BALCHEM CORPORATION

30 April 2012

Ms. Ann Michelle Arsenault
Special Assistant
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Avenue, SW
Room 2648-S, Mail Stop 0268
Washington, DC 20250-0268

Re: AMS-NOP-12-0017; NOP-12-06

Dear Ms. Arsenault:

Please accept these comments from Balchem Corporation in support of the proposal of the Handling Committee of the National Organic Standards Board (NOSB) for the addition of choline to the National List for use in:

- infant formula labeled *Organic* or *Made with Organic*, and
- agricultural products other than infant formula, labeled *Made with Organic.*

The NOSB's proposed allowance of choline fortification of *Made with Organic* processed foods is an important step in increasing the presence of this valuable nutrient in the US food supply. **In these comments, we wish to emphasize the important and essential nature of choline as a nutrient, which supports the case for its broader use in *Made with Organic* and *Organic* foods.**

In 1998, the Food and Nutrition Board of the Institute of Medicine developed dietary reference intake (DRI) values for choline for age/life stage groups based on then-current understanding of choline metabolism and intake. Choline is considered an essential nutrient for humans because the body's biosynthetic processes do not ordinarily produce quantities sufficient to sustain normal organ function, even in a state of good health. Choline need in humans varies with gender (male > female) and according to several commonplace genetic characteristics. It increases with age in both genders and in certain physiological states (pregnancy, lactation). Choline need is affected by B-vitamin status, particularly folate, due to the nutrients' complementary and partially compensatory interrelationship, as well as the use of common pharmaceutical therapies that interfere in the folate cycle (e.g. methotrexate, anticholinergics). Recent analysis of National Health and Nutrition Examination Survey (NHANES) data has shown a significant shortfall in choline intake in all segments of the US population, versus DRIs. Individuals opting to minimize their intake of foods high in fat and cholesterol (*e.g.* egg yolks, liver) are simultaneously eliminating some good natural sources of choline from their diets. Water-soluble choline salts choline chloride and choline bitartrate are very easily added to virtually any processed food or feed product, liquid, tablet or capsule. They have a long history of safe use and a minimal environmental impact in manufacture and use. Choline chloride and choline bitartrate deliver a greater cation content (74 and 40%, respectively) than do naturally-occurring forms (e.g. phosphatidylcholine) and exhibit excellent stability and high bioavailability in virtually all applications.

We also wish to provide clarification for Question 4 in the Technical Evaluation Report, regarding Generally Recognized as Safe (GRAS) status and technical function of the substance.

Synthetic water-soluble forms of choline, such as choline bitartrate and choline chloride, are GRAS when used as a nutrient source when used according to Good Manufacturing Practices (GMPs) (21 CFR 182.8250, 21 CFR 182.8252).

One of these water-soluble forms, namely choline chloride, is also GRAS for use as a flavor modifier; it is listed (#4500) on the GRAS list of the Flavor and Extracts Manufacturers Association (FEMA), a group which conducts safety assessments "pursuant to the authority granted in Section 201(s) of the U.S. Federal Food, Drug, and Cosmetic Act[1]." Choline chloride's unique non-nutritive functionality augments the taste impact of sodium chloride, which has important implications for acceptance and palatability of reduced-sodium foods. (Currently, the NOP does not allow popular salt replacers and flavor enhancers such as potassium chloride, monosodium glutamate, and autolyzed yeast.) Choline chloride was recently re-evaluated and approved by FEMA's Expert Panel for safety at higher application levels for this purpose[2]. The United States Department of Agriculture – Risk, Innovations & Management Division (USDA-RIMD) has relied upon FEMA evaluations in its expression of 'no objection' to the use of choline chloride for this non-nutritive purpose, in processed, ready-to-eat, fresh and frozen meat and poultry products (excluding eggs), with or without standards of identity or composition, at levels not to exceed 6000 parts per million (ppm) in the finished application[3].

In conclusion, Balchem Corporation supports responsible use of choline in processed foods *Made with Organic* ingredients, and advocates broader allowance of choline in *Organic* processed foods as well. Choline's necessity in growth and in maintenance of normal structure and function of the body make it an irreplaceable component of the human diet that should continue to be readily available in the organic food supply.

Thank you for your consideration of our petition and these subsequent comments.

Sincerely,

Kristine V. Lukasik, Ph.D.
Manager, Scientific & Regulatory Affairs
Food and Nutritional Ingredients Division
Balchem Corporation
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Attachments (2):
Letter from FEMA Expert Panel
Letter from USDA-RIMD

[1] http://www.femaflavor.org/gras
[2] Documentation from FEMA, provided in advance of the publication of the 2012 FEMA GRAS list, follows this letter.
[3] The revision is expected to be reflected in the next edition of *USDA-FSIS Directive 7120.1 - Safe and Suitable Ingredients Used in the Production of Meat, Poultry and Egg Products*. The USDA-RIMD No Objection letter is attached.

The Expert Panel of the Flavor and Extract Manufacturers Association of the United States

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October 21, 2011

Kristine V. Lukasik, Ph.D.
Balchem Corporation
52 Sunrise Park Road
New Hampton, NY 10958

Dear Dr. Lukasik:

Your application and supporting information regarding the use of choline chloride (FEMA 4500, CAS 67-48-1) at new use levels was reviewed by the FEMA Expert Panel at the September 2011 meeting. It was the decision of the Panel to recognize the substance as GRAS for use as a flavor modifier in food categories at the use levels specified in the GRAS application (see attachment).

Significant changes in use levels within an approved category, or use in new categories, requires a re-evaluation of this material by the Expert Panel. Re-evaluation may also be required if there is significant change in the composition of the product in commerce. The Expert Panel reserves the right the re-evaluate the GRAS status of this substance if there is a significant increase in volume of use of this substance.

If you have any questions, please feel free to contact me.

Sincerely,

Timothy B. Adams, Ph.D.
Scientific Director

Enclosure

Use Levels

Daily consumption of regular foods by males and females, 2 to 65+ years

Name: Choline Chloride

FEMA No: 4500

Food Category	Mean Consumption*	Usual Use Level (ppm) Original/Proposed**		Maximum Use Level (ppm) Original/Proposed**	
Baked Goods	**137.2**	2500	4000	4000	6000
Beverages Type I, Non-alcoholic	**104.0**	0	0	0	0
Beverages Type II, Alcoholic	**32.5**	0	0	0	0
Breakfast Cereals	**20.0**	300	4000	600	6000
Cheese	**9.4**	0	0	0	0
Chewing Gum	**0.2**	0	0	0	0
Condiments and Relishes	**8.8**	0	0	0	0
Confectionery and Frostings	**0.3**	0	0	0	0
Egg Products	**1.9**	0	0	0	0
Fats and Oils	**17.5**	0	0	0	0
Fish Products	**12.4**	600	600	1200	1200
Frozen Dairy	**25.6**	0	0	0	0
Fruit Ices	**0.7**	0	0	0	0
Gelatins and Puddings	**20.4**	0	0	0	0
Granulated Sugar	**8.6**	0	0	0	0
Gravies	**8.3**	600	4000	1200	6000
Hard Candy	**0.6**	0	0	0	0
Imitation Dairy Products	**0.9**	0	0	0	0
Instant Coffee and Tea	**121.1**	0	0	0	0
Jams and Jellies	**5.7**	0	0	0	0
Meat Products	**78.4**	600	4000	1200	6000
Milk Products	**39.5**	0	0	0	0
Nut Products	**5.2**	0	0	0	0
Other grains	**27.8**	0	0	0	0
Poultry	**12.9**	600	4000	1200	6000
Processed Fruits	**118.3**	0	0	0	0
Processed Vegetables	**85.0**	0	0	0	0
Reconstituted Vegetables	**0.2**	0	0	0	0
Seasonings and Flavors	**0.01**	0	4000	0	6000
Snack Foods	**1.3**	2500	4000	4000	6000
Soft Candy	**5.8**	0	0	0	0
Soups	**31.7**	600	2500	1200	4000
Sugar Substitutes	**0.08**	0	0	0	0
Sweet Sauce	**6.8**	0	0	0	0

REFERENCE: Market Research Corporation of America (MRCA), in conjunction with the "Food intake and nutritive value of the diets of men, women, and children in the United States, Spring 1965", a preliminary report by the consumer and Food Economics Research Division, Agricultural Research Service, United States Department of Agriculture.

*Based on MRCA mean frequency of eating and USDA mean portion size

** Bold font represents a new use level or food category

USDA United States Department of Agriculture
Food Safety and Inspection Service

Office of Policy and Program Development

Risk, Innovations, and Management Division
Patriots Plaza III, Mail Stop 3782
1400 Independence Ave. SW
Washington, DC 20250-3700

December 23, 2011

Kristine V. Lukasik, Ph.D.
Manager, Scientific and Technical Product Support
Food, Pharma and Human Nutrition
Balchem Corporation
52 Sunrise Park Road
New Hampton, NY 10958-0600

Dear Dr. Lukasik:

This letter is in response to your November 28, 2011 askFSIS notification (Reference # 11112-000028) requesting a revision to the Food Safety and Inspection Service (FSIS) no objection letter, dated March 15, 2011. Specifically, your are requesting permission to use choline chloride and a conditioned choline chloride product, C-Salt™ (with 2% added magnesium stearate), as a direct replacement for sodium chloride according to Good Manufacturing Practices (GMPs) in meat, poultry, and egg products. The new requested maximum level of choline chloride would be 6000 ppm (Log No. 10-ING-0658-N-B).

In your submission, you describe the function of choline chloride alone as a direct replacement for sodium chloride and to improve the palatability of reduced sodium food products including processed, ready-to-eat (RTE), fresh and frozen meat, poultry, and egg products with or without stated standards of identity or composition. You also describe the function of a conditioned choline chloride product, C-Salt™ (with 2% added magnesium stearate) as similar to choline chloride. The 2% magnesium stearate is added for better flow characteristics and reduced hygroscopicity.

You stated that up to 50% of the weight of sodium chloride in a product could be replaced by choline chloride or C-Salt™ with little or no loss of salty flavor. However, a more typical usage level will be replacement of 30% of the weight of sodium chloride with choline chloride or C-Salt™.

During its evaluation, FSIS consulted with the Food and Drug Administration (FDA) for a safety determination regarding the use of choline chloride and choline chloride + magnesium stearate (C-Salt™) in meat, poultry, and egg products.

Regarding safety, FDA determined that, in accordance with 21 CFR 182.8252, choline chloride is Generally Recognized as Safe (GRAS) when used in accordance with good manufacturing practice (GMP) as a nutrient. Balchem Corporation (Balchem) stated that the intended use for choline chloride is as an enhancer of salty flavor in meat, poultry, and egg products. Therefore,

FDA determined that Balchem's stated intended use would not be covered under 21 CFR 182.8252.

However, as highlighted in Balchem's notification, the Flavor and Extract Manufacturers Association (FEMA) of the United States has evaluated and found choline chloride to be GRAS when used at low levels as a flavoring agent in several food categories, including meat and poultry products. The average maximum use level (parts per million) specified in meat and poultry products is 6000 for each product category. Egg products, as a category, were not assigned a use level. Over the years, FDA has generally not challenged FEMA's determination with regard to their flavor GRAS decisions. Therefore, since Balchem states that the intended use of the choline chloride is as an enhancer of salty flavor, FDA had no safety concerns with this use of choline chloride in meat and poultry products, provided the use does not exceed 6000 ppm. Conversely, since 21 CFR 182.8252 does not authorize the use of choline chloride as a flavor ingredient and because FEMA does not list a use level for egg products, FDA can not comment on the safety of choline chloride in egg products as an enhancer of salty flavor.

In accordance with 21 CFR 184.1440, magnesium stearate, meeting specifications set forth in the Food Chemicals Codex, is considered GRAS by FDA for use as a lubricant and release agent as defined in 21 CFR 170.3(o)(18), a nutrient supplement as defined in 21 CFR 170.3(o)(20), and as a processing aid as defined in 21 CFR 170.3(o)(24). Furthermore, FDA determined that magnesium stearate could be used in food with no other limitation than current GMP and at levels not to exceed GMP. In section IV, entitled "Conditions of Use," of Balchem's notification that was submitted to FSIS, Balchem stated that the magnesium stearate in C-Salt™ functions as a processing aid. The subsequent clarification by Balchem provided to FDA in the email of November 18, 2010, stated that magnesium stearate is added to choline chloride to improve its flow characteristics.

Previously, in accordance with 21 CFR 101.100(a)(3), FDA had determined that magnesium stearate would not function as a processing aid and would not be covered under 21 CFR 184.1440. With this in mind, FDA could not comment on the safety of magnesium stearate in this notification. However, FSIS received an e-mail from FDA, dated February 14, 2011, that FDA had reevaluated their previous stance of magnesium stearate's function as a processing aid. FDA stated that because of the amount of magnesium stearate in the final meat, poultry, or egg product would be very small, as well as the fact that the only reason for magnesium stearate's use is to maintain choline chloride's free-flowing status, FDA felt that it would act as a processing aid and thus had no safety concerns with its use in meat, poultry or egg products.

In closing, FDA had no safety concerns with the use of choline chloride as an enhancer of salty flavor in meat and poultry products provided the use level does not exceed 6000 ppm. Furthermore, because 21 CFR 182.8252 does not authorize the use of choline chloride as a flavoring ingredient and because FEMA does not list a use level for egg products, FDA could not comment on the safety of choline chloride as an enhancer of salty flavor in egg products. FDA had no safety concerns with the use of the conditioned choline chloride product, C-Salt™ (with 2% added magnesium stearate) in meat and poultry products.

The Food Safety and Inspection Service (FSIS) has also completed its review of your submitted information and in conjunction with the FDA opinion stated above, has no objection to the use of choline chloride alone or the conditioned choline chloride product, C-Salt™ (with 2% added magnesium stearate) as a direct replacement for sodium chloride in meat and poultry products including processed, ready-to-eat (RTE), fresh and frozen meat and poultry products with or without stated standards of identity or composition provided the use level of choline chloride does not exceed 6000 ppm. Choline chloride must be listed as "choline chloride" on the ingredient statement in the proper order of predominance.

However, because FDA cannot give a safety determination on the use of choline chloride or the conditioned choline chloride C-Salt™ (with 2% added magnesium stearate) in egg products, FSIS cannot permit the use of choline chloride or the conditioned choline chloride C-Salt™ (with 2% added magnesium stearate) in egg products at this time.

This letter should not be considered as validation that your chemical or process would be effective in any particular official establishment.

The use of this ingredient, as described in your notification, will need to be factored into a hazard analysis and if appropriate, incorporated into a Hazard Analysis and Critical Control Point (HACCP) plan, Sanitation Standard Operating Procedures (Sanitation SOPs) or other prerequisite program validated for its application, and verified on an "on-going" basis for its effectiveness. If the establishment does not address the effects of using this ingredient in its hazard analysis, FSIS would be unable to determine that product processed using this ingredient is not adulterated, and therefore the product would not be eligible to bear the mark of inspection.

Any future changes or revisions to your November 28, 2011 notification are to be submitted to the Risk, Innovations, and Management Division (RIMD) as a revised notification prior to implementation. Balchem Corporation should provide a copy of this letter to each establishment and make it available for the FSIS inspector's review prior to its use.

If you have any further questions, please contact Dr. David Zeitz at (321) 327-2576 or David.Zeitz@fsis.usda.gov.

Sincerely,

William K Shaw Jr.

William Shaw, Jr., Director
Risk, Innovations, and Management Division
Office of Policy and Program Development