

INOSITOL

EXECUTIVE SUMMARY

REJECT the petition to add synthetic inositol to the National List.

- Synthetic inositol is **not essential** to organic handling. Inositol is a nutrient that **occurs naturally in food**, making organic food an organic alternative to synthetic inositol supplementation.
- Inositol does not appear necessary in infant formula, and the TR points out that even newborns with an inositol deficiency maintain proper function.
- Inositol **occurs naturally in milk-based infant formula**. Inositol is listed in FDA's infant formula regulations (21 CFR 107.100) and will therefore be allowed (for soy-based formula only) when the NOP finalizes the proposed change to "nutrient vitamin and minerals" annotation.

INOSITOL

For all petitioned synthetic nutrients, like inositol, the debate must take into consideration one of the most important foundational principles of the organic movement and industry: the preference for real nutrients, as they occur in nature, over synthetic ones created in laboratories and manufactured in factories.

This preference for real nutrients over synthetic nutrients is so ingrained in the organic community that the USDA organic standards reject all petrochemical fertilizers and all but a handful of synthetic ones, and for good reason. Instead, organic farmers feed the soil using nutrients as they occur naturally – in compost, composted manure, cover crops, and other methods including a biologically diverse ecosystem in the soil.

Today, chemical companies that manufacture synthetic nutrients not for the soil, but for direct addition to human foods, are petitioning their products with the NOSB. Consistent with the organic community's rejection of synthetic nutrients for the soil, the NOSB should reject petitions for synthetic nutrients for infant formula and other human foods.

Inositol is a nutrient that occurs naturally in foods, but can also be recreated synthetically for direct addition to human foods. This is analogous to nutrients that occur naturally in "food for the soil" but can also be created synthetically and added to synthetic fertilizer. According to the TR, the petitioned material is synthetic:

“Nonsynthetic production methods are not available for use on a commercial scale. Inositol is synthetic because it is industrially manufactured using chemical processes, namely acid reactions and hydrolysis (TR 319-323).”

Agricultural Products—Other than Infant Formula

In the case of inositol, the TR is abundantly clear that there is no need for this synthetic nutrient in any food other than soy-based (non-dairy) infant formula:

It is estimated that Americans consume 1,000 milligrams of inositol daily in their diet (Kirschmann, 2007).

This dietary intake is supplemental to the endogenous inositol that is naturally biosynthesized by human cells. Inositol is biosynthesized by cells in many different tissues, including the brain, testis, liver, and especially the kidneys (Carver, 2006).

It is commonly found in tissues within the skeletal system, reproductive system, heart, and nerve systems, including large amounts in spinal cord nerves, cerebral spinal fluid, and the brain (Kirschmann, 2007). See “Action of the Substance” for information about the biomolecular role of inositol in the human body.

Dietary uptake and endogenous biosynthesis are sufficient to meet the body’s inositol requirements (Navarra, 2004), and an inositol deficiency syndrome has not been identified (NLM 2011a).

No information was found to indicate that inositol is added to processed foods other than infant formulas for dietary purposes. (emphasis added, TR 61-70)

The petition requested that inositol be added to the National List for the purpose of adding it to infant formula. Even in the petition, no mention was made of adding inositol to any foods other than infant formula. Yet the Handling Committee has suggested that it be allowed in “made with organic” foods.

We see absolutely no justification for allowing this synthetic nutrient in “made with organic” foods, especially since no entity has requested this.

Infant Formula

We oppose the addition of inositol to the National List for the purpose of adding it to organic infant formula, for the simple reason that there is no need.

According to the TR, research suggests that inositol is not necessary in infant formula:

The role of dietary inositol in infant development is unclear (Carver, 2006), and therefore its action when used as an ingredient in infant formula is uncertain.

Inositol has been known to prevent fat accumulation in the liver and intestines, and control triacylglycerol and esterified cholesterol levels; however, neonatal animals fed inositol-depleted diets did not experience effects indicative of fat accumulation in the liver or intestines, suggesting that **newborns can maintain proper cellular function despite dietary inositol deficiency** (Carver, 2006). (emphasis added, TR 133-137)

The same conclusion is included in a review document included in the petition itself, which cites a study that rats on a completely inositol-free diet show no impairment in growth, fatty liver infiltration, or impairment of central nervous system myelination (see LSRO review).

Yet, since inositol is a nutrient in human milk, expert bodies and government standards worldwide recommend that it be added to non-milk-based infant formula, at a minimum level of 4 mg per 100 kcal. This minimum level is required in the U.S., EU, Canada, Codex, and nearly every other international standard.

Milk-based infant formula contains levels well above this minimum, since inositol is found naturally in cow's milk. The TR notes levels of 10 mg/100 kcal in milk-based formula (TR 451). The petition includes the following from the LSRO report: "Conventional liquid formula preparations have been shown to contain between 35 and 70 mg free inositol/100 kcal." These levels are well above the 4 mg/100 kcal required by the FDA.

The International Formula Council (an industry trade group) is concerned that the NOP will not allow inositol in products where it is required by the FDA (non-milk-based formula), and cites this as a reason in its petition for listing inositol on the National List:

"The Infant Formula Act of 1980 amended the Federal Food Drug and Cosmetic Act to require the addition of inositol to certain infant formulas [note: the IFC is referring to non-milk-based formula]. The current NOP position would prohibit inositol addition to an organic infant formula. Adding inositol to the National List would avoid this dilemma."

Note that this was written prior to the proposed rule change by NOP to amend the annotation for "nutrient vitamins and minerals," which renders this justification moot. With the proposed rule change, any infant formula requiring inositol, or any other nutrient, by the FDA would be permitted to add it according to the organic standards. **There is no longer a need for a separate petition.**

The TR agrees with this point:

The NOP recently published a proposed rule that would amend the National List cross-reference to the FDA regulation 21 CFR 104.20, and specify that inositol is allowed in non-milk based infant formulas as required by 21 CFR 107.100 (USDA, 2012) (TR 188-190)

Just to be clear, the TR repeated this point:

To clarify this situation, the NOP published a proposed rule in January 2012 (77 FR 1980) that would amend 7 CFR 205.605(b) as follows:

“Vitamins and minerals. For food—vitamins and minerals identified as essential in 21 CFR 101.9. For infant formula—vitamins and minerals as required by 21 CFR 107.100 or 107.10.”

If promulgated as a final rule, this amendment would clarify that inositol is allowed in organic-labeled non-milk based infant formulas, because it is required by 21 CFR 107.100. (TR 217-224)

It should be abundantly clear from the TR that there is no need to include inositol individually on the National List.

It also bears noting that the use of inositol in non-milk-based organic formula, where it is required by the FDA, would make the use of inositol in U.S. organic products consistent with other standards, including those with which the U.S. has equivalency agreements.

As noted in the TR (230-232), “the IFOAM Norms state that, ‘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’ (IFOAM, 2006).”

The same is true of FAO/WHO Codex, where “vitamins, minerals, essential fatty and amino acids and other nitrogen compounds are permitted for use as food additives in organic processed foods only when their use is legally required in the food products in which they are incorporated” (TR 236-238). The same is true for the EU, Canada, East African Organic Product Standard, Pacific Organic Standard and Japanese standards.

Just to be very clear: it is unnecessary to add inositol to the National List separately, as it will fall under the requirement of the “nutrient vitamins and minerals” annotation.

Safety

The Scientific Committee on Food, referenced in the petition by the International Formula Council, notes that there are no safety studies on inositol in infant formula.

The petition does include a Material Data Safety Sheet with the following information:

Skin Contact: Wash off immediately with plenty of water for at least 15 minutes. Get medical attention immediately if symptoms occur.” And
“Ingestion: Do not induce vomiting. Obtain medical attention” (Petition, Appendix D)

While these are clearly instructions for occupational exposures, it does serve as a reminder that these are not benign or naturally occurring substances but synthetics.

No Proven Benefits

We see no justification in the petition or TR for recommending inositol to be added to milk-based infant formula and adult foods. In fact, the following quotations are taken from the petition’s Appendix E:

“To date, no studies have been conducted to evaluate the impact of dietary inositol on growth and development of healthy term infants. Similarly, no studies examining safety of inositol supplementation have been reported in humans.” (Appendix E, E3)

and

“Because of its endogenous synthetic capabilities, **inositol has not been listed as an essential nutrient in the RDA for humans** (NRC, 1989).”

The following is from the TR:

“No definite dietary need of inositol as a dietary supplement has been established (Navarra, 2004).”

The only potential benefits of the synthetic form of inositol are clinical in nature. The TR notes “Positive health effects are expected to result from its use” and lists a series of potential, mostly hypothetical health benefits.

“Inositol may help lower cholesterol” (TR 435). “Inositol may also play a beneficial role in controlling kidney dysfunction...” (TR 437). “Inositol supplements may be beneficial for infants who born [sic] at low weights and with respiratory distress syndrome” (TR 441). These are all medical conditions. **We suggest that individuals experiencing these medical conditions take supplements if they believe that inositol will benefit them.** However, these conditions should not serve as justification for allowing synthetics in organic foods. It would be like

arguing that Lipitor should be allowed in organic foods because it may help lower cholesterol.

Summary

Inositol is a synthetic ingredient, and its petition for inclusion on the National List should be rejected, both for infant formula and non-formula “made with organic” foods.