Taurine
Handling/Processing

Identification of Petitioned Substance

Chemical Names:
2-aminoethanesulfonic acid

Other Name:
1-Aminoethane-2-sulfonic acid
2-Aminoethanesulfonic acid
2-Aminoethansulfonic acid
2-Aminoethylsulfonic acid
2-Sulfoethylamine
AI3-18307
Aminoethanesulfonic acid
Ethanesulfonic acid, 2-amino-
NSC 32428
O-Due
Taufon
Taukard
Tauphon
Taurin
Taurina
Taurine
β-Aminoethanesulfonic acid
β-Aminoethylsulfonic acid

Trade Names:
Taurine

CAS Numbers:
107-35-7

Other Codes:
EINECS 203-483-8

Characterization of Petitioned Substance

Composition of the Substance:

Although taurine is often referred to as an amino acid, technically it is not (it lacks a carboxyl group). It is more accurately classified as a β-amino sulfone. Taurine is produced in the body from methionine and cysteine metabolism. Some taurine is obtained via diet, which is especially important in infants and those less able to synthesize taurine in the body (Wócjik et al., 2010). Taurine is found in high concentrations in animal protein such as seafood, beef, and chicken, and is nearly absent from vegetarian foods such as vegetables, legumes, nuts, and beans (including soy beans) (Spitze et al., 2003). The linear chemical formula for taurine is $NH_2CH_2CH_2SO_3H$, or $C_2H_7NO_3S$ (Sigma Aldrich, 2010). Its chemical structure is shown in Figure 1.

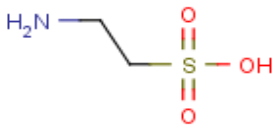

Figure 1. Chemical Structure of Taurine

Properties of the Substance:

Taurine is usually found as a white crystalline powder or solid. It has a pH of 5 in a 5% aqueous solution and a pH between 4.5 and 6 at 62.6 g/L at 25°C as a solid. Taurine has a melting point of >300°C (>572°F). Taurine is completely soluble in water (solubility of 65 g/L at 12°C) (Sigma Aldrich, 2010; Fischer Scientific, 2008).

Specific Uses of the Substance:

Taurine has been added to many infant formulas since the late 1980's (Chesney, 1987); it is now included in most, if not all, organic brands (e.g., Baby's Only Organic, Nature's One, 2011; Vermont Organics, 2011). It is also a common ingredient added to some commercial dog and virtually all cat food because it is considered essential for cats (VCA Animal Hospitals, undated). Taurine may also be added to chicken feed, although its benefits to laying hens, poultry broilers, and turkeys are questionable (Yamazaki and Takemasa, 1998; Tufft and Jensen, 1992). Finally, taurine is produced and marketed as a human dietary supplement.

Taurine is also added in high concentrations to energy drinks such as Red Bull (1000 mg), Monster (2000 mg), and Rockstar (3000 mg), even though there is no evidence that it has any effect on energy level or activity (Wócjik et al., 2010).

Approved Legal Uses of the Substance:

Animal Feed and Pet Food

Taurine does not appear on the USDA National List of Allowed and Prohibited Substances (hereafter referred to as the National List) for use in livestock feed. However, taurine is approved by the FDA for use as a nutritional supplement in conventional chicken feed at concentrations of <0.054% (21 CFR 573.980).

The FDA regulates pet food in a similar way to livestock animal feed. The Federal Food, Drug, and Cosmetic Act (FFDCA) stipulates that all animal foods "be safe to eat, produced under sanitary conditions, contain no harmful substances, and be truthfully labeled" (FDA, 2011). Canned food is further required to conform to low acid regulations (21 CFR 11), which state that foods low in acid must be sealed in such a way to ensure the food does not contain microorganisms that could make pets ill. Pet foods do not need to be approved by the FDA before they go on the market; however, additives including minerals, vitamins or other nutrients, flavorings, preservatives, or processing aids must be generally recognized as safe (GRAS) for their intended use (21 CFR 582 and 584) or have approval as food additives (21 CFR 570, 571 and 573). Taurine does not appear on the list of GRAS food additives (21 CFR 582), but as discussed above, it is allowed as a nutritional supplement in chicken feed (21 CFR 573.980; FDA, 2011) and thus considered an approved food additive in conventional products.

The Association of American Feed Control Officials (AAFCO), a voluntary membership association of local, state, and federal agencies required by law to regulate the sale and distribution of animal feed and medications, is considered the authority on pet nutrition in the United States. While AAFCO has no regulatory power, it has established a uniform code that has become the standard on which states base their feed laws and regulations (AAFCO, undated). As a result, pet food makers must follow this standard as well as regulations set forth by the FDA. In order for pet foods to be labeled "complete and balanced" by AAFCO, they must meet the nutrition standards of the AAFCO Dog or Cat Food Nutrient Profile. While taurine is not required in dog food, extruded cat food should contain 0.10% taurine and canned cat food should contain 0.20% taurine (FDA, 1997).

Human Food Additive and Dietary Supplement

Taurine does not appear of the USDA National List for use in handling/processing of organic food for human consumption.

Taurine can be used legally as a human dietary supplement, but it is not registered with the FDA for this use. The FDA does not regulate human dietary supplements in the same way as drugs or animal feed additives; generally, manufacturers do not need to register their products with FDA or get approval before producing and selling supplements for human consumption. The FDA is responsible for taking action

regarding an unsafe product after it reaches the market and to make sure the supplement's label is accurate and not misleading (FDA, 2005).

While not a required nutrient in baby formula, taurine is often added to soy-based and milk-based formulas due to their low taurine content (1.25 mg/L in cow milk-based formulas) (Klein, 2002). In 1999, sources indicated that preterm infant formula marketed in the United States contained 48–57 mg/L, or 5.9–7.0 mg of taurine/100 kcal (Gelardi and Mountford, 1999, in Klein, 2002). The manufacturer must give FDA 90 days notice prior to first processing of formula when using taurine because it is not listed in section 412(g) of the Food, Drug, and Cosmetic Act, which stipulates requirements for infant formula (FDA, 2009).

Action of the Substance:

Taurine is abundant in the body and can be found in many mammalian tissues including the heart, retina, skeletal muscle, brain, and leukocytes. It has a number of physiological functions and has been shown to exert a protective effect, reducing inflammation in injured tissue (Schuller-Levis and Park, 2003). The main action of taurine in the body is to conjugate cholesterol into bile acids so that they can be removed from the body. Several studies in animals and humans have indicated that taurine supplementation can reduce serum LDL ("bad") cholesterol caused by high-cholesterol diets (Wócjik et al., 2010). There are also a number of in vitro, animal, and human studies that suggest taurine may reduce blood pressure by affecting kidney vasodilation, and reducing several hormones responsible for increasing heart rate (Wójcik et al., 2010). Due to its anti-inflammatory property in tissues, research indicates that oral supplementation of taurine can reduce lung inflammation caused by ozone (O_3) exposure (Schuller-Levis and Park, 2003). Taurine is also important for the health of the retina (Militante and Lombardini, 2002). Taurine deficiency causes reduced or abnormal cardiac contractility, vision, growth, motor function, and reproduction in mammals (Backus et al., 2006).

In cats, taurine is considered an essential amino acid because cats are not able to synthesize it on their own. A number of studies have described immunological abnormalities leading to decreased immune system function in cats fed taurine-free diets (Schuller-Levis et al., 2003). Other studies indicate that cats with diets not supplemented with taurine have more miscarriages, fewer live births, and a lower kitten survival rate than cats with adequately supplemented diets (Sturman and Messing, 1991). Because of these studies, most cat food is supplemented with taurine (VCA Animal Hospitals, undated). While not necessarily essential for all dogs, taurine supplementation may be beneficial for certain dog breeds. A recent study in Newfoundland dogs found a high incidence of low plasma taurine in the population. The dilated cardiomyopathy (a common condition in this breed) found in some of the study dogs was reversed after taurine supplementation (Backus et al., 2006).

Combinations of the Substance:

Taurine is used in combination with other common ingredients in energy drinks/supplements, including caffeine, glucuronolactone (a carbohydrate found naturally in the body), and vitamins (Paddock, 2008). Pet foods generally contain a number of added vitamin supplements (e.g., vitamins A, B12, D3, and niacin), trace minerals and elements (e.g., iron and manganese), and possibly amino acids such as methionine and lysine (Healthwise, 2011; Orijen, undated). However, taurine is not a component of or precursor to any other substance on the National List.

Status

Historic Use:

Taurine was discovered in ox bile in 1827 (Birdsall, 1998). It was first recognized as a necessary component of the domestic cat's diet in the mid 1970s to early 1980s, resulting in taurine supplementation of cat food (VCA Animal Hospitals, undated). Shortly after the discovery of the importance of taurine in the cat's diet, research arose that suggested it may be semi-essential in humans as well. Researchers in Scandinavia found that formula-fed infants had much lower taurine levels than breast-fed infants. After further

research suggesting that retinal damage may occur from taurine deficiency, by the early to mid-1980s, manufacturers began supplementing most infant formulas with taurine (Heird, 2004; Chesney, 1987).

Red Bull, the first energy drink on the market, was introduced in 1997. Many brands have since developed, with over 500 new drinks introduced worldwide in 2006. While not all energy drinks contain taurine, it is one of the "central" ingredients in many energy drink products (Paddock, 2008). According to sources, taurine consumption in humans typically ranges from 40–400 mg/day, even in high-meat diets (European Commission, 1999). Using the European Union (EU) consumption estimate of 0.5 L/day of energy drinks containing the highest level of taurine, daily intake of taurine from energy drinks could be as high as 2000 mg/day, far above the average dietary intake (European Commission, 1999).

The history of the legal use of taurine in organic agriculture has revolved around uncertainty over the nutritional status of taurine because it is neither a vitamin nor a mineral, and there are conflicting opinions regarding its necessity in human nutrition, especially for infants. In 1995, the NOSB wrote "The Use of Nutrient Supplementation in Organic Foods" for the Secretary of the USDA, which stated:

> *Upon implementation of the National Organic Program, the use of synthetic vitamins, minerals, and/or accessory nutrients in products labeled as organic must be limited to that which is required by regulation or recommended for enrichment and fortification by independent professional associations (USDA, 2011a).*

The NOSB clarified that the term "accessory nutrients" meant "nutrients not specifically classified as a vitamin or a mineral but found to promote optimum health." However, confusion arose after the National List was established because an additional annotation (National List §205.605(b)) stated, "Nutrient Vitamins and Minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines for Foods, would be allowed for organic agriculture (USDA, 2011a)." Originally, the NOP interpreted that under 21 CFR 104.20(f), which states, "Nutrient(s) may be added to foods as permitted or required by applicable regulations established elsewhere in this chapter," taurine and other nutrients not specifically listed in the regulation were permissible. However, after further discussion with the FDA, a memomrandum (USDA, 2010) from NOP to the NOSB clarified that 21 CFR 104.20(f) pertained only to substances listed in 21 CFR 103.20(d), which does not include taurine. See "OFPA, USDA Final Rule" for more information.

OFPA, USDA Final Rule:

Taurine does not appear on the National List as a nonagricultural (nonorganic) substance allowed as an ingredient in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))"" (7 CFR § 205.605). The NOP final rule limits "vitamins and minerals" allowed for use in organic products to those in the FDA Nutritional Quality Guidelines for Food (21 CFR 104.20(d)(3)), which does not include taurine. However, due to a previous misinterpretation of the regulations, some organic infant formulas do contain taurine and other synthetic nutrient additives (Nature's One, undated; Vermont Organics, 2011; Earth's Best Organics, 2011). There has been confusion over the interpretation of the NOP regulations with regard to certain nutritive supplements, as described in the "Historic Use" Section. Currently the allowed "vitamins and minerals" do not include several nutrients considered important in specific foods, such as arachidonic acid (ARA) single-cell oil, docosahexaenoic acid (DHA), algal oil, sterols, and taurine.

While taurine does not appear on the National List for use in animal nutrition, 7 CFR § 205.238(a)(2) details the health care practice standard for livestock, which includes the requirement that, "provision of a feed ration sufficient to meet nutritional requirements, including vitamins, minerals, protein and/or amino acids, fatty acids, energy sources, and fiber (ruminants)."

International

According to the handling and processing rules of the Canadian Organic Standards Board (2011), "Food additives and processing aids shall only be used to maintain: nutritional value…" (8.3.4). Taurine and other amino acids do not appear on Canada's Organic Production Systems Permitted Substances Lists (PSL)

(CAN/CGSB-32.311-2006). In addition, it should be noted that taurine is listed as "unsuitable for use in [conventional] sports nutrition products" by the Canadian Food Inspection Agency (CFIA, 2009).

The CODEX Alimentarius Commission's Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods states, "Processing methods should be mechanical, physical or biological and minimize the use of non-agricultural ingredients and additives (§ 86)", specifically those on their permitted substances list. The allowed additives list does not contain taurine. Furthermore, amino acids are approved additives only "in so far as their use is legally required in the food products in which they are incorporated" (Codex Alimentarius Commission, 2010, Annex 3.5). It is unlikely that there are laws requiring the use of taurine in products for human consumption.

According to European Commission Regulation EC No. 889/2008, Article 27 (Use of certain products and substances in processing of food):

> *For the purpose of Article 19(2)(b) of Regulation (EC) No 834/2007, only the following substances can be used in the processing of organic food, with the exception of wine: (a) substances listed in Annex VIII to this Regulation;… (f) minerals (trace elements included), vitamins, amino acids, and micronutrients, only authorised as far their use is legally required in the foodstuffs in which they are incorporated.*

Taurine does not appear on the list "Certain products and substances for use in production of processed organic food referred to in Article 27(1)(a)" in Annex VII of EC No. 889/2008. In addition, taurine is not legally required in any foodstuffs; thus, taurine is not permitted in organic agriculture in the European Union.

The International Federation of Organic Agriculture Movements (IFOAM) states, "Minerals (including trace elements), vitamins and similar isolated ingredients shall not be used unless their use is legally required or where severe dietary or nutritional deficiency can be demonstrated." Furthermore, taurine does not appear on IFOAM'S List of Approved Additives and Processing Aids (IFOAM, 2005).

Under the Japan Agricultural Standard (JAS) for Organic Processed Foods, food additives are prohibited unless listed in the attaché table of food additives. Taurine is not included on this list (JMAFF, 2006).

The Codex Standard 72 (for conventional infant formula) and the European Commission Directive 2006/141/EC for infant formula do not require, but allow the use of taurine at no more than 12 mg/kcal (Codex Alimentarius Commission, 2007). The Canadian Food Inspection Agency requires the addition of taurine in infant formulas and formulated liquid diets (Food and Drug Regulation No. B.25; CFIA, 2011); it is assumed that these regulations would apply to all infant formulas, both organic and conventional; however, the Canadian Organic Standards do not specify guidelines for infant formula. Specific infant formula recommendations are not provided by IFOAM or JAS.

Evaluation Questions for Substances to be used in Organic Handling

<u>Evaluation Question #1:</u> Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Further, describe any chemical change that may occur during manufacture or formulation of the petitioned substance when this substance is extracted from naturally occurring plant, animal, or mineral sources (7 U.S.C. § 6502 (21)).

Much of the commercially available taurine is produced synthetically by the reaction of ethylene oxide with aqueous sodium bisulfate or the reaction of aziridine with sulfurous acid (NIIR, undated). Another method involving monoethanolamine, sulfuric acid, and sodium sulfite has also been described (Bondareva et al., 2008). Limited "natural taurine" may be available from certain manufacturers (See Evaluation Question #3).

Evaluation Question #2: Is the substance synthetic? Discuss whether the petitioned substance is formulated or manufactured by a chemical process, or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)).

Much of the taurine used in food and pharmaceuticals is created by commercial chemical processes and thus is synthetic. For example, Red Bull reports that the taurine it uses is produced synthetically in the laboratory (Red Bull, undated). However, taurine can be extracted from animal sources, mainly ox or cattle bile (BBA, 2011; New Zealand Pharmaceuticals, 2007). However, it appears that only small amounts of naturally produced taurine are available (see Evaluation Question #3). According to Gioacchini et al. (1995), it is difficult to distinguish natural from synthetic taurine; however, natural and artificial sources can be distinguished with radioisotope analysis ($^{13}C/^{12}C$ ratios) similar to carbon dating techniques. There are also indications that natural taurine is more expensive than synthetic taurine, making it impractical for use in large quantities, for example as feed additives in livestock and aquaculture (NOAA, 2010).

Evaluation Question #3: Provide a list of non-synthetic or natural source(s) of the petitioned substance (7 CFR § 205.600 (b) (1)).

Taurine is found in high quantities in meat proteins such as seafood (highest), poultry, and beef (Spitze et al., 2003). It also concentrates in organs such as the liver; however, liver taurine content can vary greatly, possibly due to its variable distribution throughout the liver and the possibility that stores are depleted due to conjugation with bile acids (Spitze et al., 2003). Available sources do not report whether there are commercially available sources of naturally extracted taurine. However, at least two manufactures market natural taurine made from ox bile (BBA, 2011; New Zealand Pharmaceuticals, 2007). A Norwegian fishing industry group also suggests that taurine extract may be obtained from fishery waste, and may have been produced by Japanese manufacturer Nippon Suisan Kaisha, Ltd (Stiftelsten Rubin, 1993); however, no information indicated that the manufacturer currently produces taurine using fishery waste.

Evaluation Question #4: Specify whether the petitioned substance is categorized as generally recognized as safe (GRAS) when used according to FDA's good manufacturing practices (7 CFR § 205.600 (b)(5)). If not categorized as GRAS, describe the regulatory status. What is the technical function of the substance?

Taurine is not listed as a GRAS substance by the FDA (21 CFR 182). Taurine is used primarily as a dietary supplement in humans and animals, and dietary supplements fall under a different set of regulations (Public Law 103-417; 21 CFR 111) than other food additives (21 CFR 171-178). Dietary supplements do not need to be recognized as GRAS to be allowed for use. Unlike food additives, generally, manufacturers do not need to register their products with FDA or get approval before producing and selling supplements for human consumption. Under the Dietary Supplement Health and Education Act of 1994 (DSHEA; Public Law 103-417), the manufacturer is responsible for ensuring that a dietary supplement/ingredient is safe before being placed on the market. The FDA is responsible for taking action regarding an unsafe product after it reaches the market and to make sure the supplement's label is accurate and not misleading (21 CFR Part 101) (FDA, 2005).

Evaluation Question #5: Describe whether the primary function/purpose of the petitioned substance is a preservative. If so, provide a detailed description of its mechanism as a preservative (7 CFR § 205.600 (b)(4)).

The petitioned substance is not used as a preservative; taurine is an amino acid used primarily as a dietary supplement for humans and animals.

Evaluation Question #6: Describe whether the petitioned substance will be used primarily to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law) and how the substance recreates or improves any of these food/feed characteristics (7 CFR § 205.600 (b)(4)).

The petitioned substance is intended to be used as a dietary supplement, not as an additive to recreate or improve flavors, colors, textures, or nutritional values lost in processing.

Some taurine is lost from natural sources during preparation. For example, cooking meat in water (i.e., boiling or basting) results in a substantial loss of taurine in the meat; while baking and frying have higher rates of taurine retention (Spitze et al, 2003). As a result, cooked, prepared pet foods may lose some taurine during processing. Cat foods must be supplemented with taurine partially for this reason; in the wild, cats consumed raw wild prey with high levels of taurine (Spitze et al., 2003). The taurine added to products for human consumption, such as energy drinks, are not intended to replace nutrients lost in processing.

Evaluation Question #7: Describe any effect or potential effect on the nutritional quality of the food or feed when the petitioned substance is used (7 CFR § 205.600 (b)(3)).

Taurine is added to infant formula, infant food, and animal feed to improve nutritional quality, specifically to supplement food/feed with taurine. Although taurine is beneficial to health, it can be metabolically synthesized to sufficient levels by most animals including humans (except in certain lifestages such as infancy and older age, and in cats), as long as the diet contains adequate amounts of the sulfur amino acids methionine and cysteine (Wócjik et al., 2010).

The main action of taurine in the body is to conjugate cholesterol into bile acids so that they can be removed from the body. Several studies in animals and humans have indicated that taurine supplementation can reduce serum LDL ("bad") cholesterol caused by high-cholesterol diets (Wócjik et al., 2010). See the "Action of the Substance" section for more information on the beneficial effects of taurine.

Research also indicates that zinc and taurine interact synergistically in the retina (in other words, zinc deficiency, when coupled with taurine deficiency, increased adverse effects compared with either deficiency alone). Zinc and taurine may also interact in other tissues (Fischer, 1997). There is also evidence that oral taurine therapy (1000 mg/day) may increase the effectiveness of oral iron in the treatment of iron-deficiency anemia (Sirdah et al., 2002), suggesting a taurine-iron interaction.

Evaluation Question #8: List any reported residues of heavy metals or other contaminants in excess of FDA tolerances that are present or have been reported in the petitioned substance (7 CFR § 205.600 (b)(5)).

Little information regarding potential contaminants in taurine could be located. One study of 11 commercially available taurine dietary products found that no substantial amounts of mercury, arsenic, or selenium were found in any of the products (Bragg et al., 2009).

Other studies indicate that taurine may reduce the toxicity of oral exposure to heavy metals. Hwang et al. (1998) fed groups of rats diets with or without supplement of 5% taurine and 150–600 ppm copper for 2 months. Levels of copper and malondialdehyde in the liver and levels of aspartate and alanine transaminase (enzymes that increase when the liver is injured or inflamed) in the rats' plasma were significantly lower in taurine-supplemented rats compared to those not fed taurine. The authors suggested that taurine may reduce the toxic effects of copper in rats (Hwang et al., 1998). A study by Jagadeesan and Pillai (2007) reported that taurine supplementation (5 mg/kg-bw for 15 days) after liver injury from mercury administration (2 mg/kg-bw mercuric chloride for 30 days) improved liver function in rats. Several studies, including Manna et al. (2008) also provide support for the notion that taurine reduces the effect of cadmium in animals. Mice administered 4 mg/kg-bw of cadmium for 6 days and 100 mg/kg-bw of taurine for 5 days did not suffer from the cadmium-induced heart impairments experienced by mice administered cadmium only (Manna et al., 2008).

Evaluation Question #9: Discuss and summarize findings on whether the manufacture and use of the petitioned substance may be harmful to the environment or biodiversity (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)).

Little data exist on the potential impact of taurine production and use on the environment. Several material safety data sheets from taurine manufacturers state, "no data available" in the sections on ecotoxicity and environmental toxicity (Fischer Scientific, 2008; Sigma Aldrich, 2010). However, some of the chemical intermediates used in the production of synthetic taurine could potentially impact the environment in the event of misuse or accidental release. For example, sulfuric acid can dissolve some of the soil it is spilled and can damage surrounding plants or animals exposed to it (HSDB, 2010). Aziridine (also known as ethyleneimine) is flammable and reactive; it may polymerize violently when exposed to high temperatures or sunlight. It is listed as a hazardous air pollutant known or expected to cause serious health problems under the Clean Air Act (HSDB, 2006).

Evaluation Question #10: Describe and summarize any reported effects upon human health from use of the petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (i)) and 7 U.S.C. § 6518 (m) (4)).

Most studies on the dietary administration of taurine detail its therapeutic effects. In most cases, taurine is well tolerated by humans at therapeutic doses. In one study, mild diarrhea and constipation were reported after oral taurine supplementation (Clauson et al., 2008). Another study found that taurine administered to patients with uncompensated adrenocortical insufficiency (when adrenal glands do not provide enough steroid hormones) caused hypothermia and hyperkalemia (elevated blood potassium) (Ikeda, 1996, as cited in Clauson et al., 2008). Another study reported nausea, headache, dizziness, and gait disturbances in some epileptic patients treated with 1.5 grams of taurine per day (Van Gelder et al., 1975 in Clauson et al., 2008).

Numerous studies report the beneficial effects of taurine supplementation in animals and humans. Taurine's ability to conjugate bile acids, which enables the excretion of cholesterol, is one reason why taurine is thought to improve cardiovascular health. There are also a number of in vitro, animal, and human studies that indicate taurine may reduce blood pressure by affecting kidney vasodilation, and reducing several hormones responsible for increasing heart rate (Wójcik et al., 2010). A recent study in Newfoundland dogs found a high incidence of low plasma taurine in the population. The dilated cardiomyopathy (a common condition in this breed) found in some of the study dogs was reversed after taurine supplementation (Backus et al., 2006).

There is evidence that taurine is anti-inflammatory in tissues, with reports that oral exposure can reduce lung inflammation caused by ozone (O_3) exposure (Schuller-Levis and Park, 2003). Taurine is important for the health of the retina, and deficiency may lead to visual dysfunction in humans and animals (Militante and Lombardini, 2002).

Some studies suggest that taurine supplementation of infant formula is needed to mimic the nutrition of human breast milk. Preterm infants fed non-supplemented, cow-milk based formula have lower serum taurine levels than infants fed breast milk; research suggests that preterm infants cannot reabsorb taurine in the kidneys (which adult kidneys actively do), due to immature renal systems (Klein, 2002). Galeano et al. (1987) found that low birthweight infants fed formula supplemented with 40 mumol/dL of taurine had improved absorption of fat, especially fatty acids, but did not have improved growth compared to infants fed formula without taurine supplementation or infants fed with breast milk. However, other authors found that taurine supplementation did not improve uptake of fat and uptake of energy compared to infants fed non-supplemented formula (Bijleveld et al., 1987). A review of infant formula taurine supplementation studies led authors to conclude that there was a "lack of evidence of benefit from randomised controlled trials" (Verner et al., 2007). However, a recent epidemiologic study by Wharton et al. (2004) suggests that low taurine status in neonates may negatively impact neurodevelopment, as measured by the Bayley mental development index at 18 months. This study is limited by its retrospective

nature and because it was not a randomized control trial. Based on the available health data, nutritional panels have recommended a maximum amount (12 mg/100 kcal) for taurine in infant formula, which is equivalent to the maximum content observed in human milk (Klein, 2002). Heird (2004) also suggests a minimum content of 5 mg/100 kcal of taurine for preterm infant formulas, but notes that this minimum is not well received due to the lack of evidence that taurine supplementation is required in infant formula to maintain adequate nutrition (Bijleveld et al., 1987; Raiten et al., 1998; Verner et al., 2007). Currently, taurine is not required in any amount in infant formula (Wharton et al., 2004).

Evaluation Information #11: Provide a list of organic agricultural products that could be alternatives for the petitioned substance (7 CFR § 205.600 (b)(1)).

Some pet foods contain adequate natural taurine content such that synthetic supplementation is unnecessary. For example, the manufacturer of Orijen cat food states that, "Orijen cat foods list taurine in the guaranteed analysis but not in the ingredient panel. This is because Orijen is very rich in meats (in which taurine is naturally present) and therefore no supplementation is required" (Orijen, undated). In addition, while some of Healthwise's formulations contain taurine (all cat formulas and dog foods that do not contain poultry), some of their formulations do not require taurine supplementation. Many of their dog foods contain chicken meal, which contains 0.08–0.1% natural taurine; Healthwise's taurine-supplemented lamb meal dog food contains 0.35% taurine (Healthwise, 2011). It appears that in some cases, it is possible to add organic meat in sufficient quantities as an alternative to taurine supplementation in pet food.

Because taurine is produced from methionine and cysteine in the body, supplementation with these sulfur amino acids may help to meet the taurine needs of certain animals. For example, Rabin et al. (1976) found that 1.0% methionine in the diet satisfied the taurine requirement in adult cats. However, methionine and cysteine supplementation did not maintain adequate plasma, retinal, or bile acid taurine levels in kittens, suggesting that the kittens had not yet developed the necessary enzymes to convert methionine and cysteine to taurine (Rabin et al., 1976). At this time, synthetic methionine is allowed for use in poultry feed (7 CFR 205.603(d)(1)). However, methionine (synthetic or non-synthetic) does not appear on the National List of substances allowed in food handling/processing (7 CFR § 205.605).

No alternatives to taurine for use in supplemented infant formula have been identified.

References

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