The Cornucopia Institute's Comments to the National Organic Standards Board

Spring 2012 meeting
Albuquerque, NM

Submitted May 3, 2012

CORNUCOPIA
INSTITUTE

Table of Contents

Inositol … page 24

Reject the petition based on the fact that synthetic inositol is not needed. The organic alternative to synthetic inositol is organic food. Inositol is listed in FDA's infant formula regulations and will be allowed in organic infant formula.

LIVESTOCK COMMITTEE

Dairy Body Scoring – Picture Sheet … page 30

We are concerned that, unlike hard benchmarks, body scoring will be subjective and subject to interpretation by inadequately trained certification officials.

Dairy Body Scoring – Tally Sheet … page 32

We urge the Livestock Committee to consider adding other measures such as culled cow rates, levels of milk production, veterinary visits and veterinary interventions, and calf mortality rates.

Guidance Document – Poultry … page 33

We suggest that the livestock committee focus on meaningful and enforceable regulation rather unenforceable guidance documents.

Standards must be strengthened for poultry genetics, catching and crating, transport, ammonia levels, artificial lighting, and other production practices.

GMO vaccines … page 37

GMO vaccines should be allowed only in *bona fide* emergencies, and only when no conventional alternative is available. Language in the proposed rule should be further strengthened to ensure strong safeguards are in place to prevent misuse.

MATERIALS COMMITTEE

Solvents and Extractants … page 40

Cornucopia believes that the use of volatile synthetic solvents should be prohibited for all ingredients in certified organic foods, including those on the National List.

Research Needs … page 45

We support the Materials Committee's proposal for Research Priorities Framework.

Significant Residues and Classification of Materials … page 46

Any residue of a synthetic in the final material or environment is significant and should trigger review. We support the Material Committee's proposed definition of "significant."

CROPS COMMITTEE

List 3 Inerts ... page 49

The Cornucopia Institute supports the Crops Committee's proposal to review List 3 inerts. These chemicals should never have been listed without the proper review that is required by OFPA, and the NOSB should move forward with their review.

AD HOC GMO COMMITTEE

Letter to Secretary Vilsack ... page 50

Cornucopia applauds the members of the Ad Hoc GMO Committee for taking the initiative to communicate to Secretary Vilsack the organic community's concerns with GMO contamination of organic crops and foods. We urge the Board to approve the letter and summarily send it to Secretary Vilsack.

POLICY DEVELOPMENT COMMITTEE

Conflict of interest ... page 51

Cornucopia supports the proposal, and respectfully asks that the Board consider taking this opportunity to add conflict of interest policies for TR consultants, public commenters and committee proposals as well.

Public Comment Procedures ... page 54

We recognize that some restrictions might be necessary, but a formula should be devised to maximize public participation. We do not support the 3-minute restriction without other modifications that would enhance public participation.

Public Communications ... page 57

We support the proposed additions to the policy manual. The ability of the NOSB to communicate with the Secretary on issues that are important to the organic community, such as GMO contamination, should be a "no-brainer."

CERTIFICATION, ACCREDITATION AND COMPLIANCE COMMITTEE

100% organic and sanitizers ... page 59

Meticulous sanitation should be the hallmark of all production systems (conventional and organic). Within the restrictions of OFPA and the federal organic

regulations, the use of sanitizers should not disqualify food products from 100% organic labeling.

ADDITIONAL ISSUES

Request for new Technical Reviews at sunset… page 61

Cornucopia respectfully requests a new TR be performed for every material that is up for sunset review, and that the Handling Committee's proposal be based on information in the current TR.

INTRODUCTION

The Cornucopia Institute is a 501(c)(3) public interest charity. The Cornucopia Institute is engaged 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, and stakeholders involved in the good food movement and the media.

We are proud to represent 7,000-7,500 paying members, the majority of whom are certified organic farmers (and at least 80,000-100,000 others who are interested in organic issues that we communicate with every month).

Now in our ninth year, we did not initially envision our role, in interfacing with the National Organic Standards Board, to encompass material reviews. We had operated under the false assumption that community-minded Board members, reviewing independently produced and impartial Technical Reviews, as required by law, were protecting the interest of organic stakeholders.

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 the decision-making at the NOSB level, current members will benefit from Cornucopia's independent perspective, assessing the health and environmental downsides 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.

The Cornucopia Institute does not support a blanket prohibition on synthetics in organic farming and food production—but we adamantly believe that a thorough and appropriate review process needs to take place first, and that all materials should conform with OFPA and the organic standards:

> Sec. 2118 [7 USC 6517] (c)(1) **EXEMPTION FOR PROHIBITED SUBSTANCES IN ORGANIC PRODUCTION AND HANDLING OPERATIONS** – The National List **may** provide for the use of substances in an organic farming or handling operation that are otherwise prohibited under this title **only if** –
>
> > (A) the Secretary determines, in consultation with the Secretary of Health and Human Services and the Administration of the Environmental Protection Agency, that the use of such substances—

(i) **would not be harmful to human health or the environment**;

7 CFR 205.600(b) In addition to the criteria set forth in the Act, any synthetic substance used as a processing aid or adjuvant will be evaluated against the following criteria:

(2) the substance's manufacture, use and disposal **do not have adverse effects on the environment** and are done in a manner compatible with organic handling;

(3) the nutritional quality of the food is maintained when the substance is used, and the substance, itself, or its breakdown products **do not have an adverse effect on human health** as defined by applicable Federal regulations. (emphasis added)

HANDLING COMMITTEE

AGAR AGAR

EXECUTIVE SUMMARY

REJECT the proposal to move agar agar from 205.605(a) nonsynthetics to 205.605(b) synthetics. We **do not support** the listing of synthetic agar agar, from *Gracilaria* species, which undergoes alkaline pre-treatment.

SUPPORT relisting of agar agar on 205.605(a) non-synthetics, with the following annotation: "from *Gelidium* species only, processed without alkaline treatment."

- *Gelidium* species is the original species used for agar agar production. Another species, *Gracilaria,* must be treated with alkali to be a commercially viable alternative to *Gelidium*. *Gracilaria* processing requires more fresh water, and creates alkali wastewater.

AGAR AGAR

Cornucopia supports the relisting of agar agar on 205.605(a) non-synthetics allowed, with the annotation, "from *Gelidium* species only, processed without alkaline treatment."

We oppose the Handling Committee's proposal to move agar agar from 205.605(a) to 205.605(b) because synthetic agar agar is incompatible with principles of organic production and handling, for reasons outlined below.

It appears that non-synthetic agar agar from *Gelidium* species is readily available, and we have identified at least one U.S. supplier of non-synthetic agar agar from *Gelidium*.

Background: Synthetic v. Non-synthetic Agar Agar

According to the TR, two different species of red seaweed are generally used to produce agar agar: *Gelidium* and *Gracilaria*. *Gelidium* was the original species used for agar agar production, until shortages during World War II led to the discovery of *Gracilaria* as a suitable alternative to *Gelidium* (Imeson 2009).

However, *Gracilaria* is only suitable as an alternative to *Gelidium* **if it is treated with alkali**, which causes a chemical change that leads to increased gel strength (Imeson 2009, McHugh 2003, TR 174).

According to McHugh 2003, "this alkaline pre-treatment causes a chemical change in the agar from *Gracilaria*, resulting in an agar with an increased gel strength. Without this alkaline pre-treatment, most *Gracilaria* species yield an agar with a gel strength that is too low for commercial use."

The TR misleadingly states that "*Graciliara* [sic] species are usually subjected to alkaline pretreatment (heated in a sodium hydroxide solution)," when in fact commercially viable agar from *Gracilaria* ***must*** be treated with alkali before extraction.

This is an important distinction, which bears repeating because it is crucial in understanding the reason for our proposed annotation: Agar agar from *Gelidium* is not treated with alkali, and therefore does not undergo chemical change, while agar agar from *Gracilaria* requires alkaline pre-treatment and chemical change to be useful for commercial applications.

The Handling Committee may have misunderstood the TR, which misleadingly suggests that the only agar agar that is not chemically modified is "natural" agar in strip form, and that it only accounts for 1.5% of the world's supply. While it may be true that agar strips are produced on a small scale in China, Japan and the Republic of Korea, it is not accurate to suggest that the only form of non-synthetic agar agar is this "natural" strip agar.

When checking McHugh 2003 and Imeson 2009, the two main sources for the TR, it becomes clear that agar agar from *Gelidium* is available in food-grade powdered form. In fact, Imeson states that "the highest strength gel agar is generally obtained from *Gelidium* seaweeds" (Imeson 2009, page 32). The Handling Committee appears to have misunderstood the TR's estimate of supplies of "natural" agar agar in strip form as an estimate of non-synthetic powdered agar agar from *Gelidium.*

A quick Internet search for commercial supplies of agar agar from *Gelidium* in the U.S. yields at least one supplier: TIC Gums. TIC Gums produces two agar agar products it claims are "certified organic," and one TICorganic® Agar Agar 150-C FCC/NF is specifically listed as being from *Gelidium* species.

Suggested annotation

Cornucopia supports the relisting of agar agar on §205.605(a) Non-synthetics allowed, and opposes the proposal to list agar agar on 205.605(b). Only non-synthetic agar agar should be allowed in organics.

To clarify this, we urge the NOSB to adopt the following annotation for agar agar: "from *Gelidium* species only, processed without alkaline treatment."

Justification for suggested annotation

Because it is not treated with alkali, agar agar from *Gelidium* does not undergo chemical change and is therefore considered a non-synthetic (TR 216). The Organic Foods Production Act of 1990 (sec. 2111(a)(1)) and organic consumers have a clear preference for avoiding synthetics in the food supply.

The main environmental concerns pointed out in the TR include overharvesting (TR 299-300) and alkaline wastewater (TR 315-316). It appears that both concerns would be alleviated by restricting the use in organics to *Gelidium* agar.

Since only *Gracilaria* requires alkali pre-treatment, the concern with alkaline wastewater applies only to *Gracilaria* and not to *Gelidium*. And the TR mentions concerns with overharvesting only in regard to *Gracilaria*:

> "Buschmann et al. (2008) report that overexploitation of many wild *Gracilaria* strands has resulted in the destruction of some of the larger genetic reserves for the species." (TR 299-300)

Indeed, the University of Hawaii's Botany Department's database notes:

> *"Gracilaria coronopifolia*, like other *Gracilaria* species, is a hardy subtidal red algae that attaches to limestone or occasionally on basalt substrates. This species is one of the 10 most common intertidal algae in the Hawaiian islands. It is widely distributed and was fairly common, but **due to its popularity as an edible algae, has been seriously overharvested**. The invasive alien *G. salicornia* is now dominant in many regions typical of the native habitat for *G. coronopifolia."* (emphasis added)[1]

Another environmental concern that was not pointed out in the TR is the high consumption of fresh water, and accompanying creation of wastewater. According to McHugh 2003, non-synthetic agar from *Gelidium* requires less water:

> "A large and reliable freshwater supply is a requirement for an agar factory. **Water consumption is high and the processing of *Gracilaria* requires more than for *Gelidium***. Higher water consumption also means larger quantities for waste disposal, so recycling of water is becoming more necessary, depending on the location of the factory." (emphasis added) (McHugh, 2003)

McHugh also points out that there are many gaps in the understanding of how agar agar is produced, especially the conditions of the alkaline treatment. This lack of clarity and transparency is another reason to prohibit agar agar that has undergone alkaline treatment. McHugh notes:

---

[1] http://www.hawaii.edu/reefalgae/invasive_algae/rhodo/gracilaria_coronopifolia.htm

"Detailed information on the commercial extraction process is not easily available. There are several short publications on the results from laboratory-scale extractions, but **commercial agar producers are generally secretive about the details of their processes**. Armisen and Galatas (1987) is one of the few publications that gives some details, but there are still many gaps, **particularly in the conditions of the alkali treatment** and the subsequent hot water extraction; nevertheless, it is the best starting point." (emphasis added)

CARRAGEENAN

EXECUTIVE SUMMARY

REJECT relisting of carrageenan on the National List, and **reject any proposed annotation**, for the following reasons:

- Scientists have warned for decades that carrageenan in foods is **harmful to human health**, because of a preponderance of scientific evidence linking carrageenan to **gastrointestinal inflammation and colon cancer**.

- Degraded carrageenan is listed as a "**possible human carcinogen**" by the WHO's International Agency for Research on Cancer.

- Industry data from 2005 show that the industry has no reliable way of testing levels of degraded carrageenan in their products. **All tested samples of food-grade carrageenan contained varying levels of potentially carcinogenic degraded carrageenan.**

- Research indicates food-grade carrageenan breaks down in the digestive tract, and becomes degraded in the human body.

CARRAGEENAN

Based on current scientific research, carrageenan is not a safe ingredient in food and should be removed from the National List.

The scientific community has recognized for decades that degraded carrageenan is harmful to human health. The carrageenan industry will therefore likely suggest an annotation, prohibiting only degraded carrageenan from organic foods. Degraded carrageenan has low molecular weight, and has been recognized since the 1960s as causing gastrointestinal inflammation. Degraded carrageenan has been listed since 1983 as a "possible human carcinogen" by the WHO's International Agency for Research on Cancer.

An annotation of this nature would have been appropriate in the mid-1990s, when this material was originally reviewed, because data did not yet exist to counter the claim that food-grade carrageenan can be entirely free of degraded carrageenan. In the mid-1990s, therefore, it would have been reasonable to assume that degraded carrageenan could be isolated in the marketplace, and prohibited in organics—but the Technical Advisory Panel (TAP) reviewers did not suggest any annotation.

But industry data from 2005 (submitted as an attachment) has revealed that varying levels of degraded carrageenan contaminate all food-grade carrageenan. Moreover, studies have shown harmful health effects of food-grade carrageenan,

and scientists suggest that carrageenan in fact degrades in the human digestive system.

The option of an annotation would therefore be virtually meaningless and should be rejected, since industry data show clearly that **no food-grade carrageenan can claim to be safe and free from degraded carrageenan**.

It is important to note that the European Commission's Scientific Committee on Food determined in 2003 that food-grade carrageenan should contain less than 5% degraded carrageenan, since carrageenan is listed as a "possible human carcinogen" by the WHO's International Agency for Research on Cancer. In response, Marinalg, the trade group for carrageenan manufacturers, set out to determine if they could meet this requirement. They concluded they could not reliably determine the levels of degraded carrageenan in their products.

Results from the 2005 Marinalg Working Group's tests (page 2, Figure 1 – submitted as an attachment) clearly show that degraded carrageenan, a substance that is known to cause colon inflammation and is classified by the WHO's International Agency for Research on Cancer as a "possible human carcinogen," was present in all samples of food-grade carrageenan. Therefore, all carrageenan should be prohibited from foods, especially organic foods.

This information was publicly available before the last sunset review. If a Technical Review had been requested by the NOSB, which it was not, and if it was independently produced and judiciously executed, the Board would have been able to weigh these concerns five years ago.

The current Technical Review on carrageenan points out negative human health and environmental impacts. In an attempt at balance, the TR mistakenly lists a study by Tobacman and Walters (line 582) as contradicting findings of gastrointestinal tract inflammation. This study does not address inflammation and should therefore not have been listed as contradicting findings of human health concerns.

The only study included in the TR that contradicts findings of gastrointestinal tract inflammation is authored by ML Weiner, who, at the time of the study, was employed by FMC Corporation, one of the major producers of carrageenan.

In this attempt at "balance," the anonymous authors of the TR fail to point out that **the vast preponderance of peer-reviewed, published scientific literature on this matter clearly indicates a threat to human health**.

Please find attached our full review of the scientific literature and our analysis of carrageenan's safety.

Based on scientific research and industry data, the inclusion of carrageenan on the National List is illegal, since it violates the Organic Foods Production Act of 1990,

Sec. 2118(c)(1)(A)(i) - "the National List may provide for the use of substances only if ... the use of such substances would not be harmful to human health or the environment."

Carrageenan fails the following criterion in the organic standards: 7 CFR 205.600(b)(3) - "The nutritional quality of the food is maintained when the substance is used, and the substance, itself, **or its breakdown products** do not have an adverse effect on human health as defined by applicable Federal regulations."

Please note that the standards include the phrase "or its breakdown products." Research shows that food-grade carrageenan is broken down in the gastrointestinal tract to degraded carrageenan, a "possible human carcinogen." Food-grade carrageenan should therefore be removed from the National List based on 7 CFR 205.600(b)(3).

It is now clear that the NOSB approval process of carrageenan in the mid-1990s, including the review by a Technical Advisory Panel, was seriously flawed. The three TAP reviewers failed to raise known concerns about carrageenan, despite a number of published peer-reviewed articles in and letters to scientific journals pointing out health concerns. **Scientists have published letters in journals such as *The Lancet* as early as 1980 pointing out human health concerns with food-grade carrageenan**.

Please also note that a petition is pending with the FDA to remove carrageenan's GRAS (Generally Recognized As Safe) status. The FDA never performed a review of carrageenan's safety, since the ingredient's GRAS approval was "grandfathered in."

Organic foods should be held to a higher standard of safety. The FDA has not acted to remove carrageenan from foods, and **the Board must show consumers that the organic industry is serious about providing a safe alternative to the conventional food supply**. We urge the Board to remove all carrageenan from the National List, and reject any attempts by carrageenan manufacturers and theircustomers to keep carrageenan on the list with a meaningless annotation.

CELLULOSE

EXECUTIVE SUMMARY

Cornucopia cannot support the relisting of cellulose on 205.605(b) without a new Technical Review that bridges the 11-year gap between 2001, when the original TR was performed, and the present day.

- The original Technical Review, performed by **OMRI** in 2001, found **microcrystalline cellulose** to be a **"highly processed material not compatible with organic handling systems,"** and the reviewers unanimously suggested that microcrystalline cellulose be **prohibited** in 95% organic foods.

- The 2001 TR pointed out **environmental concerns** with the production of microcrystalline cellulose: "acid wastes due to the use of hydrochloric and other acids" (Hanna, 2001).

- The 2001 TR also pointed out that cellulose is **prohibited in IFOAM, Codex, EU and Canadian organic standards**.

CELLULOSE

Cornucopia cannot support the relisting of cellulose on 205.605(b) without a new Technical Review that bridges the 11-year gap between 2001, when the original TR was performed, and the present day.

It is unclear what information was used by the Handling Committee when it made the following statement in its proposal: "There is no new information contradicting the original recommendation which was the basis for the previous NOSB decisions to list and again re-list this material."

Without a current Technical Review, how did the Handling Committee (HC) come to the conclusion that there is "no new information"? If members of the HC performed their own technical and scientific review, a more comprehensive summary of their findings, including references of publications and documents that were reviewed, should be included in their proposal.

If the NOSB were to vote on cellulose at the meeting in Albuquerque, the following must be added to the annotation: "microcrystalline cellulose is prohibited."

It appears that the original Technical Review, performed by OMRI in 2001, concluded the following about microcrystalline cellulose, which was part of the petition:

> "All reviewers considered microcrystalline cellulose to be a highly processed material not compatible with organic handling systems (TR 22)."

As a result, the 2001 TR's reviewers unanimously suggested that microcrystalline cellulose be prohibited in 95% organic foods (TR 59). However, the current listing for cellulose on 205.605(b) does not appear to prohibit microcrystalline cellulose, as the TR suggested.

According to the minutes of the 2001 NOSB meeting, the Board voted for the current annotation: "for use in regenerative casings, as an anti-caking agent (non-chlorine bleached) and filtering aid." Microcrystalline cellulose can be made without bleaching (Hanna 1998) and is used as an anti-caking agent, and is therefore not prohibited by the current annotation.

It appears that the Handling Committee used the 2001 TR as justification for its proposal to relist cellulose with the current annotation. And yet the 2001 TR's conclusions, which propose to prohibit microcrystalline cellulose, and the current listing, which allows microcrystalline cellulose, are incompatible.

If a current TR were available, it would likely echo the environmental concerns with microcrystalline cellulose that were noted in the 2001 TR:

> "Conventional production of microcrystalline cellulose results in production of acid wastes due to the use of hydrochloric and other acids (Hanna, 2001)."

The 2001, the TR (line 273) also points out that cellulose is prohibited in the following international organic standards:

> CODEX – Not listed. Microcrystalline cellulose was proposed by a member country prior to the May 2001 meeting, but was not adopted.
>
> EU 2092/91 – Not listed.
>
> IFOAM – Not listed. (IFOAM IBS 2000)
>
> Canada – (1999). Not listed in Appendix C, Permitted Substances for Processing.
>
> International - Uses of anti-caking agents in cheese products appears to be prohibited in Belgium, Canada, Denmark, Finland, France, Italy, Japan, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, UK, and West Germany (Branen, 1990).

In summary, the three reviewers in the 2001 TR unanimously concluded that microcrystalline cellulose should be prohibited, and pointed out that alternatives exist to microcrystalline cellulose (silicon dioxide, for example). Their concerns and

proposal appear to have been ignored by the Board in 2001, and appear to be ignored by the current Handling Committee which proposes to relist cellulose without an annotation change.

The sunset vote for cellulose should be delayed until a new Technical Review has been completed, and its concerns are taken seriously. Concerns that were noted in the original TR, such as the prohibition of microcrystalline cellulose, are likely to be noted in the new TR and should be taken seriously by the Board.

Most importantly, a new TR is the only way to find out whether new information exists regarding the material's compatibility with principles of organic production and handling.

CHOLINE

EXECUTIVE SUMMARY

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

- Synthetic choline is **not essential** for organic handling, since choline occurs naturally in food. Good sources of choline include peanuts, tofu, chicken, beef, eggs, broccoli, spinach, navy beans, fish, etc.

- **Certified organic lecithin is an organic alternative** source of choline approved for use in infant formula.

- The TR points out concerns with the use of **ethylene oxide** (TR 324) and **synthetic solvents** (Balchem petition, page 9), the possible presence of the **carcinogenic 1,4-dioxane** (TR 439) and other **toxic contaminants** (TR 515).

- The TR points out that **people suffering from depression should avoid choline supplementation**. Organic food should be a healthy and safe option for the **21 million Americans** suffering from depression.

CHOLINE

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

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

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

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

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

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

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

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

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

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

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

---

[2] http://www.nal.usda.gov/fnic/foodcomp/Data/Choline/Choln02.pdf

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

Solvents

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

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

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

Lack of GRAS Status

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

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

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

[3] http://www.gao.gov/products/GAO-10-246

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

Ethylene Oxide

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

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

Human Health Effects

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

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

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

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

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

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

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

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

Summary

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

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

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

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

GIBBERELLIC ACID

EXECUTIVE SUMMARY

REJECT because gibberellic acid is applied post-harvest primarily to act as a **preservative**. Organic standards prohibit the addition of materials to the National List if their primary purpose is to act as a preservative (7 CFR 205.605(b)(4)).

GIBBERELLIC ACID

The Cornucopia Institute urges the Board to reject the Valent Biosciences Corporation petition for adding gibberellic acid to the National List.

According to the TR, "gibberellic acid can be applied post-harvest to control fruit ripening and maintain quality through packaging, long-distance shipping, and shelf-life" (TR 100-101). In other words, gibberellic acid is applied post-harvest primarily to act as a preservative.

The Handling Committee proposed an annotation to restrict the use of gibberellic acid to post-harvest use on bananas only. The TR says the following about use on bananas: "Similarly, when used on bananas, gibberellic acid will delay fruit softening and color development, allowing for longer shipment time (i.e., further shipment distances) before bananas are considered "ripe" (TR 103-104). The TR also notes that the petitioner specifies its use on post-harvest bananas would be to "delay ripening."

Federal organic standards prohibit the use of synthetic materials if their primary use is as a preservative (7 CFR 205.600(b)(4)). Phrases such as "delay fruit ripening" and "allowing for longer shipment time" are ways of describing the purposes of a *preservative*.

When addressing the question of whether the petitioned material's primary use is as a preservative, the TR states: "Used in this way, gibberellic acid acts as a preservative of raw agricultural commodities post-harvest, and not as a preservative in processed food" (TR 415). It seems to us that the standards do not distinguish between the prohibition of preservatives in processed foods and preservatives of raw agricultural commodities, so it is unclear why the TR answers in this way. **The standards prohibit substances whose primary function is as a preservative from the National List,** and do not distinguish between preservatives for processed foods and raw agricultural commodities.

INOSITOL

EXECUTIVE SUMMARY

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

- Synthetic inositol is **not essential** to organic handling. Inositol is a nutrient that **occurs naturally in food**, making organic food an organic alternative to synthetic inositol supplementation.

- Inositol does not appear necessary in infant formula, and the TR points out that even newborns with an inositol deficiency maintain proper function.

- Inositol **occurs naturally in milk-based infant formula**. Inositol is listed in FDA's infant formula regulations (21 CFR 107.100) and will therefore be allowed (for soy-based formula only) when the NOP finalizes the proposed change to "nutrient vitamin and minerals" annotation.

INOSITOL

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

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

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

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

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

Agricultural Products—Other than Infant Formula

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

> It is estimated that Americans consume 1,000 milligrams of inositol daily in their diet (Kirschmann, 2007).
>
> This dietary intake is supplemental to the endogenous inositol that is naturally biosynthesized by human cells. Inositol is biosynthesized by cells in many different tissues, including the brain, testis, liver, and especially the kidneys (Carver, 2006).
>
> It is commonly found in tissues within the skeletal system, reproductive system, heart, and nerve systems, including large amounts in spinal cord nerves, cerebral spinal fluid, and the brain (Kirschmann, 2007). See "Action of the Substance" for information about the biomolecular role of inositol in the human body.
>
> **Dietary uptake and endogenous biosynthesis are sufficient to meet the body's inositol requirements (Navarra, 2004), and an inositol deficiency syndrome has not been identified (NLM 2011a).**
>
> No information was found to indicate that inositol is added to processed foods other than infant formulas for dietary purposes. (emphasis added, TR 61-70)

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

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

Infant Formula

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

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

> The role of dietary inositol in infant development is unclear (Carver, 2006), and therefore its action when used as an ingredient in infant formula is uncertain.
>
> Inositol has been known to prevent fat accumulation in the liver and intestines, and control triacyglycerol and esterified cholesterol levels; however, neonatal animals fed inositol-depleted diets did not experience effects indicative of fat accumulation in the liver or intestines, suggesting that **newborns can maintain proper cellular function despite dietary inositol deficiency** (Carver, 2006). (emphasis added, TR 133-137)

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

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

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

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

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

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

The TR agrees with this point:

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

Just to be clear, the TR repeated this point:

> To clarify this situation, the NOP published a proposed rule in January 2012 (77 FR 1980) that would amend 7 CFR 205.605(b) as follows:
>
> *"Vitamins and minerals. For food—vitamins and minerals identified as essential in 21 CFR 101.9. For infant formula—vitamins and minerals as required by 21 CFR 107.100 or 107.10."*
>
> If promulgated as a final rule, this amendment would clarify that inositol is allowed in organic-labeled non-milk based infant formulas, because it is required by 21 CFR 107.100. (TR 217-224)

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

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

As noted in the TR (230-232), "the IFOAM Norms state that, 'Minerals (including trace elements), vitamins and similar isolated ingredients shall not be used unless their use is legally required or where severe dietary or nutritional deficiency can be demonstrated' (IFOAM, 2006)."

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

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

Safety

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

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

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

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

No Proven Benefits

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

> "To date, no studies have been conducted to evaluate the impact of dietary inositol on growth and development of healthy term infants. Similarly, no studies examining safety of inositol supplementation have been reported in humans." (Appendix E, E3)
>
> *and*
>
> "Because of its endogenous synthetic capabilities, **inositol has not been listed as an essential nutrient in the RDA for humans** (NRC, 1989)."

The following is from the TR:

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

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

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

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

Summary

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

LIVESTOCK COMMITTEE

General Livestock Welfare

If the exercise of developing animal welfare standards and guidance is to satisfy concerns of consumers and the animal welfare community, and to create a viable marketplace alternative to inhumane conventional livestock production, then it is incumbent upon the NOSB to address these macro concerns to the satisfaction of the organic community.

This has not yet happened. For example, animal welfare advocates and consumers continue to call for higher space requirements for organic poultry.

Body Scoring Proposed Discussion Document

EXECUTIVE SUMMARY

Dairy Body Scoring – Picture Sheet

- The scorecard and picture sheet is of poor quality and should be improved.

- We are concerned that, unlike hard benchmarks, body scoring will be subjective and subject to interpretation by poorly trained certification officials.

Dairy Body Scoring – Tally Sheet

- We urge the Livestock Committee to consider adding other measures such as culled cow rates, levels of milk production, veterinary visits and veterinary interventions, and calf mortality rates.

BODY SCORING – PICTURE SHEET

The primary circumstance in which the proposed scorecard and tally sheet would be useful is to assist an inexperienced inspector with no knowledge of and familiarity with livestock production.

The scorecard is quite rudimentary and tally sheets also do not take into account the variations in body scoring that will occur on any dairy farm, including those with excellent animal welfare. Organic producers might be poorly served by the scores given to them by inspectors who are inexperienced and rely on the scorecard and tally sheet.

For example, the body scoring of a cow 1-3 months after she freshened could very well be different from the body scoring 9-11 months after freshening. An inexperienced inspector without livestock welfare knowledge might not recognize the different body scores as a factor of the stage of lactation.

Another example is cow cleanliness. An inexperienced inspector visiting a dairy farm during a wet spring might find cows to be muddy and assume them to be unclean, and give a lower score than if the inspector had visited during a summer drought. Again, environmental conditions matter, and these scorecards and tally sheets are not foolproof ways of measuring welfare.

We bring this up not only to point out the weaknesses of this particular proposed system for measuring animal welfare, but to show that the same criticisms of prescriptive requirements apply also to outcome-based scoring systems. Opponents of strong prescriptive standards for animal welfare argue that such standards do not take into account differences in individual farms, geographic conditions, etc., and argue for outcome-based standards such as body scoring. However, body scoring runs into some of the same potential issues, as body scores will differ depending on stage of lactation, climactic conditions, etc.

More importantly, unlike hard benchmarks many of these will be subjective and subject to interpretation by untrained individuals.

The same criticism that leads some in the organic community to reject the notion of strong, prescriptive standards can be applied to any other method of determining animal welfare.

Many of the pictures are poor quality, for example, picture 3 in "Body Condition Scoring." As a result, it is often difficult to distinguish between the different scores, and would certainly be a challenge for an inexperienced inspector relying on these photographs. For example, the animal's condition in pictures 3-5 in the Locomotion section looks similar. It is unclear to us how an inexperienced inspector would be expected to differentiate between these pictures. The pictures could be improved, for example, by using the same breed and circumstance for every score (in picture 3, the animal is standing, while picture 5 shows the animal attempting to walk).

If a scorecard is implemented, it might be advantageous to search for better graphic images and include more examples. Obviously, as in the implementation of the pasture provisions of the newer livestock regulations, training of accredited certifying agencies (ACAs) will be imperative.

Having all the cows be walking Holsteins, photographed from the same angle, would improve the tool (or possibly other alternative breeds). The tool could be further improved by photographing the animals from the multiple angles (providing more than one picture per score).

Dairy Body Scoring – Tally Sheet

We would appreciate seeing additional criteria on the tally sheet, including cattle with mange and lice, broken tails and ammonia concentration in buildings. We urge the Livestock Committee to consider adding other measures such as culled cow rates, levels of milk production, veterinary visits and veterinary interventions, and calf mortality rates.

There are some industrial-scale dairies, and likely some smaller ones as well, that push their cows for very high production. Since it is incumbent upon organic dairy producers to create a healthy environment, reducing or eliminating the need for drugs or other treatment protocols, high production levels are inconsistent with organic management and create auditable problems as outlined in the paragraph above.

Body condition

We take issue with the statement that "*Cows generally score less than 2 only if they are ill*". Our member producers have pointed out that other factors may impact body condition. One such factor is pregnancy with twins, especially in first calf heifers, who are still putting on body size when they become pregnant. They also tend to have a flatter production curve than older cows and tend not to drop off in milk production after conception as much, and pregnancy with twins will affect their body score, but not because they are ill. Older cows pregnant with twins will also tend to have a lower body condition score, because of the extra nutrition needed to support the development of two calves.

The scoring for Body Locomotion seems skewed, to favor confined animals. If the extremes (score 1 and 5) are considered objectionable, one would assume that score 3 would be the ideal. Yet this is not the case, as the cow pictured in Score 2 appears to be the ideal-looking, athletic, grazing dairy cow. Picture 3 is of terrible quality, and therefore a rather useless photograph. We would suggest that the cow in Picture 2, a healthy grazing cow, should be representative of the "ideal," and be pictured in Picture 3.

Cleanliness

The text under Score 2 states that manure stains are considered acceptable, but dried or wet manure on the legs or udder is not acceptable. This makes no sense, as the manure stain surely is the result of previous wet, and then dried, manure. The wet manure that is considered unacceptable will leave the stain, which is considered acceptable. However, we do not wish to suggest that a manure stain *should* be considered unacceptable, since even healthy cows with acres of pasture will sometimes deposit manure and then lay in it. It is unrealistic to assume that cows are never going to get fresh manure on their bodies.

Guidance Document – Poultry

EXECUTIVE SUMMARY

- The only way to ensure that animal welfare standards are met is to create such standards, and make them meaningful and enforceable. We urge the Board to focus on finishing the job of strengthening the standards for animal welfare, rather than spend any more of its own time and resources on unenforceable guidance documents.

- Standards must be strengthened for poultry genetics, catching and crating, transport, ammonia levels, artificial lighting, and other production practices.

- Cornucopia and its member poultry producers still strongly believe that 2 $ft.^2$ of outdoor space, for laying hens, and the amount specified for broilers, is woefully inadequate and will undermine the credibility of the organic label.

GUIDANCE DOCUMENT – POULTRY

Guidance does not carry the weight of law, and there is no such thing as "violating the guidance." One can be found to violate standards, but guidance is unenforceable. These proposed guidance documents may therefore serve as useful tools for producers and certifiers who are interested in promoting animal welfare, but can be summarily and wholly disregarded by any producer without an interest in animal welfare.

The purpose of a certification system is to provide assurance to consumers that certain standards were met and to ensure that farmers are similarly engaged in uniform practices. **The only way to ensure that animal welfare standards are met is to create such standards, and make them meaningful and enforceable.** We urge the Board to focus on finishing the job of strengthening the standards for animal welfare, rather than spend any more of its own time and resources on guidance documents.

Most of the information in the guidance documents is already available from other sources. For example, guidance on improving outdoor runs and pasture for chickens is available from ATTRA, as noted in the guidance document.

The guidance documents do identify certain welfare needs of animals that should be met on organic farms. If these are considered important enough to be included in the guidance document, they should be made into a rule so that they can be enforced.

For example, the guidance document correctly states that "lighting should provide for an 8 hour rest period daily." However, in the rule, there is no restriction on lighting times, and therefore no assurance that birds are given adequate rest periods without artificial light.

A restriction on artificial light times was included in the 2011 Livestock Committee recommendation but was not adopted in the recommendation passed by the full Board on December 2, 2011. This is a serious deficiency. Therefore, if an organic broiler producer wishes to keep the lights on for 22 hours per day to speed growth, nothing would prevent the practice since no enforcement action could be taken.

Including the restriction in the guidance document is virtually meaningless in terms of enforcement, yet including it in the guidance document reinforces that this is recognized as an important welfare need. The only way to ensure that animal welfare standards are practiced on all organic farms is by making them part of the rule.

Artificial lighting: The restriction on artificial lighting to no more than 16 hours per day should be recommended to be included in the rule, not just in guidance.

Space requirements: The guidance document includes minimum space requirements for turkeys, ducks and geese. These space requirements were not part of the recommendation that came out of the Fall 2011 meeting. We suggest that minimum space requirements be recommended as part of the rule, as they are for broilers and layers. By putting these minimum space requirements in the guidance document, they are meaningless and unenforceable. More time is needed to poll producers for their input regarding these recommendations.

Ammonia levels: The restriction on ammonia levels should be clarified. Currently, the language in both the Fall 2011 recommendation and the current proposed guidance document is very confusing. Is the maximum level 10 ppm or 25 ppm? We urge the Livestock Committee to clarify that "ammonia levels ***must be*** less than 10 ppm" indoors, rather than "should be." Many animal welfare experts believe this level to be too high, but at least it would be an improvement of the unclear language that might lead to levels as high as 25 ppm in some houses.

Genetics and minimum age of slaughter: Broilers have been bred for fast growth and large breast muscles, which has led to serious health issues and animal welfare concerns with fast-growing breeds.

Specifically, fast-growing breeds can reach market weight in as little as 7 weeks, but side effects of rapid growth include leg deformities and lameness, ruptured tendons in the legs, problems with internal organs, and mortality. Conditions including ascites are common in fast-growing breeds, whose heart and lungs cannot distribute enough oxygen throughout the enlarged body's muscles.

The European Union's organic standards address this serious welfare concern by prohibiting producers from slaughtering broilers before they reach 81 days of age (11.5 weeks). European organic producers therefore have little incentive to use fast-growing breeds, which reach market weight in as little as 6 or 7 weeks.

The guidance document currently states only the following vague, unenforceable, recommendation: "The use of slow growing breeds is therefore recommended." To ensure that producers choose slow growing breeds, a minimum age of slaughter should be proposed in the standards.

Catching and Crating: Workers that catch chickens ("catchers") to put them in crates and on the truck destined for the slaughterhouse routinely carry up to 5 chickens, held by one leg, in each hand. This practice, which can lead to leg injuries, and associated pain and suffering, in the chickens, should not only be addressed in guidance, which currently states that "Ideally, all poultry should be handled individually, upright, and carried gently using two hands." Though ideal, this is an unrealistic expectation. To ensure welfare during the catching process, there should be a limit in the rule on the number of birds carried per catcher, and a requirement that birds not be held by one leg.

Transport: The guidance document currently states that "delivery of poultry for slaughter should be scheduled such that they are not deprived of water for longer than 12 hours." Twelve hours is longer than any other welfare standard, making organics the weakest standard rather than the gold standard.

The Certified Humane label requires that the time between loading and unloading be no more than 10 hours. Global Animal Partnership requires transport to be no longer than 8 hours for all "steps," and restricts transport time to 4 hours in steps 4-5. Animal Welfare Approved restricts transport time to 4 hours. Similar restrictions on transport time should be adopted in the organic standards

Identifying Outside Consultants

Once again, the Livestock Committee has produced lengthy documents that clearly required the assistance of outside experts and consultants. Any individuals who participated in the creation of these documents should be identified, as it is clear that these documents are not the work solely of the Livestock Committee members.

We strongly feel this level of transparency should be applied to any future committee work where outside expertise has been tapped.

Space Requirements

Cornucopia and its member poultry producers still strongly believe that 2 $ft.^2$ of outdoor space, for laying hens, and the amount specified for broilers, is woefully inadequate.

Again, in Europe, where the size of the organic poultry industry is twice that of the U.S., illustrating its economic viability, laying hens are required to have 43 ft.^{2} of outdoor area per bird. The organic brand with the largest number of farmer-suppliers in the U.S., Organic Valley, has proved 5 ft.^{2} outdoors/1.75 ft.^{2} indoors is commercially viable for egg production.

2 ft.^{2} outdoors will automatically not only deprive chickens of the ability to exhibit their natural behaviors in a rich outdoor environment, but it will seriously violate soil and water conservation standards inherent in organic management.

Summary

In terms of enforceability, guidance documents are meaningless. Much of the information contained in the guidance documents put together by (or for?) the Livestock Committee is available elsewhere. We therefore urge the Livestock Committee to focus its energy and resources on strengthening the standards. In this comment, we identified areas where the organic standards should be strengthened to ensure basic welfare protections for organic poultry.

GMO Vaccines

EXECUTIVE SUMMARY

- Vaccines for which no non-GMO version exists can be petitioned individually and added to the National List.

- The Livestock Committee's proposal states that "information in the TR and information received from other sources in the field did not indicate that GMO vaccines were essential to organic production at this time."

- GMO vaccines should be allowed only in *bona fide* emergencies, and only when no conventional alternative is available. Language in the proposed rule should be further strengthened to ensure strong safeguards are in place to prevent misuse.

GMO Vaccines

According to the USDA General Counsel, GMO vaccines are not allowed in organic production unless they are specifically added to the **National List. Vaccines for which no non-GMO version exists can be petitioned individually and added to the National List**.

We urge the NOSB to fine tune the Livestock Committee's proposal in a way that will prevent GMO vaccines from being used in all but the most critical and legitimate emergency situations, and with adequate restrictions to prevent abuse.

According to the Livestock Committee, as stated in the proposal, "The TR does not point to a single or narrow group of problem diseases in organic livestock that are creating hardship and urgently need to be addressed with GMO vaccines," and, "A review the USDA's APHIS list of Livestock Vaccines, regulated by the Center for Veterinary Biologics, suggest that there are non-GMO vaccines available for virtually all common potential livestock sicknesses."

The only two vaccines for which no non-GMO vaccines are available are avian and bovine salmonellosis. We would like to see a more thorough discussion and analysis of these particular vaccines and the conditions they prevent. If organic producers need these vaccinations and they are indeed only available in GMO form, they could be petitioned for addition to the National List (with a comprehensive annotation limiting their use). A thorough and unbiased Technical Review should be completed for each one, rather than relying on the current TR, which deals with the whole class of GMO vaccines rather than individual materials.

In terms of other GMO vaccines, we would like to see more discussion of possible impending emergencies for which GMO vaccines would be required. Has such a

scenario occurred in the past, where farmers were forced to use a GMO vaccine? How likely is it that a much-needed vaccine will be available only in GMO form?

The Livestock Committee's proposal states that "information in the TR and information received from other sources in the field **did not indicate that GMO vaccines were essential to organic production at this time**."

We support the comments submitted by former NOSB Chair Jim Riddle, who suggested that the NOSB should recommend that the NOP engage in an information campaign to empower producers, inspectors and certifiers with the knowledge and tools they need to prevent the use of GMO vaccines in organic livestock production. We believe this should be achieved primarily by creating environments and management techniques that discourage communicable disease.

Yet we also understand that GMO vaccines may be necessary in the future, for legitimate reasons, and believe organic farmers should be able to use them without losing their organic certification – <u>but strong safeguards must be put in place to prevent misuse</u>.

GMO vaccines should be allowed only in *bona fide* emergencies, and only when no conventional alternative is available. Safeguards must be set up to ensure that emergency declarations are legitimate and will protect family-scale farmers. We could imagine a situation where family-scale farmers would not need a certain GMO vaccine, but industrial-scale livestock facilities may need it to solve problems caused by the model of livestock production.

As an example, an industrial-scale dairy may need a certain vaccine because they are continually purchasing animals, rather than operating with a closed herd. "Closed herds," in dairy production, are virtually synonymous with the word "organic," and certain diseases may impact only those who do not manage closed herds. In such a case, we would not want to see a loose definition of an emergency, opening up the use of GMO vaccines, when it would benefit only industrial-scale producers and allow them to keep their organic certification while turning to common industrial practices that are not compatible with organics.

However, legitimate emergencies that would negatively impact livestock operations of all sizes, including family-scale farms, may arise in the future, for which the only option could be a GMO vaccine. We share the concerns that there may not be a big enough market for the development of non-GMO vaccines, as organic alternatives, in such emergencies, which would put organic producers at a severe disadvantage.

Livestock Committee should fine tune the language related to the emergency, to answer questions such as who can declare the emergency, and how long can the emergency last.

The NOSB should remember that unintended consequences may exist from the use of GMO vaccines. Their use should be very restricted, and rule language should ensure this.

In conclusion, we would recommend that the NOSB table the approval of GMO vaccines as a class encouraging petitions to approve the two vaccines that are currently on the market and said not to have non-GMO alternatives. And in the meantime, the Livestock Committee should clarify and strengthen the language restricting the use of GMO vaccines.

MATERIALS COMMITTEE

SOLVENTS AND EXTRACTANTS

EXECUTIVE SUMMARY

Cornucopia believes that the use of volatile synthetic solvents should be prohibited for all ingredients in certified organic foods, including those on the National List.

- 205.270(c) should be rewritten as follows (addition emphasized):

> (c) ~~The handler of an organic handling operation must not use in or on agricultural~~ Products sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))," or in or on any ingredients labeled as organic **must not be made using**:
> (1) Practices prohibited under paragraphs (e) and (f) of §205.105.
> (2) A volatile synthetic solvent or other synthetic processing aid not allowed under §205.605: Except, That, nonorganic ingredients in products labeled "made with organic (specified ingredients or food group(s))" are not subject to this requirement.

SOLVENTS AND EXTRACTANTS

Thank you for the discussion document on extractants and solvents. We believe that the current rule, which prohibits the use of synthetic volatile solvents only by certified organic handlers, is extremely misleading to consumers who should rightfully expect all ingredients in a certified organic product to be produced without the use of volatile synthetic solvents.

The use of annotations to prohibit volatile synthetic solvents for some materials on the National List, but not for others, adds to the confusion and inconsistency.

Moreover, the recent decision by the NOSB, at the Fall 2011 meeting, to prohibit certain volatile synthetic solvents in annotations, has made it clear that the prohibition against volatile synthetic solvents in organic foods must be clarified immediately.

Specifically, the NOSB's recommendation to allow DHA algal oil extracted with the volatile synthetic solvent isopropyl alcohol, but to prohibit the volatile synthetic solvent hexane, makes no sense and illustrates the need for clarification and consistency.

Just as the use of genetic engineering, sewage sludge and ionizing radiation is prohibited for all ingredients in organic foods, regardless of whether they are

agricultural or nonagricultural, synthetic or non-synthetic, we believe the use of volatile synthetic solvents should be prohibited for all ingredients.

Our answers to the questions requested by the Materials Committee:

Question 1: How should "volatile synthetic solvent" be defined, especially in relationship to the rule 205.270(c)2? Should we make a distinction between different types of solvents? If possible, reference to a standard scientific or regulatory definition is preferred. Should the toxicity of a volatile synthetic solvent affect how it is treated in classification and materials evaluation? Does supercritical carbon dioxide meet the definition?

We support the definition of "volatile synthetic solvent" given in the discussion document: "a volatile synthetic solvent is a synthetic chemical with boiling point less than 287 degrees Celsius that can dissolve another substance."

We agree that using the boiling point of a chemical to determine whether it classifies as "volatile" or "very volatile" is useful, especially since it provides a specific reference point that leaves no room for interpretation. Using this definition will ensure that commonly used volatile synthetic solvents, such as hexane and isopropyl alcohol, will fall under this definition.

Supercritical carbon dioxide cannot be evaluated using this criteria, since it is a gas, and should therefore be evaluated separately by the NOSB.

Question 2: Is there a distinction between volatile solvents used for extraction vs. volatile solvents used for other purposes? Solvents are also used for purposes other than extraction, such as purification of a substance via crystallization. Solvents are also common inert ingredients in formulated pesticide products.

The rule does not specify that volatile synthetic solvents are prohibited only for the purpose of extraction. Therefore, the prohibition in the rule is against volatile synthetic solvents, regardless of how they are used.

Question 3. Should the process of extraction change the classification of an agricultural product to a non-agricultural material? Does it matter whether the extractant is synthetic or non-synthetic? When this happens to an agricultural material that is currently organically grown, does this changed material then need to be petitioned?

The process of extraction should not necessarily change the classification from agricultural to non-agricultural, since this classification depends on the original material. However, the process of extraction may result in a change of classification from non-synthetic to synthetic.

If an agricultural material is extracted with a volatile synthetic solvent, it should be classified as synthetic and be petitioned.

Question 4. Since §205.270 Organic Handling Requirements explicitly prohibits volatile organic solvents, ["(c) The handler of an organic handling operation must not use in or on agricultural products intended to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))," or in or on any ingredients labeled as organic: (2) A volatile synthetic solvent or other synthetic processing aid not allowed under §205.605: Except,
That, nonorganic ingredients in products labeled "made with organic (specified ingredients or food group(s))" are not subject to this requirement"], should consumers expect that non-agricultural ingredients identified as "organic" be produced or extracted with the same restriction? Please explain the rationale for a different standard for agricultural and non-agricultural if that is the position.

Yes, we believe the prohibition against volatile synthetic solvents should apply to **all** ingredients in an organic formulated product, regardless of whether the ingredient is agricultural or non-agricultural.

In the Preamble, the USDA intended the prohibition against volatile synthetic solvents to apply to the 5% nonorganic ingredients, just as genetic engineering and ionizing radiation is prohibited for **all** ingredients.

The current language in the rule, prohibiting certified organic handlers from using volatile synthetic solvents, but allowing certified organic handlers to purchase ingredients from non-certified handlers who **do use** volatile synthetic solvents, is a loophole with serious implications for the integrity of organic products.

One way to ensure that organic products be produced without volatile synthetic solvents is to apply the restriction against volatile synthetic solvents to the organic products, rather than the organic handler.

205.270(c) should be rewritten as follows (addition emphasized):

> (c) ~~The handler of an organic handling operation must not use in or on agricultural~~ Products sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))," or in or on any ingredients labeled as organic **must not be made using**:
> (1) Practices prohibited under paragraphs (e) and (f) of §205.105.
> (2) A volatile synthetic solvent or other synthetic processing aid not allowed under §205.605: Except, That, nonorganic ingredients in products labeled "made with organic (specified ingredients or food group(s))" are not subject to this requirement.

Question 5. Similarly, should synthetic substances allowed for use in organic crop production under §205.601 be allowed or prohibited from using volatile synthetic solvents in their production or extraction? Should non-synthetic substances used in organic crop production be allowed or prohibited from using volatile synthetic solvents in their production or extraction, regardless of chemical change or significant residues?

Any input that is produced with the use of a volatile synthetic solvent should be classified as a synthetic, and be reviewed by the Board. Classification as a synthetic and subsequent review by the Board is the only way to ensure that possible residues, environmental pollution, and other impacts of the solvent will be examined.

Question 6. Is guidance needed concerning whether or under what circumstances the use of an extractant/solvent causes chemical change in the extraction process?

Chemical change as a result of extraction would classify a material as synthetic, but a material should be classified as a synthetic when a volatile synthetic solvent is used at all.

Question 7. What is a significant residue of a synthetic solvent?

Any residue is significant. Volatile synthetic solvents should not be used in any ingredients destined for certified organic foods.

Question 8. Should the prohibition on the use of volatile synthetic solvents include the use in any ingredient in the history of the product?

Yes. Certified organic products should be produced without the use of synthetic volatile solvents, and this prohibition should apply to **all** ingredients. As we mentioned earlier, it makes no sense to apply the prohibition against volatile synthetic solvents only to organic handlers, therefore allowing an organic handler to purchase ingredients from non-certified handlers that do use volatile synthetic solvents.

Question 9. For substances already on the National List, should it be assumed that any extractant is allowed, or should the NOSB attempt to specify allowed extractants moving forward or for previously listed substances?

Volatile synthetic solvents should not be allowed in any ingredients in certified organic foods, including ingredients on 605 and 606. The language in the rule should be changed to ensure that consumers' expectations are met, and volatile synthetic solvents are not used in the production of organic foods. The prohibition against volatile synthetic solvents in 205.270(c) should apply to all products, rather than applying only to organic handlers.

Any substances already allowed should be scrutinized under the more restricted criterion as they come up for sunset review.

RESEARCH NEEDS

We support the Materials Committee's proposal for Research Priorities Framework.

We agree that there is a need to make the research priorities of the NOSB known to researchers, funders and the public. Good research on organic systems management and alternatives to synthetic inputs is needed to support organic farmers, and to ensure the continued success and growth of the organic industry.

The identification and prioritization of research needs is important, and we would like to stress that the NOSB should do as much as it can to ensure that the list of research priorities results in actual research being funded and performed.

SIGNIFICANT RESIDUES AND CLASSIFICATION OF MATERIALS

EXECUTIVE SUMMARY

Any residue of a synthetic is "significant" and should trigger review.

- Under OFPA, synthetics are prohibited unless reviewed and approved, and non-synthetics are approved unless reviewed and prohibited. This is why it is so important to ensure that **any materials that are produced with the use of synthetics be classified as synthetics**, since this is the only way to trigger the required review by the NOSB.

- We support the following definition of "significant":

  > "*any known level of a synthetic substance in the final material or in the environment, as a result of the substance's manufacture, use and disposal.*"

SIGNIFICANT RESIDUES AND CLASSIFICATION OF MATERIALS

Any residue of a synthetic is "significant" and should trigger review. Under OFPA, synthetics are prohibited unless reviewed and approved, and non-synthetics are approved unless reviewed and prohibited. This is why it is so important to ensure that any materials that are produced with the use of synthetics be classified as synthetics, since this is the only way to trigger the required review by the NOSB.

We support the following definition of "significant":

> "*any known level of a synthetic substance in the final material or in the environment, as a result of the substance's manufacture, use and disposal.*"

This ensures that OFPA is respected, since OFPA requires the examination of *all* synthetics used in organic production and handling, including their impacts from their manufacture, use, and disposal. The only way to ensure that the proper review be made of materials that are produced with the use of synthetics is by classifying them as synthetic.

Since OFPA requires review of synthetics' environmental impacts, using the benchmark of "significant residues" would not be adequate, since a material could theoretically be produced using an environmentally hazardous synthetic but contain no residues.

Also, how do we define "significant" if our understanding of the impacts of residues is constantly changing? Residues that were once believed to be insignificant have

been discovered to be deleterious to human health at much lower levels than previously thought worthy of note.

For other chemicals, very low levels have been found to actually be more harmful, and therefore more "significant," than higher levels (as in the case of endocrine disruptors). We cannot depend on the limits set by other federal agencies, nor should the organic community be subordinate to these limits. Our responsibility is to be more careful than other agencies, and make human and environmental health our priority. For these reasons, any levels at all should be considered "significant."

It is important for the Board to remember that the issue is not approving or prohibiting materials produced with synthetics, but simply whether they should be reviewed.

For this purpose, any level at all is significant and should trigger review.

Answers to questions:

Question 1. Under what circumstances, should the presence of a synthetic impurity trigger an examination of the impacts of the synthetic in relation to OFPA criteria?

Any level of a synthetic impurity should be considered "significant" and trigger a review of the material.

Question 2. Do any of the three approaches described make sense? If so, why?

Yes, Cornucopia supports the second approach.

This approach would characterize any known or detectable level of a synthetic substance in the final material or in the environment, as a result of the substance's manufacture, use, and disposal as a significant level triggering NOSB review.

Question 3: Is it reasonable to tie the definition of "significance" in materials classification to the need for review under OFPA? If not, is there another way to ensure that the presence of a synthetic impurity in levels of consequence under OFPA trigger a review? And how would "significance" be defined in the context of materials classification if not in relation to the need for review under OFPA?

The use of the term "significance" is confusing. The only way to ensure proper review is by requiring review of any substance with any known level of a synthetic substance in the final material or in the environment as a result of the substance's manufacture, use and disposal.

Question 4: The need for defining a significant residue arises from the Classification of Materials Policy adopted earlier that says that the use of a synthetic extractant or reactant does not affect the classification of a material, thereby allowing the use of synthetic extractants, reactants, or processing aids that may end up as impurities in the material. Should that policy be changed instead?

Yes, that policy should be changed. Any material processed with a synthetic extractant or reactant must be classified as a synthetic.

CROPS COMMITTEE

LIST 3 INERTS

The Cornucopia Institute supports the Crops Committee's proposal to review List 3 inerts. These chemicals should never have been listed without the proper review that is required by OFPA, and the NOSB should move forward with their review.

As outlined in the proposal, 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. Given that there are only four List 3 inerts that require review, and that the Crops Committee had no other work on its agenda for this meeting, it is inexplicable that the Crops Committee again delayed the required review of these materials.

Consumers expect organic food to be produced without the use of potentially dangerous chemicals, and they especially expect any chemicals used in organics to have been thoroughly reviewed and approved. This expectation is legally grounded in OFPA. These chemicals should not be given a free pass from the legally required review process simply because they have been referred to as "inerts."

The term "inerts" is inappropriate and misleading, and even the EPA encourages manufacturers to use the term "other ingredients" instead of "inerts." "Inerts" cannot be considered benign or harmless, especially since they often act to increase the effectiveness of the active ingredients. "Inert" ingredients can have toxicological effects, on human health or the environment, including acute and chronic effects.

We believe that all "inert" ingredients, including those formerly categorized as List 4A and List 4B by the EPA, should be reviewed. While it may seem a daunting task given the number of chemicals on this list, it is absolutely necessary for the integrity of organics that all chemicals used in organic production be reviewed. Organic consumers expect nothing less.

If strategies exist to facilitate and expedite the review of these chemicals, such as grouping certain chemicals in classes and reviewing classes rather than individual chemicals, we would support any strategy recommended by Beyond Pesticides, which is a leader in the field of protecting human health and the environment from the toxic effects of agrichemicals.

AD HOC GMO COMMITTEE

Letter to Secretary Vilsack

EXECUTIVE SUMMARY

Cornucopia applauds the members of the Ad Hoc GMO Committee for taking the initiative to communicate to Secretary Vilsack the organic community's concerns with GMO contamination of organic crops and foods. We urge the Board to approve the letter and summarily send it to Secretary Vilsack.

We support the Board's unfettered right, backed by the will of Congress, to communicate with the Secretary at any time on any issue they deem of importance to the organic community.

LETTER TO SECRETARY VILSACK

Cornucopia applauds the members of the Ad Hoc GMO Committee for taking the initiative to communicate to Secretary Vilsack the organic community's concerns with GMO contamination of organic crops and foods.

We agree with the Ad Hoc GMO Committee that the "USDA's actions to date on genetically engineered crops have been insufficient to protect the organic industry," and that "organic farmers must no longer be held solely responsible to prevent contamination from practices outside their control."

We have been very concerned with the Obama/Vilsack administration's support of GMOs and the biotechnology industry, and the threat of contamination that this poses to organic crops and foods.

We agree with the Ad Hoc GMO Committee's letter that "the GMO technology should share the burden that organic farmers now assume in mitigating the gene flow between farms and should compensate organic farmers for genetic drift." We imagine that most, if not all, organic farmers and organizations concerned with organic agriculture share this concern. We therefore appreciate the Ad Hoc GMO Committee for taking the initiative to represent the organic community in communicating these concerns to Secretary Vilsack.

We urge the Board to approve the letter and summarily send it to Secretary Vilsack.

POLICY DEVELOPMENT COMMITTEE

CONFLICT OF INTEREST

EXECUTIVE SUMMARY

Cornucopia supports the proposal, and respectfully asks that the following additions be considered:

- There should be an opportunity for Board members, or members of the public, to point out potential conflicts of interest to the Board at large, and for the full Board to vote on the conflict regardless of whether the Board member in question voluntarily mentions the conflict.

- Contractors who perform Technical Reviews for the National Organic Program and NOSB should be required to disclose to the public the identity of scientists performing the work, and sign a statement that no conflicts of interest exist (either on the part of the contractor or any staff or subcontractor working on the project).

- During public comment (written and oral), those testifying should disclose their past and current clients, or other involvement with any company or organization that has a financial interest related to the issue.

CONFLICT OF INTEREST

Cornucopia supports the Conflict of Interest (COI) proposal, which aims to enhance the current COI policy. In order to strengthen the COI policy even further, we respectfully propose the following additions for consideration.

Addition to Recommendation #3
Recommendation #3 suggests that the Board will vote on a Board member's ability to engage in discussion and vote on a particular matter, but only after said Board member voluntarily declares his/her potential conflict of interest. There should be an opportunity for Board members, or members of the public, to point out potential conflicts of interest to the Board at large, and for the full Board to vote on the conflict regardless of whether the Board member in question voluntarily mentions the conflict.

There have been instances where Board members have voluntarily mentioned inconsequential conflicts while refraining from mentioning serious ones. For example, Dr. Katrina Heinze, at the Fall 2011 meeting, failed to mention General Mills' licensing agreement with Martek Biosciences Corporation while participating in the debate and voting on Martek's petition on DHA/ARA oils.

In committee meetings, similar failures to mention conflicts have recently occurred, as when Mr. Joe Dickson, in the Handling Committee, failed to declare that his employer (Whole Foods) widely uses, in its 365 private-label products, a material up for sunset review (carrageenan). Given that Mr. Dickson failed to mention the conflict during the committee meetings, it would not be unreasonable to suspect that he might also fail to mention the conflict at the biannual meeting and final vote.

As the recommendation is currently written, the full Board would be unable to vote on a Board member's conflict of interest unless he or she voluntarily declares the conflict. As a result, only Board members with integrity will declare their conflicts, while the possibility exists that other Board members will, intentionally or unintentionally, hide their conflicts. If members of the public have convincing evidence that a Board member has a conflict, they should be able to bring this to the attention of the Chair, and be subject to a vote.

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.

As an example, for the Technical Reviews on Martek DHA Algal Oil and ARA Fungal Oil, much of the information was taken from the Linus Pauling Institute website, which is not a primary source of scientific information (a serious deficiency in terms of what is required according to the NOSB procedure manual). The DHA Algal Oil Technical Review was severely deficient in pointing out the lack of health benefits from DHA algal oil, and failed to include the most important meta-analysis studies done on the subject.

A consultant to the food industry, and former TAP author, Bob Durst, is employed at the Linus Pauling Institute, which raises questions about Mr. Durst's involvement with the TR.

We are not making allegations of any specific improprieties, but rather pointing out why it is important for any individuals and contractors involved with TRs to identify themselves.

This is especially important since individuals involved with the TRs could act as consultants for the petitioner. For example, Mr. Durst presented oral testimony at the NOSB meeting in Savannah in favor of DHA Algal Oil, without disclosing his client.

Again, we are not making allegations against Mr. Durst, but rather pointing out the importance of greater transparency of the TRs. And we want to reinforce our comments, in the area of conflict of interest, that all individuals testifying, written and oral, to the NOSB need to declare their current client and any past financial relationships which could be construed as conflicts in relationship to their testimony.

Public Commenters
During public comment, presenters should disclose their past and current clients, or other involvement with any company or organization that stands to gain financially from the vote on the issue.

During public testimony, consultants and other individuals often speak on an issue without disclosing who their client is, or who financially supported their presence at the meeting. This makes it difficult for NOSB members to gauge the level of general support or opposition for a petition or issue, versus the level of financial support. After all, consultants, scientists, physicians, farmers and other individuals who are paid to attend the meeting, or whose expenses are covered, are a reflection of the financial clout of a corporation, not necessarily a reflection of general support.

Committee Proposals
Discussion documents and committee proposals by the NOSB that are not the result of a petition should be accompanied by a declaration of which Board member initiated the document and whether this Board member has a financial relationship with any company that stands to gain from the proposal. If the proposal came from a member of the community or the public, the Board member who spearheads the proposal should identify the source. Without this information, it would be too easy for Board members to initiate and recommend rules that would directly benefit their employers.

PUBLIC COMMENT PROCEDURES

EXECUTIVE SUMMARY

- We recognize that some restrictions might be necessary, but a formula should be devised to maximize public participation. We do not support the three minute restriction without other modifications that would enhance public participation. reluctantly accept the proposal to limit public comment to 3 minutes, as long as the Board reinstates the ability to comment by proxy. Another viable alternative would be the meritorious suggestion by the National Organic Coalition providing for 5 minutes, with gradual reductions in time based on pre-registrations (again with preserving proxies).

- Another option includes extending the public comment from 3 minutes to 5 minutes at the Chair's discretion, especially when experts travel great distances to share their expertise with the Board.

- We agree that the Q&A during public comment should be unlimited.

PUBLIC COMMENT PROCEDURES

Some of the issues before the Board are very complex, and cannot easily be explained in just 3 minutes. While the Board can receive comments in writing before the meeting, there are numerous reasons why relying on extensive written comments alone is not sufficient.

First, Board members understandably become overwhelmed with the volume of written comments, and benefit from listening to oral comments during the meeting. Second, written comments are 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.

Furthermore, the opportunity for board members to ask questions, after a comprehensive presentation, is invaluable to the decision-making process.

It should be noted that during the over 20-year history of the NOSB, the current three-minute limitation on oral testimony, and the elimination of proxies, is unprecedented.

NOSB members universally viewed the opportunity for public input at the meetings to be a vital element of the community coming together twice a year. Past Boards practically bent over backwards to accommodate everyone who wanted to speak. Sometimes that meant ending meetings at 6 or 7 PM rather than 5 PM, and sometimes Board members were willing to work over lunch, sending out for food

while continuing to meet (although we hope that would only be necessary under rare circumstances). Their extra efforts were respected and universally appreciated by other meeting participants.

Furthermore, we do not support the NOP's decision to shorten the length of the meeting (in the case of the Albuquerque meeting, by one half day). Any incremental economic savings are disproportionate to the value of full input from the public.

3 minutes: We reluctantly accept the proposal to limit public comment to 3 minutes and we urge the Board to reinstate the ability to comment by proxy. We also believe the possibility of extending the public comment from 3 minutes to 5 minutes at the Chair's discretion is important, especially when experts travel great distances to share their expertise with the Board.

Proxy: The ability to comment by proxy is especially helpful for public interest organizations, who do not have the resources to match the physical presence of lobbyists and corporate representatives present at the meetings. Simply put, public interest groups cannot afford to fly in multiple staff members and pay for farmer-members or suppliers to attend the meeting and testify on their behalf. This jeopardizes true balance in the information presented to the Board.

The total time of public comment is an indication of an organization's financial resources, not an indication of public support. A multibillion-dollar corporation can essentially buy several slots at the podium (by paying and/or underwriting travel expenses for its staff members, lobbyists, lawyers, suppliers or farmers to attend) while many public interest groups – with the support of thousands of farmers and consumers – can usually afford just one slot at the podium. This dynamic has played itself out in past meetings during controversial debates on livestock standards and materials.

Since public interest groups are handicapped in this system of public comment, compared with high resource corporate participants, we believe proxy statements are important because they allow public interest groups to speak on behalf of one additional individual (typically farmer or consumer organic stakeholders).

Unlimited Q&A: We agree that the Board needs to have unlimited time for questions. 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.

Consideration of public comment: We also agree with the PDC that "there is a perception that the Board does not take the time to adequately review and apply public input prior to making their decision." We support whatever scheduling model is needed to ensure full consideration of public comment by the Board.

Electronic media: Finally, we agree the use of electronic media is not currently recommended.

PUBLIC COMMUNICATION

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."*

This seems to be a no-brainer, since the role and responsibility of the Board 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 with 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, <u>not</u> the Secretary.

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 accepts public communications to NOSB members outside of Board meetings and public comment periods to inform the ongoing deliberations of committee work. The Board requests that communications on specific subject matters be sent to the entire Board membership of the relevant committee or, on matters relating to the full Board, be sent to all Board members."*

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. It is absolutely

crucial that committee members receive comments from the public during their deliberations, which provide balancing information and positions, especially when the TR is inadequate, as has been the case in the past.

Preserving two-way communications between NOSB members and the balance of the organic community is consistent with the historically collaborative relationship that this unique regulatory framework was founded upon.

CERTIFICATION, ACCREDITATION AND COMPLIANCE COMMITTEE

100% Organic labeling and sanitizers

EXECUTIVE SUMMARY

Meticulous sanitation should be the hallmark of all production systems (conventional and organic). Within the restrictions of OFPA and the federal organic regulations, the use of sanitizers should not disqualify food products from 100% organic labeling.

Value of the 100% Organic Label

We are not aware of any consumer survey research on the importance of the 100% organic label. It seems to us that consumers are especially interested in the organic label, and that many would not know the difference between "certified organic" and "100% organic." As far as we know, consumer education about the organic label generally focuses on the importance of the organic label and the USDA Organic seal, and not on the differences between the top two labeling tiers.

Processing aids and sanitizers and 100% organic label

Contact with a non-organic input in a farm field does not disqualify a commodity from being 100% organic. Addition of a non-organic input in the handling facility (as an ingredient) does disqualify an item from being 100% organic. Processing aids such as sanitizers fall in a gray area in between. While some may say that no residues appear in the final food, this assertion should be studied more thoroughly because it does appear that residues of sanitizers may appear in the final product. As an example, certain patients being treated for thyroid cancer, and having to avoid iodine in their diets, are required to forgo dairy products as iodine is a typically used sanitation product on dairy farms.

Another complicating factor is that there appear to be no organic alternatives for sanitizers. The only alternative would therefore to be to use no sanitizers at all, and just wash with spring or well water containing no chlorine or other sanitizers (with some associated risk). Even so, that means that a farmer using municipal water with chlorine would be disqualified, while a farmer using similar practices on and off the field but using non-chlorinated well water, would qualify.

It seems to us that the use of processing aids and sanitizers, when used lawfully and within the constraints of the National List, should not disqualify a product from the 100% organic claim.

However, it is important that the use of some of these products be "restricted" and that any such restrictions be enforced by ACAs and the USDA.

It has come to our attention that some produce companies are skirting the restrictions that chlorine levels in wash water not exceed safe water drinking act maximums. By treating fruits and vegetables at much higher levels, and adding additional water prior to discharge, they are practicing "solution by dilution." This is deleterious to the environment and there very well might be other examples in addition to chlorine where abuses are taking place. We don't know if research has been done on residues or any negative human health impacts.

Food Safety

The CACC asked a question about food safety and the use of sanitizers, and we believe that some sanitizers, when carefully reviewed for use in organics, play an important role in ensuring the safety of organic foods.

Conclusion

The proper food safety environment, and meticulous sanitation, should be the hallmarks of all production systems (conventional and organic). Within the restrictions of OFPA and the federal organic regulations, their use should not disqualify food products from 100% organic labeling.

ADDITIONAL ISSUES

Request for New TRs

EXECUTIVE SUMMARY

Cornucopia respectfully requests a new TR be performed for every material that is up for sunset review, and that the Handling Committee's proposal be based on information in the current TR.

REQUEST FOR NEW TRs

We respectfully request that a new Technical Review be sought and performed for every material that is scheduled for sunset review.

First, we apparently cannot always rely on the work of past TRs/TAP reviews. While some TRs have been objective and competently produced, others have appeared patently biased, failing to identify serious human health and environmental impacts of the petitioned material.

Carrageenan, for example, was reviewed in 1995 by three scientists with professional relationships to corporate agribusiness, and none pointed out the potential human health impacts of food-grade carrageenan. This is especially outrageous since the scientific community had known for decades, based on an abundance of peer-reviewed published literature, that degraded carrageenan is an inflammatory agent and carcinogen in lab animals. **Degraded carrageenan was listed as a "possible human carcinogen" by the World Health Organization**'s International Agency for Research on Cancer in 1983 – more than a decade before the 1995 TAP review.

At a very minimum, the TAP reviewers should have suggested an annotation, prohibiting degraded carrageenan, when adding the material to the List. Today, an annotation would be meaningless since industry data from 2005 clearly shows that all food-grade carrageenan contains some levels of degraded carrageenan.

Debate about the harmful human health effects of food-grade carrageenan dates back to the late 1970s. In 1980, British scientists R. Marcus and James Watt published a letter in *The Lancet* titled "Potential Hazards of Carrageenan," which sparked an open debate in that renowned scientific journal.

It was inexcusable for the three TAP reviewers in 1995 to fail to mention the concerns with carrageenan that were so openly and publicly debated in the

scientific community. Even today, one of the three TAP reviewers, Dr. Richard Theuer, continues to publicly defend carrageenan in his recent comment to the NOSB, which raises serious doubts regarding the dozens of synthetic materials that were supposedly carefully reviewed by Dr. Theuer in the mid-1990s. It raises the question of which other materials were approved in organic foods due to negligence, bias and grossly deficient TRs, and provides justification for requesting a TR for every sunset material.

Second, the Board cannot confidently renew materials without a review of recent scientific data. Our understanding of materials, and scientific data, is constantly evolving. If new information exists that would justify the sunsetting of a material, the Board would not know about it unless they were given a new TR, or did the research themselves.

Again, using carrageenan as an example, more recent research indicates that not only does all carrageenan on the market contain some percentage of degraded carrageenan, but that food-grade carrageenan degrades in the human digestive system. Degraded carrageenan, a "possible human carcinogen," therefore appears to be a breakdown product of food-grade carrageenan. Products whose breakdown products pose a threat to human health are specifically prohibited in organics (7 CFR 205.600(b)(3)).

Currently, the Handling Committee states about several materials up for sunset review that "there is no new information contradicting the original recommendation." Yet without a current TR, it is unclear on what they are basing this conclusion. These appear to be irresponsible statements, not adequately protecting the interest of the public or carrying out the mandate by Congress.