

Synthetic Nutrients in Organic Foods

A Position Paper by The Cornucopia Institute

*Interim Rule on “Nutrient Vitamins and Minerals”
USDA seeks public comment*

Comments due December 26, 2012



C O R N U C O P I A

I N S T I T U T E

Summary

On September 26, 2012, the United States Department of Agriculture (USDA) published a rule that continues its policy of allowing the indiscriminate and illegal addition of synthetic nutrients to organic foods.

Nutrients occur naturally in foods, and many are essential for good health. But organic consumers expect the nutrients in their foods to be naturally occurring rather than added synthetics that are mass-produced in factories by chemical corporations, often using hazardous petrochemical substances.

The USDA is accepting public comment until December 26 on its “nutrient vitamins and minerals” ruling. Organic consumers who expect organic foods to be free from unnecessary synthetic ingredients, as the federal organic regulations require, must make their voice heard.

The USDA’s current policy is to allow food manufacturers to add the synthetic version of any nutrient, without the legally required review and approval process for synthetic ingredients. Their latest ruling continues this flawed policy, by further institutionalizing a loophole for food manufacturers to add any synthetic nutrient to any organic food product.

The Organic Foods Production Act of 1990, the law passed by Congress to regulate the organic food industry, requires that the National Organic Standards Board (NOSB), a 15-member expert citizen panel, carefully review all synthetic and non-organic substances before they may be used in organic production. The law prohibits the use of a petitioned synthetic material if it is found to be non-essential to producing organic foods, or to endanger human health or harm the environment, or if natural or organic alternatives exist.

At its most recent meetings, the NOSB voted to prohibit eight synthetic “nutrients” in organic foods (three of the eight were approved—with restrictions—for organic infant formula only). This was a victory for organic consumers and upholds the integrity of the organic label and the process Congress set up to protect it.

In response to their defeat at the NOSB meetings, the corporations that are adding these synthetics to organic foods turned to the political appointees at the USDA for help. The USDA cannot legally override these NOSB decisions. So the USDA, catering to corporate interests, tabled a previous proposal to correct the problem (a proposed rule to close the loophole had been put forth by the USDA earlier this year, and had been supported by both the industry and public interest groups). Instead,

the USDA ruled that it would maintain the current listing for “nutrient vitamins and minerals” with the loophole that allows any and all synthetic “nutrients” to be added indiscriminately to organic foods.

Organic farmers and consumers who are dedicated to protecting the authenticity of organic food should let the USDA know that the rule for “nutrient vitamins and minerals” is a repugnant violation of the letter and spirit of the law governing the organic industry. Synthetic nutrients have no place in organic foods unless they have been individually reviewed and approved as essential, compatible with organic handling, and non-harmful, as the law requires.

Furthermore, the USDA must take immediate enforcement action against food manufacturers that add synthetic nutrients, without the required approvals, and that have been rejected by the NOSB. These unapproved, illegal synthetics continue to appear in certified organic foods on market shelves, and the USDA must act immediately to uphold the letter and the spirit of the organic law.

To submit comments to the USDA on their “nutrient vitamins and minerals” rule, follow this link:

<http://www.regulations.gov/#!submitComment;D=AMS-NOP-10-0083-0029>

For the required field “Organization Name,” please enter “Citizen.”

The deadline for comments is December 26, 2012.

History of “Nutrient Vitamins and Minerals” in Organics

Federal law and regulations prohibit any synthetic ingredient in organic foods unless it is listed on the USDA’s official National List of Approved and Prohibited Substances (“National List”).

The National List, under “approved synthetics,” includes “nutrient vitamins and minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines for Foods.”

This listing allows for the addition of synthetic versions of essential nutrients, many of which have been added to foods for decades. This includes synthetic Vitamin A and D in milk, calcium in orange juice and soy milk, and B vitamins and iron in white flour.

By law, every synthetic on the National List has to be approved by the National Organic Standards Board (NOSB), the 15-member expert citizen panel set up by Congress to advise the USDA on organic policy and rulemaking. The “nutrient vitamins and minerals” annotation references 21 CFR 104.20, which was not recommended by the NOSB but is consistent with the NOSB’s intent when it approved “nutrient vitamins and minerals” in 1995.

The 1995 NOSB recommended the following listing: “Nutrient vitamins, minerals and accessory nutrients – accepted for use in organic foods for enrichment or fortification when required by regulation or recommended by an independent professional organization.”

According to individuals who were on the NOSB in 1995, and the transcript of the 1995 NOSB meeting, the intent of their recommendation was to avoid indiscriminate addition of synthetic nutrients to organic foods, but allow for nutrient supplementation that is either required or recommended by universally recognized authoritative scientific bodies.

When the USDA wrote the official National List, it used the reference to 21 CFR 104.20 instead of the exact annotation as it had been recommended by the NOSB. This must have seemed to the USDA to be a convenient solution to restricting the use of synthetic nutrients, and capturing the NOSB’s intent, since 21 CFR 104.20 states: “the Food and Drug Administration does not encourage indiscriminate addition of nutrients to foods.”

The FDA's rule at 21 CFR 104.20 goes on to state that "a nutrient(s) listed in paragraph (d)(3) may appropriately be added to food to correct a dietary insufficiency recognized by the scientific community to exist and known to result in nutritional deficiency disease," and then lists 21 essential nutrients, primarily vitamins and minerals, including recommended supplementation levels, in paragraph (d)(3).

Infant formula is not covered under 21 CFR 104.20, because the FDA's regulations cover infant formula under separate regulation, 21 CFR 107. Under 21 CFR 107.100, the FDA lists minimum and maximum levels for 29 nutrients that are considered essential for infant nutrition, and are therefore required in all infant formula products.

In 2006, the USDA received its first of several legal complaints against organic food manufacturers for adding synthetic "nutrients" that do not appear on the National List, do not meet the scientific definition of "vitamins" or "minerals," and are not covered under 21 CFR 104.20's list of essential nutrients. The initial complaint focused on algal oil as a source of DHA omega-3 fatty acids, fungal oil as a source of ARA omega-6 fatty acids and nucleotides added to Parents Choice (Walmart's store brand) "organic" infant formula.

The addition of algal oil and fungal oil to organic infant formula was especially egregious because the patented oils, developed and manufactured by Martek Biosciences Corporation, are extracted with the use of hexane, a neurotoxic synthetic volatile solvent that is expressly prohibited in organic production. The strains of algal and fungal microorganisms are fermented in a mixture that includes genetically engineered corn, and the algal and fungal oils are mixed with several non-organic and synthetic ingredients, including synthetic preservatives (also explicitly banned in organic production).

According to internal USDA documents obtained by Cornucopia through a Freedom of Information Act request, the USDA's National Organic Program (NOP) career enforcement staff investigated the 2006 complaint, including consultation with the FDA's experts on infant nutrition and infant formula regulations, and sent a letter of noncompliance to the certifier.

The July 2006 noncompliance letter stated the following: "A review of the NOP regulations and applicable FDA regulations has determined that Parent's Choice Organic Infant Formula contains ingredients (oils with DHA, ARA, and nucleotides) that are not approved for use under the NOP regulations."

When the infant formula manufacturers received the letter of noncompliance from Quality Assurance International (QAI), their certifying agent, rather than reformulate their products to conform to the federal organic standards, they retained a prominent Washington lawyer and lobbyist, William J. Friedman, with the firm of Covington in Burling, to address the issue.

Mr. Friedman pointed the NOP administrator, Barbara Robinson, to a loophole in the FDA's regulations, which would allow the use of any synthetic "nutrient" that is allowed in conventional foods to also be allowed in organics. The loophole is subsection (f) of 21 CFR 104.20, which states "Nutrient(s) may be added to foods as permitted or required by applicable regulations established elsewhere in this chapter."

Dr. Robinson ordered her staff to send a revised letter to QAI, with the following statement: "Nutrients allowed [on the National List] are not limited to the nutrients listed in section 104.20(d)(3), because section 104.20(f) provides that nutrients may be added to foods as permitted or required by applicable regulations elsewhere by FDA." The November 2006 letter closed by stating that the disputed nutrients could be added to organic foods, because the FDA permits them.

By taking this subsection out of the context of the 21 CFR 104.20 restrictions, the USDA allowed organic food manufacturers to add any synthetic "nutrient" that is permitted by the FDA. With the commitment by the USDA to interpret the organic standards and the FDA's standards as loosely as possible (permitting any synthetic "nutrient" in organics if it is permitted in conventional foods, without review), several additional organic food manufacturers soon followed by adding non-essential, synthetic "designer" nutraceuticals to organic products.

Most notably, the \$12-billion dairy conglomerate Dean Foods, which owns the Horizon Organic dairy brand under its White Wave division, added Martek's DHA algal oil to a line of "Horizon Organic milk with DHA" milk and launched an aggressive marketing campaign to convince consumers that their products, with the added nutrient, provides distinctive health benefits.

After multiple legal complaints by Cornucopia regarding synthetic nutrients in organic foods, and public pressure to end the indiscriminate addition of synthetics to organic foods, the USDA conceded in a public memo in April 2010 that its interpretation of 21 CFR 104.20 had been incorrect.

The USDA's Deputy Secretary, Kathleen Merrigan, apologized in April 2011 for her predecessors' decision that opened the door to multiple unapproved synthetics being added to some organic food products.

In April 2010, the USDA also promised the organic community that it "plans to publish draft guidance later this year that will align with the FDA interpretation of 21 CFR 104.20." This proposed guidance document never materialized. A Freedom of Information Act request by Cornucopia revealed that NOP staff worked diligently on completing the draft guidance by the end of 2010, but senior officials at the USDA scuttled the proposal. Exact details of the fate of the proposed guidance document were either withheld or redacted by the USDA.

Yet the USDA was under pressure from the organic community—especially consumers—to move forward with correcting its flawed policy. Prior to the Fall 2011 NOSB meeting, the USDA had received approximately 2,000 public comments on this issue through its online portal. The USDA noted that the vast majority of comments came from organic consumers who “voiced concern that the proposal would allow, without NOSB review, any synthetic nutrient additive to be allowed in organic products,” and that “only essential nutrients required by the FDA should be allowed in organic products.”

Then, in January 2012, the USDA finally took a step toward closing the loophole by publishing a proposed rule to address the issue. First, the USDA proposed changing the listing, by deleting “nutrient” and listing just “vitamins and minerals.” Rather than cross-reference 21 CFR 104.20, the USDA proposed the following annotation: “For food – vitamins and minerals identified as essential [by the FDA] in 21 CFR 101.9. For infant formula – vitamins and minerals as required by [FDA] 21 CFR 107.100 or sec. 107.10.”

Cornucopia supported the proposal, but recommended tightening the reference to 21 CFR 101.9 by listing 21 CFR 101.9(c)(8)(iv) specifically, since this clarifies the specific essential nutrients that would be allowed without leaving room for interpretation, as the reference to 21 CFR 104.20 had done. Other public interest groups, including Consumers Union and Food and Water Watch, agreed in public comment that the reference should be to 101.9(c)(8)(iv), the FDA list of essential nutrients, specifically, rather than 101.9 generally.

While comments from food manufacturers differed from those from public interest groups on an acceptable grace period, the organic community, including corporate food manufacturers involved in organics, generally supported the proposed rule. For example, Nestle, an \$87 billion multinational food manufacturer, supported the proposed rule even though its Gerber Organic baby foods line contains synthetic choline, which would not be included under the proposed listing and would need to subsequently be removed unless the NOSB would specifically approve Nestle’s petition to add synthetic choline to the National List.

Companies like Nestle were assured by the USDA that the grace period would “allow time for the NOSB’s review of petitions for substances not within the scope of the current listing or amended listing.” Nestle had already petitioned the NOSB to approve synthetic choline, and supported the USDA’s proposed rule while it waited for the NOSB’s final approval on its synthetic choline petition.

However, when the NOSB reviewed the Nestle petition at its Spring 2012 meeting, it faced tremendous pressure from both industry lobbyists, favoring its approval, and organic consumers and public interest groups opposing additional unnecessary and non-essential synthetic “nutrients” in organic foods.

In its comment to the NOSB, Cornucopia wrote: “Just as synthetic fertilizers, which are synthetic soil nutrients, are prohibited in organic farming, synthetic nutrients should be prohibited from being added directly to organic foods.” Thousands of organic consumers, agreeing with this sentiment, expressed their concern to the NOSB that additional synthetic nutrients should not be added to the National List.

The NOSB voted to allow synthetic choline, but only in organic infant formula and medical nutritional enteral products. The NOSB did not recommend that synthetic choline be allowed in other organic processed foods, including Nestle’s organic baby foods, since naturally occurring choline can be acquired from a wide variety of organic foods, including many that are acceptable first foods for babies (e.g. oats, peas).

If the January 2012 proposed rule, which Nestle and other corporate food manufacturers had supported in public comment, were to become a final rule, Nestle would be required to remove synthetic choline from its organic Gerber baby food products.

On September 26, 2012, National Organic Program officials invited executives from Nestle and other food manufacturers involved in organics, as well as Cornucopia staff, on a conference call for an announcement. Rather than adopt its proposed rule, which had received near-unanimous support in official public comment, the USDA would be publishing an “interim rule” on “nutrient vitamins and minerals.” The NOP’s interim rule made no changes to the annotation, keeping the existing reference and policy in place. One step forward and two steps backward, and the organic community was back at square one on this issue.

The NOP invited the public and food manufacturers to resubmit comments to its interim rule (which this document is now addressing). Undoubtedly, public comment from corporate food manufacturers pursuant to the interim rule will be markedly different from their comments in early 2012. Their support of the proposed rule and their support of closing of the loophole had likely been based on the assumption that the NOSB would approve their petitions for synthetic nutrients currently in use.

Not only did the NOSB reject synthetic choline (other than for use in infant formula and medical products) at its Spring 2012 meeting, it also rejected synthetic taurine, synthetic nucleotides, hexane-extracted lutein, synthetic lycopene, synthetic l-carnitine and synthetic l-methionine (other than for use in soy-based infant formula) at its Fall 2012 meeting. These materials are not considered essential to infant nutrition and not required in infant formula by FDA regulations.

The comment period for the interim rule ends December 26, 2012. The USDA stated that it was still reviewing comments to its January 2012 proposed rule, but the comments to the interim rule will undoubtedly supersede those received in response to the now obsolete January 2012 proposed rule.

It is likely that agribusiness will respond negatively in public comment to any proposed rule, or policy change, that would lead to the removal of the synthetic nutrients currently in use. They will likely support keeping the current listing, with the existing loophole, in place.

Having these comments on the public record could give the USDA justification for once again delaying action, or possibly for proposing a listing or annotation that would give corporate food manufacturers the right to continue the indiscriminate addition of synthetic nutrients to organic foods.

Comments from the public, opposing the indiscriminate addition of synthetic nutrients to organic foods, are essential in countering the comments from food manufacturers.

Synthetic nutrients do not belong in organic foods

The underlying reason for so many organic farmers' and consumers' outrage at the NOP's policy and the resulting indiscriminate addition of synthetic nutrients to organic foods is philosophical. One of the founding principles of the organic movement is the reliance on natural processes for healthy food production. "The approach to the problems of farming must be made from the field, not from the laboratory," said Sir Albert Howard, one of the founding fathers of the organic movement when critiquing the industrial approach to farming by adding synthetic, petrochemical-based fertilizers.

When soil fertility suffers, organic farmers turn to natural sources of nutrients, primarily from cover crops and composted animal manure, rather than to synthetic fertilizers. The similarities between synthetic fertilizers (for soil) and synthetic nutrients (in foods) are striking: both arise from reductionist science that ignores complexity, both are derived from petrochemicals, and both are far inferior to their natural equivalents in terms of long-term health and benefits.

The same principles that guide the organic community in soil fertility should apply to food, which should not be reduced to chemical formulas produced in a factory. Much of the outrage expressed by organic stakeholders who discovered that unapproved synthetic nutrients were added to organic foods likely stemmed from a sense of betrayal of these underlying organic values by corporate food manufacturers.

As with so many organic principles, independent scientific studies are slowly catching up to support the philosophical basis for favoring natural processes over human-made chemical "solutions."

Scientific studies, including large-scale epidemiological studies, do indeed support a link between consumption of certain foods and good health. Studies suggest that people who regularly eat fish have lower rates of heart disease, and men who regularly eat tomato sauce have lower rates of prostate cancer. These studies reveal the complexity of food and health, as tomato products are most healthful when combined with a source of fat, and fish consumption appears to be only beneficial when the overall diet is low in the types of fats that compete with healthy fats found in fish.

Profits for corporate food manufacturers do not come primarily from the sale of fresh fish or tomatoes, but rather from processed foods. For these corporations, profit from these scientific findings can be made only by isolating a "nutrient" found

in fish or tomatoes, adding a synthetically produced version of that nutrient to their processed foods, and making a health claim that appeals to consumers. The health claims likely stem from an interest in marketing—setting their product apart from others in a competitive marketplace—rather than from an interest in public health.

DHA provides a good example. DHA is an omega-3 fatty acid that is found naturally in wild fish, and is found in brain and eye tissues. Martek Biosciences Corporation, now owned by the multi-billion dollar Dutch conglomerate Royal DSM, developed a patented oil extract from algal microorganisms that had been genetically modified to produce high levels of DHA, which could be added to processed foods.

Algal DHA oil was first added to infant formula as a way to falsely market formula as containing “nutrients found in breast milk,” and therefore being “closer than ever to breast milk.” Many food manufacturers now add the isolated algal extract to processed foods, resulting in marketing claims about health benefits.

Science supporting benefits of nutrient supplementation is often lacking. As an example, many of the scientific studies that claim benefits exist to cognitive or visual health from DHA algal oil supplementation have been conducted by scientists either employed or funded by the very corporations that profit from its addition to foods. When independent scientists, not affiliated with corporate manufacturers, conduct studies, or review existing studies, the results generally do not favor supplementation.

For example, three meta-analysis studies on DHA supplementation of infant formula conclude that no benefits exist to cognitive or visual development.

The lack of scientific data supporting health benefit claims has not stopped corporate food manufacturers from adding synthetic nutrients to organic foods, and making claims of health benefits both on the product’s packaging and in commercials and advertisements. In the case of DHA algal oil, the Federal Trade Commission (FTC), and expert scientists, have attempted to rein in these claims.

In early 2011, Cornucopia filed a complaint with the FTC against Dean Foods’ White Wave Division, alleging false and misleading advertising for its Horizon Organic milk with algal DHA oil. Dean Foods/White Wave and its advertising firm retained several high-profile attorneys to assist them with their defense, including William MacLeod, a former Director of the FTC’s Bureau of Consumer Protection under President Reagan who is now a high-profile DC attorney acclaimed for “guiding” corporations through FTC investigations.

The FTC, in response to the Cornucopia complaint, forced Dean Foods/White Wave to make significant changes to its advertising. The corporation terminated its television commercials and magazine advertisements. Its website’s claims about DHA’s benefits were drastically altered, and a video featuring pediatrician-

spokesman Dr. Alan Greene was entirely changed, including a disclaimer at the end: “Alan Greene provides consulting services for, and is paid a fee by, Horizon.” The FTC issued its final letter to Dean Foods/White Wave just a few days after the NOSB voted on DHA algal oil in organic foods at its Fall 2011 meeting.

The letter stated: “The [FTC] staff encourages White Wave to exercise caution in future advertising when describing the certainty of the supporting science or characterizing the extent of any benefits of DHA beyond the support of normal brain and eye development or function in children over the age of two. Advertisements should not depict children over the age of two engaged in activities that expressly or impliedly convey extraordinary cognitive function or development, intelligence, or learning abilities from drinking Horizon milk with DHA.”

The FTC had been ready to make the letter public before the NOSB meeting, but the Dean Foods/White Wave attorneys convinced the government agency to delay the public release of the letter until after the NOSB’s vote. They clearly did not want the NOSB members to know the FTC’s findings prior to their vote, since the corporation’s argument for allowing DHA algal oil in organic foods was based almost entirely on their claim that it benefits human health.

Cornucopia’s complaint with the FTC included an assertion that the scientific citations on “Horizon with DHA” milk cartons were misleading to consumers, since they cite scientific studies that found benefits from eating fish, not from consuming Martek’s algal oil supplements. One of the two scientists cited on the carton, Dr. Penny Kris-Etherton, a professor of nutrition at Penn State University, said: “It’s not right, it’s inaccurate. It’s really a marketing strategy to sell more of their milk.” She contacted Dean Foods/White Wave to request that the citation with her name and the study she authored be taken off the carton.

As of November 2012, Dean Foods/White Wave has not removed the scientific citation from its website or milk cartons. DHA algal oil will continue to appear in organic milk because the corporate lobbyists succeeded in convincing the NOSB to vote in their favor.

Consumer Expectations—PCC Natural Markets Survey

Organic consumers have already asserted their position on synthetic nutrients in organic foods by submitting comments to the USDA and the NOSB. Moreover, consumer survey data exposes consumers’ clear opposition to synthetic nutrients.

In September 2011, PCC Natural Markets, the largest cooperative natural foods grocer in the country, released the results of a survey that aimed to better understand organic consumers’ understanding and feelings about nutrient supplementation. Nearly 1,500 organic consumers completed the survey.

The survey revealed that the overwhelming majority (95.1%) of organic shoppers either assume nutrient supplements sold at PCC Natural Markets are natural, or they do not know whether they are natural or synthetic. Only 4.9% of organic shoppers believed that nutrient supplements sold at PCC Natural Markets are synthetic. In other words, when they see nutrients listed on the label of “natural” or organic foods, the vast majority of organic consumers have no idea that these nutrients are synthetic.

The survey also showed that the majority (60.8%) of organic shoppers would not buy foods containing a synthetic nutrient, and 30.3% would be “less inclined” to buy foods containing a synthetic nutrient. Only 1.2% stated they were “more inclined” to purchase a food containing a synthetic nutrient.

When asked about their inclination to buy foods containing natural supplements, the numbers were reversed, with 67.2% stating they would be “more inclined” to buy the product, 10.8% stating they would be “less inclined,” 11% “would not purchase” and 11% had “no opinion.”

Interestingly, this inclination among organic shoppers to be more inclined to purchase a product containing an added nutrient from naturally occurring sources lines up with the results of another consumer survey. In April 2011, the Organic Trade Association collaborated with Kiwi Magazine on a consumer survey with 1,071 responses from “self-identified ‘organic believers.’” The survey found that “over six in ten say that they would be ‘more likely to buy’ an organic food fortified with any of these nutrients, vitamins and minerals.”

The OTA/Kiwi consumer survey did not ask organic consumers about their preference for synthetic or natural sources of nutrient supplementation. The PCC survey shows that the vast majority of organic shoppers either assume that nutrient supplements are natural, or they are unaware of the source. Therefore, when the Organic Trade Association concluded “specific nutrients have a largely positive impact on their [purchasing] decision,” it is unclear what the responses would be if the respondents were asked about “from synthetic sources” or “from naturally occurring sources.” The question, after all, is not about whether organic consumers like nutrients, but whether they expect nutrients in organic foods to be natural or synthetic.

Legal Requirements—Organic Foods Production Act of 1990

Another argument in the case against the addition of synthetic nutrients to organic food is purely legal. The Organic Foods Production Act of 1990 includes several criteria that must be met before a synthetic ingredient can be added to the National List.

Under Section 6517(c)(1)(A)(ii), OFPA states that synthetic substances may be added to the National List only when the use of such substances is “necessary to the production or handling of the agricultural product because of the unavailability of wholly natural substitute products.”

The USDA organic standards set out six additional criteria for adding a synthetic material to the National List, including: “The substance is essential for the handling of organically produced agricultural products.” Clearly, the National List allows for synthetic ingredients that enable food manufacturers to create organic equivalents of conventional processed foods, e.g. sodium bicarbonate (baking powder) to bring organic cookies to market shelves, or magnesium sulfate (a coagulant) to bring organic tofu to market shelves.

The intent of Congress when it included the “essentiality” criterion should be clear: synthetic ingredients should be allowed in organic foods when they meet the other criteria, such as safety for human health and the environment, and when they are essential to producing an organic version of a product. But in the debates over synthetic nutrients in organic foods, food manufacturers and their lobby groups have attempted to twist the essentiality criterion to their favor. Rather than allow synthetic nutrients that are essential for organic handling, they argued that synthetic nutrients that are essential to human health should be allowed. DHA algal oil is not essential to organic handling—it is entirely possible to bring organic milk to market without DHA algal oil—but food manufacturers argued that it should be added to the list anyway because the nutrient is essential to human health (although it should be noted that few scientific studies exist to show algal oil DHA confers the same benefits as naturally occurring DHA in the diet).

From a purely legal point of view, considering the intent of Congress, synthetic nutrients are not essential to organic handling and never will be. Every synthetic nutrient has a natural equivalent; after all, scientists only develop synthetic versions of nutrients after they have identified the naturally-occurring nutrient in real food. As long as organic food exists, no synthetic nutrient should ever be considered essential for processing/handling.

Cornucopia's position on synthetic nutrients in organic foods

Cornucopia's previous recommendation in response to the January 2012 proposed rule:

The January 2012 rule proposed to revise the cross reference to FDA regulations to specify that only vitamins and minerals which are declared essential for food in 21 CFR 101.9 and vitamins and minerals that are required for infant formula in 21 CFR 107.10 and 107.100, may be used in organic products.

In public comment in response to the January 2012 proposed rule, Cornucopia, Consumers Union, Food and Water Watch and others proposed a specific reference to 21 CFR 101.9(c)(8)(iv), which lists the "essential nutrients" for which the FDA has determined a Recommended Daily Intake (RDI):

Vitamin A, Vitamin C, Calcium, Iron, Vitamin D, Vitamin E, Vitamin K, Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Biotin, Pantothenic acid, Phosphorus, Iodine, Magnesium, Zinc, Selenium, Copper, Manganese, Chromium, Molybdenum and Chloride.

Cornucopia's updated recommendation in response to September 2012 interim rule: listing individual nutrients

Rather than include a cross-reference to the FDA rule, Cornucopia now proposes that the USDA individually list specific substances that are sources of nutrients, after each has been individually reviewed by the NOSB.

We believe individual listings of synthetic sources of nutrients is more in line with the requirements of the Organic Foods Production Act of 1990 (OFPA) which states:

*"Content of [the National] List – The list established under subsection (a) shall contain **an itemization, by specific use or application, of each synthetic substance** permitted under subsection (c)(1) or each natural substance prohibited under subsection (c)(2)." [Emphasis added]*

There are many advantages to this approach.

1. *Uncoupling USDA organic regulations from FDA regulations*

The current annotation and the January 2012 proposed annotation both cross-reference an FDA rule. The authority over each substance on the National List should lie with the NOSB and the USDA. By cross-referencing an FDA rule, the organic community to some degree loses control over this listing on the National List.

Additions and removals of vitamins and minerals should be carefully reviewed and approved by the NOSB and the USDA, and should not be contingent on FDA rulemaking.

2. *National List listings should be for substances/materials that provide specified nutrients*

Listing the name of a nutrient on the National List makes no sense, since the nutrient must be supplied by a specific substance. The substance that supplies the nutrient, rather than the nutrient, should be listed.

Vitamins are a good example of why the source of the nutrient, rather than the nutrient, should be listed. Vitamins are essential in small amounts in the diet for the normal function, growth and maintenance of body tissues. Vitamins exhibit a wide variety of chemical structures and function primarily to enable many chemical reactions to occur in the body. Vitamins carry out chemical or physiological reactions in the body. Vitamins are not substances; they are “activities” that are supplied by certain substances.

For every vitamin, there are many foods that provide a natural source, and depending on the vitamin, one or many synthetic versions that also provide the vitamin activity. The National List should list substances that are sources of Vitamin C (e.g. citric acid—which is already listed), rather than “Vitamin C.”

The NOSB should look at the source of the nutrient, and decide which sources are appropriate.

3. *Greater transparency regarding each synthetic substance*

Another advantage to individual listings for sources of nutrients is greater transparency and control over the listings. During the Sunset process (every material on the National List must be removed from the National List after five years unless the NOSB reapproves it), the NOSB should be able to review and vote on individual substances, rather than a group of substances.

Technical Evaluation Reports should be for individual substances, giving information on the manufacturing process and essentiality of each specific nutrient and the compatibility with organic handling for every substance supplying a nutrient.

While this may at first glance appear to be a disadvantage to this approach—creating more work for the NOSB and more Technical Evaluation Reports to commission—it allows the NOSB to look more closely at the legal criteria for each synthetic nutrient. For example, is it necessary to allow the synthetic version of a particular nutrient? Do some nutrients have natural versions that could be used instead? Do the synthetic substances actually provide the expected benefits found from consumption of the naturally occurring nutrients? Is supplementation of the particular nutrient necessary?

4. *Facilitate removals from/additions to the National List*

The organic industry currently has little incentive to develop natural sources of specific nutrients, since the developer of a natural version could not petition the removal of an individual synthetic nutrient. Currently, a petitioner would have to petition the removal of all “nutrient vitamins and minerals,” for which success would be dubious at best.

If individual nutrients were listed instead, the process for removing the synthetic version from the National List would be made possible, creating an incentive to develop natural versions.

5. *Consistency on the National List*

Some sources of nutrients that are commonly found in certain organic products are already specifically listed on the National List. For example, calcium carbonate, which is added to some organic soy milk as a source of dietary calcium, and calcium citrate, which is added to some organic orange juice as a source of dietary calcium, already appear individually on the National List.

The following sources of vitamins or minerals have already been reviewed and approved by the NOSB in the 1990s and already appear on the National List: Vitamin C, Calcium, Iron, Vitamin E, Iodine, and Magnesium.

205.605(a) Nonsynthetics

Citric Acid (Vitamin C)
Calcium carbonate (calcium)
Calcium chloride (calcium)
Calcium sulfate – mined (calcium)

Magnesium sulfate – nonsynthetic sources only (magnesium)
Potassium Iodide (iodine)

205.605(b) Synthetics

Ascorbic Acid (Vitamin C)
Calcium citrate (Calcium)
Calcium hydroxide (Calcium)
Calcium phosphates (monobasic, dibasic, tribasic) (Calcium)
Ferrous sulfate – for iron enrichment or fortification of foods when required by regulation or recommended (independent organization) (Iron)
Tocopherols – derived from vegetable oil when rosemary extracts are not a suitable alternative (vitamin E)

Some of these substances are already on the National List specifically as sources of essential nutrients (e.g. potassium iodide as a source of iodine).

6. *Ensure that “nutrients” not essential to organic handling are not added to the National List*

Some of the nutrients listed at 21 CFR 101.9 as essential nutrients are not necessary as synthetic supplements in foods. For example, phosphorus, biotin, molybdenum, chromium, pantothenic acid, selenium and chloride are essential nutrients and therefore listed as such by the FDA under 21 CFR 101.9, but deficiencies occur only in extremely rare cases, such as in medical patients receiving total parenteral nutrition (TPN).

Chloride, for example, is a nutrient found in table salt (sodium chloride) and even individuals on low-salt diets are not at risk of chloride deficiency. For phosphorus, the Institute of Medicine’s Food and Nutrition Board states: “Phosphorus is so ubiquitous in various foods that near total starvation is required to produce dietary phosphorus deficiency.” Pantothenic acid is named from the Greek “pantothēn” which means “from every side,” because it is found in so many different foods, and the only known cases of deficiency were a result of being intentionally induced for research purposes.

Deficiencies for nutrients such as manganese, copper and zinc can occur in the general population, but are not common. Copper deficiency, which is rare and occurs only under special circumstances such as tube feeding, use of parenteral nutrition or following gastric bypass surgery, can also occur as a result of oversupplementation with zinc, which interferes with the absorption of copper.

There is no reason to allow for synthetic supplementation of organic foods with nutrients that occur abundantly in a wide variety of foods, and for which

deficiencies are rare. With the exception of zinc, these nutrients are rarely, if ever, added to foods and their addition to the National List would be entirely unnecessary.

Some nutrients that are abundant in foods, and for which deficiencies are extremely rare in North America, are nevertheless added as synthetics to organic foods. These include the B vitamins, which occur naturally in whole grains but have been commonly added in synthetic form to milled grains (i.e. white flour).

While enrichment of milled grain products has virtually eliminated serious health conditions that arise from deficiencies in B vitamins (e.g. beriberi, pellagra), these health conditions can as easily be avoided by consuming whole grains which do not have the vitamins milled out of them. In fact, fortification with synthetic nutrients still leaves “enriched” products with less vitamin B6, vitamin E, magnesium, and zinc than that present in the whole grains. Nutritionists also recognize that whole grains contain many other nutrients that are not replaced after milling, including phytochemicals.

7. Ensure that “nutrients” that are incompatible with organic handling are not added to the National List

Many of the synthetic sources of nutrients listed under 21 CFR 101.9(c)(8)(iv) are produced in ways that are incompatible with organic handling, and therefore fail the criteria for inclusion on the National List.

For example, vitamin D2, also known as ergocalciferol, is produced by ultraviolet irradiation of ergosterol isolated from yeast. Irradiation is prohibited in organics. Moreover, the FDA currently allows ergocalciferol only in soy-based dairy substitutes, yet food manufacturers are currently adding it to organic products such as almond or flax milk.

Cornucopia’s Proposal

We recommend that sources of nutrients be individually reviewed by the NOSB. Every substance should be individually reviewed, approved and listed before it can be added to organic foods. According to the law, it is the NOSB’s responsibility to determine whether individual synthetics meet the legal criteria for inclusion on the National List.

After they have been reviewed and voted on, the problematic “nutrient vitamin and minerals” listing, which is the topic of the current USDA interim rule, can either be removed from the National List by NOSB vote or sunset in October 2017.

Nutrients: their benefits, and their current use

The risk of deficiency and natural food sources of nutrients that are considered essential by the FDA are listed in the table below, as well as their current use in organic foods.

Nutrient	Risk of deficiency	Natural food sources	Current supplementation in organic foods
Vitamin A	Deficiency is rare; abundant in the food supply	Sweet potato, spinach, mango, carrots, squash, kale	Milk; required by FDA in reduced fat or skim milk. NOSB review needed
Vitamin C	Deficiency is rare; abundant in food	Citrus fruit, potatoes, green vegetables, tomatoes	Sources of Vitamin C already appear on the National List – ascorbic acid and citric acid on 205605(a) and (b)
Calcium	Deficiency can lead to osteoporosis	Dairy, green vegetables, sardines and canned salmon	Sources of calcium already appear on the National List - both 205.605(a) and (b)
Iron	Iron deficiency is believed to be the most common nutrient deficiency in North America – anemia	Meat, lower levels found in chocolate, dried fruit, sunflower seed. An alternative source is from cast-iron cookware.	A source of iron already appears on the National List - ferrous sulfate, 205.605(b)
Vitamin D	Deficiency can lead to rickets in children, osteomalacia (“soft bones”) in adults	Sunlight. In winter, fatty fish (fish oil).	Milk – allowed but not required by FDA in milk. NOSB review needed
Vitamin E	Deficiency is rare	Plant oils, wheat germ, asparagus, peanuts, oats, nuts, seeds, finfish, shellfish	Sources of Vitamin E already appear on the National List - tocopherols 205.605(b)
Vitamin K	Deficiency is rare; abundant in food supply.	Liver, green leafy vegetables, broccoli, peas, green beans, vegetable oils	NOSB review needed.
Thiamin	Deficiency is rare;	Pork, sunflower seeds,	Currently found in

	abundant in food	legumes, wheat germ, whole grains, peanuts, mushrooms	organic cereal, organic meal replacements. NOSB review needed.
Riboflavin	Deficiency is rare; abundant in food	Liver, mushrooms, leafy green vegetables, broccoli, asparagus, milk and other dairy products	Currently found in organic cereal, organic meal replacements, crackers and bread. NOSB review needed
Niacin	Deficiency is rare; abundant in food	Mushrooms, whole wheat, fish, meat, poultry, peanuts, asparagus	Currently found in organic cereal, organic meal replacements, crackers, rice, bread. NOSB review needed
Vitamin B6	Deficiency is rare; abundant in food	Animal protein, spinach, potatoes, bananas, salmon, sunflower seeds	Currently found in organic cereal, baby food, cereal. NOSB review needed
Folate	Deficiency in pregnant women can cause birth defects; abundant in food supply	Green vegetables, legumes, oranges	Currently found in organic cereal, snack bars. NOSB review needed
Vitamin B12	Older adults and vegans may be at risk for deficiency; abundant in animal products	Meat, poultry, seafood, eggs, dairy	NOSB review needed
Biotin	Deficiency is rare; abundant in food	Widely distributed in foods	Currently found in organic meal replacements. NOSB review needed.
Pantothenic acid	Deficiency is non-existent; abundant in food	Widely distributed in foods	Currently found in organic meal replacements. NOSB review needed.
Phosphorus	Deficiency is rare; abundant in food supply	Dairy, fish, meat, whole grain, nuts	Currently found in organic meal replacements. NOSB review needed.
Iodine	Deficiency is rare in	Saltwater fish, dairy	Already on the

	North America due to common supplementation of table salt		National List – 205.605(a)
Magnesium	Deficiency is rare; abundant in food	Whole grains, broccoli, squash, green leafy vegetables, beans, nuts, seeds, chocolate	Currently found in organic meal replacements. NOSB review needed.
Zinc	Deficiency is rare; abundant in food	Meat, fish, nuts, beans, whole grains	Currently found in organic baby food, cereal, meal replacements. NOSB review needed.
Selenium	Deficiency in North America is non-existent; abundant in food	Meats, eggs, fish, whole grains, seafood	Currently found in organic meal replacements. NOSB review needed.
Copper	Deficiency is rare (caused by over supplementation with zinc); abundant in food supply	Liver, shellfish, nuts, seeds, soy, avocado, dark chocolate, legumes, whole grains	Currently found in organic meal replacements. NOSB review needed.
Manganese	Deficiency is non-existent in humans	Nuts, oats, beans, tea	Currently found in organic meal replacements. NOSB review needed.
Chromium	Deficiency is rare (intravenous nutrition, elderly with Type 2 diabetes); abundant in food supply	Egg yolks, whole grains, pork, nuts, mushrooms	Currently found in organic meal replacements. NOSB review needed.
Molybdenum	Deficiency is non-existent in healthy humans; abundant in food supply	Beans, grains, nuts	Currently found in organic meal replacements. NOSB review needed.
Chloride	Deficiency is non-existent	Table salt	No need for listing on the National List

Listing “Nutrients, only when are required by the FDA” is not feasible

Rather than a blanket approval of “vitamins and minerals” or of specific vitamins and minerals, some have suggested that the organic standards could list, “nutrients, only those that are required by the FDA to the food to which they are added.”

The problem with this approach is that the FDA does not require the addition of synthetic nutrients to any foods, with the exception of Vitamin A to reduced-fat or skim milk that enters interstate commerce.

According to the National Institute of Health’s Food and Nutrition Board: “The FDA made a decision in the 1940s that it would not require mandatory fortification for any food product; this policy is still in place.”

Though not required, enrichment of foods, such as vitamin A and D in milk or iron and B vitamins in flour and pasta, is common. While no requirement exists, the FDA has a “standard of identity” for foods such as milk and flour. Standards of identity are federal FDA rules that determine what a food product must contain to be marketed under a certain name.

The FDA has a standard of identity for “enriched” foods, which requires that foods with the “enriched” label contain certain nutrients. For example, the standard of identity for “enriched flour” mandates the addition of iron and the B vitamins thiamin, riboflavin, niacin and folate. However, for every standard of identity for which there is an enriched version of a food, there is a corresponding standard of identity for an unenriched version.

The standard of identity for milk does not require the addition of Vitamin A and D, and no other FDA rule requires the addition of Vitamin A and D to milk. However, reduced-fat or skim milk that enters interstate commerce must contain added Vitamin A, because the FDA requires under 21 CFR 130.10(b) that foods with a standard of identity which have a “nutrient content claim” must not be nutritionally inferior to the standardized food. In other words, milk with the nutrient content claim “reduced fat” or “nonfat” must contain Vitamin A levels equivalent to those found in whole milk.

This requirement does not apply to foods that are processed but that do not contain a nutrient content claim, which is why white flour can be, but does not need to be, enriched with the nutrients that are lost during processing.

The problem is that the FDA has a very simplistic notion of what nutrients are important. For example, only vitamin A must be replaced; the FDA says nothing of

replacing the beneficial fatty acid nutrients that are also removed from reduced fat or nonfat milk.

While the addition of vitamin D to milk is not required, the USDA's Agricultural Research Agency notes that "Almost all retail milk in the United States is now fortified with vitamin D." However, many organic dairies do not add synthetic Vitamin D. Straus Family Creamery, Maine's Own Organic, Organic Valley are some of the larger dairies or dairy marketers that do not add Vitamin D to their organic whole milk. Straus Family Creamery, Cedar Summit Farm and many more small-scale, local, grass-based dairies do not add Vitamin D to their reduced fat or skim milk either. They only add Vitamin A to milk that enters interstate commerce, due to the FDA requirement.

The FDA does not have a standard of identity for many foods that are mainstays in the organic market, and that are commonly enriched. For example, no standard of identity exists for soy beverages or juice, and therefore there is no FDA requirement, or even encouragement through a standard of identity, to fortify these foods.

Fortification of these foods is entirely driven by the manufacturers, and presumably by consumer interest. Unenriched versions exist in the marketplace for every enriched version; Eden Foods offers soy beverages both with and without added calcium, Uncle Matt's offers orange juice both with and without added calcium and vitamin D, etc.

While many other organic standards, such as those of the European Union, allow for synthetic nutrients only when required by law, this approach is not likely to work in the US. It seems it would be less confusing to members of the organic community to list specific nutrients, with annotations restricting their use where appropriate. For example, Vitamin A could be petitioned, reviewed and approved for inclusion on the National List, with the possible annotation "for use in organic dairy products only."

Enforcement Action

The USDA should take immediate enforcement action against the food manufacturers that are adding unapproved synthetic nutrients to organic foods.

Unapproved synthetic nutrients that meet these two criteria should immediately be removed from organic foods:

- The nutrient is not included under a correct interpretation of the current listing, and does not appear on 21 CFR 104.20(d)(3)
- A petition for the nutrient has been rejected by the National Organic Standards Board.

Conclusion

Current top officials at the USDA admitted that the National Organic Program under the Bush administration incorrectly interpreted the organic standards, which led to the indiscriminate addition of unapproved synthetic nutrients to organic foods.

But rather than correct its policy, the USDA continues to cater to corporate food interests. Its most recent ruling, which the public may comment on until December 26, 2012, maintains the status quo—which means allowing food manufacturers to continue adding any synthetic nutrient to organic foods. It is our position that this policy violates the Organic Foods Production Act of 1990.

The USDA had proposed to close the current loophole in January 2012, and both the organic community and corporate food manufacturers supported the rule. But food manufacturers, like Nestle, likely supported the proposed rule because they expected the synthetic nutrients that they are currently putting in organic food would be accepted after review by the National Organic Standards Board (NOSB).

But the NOSB appropriately upheld organic integrity and denied petitions by corporations for synthetic nutrients currently in their organic products. Following their defeat, Nestle and other corporate food manufacturers are now seeking an alternative to keeping their synthetics in organic foods, and the USDA is assisting them out with their interim rule.

The organic community must make clear that synthetic nutrients should be individually reviewed by the National Organic Standards Board and individually listed on the National List if they are approved, as the law requires. For those synthetics that have never been approved for use in organics, like synthetic choline currently added by Nestle to Gerber Organic baby food, the USDA must take immediate enforcement action.

Consumers expect wholesome and pure food when they buy organic, and food produced under the law passed by Congress regulating organics. Synthetic nutrients have no place in organic food.