

# CHOLINE

## EXECUTIVE SUMMARY

**REJECT** both petitions for adding synthetic choline to the National List. Just as synthetic fertilizers (synthetic soil nutrients) are prohibited in organic farming, synthetic nutrients should be prohibited from being added directly to organic foods.

- Synthetic choline is **not essential** for organic handling, since choline occurs naturally in food. Good sources of choline include peanuts, tofu, chicken, beef, eggs, broccoli, spinach, navy beans, fish, etc.
- **Certified organic lecithin is an organic alternative** source of choline approved for use in infant formula.
- The TR points out concerns with the use of **ethylene oxide** (TR 324) and **synthetic solvents** (Balchem petition, page 9), the possible presence of the **carcinogenic 1,4-dioxane** (TR 439) and other **toxic contaminants** (TR 515).
- The TR points out that **people suffering from depression should avoid choline supplementation**. Organic food should be a healthy and safe option for the **21 million Americans** suffering from depression.

## CHOLINE

In 1943, Sir Albert Howard, one of the founding fathers of the organic movement, wrote that “the approach to the problems of farming must be made from the field, not from the laboratory.”

When soil fertility suffers, organic farmers turn to natural sources of nutrients, rather than to synthetic fertilizers. Shouldn't the same principle apply to organic food? Chemical companies and their customers are now petitioning the NOSB to allow synthetic nutrients to be added directly to organic human foods. **For every one of these synthetic nutrients, there is an organic alternative: naturally nutrient-dense organic food.**

Cornucopia will analyze and submit comments on each petitioned synthetic nutrient, and we will point out the irony of many of these petitions in each of our formal comments.

One of the foundational principles of the organic movement is the rejection of synthetic nutrients for the soil, and the preference for naturally occurring nutrients. Moreover, the Organic Foods Production Act allows synthetic ingredients in organic foods only when the use of the substance “is necessary to the production or

handling of the agricultural product because of the unavailability of wholly natural substitute products.” No synthetic nutrient should ever be considered “necessary to the production” of organic foods because for every synthetic nutrient, there is a “wholly natural substitute product”: food.

Choline serves as a perfect example. Some baby food manufacturers add synthetic choline to baby foods. First, it is entirely possible to produce organic baby food without this synthetic ingredient. Second, what would be a “wholly natural substitute” for synthetic choline to boost levels of this nutrient? As the TR points out, **“An alternative to direct supplementation with synthetic choline would be supplementation of the diet with foods high in choline”** (TR 528-529).

According to data from the USDA<sup>2</sup> and Zeisel et al. 2003, foods that are good sources of choline (at least 20 mg of total choline per 100 grams of food) and that can be served to babies include broccoli, tofu, navy beans, wheat bread, wheat crackers, cooked spinach, yellow corn and peas. Toasted wheat germ, which contains very high levels of choline (152 mg per 100 g), and raw oat bran (58 mg per 100 g) can be added to baby cereal to boost choline content.

For toddlers, children and adults, foods with high choline content that can be added to the diet include peanut butter, fish, eggs, beef and chicken.

Even for infant formula, natural sources of choline are available. Soy lecithin, for example, is now available in organic form and contains high levels of choline. According to Magil Zeisel and Wurtman (1981), a study that is cited in the TR, “lecithin raises blood choline concentrations far more effectively than equimolar doses of choline chloride.” The study found that “both soy and egg lecithins raised serum and brain choline and brain acetylcholine to the same level, whether they are ingested only once or frequently over a 3-week period.” Synthetic sources of choline in infant formula may therefore not be necessary, as organic substitutes (e.g., organic lecithin) exist.

It is also worth noting that choline is not considered an essential nutrient according to numerous expert bodies and government agencies. As noted in the TR (92-93), “The European Society for Pediatric Gastroenterology and Nutrition and the American Academy of Pediatrics Committee on Nutrition have no specific recommendations for infant and child choline intake (Thureen and Hay, 2006).” The TR (114) also notes that “Choline addition to milk-based infant formulas is permitted but **not required** by FDA (21 CFR 107.100).”

Moreover, **no other organic standard in the world allows synthetic choline.** According to the TR, choline is not listed as a permitted substance in Canadian, EU, Japanese, FAO/WHO Codex and IFOAM standards (TR 274-315).

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<sup>2</sup> <http://www.nal.usda.gov/fnic/foodcomp/Data/Choline/Choln02.pdf>

The reasons mentioned above should be sufficient to reject the petitions for synthetic choline. In addition to these reasons, human health and environmental concerns with synthetic choline exist and should serve as further justification for a rejection of the petitions.

## **Solvents**

The Balchem petition (page 9) mentions the use of solvents, but does not specify which solvents are used:

“The choline salts are first chemically synthesized in water (or other solvent) using pure chemical feedstocks, including amine-based compounds, and acids. The resultant solutions are then filtered to remove extraneous matter. This step is followed by removal of solvent, and a final drying step, yielding a powder-granular product. A conditioning aid may be added to facilitate powder flow. Material then goes through quality checks, is packaged, and released for shipment.”

The Board should find out which solvents are used and whether adverse environmental impacts exist from the use of solvents. Synthetic solvents are incompatible with organic production.

## **Lack of GRAS Status**

As the Handling Committee has currently proposed, a form and use of choline that **does not even have GRAS status with the FDA** would be allowed in “made with organic” foods. As noted in the TR, “the use of choline chloride as a partial salt replacement and flavor enhancer of sodium chloride in processed foods is not covered under 21 CFR 182.8252 (i.e., not affirmed as GRAS)” (TR 117). Yet the Handling Committee does not acknowledge this in its proposal and does not propose an annotation, which is the very least the Handling Committee should have done.

The FDA’s GRAS system has been heavily criticized by Congress’ Governmental Accountability Office<sup>3</sup> for its severe weaknesses and subsequent failure to protect consumers, and should therefore be considered an inadequate regulatory standard of safety. In other words, for a substance to have GRAS status is rather meaningless. To NOT have GRAS status is a serious red flag and under no circumstances should any material without GRAS status be permitted in organic or “made with organic” foods.

We question whether the members of the Handling Committee were aware of the fact that one of the uses of choline that it would allow in “made with organic” foods does not have GRAS status. The fact that the Handling Committee would propose to

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<sup>3</sup> <http://www.gao.gov/products/GAO-10-246>

allow a non-GRAS use of choline in “made with organic” foods leads us to question how committee members are evaluating materials.

### **Ethylene Oxide**

According to the TR, the “possibly carcinogenic” substance 1,4-dioxane may be present in choline salts due to the use of ethylene oxide in the manufacturing process (TR 440-441). Even if the industry assures consumers that levels of 1,4-dioxane are below 10 ppm (TR 436), 1,4-dioxane is a “possible carcinogen” and **organic consumers rightfully expect their foods to be free of *any level of avoidable carcinogens (especially for infant formula and baby foods).***

The TR also points out that “The manufacture of choline salts may result in the release of trimethylamine and/or ethylene oxide to the environment (HSDB, 2009a)” (TR 476).

### **Human Health Effects**

Some of the potential effects on human health that were identified in the TR (508-511) were the result of very high doses that are unlikely to occur from supplementation in foods. However, one study mentioned in the TR (512-515) is worth noting here:

“Finally, some evidence indicates that choline bitartrate administered via the diet may induce urolithiasis (stones in the urinary tract) in rats and dogs. However, authors reported that the toxicity may not have been caused by choline, but rather synthetic tartaric acid or a toxic contaminant present at trace levels in the choline bitartrate (Newland et al., 2005; Klurfeld, 2002).”

### **The TR’s casual dismissal of the potential human health effects of synthetic choline is disturbing.**

These studies suggesting adverse effects are a reminder that we are not dealing with choline as a natural component in organic foods, but a chemical that is added to food and therefore comes with a whole host of unanswered questions about its safety. These studies suggest that “synthetic tartaric acid or a toxic contaminant present at trace levels in the choline bitartrate” may be present in synthetic choline and cause harm to organic consumers. Bear in mind that choline bitartrate is the form used in infant formula (TR 412).

Moreover, the **TR (518-519) mentions that some segments of the population should not consume foods supplemented with choline:**

Patients with trimethylaminuria (fish odor syndrome), renal disease, liver disease, depression, and Parkinson's disease may be more susceptible to the

adverse effects of choline; thus, choline supplementation is usually not recommended for these populations (IOM, 1998).

While the level of Americans suffering from trimethylaminuria (fish odor syndrome) is probably low, 21 million Americans suffer from depression and would therefore be “more susceptible to the adverse effects of choline.”

### **Summary**

The Board should reject the Balchem and IFC petitions for choline to be added to the National List. There is no need for synthetic choline, since it occurs naturally in food (what nutrient doesn't?).

Good sources of choline include peanuts, tofu, chicken, beef, eggs, broccoli, spinach, navy beans, and fish.

No other organic standard in the world allows synthetic choline; it is not listed as a permitted substance in Canadian, EU, Japanese, FAO/WHO Codex and IFOAM standards (TR 274-315).

Given concerns about the use of ethylene oxide (TR 324) and synthetic solvents (Balchem petition, page 9), the possible presence of the carcinogenic 1,4-dioxane (TR 439) and other toxic contaminants (TR 515), and recommendations for 21 million Americans suffering from depression to avoid choline supplementation (TR 519), we urge the Board to reject the petitions for synthetic choline.