The Cornucopia Institute's

Comments to the

National Organic Standards Board

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CORNUCOPIA
INSTITUTE

Table of Contents

Support the proposal to remove Ferric Phosphate from section §205.601(h), synthetic substances allowed for use in organic crop production.

Oxidized lignite … page 31

Reject the proposal to add oxidized lignite to the National List. The manufacturing process is not available for review. Coal derivatives may be toxic and coal mining adversely affects both workers and the environment.

Propylene glycol monolaurate … page 34

Reject the proposal to add propylene glycol monolaurate (PGML) to the National List. PGML kills the natural predators that control mite pests, and reduces biodiversity on organic farms.

Review of inert ingredients … page 37

Support the Crops Committee's proposal to review List 3 and List 4 inerts. We suggest some changes to the proposal before it is fully adopted. The most important change we request is a shorter timeframe for review of these materials, because the review is overdue.

Rotenone … page 43

Support the subcommittee recommendation to add rotenone to §205.602 as a prohibited natural substance.

Sulfuric Acid … page 46

Reject the proposal to add sulfuric acid to the National List for stabilization of digested poultry manure. Sulfuric acid is detrimental to human health and harmful to the environment. It is a synthetic substance that is not essential for organic production, and its use is not compatible with organic principles.

MATERIALS SUBCOMMITTEE

Research priorities … page 49

Support the proposal, but take carrageenan off the list of research priorities because independent, primary research is already available. Include commitment to use and respect independent researchers' findings and consider research funding sources when deliberating.

HANDLING SUBCOMMITTEE

Ascorbyl palmitate … page 53

Reject petition to add ascorbyl palmitate to the National List because its primary purpose is as a preservative for ingredients that are not essential or required by the FDA.

Beta carotene … page 53

Reject petition to add beta carotene to the National List because its primary purpose is as a preservative for ingredients that are not essential or required by the FDA.

Lutein … page 59

Reject the petition to add lutein to the National List because it is not required by the FDA as a nutrient in infant formula. The European Union prohibits lutein in both conventional and organic infant formula, based on insufficient scientific evidence regarding safety and efficacy.

Lycopene … page 59

Reject the petition to add lycopene to the National List because it is not required by the FDA as a nutrient in infant formula. The European Union prohibits lycopene in both conventional and organic infant formula, based on insufficient scientific evidence regarding safety and efficacy.

L-carnitine … page 63

Consider that l-carnitine is required only in soy-based formula in the European Union, to meet infant's basic nutritional requirements. L-carnitine is a synthetic material produced in ways that are not compatible with organic handling.

L-methionine … page 63

Consider that l-methionine is required only in soy-based formula in the European Union and by the FDA, to meet infant's basic nutritional requirements. L-methionine is a synthetic material produced in ways that are not compatible with organic handling.

Nucleotides … page 67

Reject because nucleotides are not required in infant formula by the FDA. Cornucopia urges the NOSB to reject petitions for synthetic nutrients that are not deemed essential by the FDA.

Taurine … page 67

Reject because taurine is not required in infant formula by the FDA. Cornucopia urges the NOSB to reject petitions for synthetic nutrients that are not deemed essential by the FDA.

"Other Ingredients" … page 73

POLICY DEVELOPMENT SUBCOMMITTEE

Conflict of interest … page 79

Cornucopia believes the proposal is a step in the right direction, but urges several issues to be addressed prior to a vote. These include questioning whether the NOP should make the final determination of whether a conflict exists, and considering whether a Board member has a conflict when his/her employer actively lobbies other Board members during the meeting.

Public Comment Procedures … page 82

We reluctantly accept the standard time commitment of 4 minutes per presenter, and urge the Board to **reject** the possibility of cutting the time allotment down to three minutes.

We urge the Board to include a line in the Policy and Procedures Manual committing to unlimited Q&A.

Public Communications … page 84

Cornucopia supports the proposal. We urge the Board to consider posting discussion documents as they become available, to maximize public input.

COMPLIANCE, ACCREDITATION AND CERTIFICATION SUBCOMMITTEE

Calculating Percentage of Organic Ingredients

This discussion document poses questions to organic certifiers. We will reserve the right to comment until the organic certifiers have had a chance to answer the questions posed.

Biodiversity Update

Cornucopia supports the work being done to increase the commitment to biodiversity conservation by organic operations.

INTRODUCTION

The Cornucopia Institute is a 501(c)(3) public interest farm and food policy research organization. Cornucopia engages in educational activities supporting the ecological principles and economic wisdom underlying sustainable and organic agriculture.

Through research and investigations on agricultural and food issues, The Cornucopia Institute provides needed information to family farms, consumers, stakeholders involved in the good food movement, and the media.

We are proud to represent 7,000-7,500 supporting members, the majority of whom (70% based on the most recent calculation) are certified organic farmers.

We do not sell materials seeking approval or sunset reauthorization, and we do not sell organic products that utilize any ingredients that might be petitioned.

With a history of agribusiness involvement in both the analysis of petitioned materials and decision-making at the NOSB level, current Board members will benefit from Cornucopia's independent perspective, assessing the health and environmental implications of any material presented for their review. We have no financial interest in the approval of any of the materials proposed for use in organic foods.

Cornucopia adamantly believes that a thorough and appropriate review process needs to take place for all petitioned materials, and that all materials should conform with the Organic Foods Production Act of 1990 (OFPA) and the federal organic standards.

LIVESTOCK COMMITTEE

NONANOIC ACID

SUMMARY

Reject the proposal to add synthetic nonanoic acid to § 205.603, for use as an insect repellent and insecticide. The livestock committee voted unanimously to reject this petition.

Rationale

- The petitioned material is synthetic.
- Nonanoic acid is not essential for insect control on livestock.
- Synthetic nonanoic acid is not permitted by organic standards outside of the U.S.

BACKGROUND

A petition was submitted by Stratacor, Inc., to add "nonanoic acid" to Section §205.603 of the National Organic Program as a synthetic substance allowed for use as an insect repellent/insecticide in organic livestock production.

Stratacor submitted this petition because they would like to market a fly repellent product that is a combination of octanoic, nonanoic, and decanoic acids, formulated in mineral oil or in clay dusts, to organic livestock producers. The petitioner submitted an application for this product, called C8910, to OMRI. The petition was rejected on the basis that nonanoic acid was a synthetic not allowed for organic livestock production because it was not listed on § 205.603 (Reifenrath, 2011).

The petitioned material is synthetic

The petitioner is requesting to use a synthetic form of nonanoic acid, which is also called pelargonic acid. However, a natural form of this substance may be available. The manufacturer, Advanced Biotech (ABT), has written their own "Organic Product Certificate" indicating that their nonanoic acid is nonsynthetic and allowed for organic use (ABT, 2012).

Nonanoic acid is used as a herbicide and blossom thinner for fruit trees. It is present in many plants, and is generally harmless to humans; however, it can be a skin irritant if a concentrated form is applied directly to skin (U.S. EPA 2000).

Nonanoic acid is not essential for insect control

Although challenging, insect problems on livestock can be minimized by using nonsynthetic substances, biological controls, and/or management practices.

Nonsynthetic substances include pyrethrins, sourced from chrysanthemum flowers, and plant-based essential oils. Many essential oils have been found to be effective: anise, chamomile, citronella, citrus, eucalyptus, geranium, lemongrass, lettuce, peppermint, rosemary, and thyme (Khater, et al., 2011; Kumar, et al., 2011; Palacios, et al., 2009). With all these nonsynthetic oils available, it hardly seems necessary to approve a synthetic substance, nonanoic acid, to be used for insect control.

Biological controls include the use of parasitic wasps and predatory insects.

Management practices include sanitation of animal living spaces so that flies have no place to breed, and mechanical controls such as fly traps and rotationally grazing poultry that eat fly larvae.

International Organic Standards

Synthetic nonanoic acid is not permitted by organic standards outside of the U.S. Neither Canada nor Japan permit nonanoic acid. Nonanoic acid is not permitted under the European Union regulations, IFOAM regulations or the Codex Alimentarius Commission.

CONCLUSION

Cornucopia fully supports the recommendation of the NOSB Livestock Subcommittee to reject the proposal to add nonanoic acid, a synthetic pesticide, to section § 205.603 of the National List.

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PET FOOD AMINO ACIDS/TAURINE

EXECUTIVE SUMMARY

These comments pertain to two related motions.

1. Motion to list amino acids (Arginine, Methionine, Cystine, Lysine, Taurine, Tryptophan, Threonine, Histidine, Isoleucine, Leucine, Phenylalanine, Tyrosine, and Valine) on section 205.603 on the National List for use in organic pet food.

2. Motion to list Taurine on section 206.603(e)(4) for cats (allow).

Reject motion 1 to list the entire group of 13 synthetic amino acids in organic pet food.

Table motion 2 to list taurine as allowed in organic pet food.

Rationale

- Taurine is an essential nutrient for cats.

- Taurine can be obtained from natural food sources such as beef and poultry.

BACKGROUND

A petition was submitted to the NOSB by the Pet Food Institute, a trade association of pet food manufacturers, to allow the addition of 13 synthetic amino acids to organic pet food: Arginine, Methionine, Cystine, Lysine, Taurine, Tryptophan, Threonine, Histidine, Isoleucine, Leucine, Phenylalanine, Tyrosine, and Valine. The Livestock Subcommittee voted unanimously to deny that petition. Cornucopia agrees with this committee vote.

The Livestock Subcommittee determined that there was a need for synthetic taurine to be added to organic cat food. We disagree with this determination and with the committee's unanimous decision to list taurine on section 206.603(e)(4), as a synthetic supplement for organic cat food. We request additional information on the possible natural sources of taurine for cats.

Taurine is an essential nutrient for cats

The American Association of American Feed Control Officials (AAFCO) develops profiles for the nutrients required in pet foods in order for them to be labeled "complete and balanced."

The NOSB livestock committee, in discussions with AAFCO, concluded that the need for most of the petitioned amino acids could be easily met through feeding whole foods to pets. The only amino acid that might need to be supplied in synthetic form was taurine for cats. Canned cat food is required to have 0.2% taurine; dry food is required to have 0.1% taurine.

Since cats are carnivorous, meat is part of their normal diet (Pet MD). Since taurine is present in meat, it seems that feeding cats meat would meet their taurine requirements. If the taurine deficiencies in commercial cat food are caused by the reliance on vegetarian protein sources, like corn and soy, organic cat food should provide a real-food alternative and should not have to rely on synthetic taurine.

The Technical Evaluation Report devotes two lines to answer the question of natural sources of taurine. We suggest that a supplemental report is needed to more thoroughly review the possible sources of taurine from natural supplements, such as seaweed, or whole foods. The TER reviewing all amino acids as a group necessarily lacked depth for each substance.

Taurine can be obtained from whole foods

One of the founding principles of the organic movement is that synthetic nutrients for the soil do not lead to long-term, sustainable soil health. The same principle should apply to the debate around synthetic nutrients for pet food.

Consumers purchasing organic food for their pets do so with the understanding that they are buying *real*, wholesome food for their pets. Synthetic nutrients do not fulfill this expectation, especially when natural alternatives – real food – are available.

Cat foods labeled "organic" should be required to derive all taurine from natural sources. In a natural diet, cats obtain taurine from seafood, poultry, and beef (Spitze, et al., 2003). Although the argument has been made that organic poultry and beef are prohibitively expensive for pet food, Cornucopia notes that cost is not a criterion for adding a synthetic substance to the National List.

At least one brand of "natural" cat food does not add any synthetic taurine. The manufacturer claims that cats can derive all the needed taurine from the animal products (meat, fish, poultry) included in the formula.

CONCLUSION

Cornucopia urges the board to table this proposal for the addition of synthetic taurine for cat food. If organic poultry and beef are prohibitively expensive, we encourage the development of natural sources of supplemental taurine. We believe

that the only way that natural sources of taurine will be developed is by rejecting the petition to add synthetic taurine to the National List. While the sunset process theoretically encourages the development of natural alternatives, it has become clear, over the years, that few materials sunset. Once a material is on the National List, manufacturers lose their incentive to develop a natural alternative.

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OMNIVORE DIETS (METHIONINE)

DISCUSSION DOCUMENT

The NOSB is seeking input from the organic community on whether omnivorous animals raised on organic farms should be allowed to receive omnivorous feed. Cornucopia believes that the persistent problem of finding a natural alternative to synthetic methionine is in large part due to the current restriction in the livestock feed regulations, which require (an unnatural) vegetarian diet for omnivorous livestock. We are pleased to see the Livestock Subcommittee's discussion document, as we believe it is a crucial first step in the right direction for resolving the methionine problem.

The following questions are posed by the NOSB:

1. *Would you recommend the Livestock Subcommittee look at a possible annotation to allow 100% organic meat scraps or by-products to be used in omnivore diets (poultry and pigs), since it is natural for these omnivores to consume both plant and animals materials? Explain.*

Cornucopia supports the proposal to allow 100% organic meat scraps to be included in the diets of poultry and pigs, with necessary restrictions to ensure safety and continued consumer confidence in the organic label (detailed below). Although there is currently no 100% organic fish, we would support the addition of fish to omnivore diets after it becomes available.

While we support the allowance of 100% organic meat scraps and by-products in omnivorous diets, we suggest some restrictions:

- Although poultry and pigs are omnivores, the vast majority of their diet would be plant-based in a natural setting. If animal products are added, it is essential that these meat scraps constitute only a small percentage of the animal's diet. This would require research to determine an appropriate level of animal products that would be consistent with the natural diet of the pig, chicken, or turkey.
- The meat products added to feed for organic livestock should not induce cannibalism. Poultry and egg by-products should not be fed to poultry, but they could be fed to pigs. Pork by-products should not be fed to pigs, but they could be fed to poultry, if there is evidence that chickens and turkeys will eat small mammals. One exception is that shells from organic eggs could be added to poultry diets as a source of calcium.

- One of the reasons that the restriction on meat by-products was incorporated into the organic regulations were concerns about the communication of transmissible spongiform encephalopathy (TSE), as evidenced in the "mad cow" outbreak in Britain, which led to increased regulatory attention. Whereas the Europeans implemented strict protocols, the US government has been criticized for allowing practices (such as feeding poultry litter contaminated with meat by-products to cattle) that could pose a risk. If the practice of feeding livestock meat by-products is approved it must incorporate a strict and conservative set of standards to assure the consuming public that organic products are indeed insulated from TSE risk.

2. *Natural herbal methionine, potato meal, and corn gluten meal are showing promising results. Should this type of research effort increase? Explain.*

Research efforts to improve livestock nutrition are always encouraged. Adding methionine by itself is only one avenue of research to pursue.

Cornucopia encourages research into cost-effective commercial production of poultry supplements based on foods eaten by free-range chickens. These typical foods might include almost any terrestrial invertebrate, such as worms, slugs, insects, and insect larvae. Commercial businesses that raise beneficial insects for sale as biological control agents have already developed protocols for insect rearing. Amending the regulatory restriction of a 100% vegetarian diet for poultry would encourage this type of research and development.

3. *There is a natural herbal methionine manufacturer in India that touts their product as being a 1:1 replacement for synthetic methionine. How can this product be brought to commercial availability/viability within the next three years in the United States?*

This manufacturer should be invited to make a presentation at the NOSB meeting.

4. *How can the organic community spur more production and manufacturing of natural amino acids, including methionine and lysine, vitamins, and minerals products for livestock and aquaculture rations in the next three to five years?*

5. *While the FDA regulates the safety of meat/slaughter by-products, what additional organic regulations or safeguards should be in place before organic livestock producers feed mammalian or avian slaughter by-products to their omnivore livestock?*

See answer to question #1 above.

6. *Would the organic brand be damaged if organic livestock producers were given the choice of feeding organic animal by-products and naturally or organically harvested fish by-products? Explain.*

Cornucopia suggests that the NOSB request a consumer survey to answer this question.

Since many consumers may seek the "vegetarian-fed" label in the wake of the Mad Cow outbreaks, which were linked to feeding bovine by-products to cattle, restrictions put in place to prevent such unintended consequences would need to be communicated with organic consumers. If consumers understood that a "vegetarian-fed" label on an omnivorous animal product (eggs, poultry, pork) is made possible only by the addition of synthetic amino acids, it is not likely that the organic brand would be damaged if animals were allowed their natural omnivorous diet, without synthetic nutrients. Obviously, consumer choice would drive marketplace options.

In addition, we believe that organic consumers would (rightfully) assume that the animal by-products offered to omnivorous animals would be 100% certified organic – from animals that themselves were raised in accordance to strict organic standards. Given these restrictions, we suspect that a consumer survey would reveal that organic consumers would welcome the change, especially since it allows animals to eat their natural diet and obtain their nutrient from natural, rather than synthetic, sources.

7. *Would a rule change at §205.237(5) (b) to allow the feeding of organic meat offal or by-products to omnivores be appropriate to help fulfill the essential amino acids, vitamins, and minerals requirement? If yes, state the language you would use. If no, offer viable suggestions to dealing with the absence of synthetic amino acids in omnivore rations.*

A rule change would be appropriate. The current rule states:

> 7CFR205.237(b) the producer of an organic operation must not:
>
> (5): Feed mammalian or poultry slaughter by-products to mammals or poultry;

Cornucopia suggests the following change:

> 7CFR205.237(b) the producer of an organic operation must not:
>
> (5): Feed **conventional** mammalian or **conventional** poultry slaughter by-products to mammals or poultry; **(addition in bold)**

We would also suggest adding the following lines:

7CFR205.237(b) the producer of an organic operation must not:

(7): “Allow cannibalism by feeding animal by-products of the same species; for example, no poultry by-products shall be fed to poultry, and no porcine by-products shall be fed to pigs;”

(8): “Feed mammalian or poultry slaughter by-products to vegetarian animals (cattle, sheep, goats, bison, rabbits)”

GMO AD HOC SUBCOMMITTEE

GMOS AND SEED PURITY

DISCUSSION DOCUMENT

The following questions were posed by the NOSB:

1. *Is there a need to establish a seed purity standard or protocol to ensure that planting seed meets the requirements of the NOP rule? Explain your answer.*

Yes. Given the increasing use of GMO seed in conventional agriculture, increasing concerns about contamination, and increasing consumer awareness of the potential dangers of GMO crops, Cornucopia believes the organic industry and consumer confidence in organics would benefit greatly from an established seed purity standard. This is an important step to ensuring organic integrity, and we thank the GMO Ad Hoc Subcommittee for its work in developing this discussion document.

Cornucopia believes that ensuring the purity of seeds used for organic production is especially important when organic growers use conventional seed, which has not been subjected to the same organic standards and oversight as organic seed.

The phrasing of the questions does not make a distinction between the testing of organic seed and conventional seed. Due to the fact that organic seeds have an Organic System Plan for protecting seed purity, but conventional seeds do not have this plan, we would like to see an explicit distinction between testing requirements for conventional versus organic seed, with a focus on testing any conventional seed being used in organic production.

Focus should be on conventional, not organic, seed

Organic agriculture is "a process not a product." Just as organic certification for food is based on the Organic System Plan, the purity of organic seed should be based on the Organic System Plan of a seed producer.

The expectation of seed purity for organic seed is analogous to the consumer expectations about pesticide residues on organic foods. Consumers expect that organic food will have no or minimal pesticide residues, yet only a small percentage of organic food is tested for pesticide residues. Even if 5% of farms are tested, only a small lot of product is tested from each farm.

In order to have a robust expectation that organically produced seed will be free of GMO contamination, it will be necessary for seed producers and certifiers to work

together to establish and enforce appropriate isolation distances and practices. However, if this is done, adding another protocol of testing each seed lot may increase the cost of organic seed. This, in turn, may make organic seed less available, as organic farmers always run the risk that their carefully grown seed will have to be sold on the conventional market because it has been found to have some GMO contamination. As a result, the seed purity standard, if applied only to organic seed, may have the unintended consequence of making organic seed less available.

Organic integrity will benefit from testing conventional seed

Although use of organic seed is "required" by organic standards, a significant amount of organic acreage is planted with conventional seed. Section 205.204 (a)(1) states that "Nonorganically produced, untreated seeds … may be used to produce an organic crop when an equivalent organically produced variety is not commercially available." Growers planting large acreages are those most likely to use nonorganic seed, because it is claimed to be more difficult to obtain the volume they need. Before establishing this seed purity standard, it would be helpful to estimate the percentage of acreage planted with conventional seed as compared to the percentage of acreage planted with organic seed, at least for high-risk crops such as corn.

We would like to see the seed purity standard focus on conventional seed, and add language to ensure that conventional seed with be the focus of this standard.

2. *What is currently known about the level of GMO contamination of seed used by organic farmers and any associated testing of seed on the farm or in the supply chain? Comments from farmers, seed companies, or buyers describing the following would be relevant:*
    - *the scope of testing (e.g. frequency, methods, costs);*
    - *the threshold used for rejection; and*
    - *the outcome of seeds that are rejected.*

In order to fully answer this question, the conventional seed industry will need to share their testing procedures for GMO contamination, as well as the organic seed industry. It is likely that conventional seed would risk a higher level of contamination than organic seed.

3. *What testing methods are appropriate to use in order to determine and label for seed purity and to verify compliance to a seed purity standard?*

Testing methods for seed purity should follow the same protocols as testing methods for pesticide residues. The sample should be taken by an organic inspector, or someone who is trained in the protocol of sample collection. The chain of custody should be clearly indicated on the sample form to ensure that no adulteration or contamination occurs as the seeds are sent to a testing laboratory. The results should be sent directly to an organic certifier or other third party, not to

the seed supplier. If this procedure is not followed, for example, if the seed company takes its own samples and directly receives the test results, there is potential for falsification of the results.

4. *How would an example such as proposed in Discussion point #7 above affect your farm or business?*

A universal standard for genetic purity could be beneficial for organic farmers, if it provides information on GE contamination of conventional seed. Given the increasing number of acres planted to genetically modified crops, it seems highly likely that contamination will be detected in future seed lots. The sampling must be done by an independent third party, as described in #3, and testing results sent directly to the certifier, to ensure accuracy.

Alternatively, a universal standard, if it does not distinguish between testing conventional and organic seed, could be harmful to organic farmers. Testing will increase the cost of organic seed, due to the cost of the tests. It will also reduce the availability of organic seed, if organically-produced seed lots are found to have unacceptable GE contamination, and are not available for organic farmers. Financial impacts must be carefully considered to ensure that small farmers are not unfairly burdened by the cost of these tests.

5. *Is there a better suggestion for a seed purity standard than that proposed in Discussion point #7 above? Describe.*
6.

Questions 5, 6, and 7 are being actively addressed by organic seed producers. We urge the NOSB to involve the conventional seed producers in this discussion as well.

7. *What is known about relevant sampling, testing, and detection level protocol necessary to implement such a standard?*

8. *What training, guidance, or resources do certifiers need to verify compliance for to a seed purity standard?*

The specifics of a seed purity standard must be clarified before this question can be answered.

9. *What approach could an organic seed producer use to safeguard against GMO contamination from an adjacent or neighboring conventional farm? Buffer zones, distance, planting time, pollination factors, and contamination possibilities/solutions could be included in your response.*

CROPS SUBCOMMITTEE

BIOPLASTIC MULCH FILM

SUMMARY

Table this petition to include biodegradable, biobased, bioplastic mulch film on the National List at §205.601(b) as a synthetic substance allowed for use in organic crop production.

We are concerned that the current petition requests an overly broad category of synthetic substances to be added to the National List. The petition includes three distinct types of synthetic plastic films; we feel that each should be reviewed individually. While some may be appropriate for organic crop production, we have concerns with at least one of the types of plastic mulch included in the current petition.

We urge the Board to request separate petitions for each type of synthetic plastic film, and delay the vote until each type can be individually reviewed and voted upon.

We are also concerned that current definitions of biodegradability do not address chemical residues in the soil. We urge the Board to gain a better understanding of chemical residues in the soil from each type of biodegradable mulch before approving them.

We hope that a more thorough approach will result in the approval of suitable bioplastic mulches, and the rejection of those inappropriate for organic production.

Benefits of bioplastic mulches

- Use of biodegradable mulch avoids plastic in landfills.
- The benefits of plastic mulches in crop production have been confirmed in research and in practice.

Concerns with bioplastic mulches

- These plastics are synthetic.
- Degradation products may include synthetic, and possibly harmful, compounds that will persist in the soil.

- Additional information is needed about the manufacturing process and degradation products of bioplastic mulches.
- The wording of the proposal allows too much leeway for manufacturers to include unknown substances that have not been reviewed by the NOSB.

BACKGROUND

This petition seeks inclusion of biodegradable mulch film on the National List at §205.601(b) as a synthetic substance allowed for use in organic crop production.

The specific wording of the proposal to be added to §205.601(b)(2) Mulches:

(iii) Biodegradable biobased bioplastic mulch meeting the following criteria:
(A) Completely biodegradable as shown by:
1) meeting the requirements of ASTM Standard D6400 or D6868 specifications, or of other international standard specifications with essentially identical criteria, i.e. EN 13432, EN 14995, ISO 17088; and
2) showing at least 90% biodegradation absolute or relative to microcrystalline cellulose in less than two years, in soil, tested according to ISO 17556 or ASTM 5988;
(B) Biobased certified using the ASTM D6866 method;
(C) Must be produced without excluded methods;
(D) Must be produced without engineered nanomaterials; and
(E) Grower must take appropriate actions to ensure complete degradation at the end of each growing or harvest season.

Other mulches currently listed are (i) newspaper or other recycled paper, and (ii) plastic mulch and covers, classified as synthetic substances allowed as weed barriers.

To fully evaluate this proposal, it is necessary to have clear definitions of the terms biodegradable, biobased, and bioplastic.

Biodegradable materials are defined above.

Biobased material is "organic material in which carbon is derived from a renewable resource via biological processes. Biobased materials include all plant and animal mass derived from CO2 recently fixed via photosynthesis (BPI, 2012)." In other words, biobased materials are those in which the carbon source is derived from recent photosynthesis of green plants. This is the ASTM (formerly the American Society for Testing and Materials) definition of biobased material, as stated in the petition. This definition does not address the possibility that the final product may contain synthetic compounds added during manufacture. Although the ASTM is internationally respected, their standards are not based on organic practices.

Bioplastics are polyesters, which are polymers formed by the reaction of a hydroxyl group and a carboxyl group. They differ from the traditional plastic allowed for organic crops, which is polyethylene.

Concerns of the NOSB Crops Subcommittee

Although the Crops Subcommittee approved the proposal to add bioplastic mulches for organic crop production, it was not without some reservations. As noted in the proposal:

> *"The subcommittee believes that it may be difficult to separate claims from truth concerning biodegradability and the source of the material."*

We certainly agree with this statement, and urge caution before approving bioplastic materials. The subcommittee also wanted to ensure that their recommendation was able to accurately describe biodegradable, biobased, bioplastic mulches. The committee intends this recommendation to cover those bioplastics that are both biobased and biodegradable.

Description of the petitioned substances

Although the petition requests only one category to be added to the National List, it appears that three fundamentally different types of bioplastic mulches are included in this one petition. The following information is summarized from the Technical Evaluation Report (TER) (ICF, 2012).

Commercial bioplastic mulches are produced by multiple companies worldwide and in variable formulations. Biodegradable mulches are made from biodegradable polymers, including the three types described in the petition:

- polylactic acid (PLA), a polymer derived from bacterial fermentation of plant starch (such as corn or wheat starch).
- polyhydroxyalkanoates (PHA), a polymer derived from the fermentation of sugars or lipids.
- aliphatic-aromatic copolymers (AAC), synthesized from various constituents. The raw materials may include corn syrup (fermented by GE bacteria), petroleum, acetylene, and formaldehyde.

Although these substances were petitioned to the NOSB for review as a group, each type of mulch has a different production method. The production methods, as described in the TER:

- PLA – Plant starches are fermented by bacteria.

- PHA – Chemical synthesis, bacterial fermentation (possibly GMO), or transgenic plant cells.
- AAC – Chemical synthesis.

Each of these classes has unique starting materials and would be expected to have unique breakdown products.

It is extremely challenging to reach a real understanding of the nature of these products. The TER describes the AAC bioplastic mulches as follows:

> *"Aliphatic-aromatic copolymers (AAC)are synthetically produced by reacting a diacid constituent (including adipic acid, azelaic acid, sebacic acid, and terephthalic acid) with a diol constituent (1,3- propylen glycol, 1,4-butanediol, or 1,6-hexanediol), which are then linked with an ester linkage."* TER 68-70

Cornucopia believes that the TER should explain the materials reviewed in language that can be understood by all members of the NOSB and the organic community.

International standards

According to the petition (BPI, 2012), there are several forms of bioplastics in mulch films currently available and being used in organic production systems in Canada and Europe:

- The biodegradable bioplastic, Mater-Bi®, is produced by Novamont. Mater-Bi®'s ingredients consist of starches derived from plants, mainly corn starch, and biodegradable aliphatic-aromatic polymers from both renewable raw materials (mainly vegetable oils) and fossil raw materials. BioTelo and Garden Bio-Film, known also as BioBag AgroFilm, are made from Mater-Bi®.
- NatureWorks' PLA INGEO™ is one of a broad family of over 15 plant based Ingeo™ biopolymer grades produced in NatureWorks' plant.
- Ecoflex® F Blend C1200 is a biodegradable aliphatic-aromatic copolyester produced by BASF from the monomers 1,4-butanediol, adipic acid and terephthalic acid. BASF also produces Ecovio® F Film and Ecovio® F Blend products
- Mirel™ is a bioplastic made by Metabolix, in a joint venture with Archer Daniels Midland, from polymers known as polyhydroxyalkanoates (PHA). Polyhydroxyalkanoates are linear polyesters produced in nature by bacterial fermentation of sugar and lipids.

The Canadian General Standards Board allows for "plastic mulch" as a permitted substance (ICF, 2012). Fully biodegradable films are permitted as mulches if they do

not contain any substances prohibited by paragraph 1.4.1 of CAN/CGSB-32.310. These prohibited substances include:

- Materials produced from genetic engineering
- Synthetic processing substances, aids and ingredients
- Nano-technology products

CONCERNS WITH THE PETITION

These plastics are synthetic

Although some natural ingredients are used, chemicals are added to these bioplastic products. The percentage of chemicals added varies for the different types of products. The Crops Subcommittee unanimously voted that bioplastics are synthetic.

The TER stated:

> *"Systematic reviews of the environmental impact from manufacturing of bioplastics were not found."*

We urge the NOSB to table the petition, request further information on the manufacturing process and the use of synthetic materials, and reconsider the petition (or, ideally, separate petitions for separate categories of biodegradable mulch) when this information is available. Degradation products may include compounds that will persist in the soil.

The proposal indicates that full biodegradability is achieved when 90% biodegradation is achieved. Research reports indicate that the mulch has broken down when individual particles are not visible in the soil. Both of these definitions of biodegradability do not address chemical residues. Synthetic chemicals are used in the manufacture of these bioplastics, which indicates that there is a possibility for residues of synthetic chemicals in the soil, even after the mulch appears to have visibly broken down.

These synthetic mulches, and their breakdown metabolites, should be viewed and reviewed the same way that any other soil amendment should be scrutinized. The uptake of some of these constituents, by plants, appears to be currently unknown.

Since three types of films are each manufactured differently, each would be expected to have different breakdown products. The three types of films do indeed appear to have different breakdown products (ICF, 2012). AAC, in particular, may leave residues of synthetic chemicals in the soil, but no studies were found that quantified the type of these aromatic hydrocarbons that might remain (ICF, 2012). We urge the Board to use caution, and follow the Precautionary Principle, before

approving materials that may leave harmful and persistent chemical residues in the soil on organic farms.

Plastic mulch films may contain titanium dioxide, carbon black (a petroleum derivative), and plasticizers, all synthetic. Given these synthetic starting materials, and the chemical processes used to make bioplastic mulches, degradation products might include heavy metals or recalcitrant synthetic compounds (aromatic hydrocarbons). The degradation products would be different for each type of mulch, due to the different chemical elements in the mulch. If mulch is used repeatedly for many years, and small amounts of these synthetic chemicals are left in the soil each year, it raises the concern that these synthetic materials could accumulate to unacceptable amounts.

Further research into the biodegradation of the various bioplastics is needed for a more complete understanding of the potential impacts. Due to the diversity of bioplastics currently being developed, and the lack of information about their degradation products, further research is needed to evaluate their effects on the agro-ecosystem (Shah et al., 2008).

The technical evaluation report repeatedly raises concerns about the breakdown products of these bioplastic mulches:

> *"Comprehensive studies were not found that described the environmental impacts of the use of bioplastic mulch… Due to the wide variety of potential chemicals released from the incomplete degradation of bioplastics, this is a data gap."* TER 649-652

Additional deliberation is needed

The wording of the proposed language needs further clarification. In particular, the definition of "biodegradable" needs to be specific and relevant for organic crop producers, rather than referring to ASTM standards.

Addition of an entire class allows too much leeway for manufacturers to include unknown substances in their formulations of new products. New bioplastics are being developed, and this is a new group of materials to be added to the National List.

While Cornucopia greatly appreciates the efforts of the Crops Subcommittee in developing this proposal, we urge the NOSB to answer important questions before proceeding with a vote. The petition alone, received March 2012, was 299 pages. The TER was received in August 2012 and the proposal was completed August 15. Given the challenging technical nature of the reviewed materials, we question whether a thorough review by the subcommittee was able to be completed.

Cornucopia researchers certainly feel that more time is needed to fully research and understand the potential effects of all types of bioplastic mulch.

We advise the NOP to allow time for the organic stakeholders to review these materials and have input into the approval process. In the meantime, we urge the NOSB to request that each type of bioplastic biodegradable mulch be petitioned separately, and that a TER, which explains the manufacturing process in terms that can be understood by organic stakeholders without a doctorate in chemistry, be developed for each petition.

SUGGESTED COURSE OF ACTION

- Table vote on the petition at this meeting.
- Request individual petitions and individual review of each type of product.
- Request a TER for each class of product (PHA, PLA, AAC).
- Request a TER in plain language, with explanations of scientific jargon (see TER 68-70, quoted above).
- Obtain more information about breakdown products of these mulches.
- Allow more time to review the complex chemistry of each individual product.
- Consider adding restrictions on use because these mulches do not feed the soil.

CONCLUSION

Certainly many organic growers will agree that weed control is a challenge in organic systems. The promise of an environmentally sound weed barrier to replace petroleum-based plastic makes it tempting to approve these mulches.

Before the NOSB approves these new materials, it is important to verify that they truly are biobased and biodegradable, and do not leave any harmful residues in the soil. The benefits of plastic mulches have been confirmed in research and in practice. An environmentally sustainable alternative to non-biodegradable polyethylene plastics is a worthy goal.

In the face of all these potential advantages, we urge the NOSB to also conservatively approach the potential harm that unlimited use of this novel substance may have. No matter how desirable the option, it is important to take the time to carefully evaluate whether these bioplastics can deliver on their promise, before the bioplastics can be approved for organic production.

A thorough evaluation requires:

(1) a separate evaluation of each type of plastic mulch,
(2) a technical evaluation report (TER) written in layman's terms that can be easily understood by all members of the NOSB and the interested organic community, and

(3) sufficient time to read both the manufacturer's petition and the TER.

Cornucopia recommends tabling the petition at this time.

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FERRIC PHOSPHATE

SUMMARY

Support the proposal to remove ferric phosphate from section 205.601(h), synthetic substances allowed for use in organic crop production.

Rationale
Concerns about EDTA were raised in 2007 by the NOSB, in 2012 by the Supplemental Technical Review (STR), and by the Agricultural Research Service (ARS) review of the STR.

- Currently, all available ferric phosphate products contain EDTA.
- EDTA should be evaluated separately as an active ingredient.
- EDTA is not compatible with organic agriculture.

BACKGROUND

Cornucopia supports the minority opinion to remove ferric phosphate from 205.601(h), synthetic substances allowed for use in organic crop production. These products, listed as slug or snail baits, are molluscicides (products used to kill snails and slugs).

In 2007, the NOSB Crops Subcommittee voted to reject sodium ferric hydroxyl EDTA (SFH EDTA) for use as a slug and snail bait. The reasons given were that EDTA has potential to be harmful to humans and the environment, and the material is not consistent with organic farming. The subcommittee was also concerned that EDTA is persistent in the environment (NOSB Crops Subcommittee, 2007).

As was noted in the Supplemental Technical Review (ICF, 2012), those concerns are still valid as the petition for ferric phosphate is reviewed. The Agricultural Research Service (ARS) agreed that concerns about EDTA are reasonable, in their review of the STR. The ARS comments are included in the proposal of the Crops Subcommittee.

This proposal results from a recent petition to remove ferric phosphate from the list of allowed synthetic substances. A TER was done in 2010 by the Technical Services Branch of the USDA. A supplemental TER (STR) was dated July 26, 2012. The STR was reviewed by the Agricultural Research Service (ARS), and their comments are included as part of the Crops Subcommittee proposal.

Currently available products all contain EDTA

Ferric phosphate is listed as the active ingredient in molluscicides. However, all products available for sale in the U.S. also include EDTA. According to the Organic Materials Review Institute (OMRI) Products List there are 13 slug and snail bait products containing ferric phosphate. According to product labels, they all contain the compound EDTA. (STR 76-79).

EDTA should be evaluated as an active ingredient

The patent by Puritch et al. included in the petition itself states in the Abstract:

> *"An effective, readily ingested molluscicidal bait poison includes an inert mollusk bait and two active ingredient precursors. These precursors are edible and non-toxic to terrestrial molluscs when consumed alone. However, the composition which includes the two precursors is fatally toxic to terrestrial molluscs. One precursor is a simple iron compound, while the other precursor is selected from edetic acid, its hydroxyl derivatives, and salts of these acids." (Puritch, et al., 1995)*

Since the patent itself considers Edetic acid (EDTA) to be an active ingredient, the NOSB should evaluate it as an active ingredient. Presumably, EDTA is added to increase the efficacy of the product, therefore acting as either a synergist or an active ingredient. Clearly, EDTA is <u>not</u> an inert ingredient. Several studies summarized in the STR indicate that researchers were not able to demonstrate that ferric phosphate alone is effective as a molluscicide. EDTA significantly increases the efficacy of ferric phosphate (Henderson et al.,1989, Whaley, 2007, Zheng et al., 2008) (STR Table 1). Although the Whaley study showed some effectiveness of ferric phosphate, a formulated commercial product must show high efficacy, which in this case requires the addition of EDTA.

The fact that all labeled products include EDTA indicates that it should be evaluated by the NOSB as an active ingredient because it increases the efficacy of the product. Some members of the Crops Subcommitee opined that EDTA is indeed inert, and therefore is allowed under section 205.601(m)(1). Currently the EPA does not maintain the List 4 inerts, and they urge manufacturers to use the term "other ingredients." Whether EDTA is considered an active ingredient, a synergist, an inert, or an "other" ingredient, it is clearly synthetic and is not compatible with organic agriculture.

EDTA is not compatible with organic agriculture

Previous reviews of ferric phosphate with EDTA by the NOSB Crops Subcommittee have agreed that EDTA may be harmful to the environment, EDTA may persist in the environment, and EDTA has potential for mammalian toxicity.

The TER quotes: "Clearly, molluscicides containing iron phosphate and EDTA or EDDS chelating agents may present significant environmental hazards to earthworms, domestic animals and humans and these issues need further investigation. The registration statuses of these chemicals in USA and Europe should be reviewed in light of these new data and conclusions" (Edwards, et al. 2009). (TER 348-351)

The proposal states that there are detectable residues of EDTA in oceans and surface waters, indicating that it persists in the environment. The technical reviews primarily focused on ferric phosphate, not EDTA. Additional information on EDTA is needed before approving ferric phosphate with EDTA.

EDTA is a strong chelating agent, which can bind to calcium and lead to calcium deficiencies in humans. According to Web MD, EDTA is used as a prescription medicine but it does have side effects: abdominal cramps, nausea, vomiting, diarrhea, headache, low blood pressure, skin problems, and fever. EDTA can decrease levels of calcium, magnesium, or potassium to dangerous levels in humans.

CONCLUSION

Cornucopia supports the petition to remove ferric phosphate from section 205.601(h), synthetic substances allowed for use in organic crop production. We agree with the minority view that EDTA must be considered an active ingredient in the ferric phosphate materials petitioned for use as slug baits. Therefore, a TER to evaluate the impacts of EDTA is needed before allowing its use.

We agree with the opinion of the public interest group Beyond Pesticides, which supports the petition to delist ferric phosphate. They argue that ferric phosphate alone is not essential, because it is not effective when used alone, and ferric phosphate in combination with EDTA poses risks to soil organisms, uses highly toxic materials in manufacture, and is not compatible with organic agriculture.

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OXIDIZED LIGNITE (HUMIC ACID)

SUMMARY

Reject the proposal to add "Humic Acid Derivatives – Hydrogen Peroxide extracted," also called oxidized lignite, to § 205.601, synthetic substances allowed for use in organic crop production.

Rationale

- "Humic Acid Derivatives – Hydrogen Peroxide extracted" are synthetic materials.
- The manufacturing process is not available for review.
- Coal derivatives may be toxic.
- Coal mining adversely affects both workers and the environment.
- Oxidized lignite is not allowed by other international organic standards.
- This material is not essential for organic production.

BACKGROUND

A petition was submitted by SHAC Environmental Products, Inc., a Canadian company. The petitioner requested to classify "Humic Acid Derivatives – Hydrogen Peroxide extracted" as a synthetic material allowed for organic crop production. This material is also called oxidized lignite. According to the petition, dated June 2011, no products are being marketed or sold at this time for use in agriculture. The company is seeking registration for a product called SHAC *Revitagro* as a humic acid based soil amendment (SHAC, 2011).

The NOP currently allows some humic acids as plant or soil amendments:

> *§ 205.601 (j) (3) Humic acids – naturally occurring deposits, water and alkali extracts only.*

However, humic acids extracted with hydrogen peroxide are currently prohibited.

Manufacturing process is not available for review

Humic substances are natural materials produced from the decomposition of organic matter (McCarthy, 2001). The petitioned material is a synthetic substance made from the ingredients sub-bituminous coal (a low-grade brown coal also known as lignite) and hydrogen peroxide. Specific information about the manufacturing process has been redacted from the petition as *confidential business information* (SHAC 2011).

Toxicity is not known

Since the starting material is coal, and coal is a carcinogen, this product may be hazardous. Previous Technical Reviews that have been conducted for humic acid materials (TAP, 1996; ICF, 2006) have not emphasized the possible hazards. However, the 2012 Technical Evaluation Report states:

> *"Given the complex nature of humic acids from oxidized lignite, the toxicity is difficult to estimate, but cannot be assumed non-toxic as previous reviews have asserted (The Organic Center, 2012)."*

Environmental effects of coal mining

The petition states that lignite, a brown coal, is the raw material. Lignite is typically produced from surface mines, which are known to have negative environmental impacts. Surface mines may cause erosion, contamination of streams, and acid runoff. Coal mining is also directly hazardous to humans. Mining is linked to respiratory problems in the workers (Finkelman, et al., 2002).

Current use in organic crop production – International Standards

According to the Technical Evaluation Review (The Organic Center, 2012), international standards prohibit the use of lignite extracted with hydrogen peroxide:

- US – Prohibited
- Canada – Prohibited
- CODEX – Prohibited
- EEC – Not allowed (possibly used in some countries)
- IFOAM – Prohibited
- Japan – Prohibited

Humic acids are not essential for organic production

Oxidized lignite is not essential for organic production. Although humic acids have many benefits for plant growth, the humic acids from decaying organic matter have the same benefits as humic acids from lignite (Weil and Magdoff, 2004). Therefore, there are many natural alternatives to this synthetic substance. Alternatives include any decomposition of organic materials, such as mulch, compost, or green manure crops. These natural practices are more consistent with the principles of organic agriculture than the application of synthetic humic acids. In addition, the natural materials will have a beneficial effect on soil structure.

CONCLUSION

The Cornucopia Institute agrees with the majority view of the Crops Subcommittee. Humic acid derivatives extracted with hydrogen peroxide are synthetic substances that are not consistent with organic agriculture. This is a synthetic material, its manufacturing process has adverse impacts on the environment, and it is not essential for organic production.

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PROPYLENE GLYCOL MONOLAURATE (PGML)

SUMMARY

Reject the proposal to add propylene glycol monolaurate (PGML) to the National List section §205.601(e) as insecticides (including acaricides or mite control).

Rationale

- PGML is synthetic.
- PGML is not essential because alternatives are available.
- Broad-spectrum activity can reduce biodiversity.
- PGML kills the natural predators that control mite pests.
- International organic standards do not allow PGML.

BACKGROUND

A petition was submitted in 2009 to add propylene glycol monolaurate (PGML) to the National List §205.601(e) As insecticides (including acaricides or mite control). The petition states that PGML is the sole active ingredient in *Acaritouch*, a contact miticide that is registered for use in conventional crop production (Weatherston, 2009). In conventional crop production, PGML is also registered with the EPA for use as a fungicide, bactericide, and viricide to control post-harvest decay in stored crops (US EPA, 2004).

PGML is synthetic

Propylene glycol, the raw material to manufacture PGML, is obtained from petroleum, natural gas, or coal (The Organic Center, 2012). As a synthetic material, PGML is not consistent with organic crop production systems.

PGML is not essential

Alternatives to PGML for mite control include biological controls, cultural controls, synthetic materials, and natural materials.

Biological controls can be purchased for release on crops. Populations of phytophagous (plant-eating) mites often are kept at low levels by their natural enemies, including predator mites. When broad-spectrum miticides destroy these natural enemies, the populations of plant-eating mites can grow rapidly (Gerson, U. and R.L. Smiley. 1990). Mites can be controlled by several predators, including predatory mites, lady beetles, pirate bugs, and lacewings (The Organic Center, 2012).

Cultural controls include dust control and providing habitat for predators. Since dust is a vector for mites, reducing the dust levels can prevent mites from reaching plant foliage (The Organic Center, 2012). To encourage predators, crops can be grown that provide natural habitat for the predators. Both methods are commonly used in tree fruit crops.

If mite populations increase beyond acceptable levels, there are alternative synthetic materials on the National List that can be used for mite control. These include horticultural oils, insecticidal soaps, sulfur, and sucrose octanoate esters. Natural materials, including Neem and Spinosad are also used to control spider mites and other mites on several crops (The Organic Center, 2012).

The broad-spectrum activity of PGML can reduce biological diversity

PGML can be detrimental to organic production, because it has a broad-spectrum activity that kills both plant pests and beneficial bugs. The fact that it is registered as a fungicide, bacteriocide, and viricide suggests that it will reduce populations of microorganisms, in addition to killing mites.

PGML reduces populations of beneficial mites

PGML kills all mites, both the plant pests and their natural enemies, the predator mites. Beers, et al. (1993) discuss how the implementation of integrated mite control in apple orchards has significantly reduced the use of chemical controls for spider mites in Washington State.

For example, the spider mites are one of the largest, most important and most destructive groups of pests in agriculture. Spider mite populations are typically kept low, because spider mites have several natural enemies. However, in the 1960s, severe spider mite damage was seen on the apple trees, because the broad-spectrum pesticides used for insect control had reduced populations of their natural enemies. Miticides can be highly toxic to predatory mites.

The practice of integrated control involves providing habitat for predator mites, and avoiding the use of broad-spectrum miticides that can harm the predatory mites. This leads to more stable, long-term mite control. As a result of these practices

being implemented, only about 10% of Washington apple orchards are treated with pesticides for control of spider mites.

International organic standards do not allow PGML

According to the Technical Evaluation Report (TER), PGML is not allowed for organic use by any international standard (The Organic Center, 2012). The TER reviewed the organic standards for Canada, The European Union, Japan, Codex Alimentarius, and IFOAM.

CONCLUSION

Organic farmers have found that maintaining a diverse, balanced ecosystem approach to agriculture will prevent or minimize mite damage on their crops. A broad-spectrum miticide is not only unnecessary, but can actually upset the balance of the ecosystem and increase the mite damage on organic crops. Propylene glycol monolaurate (PGML) should not be allowed for use in organic crop production.

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INERT INGREDIENTS IN PESTICIDES

SUMMARY

Support the Crops Subcommittee's proposal to review List 3 and List 4 inerts. We suggest some changes to the proposal before it is fully adopted. The most important change we request is a shorter timeframe for review of these materials, because the review is overdue.

This proposal consists of a roadmap for initiating the review of "inert" ingredients in pesticide formulations. The inert ingredients to be reviewed include the following substances:

- EPA List 4 – Inerts of Minimal Concern
- EPA List 3 – Inerts of Unknown Toxicity

The Crops Subcommittee unanimously approved a motion to adopt the proposed Policy and Procedure Proposal on Other ("Inert") Ingredients in Pesticide Formulations on the National List.

Rationale

- The EPA reassessed inert ingredients and eliminated the list categories in 2006. The NOP regulations that refer to List 3 and List 4 inerts are now out of date.
- Ingredients labeled inert may be harmful to humans or the environment.
- Former EPA List 3 and List 4 inerts may be synthetic substances not appropriate for organic agriculture.

The NOSB Discussion Document has several parts, each of which will be individually reviewed in our comments:

- Proposal for regulatory language
- Steps for review of inerts
- Screening guidelines for the future TERs
- Tentative groupings of substances
- Timeline for review

BACKGROUND

At the present time, the USDA National Organic Program Regulations state that substances on the EPA List 4 are allowed for use in organic livestock production per §205.603(e) and organic crop production per §205.601(m). Substances on the EPA List 3 are allowed for use in passive pheromone dispensers used in organic crop production per §205.601(m).

> *§205.601 (m) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.*
> *(1) EPA List 4—Inerts of Minimal Concern.*
> *(2) EPA List 3—Inerts of unknown toxicity—for use only in passive pheromone dispensers.*
>
> *§205.603 (e) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.*
> *(1) EPA List 4—Inerts of Minimal Concern.*

The references to EPA List 3 and List 4 are now out of date

The EPA reassessed inert ingredients and eliminated the list categories in 2006. The NOP regulations that refer to List 3 and List 4 inerts are now out of date. It is essential to prioritize the evaluation of these substances for their suitability for organic agriculture.

Ingredients labeled inert may be harmful to humans or the environment

The term "inert" has been interpreted to refer to any ingredient that is not listed on the label as the active ingredient. In a pesticide formulation, an ingredient labeled inert may be an essential part of the formulation. Although it may have no pesticidal efficacy on its own, but it may act to increase the effectiveness of the active ingredients.

Although calling a substance "inert" may imply that it is harmless, that is in fact not the case. Some of these materials are by no means harmless. To avoid misleading the consumer, the EPA encourages manufacturers to use the term "other ingredients" instead of "inerts." "Inert" ingredients can have harmful effects on human health or the environment.

Former EPA List 3 and 4 inerts may be synthetic substances not appropriate for organic agriculture

Cornucopia believes that all "inert" ingredients, including those formerly categorized as List 3, List 4A and List 4B by the EPA, should be reviewed as soon as possible. All ingredients in all formulated materials for agricultural production should be reviewed to ensure that they are compatible with organic principles. It is absolutely necessary for the integrity of organics. Organic consumers expect nothing less.

COMMENTS ON THE DISCUSSION DOCUMENT

The NOSB Discussion Document has several parts, each of which will be individually reviewed in our comments:

- Proposal for regulatory language
- Steps for review of inerts
- Screening guidelines for the future TERs
- Tentative groupings of substances
- Timeline for review

Proposal for regulatory language

This proposal would require that above inerts would be reviewed in groups over a four year timespan, with the goal of completing the majority of the reviews by October 2017, the end of the current sunset period.

The NOSB proposes language to replace the current listing at section 205.601(m) and 205.603(e):

> *As synthetic other ("inert") ingredients in pesticide formulations as classified by the Environmental Protection Agency (EPA) for use with nonsynthetic substances or synthetic substances listed in this section that are used as an active pesticide ingredient in accordance with any limitations on the use of such substances.*
> *(i) Substances permitted for use in minimal risk products exempt from pesticide registration under FIFRA section 25(b);*
> *(ii) Reserved (for list of approved other ("inert") ingredients)*

In order to evaluate this new regulatory language, it is necessary to understand FIFRA section 25 B. According to the EPA website, www.epa.gov, pesticides that are exempt from federal registration under section 25(b) of the Federal Insecticide,

Fungicide, and Rodenticide Act (FIFRA), must contain only those inert ingredients that have been classified by EPA as List 4A "Inert Ingredients of Minimal Concern."

Further, the website states:

EPA's determination that an inert ingredient poses minimal risk is based on the following:

- The Agency's recognition of the overall safety of the substance (such as very low toxicity or being practically non-toxic)
- Consideration of the widely available information on the substance's known properties
- A history of safe use under reasonable circumstances

As seen in the above explanation, the EPA does not evaluate substances based on their suitability for organic agriculture. The list of substances, from aluminum silicate to zinc stearate, is more than 9 pages long, and includes a diversity of materials. These substances need to be evaluated for organic use on a case-by-case basis by the NOSB.

We agree that the regulation needs to be changed, but we suggest that section (i) should be deleted. Each synthetic ingredient in a pesticide formulation should be reviewed for approval by the NOSB and listed individually in the regulations. It also allows the NOSB to make the decisions about the chemicals used in organic agriculture, rather than allowing the EPA to make those decisions.

Steps for review of inerts

We support the Proposed Procedure outlining the steps for review. We suggest further clarification on the responsibilities of the CropsSubcommittee, LivestockSubcommittee, and IWG (Inerts Working Group). For example, step F:

> *F. Based on results of group TER, the NOSB **Crops** Subcommittee accepts group to move forward to NOSB agenda, or singles out one or more for individual review. The group will then move forward without the singled out one and that one will be re-reviewed in more detail if necessary.*

While this procedure is fine for materials used in crop production, it does not clarify the procedure for materials allowed for use in organic livestock production per §205.603(e).

Screening guidelines for the future TERs

The inerts screen was modified from one presented an NOSB meeting in 2010. This screening is acceptable.

Tentative groupings of substances

Cornucopia supports the grouping of similar substances classes and reviewing the class as a whole in order to facilitate the review process. Most of the categories are logical because they reflect chemical and functional similarities. However, we caution that each chemical must be individually researched as part of the technical review. The two groups **Nonsynthetic** and **Other** are composed of dissimilar chemicals and need further review. Substances in these two groups will need to be evaluated individually.

Timeline for review

As outlined in the proposal submitted at the NOSB meeting in May 2011, List 3 inerts should have been reviewed by January 1, 2002. Previous Boards have repeatedly stated that List 3 inerts need to be individually reviewed.

Although the timeline for review of these substances currently lists October of 2017 as the expiration date for List 3 and List 4 inerts, we believe that the review process should be expedited to complete these reviews well before that date. Review of the List 3 inerts should have been completed 10 years ago. Review of the List 4 inerts should have been initiated 6 years ago. Given this notable lack of timeliness, review of all inerts should be given a higher priority than review of new petitions to add substances to the National List.

The proposal states, "The NOSB will assess the viability of the timeline after it completes the recommendation on the first few groups of materials." We hope that the timeline will not be extended any further. The timeline for review of inerts has been overly generous. These reviews have been postponed, while reviews of petitions from manufacturers have been prioritized. For example, a petition submitted in March of 2012 for biodegradable mulch has been reviewed and is now ready for full NOP vote, all within 7 months.

To facilitate NOSB review of these materials, a comprehensive, high-quality approach to obtaining the requisite Technical Evaluation Reports should be considered by the NOP.

CONCLUSION

Cornucopia congratulates the Crops Subcommittee for developing this clear and comprehensive proposal for review of inert ingredients from EPA Lists 3 and 4. We

believe that the NOSB should make the review of inert materials a high priority. We urge the National Organic Program to support the NOSB as they expedite these reviews.

ROTENONE

SUMMARY

Support the subcommittee recommendation to add rotenone to section § 205.602 as a prohibited natural substance.

Rationale

- Rotenone is no longer registered by the EPA for use on crops.
- Rotenone is harmful to humans.
- Rotenone is toxic to fish.
- Prohibition protects the reputation of organic agriculture.

BACKGROUND

Rotenone is a botanical pesticide that is currently allowed for organic crop production because it is classified as a natural substance by the NOP. Rotenone acts as a broad-spectrum insecticide when used in crop production. Rotenone also acts as a piscicide, thus it is sprayed on waterbodies to kill fish.

Recent research indicates that rotenone is harmful to humans, and it has been taken off the market for insect control on crops.

The NOSB Crops Subcommittee recommends that rotenone be prohibited for organic production. Although no Technical Evaluation Report was conducted for rotenone, evidence that it should be prohibited is compelling.

Rotenone is no longer registered by the EPA for use on crops

In 2006, registrants of rotenone in the U.S. requested voluntarily cancellation from the U.S. Environmental Protection Agency (EPA) of all livestock, residential and home owner uses, domestic pet uses, and all other uses except for piscicide uses. According to the proposal, the remaining rotenone products are classified as Restricted Use Pesticides, due to acute inhalation, acute oral, and aquatic toxicity.

Rotenone is only labeled for application to waterbodies to kill fish.

A review of the OMRI products list and the WSDA Brand Name Materials List yielded no listings for rotenone. Although the products for crop pest control should have been taken off the market, an internet search in September 2012, revealed some products that contain rotenone may still on the market, for example:

- Bonide Garden Dust, with Copper Sulfate and Rotenone, Dust formulation

Additional internet searches indicate that these products are being replaced by new formulations, but some older products are still available, and are being advertised as allowed for organic gardeners and farmers. Products that contain rotenone may still be on the shelves of farmers and home gardeners. Therefore, given that rotenone may still be available, we support this proposal to clarify its status as a prohibited material.

Rotenone is harmful to humans

The EPA Reregistration Eligibility Decision for Rotenone stated that it has acute oral and inhalation toxicity (USEPA, 2007). This is of particular concern to crop producers because the formulations for crop applications typically are dusts or, less commonly, liquids.

Researchers have found that use of rotenone is correlated with Parkinson's Disease (Tanner CM, et al. 2011). This is particularly important because the data were collected by studying human health as part of the Farming and Movement Evaluation study (FAME). The FAME study was part of the Agricultural Health Study (AHS), a prospective study including 84,740 private pesticide applicators (mostly farmers), recruited 1993–1997.

Rotenone is toxic to fish

Rotenone is registered by the EPA for killing fish. When used on crops, there is potential for rotenone to be washed off crop leaves and into waterbodies, resulting in fish kills.

Prohibition protects the reputation of organic agriculture

Although rotenone is currently rarely, if ever, used in organic agriculture, the reputation of the organic community would benefit greatly from a specific prohibition of rotenone. Organizations that wish to discredit organic agriculture, such as the Hudson Institute and the Heartland Institute, otherwise may use rotenone as an example of a harmful organic pesticide. It would therefore make sense to clearly prohibit rotenone.

CONCLUSION

Rotenone was initially allowed for organic production, along with other botanically-based materials, because it is a non-synthetic. Current research indicates that rotenone is harmful to humans and the environment. Although use of rotenone is probably minimal, at this time, Cornucopia recommends the addition of rotenone to the list of prohibited natural substances, in order to clarify its status.

Cornucopia **supports** the proposal to add rotenone to section § 205.602 as a prohibited natural substance.

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SULFURIC ACID

SUMMARY

Reject the proposal to add sulfuric acid (H2SO4) to the National List (7 CFR §205.601) for stabilization of digested poultry manure to a pH under 4.5 but not below 3.5. This proposal was unanimously rejected by the NOSB Crops Subcommittee.

Rationale

- ✓ Sulfuric acid is detrimental to human health.
- ✓ Sulfuric acid is harmful to the environment. It is one of the primary chemicals in acid rain.
- ✓ Sulfuric acid is a synthetic substance that is not essential for organic production.
- ✓ Use of sulfuric acid is not compatible with organic principles.

BACKGROUND

A petition was submitted to add sulfuric acid (H2SO4) to the National List (7 CFR §205.601) for stabilization of digested poultry manure. As explained in the petition, the digestion of poultry manure is carried out by several types of anaerobic bacteria. The process results in methane gas, a solid granular fertilizer, and a liquid fertilizer, which is the bulk of the end products. The solid product is in a stable form that can be sold as a fertilizer, but the liquid retains its biological activity, which makes it too unstable for transport and storage. It is necessary to reduce the pH of digested poultry manure to a range of 3.5 to 4.5, in order to stop microbial activity, stabilize the product, and ensure a reasonable shelf life (Torello, 2012).

A Technical Evaluation Report (TER) was prepared in 2006, in response to a petition for a similar use of sulfuric acid. The information about the chemical sulfuric acid presented in that TER was accurate. However, the description of the way that the petitioner will use sulfuric acid is not applicable for this petition. The TER states that the sulfuric acid is used to stabilize the solid manure, but the current petition clearly states that the sulfuric acid is needed to stabilize the liquid poultry waste, not the solid.

Hazards to human health

Sulfuric acid is a strong acid. Concentrated sulfuric acid is dangerous to handle because it is very corrosive, causing burns to skin and eyes on contact. Exposure to the mist can irritate the eyes, nose, and throat. Sulfuric acid can also react strongly

with water, liberating heat, and with many solid materials (ICF, 2012). NIOSH recommends that workers who handle sulfuric acid wear protective clothing, eyewear, and breathing protection (NIOSH 2000, 2005).

Sulfuric acid is harmful to the environment

The petition claims that sulfuric acid is obtained by recapturing sulfur dioxide from pollution control devices (Torello, 2012) and its manufacture would be environmentally friendly. This is not adequately verified in the TER. When it is released into the environment, sulfuric acid readily dissolves in water, acidifying lakes. It is one of the primary chemicals in acid rain (ASTDR, 1998).

Sulfuric acid is not essential

Chicken manure can be composted rather than treated with H2SO4. The aerobic process of composting manure results in a product that has several benefits for soil-building. In addition to supplying fertility, compost adds organic matter and introduces beneficial microbes. The liquid fertilizer resulting from digestion of poultry manure, on the other hand, will not add organic matter or beneficial microbes. Although bacteria are used in the process of manure digestion, they are called anaerobic bacteria because they grow in the absence of oxygen. These are not the typical bacteria found in soil, called aerobic bacteria, because they grow in presence of oxygen. Since the purpose of the sulfuric acid is to reduce microbial growth, one would expect the bacteria populations in the liquid fertilizer to be low.

The commercial liquid fertilizer produced as a result of the anaerobic digestion of poultry manure, a liquid fertilizer, will have a pH of approximately 4, which is quite acidic. Although this pH is ideal for a few acid-loving crops, such as blueberries, the soil pH that is best for most crops is pH 7. A pH of 4 is 1,000 times as acidic as neutral pH of 7. The petition and TER do not mention how this liquid fertilizer will affect the microbial life of the soil. Since the few bacteria present will not be typical soil bacteria, and since the fertilizer will be acidic, we expect that this liquid will not benefit soil microbial ecology for most soils.

The TER states that "If the acid is added to manure in the manner described in the petition, … it is unlikely to … result in adverse chemical or biological interactions in the agro-ecosystem. This is because the acid is neutralized by the manure …" (ICF, 2006). Note that this statement refers to a completely different process than the one petitioned. The acid in the petitioned liquid fertilizer will not be neutralized, it will be at a pH of 3.5 to 4.5.

Use of sulfuric acid is not compatible with organic principles

Sulfuric acid is a synthetic substance that is harmful to humans and the environment. The petitioner plans to take poultry manure, a natural substance that has many benefits in organic crop production, and add a synthetic substance to

stabilize it so that the final product can be stored and transported. It is not clear whether the poultry manure would then need to be classified as a synthetic product, due to the synthetic ingredients and processes involved in its manufacture. In this process, the final product is a low pH, biologically inert liquid fertilizer. This product has lost many of the benefits of fresh or composted manure. This use of sulfuric acid is not compatible with organic production.

CONCLUSION

Cornucopia agrees with the Crops Subcommittee vote to reject the proposal to add sulfuric acid (H2SO4) to the National List (7 CFR §205.601) for stabilization of digested poultry manure. We support alternative methods to compost livestock manure.

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MATERIALS SUBCOMMITTEE

RESEARCH PRIORITIES

SUMMARY

Cornucopia **supports** the proposal, with some suggested changes:

- Primary, publicly funded/independent research already exists for carrageenan. We urge the Board to remove carrageenan from the list of research priorities since academic researchers have provided published studies addressing concerns about its health effects.

- Cornucopia urges the Board to include a commitment to utilize the findings of requested research in their deliberations.

- Research priorities should benefit the entire organic community. More effort should be made to solicit comments on research priorities from rank-and-file organic farmers and stakeholders in the independent business community.

Suggested changes to research priorities proposal

We support the Materials Subcommittee's proposal, with some reservations and suggested changes and additions. We agree that primary research should be promoted for topics of interest to the organic community that are persistent and chronic, challenging, and for which primary research is lacking.

We are especially supportive of promoting research on topics that are nebulous (i.e., the research need is hard to identify but the organic agriculture need is clear). For example, improved methods of weed control" because such topics are often most difficult to fund, yet of most interest to organic producers whose methods are complex and not easily reduced to simple research questions.

We take issue, however, with the third criterion, "controversial, (i.e., topics on which there are widely differing perspectives or for which there have been close NOSB votes)."

When a topic has "widely differing perspectives" and led to a "close NOSB vote," it has nearly universally been because researchers funded by public institutions like the National Institutes of Health, or the USDA's Agricultural Research Service, or other public institutions, present one viewpoint, backed by their independently-

funded research, which is made "controversial" only by the attempts of corporate-funded researchers and interests with a financial stake in the research's outcome.

Before we use a recent example relevant to the organic community, we might also cite the current "debate" on climate change. Qualified climatologists have been ringing the alarm bell for decades. However, commercial interests, mostly in the fossil fuels sector, and some of their largest customers, have funded "research" that purposely attempts to perpetuate a continuing debate. The same was true when tobacco industry interests funded doctors and researchers to purposely dispute the deleterious effects of smoking. Today, some of the same academics who were paid by the tobacco industry in the 1970s are using "science" to dispute the benefits of eating organic foods.

Now let's take as an example the most recent close vote on a "controversial" topic in organics: carrageenan. We suspect that carrageenan was added to the list of "research priorities" because it fulfills the "controversial" criterion. Surely, this topic is not "lacking in primary research," and it is neither "persistent," "chronic," "challenging" nor "nebulous." Rather, carrageenan became controversial when corporate-funded scientists encouraged Board members to question the credibility and validity of decades of research funded by the National Institutes of Health and other public institutions, which has not only linked carrageenan to cancer in laboratory animals, but has identified the molecular mechanisms by which carrageenan causes gastrointestinal inflammation.

We therefore request a change to the following language, which we suspect will be used in the future:

- Controversial (i.e., topics on which there are widely differing perspectives **within the independent scientific community** or for which there have been close NOSB votes) **(addition in bold)**

If a topic is controversial because corporate interests oppose research pointing to health or environmental impacts of the products they sell and profit from, it should not be added to the list of "research topics." In the case of carrageenan, if the only scientists who question the credibility of academic researchers are industry-affiliated, we would hope that the NOSB members would weigh the scientists' interests (public interest v. industry interests) in their decision-making process.

Remove "carrageenan" from the list

We urge the Board to remove "carrageenan" from the list of research topics, for the simple reason that **researchers, funded by the NIH and Veterans Administration, have already provided answers to these questions**.

The problem is not that the research is lacking, but rather that the majority of NOSB members during carrageenan's sunset vote accepted the critique of one of their

colleagues that discounted publicly-funded research in deference to the industry's position.

Include commitment to respect the findings of requested research

A comprehensive analysis of primary research, including a review of primary research publications, much of it funded by the NIH and pointing to health concerns of food-grade carrageenan, was submitted to the NOSB both during the written comment period and during the oral testimony at the last NOSB meeting, in Albuquerque.

A physician-scientist with expertise in carrageenan travelled to the NOSB meeting at her own expense to present research that answers most of the questions now listed as "research priorities."

The fact that the presented research was not considered compelling, credible or scientifically valid enough to lead to the removal of carrageenan from the National List, leads us to question the value of the entire "Research Priorities" proposal and exercise.

If the NOSB can so readily ignore primary research that answers questions about relevant topics like carrageenan, why should any scientist or researcher answer the NOSB's call to perform independent research? Will they be assured, if their research findings contradict or inconvenience corporate interests in organics, that their research will at the very least be considered and respected?

We urge the Board to add the following language to the Research Priorities proposal:

> *When researchers answer the NOSB's call to perform primary research on topics that are listed as priorities, the NOSB will consider this research in its decision-making process. NOSB members in their deliberations will also take into consideration the funding source of research that is presented, especially when research is funded by entities with a financial stake in the outcome of the research.*

Research priorities should benefit the entire organic community

The inclusion of "carrageenan" on the list of research priorities raises another concern: research priorities put forth by the NOSB should benefit the organic community as a whole, rather than benefit a handful of stakeholders.

If the NOSB will submit these research questions and priorities to important funders in the organic community, we would encourage that the NOSB make an attempt to gather input from the organic farming community. We doubt that, if asked about

research priorities, anyone other than a handful of processors would include a topic like “carrageenan.”

Organic farmers are faced with serious, on-the-ground problems that must be addressed by research. If the Board is committed to encouraging research funding, it needs to make a systematic attempt to poll farmers on the ground about what they consider to be research priorities.

These research priorities should not focus on the NOSB, but on the organic community as a whole, with a special focus on organic farmers.

HANDLING SUBCOMMITTEE

ASCORBYL PALMITATE AND BETA CAROTENE

SUMMARY

Cornucopia **supports** the unanimous votes of the Handling Subcommittee.

REJECT the proposals to add ascorbyl palmitate and beta carotene to the National List, 7CFR205.605.

- Ascorbyl palmitate and beta carotene are synthetics that have been petitioned for use as preservatives in infant formula, to "prevent rancidity" of oils that are **not** required by the FDA to be added to infant formula.

- Organic standards, under 7CFR205.600(b)(4), prohibit the use of synthetics whose primary purpose is as a preservative.

Fail legal criteria for inclusion on the National List

We agree with the unanimous decisions of the Handling Subcommittee to reject ascorbyl palmitate and beta carotene, which were both petitioned for use as synthetic preservatives.

The organic standards prohibit adding synthetic preservatives to the National List under 7CFR205.600(b)(4).

For both ascorbyl palmitate and beta carotene, the petitioner states that the substance is added to infant formula as a preservative, "preventing oxidation and rancidity" of the lipids in infant formula. The lipids refer to DHA and ARA oil from algae and fungus. Neither ascorbyl palmitate, beta carotene, DHA oil or ARA oil are required by the FDA in infant formula. The two petitioned substances therefore also fail the essentiality criterion, 7CFR205.600(b)(6).

Other uses are allowed under current NOP regulations

Some may attempt to argue that beta carotene and ascorbyl palmitate may be classified as vitamins and should therefore be added to the National List, regardless of their primary purpose as preservatives. We urge the Board to reject this line of reasoning, because if added to foods for their vitamin activity, these materials are already allowed under the "nutrient vitamins and minerals" listing under §205.605(b)(*synthetics allowed*).

Rewarding violations of OFPA

It is worth noting that ascorbyl palmitate and beta carotene are already added to organic infant formula, in violation of OFPA and the organic standards. When will infant formula corporations, with their primary market in conventional, GMO formula, respect our law and regulations?

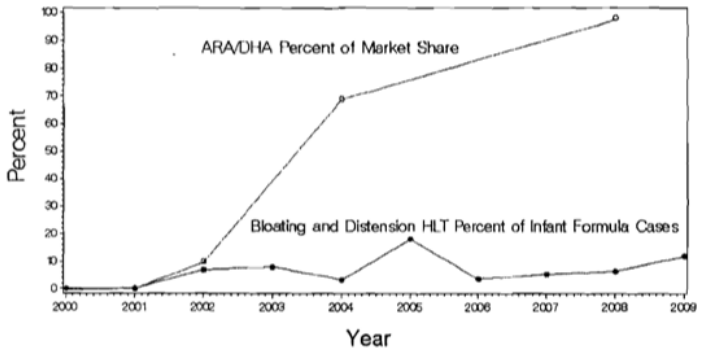
OFPA is clear and straightforward: synthetic ingredients cannot be added to organic foods unless they are specifically allowed. Unfortunately, some NOSB members in the past have been swayed by the argument that materials already found in organic foods should be approved simply by virtue of already being on the market.

If a formula industry lobbyist should dare to claim that the petitions for these two synthetic preservatives should be accepted because a rejection would lead to so-called market disruption, we hope that the NOSB will kindly point out to them that a violation of OFPA should not serve as a reason for accepting a petition, and that the best way to prevent "market disruption" in the future is by petitioning the material and gaining approval **before** adding it to organic foods (as the law requires).

Moreover, synthetic beta carotene and ascorbyl palmitate are added, according to the petitioner, to preserve DHA and ARA oils. While some argue that these materials are "proven safe" and beneficial, the FDA reports that no post-market surveillance has taken place to assure the safety and tolerance of DHA/ARA.

Moreover, FDA data show that the incidence of complaints related to "bloating and distention" in formula-fed infants rose from 0% of adverse reaction reports in 2000, when DHA and ARA were not yet added to formula in the US, to nearly 10% in 2009 when DHA and ARA were present in nearly all formula.

Figure 4. Percent of Bloating and Distension Adverse Events Over Time



The MedDRA symptom categories that we analyzed for were: 1) System Organ Class (SOC) for GI, 2) Preferred Terms (PT) for diarrhea, 3) (PT) for vomiting, and 4) High Level Terms (HTL) bloating and distention.

Furthermore, numerous adverse reaction reports were submitted to the FDA by caregivers and medical professionals after DHA algal oil and ARA fungal oil were first added to infant formula. The rates of these adverse reports only decreased when the alternative of non-fortified formula (formula without DHA and ARA) was no longer available on the market and casual comparisons on their impact to sensitive infants was no longer possible.

CONCLUSION

Ascorbyl palmitate and beta carotene fail two criteria for inclusion on the National List:

- § 205.600(b)(4), prohibiting the use of synthetics whose primary purpose is as a preservative, and
- § 205.600(b)(6), prohibiting the use of synthetics that are not essential to organic handling.

INTRODUCTION: INFANT FORMULA NUTRIENTS

(Lutein, Lycopene, L-carnitine, L-methionine, Taurine, Nucleotides)

Consensus among doctors, scientists, and health advocates is that the only ideal food for an infant is breast milk. While formula feeding has been linked to a long list of health risks, ranging from increased rates of acute infectious diseases and diarrhea to obesity and diabetes later in life, many organic consumers with infants find themselves in the difficult situation of needing to buy infant formula.

Parents or caregivers who need infant formula should be able to buy organic formula with confidence that it conforms to the same legal standards as other organic foods. If produced in accordance with the organic standards, formula would contain only organically produced ingredients, and contain no more than 5% synthetic ingredients **only when they are deemed safe and essential**.

Consumer Demand

In Europe, such options exist. For example, the German company Holle produces a stage 1 infant formula (from birth onwards) that contains organic skimmed milk and organic whey powder as its first two ingredients, organic vegetable oils as the third ingredient, and organic maltodextrin as the fourth ingredient. The only synthetic ingredients are twenty vitamins and minerals that are required by EU infant formula regulations. This formula contains none of the ingredients that US formula manufacturers routinely add to organic formula, such as sugars or syrups, soy lecithin, and synthetic nutrients that are not required by federal infant formula regulations.

In the US, there is currently no infant formula product that fully conforms to the organic standards. All contain at least one synthetic ingredient that is not on the National List, not essential, and not required by the FDA. Most contain multiple non-essential synthetic ingredients.

We have heard from parents who, unable to breastfeed, pay exorbitant shipping costs to import Holle infant formula from Europe. Others have told us that they do not trust any of the "synthetic formulas" and prepare their own formula at home, using ingredients such as raw organic cow's milk, home-made liquid whey, organic coconut oil, etc. Since not everyone has the time to make home-made baby formula (the practice is discouraged by the FDA and the American Academy of Pediatrics), or the money to pay international shipping costs for European organic infant formula, there is clearly a need for truly organic, minimally synthetic infant formula in the US.

Precautionary Principle

Not only is the inclusion of non-approved and non-essential synthetic ingredients in violation of the organic standards (§ 205.600(b)(6)), it goes against the Precautionary Principle. The ESPGHAN (European Society for Pediatric Gastroenterology, Hepatology and Nutrition) Coordinated International Expert Group states:

> ***The inclusion of unnecessary components, or unnecessary amounts of components****, may put a burden on metabolic and other physiologic functions of the infant. Those components taken in the diet, which are not utilized or stored by the body, have to be excreted, often as solutes in the urine. Since water available to form urine is limited and the infant's ability to concentrate urine is not fully developed during the first months of life, the need to excrete any additional solutes* ***will reduce the margin of safety****, especially under conditions of stress, such as fever, diarrhea or during weight loss. [emphasis added]*

While some may counter that synthetic versions of naturally occurring human milk nutrients should not be considered "unnecessary components," it is worth noting that synthetic nutrients are not always absorbed by the infant's body in ways similar to naturally occurring nutrients in breast milk. For example, the technical evaluation report for lutein points out "differences in bioavailability between supplemental lutein in formula and natural lutein in breast milk" (TER 111-112).

In fact, the TER states that due to substantial differences in bioavailability, manufacturers add synthetic lutein at **four times** the levels of naturally occurring lutein in breast milk. We urge the NOSB to take seriously the fact that synthetic versions of nutrients are **not equivalent** to naturally occurring nutrients (this would not be the first time that the organic community disagrees with claims of "substantial equivalency") and reject petitions for unnecessary synthetic nutrients.

"Essentiality"

Cornucopia believes that the National Organic Standards Board is not in a position to determine which nutrients are essential for proper infant growth and development. NOSB members rarely have the necessary credentials and expertise in infant nutrition to make these determinations. The NOSB's job is to determine whether a synthetic ingredient is essential for organic handling.

The responsibility for determining which nutrients are essential in infant formula should lie with the Food and Drug Administration, which in turn relies on expert analyses (such as the Life Sciences Report Office of the American Society for Nutritional Sciences). We believe that the NOSB should only approve petitions for synthetic nutrients that have been deemed mandatory (essential) by the FDA, and then only with an annotation restricting the use to the type of infant formula that

requires the additional synthetic nutrient (commonly soy-based formulas require certain supplements that are naturally found in dairy-based products).

LUTEIN AND LYCOPENE

SUMMARY

Reject the proposals to add lutein and lycopene to the National List, 7CFR205.605.

The organic standards prohibit the addition of synthetic ingredients that are not essential (§ 205.600(b)(6)).

Cornucopia supports the majority positions of the Handling Subcommittee.

Both lutein and lycopene are:

- **Not** mandatory according to FDA infant formula regulations
- **Not** permitted in EU conventional or organic infant formula
- **Unproven** to be beneficial: no studies showing benefits to infant health or development from the addition of synthetic lutein or lycopene have been published.

Without any scientific evidence that these synthetic nutrients benefit infant health or development, and given that these nutrients are **prohibited even in conventional infant formula in the EU**, we urge the Board to reject the petitions for lutein and lycopene.

Legal basis for rejecting the lutein petition

Handling Subcommittee (HS) members who voted in favor of lutein gave two reasons. One is that lutein is currently used in some organic products. There is no provision in the law or regulations that justifies approving a synthetic ingredient simply because it is added to organic foods before it was reviewed and legally added to the National List.

Scientific basis for rejecting the lutein petition

The second reason listed in the HS recommendation for why some members voted to accept the lutein petition is "the role it plays in eye health of infants (and adults)." If lutein is important for eye health, consumers can choose to eat more organic foods naturally containing lutein.

Under no circumstance should a synthetic nutrient be approved for use in foods other than when required in infant formula (unless required by law in another type of food). Nutrients are always present in food, and toddlers, children and adults do

not need synthetic supplementation when organic food is a perfectly suitable "alternative."

Moreover, when the European Food Safety Authority examined the scientific evidence for a health claim related to lutein and eye health, the expert panel concluded: "On the basis of the data presented, the Panel concludes that the **evidence provided is insufficient to establish a cause and effect relationship between the consumption of lutein and maintenance of normal vision**."

We question the scientific basis for the HS's minority view that lutein is important in eye health. A 2010 study by Capeding et al. explored the effects of lutein supplementation on infant growth, and found no differences. The authors also noted: "No data currently exists which demonstrates that lutein supplementation can influence visual acuity in infants."[1]

A search on PubMed, the scientific database of the National Institutes of Health, retrieved no published studies of clinical trials exploring the benefits to eye health and development when synthetic lutein is added to infant formula.

The only infant formula maker that currently adds lutein is Abbott Nutrition, makers of Similac. On its website, no studies are cited to support marketing claims that lutein benefits eye health. Language is vague: "Lutein concentrates in the eye, and a new study shows Lutein is found in parts of the brain involved in memory and learning."[2] No scientific studies are provided to back claims that adding lutein to infant formula benefits infant eye health or development.

The petition, by Kemin Foods, lists some hypotheses based on the fact that lutein is found in human breast milk, but studies have shown that lutein in infant formula is not as bioavailable (TR 111-112).

Even the petition itself merely states that infants "could likely benefit" from lutein, but provides no clinical trials to back this statement. Only one clinical trial is cited, which found higher levels of biological antioxidant potential (BAP) but no other measurable beneficial outcome on eye development.

Since even the petitioner is unable to provide convincing scientific evidence of lutein's benefits, it is premature for the three supporting members of the HS to state that lutein should be approved because of "the role it plays in eye health of infants (and adults)."

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[1] Capeding R, Gepanayao CP, Calimon N, Lebumfacil J, Davis AM, Stouffer N and Harris BJ (2010) Lutein-fortified infant formula fed to health term infants: evaluation of growth effects and safety. Nutr. J 9:22.

[2] http://m.similac.com/brain-and-eye-development

Other ingredients in lutein

The petitioner failed to comply with OFPA's requirement that the NOSB obtain a full list of ingredients used in the manufacturing of the material. Details regarding the manufacturing process were withheld as "confidential business information."

We urge the Board to reject any petition for which the petitioner refuses to share the manufacturing process and all the inputs and ingredients used to produce the material.

No scientific basis for accepting lycopene

Lycopene is **not** considered mandatory by FDA infant formula regulations. It is not permitted to be added to infant formula in the European Union (conventional or organic). The Life Sciences Research Office's American Society for Nutritional Sciences' report does **not** list lycopene as a mandatory or recommended nutrient in infant formula.[3] The Scientific Committee on Food of the European Union does **not** list lycopene as a mandatory or recommended ingredient.[4]

The European Society for Pediatric Gastroenterelogy, Hepatology and Nutrition, Expert Committee does **not** consider lycopene to be a mandatory ingredient; in fact, the expert committee did not even consider lycopene in its analysis.

Cornucopia researchers could not locate scientific studies that report on benefits to infant health and development from the addition of synthetic lycopene to formula.[5]

The only formula manufacturer that currently adds lycopene to infant formula is Abbott Nutrition (Similac Organic). On its website, it does not specifically market the addition of lycopene, which is rarely mentioned, and no scientific citations are given to justify the addition of lycopene.

In the petition, the justification for adding synthetic lycopene seems to be based on studies showing naturally occurring levels of lycopene in human colostrum and breast milk. Naturally occurring lycopene is the product of a mother's consumption of naturally occurring lycopene in foods like tomatoes. We have stated this repeatedly in past public comment, but it is point that bears repeating: the organic community has long rejected the notion that synthetic nutrients are equivalent to naturally occurring nutrients. A mother's body, for example, does not utilize toluene, a neurological toxin derived from benzene (utilized to make synthetic

[3] http://jn.nutrition.org/content/128/11/suppl/DC1

[4] http://ec.europa.eu/food/fs/sc/scf/out199_en.pdf

[5] Using PubMed and search terms such as "lycopene and infant formula"

lycopene for infant formula), to extract the lycopene from the tomato before it enters her breast milk.

Synthetic nutrients are different from naturally occurring nutrients in breast milk, and until credible scientific studies show benefits from the addition of synthetic nutrients and the FDA mandates their addition to infant formula, they should not be considered essential in organics and should not be allowed.

CONCLUSION

Cornucopia urges the Board to reject the petitions for lutein and lycopene. These synthetic nutrients are not required to be added to infant formula by the FDA and are therefore not essential to organic handling. It bears noting that the European infant formula regulations prohibit the addition of synthetic lutein and lycopene to any kind of formula – conventional or organic, infant formula or toddler formula – because scientific evidence of benefits is lacking.

L-CARNITINE AND L-METHIONINE

SUMMARY

L-methionine and l-carnitine raise a dilemma that the NOSB will need to address. In addressing the petitions for l-methionine and l-carnitine, we urge the Board to consider the following:

- l-methionine and l-carnitine are produced in ways that are not compatible with organic handling (their manufacture involves toxic and environmentally polluting materials).

- L-methionine and l-carnitine must be added to soy-based infant formula to ensure basic nutritional needs are met. Humans are omnivores, and soy-based infant formula is vegan and therefore does not provide a number of basic nutrients needed for proper infant growth.

The dilemma with l-carnitine and l-methionine

While the decision to reject synthetic nutrients that are not deemed essential by the FDA should be easy, two of the petitioned nutrients present the NOSB with a difficult dilemma.

L-carnitine and l-methionine appear to be necessary supplements in soy-based infant formula. Since humans are omnivores, and newborn humans naturally rely exclusively on human milk for sustenance for the first 4-6 months of life, the formulation of a completely vegan milk substitute that meets basic protein requirements of infants seems impossible without the addition of l-methionine and l-carnitine. Currently, the only sources that appear available are synthetic.

During the Handling Subcommittee meeting on July 17, 2012, a Team Leader for Infant Formula Regulation at the FDA presented to the HS that l-methionine is required to be added to soy-based formula in order to meet basic protein requirements listed in FDA regulations.

The Team Leader did not appear present at the HS's discussion on l-carnitine. While a search of the FDA regulations suggests that l-carnitine is not specifically mentioned, the European Union's Directive for infant formula does list l-carnitine as a required nutrient in soy-based infant formula.

It appears that soy-based infant formula without added l-carnitine could harm the development of a formula-fed infant, hence its listing as a required nutrient in soy-based formula the EU.

The EU's decision to require l-carnitine in soy-based formula is based on an analysis by the EU's Scientific Committee on Food:

> ***The addition of L-carnitine to infant formula based on soy protein isolate and hydrolysed protein to give a content of at least 7.5 moles/100 kcal (1.2 mg/100 kcal) is required*** *in the EU and the Committee does not propose a change.*
>
> *Cow's milk is rich in carnitine (around 5mg/100 kcal*) compared to human milk, therefore carnitine addition to cows' milk-based formula is not necessary.*
>
> *The Committee considers the addition of carnitine to follow-on formula is not necessary. Supply from appropriate complementary food and from endogeneous synthesis should be sufficient in older infants.*[6]

The European Society for Pediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) also recommends the addition of l-carnitine:

> *The recommendations of previous expert reviews (2,3) for a minimum L-carnitine content of 1.2 mg/100 kcal are supported. In contrast to the SCF, LSRO suggested a maximum level of 2 mg/100 kcal based on the upper end of the usual range found in human milk (2). In the absence of indications of any untoward effects of higher L-carnitine intakes in infants, the IEG concluded that no maximum level is needed to be set.*

While apparently essential in soy-based infant formula to prevent serious malnutrition, the materials used in the processing of synthetic l-methionine and l-carnitine present the Board with a dilemma.

L-methionine's production includes materials such as acrolein, an EPA Hazardous Air Pollutant, and hydrogen cyanide, described by the Centers for Disease Control and Prevention as a "systemic chemical asphyxiant" and "chemical warfare agent," "used commercially for fumigation, electroplating, mining, chemical synthesis, and the production of synthetic fibers, plastics, dyes, and pesticides."

The production of synthetic l-carnitine may involve biotechnology (we urge the Board to find out whether l-carnitine currently used in organic infant formula meets the organic standard's requirements prohibiting "excluded methods") and

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[6] http://ec.europa.eu/food/fs/sc/scf/out199_en.pdf

epichlorhydrin, a list 2B material (possible human carcinogen) by the International Agency for Research on Cancer.

Given this dilemma, we urge the Board to consider two options for l-methionine and l-carnitine.

Option 1

Approve l-methionine and l-carnitine with the annotation: "For use in soy-based infant formula only."

Option 2

Reject l-methionine and l-carnitine, with the understanding that organic soy-based infant formula will no longer be available on the US market (**this would be equivalent to the European Union, where organic soy-based infant formula does not exist**).

We urge the NOSB to be consistent – either reject both l-carnitine and l-methionine, or accept both with the proposed annotation that it be allowed only in soy-based infant formula.

Cornucopia would not be opposed to the NOSB voting to reject the petitions for l-carnitine and l-methionine, but only with the understanding that organic soy-based formula would therefore be unavailable on the market.

Recommended change to annotation

Please note that our annotation differs slightly from the annotation recommended by the HS. The HS wrote "formula made with isolated soy-based protein." Not all infant formula manufacturers use isolated soy protein, which has, in fact, never been approved by the NOSB for use in organic handling. Soy protein isolate is notoriously difficult to produce without the use of strong solvents such as hexane. Some formula manufacturers use soy protein concentrate, which can be manufactured without the use of solvents, but rather uses mechanical extraction techniques.

Therefore, we urge the Board to change the annotation to "soy-based" rather than "isolated soy-based protein."

Search for alternatives

If the Board approves the petitions, we would urge the Board to include a statement in the recommendation that formula manufacturers should actively engage in research to develop a **natural** source of l-methionine and l-carnitine.

CONCLUSION

Unlike the other petitioned synthetic nutrients, l-methionine and l-carnitine are considered essential nutrients in soy-based infant formula according to the European Union, the European Society for Pediatric Gastroenterology, Hepatology and Nutrition, and in the case of l-methionine, the US Food and Drug Administration.

Synthetic l-methionine and l-carnitine involve toxic and polluting substances in their manufacturing processes, and therefore fail the criteria in section 205.600(b)(2) which require that the substance's manufacture do not have adverse effects on the environment and are done in a manner compatible with organic handling. We would not be opposed to the NOSB rejecting the petitions on these grounds, but would caution that organic soy-based infant formula may therefore not be available.

It appears that l-methionine and l-carnitine do meet the essentiality criterion, since experts in the European Union have deemed the nutrients to be mandatory in soy-based formula (note, however, that organic soy-based formula does not appear to be available in the EU).

TAURINE AND NUCLEOTIDES

SUMMARY

Rejectthe proposals to add taurine and nucleotides to the National List, 7CFR 205.605.

Cornucopia supports the majority position on taurine but opposes the majority position to add nucleotides. It is unclear why the majority position for taurine and nucleotides differ, since both are:

- **Not** mandatory according to FDA infant formula regulations
- **Not** mandatory in EU conventional or organic infant formula; not permitted in EU organic infant formula
- **Unproven** to be beneficial: while some studies exist suggesting benefits to infant health or development from the addition of synthetic taurine or nucleotides, expert groups have not determined the scientific evidence to be strong enough to mandate their addition to infant formula.

While some scientific studies point to benefits from the addition of synthetic taurine and nucleotides to infant formula, the evidence remains mixed. The FDA does not require the addition of these nutrients to infant formula. The EU allows these nutrients in conventional infant formula, but does not require them. Because they are not required in infant formula, and do not appear on the EU's list of approved synthetics, EU regulations prohibit taurine and nucleotides in organic infant formula.

Taurine

The EU's decision not to mandate the addition of taurine to infant formula is based on their Scientific Committee on Food's 2003 analysis of the scientific literature: "it is added to many infant formulae without adverse effects and **little evidence of benefit**."[7] The SCF concluded that the mandatory addition of taurine, including in hydrolyzed protein formula, is not necessary.

The European Society for Pediatric Gastroenterelogy, Hepatology and Nutrition, Expert Committee does not consider taurine to be a mandatory ingredient, and sets the optional supplementation level at a maximum of 12 mg/100 kcal.

Nucleotides

[7] http://ec.europa.eu/food/fs/sc/scf/out199_en.pdf

While some studies exist, including one meta-analysis, that suggest benefits to formula-fed infant health from the addition of nucleotides, no international regulatory body (EU, FDA) or expert group (AAP, ESPGHAN, LSRO) considers nucleotides to be essential or required in infant formula.

Currently, expert groups recognize that the scientific basis for adding nucleotides is mixed. For example, the United Nation's UNICEF writes:

> *Dietary nucleotides have long been suggested to have beneficial gastrointestinal and immunological effects and have been added to infant formulas for over 30 years.*
>
> ***However the evidence to support this is not strong*** *(Yu 1998, Gutiérrez–Castrellón et al 2007).*
>
> *Although nucleotide supplementation may "improve" the composition of the gut bacteria in formula–fed infants, this does not necessarily translate into a reduced incidence of gastrointestinal infections (Singhal et al 2008).*[8]

The EU's decision to permit, but not to mandate the addition of nucleotides is based on the Scientific Committee on Food's review of the science. The committee also noted the possibility that nucleotides "might occur in human milk only as a by-product of milk formation that reflect metabolic activity of the mammary gland tissue." Without convincing scientific evidence that nucleotides benefit infant health, the addition of synthetic nucleotides to organic infant formula should not be allowed until the FDA considers them necessary and mandatory.

Reject the HS proposed annotation for nucleotides

We are especially opposed to the annotation proposed by the HS:

> *Nucleotides—allowed for infant formulas only in the "organic" and "made with organic categories". Nucleotides are allowed for the "made with organic claim" on all other food products.*

We see no justification for even considering allowing nucleotides in the "made with organic" category for foods <u>other</u> than infant formula, because nobody has requested or recommended this. The petitioner stated its current use to be infant formula, and does not suggest nucleotides should be added to other foods, or even that their addition would confer any benefits to consumers other than formula-fed infants.

8

http://www.unicef.org.uk/Documents/Baby_Friendly/Leaflets/health_professionals_guide_infant_formula.pdf

The European Food Safety Authority concurs when it examined possible health benefits in adult foods and concluded: "On the basis of the data presented, the Panel concludes that a cause and effect relationship has **not** been established between the consumption of nucleotides and immune defence against pathogens."

It is therefore unclear why some members of the HS would vote to allow for uses **beyond** what is requested by the petitioner, and we question whether the NOSB has the authority to approve a material other than for uses listed in the petition.

Furthermore, we are currently not aware of any conventional foods (other than infant formula) containing nucleotides.

FDA should decide, not NOSB

Taurine and nucleotides are not essential in organic handling, because organic infant formula can legally be manufactured without these ingredients. The FDA does not require taurine or nucleotides.

If, in the future, scientific evidence becomes convincing that infant formula should be required to contain these ingredients, we urge infant formula manufacturers to devote equivalent resources to convincing the FDA to add them to their infant formula regulations.

CONCLUSION

Cornucopia urges the NOSB to reject the petitions for taurine and nucleotides, which are not mandatory nutrients in infant formula according to the FDA. No international regulatory agency or expert body that we reviewed has mandated the addition of these nutrients to infant formula.

INFANT FORMULA PETITIONS: CONCLUSION

The organic standards prohibit the addition of synthetic ingredients that are not essential (§ 205.600(b)(6)). With the possible exception of l-carnitine and l-methionine in soy-based formula, all petitioned synthetic nutrients are neither required in infant formula by the FDA nor considered mandatory by expert infant feeding groups. The petitioned ingredients therefore fail the essentiality criterion.

The synthetic nutrients also all fail the criterion in section 205.600(b)(2) since all are synthetic, often using toxic and polluting substances such as acrolein, hydrogen cyanide and hexane in their manufacture.

If, in the future, infant nutrition experts at the Food and Drug Administration consider any of these petitioned nutrients to be essential, they should be added to the FDA's list of required ingredients (21CFR107.100). Assuming the NOP's proposed rule from January 2012, to amend the annotation for "vitamins and minerals" on § 205.605(b), goes into effect, these nutrients will then be automatically allowed in organic infant formula. The proposed rule's annotation would allow any nutrient required in infant formula to be present in organic infant formula:

> *"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."*

This proposed rule would put the responsibility for determining which nutrients are necessary in infant formula in the hands of FDA infant nutrition experts, rather than on the NOSB – a citizen panel with expertise in organics, not infant nutrition.

APPENDIX A

	Cornucopia recommendation
Lutein	No
Lycopene	No
Taurine	No
L-Carnitine	Only with the annotation: "for use in soy-based infant formula only"
L-Methionine	Only with the annotation: "for use in soy-based infant formula only"
Ascorbyl Palmitate (preservative)	No
Beta carotene (preservative)	No
Nucleotides	No

APPENDIX B

Current Uses by Dairy Infant Formula Manufacturers[i]

	Similac Organic	Earth's Best organic	Baby's Only Organic	Vermont Organics	Bright Beginnings Organic	Parent's Choice Organic (Walmart)
Lutein	Yes	No	No	No	No	No
Lycopene	Yes	No	No	No	No	No
Taurine	Yes	Yes	Yes	Yes	Yes	Yes
L-Carnitine	Yes	No	No	No	No	No
L-Methionine	No	No	No	No	No	No
Ascorbyl Palmitate (preservative)	Yes	Yes	No	Yes	Yes	Yes
Beta carotene (preservative)	Yes	Yes	No	Yes	Yes	Yes
Nucleotides	Yes	Yes	no	Yes	Yes	Yes

APPENDIX C

Current Uses by Soy Infant Formula Manufacturers[ii]

	Earth's Best Soy	**Baby's Only Organic Soy**	**Vermont Organics Soy**
Lutein	No	No	No
Lycopene	No	No	No
Taurine	Yes	Yes	Yes
L-Carnitine	Yes	Yes	Yes
L-Methionine	Yes	Yes	Yes
Ascorbyl Palmitate (preservative)	Yes	No	Yes
Beta carotene	Yes	No	Yes
Nucleotides	Yes	No	No

APPENDIX D

FDA Requirements and Expert Recommendations[iii]

	Food and Drug Administration	**European Society for Pediatric Gastroenterelogy, Hepatology and Nutrition, Expert**	**European Union Infant Formula Directive**	**American Academy of Pediatrics***

		Committee (2005)		
Lutein	Not required	Not reviewed	Not allowed	Not recommended
Lycopene	Not required	Not reviewed	Not allowed	Not recommended
Taurine	Not required	Not mandatory; optional up to 12 mg/100 kcal	Permitted; not mandatory	Not recommended
L-Carnitine	Not required	Recommended at a minimum of 1.2 mg/100 kcal (only needed in soy)	Must be added to soy formula to achieve 1.2 mg/100 kcal	Not recommended
L-Methionine	Not required	Proposed level: 24 mg/100 kcal	Must be added to soy formula to achieve 29mg/100 kcal	Recommended to bring protein quality to levels equivalent to human milk
Ascorbyl Palmitate (preservative)	Not required	Not mandatory; not recommended	Not allowed	Not recommended
Beta carotene	Not required	Not mandatory; not recommended	Not allowed	Not recommended
Nucleotides	Not required	Not mandatory; recommended as optional	Permitted but not mandatory, max. level: 5 mg/100 kcal	Not recommended

* The AAP recommends the addition of iron to infant formula, but does not recommend any nutrients that are not required by the FDA. The AAP merely states that L-methionine, L-carnitine and taurine are added to soy formula because these animal-based amino acids are present in human milk but absent in plant-based foods such as soy formula.
http://pediatrics.aappublications.org/content/101/1/148.full

OTHER INGREDIENTS

DISCUSSION DOCUMENT

The law (Organic Foods Production Act of 1990) is clear: a synthetic ingredient not appearing on the National List may not be added to an organic product during processing or any postharvest handling.

> ***SEC. 2111. [7 U.S.C. 6510] HANDLING.***
> *(a) IN GENERAL.—For a handling operation to be certified under this title, each person on such handling operation shall not, with respect to any agricultural product covered by this title—*
> *(1) add any synthetic ingredient not appearing on the National List during the processing or any postharvest handling*

The law does not distinguish between ingredients and "other ingredients," it simply and straightforwardly states that ***all ingredients*** in certified organic foods must meet the law's criteria for inclusion in organic foods.

The organic standards state:

> ***7CFR§ 205.301(b)*** *"Products sold, labeled, or represented as "organic."*
>
> *A raw or processed agricultural product sold, labeled, or represented as "organic" must contain (by weight or fluid volume, excluding water and salt) not less than 95 percent organically produced raw or processed agricultural products.*
>
> ***Any remaining product ingredients must be organically produced****, unless not commercially available in organic form,* ***or must be nonagricultural substances or nonorganically produced agricultural products produced consistent with the National List*** *in subpart G of this part. If labeled as organically produced, such product must be labeled pursuant to §§ 205.303. [Emphasis added]*

To address any potential confusion, the National Organic Program specified in 2007 in a notice published in the Federal Register that "only single substances may be petitioned for evaluation; formulated products cannot appear on the National List."[iv]

As noted in the Handling Subcommittee's discussion document, when challenged in court during the Harvey case, the courts agreed that all non-organic non-agricultural ingredients must be on the National List:

> *"In the final ruling on the Harvey II case the Courts determined that Congress did not distinguish between the general term "ingredients" and "processing*

aids," and authorized the use of synthetic substances, whether ingredients or processing aids, for the use in handling operations so long as they appear on the National List."

Massive and widespread violations of OFPA and consumer trust

The success and continued growth of the organic industry depends in large part on consumer trust in the organic label, which in turn depends on the NOSB, USDA and industry's adherence to the law.

Without question, if organic consumers knew that the organic products they buy could contain unapproved ingredients such as polysorbate 80, sodium benzoate, polyacrylamide, etc. and processed with materials such as hexane and propylene glycol (and these are just a few of the "other ingredients" that are mentioned in past materials petitions and TRs), they would likely feel betrayed.

Survey data from PCC Natural Markets in Seattle, the largest cooperative grocer in the country, support our understanding that the majority of organic consumers likely expect ***all ingredients*** in organic foods to be free from unapproved ingredients and processing aids. PCC Natural Markets surveyed 1,432 consumers and published its results in August 2011. The survey found that algal oil containing unapproved "other ingredients" would <u>not</u> be purchased by an overwhelming majority of shoppers.

For example, 78.3% of shoppers would not purchase products with algal oil containing synthetic stabilizers, and 88.6% would not purchase products containing algal oil with glucose syrup solids. Both ingredients are currently found in certain brands of organic baby food containing algal oil. 88.6% would not purchase a source of DHA if it were extracted with hexane. Yet, since these ingredients are not required to be listed in the ingredients lists, most consumers likely do not realize that when they buy an organic product with "algal oil" in the ingredients list, they are buying a product with glucose syrup solids and synthetic stabilizers.

Clearly, the failure of past Boards, and the National Organic Program, to fulfill the law's requirements has created an unfortunate situation of massive consumer fraud and widespread violations of the law. Consumers expect all ingredients in their foods to be organic or carefully reviewed and approved, as stated in the law, but the opposite is the case. Ingredients such as polysorbate 80, sodium benzoate, polyacrylamide and countless others, are routinely added, as "ingredients of ingredients," to organic foods.

While an organic parent would likely avoid any food listing sodium benzoate as an ingredient, given its potential link to ADHD in children, these same parents may unknowingly be feeding foods with sodium benzoate to their children; for example, sodium benzoate is listed as an ingredient in rennet, which appears in many organic cheeses.

It is unclear what has been the legal basis for the NOSB, USDA and industry's assumption that "other ingredients" are allowed unless prohibited in an annotation, when the law states the exact opposite: OFPA requires that all ingredients are prohibited unless organic or specifically allowed.

According to the current *modus operandi* of the organic industry and the USDA, an ingredient containing multiple unapproved sub-ingredients, which could include anything ranging from artificial sweeteners, to GMOs, to synthetic preservatives, could be added to organic foods.

For a vast number of materials currently on the National List, neither the petition nor the TR identifies the ingredients and processing aids used, despite the clear requirement in OFPA that the Board work with manufacturers of petitioned materials to obtain a full list of ingredients.

Alarmingly, a handful of petitions and TRs even mention that ingredients and processing aids cannot be disclosed because of "trade secrets," yet the materials were approved. As a result, it is unclear whether anybody actually knows whether potentially harmful ingredients, like artificial sweeteners and preservatives, are appropriately kept out of organic foods, as the law requires.

Solutions

The Handling Subcommittee, in concert with the Materials Working Group (dominated by the largest organic industry trade/lobby group and its members), offers three possible solutions, which we urge the Board to reject. Instead, we urge the Board to adopt a fourth option ("Option D"), designed to ensure that widespread past violations of OFPA will be corrected, and future violations prevented.

Shortcomings of Option A and B

Options A and B do not adequately correct the shortcomings of the current situation, and fail to conform to the law's requirement that all ingredients be either organic or allowed.

Reject Option A

Option A would merely require that "other ingredients" meet "baseline criteria." We question the legality of substituting "baseline criteria" for current requirements in the law and organic standards.

The first of the "baseline criteria" is that the material must be on the National List. We believe this is the only criterion of the "baseline criteria" that meets the requirement in OFPA.

All other criteria listed in the "baseline criteria" are in violation of OFPA, since OFPA clearly states that all ingredients must either be organic or on the National List.

Moreover, one of the criteria is GRAS status. We would hope that the NOSB, by now, realizes that GRAS is perhaps the most meaningless regulatory term in US food policy history.

GRAS can be self-determined (e.g. "self-assigned") by the manufacturer of the product. Nanotechnology ingredients are GRAS. Aspartame is GRAS. Sodium benzoate is GRAS. High fructose corn syrup is GRAS. We urge the NOSB to consider, now and in future discussions, that GRAS is the epitome of the corporate-friendly, anything-goes regulatory framework from which organic consumers seek protection in the more highly regulated organic label. Listing "GRAS" as a criterion for anything in the organic standards or organic policy is absurd—it merely institutionalizes the blessing of virtually any material that is currently used in conventional food production.

Reject Option B

Option B has positive aspects, but does not go far enough. For example, it would still allow prohibited synthetic incidental additives in substances on § 205,605(b): "Synthetic incidental additives are allowed in § 205.605(b) items if they are included and documented in the NOSB review." Option B would also allow exceptions for no apparent reason: "NOSB can recommend exceptions for new materials that are petitioned as appropriate."

Shortcomings of Option C

While there are many virtues to Option C, it seems unnecessary to suggest that the regulatory framework of the National List be changed. We believe that the problem can be addressed without adding new sections to the National List. Synthetic incidental additives currently can be petitioned to § 205.605(b) for a specific purpose. For example, sodium benzoate could be petitioned for use in rennet only.

Moreover, we urge the Board to reject Option C because it relies on regulatory definitions used by the FDA, which we consider inappropriate for the organic community.

Specifically, Option C adopts FDA's regulatory distinctions between "ingredients" and "incidental additives." We oppose the adoption of this FDA distinction, because they keep consumers in the dark about what is in their food. While "ingredients" have to be listed in the ingredients listing on packaging, "incidental additives" do not – **even though they are <u>not removed</u> during processing and <u>are present in the final product</u>**.

As a result, if an ingredient like sodium benzoate is added as a component of another ingredient, **it does not have to be listed on the ingredient list**. Without a doubt, organic consumers want to know what is in their food, regardless of whether it was added as an "ingredient" or an "incidental additive."

It is also worth mentioning that the FDA's determination of what has to be listed and what doesn't have to be listed seems arbitrary – the definition includes vague terms such as "significant amounts" and "technical effect in the final product." Current research, especially new findings about endocrine disruptors, brings into question the appropriateness of using terms such as "significant amounts."

Our understanding of "significant amounts" is constantly shifting as science evolves, and in the case of endocrine disruptors, "low levels" and "significant amounts" are not necessarily interchangeable as low doses may do the most harm. Moreover, many concerned parents undoubtedly consider **any** amount of a potentially harmful substance such as sodium benzoate to be "significant." We therefore strongly urge the NOSB not to adopt the FDA's arbitrary language distinguishing "ingredients" and "incidental additives."

Instead, **we strongly urge the NOSB to use OFPA and the current standards as the legal basis for developing the "other ingredients" policy, rather than incorporating FDA's terminology which keeps consumers from knowing the full list of ingredients in their foods.**

The USDA's organic regulations clearly state that an "ingredient" is "any substance used in the preparation of an agricultural product that is still present in the final commercial product as consumed." We see no reason to change this definition. If it is present in the final product, it is an ingredient – period.

Option D

- In accordance with OFPA (SEC. 2111. (7 U.S.C. 6510)), all non-organic non-agricultural ingredients and processing aids used during organic handling must appear on the National List.

- The NOSB uses OFPA's criteria for evaluating petitioned materials (SEC. 2118 7 USC 6517(c))

- Only single substances can be petitioned, formulated products cannot appear on the National List.
    - Example: "algal oil" contains other types of oil, artificial sweeteners and preservatives. "Algal oil" can appear in an organic product only if all ingredients are either organic (e.g. organic sunflower oil) or on the National List (e.g. tocopherols).

- During the petition process, the NOSB works with manufacturers to obtain a full list of ingredients, in accordance with OFPA (7 USC 6518(l)(2))[v] to allow the NOSB to determine whether all ingredients meet OFPA's requirements. No petition will be approved unless all ingredients have been disclosed and deemed legal by the NOSB.

We would encourage adding a priority list, with categories such as "vitamins and minerals" and "enzymes" prioritized and cleaners, sanitizers, disinfectants and other substances that are secondary direct and indirect food additives listed as a low priority.

Incorporating § 205.606 in the discussion document

We agree with the Handling Subcommittee's decision to incorporate § § 205.606 into the policy options in the discussion paper. We believe that the materials on § § 205.606 should be held to the same standard, and should not be preserved, diluted, colored, flavored or stabilized with a prohibited substance.

CONCLUSION

The impetus for the request by the NOP to develop a policy for "other ingredients" is simple, and the solution can be simple as well. All ingredients that end up in organic foods, whether as major ingredients, minor ingredients, or ingredients of ingredients, must either be organic or appear on the National List.

In short, this is an opportunity to correct widespread organic fraud, which most organic consumers are not aware of. OFPA requires that every non-organic ingredient be prohibited unless specifically allowed. If it is true that ingredients contain synthetic preservatives, synthetic sweeteners, and other unapproved ingredients, this constitutes a massive, industry-wide violation of OFPA.

These mistakes need to be corrected. The NOSB needs to recognize and understand the requirements of OFPA and implement them. It does not help to make things more complicated, as Option C proposes. And for Option A and B, the legal requirements of OFPA simply are not met (the HS failed to note a "con" for Option A and B: " violates OFPA.").

POLICY DEVELOPMENT SUBCOMMITTEE

CONFLICT OF INTEREST

SUMMARY

Cornucopia believes the proposal is a step in the right direction, but urges the following issues to be considered prior to a vote:

- A Board member whose employer is actively lobbying other Board members to vote a certain way should be considered to have a conflict of interest. If such activity comes to light during the Board meeting, the Board member in question should not vote on that issue.

- Consider whether the NOP should make the final determination of whether a conflict of interest exists.

- Cornucopia suggests adding a line to this recommendation to clarify that if a Board member is an employee of an entity that sells a substance on the agenda, or products containing a reviewed substance, the Board member has a perceived conflict of interest and should recuse him/herself from discussion and voting.

- We continue to urge the COI policy to include a section on contractors working on Technical Evaluation Reports.

Background

Like many others in the organic community, The Cornucopia Institute believes in transparency, clear Conflict of Interest (COI) definitions, and supports procedures for NOSB members in disclosing a COI or potential COI in order to ensure confidence in NOSB decision and policy making. The Cornucopia Institute believes that the policy proposal on Conflict of Interest/Ethics is a step in the right direction. The following comments address specific aspects of the COI/Ethics proposal.

Cornucopia agrees with the Policy Development Subcommittee's acknowledgement that COI is as much about the "*appearance"* of a personal conflict and loss of impartiality as it is about actual direct interest. We also agree that an effective COI definition must be clearly understood by Board members in a way that can be effectively applied while considering specific proposals. This process and the

definition must be easily understood by the public. This has not always been the case in the past.

Specific comments on the proposal's recommendations

Regarding Recommendation #5, Cornucopia supports the proposal that a Board member provide to the NOP in "adequate time" a disclosure of any potential financial opportunity concerning an agenda item, while describing it in sufficient detail, to allow for a determination by the NOP of a COI.

Regarding Recommendation #6, a Board member's acknowledgement of "support for comments published by their own organization/employer, or an organization she/he is closely affiliated with" is too narrow. In the past, a Board member's employer has both lobbied the NOSB for a specific decision (outside of the public meeting) and had their employer-representatives provide direct public testimony urging action on a specific decision during the NOSB meeting. The Board member should additionally acknowledge these actions attempting to influence the outcome of a decision by their employer.

Recommendation #7, "NOP will determine whether it is appropriate for the member to vote" is a significant change from the previous COI proposal. In the Spring 2012 discussion document, recommendation #3 suggested that the Board members would decide a Board member's ability to engage in discussion and vote on a particular matter. In the current proposal, this has been changed to shifting this responsibility from the NOSB to the NOP. We are unaware of any public comment supporting or recommending that this authority be taken away from the NOSB and put in the hands of NOP. There could also be a question in terms of its legality under OFPA, under which Congress formed this autonomous body.

We would encourage further discussion by the NOSB regarding the propriety of the NOP making these important decisions, before the NOSB hands over this important responsibility.

Regarding Recommendation #8, we strongly support the inclusion of "employee" as a scenario in which there is an actual or potential direct financial interest of a Board member which could impair the individual's objectivity or which has the potential to create an unfair competitive advantage. This is a situation which requires greater acknowledgement and consideration.

For example, what are the expectations and pressures (perceived or real) that impact the final vote of a full-time employee working for a processor or retailer when that entity has submitted public comments and provided public testimony and perhaps lobbied board members for a vote favoring their interests? Does the possibility even exist that the employee could be fired or sanctioned by their employer for making a contrary vote? A recusal by that Board member on that

specific matter graciously removes any appearance of impropriety and undue influence on the part of their employer.

Cornucopia suggests adding a line to this recommendation to clarify that if a Board member is an employee of an entity that sells a substance on the agenda, or products containing a reviewed substance, the Board member has a perceived conflict of interest and should recuse him/herself from discussion and voting.

Cornucopia also welcomes the inclusion of the definition of "potential conflict of interest" defined as the appearance of a loss of impartiality based on the relationship outlined in the proposed definition of a conflict of interest.

Regarding Recommendation #10, Cornucopia supports the proposal to allow for a "reconsideration" of a NOSB vote should a Board member fail to disclose a COI that is then later revealed.

We also endorse the request that all public commenters (written and oral) state their affiliations at the beginning of their testimony.

Cornucopia supports the extension of the COI declaration and evaluation to the Board's subcommittees. With many preliminary decisions and reviews of matters coming before the NOSB occurring in subcommittees, it is vital that the COI process include this level and that any COI determinations be recorded in subcommittee minutes.

Additional comments: Contractors and Technical Reviewers

Currently, the identity of technical reviewers is not publicly available, much less the potential conflicts of interest held by the reviewers.

Contractors who perform Technical Reviews for the National Organic Program and NOSB should be required to disclose their identity to the public. This will give the public an opportunity to determine whether conflicts of interest exist.

The contractors should also sign a statement stating that no conflicts of interest exist, prior to commencing work on the Technical Review. If the reviewers are unable or unwilling to sign this statement, the USDA should find a different agency or organization to conduct the Technical Review.

Moreover, when the Technical Review is finished, the reviewers should disclose for the public record any individuals, within and outside their organization, that provided assistance. Currently, it is possible that outside consultants with conflicts of interest assist technical reviewers. Just as written documentation must be referenced in the TR, so should telephone conversations and other types of assistance. This will help the public understand who was involved in the TR, and whether conflicts of interest exist.

PUBLIC COMMENT PROCEDURES

SUMMARY

- We reluctantly accept the standard time commitment of 4 minutes per presenter, and urge the Board to **reject** the possibility of cutting the time allotment down to three minutes.

- We urge the Board to include a line in the Policy and Procedures Manual committing to unlimited Q&A.

Background

Oral public comment is an integral part of the NOSB decision-making process. Given the volume of written comments, members of the public feel it is important to be able to make an oral presentation – face-to-face with Board members – to give a sense of assurance that their comments are heard and considered. We also believe that board members benefit from listening to oral comments during the meeting, especially if they felt overwhelmed by the volume of written comments.

Written comments may provide an opportunity for the public to convey background information and their position, but do not provide the opportunity to respond to positions or claims made by other commenters, either in their written comment or during previous public comment. Oral public comment is therefore especially important because it provides an opportunity to respond to different positions, and respond to any inaccurate or misleading information presented by others.

4 minutes

We reluctantly accept the proposal to limit public comment to 4 minutes.

We appreciate the proposal to include the possibility of extending public comment from 4 minutes to 5 minutes at the NOP and Chair's discretion, and would encourage implementing this extension whenever time allows.

We strongly oppose the proposal to allow the Chair and NOP to cut public comment down to 3 minutes. We agree with the idea that "the length of time is not as important as that the designation of a time be regarded as a commitment." If the possibility exists that 4 minutes – already a too short amount of time for presenting complex issues to the Board – could be cut down to 3 minutes, it undermines the commitment to a designated minimum amount of time.

Unlimited Q&A

The Board needs to have unlimited time for questions—possibly the most important component in interacting with the general public and expert witnesses. The Q&A allows speakers with expertise to have more time at the podium, at the discretion of Board members. It is also a way to make the public comment more of a conversation with the Board members, which means presenters will spend more time directly addressing questions of interest to the Board.

At times during the last meeting, in Albuquerque, committee chairs put pressure on Board members to limit their questions. Past chairs have even attempted to limit the time, or number of questions. Every Board member should have the opportunity to ask unlimited questions, and this commitment should be written in the PPM. After all, Board members are being asked to make critically important decisions. They should not have to be forced to do so with any lingering questions in their mind concerning the propriety of any given proposal.

Currently the PPM makes no mention of Q&A. We urge the Board to include a line in the PPM committing to unlimited Q&A.

PUBLIC COMMUNICATIONS

SUMMARY

Cornucopia supports the proposal. We urge the Board to consider posting discussion documents as they become available, to maximize public input.

Communication with the Secretary

We fully support the following addition to the Policy Manual, as proposed by the PDC:

> *"NOSB Policy on Its Advisory Role and Communication with the Secretary of Agriculture.*
>
> *Based on the communications and input it receives from the public the National Organic Standards Board may provide effective and constructive advice, clarification, and written information, as it deems necessary, directly to the Secretary of Agriculture after each of its Board meetings. This information is intended to facilitate public communication with the Secretary on critical issues that may emerge that it believes are important to the implementation and integrity of the organic standards and practices under the Organic Foods Production Act."*

It seems that this statement should stand without question, since the role and responsibility of the Board, as empowered by Congress, is to advise the Secretary of Agriculture (7 USC 6518). We understand that the USDA Secretary may not always like to hear the concerns of the organic community, as has apparently been the case with the NOSB's statement on GMOs. However, this should be no justification for USDA officials to discourage the NOSB from communicating the organic community's concerns.

The NOSB, and the scope of its responsibilities, were set up and mandated by Congress, not the Secretary.

Public communication between NOSB meetings

We also fully support the following addition to the Policy Manual, as proposed by the PDC:

> ***NOSB Policy for Public Communication Between NOSB Meetings.***
> *The NOSB seeks public communication outside of Board meetings and public comment periods to inform Board and Program work.*

PPM Section II (page 13) Role of the Executive Director is amended to include the following language (in italics):

Identify, implement, administer and maintain a year-round mechanism by which public feedback can be received, posted and archived for viewing by the NOP, the NOSB, and the public itself.

We agree that the Board must receive and review information from the public during its deliberations, and that the opportunity for public comment should not be limited to the official public comment period, which occurs biannually.

The opportunity to formally communicate with the NOSB is especially important regarding materials petitions. Without the opportunity to formally receive comments from the public, the committees are likely to hear only from the petitioner and the TR when developing the committee proposal.

Committee members should be able to receive comments from the public during their deliberations, since public comments are the only available mechanism for providing balancing information and positions. This is especially important when the TR is inadequate, as has been the case in the past.

We do have some concerns with the proposed mechanisms that we hope will be addressed

- Will NOSB members have to check or will they receive the comments in their email? Will someone alert them if something is posted?

- Is there an opportunity for the NOSB members to respond? Two-way communication is important.

Additional Issues: Maximizing Public Input

We are concerned with the short timeframe given to the public to comment on issues on the NOSB meeting agenda.

The agenda, proposals and discussion documents were posted in the August 30 Federal Register, with a deadline of September 24. The agenda packet itself consists of 237 pages, which does not include the thousands of pages of petitions and TERs that accompany the proposals.

For a group or a business with a single focus, such as a petitioner of a single material, 26 days of public comment may be enough. But for public interest groups that wish to comment on many, or all, agenda items, 26 days to comment on 21 proposals and 5 discussion documents is challenging, to say the least.

We are not suggesting that the comment period be extended, because we realize that NOSB members work hard to finish the proposals, biannually. We do, however, believe that changes can be made, without burdening the NOSB, to improve the ability of the public, including technical experts, to provide meaningful comments.

Our suggestions for improving the ability of the public to comment on NOSB issues include:

1. Post discussion documents early

Discussion documents, which will not be voted upon but which seek public input on issues in order to develop a proposal at a later meeting, could be made available to the public as they are finalized by the subcommittee. More time will mean maximum participation, maximizing input.

The Policy Development Committee has proposed "a year-round mechanism by which public feedback can be received, posted and archived for viewing by the NOP, the NOSB, and the public itself," which we believe could be useful for posting discussion documents as they become available.

Often, discussion documents seek input from the organic community – questions are posed to farmers, handlers, certifiers and even questions about consumer perception are sometimes asked. Groups like Cornucopia would be more than willing to take an active role in surveying our 7,000+ members, most of whom are organic farmers, as well as the 80,000+ other organic stakeholders that we have direct contact with through Facebook, e-newsletters and other media. However, in order for Cornucopia to effectively solicit input, we need more time than the 4 weeks that constitute public comment period for NOSB agenda items. This is especially crucial in light of the fact that a considerable percentage of our membership, and organic farmers in general, belong to Amish communities with whom we communicate via the postal service, not the Internet.

2. Post meeting minutes as they become available

It would be helpful for public interest groups to have access to the subcommittee minutes as they become available, to allow staff to start working on public comment. Currently, subcommittee meeting minutes are posted once a month, at the end of the month. This causes a considerable delay in posting. Again, we suggest posting subcommittee meeting minutes as soon as they are approved by the committee, using the Policy Development Subcommittee's suggested "year-round mechanisms" for communicating with the public.

Thank you for considering our suggestions.

[i] Earth's Best: http://www.earthsbest.com/products/product/2392310040

Similac: http://abbottnutrition.com/products/similac-advance-organic

Baby's Only Organic: http://www.naturesone.com/dairy/

Vermont Organics: http://www.vermontorganicsformula.com/milknutrition.aspx

Bright Beginnings: http://www.brightbeginnings.com/organic.aspx

Parent's Choice: http://www.walmart.com/ip/16932132#Ingredients

[ii] Earth's Best Soy: http://www.earthsbest.com/products/product/2392310070

Vermont Organics: http://www.vermontorganicsformula.com/soynutrition.aspx

Baby's Only Organic: http://www.naturesone.com/soy/

[iii] FDA Requirements: 21CFR107.100, http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=412a5e7c7190a8e4fd6a44a0e6ad1659&rgn=div8&view=text&node=21:2.0.1.1.7.4.1.1&idno=21

ESPGHAN: http://www.espghan.med.up.pt/position_papers/con_23.pdf

NOTE about ESPGHAN: ESPGHAN is funded in part by the Child Health Foundation, received funding from formula and baby food corporations including Nestle, Mead Johnson and Danone.

European Commission Scientific Committee on Food:
http://ec.europa.eu/food/fs/sc/scf/out199_en.pdf

[iv] Federal Register / Vol. 72, No. 11 / Thursday, January 18, 2007

[v] *7 USC 6518(l)(2): Requirements – In establishing the proposed National List or proposed amendments to the National List, the Board shall work with manufacturers of substances considered for inclusion in the proposed National List to obtain a complete list of ingredients and determine whether such substances contain inert materials that are synthetically produced*