystals, which is especially common in cats that are fed with a dry cat food. When it is no longer allowed to add DL-methionine as a synthetic nutrient in organically produced pet food, a valuable and safe method of urine acidification will be lost, herewith increasing the chance of urolith formation in cats fed with an organic dry pet food. It is important to note that without the possibility of DL-methionine supplementation, it is nearly impossible to formulate vegetarian or vegan complete organic Petfood that complies with FEDIAF Nutritional guidelines, as plant-based protein contains a low amount of sulfur-containing amino acids (Burley et al., 2015).

What alternative solutions are currently authorised or possible?

Methionine is naturally occurring in animal protein raw materials. There is no natural purified Methionine available. L-Methionine produced by fermentation is available, but fermentation strains are genetically modified. Therefore, supplementation with synthetic DL-methionine is required to formulate 100% complete petfood and comply with FEDIAF Nutritional guidelines.

Is there any traditional use or precedents in organic production?

None

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
Methionine is a physiological and natural component in animals and plants. Like its salts and the hydroxy analogue, it is not excreted as such (but as urea/uric acid, sulphate and CO ₂). The use of methionine, its analogue and their salts in animal nutrition would not lead to any localised increase in the concentration in the environment. It is concluded that the use of these products as feed additives does not represent a risk to the environment.
Animal health and welfare
Essential to maintain health of pets fed with Organic products
Human health
None of the products are considered to present a significant inhalation risk. DL-Methionine, is considered non-irritant to skin and eyes. DL-Methionine sodium salt is considered corrosive to skin and eyes and harmful if swallowed. The hydroxy analogue of Methionine is an irritant to the skin and corrosive to the eyes but is not a dermal sensitiser. The Calcium salt of methionine hydroxy analogue is irritant to the eyes but not to the skin. The absence of a dermal sensitisation potential demonstrated for the hydroxy analogue of methionine is considered to apply also to its Calcium salt.
Food quality and authenticity
Essential to formulate Complete petfood and safe dry cat food

11. Other aspects

Various aspects, further remarks

12. Annexes

13. References

- 1-Scientific Opinion on DL-methionine, DL-methionine sodium salt, the hydroxy analogue of methionine and the calcium salt of methionine hydroxy analogue in all animal species; on the isopropyl ester of methionine hydroxy analogue and DL-methionine technically pure protected with copolymer vinylpyridine/styrene in dairy cows; and on DLmethionine technically pure protected with ethylcellulose in ruminants. EFSA Journal 2012;10(3):2623
- 2-Cahier des Charges “Aliments pour animaux de compagnie” à base de matières premières issues du mode de production biologique » - JORF 25/02/04
- 3-Nutrient Requirements of Dogs and Cats. National Research Council 2006. Amino acids
- 4-FEDIAF Nutritional guidelines for complete and complementary pet food for cats and dogs – March 2019
http://www.fediaf.org/images/FEDIAF_Nutritional_Guidelines_2019_Update_030519.pdf
- 5-Burley, H. K., Patterson, P. H., & Anderson, K. E. (2015). Alternative ingredients for providing adequate methionine in organic poultry diets in the United States with limited synthetic amino acid use. World's Poultry Science Journal, 71(3), 493-504

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)	Yes	
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	Complete petfood
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	Essential nutrient
Does it have nutritional value?	Art 14(1)(d)(ii)	Yes	Essential nutrient in cat and dog and urine acidifier 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 with the principle of sustainable fisheries/using natural internal resources?	Art. 5 (o) Art. 4 (a) (b) and Art. 5 (g)	No	
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	Art. 14(1) (d) (i)	N/A	

from the holding where animals are kept or from other holding in the same region?			
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	Essential in cat and dog
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 has negative impact on animal 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	