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"Where a Member State considers that a product or substance should be added to, or withdrawn from the list referred to in paragraph 1, or that the specifications of use mentioned in subparagraph (a) should be amended, the Member State shall ensure that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	X 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
Taurine	Used as a Nutritional additive to match minimum nutritional requirement in pet food.

3. Status

Authorization in general agriculture or food processing

Historic use

Used in cat food to reach minimum nutritional requirements. Taurine being an essential nutrient in cats.

Taurine is a beta-aminosulfonic acid, an essential dietary nutrient for cats but dispensable for dogs fed adequate quantities of sulfur-containing amino acids, i.e. Methionine and Cysteine.

Cat:

Taurine deficiency in cats results in feline central retinal degeneration and heart failure; inadequate immune response; poor neonatal growth; reduced auditory brain stem evoked potential resulting deafness; poor reproduction resulting in a low number of foetuses, resorptions, abortions, decreased birth weight, and low survival rate of kittens; and congenital defects including hydrocephalus and anencephaly. (NRC 2006)

Dog:

Although in general dogs are believed to be able to synthesize adequate amounts of taurine from its precursors (cysteine and methionine,) diet-induced taurine deficiency is currently

investigated as potential cause of an outbreak of canine cases of dilated cardiomyopathy (DCM) in the US (FDA, 2019). In their study FDA concluded that the ingredients used in the diets that were fed to the dogs that developed DCM showed similarities. More than 90 percent of diets were “grain-free”, and 93 percent of reported diets contained peas and/or lentils. The suggestion that diet-induced taurine deficiency underlies this US outbreak of canine DCM reminds of observations published in 2003, where 12 dogs of different breeds shared DCM, low plasma Taurine and specific lamb-meal containing foods (Fascetti et al., 2003). It cannot be ruled out that under certain dietary conditions, individual dogs are indeed able to develop diet-induced signs of taurine deficiency. The most common clinical sign of taurine deficiency in dogs is dilated cardiomyopathy. It has been reported that dogs with low plasma taurine also have bilaterally symmetrical hyperreflective retinal lesions, which is similar to classic feline central retinal degeneration, and poor reproduction has been reported in Newfoundlands that had low plasma and whole-blood taurine concentrations. (NRC 2006)
Regulatory status (EU, national, others) (including expiry dates of authorisation if applicable) Commission Implementing Regulation (EU) No 2015/722 of 5 May 2015 in OJ L 115, 06.05.2015, p. 18

4. Identification [1]

Common name Taurine
Name(s) of active substance Taurine
Other names N/A
Trade names N/A
CAS[2] No. 107-35-7
IUPAC[3] Name 2-aminoethanesulfonic acid
E.C Additive Identification No 3a370
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

Geographical relevance (Member States, regions, …) Relevant in all member states
Socio-economic relevance (acreage, turnover, number of stakeholders affected, …) Without authorization of Taurine use in the EU organic Regulation, complete organic dog and cat food cannot be delivered to consumers anymore from 01/01/2022 Currently National standards authorize its use based on its essentiality to maintain healthy cats.
Sectors affected Dry and Wet Cat Organic petfood primarily and potentially Dry and Wet Dog Organic petfood as well.
Stakeholder engagement/consultation in dossier preparation 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).
Market presence: availability (quantity / quality) and origin (local / imported) Global volumes for Taurine are 57.000 tons per year coming exclusively from China.
Aspects of international harmonization / market distortion Taurine 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 not produce organic products.
A (possible) authorization leads to amendment(s) in the respective Annex[4] 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. Taurine authorization in Organic is key for the development / formulation of complete dry and canned petfood and Organic petfood sector. Complete products are already existing on the French market as Taurine is approved in the French standard. A lack of authorization at EU level will damage the current growing market of Organic petfood in France and in Europe.

6. Characterisation [5]

Chemical formula/composition of active substance $C_2H_7NO_3S$
Concentration of active substance

[4] It should be carefully analysed whether the specific use of a substance is already (impicitly) 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

100%
If preparation, other components In preparation the premixture may contain min. 98% taurine and max. 0,8% anti-caking agent ($Si0_2$).
Physical properties The molecular formula of taurine is C2H7NO3S and its molecular weight is 125.15. It has a pKa of 1.5 (at 25 °C) and a melting point of 300 °C (decomposition) and shows a bulk density of 0.65–0.75 g/cm3 and a density of approximately 1.7 g/cm3. It is soluble in water (10 g dissolves in 100 mL at 25 °C) and insoluble in ethanol, ethyl ether and acetone. The pH of a 5 % solution in water is 4.1–5.6. Taurine is a white crystalline powder that is almost odourless but with a slightly acidic taste. It contains by specification at least 98.0 % taurine in dried substance. Analysis of five batches of the active substance showed an average content of 99.5 ± 0.1 % taurine and a loss on drying of 0.07 ± 0.01 %.
Origin, inputs and production method of the active substance Taurine is synthesised starting from ethylene oxide and sodium bisulphite. Subsequently, liquid ammonia and sulphuric acid are added. The product is then decolourised, purified, crystallised, centrifuged, dried, sieved and blended with the carrier to obtain the additive.
Method(s) of analysis For the determination of taurine in feed additive: ion-exchange chromatography with post column ninhydrin derivatisation (European Pharmacopoeia method for the determination of amino acids (Ph. Eur. 6.6, 2.2.56 Method 1)). For the determination of taurine in premixtures and feedingstuffs: ion-exchange chromatography with post column ninhydrin derivatisation and photometric detection: based on Commission Regulation (EC) No 152/2009 (Annex III, F), or Reverse Phase High- Performance Liquid Chromatography (RP-HPLC) coupled to fluorescence detector (AOAC 999.12).

7. Specification of use

Material/additive category Nutritional additive
Material/additive functional group Vitamins, provitamins and chemically well-defined substances having similar effect
Species groups Cat and Dog
Minimum or maximum rate according to species group (if appropriate) Minimum: Dog: None (but possibly conditionally essential given the recent outbreak of diet-induced DCM in dogs in the US, e.g. in vegetarian/vegan or grain free organic products) Cat: 0.10/0.25% DM (Dry/Wet food) for Growth and 0.10/0.20% DM (Dry/Wet food) for adult cat Recommended Maximum: 0.9% DM or 2.25 g/1000 kcal, based on a standard diet of 4000 kcal/kg DM

Method of application Added as such or as a premixture in a pet food product

8. Reasons for the inclusion, withdrawal or amendments,

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

V ☐ VI X

Explain the need for the proposed feed material or additive change Taurine being essential in cat or conditionally essential in dog its addition is necessary to formulate complete pet food that will meet the daily nutritional requirements of cats and dogs.
What alternative solutions are currently authorised or possible? Taurine is naturally occurring in animal protein raw materials. There is no natural purified Taurine available. The only source on the market being synthetic. In dry pet food, the process (based on starch extrusion) is limiting the use of meat and animal derivatives. On top of that, it has also been shown that heat-processed cat foods resulted in lower taurine plasma levels and greater losses compared to the same food but frozen-preserved (Hickman MA et al. 1990, Hickman MA et al. 1992), owing to the increased sensitivity of Taurine to intestinal bacterial degradation after heat processing (Morris JG et al. 1994). Therefore, a supplementation with synthetic Taurine is required to formulate 100% complete product in cat and comply with FEDIAF Nutritional guidelines. The composition of the food, as well as the type of production process influence this intestinal degradation. Processing of canned food induces the largest losses in Taurine. For this reason, the FEDIAF recommendation for Taurine in canned cat food is higher than that for dry food or purified diets (FEDIAF, 2020). Based on the recent outbreak of diet-induced DCM in dogs in the US, it can be argued that taurine supplementation is required in organic dog diets as well. Especially in situations where the level of meat and animal derivatives raw materials (natural sources of taurine) and the associated sulfur amino acids levels are low (i.e. when formulating organic vegetarian/vegan or grain free canine diets).
Is there any traditional use or precedents in organic production? In countries where a National standard exist, Taurine was authorized (e.g. French Cahier des Charges on organic petfood). All current organic cat food products on the market are supplemented with Taurine.

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 the EFSA Journal 2012; 10(6):2736 it was stated that the use of taurine as an additive in

animal nutrition is not expected to substantially increase the concentration in the environment. It was concluded that a risk to the environment resulting from the use of taurine in animal nutrition is not expected.
Animal health and welfare Taurine supplementation is essential to maintain health of pets fed with organic products
Human health In the EFSA Journal 2012; 10(6):2736 it was stated that in the absence of any data, taurine is considered as a skin and eye irritant and skin sensitiser, and as hazardous if inhaled.
Food quality and authenticity The efficacy of taurine in cats is widely demonstrated in the literature, and consequently requirement data exist. The situation in dogs is different as no requirement exists and dose–effect relationships in the case of dilated cardiomyopathy, for which beneficial effects of taurine have been described for certain breeds, are not available. Although its use in dog nutrition is primarily driven by a medical indication, the FEEDAP Panel suggests that taurine might be effective in preventing dilated cardiomyopathy in dogs.

11. Other aspects

Various aspects, further remarks Taurine is authorised as an additive for specific nutritional purposes in foods for particular nutritional uses (Regulation (EC) No 953/2009), in infant formulae and in follow-on formulae when reconstituted as instructed by the manufacturer (Directive 2006/141/EC, Annex III). It is also used as an active ingredient in energy drinks (EFSA, 2009a). Taurine is listed as ingredient in cosmetic products as buffering agent (Commission decision 2006/257/EEC).

12. Annexes

13. References

1. EFSA. Scientific Opinion on the safety and efficacy of taurine as a feed additive for all animal species. EFSA Journal 2012: 10(6):2736.
2. Fascetti AJ, Reed JR, Rogers QR, Backus RC. Taurine deficiency in dogs with cardiomyopathy: 12 cases (1997-2001). J Am Vet Med Assoc 2003; 223: 1137-1141.
3. Freeman LM, Rush JE, Markwell PJ. Effects of dietary modification in dogs with early chronic valvular disease. J Vet Intern Med. 2006; 20(5):1116-26.
4. FDA investigating potential connection between diet and cases of heart disease (June 27, 2019). https://www.fda.gov/animal-veterinary/outbreaks-and-advisories/fda-investigation-potential-link-between-certain-diets-and-canine-dilated-cardiomyopathy.
5. Hickman MA, Rogers QR, Morris JG. Effect of Processing on Fate of Dietary [14C]Taurine in Cats. J Nutr. 1990: 120(9):995-1000.
6. Hickman MA, Rogers QR, Morris JG. Taurine Balance is Different in Cats Fed Purified and Commercial Diets. J Nutr. 1992: 122(3):553-559.
7. Huxtable RJ. The physiological actions of taurine. Physiol. Rev. 1992; 72:101-163

8. Morris JG, Rogers QR, Kim SW, et al. Dietary Taurine Requirement of Cats is Determined by Microbial Degradation of Taurine in the Gut. In: Advances in Experimental Medicine and Biology. 1994; Springer US, pp 59-70.
9. National Research Council (NRC 2006). Nutrient Requirements of Dogs and Cats. The National Academies Press. pgs. 134,135,137,364,365.
10. Pion PD, Sanderson SL, Kittleson MD. (1998). The effectiveness of taurine and levocarnitine in dogs with heart disease. Vet. Clin. North Am. Small Anim. Pract. 28:1495-1514.
11. Sanderson SL. Taurine and carnitine in canine cardiomyopathy. Vet Clin North Am Small Anim Pract. 2006; 36(6):1325-43, vii-viii.
12. Sturman JA and Messing JM. High dietary taurine effects on feline tissue taurine concentrations and reproductive performance. J. Nutr. 1992; 122(1):82-88.
13. Torres CL, Backus RC, Fascetti AJ, Rogers QR. Taurine status in normal dogs fed a commercial diet associated with taurine deficiency and dilated cardiomyopathy. J. Anim. Physiol. Anim. Nutr. 2003; 87(9-10): 359-372
14. Cahier des Charges "Aliments pour animaux de compagnie" à base de matières premières issues du mode de production biologique » - JORF 25/02/04
15. Nutrient Requirements of Dogs and Cats. National Research Council 2006. Amino acids
16. FEDIAF Nutritional guidelines for complete and complementary pet food for cats and dogs – September 2020. https://fediaf.org/images/FEDIAF_Nutritional_Guidelines_2020_20200917.pdfhttps://fediaf.org/images/FEDIAF_Nutritional_Guidelines_2020_20200917.pdf

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	Beta-amino acid
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)	Yes	
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
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 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	Essential in cat. Dispensable but conditionally essential in dog.
Does it have negative environmental impacts?	Art. 3 (a) (i) and Art. 4 (c) (iii)		
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	