Comments to the National Organic Standards Board

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CORNUCOPIA
INSTITUTE

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INTRODUCTION

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

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

We are proud to represent approximately 8,000 supporting members, the majority of whom (70% based on the last calculation) are certified organic farmers.

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

With a history of agribusiness involvement in both the analysis of petitioned materials and decision-making at the NOSB level, we hope that current Board members will benefit from Cornucopia's independent perspective, assessing the health and environmental implications of any material presented for their review.

We have no financial interest in the approval of any of the materials proposed for use in organic foods.

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

All petitioned materials on this meeting's agenda fail at least one, and sometimes several, of the criteria outlined in OFPA and the regulations. We urge you to reject all petitioned materials.

We also urge you to keep the current expiration date for oxytetracycline for use in organic apple and pear production, and we support the minority position.

Furthermore, we are very concerned with the Handling Subcommittee's proposal ignoring the criteria outlined in OFPA and the federal regulations in dealing with auxiliary/"other" ingredients that are found in multi-ingredient materials, and that will ultimately end up in organic foods. We urge the Board to adopt Option D, which is supported by Cornucopia and numerous other public interest organizations.

Finally, we support the proposal to establish an online mechanism to facilitate year-round communication between Board members and the public. We also support the proposal for limited scope technical reviews.

I. MATERIALS SUBCOMMITTEE

PROPOSAL:

PROCESS FOR LIMITED SCOPE TECHNICAL REVIEWS

We support the proposal to establish a process for *limited scope* Technical Reviews (TRs). We support this proposal as a way to save time and resources in cases where certain threshold criteria are not met, and a full TR would not be warranted.

However, we believe it is important to specify that the limited scope TR would only be used as an interim step, and that no material could ever be added to the National List unless a full TR has been conducted. It should be specified that the interim TR could only lead to a rejection of the material by the full board or a decision by the subcommittee to move a petition forward by subsequently requesting a full TR before the material is brought to the full Board.

In essence, the purpose for a limited edition TR would be to facilitate a go/no-go interim decision.

Under no circumstances should a material be added to the National List when only a limited scope TR has been performed. While we believe this is the intent of the proposal, we suggest making this very clear in the proposed language to circumvent potential future abuse.

In fairness to petitioners, we also suggest that the responsibility for rejecting a material, based on a limited scope TR, still lies with the full Board, rather than the subcommittee.

DISCUSSION DOCUMENT:

CONFIDENTIAL BUSINESS INFORMATION IN PETITIONS

SUMMARY

We support proposed recommendation #1.

The Organic Foods Production Act of 1990 (OFPA) specifies that materials may only be added to organic foods or to the National List if certain criteria are met. The NOSB is not able to make an informed decision whether a material meets these criteria if critical information is withheld.

Information necessary to make an informed decision based on OFPA's criteria includes the full list of ingredients, sub-ingredients, processing aids, manufacturing processes, and complete disclosure of all known human health/environmental impacts.

CORNUCOPIA'S COMMENTS

We agree with the Materials Subcommittee that the misunderstanding that certain information can be withheld in petitions "has not served either the petitioner or the NOSB particularly well."

OFPA specifically states (7 USC 6518(l)(2)) that the NOSB must work with manufacturers to obtain a full list of ingredients of petitioned materials.

OFPA also states that materials cannot be added to the National List if they are harmful to human health or the environment. The only way to determine whether a material is harmful to health or the environment is by considering all available data, including knowing which processing aids are used and having access to results from all safety studies. Therefore, petitioners should not be able to withhold any information regarding processing aids or studies on human health effects or environmental impacts.

The discussion document mentions the Trade Secrets Act, but it is important to note that OFPA is not subordinate to the Trade Secrets Act nor does it state that any information necessary to carry out the requirements in OFPA is exempt under the Trade Secrets Act. Clearly, the Trade Secrets Act does not supersede OFPA or the responsibilities of the NOSB to carry out their responsibilities.

Participation in the organic industry is voluntary; if a manufacturer is unwilling to share information about ingredients, processing aids or human health/environmental impacts to protect trade secrets, the USDA is under no obligation to make an exception for such manufacturers.

Manufacturers who wish to keep the public in the dark about the ingredients and processing aids they use can sell their products in conventional foods. The organic label is an alternative to conventional foods—an alternative food system marked by transparency and careful scrutiny of potential health/environmental impacts.

Manufacturers cannot have it both ways; transparency is a prerequisite to participation in the organic food system. Any petition with ingredients, processing aids, and human health/environmental impacts withheld as CBI should automatically be sent back to the petitioner by the NOP. Such petitions should not be forwarded to the NOSB, so as not to waste the NOSB's time with petitions that should never legally be approved.

If a manufacturer has a unique, proprietary manufacturing system, or product formulation, we suggest that they seek protection through the US patent office prior to seeking NOSB approval.

The following should never be considered trade secrets and should not be withheld as CBI:

1. **A full list of "other ingredients"**

We do not expect a petitioner to disclose the exact recipe with detailed percentages or proportions of the ingredients, but it is clear that a full list of all ingredients should be disclosed.

OFPA states that the NOSB must work with manufacturers to obtain a full list of ingredients (7 USC 6518(l)(2))[1] to allow the NOSB to determine whether all ingredients meet OFPA's requirements.

2. **Effects on human health and/or the environment**

OFPA requires that materials on the National List must not be harmful to human health or the environment. Such information cannot be withheld as Confidential Business Information.

[1] 7 USC 6518(l)(2): Requirements – In establishing the proposed National List or proposed amendments to the National List, the Board shall work with manufacturers of substances considered for inclusion in the proposed National List to obtain a complete list of ingredients and determine whether such substances contain inert materials that are synthetically produced

In Albemarle Corporation's current petition for the antimicrobial chemical DBDMH, an entire section titled "Effects on Human Health" was redacted as CBI. This suggests that Albemarle Corporation has performed studies and has information on this chemical's effects on human health, but is unwilling to share these results with the public. Under no circumstances should a petition with such redactions be considered eligible for review by the NOSB. Such petitions should be sent back to the petitioner by the NOP.

3. **Manufacturing process**

While the Material Subcommittee notes that the manufacturing process is considered eligible as a trade secret by the Trade Secrets Act, the Trade Secrets Act does not supersede OFPA. OFPA requires that a material not be harmful to human health and the environment, and that it be compatible with organic handling. The NOSB can only make this determination if the full list of processing aids and manufacturing steps is known.

This information is also needed to determine whether excluded methods were involved in the manufacturing of the product.

CORNUCOPIA'S POSITION

We support Possible Recommendation 1:

> *"CBI is not allowed in petitions. Petitioners must provide complete information about manufacturing processes and ingredients so that the NOSB and the public can fully evaluate each petitioned material."*

Organic foods provide consumers with an alternative to the highly secretive conventional food supply. Approving materials without full disclosure is unacceptable. Petitions with CBI withheld cannot legally be approved, so they are an unproductive use of time for everyone involved, including NOP staff, Technical Review contractors, the NOSB and the public stakeholders who perform requisite research and comment on NOSB recommendations.

These petitions should be sent back to the petitioner by the NOP, so as not to waste the NOSB's time.

DISCUSSION QUESTIONS

1. **Should Confidential Business Information be allowed in petitions? Please explain your answer.**

It would be reasonable for a petitioner to withhold certain details about proprietary formulations and/or manufacturing processes.

However, OFPA specifically requires that every ingredient and processing aid in a certified organic product must either be organically produced or appear on the National List. If information about ingredients and processing aids is withheld as Confidential Business Information, the NOSB and USDA cannot legally approve the material.

We therefore believe that a full list of ingredients and processing aids must be disclosed, and this information cannot be considered Confidential Business Information.

The NOP must be clear with petitioners that no petition will be accepted, and will not be forwarded to the NOSB, if the petitioner withholds the full list of ingredients and processing aids as CBI.

However, details about formulations, such as specific quantities and ratios of ingredients, could be withheld as CBI.

2. **If CBI is allowed, should it be limited so that it does not involve ingredients or manufacturing processes?**

The full list of ingredients, processing aids and manufacturing steps should not be withheld as CBI, but it would be reasonable to allow a petitioner to withhold the specific quantities/ratios of ingredients and processing aids.

Furthermore, information and studies on environmental and human health impacts should never be allowed to be withheld as CBI, as Albemarle Corporation has done in its petition for DMDBH.

3. **Do the provisions in Possible Recommendation 2 make sense and are there others that the Board should consider?**

We do not support Possible Recommendation 2.

4. **Provision I in Possible Recommendation 2 is about using an affidavit to supplement a CBI petition. Comment on whether this is valuable.**

<u>Under no circumstances</u> should a petitioner be allowed to sign an affidavit stating that its ingredients and processing aids comply with OFPA, which is essentially a proposal to allow manufacturers to regulate themselves. Such a provision would prevent NOSB members from fulfilling their legal responsibilities under OFPA.

Manufacturers are allowed to "police themselves" by the FDA, which allows manufacturers to make their own determination regarding the safety of new food

additives (the GRAS system). This system has come under heavy criticism—rightfully so—from the Governmental Accountability Office,[2] the Pew Trust[3] and the media.[4]

The organic system was designed to offer an alternative—where independent panels (the NOSB), independent scientists (Technical Reviewers), and the public collaborate on determining whether ingredients, additives and inputs are appropriate in food production and processing.

Allowing manufacturers to sign affidavits would be asking them to essentially perform their own Technical Review, which is entirely unacceptable both in terms of OFPA and consumer confidence in the organic label.

5. **Should procedures, such as a Confidentiality Agreement, be developed that would allow the NOSB, but not the public, to see any CBI?**

No, for several reasons.

First, the NOSB benefits from public input. If certain information is withheld from the public, it weakens the NOSB's ability to solicit and consider input from the public. Collaboration with members of the public is vital to the NOSB process, and we oppose the proposal to introduce Confidentiality Agreements designed to keep the public in the dark.

The NOSB is not a scientific panel. Members depend on research and a diversity of opinion from professionals in the organic community to help them in their decision-making process.

Second, the NOSB members need to be able to speak freely, and discussions during public meetings must be uninhibited. It would be impossible for NOSB members to discuss a petition if they have information that is confidential and protected from public disclosure.

Furthermore, it would expose Board members and the USDA to possible legal repercussions if it were claimed that a breach of confidentiality took place.

CONCLUSION

We support Possible Recommendation 1.

[2] http://www.gao.gov/products/GAO-10-246
[3] http://www.pewtrusts.org/our_work_detail.aspx?id=1203
[4] http://articles.chicagotribune.com/2012-08-25/health/ct-met-food-ingredients-20120825_1_food-ingredients-pew-health-group-fda

The only way for the NOSB to make the legally required determination on petitions and sunset reviews, based on criteria in OFPA and the federal organic standards, is to have full access to all information necessary to make these determinations. This includes all ingredients, processing aids, manufacturing steps and information on human health/environmental impacts.

Possible Recommendation 2 appears to be an attempt to keep the NOSB and/or the public in the dark. We need to move toward more transparency, not more secrecy.

DISCUSSION DOCUMENT:

DEFINITION OF PRODUCTION AIDS

DISCUSSION QUESTIONS

1. Is clarification of the term "production aids" needed?

Yes, it is important to clarify the term "production aids." This will save time, as the NOSB members will not need to spend time evaluating materials that clearly should not be used in organic production. Based on the current definition, production aids do not become part of the ecosystem and are never taken up by the plant.

The discussion document states: "NOP frequently identifies petitioned substances as production aids or possible production aids when assessing the eligibility of a substance prior to NOSB review." For example, chlorine for aquaculture, and carbon dioxide for aquaculture, were classified as production aids by the NOP, but they clearly do not belong in that category. Apparently, it is not only necessary to clarify the definition of production aids, it is also necessary to request that the NOP adhere to that definition.

2. Should clarification give further examples of what is and is not covered by the term? If so, please suggest inclusions and/or exclusions.

Clarification of the term "production aids" should be provided for NOSB members. This would include the materials proposed for the category of production aids, and the reasons for their inclusion or exclusion from the category.

The Discussion Document lists several items that have been identified as production aids by the NOP, and other items that have been referred to as production aids. None of these substances fits the definition of production aids, for the reasons given below.

Ethylene gas, indole-3-butyric acid, oxidized lignite, and 6-benzyladenine are not production aids because they are taken up by plants.

Hydrated lime, ferric phosphate, and oxidized lignite are not production aids because they become part of the terrestrial ecosystem (soil or plants).

Carbon dioxide for aquaculture and chlorine for aquaculture are not production aids because they become part of the aquatic ecosystem.

3. What kinds of materials have historically been covered by the term "production aids"?

The Discussion Document states that the only material listed as a production aid is microcrystalline cheesewax for mushroom production on logs. This material is correctly considered a production aid. Our response to question 2 is also relevant here.

4. Should clarification give a narrative definition, such as "materials used in production but not having direct impact on plants, soil, or the ecosystem"? If so, please suggest language.

In general, we agree with the definition proposed by Beyond Pesticides. We added some clarifying language, and present the full definition here:

- Production aids include:
    - Physical items used in production but not leaving any residues in the aquatic or terrestrial ecosystem.
    - Chemical substances used on equipment, but not used on crops or livestock.
- Production aids do not include:
    - Any substance taken up by plants.
    - Chemical substances dispersed into soil, water, air, or plant surfaces.

II. GMO AD HOC SUBCOMMITTEE

DISCUSSION DOCUMENT:

GMOs and SEED PURITY

This Discussion Document on seed purity is part of the effort to avoid the contamination of organic crops with genetically modified organisms (GMOs). The subcommittee listed eight Discussion Points, and separately listed eight Discussion Questions.

DISCUSSION QUESTIONS

The following Discussion Questions were posed:

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

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

In addition, if organic farmers seek compensation for damages due to GMO contamination of their crops, there must be an initial threshold set. Currently, "organic is a process, not a product," therefore the producers of GMO crops can claim that pollen drift does not harm the crops of their organic neighbors. That said, some organic buyers are setting their own thresholds and rejecting contaminated commodities.

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

The phrasing of the questions does not make a distinction between the testing of organic seed and conventional seed used in organic production. Due to the fact that organic seeds have an organic system plan for protecting seed purity, but conventional seeds do not have a plan or certification oversight, we would like to

see an explicit distinction between testing requirements for conventional versus organic seed, with a focus on testing any conventional seed being used in organic production.

The focus should be on conventional, not organic, seed

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

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

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

Organic integrity will benefit from testing conventional seed

Although use of organic seed is required by organic regulations, there are exceptions to this rule, which has resulted in a significant amount of organic acreage planted with conventional seed. Section 205.204 (a)(1) states that "[n]onorganically produced, untreated seeds … may be used to produce an organic crop when an equivalent organically produced variety is not commercially available." Since the organic seed industry represents only a small portion of the total seed available, growers planting large acreages can find it difficult to obtain the volume they need. As a result, they may depend on nonorganic seed, because the organic varieties are not commercially available in sufficient quantity. Before establishing a seed purity standard, it would be helpful to estimate the percentage of organic acreage planted with conventional seed as compared to the percentage of acreage planted with organic seed, at least for high-risk crops such as corn.

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

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

In order to fully answer this question, both the conventional and organic seed industry will need to share their testing procedures for GMO contamination, as well as their results.

Lynn Clarkson, of Clarkson Grain, indicated in a webinar that plant breeders at seed companies estimate that there is about 3% GMO contamination in their conventionally grown "non-GMO" seeds[5]. He suspects that organic seed may be contaminated as well, because the organic fields are smaller, which makes them more prone to GMO contamination from drift.

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

Testing methods for seed purity should follow the same protocols as testing methods for pesticide residues. The sample should be taken by an organic inspector, or someone who is trained in the protocol of sample collection. The chain of custody should be clearly indicated on the sample form to ensure that no adulteration or contamination occurs as the seeds are sent to a testing laboratory. The results should be sent directly to an organic certifier or other third party, not to the seed supplier. If this procedure is not followed, for example if the seed company takes its own samples and directly receives the test results, there is potential for falsification of the results.

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

The Discussion Point #7 suggested a purity standard of "none found in a 3,000 seed sample." This standard may be impossible to meet. The Organic Seed Alliance asked seed companies if they could meet a genetic purity standard of "none found in a 3,000 seed sample." Half the companies had concerns about their ability to meet the standard, and the harm it might cause to organic farmers and the organic seed industry.[6]

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[5] Clarkson, Lynn. 2013. *How Can Organic, Non-GMO, and GMO Crops Coexist?* Available on eOrganic at http://www.extension.org/pages/66781/live-broadcast:-how-can-organic-non-gmo-and-gmo-crops-coexist

[6] Organic Seed Alliance, 2012. Seed Integrity Survey: Findings from the Organic Seed Industry

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

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

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

A seed purity standard should be based on a threshold system—a percentage of GMO contamination—not on presence or absence of GMOs. Seed growers, handlers and buyers currently appear to use a percentage basis of contamination, rather than the "none found" purity standard.

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

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

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

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

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

The methods used to prevent GMO contamination from pollen drift will vary from crop to crop. The pollen from tall, wind-pollinated crops, such as corn, will drift long distances. Europe has done extensive testing to show that 100 feet of

separation is needed to reduce pollen drift by 99%.[7] One way to verify this is to plant blue corn. Pollen drift will be evident as blue kernels in the neighboring corn fields.

[7] Clarkson, Lynn. 2013. *How Can Organic, Non-GMO, and GMO Crops Coexist?* Available on eOrganic at http://www.extension.org/pages/66781/live-broadcast:-how-can-organic-non-gmo-and-gmo-crops-coexist

DISCUSSION DOCUMENT:

EXCLUDED METHODS TERMINOLOGY

SUMMARY

A clarification of the term "excluded methods" is needed, and additional time should be allowed for comments on this subject.

It is essential to provide adequate time to involve the organic community in this process of clarification of the term "excluded methods." We request that Discussion Documents be kept open for comments for a longer period of time than the petitions.

The public was given three weeks for comments on the entire slate of agenda items for this meeting. This Discussion Document, in particular, was completely new and highly technical. It deserves in-depth review. Although we understand the short time frame for items that will be voted on, we also believe that a longer time frame is essential for discussion items. Possibly discussion could be open until 30 days after the NOSB meeting. This may result in more thoughtful and complete responses.

DISCUSSION QUESTIONS

1. **Does the definition of "excluded methods" in the Organic Rule need to be revised? Please provide reasoning for either a "yes" or a "no" answer.**

Yes, the definition of the term "excluded methods" needs to be clarified, because the definition includes the terms "natural conditions" and "traditional breeding." Those two terms have been subject to different interpretations. The current phrase—"A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions—is a workable definition, but only if we use a narrow definition of the term "natural conditions." Similarly, the Discussion Document states, "It is not clear at what point traditional breeding techniques are divided from modern or non-traditional breeding techniques."

2. **On what general principle(s) should practical and consistent distinctions be made between "excluded" and permitted methods of breeding that could apply to plants, animals and micro-organisms? Under such general principles should we further define or replace terms such as "natural conditions" and "traditional breeding"?**

"A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions" is a workable definition, if we use a narrow definition of the term "natural conditions." We suggest that the term "traditional breeding" can be defined as "methods used to change the genetics of a plant or animal by means that are only possible under natural conditions." This is straightforward in the case of sexual reproduction in higher organisms.

The term "traditional breeding" does not really apply to microorganisms, because they do not require male and female genders for mating. The definition of permitted methods must take into account the fact that reproduction of bacteria, fungi and viruses is significantly different from that of plants and animals. It must also consider the uses of a genetically modified organism. Some methods may be prohibited for plants and animals, but allowed for microbes. Examples might include viruses used for vaccines (if viruses are killed before injecting them into an animal).

3. **Are there other terms beyond those discussed here that should be addressed in the context of excluded methods?**

At this time, we have no additional terms to suggest. However, we request that the NOSB allow more time for review of this document so that organic stakeholders can participate in the upcoming public discussion and then submit additional comments. We also note that the science of genetic engineering changes rapidly. There should be some mechanism to evaluate new techniques as they are developed.

4. **Of the terms and practices discussed here, which ones should be in the definition of excluded methods and which not included? Why?**

Most of the terms and practices that are currently included in the definition of "excluded methods" should be retained. In particular, the term "cell fusion" should be retained. Cornucopia disagrees with the Policy Memorandum issued by the NOP on February 1, 2013, which states:

> *The NOP further concludes that cell fusion (including protoplast fusion) is not considered an excluded method when the donor cell/protoplasts fall within the same taxonomic plant family …*

The memo says that cell fusion is natural, as in an egg and sperm. In that case, cell fusion within a species, which could occur under natural conditions, should be allowed**. Cell fusion between two different species, even if they are in the same taxonomic family, should not be allowed**.

The technique used in plant breeding could not occur under natural conditions. It involves chemical removal of cell walls, and chemical or electrical fusion of nuclei.

Why is cell fusion used? It is used to overcome "sexual incompatibility." In other words, it is used to produce a hybrid between two plants that would never cross in nature. The organic regulations specifically prohibit "methods used to genetically modify organisms … that are not possible under natural conditions." The only genetic recombination that is natural in higher organisms is that within a plant (or animal) species.

An example within the family Solanaceae:

- Tomato breeds with tomato = within species (Solanum lycopersicon). This is "possible under natural conditions."
- Tomato breeds with pepper, potato, or eggplant = within taxonomic family, but not within species. These crosses are not possible under natural conditions.

Demeter, the biodynamic certifier, prohibits the use of protoplasmic cell fusion. They maintain a list of about 400 varieties that have been created with this technique. Furthermore, Europe considers protoplasmic cell fusion to be genetic manipulation.

The only terms that could be removed are fermentation and gene doubling. Gene doubling should be removed because it can occur in nature, at least in plants. It should be clarified that gene doubling for organisms other than plants remains prohibited. Fermentation should be removed because it is not a method of genetic engineering; it is a method of production of fungal or bacterial biomass, or production of a metabolite. Fermentation should be allowed in organic agriculture. After all, composting and mushroom production on compost are often referred to as "solid-state fermentation."

Some of the emerging breeding strategies discussed in part B need to be added to the recitation of "excluded methods." Microinjection and biolistic transfer should be added; others may need to be added after the organic community has had time to review the Discussion Document in more detail.

5. **How far back into the development or manufacture of a substance, or in the development of vaccines, or in the lineage of a breeding line, should the excluded methods prohibition apply? How far back is practical and verifiable?**

This question is three questions in one.

- In the development or manufacture of a substance, the prohibition on excluded methods should cover the **entire** development or manufacture of that substance. Once an organism is modified through an excluded method (genetic engineering) all of its progeny remains "novel."
- In the development of vaccines, the prohibition on excluded methods should cover the **entire** development and manufacture of the vaccines.

- In the lineage of a breeding line, the prohibition on excluded methods should go as far back as possible.

III. POLICY DEVELOPMENT SUCBOMMITTEE

PROPOSAL:

PUBLIC COMMUNICATION

SUMMARY

We support the proposal to "establish a year-round online communication mechanism for stakeholders to communicate with NOSB and the NOP on matters of interest and concern."

It is important for all members of the organic community to be able to communicate with all NOSB members throughout the year. This will benefit the NOSB and the organic community as a whole.

However, we strongly urge the NOP and NOSB to ensure that this mechanism will not become a substitute for any of the other vehicles for public announcements and participation that are already in place.

CORNUCOPIA'S COMMENTS

"Daily Digest" – Compiled by NOSB Special Assistant

We also believe it is unrealistic to expect NOSB members, who are busy enough volunteers as it is, to log on to the online forum on a regular basis to ascertain if there are any recent postings that are of note.

Therefore, we suggest that a "Daily Digest" email be sent to the NOSB members' email addresses (as well as to interested public stakeholders). This will allow the proposed forum to become a means for NOSB members to keep a pulse on the organic community, without becoming overwhelmed with additional responsibilities for logging on or reading comments, some of which may be repetitive citizen comments on controversial issues of the day. The "Daily Digest" could synthesize citizen comments (e.g., "42 citizen comments opposing the use of XYZ in organics were posted").

Again, the goal here is to leverage the time of NOSB members.

The "Daily Digest," compiled and managed by the NOSB Special Assistant, would alert NOSB members if a document of interest is posted, and NOSB members could then log on and retrieve the document.

Early posting of discussion documents and other agenda items

We have been concerned with the short time frame for submitting comments to NOSB Discussion Documents and proposals.

For the Fall 2012 meeting, the agenda, proposals and discussion documents were posted in the August 30 Federal Register, with a deadline of September 24, giving the public 25 days to comment.

For the Spring 2013 meeting, the documents were posted on February 22 with a deadline of March 19, again giving the public 25 days. However, this time, the announcement to the organic community was delayed until February 25, cutting the comment period short an additional 3 days, to 21 days.

We urge the NOSB and NOP to consider ways to ensure the public has adequate time to analyze and comment on issues (and in the case of public interest groups, engage their membership). One way to lengthen the time frame for submitting comments is by posting discussion documents as they become available, rather than waiting for the semiannual meeting notice, using the proposed online communication mechanism and using the *NOP Insider* to alert the public.

Recent discussion documents have often been long, detailed and highly technical papers. These take time to read, research and analyze, and 30 days (or 21 days, as was recently the case) is simply not enough time to adequately address these extensive documents.

Some of these discussion documents were finalized prior to the agenda posting, sometimes weeks ahead of time. Since it is a discussion document, often with a long list of questions that the NOSB subcommittee seeks public input on, it would be helpful for the public to have access to these documents as they become available.

For example, the discussion document on "GMOs and seed purity" was first posted on August 17, 2012, for the fall meeting. The same discussion and questions were posted for the Spring 2013 meeting, but the public was not notified that this was forthcoming. The February re-issuance of the document states:

> *The Subcommittee would particularly like to hear from organic and identity-preserved seed and crop producers to learn about the challenges in preserving seed purity and enforcing protections from contamination.*

The purpose for the re-posting was to gather additional input from organic seed producers and handlers. If additional input is desired on a discussion document, that can be decided at the NOSB meeting, and the document can be immediately re-posted. This would allow discussion within the organic community, and allow time for the input the NOSB is seeking. This was a missed opportunity.

The discussion document titled "Terminology for excluded methods" is dated February 6, so was presumably finalized on this date. But the public was not given the opportunity to begin analyzing the document until February 25, when the NOP publicized the availability of the documents. Nearly three weeks were lost when individuals and organizations could have been working on these discussion documents.

This could have allowed organic stakeholder organizations to spread out their workload as this discussion document was released, simultaneously, with many other proposals that deserved careful scrutiny and that might not have been, unlike the document in question, available for prior review.

Lengthen the public comment period for discussion documents.

We would also suggest that the deadline for commenting on discussion documents be lengthened, to at least 30 days past the date of the meeting.

Since discussion documents are not voted on, and additional information on discussion documents is helpful at any time before the subcommittee meets to draft a proposal, we believe an extended deadline for discussion documents would allow for more thorough analysis of and engagement with these documents by the public.

Based on written comments and public testimony, some stakeholders who originally communicated their opinions might want to add additional data or modify their positions subsequent to the meeting.

Previous suggestions

We appreciate the implementation of the suggestion by public interest groups, including The Cornucopia Institute, to post subcommittee meeting minutes as they become available. While there are still delays to the posting of the minutes, the availability of meeting minutes throughout the year has been of value and we hope that the NOP will further endeavor to reduce the lag time before these important documents become publicly available.

CONCLUSION

Cornucopia supports the proposal. We hope the communication mechanism will allow for two-way communication, and we urge the NOP and NOSB to post discussion documents as they become available.

DISCUSSION DOCUMENT:

MATERIAL INITIATION POLICY

SUMMARY

Cornucopia believes in transparency and maximizing public engagement. For this reason, we believe that the NOSB and NOP should follow the same procedures as the public in initiating material review.

DISCUSSION QUESTIONS

1. **Should an NOSB subcommittee utilize the public petition process when proposing changes to the National List?**

Yes. Whether it comes from a manufacturer, a public interest group, a trade organization, a subcommittee of the NOSB, or the NOP, every proposed change to the National List should go through the same process to maximize public participation in the process.

2. **Are there situations when it would be appropriate for the NOSB to use an expedited or alternative petition process to consider a National List change? What are those situations?**

We can think of no situations when it would be appropriate for a change to the National List to bypass the public petition process. While it is entirely reasonable and appropriate for NOSB members to be proactive and initiate material review, their position on the Board should not enable them to bypass the public petition process, as it could lead to decreased transparency and public participation.

We believe the existing prioritization schedule, as outlined in the Policy and Procedures Manual, already adequately ensures that the most important items—petitions to remove materials from the list with a priority given to materials for which environmental or health concerns exist—be dealt with on an expedited basis. Material review initiated by the NOSB or NOP should be held to the same prioritization schedule.

3. **If the answer to #2 is yes, what elements to the process are important to ensure transparency and facilitate public involvement, such as posting on the petition database or similar database?**

It would be absolutely crucial that any proposed change to the National List be posted on the petition database, and that the same procedures for facilitating public involvement be followed.

4. **How and when should the public be notified that the NOSB has initiated a review if it is added to the work plan?**

Initiation of material reviews should be initiated using the same procedure, regardless of where the review initiated.

5. **Is it reasonable to interpret the NOSB-NOP Collaboration section of the PPM (p. 25), #2 Recommendation for modification of existing standards or new standards, as quoted above, to include the listing, delisting, or annotating National List materials?**

The PPM (p. 25) states that "the NOP may request that the NOSB develop recommendations for new or existing standards. The request should be in writing and should include a statement of the problem to be addressed, background, including the current policy or situation, statutory/regulatory authority, legal situation, and desired timeframe for the receiving the recommendation. The request would be posted on the NOP website."

The NOP should be held to the same process as the public. Their petitions should be posted as others are, and held to the same prioritization schedule as petitions initiated by the public. Petitions for the removal of a material from the National List are already prioritized, especially when there are documented human health or environmental effects, and we believe this serves the organic community well.

6. **Is the current system for determining the priority of review (PPM, p 49) acceptable? If not, please any concerns?**

We agree with the prioritization schedule.

7. **Are there other related issues that should be raised?**

Reconsideration of "yes" votes on material review

Under Robert's Rules of Order, a member of the NOSB who voted with the majority to, for example, add a material to the National List, but then changes his/her mind after the vote, can offer a motion to put the item back on the agenda. There have been numerous instances in the past when Board members, especially new Board members, voted to approve a material or policy during the meeting, only to discover after the meeting that some of the information they relied on to make this decision was flawed. In such cases, we believe there should be an established mechanism, outlined in the PPM, for Board members to put the item back on the agenda, and call for a revote at the next meeting.

Prioritization for standards development in instances where clarification is needed

The NOP currently instructs the NOSB to give priority to petitioned materials. This has led to slow development of standards, including in cases where existing standards needed clarification (pasture rule, outdoor access for poultry). We would encourage the NOSB to consider recommending a prioritization schedule for standards development. We believe that clarifications to standards, especially when they involve loopholes, should be given priority over the development of new standards. We would recommend the following prioritization schedule for standards development:

1. Clarification of existing standards, when members of the organic community experience economic harm or are put at a competitive disadvantage arising from the lack of clarity in the existing rule. Examples include the clarification for outdoor space for organic poultry or closing the alleged "loophole" allowing continual introduction of conventional replacement dairy cattle on organic dairy farms.
2. Clarification for existing standards, when members of the organic community have requested clarification, but no clear economic harm or other negative consequences are expressed. An example is the clarification of the "calculating organic percentages" rule.
3. Development of new standards, which are required by OFPA. An example is the development of standards for peer-review, which is required by OFPA.
4. Development of new standards, which are not explicitly required by OFPA, but which meet the intent of OFPA. An example is the development of aquaculture standards.

IV. LIVESTOCK SUBCOMMITTEE

PROPOSAL:

PET FOOD AMINO ACIDS

SUMMARY

These comments pertain to two related motions.

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

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

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

Rationale

- Whole foods can supply the required amino acids.

Reject motion 2 to list Taurine as allowed in organic pet food.

Rationale

- Taurine is an essential nutrient for cats, but the synthetic version appears to be not essential since the nutrient can be obtained from natural sources such as beef and poultry.

- In our comments to the Fall 2012 NOSB meeting, Cornucopia requested an additional TR to focus only on taurine.

BACKGROUND

A petition was submitted to the NOSB by the Pet Food Institute, a trade association of pet food manufacturers, to allow the addition of 13 synthetic amino acids to organic pet food: Arginine, Methionine, Cystine, Lysine, Taurine, Tryptophan, Threonine, Histidine, Isoleucine, Leucine, Phenylalanine, Tyrosine, and Valine. The

livestock subcommittee voted unanimously to deny that petition. Cornucopia agrees with this committee vote.

Whole foods can, and should, be used to supply nutrients in organic pet foods. Synthetic versions of these amino acids, which are essential for optimal health, are not necessary because pet food made from whole foods can supply them. Nature's Logic pet food (www.natureslogic.com), sold as natural, not certified as organic, states that it supplies complete and balanced nutrition with no "chemically synthesized vitamins, minerals, or trace nutrients."

The Livestock Subcommittee determined that there was a need for synthetic taurine to be added to organic cat food because the heat used in processing reduces the bioavailability of taurine.[8] They voted to list taurine on section 206.603(e)(4), as a synthetic supplement for organic cat food. We disagree with this determination. We request additional information on the possible natural sources of taurine for cats. Without this information there is no way to determine whether synthetic taurine is "essential" for use in organic production.

CONCERNS WITH SYNTHETIC AMINO ACIDS

Taurine can be obtained from whole foods.

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

The NOSB Livestock Subcommittee, in discussions with AAFCO, concluded that the need for most of the petitioned amino acids could be easily met through feeding whole foods to pets. The only amino acid that the AAFCO believes needs to be supplied in synthetic form is taurine for cats. To meet AAFCO standards, canned cat food is required to have 0.2% taurine; dry food is required to have 0.1% taurine.

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

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

[8] ICF International. 2012. Technical Evaluation Report. Amino Acids, Pet Food, line 148

Since cats are carnivorous, meat is part of their normal diet.[9] Since taurine is present in meat, it seems that feeding cats meat should meet their taurine requirements. If the taurine deficiencies in commercial cat food are caused by the reliance on vegetarian protein sources, like corn and soy, organic cat food should provide a real-food alternative and should not have to rely on synthetic taurine.

Cat foods labeled "organic" should be required to derive all taurine from natural sources. In a natural diet, cats obtain taurine from seafood, poultry, and beef.[10] Although the argument has been made that organic poultry and beef are prohibitively expensive for pet food, Cornucopia notes that cost is not a criterion for adding a synthetic substance to the National List. Furthermore, there are some existing canned cat foods on the market which are indeed certified organic where the principal ingredients are meat or organ meat.

The Technical Review conducted on the full complement of petitioned amino acids devotes two lines to answer the question of natural sources of taurine. We suggest that a supplemental report, focusing only on taurine, is needed to more thoroughly review the possible sources of taurine from natural supplements, such as seaweed, or whole foods. The proposal states, "In the case of organic pet foods, manufacturers have limited access to organic ingredients, thus the petitioner's stated need to utilize synthetic nutrients to balance the formulations." Reliance on information from the petitioner is not sufficient to determine the need for synthetic materials.

CONCLUSION

Cornucopia urges the board to **reject** the addition of all synthetic amino acids, including synthetic taurine for cat food (at this time). The high cost of organic, whole food sources of taurine is not a justification for adding the synthetic version of this nutrient to the National List.

And, as more organic meat comes on the market, additional byproducts and low-value cuts, and organ meats, will become available. Creating the demand in the pet foods market will help fuel efficient, cost-effective and profitable growth in expanding the capacity to create organic meat products for human consumption.

Before adding taurine to the National List, a full TR is needed, with particular attention given to the natural and organic alternatives to synthetic taurine.

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[9] PetMD. Cats Are Different: How a Cat's Nutritional Needs are Different from a Dog's. Retrieved from http://www.petmd.com/cat/nutrition/evr_ct_cat_nutritional_needs_different

[10] Spitze, A.R.; Wong, D.L.; Rogers, Q.R.; and Fascetti, A.J. 2003. Taurine concentrations in animal feed ingredients; cooking influences taurine content. Journal of Animal Physiology and Animal Nutrition 87:251-262

We also encourage the development of natural/organic sources of supplemental taurine. If synthetic taurine is added to the National List, manufacturers lose incentive to develop natural alternatives. It has become clear, over the years, that few materials are removed from the National list through the sunset process. Once a material is on the National List, manufacturers lose their incentive to develop compliant alternatives.

WORKING GROUP INTERIM REPORT:

IDENTIFYING VACCINES MADE WITH EXCLUDED METHODS

SUMMARY

An interim report was prepared by the Vaccines Made With Excluded Methods Working Group. We appreciate the work involved to clarify the issues on GMO vaccines. It is essential to prevent GMO contamination in organic livestock and the organic food derived from them.

These comments only include reactions to the process of developing the proposal. Cornucopia will prepare a more complete analysis of the report itself after the NOSB meeting.

Rationale

- The organic community needs to have adequate time to craft thoughtful comments.
- This working group needs to represent a greater diversity of interests.

BACKGROUND

It is essential to prevent GMO contamination in organic livestock and the organic food derived from them. Use of any GMO vaccine would be inconsistent with organic principles.

The challenge presented in this report is the identification of such GMO vaccines. The central questions appear to be:

1. How should traditional breeding techniques be divided from modern breeding techniques as they pertain to vaccine production?
2. How should a pragmatic line be drawn between techniques which use recombination (allowed) and techniques which rise to the level of recombinant technology (excluded)?
3. How should the vaccines be evaluated?
    a. Should a given technique (method) be declared excluded or allowed?
    b. Or should the effects of each method be analyzed? Then all random genetic modifications would be allowed and all targeted genetic modifications would be prohibited.
4. How far back into the development or manufacturing process should the excluded method prohibition apply?

CORNUCOPIA'S COMMENTS AND CONCERNS

The organic community needs to have adequate time to craft thoughtful comments

It is essential to involve the organic community in the review of vaccines made with excluded methods. In order to receive the best input, the public must be given adequate time to read the material, consult with stakeholders, conduct research, and write a thoughtful response. In this case, the public was given three weeks for comments on the entire slate of agenda items for this meeting. This discussion document, in particular, was completely new and highly technical. It deserves a more in-depth review than is possible, given the short time frame.

We request that discussion documents be kept open for comments for a longer period of time than the petitions. Although we understand the short time frame for items that will be voted on, we also believe that a longer time frame is essential for discussion items. Possibly discussion could be open until 30 days after the NOSB meeting. This may result in more thoughtful and complete responses.

At the very least, we would like to see this document available for public input at the next NOSB meeting as well.

This working group needs to represent a greater diversity of interests

The Organic Tree Fruit Industry Work Group consists of 17 members, representing a wide diversity of stakeholders, including growers, consultants, and university researchers. The Vaccines WG, in contrast, consists of only five members: two NOSB members and three USDA employees.

Membership of the Vaccines WG should be expanded to include a wider range of stakeholders. We would recommend that the working group include representatives of the following stakeholders, at least one from each group:

- Holistic large-animal veterinarians (member(s) should be practicing veterinarians)
- Dairy producers
- Beef producers
- Pork producers
- Poultry producers
- University researchers

Cornucopia plans to prepare a more complete analysis of this important topic.

V. CROPS SUBCOMMITTEE

PROPOSAL:

OXYTETRACYCLINE (TETRACYCLINE)

SUMMARY

Reject the petition to add tetracycline to the National List.

Reject the petitioner's request to remove the 2014 expiration date for tetracycline use in organic apples.

Reject the Crops Subcommittee's proposal:

> *Remove the existing expiration date of October 21, 2014 for oxytetracycline and replace that with a new expiration date of October 21, 2016. This would be for use in both apples and pears for control of fire blight.*

The antibiotic oxytetracycline, also called tetracycline, is currently allowed for use in organic crop production only until October 21, 2014. The NOSB voted in favor of specifying this sunset date in 2011.

In order to be approved for use in organic production, synthetic materials such as antibiotics must meet three criteria: They must be **essential** for organic production, **compatible** with organic production practices, and cause no adverse impacts on humans or the environment. We believe that tetracycline fails to meet all these criteria set forth in OFPA.

The "dealbreaker" in reviewing the current petition, for The Cornucopia Institute, is the fact that measurable antibiotic residues can be found in apples and pears treated with antibiotics, which, upon reviewing alternatives, are not essential in organic production.

In response to the petition for continued use of tetracycline the Crops Subcommittee prepared a well-researched proposal—a total of 40 pages, including eight pages of references and endnotes. The majority (five members) voted in favor of extending the expiration date for tetracycline. The minority (three members) opposed the motion. In the discussion, the majority opinion ignores or discounts important and relevant research in several areas. (Some instances of this are noted below.) The minority opinion presents important research to support a prohibition of

tetracycline. We agree with the discussion and conclusions presented by the minority, who opposed the extension on the use of antibiotics.

Rationale

- **Tetracycline is not essential for control of fire blight.**
  - Cultural controls are available to manage fire blight.
  - Biological controls are available to manage fire blight.
  - Many orchardists, both in the US and in Europe, grow apples without using tetracycline or other antibiotics.

- **Tetracycline is harmful to humans and the environment.**
  - Tetracycline is a broad-spectrum antibiotic that is active against a wide variety of bacteria, which could have deleterious impacts on biodiversity and the ecosystem.
  - Tetracycline use in orchards may contribute to development of antibiotic resistance, with serious consequences for human health.

Much research has been conducted on apples to demonstrate that the cultural practices and materials available to organic growers are sufficient to manage fire blight without tetracycline. The expiration date for tetracycline on apples should be maintained at October 21, 2014.

Research on pears, however, is more limited. Since pears are naturally more susceptible to fire blight, and there are fewer research studies available to demonstrate effective controls, it may be necessary to consider extending the expiration date until October 21, 2016 for pears only.

BACKGROUND

Tetracyclines are a group of broad-spectrum antibiotics that include chlortetracycline, oxytetracycline, and others. The National List, Section 205.601(i)(12), lists tetracycline as an allowed material for plant disease control; therefore, we use the term "tetracycline" in these comments.

The petitioned use of tetracycline is to control fire blight on apples and pears, caused by the bacterium *Erwinia amylovora*, which infects blossoms of apple and pear trees. If the disease is not controlled, flowers die, resulting in crop loss, and the woody branches can become infected, resulting in loss of limbs or an entire tree.

Tetracycline does not kill the bacteria, it only prevents them from growing and multiplying. Streptomycin has been the antibiotic of choice because it kills the

pathogen. Tetracycline, which stops the growth of the pathogens but does not kill existing populations, is less effective than streptomycin. Tetracycline is only used where the pathogenic bacteria are resistant to the antibiotic streptomycin, primarily California, Oregon and Washington.

NOSB proposal for use of antibiotics

Antibiotics are prohibited for production of organic livestock and for most organic crops in the US. The only exception is the use of tetracycline and streptomycin, which are allowed for control of fire blight, a disease of apple and pear trees. They are listed on National List Section 205.601:

(i) As plant disease control.

(11) Streptomycin, for fire blight control in apples and pears only until October 21, 2014.

(12) Tetracycline, for fire blight control in apples and pears only until October 21, 2014.

This exception to organic standards has been controversial since 2000, when the regulations were being drafted. Antibiotics were added to the National List in 2000, and renewed in 2006. A different form of tetracycline was petitioned in 2008, at which time an expiration date of 2012 was established. A petition submitted in 2011 led the NOSB to extend the expiration date to 2014. One year later, in June of 2012, the Washington State Horticultural Association submitted a petition to overturn this rule, specifically requesting the removal of the 2014 expiration date. Tetracycline would be added to the National List and would be subject to review every five years through the sunset process.

As they reviewed the petition for this NOSB meeting, the Crops Subcommittee split into equal camps—four in favor and four opposed to the motion. A second, "compromise" proposal was then drafted:

> *Remove the existing expiration date of October 21, 2014 for oxytetracycline and replace that with a new expiration date of October 21, 2016. This would be for use in both apples and pears for control of fire blight.*

A majority (five members) of the subcommittee voted in favor of this proposal; a minority (three members) voted against it.

Evaluation for approval of synthetics to be added to the National List

In organic agriculture, synthetic materials such as antibiotics are prohibited unless:

1. The substance is **essential** for organic production.

2. The substance is **compatible** with organic production practices.
3. There are **no** adverse impacts on humans or the environment.

In the following section we discuss reasons why the use of tetracycline in organic agriculture is not essential, is not compatible with organic principles, and is harmful to humans.

TETRACYCLINE IS NOT ESSENTIAL TO CONTROL FIRE BLIGHT

Cultural, biological and chemical controls are available to manage fire blight

The fire blight disease initially infects blossoms of apple and pear trees. Effective management of fire blight must rely on prevention of these initial infections, rather than control after the bacterial populations are high. Fortunately, there are many ways to prevent fire blight infections. This principle of management of diseases by prevention rather than control is one of the organic principles mandated by OFPA. The principles are outlined in section 205.206 *Crop pest, weed, and disease management practice standard*, and explained in the *Guide for Organic Crop Producers*,[11] available for download from the NOP website.

7 CFR 205.206 lists the following as management practices to prevent disease that are applicable to orchardists:

> *(a)(3) "Cultural practices that enhance crop health, including selection of plant species and varieties with regard to suitability to site-specific conditions and resistance to prevalent pests, weeds, and diseases" and*
> *(d)(1): "Disease problems may be controlled through: Management practices which suppress the spread of disease organisms."*

Level A, the systems approach, as outlined in the *Guide for Organic Crop Producers*, includes use of resistant varieties and resistant rootstocks, specifically non-dwarfing rootstocks. The systems approach should be the first line of defense against fire blight, because a properly designed system will have less disease.

Level B, cultural practices, include blossom thinning and canopy management, specifically avoiding high-density plantings to allow greater air flow in the orchard.

Level C, inputs, includes natural materials, biological controls and synthetic materials such as antibiotics. In general, inputs should only be used after other practices have failed to control the disease. If inputs are required, farmers should use natural materials and biological controls before using synthetic materials such as antibiotics.

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[11] Coleman, P. 2012. *Guide for Organic Crop Producers*. National Center for Appropriate Technology, 64 pages. www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5101542

Even if cultural practices are not adequate, there are several natural materials and biological controls that can be used to manage fire blight, as we discuss below. With all these cultural practices and materials available, antibiotics have been proven unnecessary for control of fire blight.

Resistant varieties and rootstocks

Selection of a resistant cultivar is the most effective method of controlling fire blight.[12] The relative resistance and susceptibility of different apple cultivars in well-known; university extension specialists in many parts of the country publish this information. To manage fire blight, it is also important to avoid planting apples on susceptible rootstocks. The dwarfing rootstocks, in particular, such as Malling 9 and 26, are highly susceptible to fire blight.[13]

Apple and pear growers have known that antibiotics would likely be prohibited for organic production in the future, either through removal from the National List via the sunset process, or by an expiration date in the listing. Growers taking a proactive approach would plant resistant varieties on resistant rootstocks. This has not been the case. Instead, cultivars with greater susceptibility to the disease, such as Braeburn, Fuji, Gala, and Pink Lady, have been planted.[14]

In 2009 in Washington State, 45% of the organic apple acreage was planted to Gala and Fuji, both of which are susceptible to fire blight.[15] At one point, fire blight primarily was a concern to pear growers only, not apple growers, but the situation has changed: "Now that there are extensive acreages of highly susceptible apple varieties on super-susceptible rootstocks in warmer parts of the state, the possibility of serious fire blight damage in Washington apples has evolved into a reality."[16] The current practice of high-density plantings increases the speed at which fire blight can spread.

Biological controls and other inputs are available to manage fire blight

Even with the planting of susceptible varieties, there is a wealth of materials available to control fire blight without antibiotics. The TR mentions biological controls: Bloomtime Biological, BlightBan C9-1, BlightBan A506 and Blossom

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[12] Johnson, K.B. 2000. Fire blight of apple and pear. *The Plant Health Instructor*. DOI: 10.1094/PHI-I-2000-0726-01. *Updated 2005.*

[13] Ibid.

[14] Johnson, K.B. 2000. Fire blight of apple and pear. *The Plant Health Instructor*. DOI: 10.1094/PHI-I-2000-0726-01. *Updated 2005.*

[15] Kirby, E. and D. Granatstein. 2011. Status of Organic Tree Fruit in Washington State an Other Regions: 2010. Center for Sustaining Agriculture and Natural Resources, Washington State University

[16] Smith, T. 2012. Fireblight Management in the Pacific Northwest USA. Downloaded Nov 2012 from http://county.wsu.edu/chelan-douglas/agriculture/treefruit/Pages/Fire_Blight.aspx

Protect. Other materials available include several brands of lime sulfur, fish oil and copper sulfate. Finally, Serenade Max is an antimicrobial product made from bacteria.

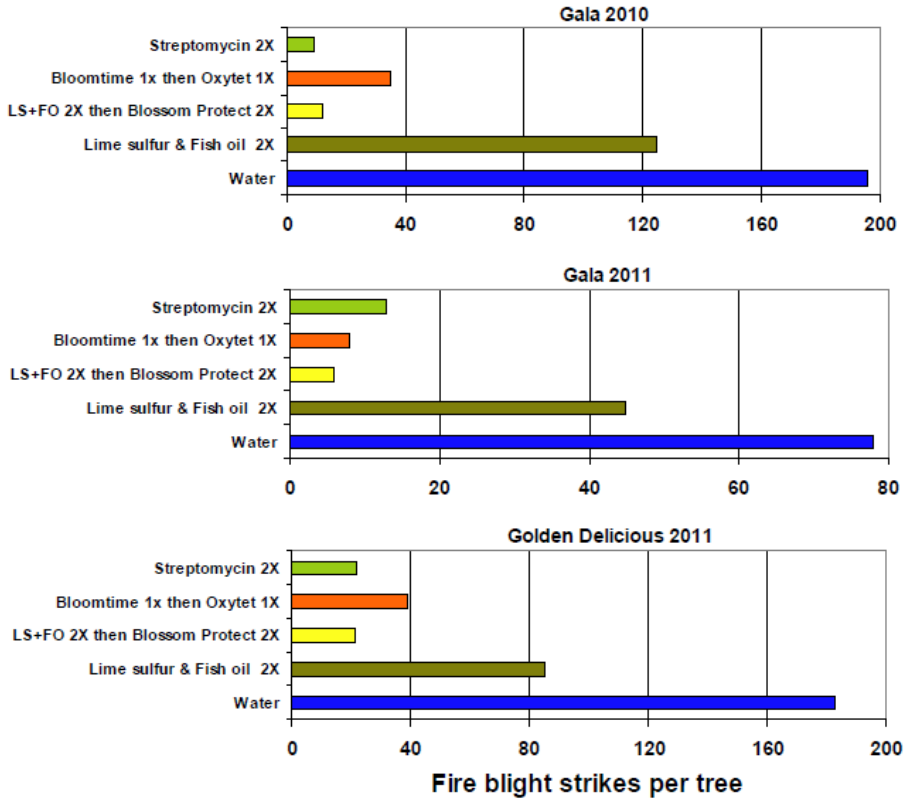
Blossom Protect is a biological control agent made from *Aureobasidium pullulans* (note: the name of this microorganism is misspelled in the TR; it is spelled correctly here). Field trials in eastern Washington have found that Blossom Protect provided control similar to oxytetracycline.[17]

Ken Johnson, in a webinar in March 2012, presented his research on materials that provided **"a fantastic level of control" of fire blight**. He stressed that management is vitally important—growers must begin to manage fire blight early in the season, when pathogen populations first start to build up. He suggested that growers begin with copper products, to delay the onset of disease. When trees begin to bloom, several different materials must be used at the appropriate times, first to reduce the number of infection sites, then to protect the remaining blossoms with biological controls.

Blossom thinning to remove flowers is essential because the bacteria that cause fire blight will initially infect the stigmas of the flowers. When flowers are removed, there are fewer places where bacteria can cause fire blight infections. Blossom thinning also reduces the crop load, reduces stress on the tree, and results in larger and more marketable apples. In Johnson's research study, he used lime sulfur (LS) and fish oil (FO) for blossom thinning. The remaining flowers were sprayed with Blossom Protect, a microbe that colonizes the flowers. Results in the graph below indicate that those treatments were as effective as antibiotics, even on Gala apples, a susceptible variety. The experiment was repeated in 2012, with the same results, showing the effectiveness of lime sulfur plus fish oil followed by Blossom Protect.[18]

[17] Smith, T. 2011. Improving the management of two critical pome fruit diseases. Final Project Report, WA Tree Fruit Research Commission Project Number CP-09-904

[18] Granatstein, D. 2012. Fire Blight Update. Organic Tree Fruit Industry Work Group. Presented at the NOSB Meeting, Providence, Rhode Island, 10/16/2012



Johnson also tested the use of Bloomtime Biological early in the season, followed by Serenade Max, which resulted in "very good to excellent control." In a recent webinar, Johnson[19] presented results of additional research, and verified that effective non-antibiotic control of fire blight can be achieved on apples through an integrated control program. Johnson was also able to achieve fire blight control on pears, although reliable control is expected to be more difficult than on apples.

Although these biological products control infections as well as antibiotics, they must be sprayed more frequently—four sprays instead of two. As long as antibiotics remain allowed in organic agriculture, growers are more likely to use them rather than biological controls, as a cost-saving measure. If antibiotics are prohibited, cost of apple production may increase slightly. However, cost is not a factor, by law, in deciding which materials to allow. We believe that organic consumers, who already expect to pay a price premium for organics in order to avoid harmful inputs, including antibiotics, will be willing to pay the extra price, if any, to avoid the harmful effects of antibiotics on humans and the environment.

[19] Johnson, K. 2013. Research Update on Non-antibiotic Control of Fire Blight. Webinar date March 19, 2013. www.extension.org/organic_production

Many orchardists grow apples without using antibiotics

Europe does not allow antibiotics in organic production of apples or pears, yet there were approximately 57,582 acres planted to organic apples in Europe in 2008.[20]

Many organic apple growers in Washington State grow fruit to be exported to Europe, and do not use antibiotics on those trees. As of March 2011, approximately one-third of the organic apple producers in Washington had not used antibiotics for at least three years, because they were certified to sell apples to Europe.[21]

A national poll of organic apple and pear producers, conducted by The Cornucopia Institute in early 2013, shows a wide disparity in the use of antibiotics. The poll results, being compiled in March 2013, will be presented to the NOSB at their spring meeting in Portland, Oregon.

Tetracycline is not compatible with organic production practices

NOP regulations prohibit the use of antibiotics on livestock for meat or milk production. Antibiotics may not be used on any organic crops, other than apples and pears.

Tetracycline is prohibited by international standards. It is not allowed for organic production in Canada, Europe or Japan. It is not allowed by the CODEX Alimentarius Commission, or the International Federation of Organic Agriculture Movements (IFOAM).[22]

Antibiotics represent an input-substitution mentality

As discussed above, fire blight is a serious disease that has been aggravated by the planting of vast acres of susceptible apple varieties on susceptible rootstock at high densities. Growers who have ignored preventative practices are relying on inputs for disease control.

The following graph shows how the risk of fire blight increases in the spring.[23] As bacterial populations increase, the risk of disease increases. In order to manage the

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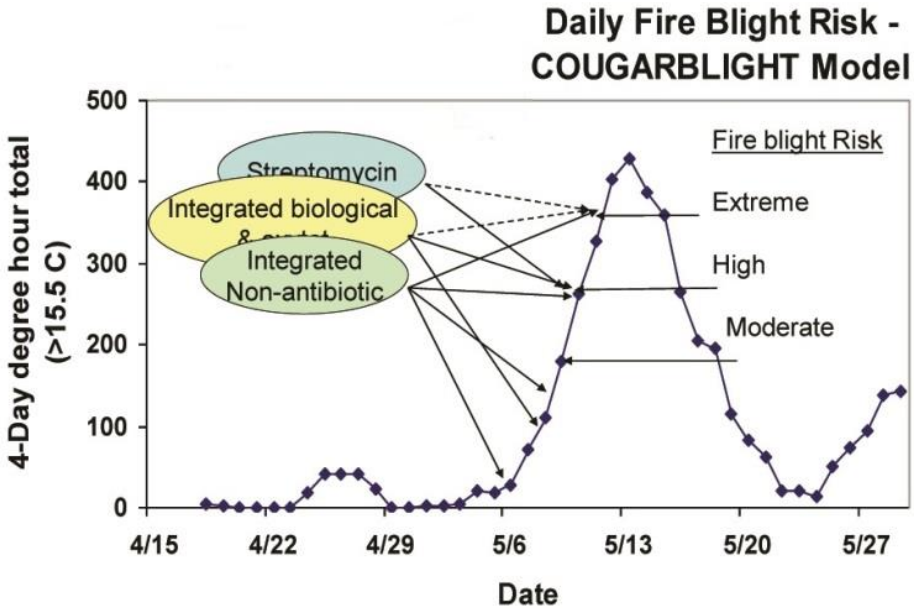
[20] Kirby, E. and D. Granatstein. 2011. Status of Organic Tree Fruit in Washington State an Other Regions: 2010. Center for Sustaining Agriculture and Natural Resources, Washington State University

[21] Washington State Department of Agriculture. 2011. *International Organic Program—EU Compliant Operations, March 10, 2011*. http://agr.wa.gov/FP/Pubs/docs/wsda_eu_compliant.pdf

[22] ICF International. 2011. Tetracycline (Oxytetracycline) Technical Evaluation Report, April 1, 2011

[23] Johnson, K. 2012. Fire Blight Control in Organic Pome Fruit Systems Under the Proposed Non-antibiotic Standard. Webinar date March 13, 2012. *www.extension.org/organic_production*

disease without antibiotics, growers must use integrated control measures early in the spring, when the pathogen population is starting to build. However, if antibiotics are available, this investment in a proactive approach is less important. As Dr. Johnson said in his webinar, "When streptomycin was effective, for us on the west coast, we could ignore the whole pathogen build-up phase…. We could come in with streptomycin at fairly high levels of risk and … we could get good control." This philosophy relies on treating the disease after it becomes serious. An organic philosophy should rely on management to prevent the disease from becoming serious.



Effects on humans and the environment

Tetracycline is a broad-spectrum antibiotic; therefore, the environmental effects of tetracycline are significant. Application of tetracycline involves aerial spraying. Although the tetracycline is needed only on the flower surfaces, the spraying applications ensure that it lands on the tree leaves, tree trunk, cover crops in the orchard and soil, as well as the flowers. Rain washes some tetracycline off the plant

surfaces, into the soil. There is evidence to indicate that tetracycline can also be taken up by plants and translocated through their tissues.[24]

Antibiotic residues may be detected in or on the apple fruit. When apple trees at blossom stage were sprayed with streptomycin, residues were found on the apple fruit sampled 86 days later.[25] The Environmental Protection Agency has found detectable residues of tetracycline on apple fruit up at 49 to 61 days after application.[26]

Tetracycline in the soil

As reported in the TR (lines 296-307), several studies demonstrated that tetracycline degrades very slowly in the soil, remaining present and retaining antimicrobial activity for up to ten months.[27],[28],[29] Antibiotics, including tetracycline, have been found to reduce the numbers of bacteria in the soil, under field and laboratory conditions.[30],[31],[32],[33] The Technical Review (lines 469-490) provides details of these studies.

The majority opinion expressed in the oxytetracycline proposal states that the report by Thiele-Bruhn and Beck refers to European soil, not US soils. It does not seem reasonable to believe that an antibiotic would decrease soil bacterial populations in Europe, but would not decrease soil bacterial populations in the US. We agree with the scientific validity of the minority opinion. Tetracycline is harmful

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[24] Kong, WD, Y.G. Zhu,,, Y.C. Liang, J. Zhang, F.A. Smith, and M. Yang, 2007. Uptake of oxytetracycline and its phytotoxicity to alfalfa (*Medicago sativa* L.). Environmental Pollution, Volume 147, Issue 1, May 2007, Pages 187-193

[25] Mayerhofer, G, I Schwaiger-Nemivora, T Kuhn, L Girsch, F Allerberger. 2009. Detecting Streptomycin in apples from orchards treated for fire blight. J. Antimicrob. Chemother. 63(5):1076-1077

[26] EPA (United States Environmental Protection Agency). 2005. Oxytetracycline. Section 3 Use on Apples. Summary of Analytical Chemistry and Residue Data. HED Records Center Series 361 Science Reviews, File R104981. Washington, DC.
http://www.epa.gov/pesticides/chem_search/cleared_reviews/csr_PC-006304_3-Jan-05_a.pdf

[27] Thiele-Bruhn, S. 2003. Pharmaceutical antibiotic compounds in soils – a review. J. Plant Nutri. Soil Sci. 970 145-167

[28] Aga, D.S., O'Connor, S., Ensley, S., Payero, J.O., Snow, D., Tarkalson, D. 2005. Determination of the persistence of tetracycline antibiotics and their degradates in manure-amended soil using enzyme-linked immunosorbent assay and liquid chromatography-mass spectrometry. J. Agric. Food Chem. 53: 7165-7171

[29] Cengiz, M., Balcioglu, I., Oruc, H.H. 2010. Detection of oxytetracycline and chlortetracline residues in agricultural fields in Turkey. J. Biol. Environ. Sci. 4(10): 23-27

[30] Thiele-Bruhn, S., Beck, I-C. 2005. Effects of sulfonamide and tetracycline antibiotics on soil microbial activity and microbial biomass. Chemosphere 59: 457-465

[31] Piotrowska-Seget, Z., Engel, R., Nowak, E. 2008. Successive soil treatment with captan or oxytetracycline affects non-target microorganisms. World J Microbiol Biotechnol 24: 2843-284

[32] Colinas, C., Ingham, E., Molina, R. 1994. Population responses of target and non-target forest soil organisms to selected biocides. Soil Biol. Biochem. 26: 41–47

[33] Popowska, M., Miernik, A., Rzeczycka, M., Lopaaciuk, A. 2010. The impact of environmental contamination with antibiotics on levels of resistance in soil bacteria. J. Environ. Qual. 39: 1679-1687

to the environment, and reduces biodiversity in the soil, with particular damage to bacterial populations.

Tetracycline may retain its antibiotic activity in the soil, where it may influence the selection of antibiotic resistant bacteria.[34] When tetracycline was applied to three soil types in a laboratory setting, researchers were able to isolate several strains of bacteria that were resistant to tetracycline.[35] Antibiotic resistance is a significant issue, as discussed in the next section.

Tetracycline use in orchards may contribute to development of antibiotic resistance

We agree with the sentiment expressed by Beyond Pesticides in their formal comments to the Board—it is shocking that some members of the Crops Subcommittee are willing to downplay the risk of tetracycline resistance in human pathogens. The World Health Organization includes chlortetracycline, oxytetracycline, tetracycline and streptomycin antibiotics on its list of critically important antimicrobials. They state, "**It is critically important to prevent resistance to these antibiotics due to non-human antimicrobial use**."[36] Since tetracycline resistance has not yet occurred, as stated by the Crops Subcommittee proposal, that is all the more reason to prohibit tetracycline use in all agricultural settings to prevent resistance from occurring.

The increase in apple acreage, and the increase in high-density plantings of susceptible varieties, only increases the likelihood of resistance to tetracycline. An article published in *ASM News*, by the American Society for Microbiology, states, "Although antibiotic use on plants is minor relative to total use, application of antibiotics in the agroecosystem presents unique circumstances that might influence the buildup and persistence of resistance genes in the environment. Antibiotics are applied over physically large expanses. In regions of dense apple and pear production, antibiotics are applied to hundreds of acres of nearly contiguous orchards. Moreover, the past decade has seen a dramatic increase in the planting of apple varieties and rootstocks that are susceptible to the devastating bacterial disease fire blight."[37]

The tree fruit industry has already experienced a problem with antibiotics—bacterium *Erwinia amylovora* has developed resistance to streptomycin. Since tetracycline is now being used in the same way that streptomycin was used, it is

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[34] Chander, Y, K Kumar, SM Goval, and SC Gupta. 2005. Antibacterial Activity of Soil-Bound Antibiotics. Published online Oct 12, 2005

[35] Popowska, M., Miernik, A., Rzeczycka, M., Lopaaciuk, A. 2010. The impact of environmental contamination with antibiotics on levels of resistance in soil bacteria. J. Environ. Qual. 39: 1679-1687

[36] World Health Organization (WHO). 2009. Critically Important Antimicrobials for Human Medicine, 2nd Revision

[37] McManus, P. 2000. Antibiotic Use and Microbial Resistance in Plant Agriculture. ASM News

likely that *Erwinia amylovora* will develop resistance to tetracycline as well. This resistance can easily be transferred to human pathogens.

Although there is no research that proves conclusively that use of tetracycline in apple orchards will cause resistance to tetracycline in human pathogens, there are numerous studies to prove that the use of antibiotics in agriculture has increased the prevalence of antibiotic-resistant bacteria.

The threat of tetracycline-resistant bacteria is a serious one, and we need to use the precautionary principle. Scientists must assume antibiotic resistance will occur in the future, because we know that it has happened in the past. Bacteria that develop antibiotic resistance typically remain resistant for a long period of time.[38]

CONCLUSION

Cornucopia agrees with the concerns about tetracycline use in agriculture expressed by the minority view of the Crops Subcommittee. We applaud their research efforts and agree with the scientific validity of their views. We chose not to repeat their findings in detail, since they are already clearly expressed.

The research that has been conducted on the control of fire blight in apples indicates that fire blight can be managed in apples without the use of antibiotics.

We do recognize that pears are highly susceptible to fire blight, and there has been relatively little research done on alternatives to antibiotics on pears. Due to these differences, we suggest that the regulations be written differently for apples and pears. This would allow removal of antibiotics from apple production without impacting pear growers, while further research can be conducted. Eventually all uses of antibiotics on organic crops should be prohibited.

Prohibition of antibiotics on organic apples is essential to maintain consumer confidence. Parents feed large numbers of apples to their children in the form of applesauce, apple butter, fruit leathers, juice and of course, apples. Given the prohibition against antibiotics in all other areas of organic food production, consumers expect that fruit is also grown without antibiotics, especially antibiotics that are important in human medicine.

[38] Levy, SB, and B Marshall, 2004. Antibacterial resistance worldwide: causes, challenges and responses. Nature Medicine Supplement, Published online 30 November 2004; doi:10.1038/nm1145

PROPOSAL:

POLYOXIN D ZINC SALT (Polyoxin DZS)

SUMMARY

Reject the petition to allow polyoxin D zinc salt in organic crop production.

Rationale

- Production process is not available for review by NOSB members and organic stakeholders.
- The petition does not give enough information to determine if polyoxin DZS is synthetic.
- Polyoxin DZS is not compatible with organic production.
- Polyoxin DZS is not essential.
- Potential post-harvest uses have not been clarified.

Cornucopia agrees with the Crops Subcommittee majority opinion:

- Polyoxin DZS is synthetic.
- Polyoxin DZS should **not** be added to the National List at Section 205.601.

BACKGROUND

Polyoxin D zinc salt was petitioned as a disease control material to be used in organic crop production. It is currently used as a pre-harvest foliar spray on conventional crops to control fungal diseases. There are possible additional uses as a post-harvest material.

Polyoxin D inhibits the growth of fungal cell walls. It does not kill the fungus or the fungal spores; it simply stops the growth of hyphae.

International organic regulations

Polyoxin D zinc salt is not allowed in Canada, Europe, or Japan. It is not listed on IFOAM or CODEX Alimentarius (TER, 2012).

CONCERNS WITH POLYOXIN D ZINC SALT

Production process is not available for review by organic stakeholders

The description of the production of polyoxin DZS is withheld as Confidential Business Information. The petition states that it is produced by a microorganism (*Streptomyces*) in a fermentation process.

The NOSB Manual states that Board members have a responsibility to:

> *Be reasonably informed—It is the duty of all Board members to seek and study the information needed to make a reasoned decision and/or recommendation on all business brought before the Board.*

When the needed information is kept confidential, it is not possible for Board members to exercise this duty. The authors of the Technical Review (TR) did have access to the confidential information, but their conclusions should not be used as a basis for decision-making. To further complicate the matter, the authors' names, and possible conflicts of interest, are not disclosed. Any petition that contains Confidential Business Information should be declared insufficient for review by the NOSB.

In order to evaluate this material, all information about the manufacturing process needs to be disclosed to the public, including, but not limited to, answers to the following questions:

- Is this strain of *Streptomyces* genetically engineered?
- What are the ingredients in the growth medium for *Streptomyces*?
- Are any ingredients in the growth medium genetically modified? How is this monitored?
- What is the process for extracting the polyoxin D zinc salt from the growth medium?
- Are inerts used in the final pesticide formulation? If so, which ones?

The petition does not give enough information to determine if polyoxin DZS is synthetic

The petitioner believes that this is a non-synthetic material and therefore its use should be allowed without going through the petition process. The determination on whether a material is synthetic or natural must be made by the NOSB, not by the petitioner.

Because the petitioner refused to supply the needed information the NOSB must rely on the TR, which states that PDZS "may" be synthetic.[39]

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[39] Technical Review: Polyoxin D Zinc Salt. 2012. Compiled by The Organic Center

The definition of "synthetic" states that: *"such term shall not apply to substances created by naturally occurring biological processes."* Composting, for example, is a naturally occurring biological process. All microbial growth is a **biological** process. However, growing one microbe in a controlled environment, and feeding it with a chemical soup, is not a **naturally occurring** process.

Polyoxin DZS is not compatible with organic production

This material is a broad-spectrum fungicide that acts by inhibiting synthesis of the fungal cell walls. It prevents growth of both disease-causing fungi and beneficial fungi, according to the TR.

A long list of the proposed uses of this fungicide is included in the petition, pages 6-8. This is evidence that the fungicide has broad-spectrum activity; in other words, it is harmful to many kinds of fungi. This is not consistent with the organic principle that requires farmers to maintain biodiversity on the farm.

It appears that this fungicide will be used both as a foliar spray to control leaf diseases and a soil application to control soil-borne diseases. Therefore, the reduced biodiversity may occur both on above-ground surfaces and in the soil. Soil biodiversity is particularly critical for decomposition and nutrient cycling.

Polyoxin DZS is not essential

The Organic Materials Review Institute (OMRI) lists many materials available to organic growers for plant disease control. These materials include copper, sulfur, oils and other products. With all these other options available, polyoxin DZS is not essential and should seldom be necessary.

There are many practices available to prevent or minimize fungal diseases, such as increased plant spacing, reduced water use, resistant varieties, nutrient management, sanitation and crop rotation. If cultural controls are not adequate, biological controls and non-synthetic materials are available for disease control. If, and only if, these practices are insufficient to manage the disease, synthetic materials can be used.

Potential post-harvest uses have not been clarified

The petition discusses potential post-harvest uses, but does not clarify the crops or method of use. The petition states:

> *Proposed new uses are summarized in Confidential Appendix 1.*[40]

[40] Kaken, 2012. Petition to Amend 7 CFR §205.601 to Add Polyoxin D Zinc Salt as a Synthetic Substance Allowed for Use In Organic Crop Production

All uses must be explicitly stated before a material can be added to the National List.

CONCLUSION

Cornucopia agrees with the majority opinion: polyoxin DZS should **not** be added to the National List at Section 205.601.

In the future, any petition that contains Confidential Business Information should be returned to the petitioner as insufficient. This will save time for the volunteer NOSB members and the government employees of the NOP.

PROPOSAL:

INDOLE-3-BUTYRIC ACID (IBA)

SUMMARY

Reject the proposal to add Indole-3-Butyric Acid (IBA) to the National List (7 CFR §205.601) for the purpose of plant propagation via dipping.

Rationale

- IBA is not essential in organic production.
- Synthetic growth hormones are not consistent with organic production.
- Application methods require clarification.

BACKGROUND

Indole-3-Butyric Acid (IBA) is a plant hormone, specifically an auxin, that is commonly used in conventional agriculture. When propagating plants from cuttings, IBA is applied directly to plants to encourage root formation. This type of use, when the cut stem is dipped into an IBA solution, is called a "point application." Another type of use, called "area application," involves applying a broadcast spray over the field.

IBA was previously petitioned for both point and area applications. At the Fall 2011 NOSB meeting, the NOSB voted against the proposal (12 No, 2 Yes). The petition was then resubmitted on August 8, 2012, for point applications only, on plants propagated from cuttings in enclosed structures. The Crops Subcommittee again voted to deny the petition (5 No, 3 Yes).

CONCERNS WITH IBA

IBA is not essential for organic production

The petition[41] mentions several crops where IBA may facilitate plant propagation, including herbaceous perennials, woody perennials and annual vegetables. In each case, IBA is not essential for organic production, because there are effective alternative practices available.

[41] Hortus USA Corp. 2012. Petition of substance for inclusion on the National List of Substances allowed in Organic Production and Handling, Indole-3-butyric acid, IBA

Some crops, such as mint and strawberries, readily propagate themselves through natural production of stolons, or runners. Woody perennial crops, such as rosemary, can be propagated by stem cuttings or root division, even without the use of hormones.

The petition states that many seedless crop plants are not available to the organic market; examples include seedless tomato, cucumber, melon and squash. Although a few varieties of those crops may not be available to organic growers, they represent only a very small portion of the available varieties. Seedless varieties are not essential, as there are many alternatives.

If a certain perennial crop requires IBA for propagation, there is already a mechanism to allow its use in Section 205.204 (a)(4). If IBA is used on perennial planting stock, that stock may be sold as organic after it is managed organically for at least one year. This is a reasonable approach, especially when considering that seeds treated with prohibited materials are not allowed at all in organic production.

Synthetic growth hormones are not consistent with organic production

The Organic Foods Production Act (OFPA), Section 6517 (c)(1)(B)(i) allows substances to be added to the National List if (among other requirements):
(B) the substance -
(i) is used in production and contains an active synthetic ingredient in the following categories: copper and sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers;

There is no category to add plant hormones to the National List. Although the members of the Crops Subcommittee suggested that IBA could be called a "production aid," it does not belong in that category. All the other production aids are materials that are outside the plant, and they can easily be removed from the environment (such as tree wrap). Plant hormones are effective only if they are taken up by the vascular system of the plant. In this respect they more closely resemble synthetic fertilizers, or systemic insecticides, rather than production aids.

Application methods require clarification

The wording in the petition differs slightly form the wording in the proposal, which could result in confusion.

> The petition states "*for purposes of plant propagation from cuttings*."
> The proposal states "*for the purpose of plant propagation via dipping*."

The proposal mentions dipping of cuttings into a solution, which is clearly a point application, and would use only a small amount of IBA. The language of the petition, on the other hand, does not mention dipping. The petition does not preclude putting the cuttings in the ground and using an area application over the ground. IBA should not be broadcast over the soil. Use of area applications should be prohibited, even in enclosed structures, such as greenhouses and hoop-houses. The wording "enclosed structures" is irrelevant—the same organic principles must be followed whether the substance is used in the field or an enclosed structure. This is of particular concern because many of the new "enclosed structures" are temporary hoop-houses used to grow crops in the soil. The hoop-houses are then taken down and the plants grow outside. Use of IBA on plants in the ground should be prohibited, even if they are cuttings planted in an enclosed structure.

CONCLUSION

Cornucopia agrees with the majority position of the Crops Subcommittee. IBA is a synthetic material that should not be added to the National List.

VI. HANDLING SUBCOMMITTEE

PROPOSAL:

SULFURIC ACID

SUMMARY

Reject the petition to add sulfuric acid to the National List at Section 205.605.

Rationale

- Sulfuric acid is an environmental pollutant and a component of "acid rain."
- Sulfuric acid mist is classified as a Group 1 carcinogen and is toxic to humans.
- Sulfuric acid may not be essential. The petition lists other acids, including citric, as being "not suited to the innovative process," but does not state why. The manufacturing process is withheld as Confidential Business Information, so it is not possible to determine why the petitioner considers less toxic alternatives to be "not suited."

Cornucopia agrees with the Handling Subcommittee that sulfuric acid should not be added to the National List.

BACKGROUND

Sulfuric acid is petitioned by Marinova, an Australian supplement manufacturer, for use in adjusting the pH during the manufacture of an organic seaweed extract. The seaweed extracts, called fucoidans, are sold as "ingredients in the food supplement, function food and beverage, and cosmetic markets."

International regulations

Sulfuric acid is currently allowed by NOP standards to adjust the pH of liquid fish products for use in organic crop production (205.601(j)(7)). No other use of sulfuric acid is allowed.

IFOAM[42] and the European Union's[43] organic regulations allow sulfuric acid in organic sugar and gelatin processing.

[42] IFOAM Indicative List of Substances for Organic Production and Processing. INS 513. Available online at: http://www.ifoam.org/about_ifoam/standards/pdfs/20080423_IFOAM_Indicative_List.pdf

CONCERNS WITH SULFURIC ACID

Environmental concerns

Sulfuric acid is one of the two primary components of acid rain (the other is nitric acid).[44] The TR notes that during the manufacture of sulfuric acid, emissions may be released into the air. The TR includes a discussion of the environmental impacts of acid rain, and concludes: "sulfuric acid contributes to the formation of acid rain and is considered a regulatory and environmental concern" (TR 345-346).

On the worksheet for NOSB evaluation criteria, the Handling Subcommittee answered "yes" the question, "Are there any adverse effects on environment from manufacture, use, or disposal?" and therefore correctly recommended that the petition be rejected.

Human health concerns

According to the National Institutes of Health, sulfuric acid is a "very strong, corrosive chemical" that "can cause severe burns and tissue damage when it comes in contact with the skin or mucous membranes."[45]

According to the UN's International Agency for Research on Cancer, there is "sufficient evidence that occupational exposure to strong-inorganic-acid mists containing sulfuric acid is carcinogenic."[46]

Please note that the TR, performed by ICF International, includes the following line: "However, available human studies are considered conflicting or insufficient to confirm an increased risk of cancer in exposed humans." The technical reviewer gives no scientific backup, citation or reference for this statement. It is unclear why the ICF technical reviewer felt the need to "balance" or dispute the determination of carcinogenicity by the UN's International Agency for Research on Cancer, which is the world's foremost authority on determination of carcinogenicity. Unfortunately, this appears to continue the tradition of ICF International defending toxic or harmful substances, without providing scientific support.

The Material Safety Data Sheet for sulfuric acid, which was included in the petition, further exposes the toxicity of this petitioned material:

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[43] Commission Regulation (EC) No 889/2008 of 5 September 2008. Annex VIII, Section B.
[44] EPA, http://www.epa.gov/acidrain/what/index.html
[45] MedlinePlus, http://www.nlm.nih.gov/medlineplus/ency/article/002492.htm
[46] IARC Volume 54, http://monographs.iarc.fr/ENG/Monographs/vol54/volume54.pdf

"Very hazardous in case of skin contact (corrosive, irritant, permeator), of eye contact (irritant, corrosive), of ingestion, of inhalation.

Liquid or spray mist may produce tissue damage particularly on mucous membranes of eyes, mouth and respiratory tract.

Skin contact may produce burns. Inhalation of the spray mist may produce severe irritation of respiratory tract, characterized by coughing, choking, or shortness of breath. Severe over-exposure can result in death.

Inflammation of the eye is characterized by redness, watering, and itching.

Skin inflammation is characterized by itching, scaling, reddening, or, occasionally, blistering."

Questions regarding essentiality/alternatives and Confidential Business Information withheld

The petitioner claims that other acids, such as citric and hydrochloric acid, are "not suited to the innovative process developed by Marinova."[47] However, the innovative process is withheld as Confidential Business Information, including a section on "chemical interactions with other substances." While we do not believe that the manufacturing process of organic fucoidan production must necessarily be disclosed, because the petition is for sulfuric acid and not fucoidans, we are concerned that these redactions make it impossible to verify the claim that alternative, less toxic acids are "not suited."

CONCLUSION

Due to its risks to the environment and human health, sulfuric acid fails the criteria for inclusion on the National List. Given the redaction of the manufacturing process as Confidential Business Information, it is also not possible to verify the petitioner's claim that other acids are "not suited."

Cornucopia supports the Handling Subcommittee's recommendation to reject the petition.

[47] Petition to add sulfuric acid by Marinova. July 29, 2010

PROPOSAL:

BARLEY BETAFIBER

SUMMARY

Reject the petition to add barley betafiber to the National List at Section 205.606.

Adding conventional barley betafiber to the National List would be illegal, as it fails OFPA's criteria: it is not essential, its production is harmful to the environment, and it is not consistent with organic farming and handling.

Rationale

- The production of barley betafiber, under conventional agricultural management, potentially involves many environmentally damaging inputs and practices, including: synthetic fertilizers; monoculture; synthetic and toxic pesticides, herbicides and fumigants; synthetic volatile solvents.

- Enzymes used during the production of barley betafiber are likely genetically engineered.

- Barley betafiber's primary use is to replace nutrients (fiber) that have either been lost during processing, or were never present in the first place, to allow for an FDA-approved health claim. Health claims on packaged foods are marketing tools, and not essential to organic handling.

- Unnecessary or gimmicky conventional ingredients in organic foods threaten consumer confidence in the organic label.

- Organic consumers overwhelmingly reject synthetic or non-organic "nutrients" in organic foods, according to a consumer survey by PCC Natural Markets.

- The petitioner withheld important information as "Confidential Business Information." This information is vital for the NOSB to make an informed decision on this material.

- Not all "other ingredients" are disclosed, violating the requirement in OFPA that the NOSB must obtain a full list of "other ingredients" before adding a material to the National List.

Cornucopia disagrees with the Handling Subcommittee that barley betafiber should be added to the National List simply because it is "unique." "Uniqueness" is not a

criterion for adding a material to the National List; if it were, what would prevent other "unique" materials, such as hydrogenated oils or artificial sweeteners, from being added to the National List?

BACKGROUND

Barley betafiber is petitioned by Cargill, which manufactures barley betafiber under the Barliv™ brand name. Cargill argues that barley betafiber is a unique source of fiber, which allows manufacturers to add an FDA-approved health claim to packaged foods, including beverages.

International regulations

Conventional barley betafiber is not allowed by any other organic regulations.

CONCERNS WITH BARLEY BETAFIBER

Negative environmental impacts of conventional production

Conventional agricultural practices are harmful to the environment. Yet, to our surprise, the Handling Subcommittee answered "no" to the question, "Are there adverse effects on environment from manufacture, use and disposal?" For this reason, we feel it is important to outline some of the environmental impacts of conventional barley production. The following were pointed out in the Technical Review:

- Synthetic fertilizers, including anhydrous ammonia, urea and ammonium sulfate are allowed on fields for conventional barley production.[48]

- Conventional barley growers and handlers are permitted to use a wide variety of pesticides and herbicides that are potentially harmful to the environment and human health, including malathion (an organophosphate insecticide), methomyl (a carbamate),[49] pinoxaden and fenoxaprop, glyphosate, atrazine and 2,4-D.[50]

- Conventional barley is commonly fumigated with toxic insecticidal gases to kill pests in storage. Methyl bromide, which has been recognized as an ozone-depleting chemical, is being phased out, but is still used to fumigate barley.

[48] TR 366-367
[49] http://www.amaroc.ma/produits/Details-produits/Presentations-produit/Lannate%2025%20wp/lannate.pdf and http://www.epa.gov/oppsrrd1/REDs/0028red.pdf
[50] http://www.ag.ndsu.edu/ibms/documents/GEbarley2012.pdf

> An alternative to methyl bromide is sulfuryl fluoride. But like methyl bromide, sulfuryl fluoride appears to have serious environmental impacts. Researchers at the University of California at Irvine discovered that sulfuryl fluoride is a greenhouse gas that is 4,000 times more efficient at trapping heat than carbon dioxide.[51] According to the researchers, the climate impact of using sulfuryl fluoride to fumigate foods is equivalent to the carbon dioxide emitted from about 1 million vehicles.
>
> Other synthetic insecticidal fumigants ("grain protectants") registered for use on barley grain in storage include chlorpyrifos methyl, deltamethrin, pirimiphos-methyl and malathion.[52]

Let's be clear: there absolutely are negative environmental impacts from the manufacture of barley betafiber, and these should not be taken lightly (or ignored, as the Handling Subcommittee appears to have done so far).

Possible use of excluded methods in processing of barley betafiber

The petition points out that enzymes and ethanol are used in the processing of barley betafiber, but does not indicate whether these products are derived from excluded methods (genetic engineering). The TR questions whether excluded methods are involved, and points out that "the manufacturing process does not provide enough information to confirm whether excluded methods are used in the process" (TR 203-204).

The TR also points out that both Genencor and Novozyme have patented genetically engineered versions of the enzymes used in barley betafiber processing. In our own research, we found that Cargill has identified Genencor Spezyme, from the bacterium *Bacillus lichenformis*, as an enzyme used specifically in barley betafiber production. The patent to Genencor states that the amino acids in the bacteria have been rearranged and that "these mutants showed a slightly higher activity level than the wild type enzyme."[53]

Genencor, the manufacturer of the enzymes used, is a subsidiary of DuPont, which contributed more than $5 million to defeat Proposition 37 for labeling of genetically engineered foods.[54]

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[51] University of California – Irvine (January 30, 2009) "Termite Insecticide Found to Be Potent Greenhouse Gas," *ScienceDaily*. (Available online at http://www.sciencedaily.com-/releases/2009/01/090121144059.htm.)
[52] http://www.sites.ext.vt.edu/newsletter-archive/cses/2005-10/grain.html
[53] Patent 6,939,703 is a patent assigned to Genencor
[54] California Secretary of State public records, available online at http://cal-access.sos.ca.gov/Campaign/Measures/Detail.aspx?id=1344799&session=2011

The petitioner, Cargill, is the sole manufacturer of barley betafiber in the US. Cargill routinely uses excluded methods (genetic engineering); in fact, the corporation contributed a quarter million dollars to oppose Proposition 37 in California (the citizen ballot initiative to require labeling genetically engineered foods).[55]

The petitioner's unwillingness to publicly disclose whether the enzymes used are genetically engineered is in line with its past actions attempting to keep consumers in the dark about the use of genetically engineered ingredients and inputs.

Barley betafiber replaces nutrients lost during processing

According to the petitioner, the primary purpose why a food manufacturer would add barley betafiber to a product is to increase fiber content. In other words, the primary purpose would be either to replace nutrients lost during processing, or to add nutrients that were never supposed to be in the food in the first place. Low consumption of dietary fiber is in large part due to consumption of overly processed grains, and low consumption of whole fruits, vegetables, legumes and other high-fiber foods.

It is interesting to note that the petitioner points out barley betafiber's usefulness as a source of fiber in juice. By its very nature, processing a fruit or vegetable into juice removes the fiber. In that case, the primary purpose of barley betafiber would be to replace nutrients lost during processing.

For consumers, alternatives to barley betafiber include any food with a high fiber content, including barley, oats, whole grains, legumes, fruits and vegetables (or whole fruits and vegetables rather than juice).

Maintaining consumer confidence in the organic label

The growth of the organic industry is due, in large part, to the willingness of a growing number of consumers to pay a price premium for foods and beverages that are produced to high standards of environmental stewardship and safety to human health.

Consumers rightfully expect that ingredients in certified organic products be either organically grown and processed, or carefully vetted and determined to be both essential to producing the food and poses no harmful effects on the environment and human health. Barley betafiber is neither essential nor is its production harmless to the environment. Any addition of an unnecessary, conventionally produced ingredient threatens to erode consumer confidence in organics.

Consumers overwhelmingly reject conventional "nutraceuticals" in organic foods

[55] Ibid

The Handling Subcommittee requested public comment on the "uniqueness" of barley betafiber and on market demand. A consumer survey of nearly 1,500 organic shoppers by the nation's largest natural food cooperative, PCC Natural Markets in Seattle, shows that there is very little demand for conventionally grown, solvent-extracted ingredients that serve as "nutrients."

For example, when asked about their inclination to purchase a product containing an added nutrient from non-organic sunflower oil, nearly two-thirds of respondents said they "would not purchase" the product; nearly one quarter said they would be "less inclined" to purchase; and only 4.7% would be "more inclined" to purchase a product with the added nutrient from conventional sunflower oil. We imagine responses would be similar if asked about added fiber from a conventional processed barley product.[56]

The petitioner withheld Confidential Business Information (CBI)

When a petitioner withholds important information, including from the technical reviewer, the petition should automatically be tabled until all information is made available to the NOSB and the public. Withheld information includes parts of the manufacturing process, quality control test results, and commercial information.

We are especially concerned that the entire appendix 2, explaining the manufacturing process, and appendix 7, outlining safety and toxicology reviews, have been withheld as CBI.

Under no circumstances should a conventionally grown and processed ingredient be approved for use in organics if the petitioner—in this case, Cargill—is unwilling to share basic manufacturing and safety data with the NOSB, the technical reviewer, and the organic community.

"Other ingredients" are not disclosed

"Other ingredients" are not disclosed. Since any information regarding the "manufacturing process" has been withheld as Confidential Business Information, the NOSB does not have a complete list of "other ingredients," as the law clearly requires.

> Sec 2119(l) REQUIREMENTS. – In establishing the National List or proposed amendments to the National List, the Board shall –
>
> > (2) work with manufacturers of substances considered for inclusion in the proposed National List to obtain a complete list of ingredients

[56] PCC Natural Markets. Nutrient Additives PCC Shopper Survey. August-September 2011. Submitted to the NOSB through regulations.gov

and determine whether such substances contain inert materials that are synthetically produced"

The Board cannot approve barley betafiber without the cooperation of the manufacturer in disclosing the full list of "other ingredients."

CONCLUSION

Barley betafiber fails many legal criteria for inclusion on the National List:

- Barley betafiber is a marketing tool and is not essential to organic handling;
- Barley betafiber is manufactured in ways that are harmful to the environment;
- The petitioner has withheld information outlining safety and toxicological reviews;
- Barley betafiber is likely produced using excluded methods;
- The petitioner has not disclosed all ingredients and processing aids used in the material's production.

The petition should be rejected.

PROPOSAL:

SUGAR BEET FIBER

SUMMARY

Reject the petition to add sugar beet fiber to the National List at Section 205.606.

Adding conventional sugar beet fiber to the National List would be illegal, as it fails OFPA's criteria: it is not essential, its production and manufacturing processes are harmful to the environment, and its use is not consistent with organic farming and handling.

Rationale

- The production of sugar beet fiber involves environmentally damaging inputs and processing aids.
- Possible harm to human health exists from processing aids in sugar beet production and sugar beet fiber production.
- Petition failed to provide any information on processing aids used.
- "Other ingredients" are not disclosed.
- Sugar beet fiber is marketed as an added nutrient that allows for a health claim on food packaging—it is a marketing tool and therefore not essential.
- Sugar beet fiber's primary purpose is to replace or add nutrients lost during processing or, in some cases, nutrients that were never part of the original food to which they are added.
- Dubious market demand: organic consumers overwhelmingly reject the addition of unnecessary conventional ingredients to organic foods.
- There are concerns regarding the widespread use of genetically engineered sugar beets.

The near-unanimous vote (7 Yes, 1 Abstain) to add sugar beet fiber to the National List is inconsistent with the Handling Subcommittee's answers to whether the material meets the legal criteria for inclusion on the National List. The Handling Subcommittee officially recognizes that:

1. The manufacture of sugar beet fiber is harmful to the environment;
2. Organic alternatives exist; and
3. The substance is not essential for organic handling.

Yet the Handling Subcommittee voted to recommend the addition of sugar beet fiber to the National List.

The criteria in the decision tree/worksheet are based on legal criteria from OFPA and the federal organic standards. The Handling Subcommittee has given no justification whatsoever for its vote to add sugar beet fiber to the National List.

BACKGROUND

Sugar beet fiber is petitioned by Nordic Sugar for inclusion on 205.606 as a conventional agricultural product allowed in organic foods.

International regulations

Sugar beet fiber, as the product of conventional agriculture and conventional processing, is not allowed by any other organic regulations.

CONCERNS WITH SUGAR BEET FIBER

Negative environmental impacts from conventional agriculture

The production of conventional sugar beets is damaging to the environment. The TR clearly outlines many of the negative environmental impacts of conventional beet production, yet the vast majority of these concerns appear to have been entirely disregarded by the Handling Subcommittee.

We realize that outlining the environmentally damaging inputs used in conventional sugar beet production may seem superfluous to many NOSB members—after all, it seems that the understanding that organic agriculture is a positive alternative to the environmentally damaging system of conventional food production should be a prerequisite for serving on the Board. Yet seven Handling Subcommittee members voted to allow this product of conventional agriculture in organic foods, without justification. For this reason, we feel it is incumbent on us to detail the environmentally damaging inputs commonly used in conventional sugar beet fiber production.

According to the American Society of Sugar Beet Technologists,[57] the following pesticides and herbicides are recommended for growing conventional sugar beets:

- Terbufos, an organophosphate insecticide, to control sugar beet maggot, leafhoppers and other pests
- Ethofumesate and pyrazon, applied preemergence, for weed control
- Desmedipham, phenmedipham, and clopyralid applied postemergence, for weed control
- 1,3-dichloropropene, a possible human carcinogen and a toxin,[58] for soil fumigation
- Hymexazol, an acutely toxic fungicide, for control of damping-off in sugar beet seedlings

The Technical Review (TR) by The Organic Center identified these additional pesticides, which are either commonly used to grow sugar beets (both in Sweden and in the US) or registered for use on sugar beets in the United States:

- Imidacloprid, a neonicotinoid known to be a toxin to honeybees[59]
- Metamitron, an herbicide
- Aldicarb, a carbamate insecticide and cholinesterase inhibitor
- EPTC, a thiocarbamate herbicide that is toxic to mammals[60]
- Methyl bromide, an ozone-depleting chemical[61]

The petitioner uses sugar beets grown in Sweden. The TR points out that Swedish sugar beets are treated with the following:

- An average of 1.00 kg/Ha biscarbamate herbicides
- An average of 0.3 kg/Ha pyridazinone herbicides
- An average of 0.2 kg/Ha cyclohexanedione herbicides (TR 327)

While agrochemical manufacturers may claim that the use of pesticides and fumigants such as aldicarb, EPTC, terbufos and methyl bromide are environmentally benign, we disagree. We certainly hope that that the members of the NOSB recognize that the manufacture of sugar beet fiber, which uses conventionally grown sugar beets as the starting material, comes with a significant cost to the environment.

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[57] American Society for Sugar Beet Technologists. http://assbt-jsbr.org/JSBR/Vol28/JSBRVol28No1and2P61o95AmericanSocietyofSugarbeetTechnologistsAbstracts.pdf

[58] Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention. http://www.atsdr.cdc.gov/toxfaqs/tf.asp?id=835&tid=163

[59] National Pesticide Information Center. http://npic.orst.edu/factsheets/imidacloprid.pdf

[60] Environmental Protection Agency Reregistration Eligibility Decision on EPTC, http://www.epa.gov/oppsrrd1/REDs/factsheets/0064fact.pdf

[61] Environmental Protection Agency, http://www.epa.gov/ozone/mbr/

Pollution from processing sugar beets

To remove taste, color and odor from both the sugar beet pulp and the finished sugar beet fiber, processors use physical treatments including cleaning, extraction, sieving, heating and chemical treatments.[62] The petitioner gave no information on the manufacturing process, and it is therefore unknown which chemical processing aids are used in the manufacture of sugar beet fiber.

FDA regulations identify the following processing aids for use in flume water for washing beets prior to slicing. These chemicals are prohibited in organics, but would be allowed in the processing of the petitioned material:[63]

- Alpha-alkyl-omega-hydroxypoly-(oxyethylene)
- Linear undecylbenzenesulfonic acid
- Dialkanolamide
- Monoethanolamine
- Triethanolamine
- Oleic acid
- Ethylene dichloride
- Ethylene glycol monobutyl ether
- Tetrasodium ethylenediaminetetraacetate

Some of these chemicals have been found to promote tumors in animal studies (triethanolamine[64] and ethylene dichloride[65]), to be potential occupational carcinogens (ethylene dichloride),[66] and to be toxic to aquatic species (ethylene dichloride).[67]

The TR (TR 185-189) identified the following as additional processing aids that may be used to remove colors and flavors:

- Sulfites
- Ethyl alcohol cis-3-hexenol
- Trans-2-heptenal
- Trans,ci-2,6-nonadienal

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[62] Thibault, Renard and Guillon. Sugar Beet Fiber: Production, Composition, Physicochemical properties, Physiological Effects, Safety and Food Applications Handbook of Dietary Fiber. Page 553
[63] 21 CFR 173.315(a)(4) Chemicals used in washing or to assist in the peeling of fruits and vegetables
[64] National Toxicology Program (NTP) (CAS No. 102–71–6) in F344/N Rats and B6C3F1 Mice (Dermal Studies), NTP TR 518, NIH Publication No. 03–4452. Toxicology and Carcinogenesis Studies of Triethanolamine. 2003
[65] Environmental Protection Agency, http://www.epa.gov/ttnatw01/hlthef/di-ethan.html
[66] Environmental Protection Agency, http://www.cdc.gov/niosh/idlh/107062.html
[67] Libralato G, Volpi Ghirardini A, Avezzù F (2009). "Seawater ecotoxicity of monoethanolamine, diethanolamine and triethanolamine". *J Hazard Mater* 176 (1-3): 535–9

- Trans-2-nonenal
- Trans-2,4-heptadienal
- Isopropyl or ethyl alcohol
- Potassium oxalate
- Hydrochloric acid
- Potassium hydroxide

Some of these solvents are highly toxic, corrosive and/or flammable, and all are strictly prohibited in organic processing (with the exception of potassium hydroxide in peeling of peaches).

The TR also points out that the following chemicals may be used to control microbial growth during sugar beet fiber processing (TR 277-281):

- Formaldehyde (not legal in the US but may be used in other countries)
- Ammonium bisulfate
- Thiocarbamate fungicides
- Glutaraldehyde
- Other commercial biocides

Finally, the TR points out that beet sugar production is notorious for discharging large amounts of wastewater with high biological oxygen demand (TR 295-297).

Sugar beet pulp has historically been a waste product that has been disposed of as animal feed. Manufacturers have sought alternative, high value uses for this agricultural waste product, and studied the use of sugar beet fiber as a high-fiber food ingredient or dietary fiber that could be marketed as a health food—turning an agricultural waste product into profit.

Potential harm to human health

Since sugar beet fiber is manufactured from a byproduct of conventional sugar beet processing, we question whether human health effects could exist from the use of pesticides, fungicides, microbial disinfectants, peeling chemicals, and other processing aids that are used. All the chemicals listed in the previous section ("negative environmental impacts from conventional sugar beet production") should be considered for their potential effects on human health.

Consumers who purchase organic foods to avoid chemical residues should not be exposed to the potential chemical residues on sugar beet fiber when they purchase organic foods.

"Other ingredients" are not disclosed

Details of the manufacturing process, including the use of "other ingredients" and processing aids, are not disclosed.

The NOSB does not have a complete list of ingredients, as the law requires:

> Sec 2119 [7 USC 6518] (l) REQUIREMENTS. – In establishing the National List or proposed amendments to the National List, the Board shall –
>
> (2) work with manufacturers of substances considered for inclusion in the proposed National List to obtain a complete list of ingredients and determine whether such substances contain inert materials that are synthetically produced"

The Board cannot legally approve sugar beet fiber without the cooperation of the manufacturer in disclosing the full list of "other ingredients" and processing aids.

Sugar beet fiber is not essential

OFPA requires that any addition to the National List must be "necessary to the production and handling of the agricultural product because of the unavailability of whole natural substitute products" (Sec. 2118 [7 USC 6517] (c)(1)(A)(ii)).

In the case of sugar beet fiber, as with barley betafiber, the primary function is to increase the fiber content, which serves as a marketing tool for the manufacturer. According to the Mayo Clinic, "[A]dding too much fiber too quickly can promote intestinal gas, abdominal bloating and cramping."[68] It seems entirely unnecessary to add fiber to processed organic foods when organic whole foods that are naturally rich in fiber are the obvious—and safer—alternative.

Replacing nutrients lost during processing

Moreover, when added to increase the fiber content of foods, sugar beet fiber fails 7 CFR 206.600(b)(4), which states that a material's primary purpose cannot be to replace nutrients lost during processing. Not only would sugar beet fiber sometimes be added to replace fiber lost during processing, it could in some cases "replace" fiber that was never a component of the original, unprocessed food.

Questionable market demand

The petitioner states that they produced certified organic sugar beet fiber in the past but discontinued due to market conditions: "demand was low." The petitioner admits that demand was low due to the higher price of organic sugar beet fiber. The higher price of an organic product should not justify its conventional counterpart's addition to the National List.

[68] Mayo Clinic, http://www.mayoclinic.com/health/fiber/NU00033/NSECTIONGROUP=2

But more importantly, organic consumers overwhelmingly reject the addition of unnecessary non-organic ingredients in organic foods. The Handling Subcommittee requested public comments on the supply and demand of conventional sugar beet fiber for use in organic foods. While we cannot speak to the supply, survey data from the largest food cooperative, PCC Natural Markets in Seattle, clearly shows that organic consumers do not want conventional nutraceutical ingredients in organic foods.

For example, when asked about their inclination to purchase a product containing an added nutrient from non-organic sunflower oil, nearly two-thirds of respondents said they "would not purchase" the product; nearly one quarter said they would be "less inclined" to purchase; and only 4.7% would be "more inclined" to purchase a product with the added nutrient from conventional sunflower oil. We imagine responses would be similar if asked about added fiber from conventional sugar beet.[69]

Concerns with genetically engineered sugar beets

According to the TR, 95% of conventional sugar beets are GMO in the US (TR 364). Although the petitioner is in Europe, where GMO sugar beets are currently not an issue, the approval would not be restricted to European sugar beet fiber. If added to the National List, non-organic sugar beet fiber would have to be Identity-Preserved Non-GMO. The risk of contamination could be an ongoing issue with this material.

CONCLUSION

As with other conventional agricultural products, the production of sugar beet fiber material involves environmentally damaging synthetic fertilizers, toxic pesticides and chemical processing aids.

The primary purpose of adding sugar beet fiber to organic foods appears to be to allow manufacturers to add a health claim; it is therefore petitioned as a marketing tool and entirely unnecessary and non-essential to organic handling.

Sugar beet fiber fails all criteria for inclusion on the National List. Cornucopia urges the Board to reject the petition.

[69] PCC Natural Markets. Nutrient Additives PCC Shopper Survey. August-September 2011. Submitted to the NOSB through regulations.gov

PROPOSAL:

1,3-DIBROMO-5,5-DIMETHYLHYDANTOIN (DBDMH)

SUMMARY

DBDMH is an antimicrobial chemical used in conventional slaughterhouses to control pathogenic bacteria such as *E. coli*.

Cornucopia supports the recommendation of the Handling Subcommittee to **reject** DBDMH's addition to the National List.

Rationale

- DBDMH is a chemical antimicrobial with potentially negative effects on human health and the environment. Many questions regarding its safety remain unanswered.

- DBDMH fails every criterion for inclusion on Section 205.605, including that it does not have GRAS (Generally Recognized as Safe) status with the FDA. The FDA considers DBDMH to be a "food contact substance" and the EPA considers it a pesticide.

- The petitioner withheld important information from the NOSB, the TR reviewer and the public. Withheld Confidential Business Information included an entire section titled "Effects on Human Health."

- Alternatives exist, including those discussed at length in the TR: peracetic acid, hot water washing, chlorine and hydrogen peroxide.

- Furthermore, another alternative practice for controlling *E. coli* must be considered: grass-finishing ruminants. Research has established that 100% grass-finished ruminants, and grain-fed animals that are switched back to 100% forage for a period of time prior to slaughter, have demonstrably lower levels of *E. coli* contamination. This management model would greatly reduce the justification for using materials such as DBDMH in processing.

BACKGROUND

DBDMH has been petitioned by Albemarle Corporation as an antimicrobial for use in meat processing, to control pathogenic bacteria including *E. coli*.

International regulations

DBDMH is not allowed in any international organic regulations.

CONCERNS WITH DBDMH

Negative effects on the environment (fails 205.600(b)(2))

First, it is important to note that very little information appears to exist regarding the environmental effects of DBDMH. This is made apparent in the TR, which lists only two sources in its discussion on DBDMH's environmental effects: the petitioner and the EPA (TR 281-309).

The Material Safety and Data Sheet (MSDS) on DBDMH states that the material is "very toxic to aquatic life." The MSDS also states, "An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. Very toxic to aquatic life."

Since DBDMH breaks down to DMH and hypobromous acid (HBrO), it is important to consider the possible environmental effects of these two breakdown products.

According to the petitioner, Albemarle Corporation, in its Environmental Assessment report prepared for the FDA, "DMH is slightly toxic to fish and aquatic invertebrates."[70] It is interesting to note that this information, which was supplied to the FDA, was not included in its petition to the NOSB.

Furthermore, in its FDA notification, Albemarle calculated that the level of exposure to aquatic wildlife from DMH in wastewater from a poultry processing plant would be well below toxic and harmful levels. It is worth noting that the only information available on this topic is from the petitioner itself. It appears that the effects on wildlife of DMH have not been adequately studied and independently verified.

The other breakdown product is hypobromous acid (HBrO), a bromide, which is in fact the "active ingredient" of DBDMH. The TR cites Albemarle Corporation's claim that "no HBrO is expected to be released into wastewater," but again, this has not been independently verified since no independent information or data appears to exist.

[70] Albemarle Corporation, Environmental Assessment. http://www.fda.gov/downloads/Food/FoodIngredientsPackaging/EnvironmentalDecisions/UCM287539.pdf?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=1,3-dibromo-5,5-dimethylhydantoin&utm_content=9

If hypobromous acid were to be released into wastewater, it could have negative effects on wildlife. A study by Dutch researchers found bromide affected reproductive health and endocrine function of crustaceans and fish:

> "Bromide ion markedly impaired reproduction in both crustaceans and fish. Histologically no effects were observed in the long-term test with Oryzias, but in the reproduction test with Poecilia, hyperplasia of the thyroid, atrophy and degeneration of the musculature and regressive changes in the female reproductive tract were observed."[71]

Albemarle Corporation has stated to the FDA that studies with sodium bromide are appropriate for determining the effects of hypobromous acid: "Since sodium bromide dissociates in water to yield the free sodium and bromide ions, the data on sodium bromide serve to provide useful information on the toxicity of the bromide ion, itself."[72]

In an EPA Reregistration Eligibility Decision document for sodium bromide, the EPA noted: "The results indicate that sodium bromide, measured as bromine, is highly toxic to estuarine/marine organisms on an acute basis."[73]

The EPA states that "chronic testing of sodium bromide is not required," based on the assumption that "residues of sodium bromide (hypobromous acid) are short-lived." The EPA states that "residues of [hypobromous acid] are highly toxic on an acute basis," and then states that "ultimate biodegradation [will be] completed within a few weeks." For this reason, the EPA waived the requirement for standard chronic toxicity tests. However, the effects of this "highly toxic" substance on aquatic wildlife, in the weeks before the material is completely degraded, must be considered. For this reason—to protect aquatic life from the toxicity of DBDMH's breakdown product—the material should not be approved for use in organics.

Negative effects on human health (fails 205.600(b)(3))

National Institutes of Health

The National Institutes of Health, in a Haz-Map[74] listing for DBDMH, states that evidence exists of "thyroid hypofunction in repeated dose study of rats."[75]

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[71] Canton JH, Wester PW, Mathijssen-Spiekman EAM (1983) Study on the toxicity of sodium bromide to different freshwater organisms. Food and Chemical Toxicology 21(4): 369-378.
[72]http://www.fda.gov/downloads/Food/FoodIngredientsPackaging/EnvironmentalDecisions/UCM287539.pdf?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=1,3-dibromo-5,5-dimethylhydantoin&utm_content=9
[73] http://www.epa.gov/pesticides/chem_search/cleared_reviews/csr_PC-013907_30-Jun-05_a.pdf
[74] HazMap is an online database of chemicals by the National Institutes of Health. All information on the HazMap has been scientifically verified.
[75] http://hazmap.nlm.nih.gov/category-details?id=9444&table=copytblagents

The NIH Hazmap also lists the following for DBDMH: "inhalation may cause corrosive injuries to upper respiratory tract and lungs; toxic by ingestion."[76]

Environmental Protection Agency

It is important to note that the EPA regulates DBDMH as a pesticide. It is used as a microbial control and disinfectant in water systems, ornamental ponds, swimming pools, toilet bowls, etc. The EPA recognizes the only food-use of DBDMH to be in the manufacture of food-contact paper and paperboard.[77]

The EPA reviewed DBDMH[78] in 2007 as a multi-purpose biocide. The EPA writes that the Reregistration Eligibility Decision (RED) does not cover any food-related uses other than use as a slimicide in food-contact paper and paperboard.[79] Therefore, it appears the EPA and FDA have not considered accumulative exposure to DBDMH.

In its Reregistration Eligibility Decision, the EPA considered the following toxicity data, from laboratory animal studies using DBDMH:

1,3-Dibromo-5,5-dimethylhydantoin			
870.1100 Acute oral toxicity-Rat	93076011, 00137105 (4334-012-01)	LD_{50} = 760 mg/kg	III
870.1100 Acute oral toxicity-Rat	44988002,)	combined LD_{50} = 448 mg/kg	II
870.1200 Acute dermal toxicity-Rabbit	93076025, 00137110 (4334-012-07)	LD_{50} cannot be ascertained (study is classified as Unacceptable/non-guideline	--
870.1200 Acute dermal toxicity-Rat	44988001	LD50 > 2000 mg/kg	III
870.1300 Acute inhalation toxicity-Rabbit	44988003	LC50 between0.51-2.02 mg/L	II

Guideline No./ Study Type	MRID No. (TRID No.)	Results	Toxicity Category
870.2500 Primary dermal irritation-Rabbit	93076017, 00137109 (4334-012-05)	severe skin irritant	I
870.2500 Primary dermal irritation-Rabbit	44988004	corrosive	I
870.2600 Dermal Sensitization - guinea pig	44988005	non-sensitizer	N/A

Category I is "highly toxic and severely irritating," and applies to two dermal irritations in rabbit studies.

[76] http://hazmap.nlm.nih.gov/category-details?id=9444&table=copytblagents
[77] http://www.epa.gov/oppsrrd1/REDs/halohydantoins-red.pdf
[78] EPA's review covered halohydantoins and issued a Reregistration Eligibility Decision in September 2007. DBDMH is one of five halohydantoins covered in the RED.
[79] http://www.epa.gov/oppsrrd1/REDs/halohydantoins-red.pdf

Category II is "moderately toxic and moderately irritating," and applies to the acute inhalation (rabbit) study and the acute oral toxicity (rat) studies.

Category III is "slightly toxic and slightly irritating," and applies to the acute oral toxicity (rat) test and acute dermal toxicity (rat) test.

The EPA also raised concerns about one of the breakdown products of DBDMH, which is DMH. The EPA wrote: "Available metabolism data indicate that DMH and EMH are excreted unchanged in the rat. However, it is known that hydroxymethylhydantoins are formaldehyde releasers."

Ultimately, much remains unknown regarding these antimicrobial chemicals' effects on human health. The EPA wrote that further studies would be needed, especially "to better characterize effects related to endocrine disruption."

Food and Drug Administration

Both DBDMH and its breakdown product, HBrO, which is its active ingredient, are listed in the FDA's food contact substance database. As with the FDA's Generally Recognized As Safe (GRAS) system, the FDA does not require any independent safety testing or evaluation before a food contact substance can be used. As a result, virtually no information from independent sources is available regarding potential human health effects from eating foods treated with this chemical biocide.

The FDA database of Food Contact Substances contains the Albemarle Corporation notifications for HBrO[80] and DBDMH.[81] These notifications are remarkably lacking in safety test results. Not surprisingly, Albemarle assured the FDA that DBDMH and HBrO are safe, and since the FDA requires no independent safety testing, it has allowed its use in conventional food production.

Scientific literature (peer-reviewed academic articles)

OFPA requires that the potential impact on human health of breakdown products be considered as well. DBDMH breaks down to hypobromous acid (HBrO), which is a bromide. Albemarle writes in its petition to the FDA: "Since sodium bromide dissociates in water to yield the free sodium and bromide ions, the data on sodium bromide serve to provide useful information on the toxicity of the bromide ion, itself."[82]

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[80]http://www.accessdata.fda.gov/scripts/fcn/fcnDetailNavigation.cfm?rpt=fcsListing&id=1197
[81]http://www.accessdata.fda.gov/scripts/fcn/fcnDetailNavigation.cfm?rpt=fcsListing&id=1190
[82]http://www.fda.gov/downloads/Food/FoodIngredientsPackaging/EnvironmentalDecisions/UCM287539.pdf?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=1,3-dibromo-5,5-dimethylhydantoin&utm_content=9

We searched the literature for toxicity and endocrine effects of sodium bromide. A study found that rats exposed to sodium bromide experienced "complex of changes in the endocrine system, thyroid activation being the most prominent." A multi-generation study showed a decrease in fertility following high sodium bromide exposure. It would seem that one of the breakdown products of DBDMH may be a potential endocrine disruptor.[83]

Centers for Disease Control and Prevention/National Institute for Occupational Safety and Health

The CDC and NIOSH Occupational Health Guidelines[84] for DBDMH include the following:

- "Contact with water, strong acids, and easily oxidized materials such as ammonium salts, sulfides, etc., may cause fires and explosions and formation of toxic fumes of chlorine and nitrogen trichloride."
- "Toxic gases may be released in a fire involving DBDMH."
- "Employees should be provided with and required to use impervious clothing, gloves, face shields and other appropriate protecting clothing necessary to prevent repeated or prolonged skin contact with solid or liquids containing DBDMH."
- Causes irreversible eye damage
- Causes burns. May be absorbed through the skin in harmful amounts.
- "May be harmful if inhaled. Material is extremely destructive to the tissue of the mucous membranes and upper respiratory tract."
- "Causes severe burns and eye damage"
- "Toxic if swallowed." "May be fatal if swallowed."

DBDMH does not have GRAS status with the FDA (205.600(b)(5))

DBDMH does not have GRAS status with the FDA. It is regulated as a "food contact substance" by the FDA and as a pesticide by the EPA.

Alternatives exist (205.600(b)(1)) and DBDMH is not essential (205.600(b)(6))

[83] Van Leeuwen FXR, den Tonkelaar EM, van Logten MJ (1983) Toxicity of sodium bromide in rats: effects on endocrine system and reproduction. Food and Chemical Toxicology 21(4): 383-389.
[84] http://www.cdc.gov/niosh/docs/81-123/pdfs/0193.pdf

Alternatives to DBDMH exist, including hot water sprays and other antimicrobials already on the National List, including lactic acid, peracetic acid and ozone. These appear to be working fine, as the FDA outbreaks database shows that there have been no outbreaks of illnesses traced to the consumption of organic meat.[85]

Grass-finishing ruminants reduces potential **E. coli** *contamination*

Studies show that *E. coli* contamination of beef carcasses may be preventable when ruminants are given their natural diet of pasture and hay prior to slaughter.

Early studies from the 1960s and 1970s showed that a decrease in hay intake and overfeeding with grains causes an increase in total fecal coliform counts.[86] The groundbreaking study that defined this debate was by Cornell researchers in 1998.[87] They found that cattle fed a 90% corn/soy ration (typical of feedlot diets) contained generic *E. coli* populations that were 1000-fold higher than cattle fed a 100% good-quality hay diet. The researchers also found that the *E. coli* recovered from the feces were 1,000-fold more resistant to the "acid shock" test (simulating whether it would survive the 'acid shock' of entering the human stomach) than the *E. coli* recovered from cattle fed 100% hay. The scientists found that switching cattle from a grain-diet to a hay-diet five days prior to slaughter could reduce the prevalence of *E. coli*. One limitation of this study is that no O157:H7 *e. coli*, a particularly dangerous strain, were detected.

Numerous studies have been conducted, and a 2009 review of these studies concludes that "comparing grain-fed to forage-fed cattle still indicates that more E. coli (including O157:H7) is present in the feces of grain-fed cattle."[88]

Additional human health concerns

Since DBDMH is an antimicrobial, it raises the question of whether residues on meat would impact beneficial intestinal flora of the consumer.

There appears to be no scientific studies conducted to ensure that foods treated with this antimicrobial chemical do not negatively impact beneficial intestinal flora.

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[85] Food and Drug Administration, based on a search of the Recalls, Market Withdrawals and Safety Alerts Database. Available: http://www.fda.gov/Safety/Recalls/default.htm

[86] Brownlie, L.E. and F.H. Grau (1967) Effect of food intake on growth and survival of salmonellas and Escherichia coli in the bovine rumen. *Journal of General Microbiology* 46: 125; see also Allison, M. J., Robinson, I. M., Dougherty, R. W and J. A. Bucklin (1975) Grain overload in cattle and sheep: changes in microbial populations in the cecum and rumen. *American Journal of Veterinary Research* 36: 181–185

[87] Diez-Gonzalez, T., Calloway, T.R., Kizoulis, M.G. and J.B. Russell (1998) Grain feeding and the dissemination of acid-resistant Escherichia coli from cattle. *Science* 281:1666-8

[88] Callaway et al. (2009) "Diet, E. Coli O157:H7, and Cattle: A Review after 10 Years." *Current Issues in Molecular Biology* 11:67-80

CONCLUSION

The Handling Subcommittee voted unanimously to reject DBDMH from addition to the National List. We agree that the petition for DBDMH should be rejected.

The lack of publicly available safety testing data, combined with strong indications that human health and environmental concerns exist, renders this material a "poster child" of why US consumers are switching to the organic label, which mandates greater scrutiny of chemical inputs in food production.

Moreover, some of the answers on the decision tree should be corrected. We do not agree that the answer to "Are there adverse effects on environment from manufacture, use and disposal?" should be "no." It appears that DBDMH and its breakdown product, HBrO, are both toxic to aquatic life. The only information regarding the environmental impacts of DBDMH comes from the petitioner. If anything, the environmental impacts are unknown, and we do not believe the Handling Subcommittee has enough information to confidently state that no negative environmental effects exist.

The Handling Subcommittee answered "no" to the question, "Is there any harmful effect on human health?" The entire section titled "Effects on Human Health" was redacted from the petition, as "Confidential Business Information." This causes suspicion. If the content of this section revealed that test results affirmed DBDMH's safety, would it be considered Confidential Business Information? Multiple animal studies on DBDMH and its breakdown product, HBrO, have shown effects on reproductive and endocrine function. Again, the fact that the Handling Subcommittee does not know the answer to this question does not justify the assumption that the material is perfectly safe for human health.

Serious concerns exist about this chemical antimicrobial, which is regulated as a pesticide by the EPA. Operating under the Precautionary Principle, the NOSB should reject the petition to add DBDMH to the National List.

PROPOSAL:

OTHER/AUXILIARY INGREDIENTS

SUMMARY

The Organic Foods Production Act of 1990 (OFPA), USDA organic regulations, previous USDA statements, and case law (Harvey II) have all made it indisputably clear that **all ingredients** in an organic product must either be organically produced or appear on the National List. No distinction exists between ingredients and "other ingredients."

We urge the NOSB to use the organic law and regulations for setting policy regarding "other ingredients." OFPA states that every synthetic and non-organic ingredient must be listed for its specified purpose. For example, if rennet cannot be made without sodium benzoate, a currently unapproved synthetic, then sodium benzoate should be petitioned for the specific purpose of use in rennet.

The current practice of allowing ingredient suppliers to use any synthetic preservative, stabilizer or other ingredient, and justify this because these suppliers are not certified organic handlers, is a violation of OFPA and must end.

BACKGROUND

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

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

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

The organic standards state:

> ***7CFR§ 205.301(b)*** *"Products sold, labeled, or represented as "organic."*

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

To address any potential confusion, the National Organic Program specified in 2007 in a notice published in the Federal Register that "only single substances may be petitioned for evaluation; formulated products cannot appear on the National List."[89]

When challenged in court during the Harvey case, the courts agreed that all non-organic non-agricultural ingredients must be on the National List:

> *In the final ruling on the Harvey II case the Courts determined that Congress did not distinguish between the general term "ingredients" and "processing aids," and authorized the use of synthetic substances, whether ingredients or processing aids, for the use in handling operations so long as they appear on the National List.*

Risking consumer confidence in organics

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

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

Survey data from PCC Natural Markets in Seattle, the largest cooperative grocer in the country, support our claim that organic consumers expect ***all ingredients*** in organic foods to be free from unapproved ingredients and processing aids. PCC Natural Markets surveyed 1,432 consumers and published its results in August

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

2011.[90] The survey found that products containing an added nutrient (in this case, algal oil) containing unapproved "other ingredients" would not be purchased by an overwhelming majority of organic shoppers.

For example, 78.3% of shoppers would not purchase products with algal oil containing synthetic stabilizers, and 88.6% would not purchase products containing algal oil with glucose syrup solids. Both ingredients are currently found in certain brands of organic baby food containing algal oil. And 88.6% would not purchase an organic product with algal oil if it were extracted with hexane (currently the case with organic infant formula).

Yet, since these "other ingredients" are not required to be listed in the ingredients lists of a processed food, most consumers likely do not realize that when they buy an organic product with "algal oil," they are buying a product with glucose syrup solids (possibly derived from genetically engineered corn), synthetic stabilizers and additional unapproved synthetic "other ingredients." These "other ingredients" do have to be listed on algal oil sold as a supplement. A consumer who would not buy an algal oil supplement that lists ingredients such as modified starch, glucose syrup solids, mannitol and sodium polyphosphate might buy an organic product listing "algal oil," not knowing that the algal oil in the organic food contains the exact same ingredients as the algal oil in the supplements aisle.

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

While an organic parent would likely avoid any food listing sodium benzoate as an ingredient, given its documented potential link to ADHD in children, these same parents may unknowingly be feeding foods with sodium benzoate to their children; for example, sodium benzoate is listed as an ingredient in rennet, which appears in many organic cheeses. Since it is not listed in the ingredients list, parents have no way of knowing whether the organic cheese they buy contains sodium benzoate or not; most parents likely, and mistakenly, assume that because it is organic, it does not contain this potentially harmful synthetic substance.

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

[90] PCC Natural Markets. Nutrient Additives PCC Shopper Survey. August-September 2011. Submitted to the NOSB through regulations.gov

ingredients are prohibited unless they are produced in accordance to the organic standards or are present on the National List.

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

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

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

We are disappointed that the Handling Subcommittee continues to ignore the law, and is now attempting to institutionalize the massive consumer deception perpetuated by the organic industry with its proposal. We should be moving forward, toward closer adherence to the law and to organic integrity, not backward.

If the NOSB fails to turn this ship around, this issue will likely end up being adjudicated in federal court.

CORNUCOPIA'S POSITION

The law and regulations are clear: no synthetics or non-organic ingredients may appear in organic foods unless they appear on the National List. Organic processors currently purchase non-organic ingredients from conventional suppliers, who face no restrictions in terms of synthetic preservatives, flavors, stabilizers, carriers, binders and other ingredients.

OFPA clearly states that synthetics should be listed on the National List "by specific use or application."

We propose that the only solution to these past mistakes is to use OFPA and the organic standards moving forward. Any other policy would be illegal. We propose Option D, which we and other public interest groups proposed in our public comments for the Fall 2012 meeting. Option D is explained again below.

Response to the Handling Subcommittee Proposal

The Handling Subcommittee's proposal does not correct the OFPA violations. The proposed baseline criteria are woefully inadequate. To use the FDA's GRAS (Generally Recognized as Safe) or EAFUS (Everything Added to Food in the United States) status as baseline criteria is simply illegal, since OFPA specifically states that every synthetic appearing in organic foods should be held to higher standards. Virtually anything is allowed as GRAS or EAFUS by the FDA, including artificial sweeteners, synthetic dyes, etc. The FDA does not consider independent research on human health effects or environmental impacts before granting an ingredient GRAS status. The agency depends on chemical manufacturers and food processors to do their own due diligence. These baseline criteria are meaningless.

The HS proposes that a checklist be developed and used, to make clear which "other ingredients" were reviewed, and which restrictions the Board decided on. We reject this proposal. Again, OFPA requires that <u>every</u> ingredient must be organic or approved; the way to move forward is to review every ingredient.

In addition, a checklist currently exists for evaluation criteria, yet it has routinely been disregarded. In the most current example, the Handling Subcommittee incorrectly answered many questions regarding environmental impacts, and even in cases where it acknowledges that the material fails the criteria, the subcommittee voted to approve the material anyway. We doubt that a "checklist" will lead to a correction of the violations of OFPA.

Option D

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

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

We propose the following policies be adopted:

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

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

- Only single substances can be petitioned, formulated products cannot appear on the National List.

    - Example: "algal oil" contains other types of conventionally-produced edible oil, sweeteners and synthetic preservatives. "Algal oil" can appear in an organic product only if all ingredients are either organic (e.g. organic sunflower oil) or on the National List (e.g. tocopherols).

- During the petition process, the NOSB works with manufacturers to obtain a full list of ingredients, in accordance with OFPA (7 USC 6518(l)(2))[91] to allow the NOSB to determine whether all ingredients meet OFPA's requirements.

- No petition will be approved unless all ingredients have been disclosed and deemed legal by the NOSB.

Additional Comments in Response to the HS Proposal

We do not support the proposal to create a separate list for cleaners, sanitizers and boiler additives. In some cases, direct steam injection used in food processing applications may lead to residues in the food.[92] These materials should be held to the same standards in terms of human health/environmental effects.

CONCLUSION

- OFPA states that every ingredient appearing in an organic product must be either organic or on the National List.

- OFPA states that the National List should contain an "itemization, by specific use or application, of each synthetic substance."

- The NOP has declared that only single substances, not multi-component materials, may appear on the National List.

- The law states that the NOSB must work with petitioners to obtain a full list of ingredients.

In future petition reviews and sunset reviews, the NOSB must adhere to the above criteria of the law. If an organic handler would like to include a multi-component

[91] 7 USC 6518(l)(2): Requirements – In establishing the proposed National List or proposed amendments to the National List, the Board shall work with manufacturers of substances considered for inclusion in the proposed National List to obtain a complete list of ingredients and determine whether such substances contain inert materials that are synthetically produced
[92] Theuer, R (2012) Getting Steamed Up Over Boiler Additives

ingredient in an organic product, every ingredient of that multi-component material must be either organic or on the National List.

For any “minor” ingredients that the industry believes are absolutely essential to organic handling, like sodium benzoate for rennet, we propose that these be petitioned for their specific use.

VII. COMPLIANCE, ACCREDITATION AND CERTIFICATION SUBCOMMITTEE

PROPOSAL:

CALCULATING PERCENTAGE OF ORGANIC INGREDIENTS IN MULTI-INGREDIENT PRODUCTS

Cornucopia supports the proposal. While public comment to the Fall 2012 discussion document suggests that the change in language in 7CFR205.302—substituting "of all ingredients" for the existing "of the finished product"—is not a priority, we agree that the recommended change would bring the regulatory language in line with current practices.

We agree that organic single ingredients in multi-ingredient products can be counted as 100% organic, even if they do not meet the 100% organic labeling requirements due to the use of non-organic processing aids. However, it must be made abundantly clear that a single ingredient that is organic but not eligible for the 100% claim should be considered 100% organic only for the purposes of calculating the organic percentage of a multi-ingredient product, and not for the purposes of determining the labeling claim. A multi-ingredient product with only organic ingredients should not be eligible for the 100% organic claim, unless each organic ingredient qualifies for the 100% labeling claim.

In line with apparent unanimous agreement in public comment in response to the Fall 2012 discussion document, we support the proposal that sodium chloride is the only "salt" that may be excluded from the organic percentage calculation. Any source of salt that appears on the National List must be entered into the calculation and cannot be excluded.

VIII. OTHER ISSUES

CONFLICT OF INTEREST

Although it is not on the agenda, we would like to comment on the Conflict of Interest issue. We believe that now more than ever, as the organic industry grows, it is especially important to preserve transparency in the NOSB process and protect organic integrity. A clear Conflict of Interest (COI) policy that benefits the organic community and the public interest is long overdue.

We urge the Board, rather than the NOP, to reclaim authority over the conflict of interest issue.

We have several concerns:

1. **The NOSB must reclaim authority.**

As we noted in previous public comment, we urge Board members not to hand over authority for deciding whether a conflict of interest exists to the NOP. This dynamic was unprecedented until recently; unfortunately, it has happened repeatedly at the most recent meetings and it now appears to be the standard practice.

Even in cases where an NOSB member's employer, fellow employees, or even the organizations CEO, actively lobbied for the approval of a particular material, as happened with the carrageenan sunset vote, an NOP staff member decided that no conflict of interest existed. Given its track record in letting members with conflicts of interest vote on controversial materials, in some cases supplying the deciding vote favoring industry over the public interest, we believe it is important for the NOSB to reclaim its authority over COI decisions.

2. **Until a strengthened COI policy is adopted, the existing COI policy remains in place and must be followed.**

For the upcoming tetracycline vote, we believe two Board members involved in organic apple and pear production have a conflict of interest and should recuse themselves to protect the integrity of the process.

If these Board members do not recuse themselves voluntarily, as the Duty of Loyalty requires, then it is up to the entire Board to decide, not the NOP. The PPM states:

> ***Board members shall disclose their interest to the Board and the public, when they or their affiliated business stand to gain from a vote, which they cast in the course of Board business. Under certain circumstances,***

the Board may determine whether it is appropriate for the member to vote.

The current Policy and Procedures Manual states that the Board decides whether a conflict exists, not the NOP. Unless this policy is officially changed, the NOSB should not hand over authority to decide on conflicts of interest; that responsibility remains with the Board itself.

3. **Continue to develop a COI policy for TR contractors.**

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.

For example, during the Fall 2011 meeting, the Board voted to expand the use of potassium hydroxide, a toxic chemical used for peeling peaches. We believe that the author of the petition and one of the three technical reviewers was the same individual.

Given the tight circle of technical reviewers who also act as industry consultants, it is important to ensure that such conflicts do not occur in the future. It is certainly possible that other incidents of this nature have taken place but we have not yet identified them. The only way to ensure this doesn't happen again is to require that technical reviewers disclose their identity.

Also, it is our understanding that in some cases, technical reviewers may consult individuals whose names and identities do not appear on the Technical Review. Technical reviewers should disclose for the public record any individuals, within and outside their organization, who provided assistance.

Just as written documentation must be referenced in the TR, so should telephone conversations and other types of assistance. (Contacts may be cited as "John Smith, XYZ Corporation/Institution, personal communication.") This will help the public understand who was involved in the TR, and whether conflicts of interest exist. **This is also a requirement of scientific papers—all statements and facts must be referenced**. Peer-reviewed publications would never allow anonymous authors or sources.

In summary, we propose the following:

1. Technical reviewers should disclose their name and affiliation on the Technical Review (TR) report.

2. Prior to commencing a TR, every individual who will be involved in the development of the TR must sign a Conflict of Interest statement to ensure that no conflicts exist. This should be maintained on file with the NOP and made available to the public on the Petitioned Substances Database.

3. Technical reviewers must disclose every individual they consulted during the Technical Review, including personal interviews and telephone conversation with industry members, consultants, farmers, and any other individual.

CONCLUSION

Thank you for considering our comments.

We urge you to base your votes on the legal criteria outlined in the Organic Foods Production Act of 1990 (OFPA) and the federal organic standards. Doing otherwise will expose the program to potential protracted legal challenges.

The success and continued growth of the organic industry depends in large part on consumer trust in the organic label, which in turn depends on the NOSB, USDA and industry's adherence to the law. The NOSB, as gatekeepers of the National List, must ensure that petitioned materials are carefully reviewed and that decisions are based on sound science, the precautionary principle, and sincere answers to questions in the decision tree, which are based on criteria in the organic law and regulations.

The decisions made at the NOSB meetings do not occur in a vacuum—what happens at NOSB does not stay at NOSB. When materials that are incompatible with organic principles are approved, or when policies that run counter to the requirements in OFPA are adopted, it deals a blow to organic integrity and to the reputation of the organic label.

It is therefore in everyone's best interest—from organic farmers, to consumers, to business interests—for the NOSB to make decisions based on OFPA's criteria. We strive to base our comments on legal criteria and published science. We hope our comments will be useful in your deliberations and we welcome questions at any time during the process (before, during or after the meeting).