National Organic Standards Board Meeting

Portland, OR April 9-11, 2013

Agenda

Schedule at a Glance:

	Tuesday April 9	Wednesday April 10	Thursday April 11
AM	- Call to Order - Secretary's Report - NOP Update - Open Public Comment	- Policy Development Subcommittee - Aquaculture WG Update - Livestock Subcommittee	- Handling Subcommittee - Compliance, Accreditation & Certification Subcommittee - Misc Public Comment
PM	- Materials Subcommittee - GMO ad hoc Subcommittee	- Tree Fruit (Antibiotics) Panel - Crops Subcommittee	- Inerts WG Update - Deferred Items/Final Votes - Work Plans and Other Business - Closing Remarks

Meeting Format

- The USDA National Organic Program (NOP) National List Manager presents an overview of petitioned substances and Technical Reports in consistent format.
- NOSB members present Subcommittee proposals on petitioned substances and discussion documents.
- Public comments are grouped to correspond with each Subcommittee's presentation.
- Each Subcommittee's proposals are discussed and may be voted on by the Board before moving to the next Subcommittee.
- If more deliberation is needed, final votes will be deferred to Thursday, April 11.
- NOTE: Agenda items may be withdrawn or votes may be postponed at the discretion of the Board.

Public Comments:

- All persons wishing to comment at NOSB meetings during public comment periods must sign up in advance. Instructions are available at www.ams.usda.gov/NOSBMeetings. Speaking slots for walk-in commenters may be available, but are not guaranteed. Commenters can sign up in person at the meeting if the schedule allows.
- Each commenter must give their name and affiliation for the record at the beginning of his or her public comment.
- Each speaker will have 4 minutes to present their comments to the NOSB followed by time for questions from the Board. Each person may sign up for only one speaking slot during the meeting.

Tuesday, April 9	8:00 AM	**Call to Order** ***Mac Stone, Chairperson*** Announcements Introductions NOSB Mission **Secretary's Report** ***Dr. Calvin Walker, Secretary*** Acceptance of May 2012 and October 2012 Meeting Transcripts and Voting Results as Official Record
	8:20 AM	**National Organic Program Update** ***Miles McEvoy, Deputy Administrator, National Organic Program***
	9:00 AM	**Open Public Comment** Public comments not specific to a particular Subcommittee, or that address topics not on the agenda
	10:00 AM	**BREAK**
	10:15 AM	Open Public Comment Continued
	12:00 PM	**LUNCH**
	1:00 PM	Open Public Comment Continued
	3:05 PM	**BREAK**
	3:20 PM	**Materials Subcommittee** ***Zea Sonnabend, Chairperson*** Present Subcommittee proposals and summarize written comments **Topics:** Discussion Document: Confidential Business Information (CBI) Transparency and Process Discussion Document: Definition of Production Aids Proposal: Process for Limited Scope Technical Reviews (TRs)
	3:50 PM	Public comments related to Materials Subcommittee

Tuesday, April 9	4:15 PM	**GMO ad hoc Subcommittee** **Dr. Jennifer Taylor, Chairperson** Present Subcommittee proposals and summarize written comments **Topics:** Discussion Document: GMOs and Seed Purity Discussion Document: Terminology for Excluded Methods
	4:35 PM	Public comments related to GMO ad hoc Subcommittee
	5:30 PM	**RECESS**

Wednesday, April 10	8:00 AM	**Policy Development Subcommittee** ***Colehour Bondera, Chairperson*** Present Subcommittee proposals and summarize written comments **Topics:** Discussion Document: Material Initiation Policy Proposal: New Member Guide update Proposal: Public Communications
	8:30 AM	Public comments related to Policy Development Subcommittee
	8:45 AM	**Presentation: Aquaculture Working Group**
	9:45 AM	**BREAK**
	10:00 AM	**Livestock Subcommittee** ***Tracy Favre, Chairperson*** Present Subcommittee proposals and summarize written comments **Topics:** Proposal: Pet Food Amino Acids - petitioned Vaccines Made with Excluded Methods (VMWEM) Working Group Interim Report: Dr. Jean Richardson
	10:25AM	Public comments related to Livestock Subcommittee
	11:10 AM	Break for Subcommittee to modify proposals as needed Board votes if ready
	11:45 AM	**LUNCH**

Wednesday, April 10	1:00 PM	**Tree Fruit (antibiotics) panel**
	2:15 PM	**Crops Subcommittee** ***Jay Feldman, Chairperson*** Present Subcommittee proposals and summarize written comments **Topics:** Proposal: Tetracycline - petitioned Proposal: Polyoxin D Zinc Salt - petitioned Proposal: Indole-3-butyric acid (IBA) - petitioned
	2:45 PM	Public comments related to Crops Subcommittee
	3:15 PM	**BREAK**
	3:30 PM	Public comments related to Crops Subcommittee continued
	5:40 PM	**RECESS**

Thursday, April 11	8:00 AM	**Handling Subcommittee** ***John Foster, Chairperson*** Present Subcommittee proposals and summarize written comments **Topics:** Proposal: Sulfuric acid - petitioned Proposal: Barley beta fiber - petitioned Proposal: Sugar beet fiber - petitioned Proposal: Proposal: 1,3-Dibromo-5,5-dimethylhydantoin (DBDMH) - petitioned Proposal: Auxiliary/"other" ingredients
	8:50 AM	Public comments related to Handling Subcommittee
	9:45 AM	**BREAK**
	10:00 AM	Break for Subcommittee to modify proposals as needed Board votes if ready
	11:00 AM	**Compliance, Accreditation and Certification Subcommittee** ***Joe Dickson, Chairperson*** Present Subcommittee proposals and summarize written comments **Topics:** Proposal: Calculating Percent of Organic Ingredients in Multi-ingredient Products
	11:15 AM	Public comments related to CAC Subcommittee
	12:15 AM	**LUNCH**
	1:30 PM	**Inerts Working Group Update: Dr. Lisa M. Brines (NOP)**
	1:45 PM	Deferred Proposals/Final Votes
	3:00 PM	**BREAK**
	3:15 PM	Deferred Proposals/Final Votes
	4:45 PM	Subcommittee Workplans
	5:00 PM	Other Business and Closing Remarks
	5:30 PM	**ADJOURN**

National Organic Standards Board
Materials Subcommittee
Discussion Document
Confidential Business Information in Petitions

Date of Vote: February 12, 2013

Introduction

The role of the NOSB under OFPA and the Federal Rule is to review substances for inclusion on the National List. The primary way for affected parties to bring something before the NOSB is by submitting a petition for it pursuant to 72 FR 2167 Petition Guidelines. These guidelines discuss the right and ability of petitioners to submit some information in a petition as Confidential Business Information (CBI) following the guidelines in 7 CFR 1.27 [d].

This procedure has not served either the petitioner or the NOSB particularly well. The petitioners do not realize and are not notified that the NOSB members do not have access to their CBI. The Technical Reviewers are able to ask for the full petition with the CBI but may not disclose the CBI in their Technical Evaluation Reports. For some petitions, NOSB members do not have key information they need to be able to classify a petitioned material as synthetic or non-synthetic, or to understand the formulation challenges around the petitioned material and the alternatives. Therefore very few petitions containing CBI have actually been approved for the National List by the NOSB because the board does not have enough information to make a positive decision. Yet the petitioners are not told in the petition guidelines that this is the case.

In addition, petitioners often do not follow the CBI procedures spelled out in the Petition Guidelines well and so petitions often are sent back to petitioners because they have not provided details on why information is claimed as CBI, they identified public information as CBI, or they did not submit in the correct format according to the petition guidelines.

The NOSB is in a unique position in being members of the public who advise a federal agency. NOSB operates in a transparent environment and all its documents are either publicly posted or can be shared under the Freedom of Information Act (FOIA). Ideally, petitions should comply with the openness required under FOIA. In this discussion document we are asking for input on whether CBI should still be allowed in petitions, and if so, what limitations should be placed on it. Further, if there is to be CBI in a petition, it needs to be made much clearer to petitioners, the NOSB, and the public who has access to that information and what outcome can be expected from CBI.

Background

On January 21, 2009, President Obama issued a memorandum for heads of departments and agencies that says:

> A democracy requires accountability, and accountability requires transparency. As Justice Louis Brandeis wrote, ‘‘Sunlight is said to be the best of disinfectants.’’ In our democracy, the Freedom of Information Act (FOIA), which encourages accountability through transparency, is the most prominent expression of a

> profound national commitment to ensuring an open Government. At the heart of that commitment is the idea that accountability is in the interest of the Government and the citizenry alike.
>
> .....
> All agencies should adopt a presumption in favor of disclosure, in order to renew their commitment to the principles embodied in FOIA, and to usher in a new era of open Government. … The presumption of disclosure also means that agencies should take affirmative steps to make information public.

The USDA and AMS have adopted regulations and directives relating to CBI that are addressed below:

What can and can't be claimed as CBI.
The considerable body of case law concerning Exemption 4 of FOIA, which includes CBI, has been reviewed by the Department of Justice in the DOJ Guide to the Freedom of Information Act,[1] It concludes, "[T]he Court of Appeals for the District of Columbia Circuit and nearly every court that has considered the issue has found the Trade Secrets Act and Exemption 4 to be 'coextensive.'"

The Trade Secrets Act defines trade secrets:

> (3) the term "trade secret" means all forms and types of financial, business, scientific, technical, economic, or engineering information, including patterns, plans, compilations, program devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes, whether tangible or intangible, and whether or how stored, compiled, or memorialized physically, electronically, graphically, photographically, or in writing if—
> (A) the owner thereof has taken reasonable measures to keep such information secret; and
> (B) the information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, the public;

Under the Act, the tests for trade secrets are thus the following (all must be met):

1. Is the information secret? Particularly, is it secret from competitors?
2. Has the owner of the information taken measures to keep it secret?
3. Would a competitor gain advantage by knowing the information?

As a result, some kinds of information are <u>not</u> trade secrets:

1. Environmental and health effects of chemicals, because they are widely known and published.
2. Emissions data and other data that must be reported in publicly available forms, such as National Pollution Discharge Elimination System (NPDES) permits or Toxics Release Inventory (TRI) reports.
3. Published articles or other references that are publicly available.
4. Fertilizer ingredients, which are listed in publicly-available forms.

[1] Department of Justice, 2009. Guide to the Freedom of Information Act. http://www.justice.gov/oip/foia_guide09.htm

5. Food ingredients.
6. Information about a manufacturing process that can be found in a patent.

It is generally accepted that proprietary manufacturing processes that are not revealed in a patent and are kept secret from competitors do qualify as trade secrets. Other examples are software code, business plans, and financial data, if kept secret.

The USDA has regulations relating to the release of information claimed as CBI that the agency decides is not CBI.[2] "[T]he policy of USDA is to obtain and consider the views of the submitter of the information and to provide the submitter an opportunity to object to any decision to disclose the information." Some of the steps that are relevant to the petition process are described in the Petition Guidelines #13 (below).

Relevant areas in the Rule

The relevant areas here are in the Code of Federal Regulations 7 CFR 1.27[d] & [e], and in the Federal Register notice regarding Petition Guidelines, 72 FR 2167 from January 18, 2007.

7 CFR 1.27[d]

Title 7: Agriculture

1.27 - Rulemaking and other notice procedures.

(d)(1) Any written submission, pursuant to a notice, may be held confidential if the person making the submission requests that the submission be held confidential, the person making the submission has shown that the written submission may be withheld under the Freedom of Information Act, and the Department official authorized to issue the notice determines that the submission may be withheld under the Freedom of Information Act.

2) If a request is made in accordance with paragraph (d)(1) of this section for confidential treatment of a written submission, the person making the request shall be informed promptly in the event the request is denied and afforded an opportunity to withdraw the submission.

(3) If a determination is made to grant a request for confidential treatment under paragraph (d)(1) of this section, a statement of the specific basis for the determination that will not be susceptible of identifying the person making the request will be made available for public inspection.

(e) If the subject of the notice is such that meaningful submissions cannot be expected unless they disclose information that may be withheld under the Freedom of Information Act, the notice shall so indicate and contain a statement that written submissions pursuant to the notice will be treated as confidential and withheld under the Freedom of Information Act. Provided, That the policy regarding availability of written submissions set forth in this paragraph may only be used with the prior approval of the Secretary, or the Under Secretary or

[2] 7 CFR Part 1 § 1.12 Handling information from a private business.

Assistant Secretary that administers the program that is the subject of the notice.

72 FR 2167 from January 18, 2007

Procedures for Submitting National List Petitions

..... Petitions for substance evaluations to add a substance onto, remove a substance from, or amend a substance presently on the National List involves a public and open process. Petition information not categorized and accepted by USDA, pursuant to 7 CFR 1.27(d), as Confidential Business Information (CBI) will be considered available to the public for inspection. Published information usually cannot be claimed as confidential.

Information to be included in a Petition

.....

13. A Confidential Business Information Statement which describes the specific required information contained in the petition that is considered to be Confidential Business Information (CBI) or confidential commercial information and the basis for that determination. Petitioners should limit their submission of confidential information to that needed to address the areas for which this notice requests information. Final determination regarding whether to afford CBI treatment to submitted petitions will be made by USDA pursuant to 7 CFR 1.27(d). Instructions for submitting CBI to the National List Petition process are presented in the instructions below:

(a) Financial or commercial information the petitioner does not want disclosed for competitive reasons may be claimed as CBI. Applicants must submit a written justification to support each claim.

(b) ‘‘Trade secrets’’ (information relating to the production process, such as formulas, processes, quality control tests and data, and research methodology) may be claimed as CBI. This information must be (1) commercially valuable, (2) used in the applicant’s business, and (3) maintained in secrecy....

The above information is repeated in detail in the NOSB Policy and Procedures Manual on page 48.[3]

Discussion

There are four groups who have needs regarding the issue of CBI:

1. The petitioner may have valid trade secrets that they do not wish to disclose publicly because they do not want competitors to get their formula or other details.

2. The USDA and their contracted Technical Reviewers must honor the CBI regulations while at the same time provide a clear and consistent process for petitions and their review.

3. The NOSB must learn as much as it can about each petitioned substance in order to classify it properly on the National List and to determine whether it is compatible with organic production and handling.

[3] National Organic Standards Board Policies and Procedures Manual. http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELDEV3013893

4. The public has the right to know that the NOSB has used a fair and transparent process in reviewing petitions and making recommendations.

The NOSB makes decisions about generic materials and not formulated products, and in order to do this, the NOSB needs to know how each petitioned material is made and what all the components are. The NOSB looks at everything that goes into a material, including growth media, processing aids, carriers and the ecological interactions and environmental fate of each material. The NOSB has the discretion to reject a petition if the CBI makes it such that either the manufacturing process or the components are not disclosed. However, the board does not want to do this if possible and is proposing this discussion document as a series of solutions so that all the affected parties have confidence in the review process. There may still be cases where the NOSB will have to either deny or vote down the petition if the CBI is too critical to making a good decision.

Any recommendation on this subject needs to include the following components:

-- What explanation the petitioners receive about the impact of their CBI.
-- What happens to CBI and who has access to it.
-- How the NOSB can gain assurance about the portion of the CBI that is instrumental to their deliberations.

The possible recommendations presented here recognize that CBI may be necessary in some petitions. However the subcommittee is also posing the question to see whether stakeholders think it is necessary to have CBI. The NOP needs to work with the petitioners to keep the CBI to a minimum, to give access to necessary information in the preparation of the Technical Evaluation Reports (TERs), and to let petitioners know what to expect from the process.

Recommendations for Discussion Purposes

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. A modified version of this choice would be to not allow CBI for manufacturing processes or ingredients but to allow back up research and references to be submitted as CBI to assist the TR development.

Possible Recommendation 2:
CBI be allowed in petitions with the following stakeholder responsibilities:

<u>For the National Organic Program</u>

• A. The NOP will allow only information meeting the strict definition of CBI to be deleted from petitions considered by the board and posted for public viewing.

• B. The NOP must make it clear to petitioners what happens to the CBI submitted and who does and does not have access to it, preferably by revising the Petition Guidelines.

It should be very clear to petitioners that the NOSB does not see the confidential information.

• C. The Technical Review contractor will have access to the CBI upon request. The contractor may then evaluate the CBI and conduct additional research to verify similar information.

• D. The TR contractor will indicate that they looked at CBI in the course of their review.

For Petitioners

• E. Petitioners are highly urged to provide complete information in their petitions, and keep CBI to the absolute minimum.

• F. Petitions Guideline B.13 requires a statement of reasons for the CBI. This statement needs to be clearly stated, and is part of the public petition that will be seen by the NOSB.

• G. Petitions will not be considered unless the rules in the Petitions Guidelines for CBI are followed completely.

• H. Petitioners need to be aware that petitions containing CBI are rarely approved by the NOSB and the board reserves the right to reject such a petition that does not give complete manufacturing information. The NOSB may also send back a petition as incomplete if there is simply not enough information to make a decision.

• I. (optional) The petitioner may be given the option to affirm that the information withheld as CBI is consistent with the review criteria by affidavit. For instance if a manufacturing process is CBI the affidavit would contain legally binding language that states something like:

> "The manufacturing process of _____ does not include additional ingredients that are not disclosed in the petition. The process involves only mechanical, physical or biological steps."

The affirmation would not take the place of an objective TR to verify the stated information. Petitioners could be given the opportunity to cite similar materials or processes that are public.

This affirmation will be easier to develop once the Classification of Materials Guidance is issued so there are more comprehensive definitions for it to be based on. There could be other affidavits created for synthetic substances or for handling situations that involve CBI.

For the National Organic Standards Board

• J. The Policy and Procedures Manual will be updated to reflect any changes to CBI procedures based on this recommendation and the NOP revising the petition guidelines.

• K. Petitions that come in with CBI will be looked at in the usual way by the subcommittees and any that have withheld too much information to allow the Board to make an informed decision may be returned to the petitioner. Others will move forward for a Technical Review.

• L. If a petition is rejected because of CBI, the petitioner may re-petition and disclose the CBI, however, the NOSB will treat this at a lower priority level with other re-petitioned substances.

Discussion Questions

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

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

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

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

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

Subcommittee Vote

Motion: The Materials Subcommittee moves to accept this discussion document and present it for full Board discussion at the spring 2013 NOSB meeting.

Motion by: Zea Sonnabend Second: Calvin Walker
Yes: 5 No: 0 Absent: 2 Abstain: 0 Recuse: 0

National Organic Standards Board
Materials Subcommittee
Proposal
Process for Limited Scope Technical Reviews

February 12, 2013

Background

The Policy and Procedures Manual (PPM) currently allows considerable flexibility in topics/questions to be considered in a technical review (TR). If the reason the petitioner is petitioning is to get a National Organic Standards Board (NOSB) finding on classification, and it is controversial because Material Review Organizations (MROs) are in disagreement or a MRO changed its determination on synthetic non-synthetic, then a truncated TR would be helpful before launching into a full blown review. Since the determination of category compliance is left to the NOSB, not National Organic Program (NOP), a truncated TR can provide an important third-party assessment.

The PPM describes the process for determining whether a TR is needed, and if so, what the scope should be in “Phase 2: Determine if a Third Party Technical Review is required” (PPM, p.35) and “Procedures for Handling Technical Reviews” (PPM, p.37). The former section says:

> The NOSB committee assigned for the review (as identified by the Materials Committee Chair) must decide whether
> a) there is sufficient information in the petition,
> b) the committee can reasonably research any pending technical information, or
> c) there is the need to secure a technical review from a third party expert (see section titled Procedures for Handling Technical Reviews)

The latter section provides more detail concerning the scope of the TR:

> 3. When requesting the assistance of a third party expert to evaluate a material, a committee must identify the main technical issues needed to be addressed including, but not limited to:
> a. All uses of the petitioned material beyond what the petitioner has requested
> b. All uses of the petitioned material in combination with other material(s) that have been already approved on the same section of the National List
> c. Interactions of the petitioned material, not addressed by the petitioner, and that may involve materials currently on the same section of the National List.
> d. All possible manufacturing methods for a petitioned material.
> e. Potential effects on public health and biodiversity
> f. Environmental risks and hazards including, but not limited to potential for developing pesticide resistance, or long-term effects on sustainability.

Since the three criteria of environmental and health effects, essentiality, and compatibility with organic production practices, all must be met in order for the material to be listed, there really is no need for a full Technical Review if certain threshold issues, such as synthetic/nonsynthetic and compatibility with organic, are not met during the review process. Should those threshold issues not be met, considerable resources of time and money could be saved by conducting a first-stage TR that would only be followed by a complete TR if necessary.

Proposal

Revise the Petition Checklist Protocol to establish a more streamlined process for review of certain petitions.

The following process applies in those cases in which the NOP's review of the petition is unable to assign the substance petitioned for a crop or livestock use to an OFPA category (6517 (c)(1)(B)(i) or 6517(c)(1)(B)(ii)) or when the material comes to the NOSB because of a question of its synthetic/nonsynthetic classification, usually identified as "TBD." Before requesting a complete TR, the review subcommittee receives a more limited review that would answer the questions below. If these questions are answered satisfactorily, the subcommittee conducting the material review could proceed to a full TR. The following checklist questions will be considered by a limited scope TR.

> Evaluation Question #1: What category in OFPA does this substance fall under? (A) Does the substance contain an active ingredient in any of 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? (B) Is the substance a synthetic inert or other ingredient that has not been classified by the EPA as inerts of toxicological concern (i.e., EPA List 4 inerts) (7 U.S.C. 6517(c)(1)(B)(ii)) and otherwise complies with the material review criteria? Is the synthetic substance an inert ingredient which was not on EPA List 4, but is exempt from a requirement of a tolerance, per 40 CFR part 180?
>
> Evaluation Question #2: Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Further, describe any chemical change that may occur during manufacture or formulation of the petitioned substance when this substance is extracted from naturally occurring plant, animal, or mineral sources (7 U.S.C. 6502 (21)).
>
> Evaluation Question #3: Is the substance synthetic? Discuss whether the petitioned substance is formulated or manufactured by a chemical process, or created by naturally occurring biological processes (7 U.S.C. 6502 (21)).

Subcommittee Vote:
Motion: The Materials Subcommittee moves to accept the proposal to establish a process for limited scope technical reviews as described above.

Moved: Tracy Favre Second: Jay Feldman

Yes: 5 No: 0 Abstain: 0 Absent: 2 Recuse: 0

National Organic Standards Board
Materials Subcommittee
Discussion Document
Defining "Production Aids" As Used in OFPA §6517

February 12, 2013

Background

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 has been some discussion on the National Organic Standards Board (NOSB) over past years concerning the meaning of "production aids." The examples given in the law are materials that have a minimal impact on food, soil, or the ecosystem. However, there have in the past been requests to allow a range of substances under this category, including (as recommended by the NOSB in August 2005) "carriers, stabilizers, adjuvants, fillers, extractants, excipients and solvents that do have an active function in the formulations of farm production aids such as fertilizers, soil amendments, compost inoculants, sanitizers, aquatic plant extracts, and fish emulsions" and "active substances used in pest control (disease, weed, insects and nematodes) that do not fit into other OFPA categories."[1]

On the other hand, some interpret OFPA's definition of "production aids" as disallowing materials similar to the groups mentioned in the August 2005 recommendation. The interpretation of the list in OFPA seems to hinge on whether one views the list "including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers" as exemplary (that is, a list exemplifying the kinds of things that might be considered "production aids") or as items meant to be included, but not limited by type of substance. If it is the latter, then clearly some limitation is still implied by the fact that OFPA §6517 (c)(1)(B)(i) is stated as a constraint on what can be on the National List: "The National List may provide for the use of substances in an organic farming or handling operation that are otherwise prohibited under this chapter only if -(B) the substance - (i) is used in production and contains an active synthetic ingredient in the following categories:…" [Emphasis added.]

[1] http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELDEV3104476 This recommendation was referred to the NOP to check on its legality and was never implemented.

Although only one substance –microcrystalline cheesewax for use in log grown mushroom production– is listed as a "production aid" on the National List, there are several items listed as crop or livestock inputs on the National List that do not fit into any of the OFPA categories, and some recommendations for these materials refer to them as "production aids." For example,

> In the opinion of this committee, hydrated lime should be considered a production aid, insofar as it is vital to the production of two exempted sulfur or copper containing materials in order to make these materials non-phytotoxic to plants. (4/20/2006 hydrated lime sunset recommendation)
>
> Regarding whether the OFPA provides an exemption category that would permit hydrogen peroxide to be considered for inclusion on the National List, the NOP provided feedback to the NOSB that hydrogen peroxide could be considered a "production aid" under section 6517 of the OFPA. As a result, hydrogen peroxide would be eligible for continued use in organic production. (4/20/2006 hydrogen peroxide sunset recommendation)
>
> Bioplastic mulch is used as a production aid, but is not technically considered a row cover because it increases soil temperature, reduces weed pressure, maintains soil moisture levels, and may help extend the growing season. (8/15/2012 committee recommendation (checklist) for biodegradable biobased mulch film)
>
> This [6-benzyladenine] is a production aid; thins fruit thus improving quality of fruit; improves air circulation thus reducing pests and disease; "enhances lateral bud break and lateral shoot growth, which leads to improved branching" TAP pg. 2 (5/2004 committee recommendation (checklist) for 6-Benzyladenine)
>
> Its [Ethylene gas'] use as a synthetic is not specifically listed in the exempt categories of 6517(1)(B)(i) unless it is considered a crop production aid. This term should be more carefully defined for consistent use in decision making on synthetic crop materials. (Supplementary information on ethylene gas provided to NOSB, to be added to 1999 Technical Advisory Panel review for review of use in crop production. This information was prepared by OMRI staff and did not receive additional review by the initial three TAP reviewers.)
>
> This material [ferric phosphate] is a production aid. (March 2005 recommendation (checklist) for ferric phosphate.)

In addition, NOP frequently identifies petitioned substances as production aids or possible production aids when assessing the eligibility of a substance prior to NOSB review. If these materials were not so identified, they would not fit into an OFPA category, and the board would not need to commit resources to their evaluation. Some recent examples include:

Indole-3-butyric acid (IBA): “Plant hormone used for root cuttings. Does not fall under specific category, but could be considered a production aid.”

Carbon monoxide/exhaust gas: “TBD - unclear if product could be considered a production aid. EPA categorizes it as a device, rather than a pesticide.”

Carbon dioxide for aquaculture: “TBD - Unclear is use of petitioned substance may be considered a production aid.”

Chlorine in aquaculture: NOP underlined “equipment sanitizers,” but the petition also included use for disinfecting water.

Oxidized lignite: “Petitioned as a soil amendment.” (No such category.)

Biodegradable bioplastic mulch: NOP underlined “row covers,” but as the TR pointed out, the use is not “row covers,” but mulch.

Discussion

There are at least two distinct interpretations of the phrase “production aids.” One, a strict reading of the law and the legislative history, limits the application of the category to a narrow type of material that is delineated in the statute by example, “including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers.” Another interpretation of the phrase would allow materials that enable production of a crop and/or help inputs to work better.

Several pesticides are allowed on the National List because they fit into other categories –copper and sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines– so the use of "production aids" as a catch-all for pesticides is considered contrary to the intention of OFPA. Furthermore, the examples listed in OFPA as production aids do all have something in common because they are all things that have only a minimal impact on the crop, soil, or surrounding ecosystem. In fact, the original Senate bill referred to “production aids such as machinery cleansers,” and the House bill did not contain any reference to production aids. The conference committee came up with the current language.

As noted above, others have argued for a much broader interpretation of the term – arguing that the examples listed are not meant to limit the types of materials covered by the term “production aids.”

Questions:

1. Is clarification of the term “production aids” needed?

2. Should clarification give further examples of what is and is not covered by the term? If so, please suggest inclusions and/or exclusions
3. What kinds of materials have historically been covered by the term “production aids”?
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.

Subcommittee Vote:
Motion: The Materials Subcommittee moves to accept this document and present it for full Board discussion at the spring 2013 NOSB meeting:

Moved: Jay Feldman Second: Jennifer Taylor

Yes: 5 No: 0 Abstain: 0 Absent: 2 Recuse: 0

National Organic Standards Board
GMO ad hoc Subcommittee
Discussion Document
GMOs and Seed Purity

February 6, 2013

Introduction

The GMO ad hoc Subcommittee is extending the public comment period on the GMOs and Seed Purity Discussion Document by reissuing this document and is especially interested in hearing suggestions from those in the organic community who did not previously submit comments. 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.

Organic stakeholders are concerned about keeping genetically modified organisms (GMOs) (i.e., the products of transgenic plant or animal breeding) out of organic livestock feed, crops, and food. The use of “excluded methods,” including transgenic modification, are prohibited in the production and handling of organic goods. This prohibition applies to seeds used on organic farms. The organic community continues to be proactive in developing positions, procedures, and practices to encourage prevention of GMO contamination. An important part of this is ensuring genetic purity of seed used on organic farms. Pure seed is a cornerstone of true sustainability in an organic farming system.

Policy Memo 11-13 from the National Organic Program (NOP) affirms that organic certification is process-based. The public comments to National Organic Standards Board (NOSB) and NOP continue to indicate a strong concern by both producers and consumers of organic foods for stronger steps to limit the potential and/or unintended presence of GMOs.

In 2012, the NOSB established the GMO ad hoc Subcommittee. In this discussion document, the subcommittee seeks input from organic stakeholders on the possibility of strengthening seed purity as one step to avoid the potential contamination of crops with GMOs. Seed may be the most impactful and efficient point in the supply chain at which GMO contamination of organic feed, crops, and food could be limited and controlled. This suggestion implies that recommending standards for the genetic content of seeds used in organic production would be an appropriate point of focus for NOSB.

Background

• The NOP Organic Rule refers to Genetic Engineering (GE) as an "excluded method". “Organic” is a label that indicates that a process has been followed to exclude GMOs.

• Producing organic feed, crops, and food 'free' of GMOs requires starting with seed that is not contaminated by GMOs.
• Public and marketplace expectations for the absence of GMOs in organic goods call for implementing best practices on conventional and organic farms to minimize the potential for such contamination.

• We suggest that the process for ensuring genetic purity of commercial seeds in organic production must be stricter than conventional crop production. Clean seed must be planted for the farmer to harvest uncontaminated food or feed. Planting and harvesting contaminated seed can increase the likelihood of "creeping contamination" from year to year, since any additional GE drift into a field planted with partially contaminated seed would produce food, crops, or feed with a higher level of contamination than in the original seed.

• Genetic purity in seed cannot be addressed by field observations of various visual off-types as has been practiced by the seed industry in the past. Genetic purity must also now encompass the presence or absence of GE contamination, with the protocols for making such a determination structured to meet the concerns and demands in the marketplace.

Relevant Areas of the Rule

NOP standards[1] adopted by USDA in a final rule published in December 2000 and fully implemented in October 2002 prohibited the use of GMOs in the production and handling of organic products certified to national organic standards.

The terminology used for GMOs in the NOP Regulation is "excluded methods" and is specified under section 205.2 (Terms Defined) as:

Excluded methods. A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Excluded methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, *in vitro* fertilization, or tissue culture.

Detection and Testing Requirements: Under the residue testing requirements of NOP, products from certified organic operations may require testing when there is reason to believe that certified products have come into contact with prohibited substances or have been produced using excluded methods.

This requirement is specified in Subpart G (Administrative) of the regulations:

[1] Title 7 CFR Part 205 - National Organic Program

§ 205.670 Inspection and testing of agricultural product to be sold or labeled "organic."

(b) The Administrator, applicable State organic program's governing State official, or the certifying agent may require pre-harvest or post-harvest testing of any agricultural input used or agricultural product to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" when there is reason to believe that the agricultural input or product has come into contact with a prohibited substance or has been produced using excluded methods. Such tests must be conducted by the applicable State organic program's governing State official or the certifying agent at the official's or certifying agent's own expense.

NOP Policy: The NOP finalized a Policy Memo on July 22, 2011 (Policy Memo 11-13) on GMOs. This policy memo reiterates that the use of GMOs is prohibited under NOP regulations, and answers questions that have been raised concerning GMOs, organic production, and handling. The clarification provided is consistent with the explanations provided in the preamble, thus emphasizing that organic certification is a process-based standard and the presence of detectable GMO residue alone does not necessarily constitute a violation of the regulation.

Commercial Availability of Organic Seed: The NOP regulations at 7 CFR § 205.204 require that organic producers use organic seeds, annual seedlings, and planting stock. The regulations allow producers to utilize non-organic seeds and annual or perennial planting stock when organic varieties are not commercially available.

The term "commercial availability" is defined under section 205.2 (Terms Defined) as: *The ability to obtain a production input in an appropriate form, quality, or quantity to fulfill an essential function in a system of organic production or handling, as determined by the certifying agent in the course of reviewing the organic plan.*

Discussion

1. Currently the organic standards require that seed used in organic production not be produced using excluded methods; and the marketplace is increasingly sensitive to contamination of organic crops by GMOs yet no standard or system exists to determine that the foundation of the value chain – seed – is free of GMOs.

2. The private sector has a variety of requirements and standards related to quantification of genetic materials (GM) content yet most of that data is not accessible to an accredited certifying agent and, therefore, is not currently helpful in terms of oversight and compliance. If it were available, there is no protocol within the organic sector for evaluating and using the testing results.

3. Farmers growing seed are increasingly being required to test for GMOs by their buyers in an ad hoc manner. Buyers may have different test protocols and evaluation of results which makes it difficult to compare and use the information.

4. Securing a supply of GMO free seed is critical to the long-term ability of organic to meet consumers' expectation of organic vis a vis GMOs.

5. Current NOP policy does not require verification that seed is free of GMOs. However, if someone desires to have as thorough a process as possible to exclude GMOs, they may want to address their seed purity to the extent possible.

6. Despite the distinction between "excluded methods are not used" and "no traces of GMOs are present," the expectations of some consumers confuse these claims (and some marketers encourage this confusion).

7. The NOSB may consider in the future a universal genetic purity standard for seed to be used in organic production systems. An example of the standard would be the presence or absence of GE content, and the standard is equally applicable to conventional and organic seed. For example, no GE seeds found in a 3,000 seed sample. "None found" in a 3,000 seed sample corresponds statistically to a 95% probability that the actual GE contamination level in the seed lot is between zero percent and 0.10%. The use of terms like "non-detect" or" none found in the sample" is consistent with this goal, and less confusing than the statistical expression summarizing what "none found" in a sample means relative to the level of certainty that the whole lot is not contaminated.

8. The need to use organically grown seed is affected by the need for commercially available GMO-tested seed to satisfy buyers. Farmers are challenged to balance prevention of GMO contamination with adherence to the guidance on organic seed.

Discussion Questions

The GMO ad-hoc subcommittee is seeking response from the organic community to several questions regarding seed purity as follow:

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.

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.

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?

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

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

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

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

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

Subcommittee Vote:

Motion to adopt the proposed Discussion Document on GMOs and Seed Purity.

Moved: Colehour Bondera Second: Jennifer Taylor

Yes: 7 No: 0 Abstain: 0 Absent: 0 Recuse: 0

National Organic Standards Board
GMO ad hoc Subcommittee
Discussion Document
Excluded Methods Terminology

February 6, 2013

Introduction

There is a fundamental contradiction at the heart of the regulatory approaches to organic agriculture and biotechnology. Organic certification is a **process-based** guarantee while biotechnology is subject to a **product-based** assessment (Caruso 2006).

One of the strengths of the process-based regulation is that it takes into consideration the entire production system. If biotechnology were assessed on the basis of its impacts on the system rather than the narrow focus of whether or not a particular transgenic crop poses a “plant pest” risk, regulators would have to take into account the environmental impacts of increased herbicide applications, increased use of more volatile and toxic herbicides, impacts on pollinator populations, reduction of vegetative diversity, introduction of novel proteins into soil and water ecosystems, likelihood of selecting for resistance in weed and pest populations, negative socioeconomic impacts, and reduction of transgene-free germplasm availability.

There are contradictions concerning what are defined as “excluded methods,” the phrase used in the USDA organic regulations to describe certain products of biotechnology. Furthermore, the concepts of "excluded methods" have widened to includequestions about what vaccines for livestock are being produced through use of “excluded methods”, issues around the use of micro-organisms in processed foods and the discussion leading up to a October 2012 NOSB recommendation to allow the use of biodegradable mulch film with a prohibition on the use of organisms or feedstock derived from “excluded methods”. Now that the USDA organic regulations have been fully implemented for 10 years, new issues and technologies in plant and animal breeding have been identified and it may be necessary to clarify the language in these regulations.

The purpose of this Discussion Document is to provide definitions of the terms included in the definition of “excluded methods” and to ask for stakeholder input on what changes may need to be made to the definition of “excluded methods” or what clarifications and interpretations may need to be made through guidance.

Background and Relevant areas in the Rule

Here is the definition of “excluded methods” in the National Organic Standards (7 CFR 205.2; Terms Defined):

> Excluded methods. A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a

> foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture. (Federal Register / Vol. 65, No. 246 / Thursday, December 21, 2000 / Rules and Regulations p. 80639)

Since the rule went into effect in 2002, no changes have been made to the definition of "excluded methods" in the regulations. Due to the lack of specificity in the definition, ACAs (Accredited Certifying Agents) have made their own determinations of how far back in the ingredient and input chain (or breeding line) to verify compliance with the prohibition on excluded methods in organic production and handling and interpret what these terms within the definition mean. This has caused confusion among stakeholders at times, where other techniques not mentioned in the definition are also considered by some as excluded, while some terms within the definition are open to multiple interpretations.

Three separate topic areas that came up in the last two years have caused this confusion to become more important to try to address. The NOSB Livestock Subcommittee has been grappling with the subject of excluded methods used in vaccines and, to guide their further deliberations, a Vaccines Working Group[1] developed a parallel discussion of the terms relevant to vaccine production to solicit comment on what vaccine production methods may or may not be considered excluded. This discussion is posted as an Interim Report and the Working Group is seeking public input.[2] In December 2011, the NOSB's review of Docosahexaenoic acid (DHA) algal oil, an ingredient petitioned for use in organic handling, prompted discussion over whether the form of mutagenesis that may be used to develop this ingredient should be considered an "excluded method".[3] Lastly, the NOP recently issued Policy Memo 13-1 on February 1, 2013 concerning Cell Fusion Techniques used in Seed Production (discussed in the cell fusion section below) to clarify which cell fusion techniques should be considered use of an "excluded method".[4]

Some ACAs and groups such as Organic Materials Review Institute (OMRI) have developed their own decision making protocols for interpreting the definition of "excluded methods". With advances in biotechnology since the time the "excluded methods" definition was first adopted by the NOSB in 1995 and innovations in product development from biotechnology, the decision making is getting more and more complicated.

Discussion

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[1] In May 2012, the NOSB Livestock Subcommittee issued a resolution requesting that USDA provide information regarding which vaccine products were produced through the use of biotechnology. Available at: http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5098924. In response, the NOP initiated a Vaccines Working Group comprised of NOP staff, NOSB members, and staff from APHIS' Center for Veterinary Biologics. The Working Group began meeting in July 2012 and provided an interim report to the Livestock Subcommittee in February 2012 on this issue.

[2] Vaccines Working Group Interim Report: Identifying Vaccines Made with Excluded Methods. Available at: http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5102576

[3] December 2011 NOSB Recommendation on DHA algal oil. Available at: http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5097102

[4] National Organic Program, Policy Memo 13-1: Cell Fusion Techniques Used in Seed Production. Available at: http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5102380

The GMO ad hoc Subcommittee believes that strengthening and clarifying the definition of "excluded methods" in the USDA organic regulations will help all stakeholders with implementation of the regulations and strengthen processes behind keeping GMOs out of organic food. To do this, the GMO ad hoc subcommittee has prepared this discussion document to 1) examine the language currently in the "excluded methods" definition (Part A), and 2) outline other terms that could be added to the definition (Part B), providing context for regulatory definitions from organic standards of other countries (Appendix I). The Subcommittee is seeking public input on which of these terms belong in a revised definition for "excluded methods" under the USDA organic regulations, as well as the guiding principle(s) to use in crafting a new definition.

Part A

Examination of the exact language of the excluded methods definition at 7 CFR 205.2 will bring out the key issues.

1. A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production.

The phrase "not possible under natural conditions or processes" has become problematic in the context of "traditional" breeding methods that involve disruption of normal plant cell growth. For example, mutagenesis can be a process in which chemical or radiation stress is applied on a cell to force mutation to happen, but it also commonly occurs in nature and at least some of the mutagenesis chemicals are derived from nature. (More on mutagenesis under *5. traditional breeding*). The concept of "natural" is not defined in any regulations and is very blurred after centuries of humans manipulating the environment and plants, animals and microbes.

This brings up the question, what exactly is it about a genetic modification process that is objectionable in the organic context? This larger question is what the GMO Subcommittee is re-visiting here in order for organic stakeholders to clarify the basis of objection to the technology because **even acceptable breeding methods could very well not be possible under natural conditions**. It may be that the species line is where people object to genetic exchange occurring. If this is the case, the terms *interspecific* (between species) and *intraspecific* (within species) or *intergeneric* (between genera) and *intrageneric* (within a genus) may come in handy. So many different techniques are used now that wording must be very carefully chosen or some crops already accepted in organic cultivation might be ruled out. Examples include triticale (created from breeding two different genera), bananas and seedless watermelon from somatic doubling, and more.

Dutch organic plant breeder Edith Lammerts van Bueren has proposed that organisms have "intrinsic value" and "integrity" represented by an intact genome (Lammerts van Bueren et al. 2003). While this argument may seem to have more of a philosophical than scientific basis to it, it may be a useful organizing statement in describing what the organic community finds acceptable means of plant and animal breeding. It also may be relevant to consider that while the prohibition on genetically modified organisms allows for certain traditional methods used to produce nonorganic seeds, (e.g. mutagenesis), the standards for organic plant breeding can be considered more restrictive, since the chemicals or irradiation techniques used are not permitted methods under organic standards.

2. Such methods include cell fusion

Cell fusion: The process in which two different cells fuse into one single cell. The resulting cell has all of the contents from the original cells and has one nucleus containing the genetic material from both of the original cells. This occurs naturally during sexual reproduction, when gametes (eggs and sperm) fuse to produce the zygote, and can also occur under laboratory conditions between somatic cells (any cell other than a gamete). (Websters Online Dictionary[5])

Protoplast fusion
A technique in which protoplasts (plant cells from which the cell wall has been removed by mechanical or enzymatic means) are fused into a single cell. (National Academies 2004 glossary)
or
The fusing of two protoplasts (a bacterial or plant cell deprived of its cell wall but having an intact plasma membrane).- (CAN/CGSB-32.315-2004 **Voluntary** Labelling And Advertising of Foods That Are and Are Not Products of Genetic Engineering)

Also relevant here:
Somatic hybridization : "The technique of hybrid production of plants through the fusion of isolated somatic (body) protoplasts under in vitro conditions and subsequent development of their product (heterokaryon) to a hybrid plant is known as somatic hybridization." (Chawla, H.S. 2001. Introduction to Plant Biotechnology, 2nd ed. Science Publishers, Inc.)

The NOP was asked to clarify its position on cell fusion because it has been used as an "acceptable" means of developing varieties of Brassica and citrus crops among others. Cell fusion has been used in traditional breeding and hybridization programs as well as in general propagation using tissue culture. It can be used within a genus or species or between very different species.

So why might cell fusion be considered an excluded method? A form of cell fusion called *somatic cell hybridization, somatic hybridization,* or *protoplast fusion* involves destruction of cell walls using chemical or electrical stimuli, which then allows the genetic material to be fused. This approach has been used to develop both *intraspecific* and *interspecific* crosses (see selected citations A).

In 2012, the NOP received questions about whether seed varieties produced through cell fusion techniques are allowed in organic production. The issue for certifiers is complicated by the fact that it is not disclosed publically which varieties may have been bred using cell fusion and so enforcement of any prohibition is extremely problematic. Additionally the cell fusion event may have happened up to 30 years ago and the resulting trait simply passed to subsequent generations by traditional breeding methods.

[5] http://www.websters-online-dictionary.org/definitions/Cell+Fusion

In NOP Policy Memo 13-1, the type of cell fusion used to transfer traits such as male sterility within a plant family was determined to be possible with natural breeding techniques and compatible with organic production.

> "... the NOP further concludes that cell fusion (including protoplast fusion) is not considered an excluded method when the donor cells/protoplasts fall within the same taxonomic plant family, and when donor or recipient organisms are not derived using techniques of recombinant DNA technology."

This Policy Memo also explains that cell fusion techniques are considered an “excluded method” when the donor cells/protoplasts do not fall within the same taxonomic family. Cell fusion is also an “excluded method” when the donor or recipient organism is derived using techniques of recombinant DNA technology and techniques involving the direct introduction into the organism of hereditary materials prepared outside of the organism.

Here again it seems as if the technology itself is not the issue so much as the crossing of the species or taxonomic family line.

3. *microencapsulation and macroencapsulation*

Micro-encapsulation: a process in which tiny particles or droplets are surrounded by a coating to give small capsules many useful properties. (Wikipedia)
Macroencapsulation: (cell and molecular biology) The envelopment of a large mass of xenotransplanted cells or tissue in planar membranes, hollow fibers, or diffusion chambers to isolate the cells from the body, thereby avoiding the immune responses that the foreign cells could initiate, and also to allow the desired metabolites (such as insulin and glucose for pancreatic islet cells) to diffuse in and out of the membrane.
(McGraw Hill Science and Reading Dictionary)
http://www.answers.com/topic/macroencapsulation#ixzz2E2MQK67W

It may be time to remove these processes from the definition of “excluded methods” because they don’t involve recombining genes. They may be more appropriately classified as “nonagricultural” or “synthetic” materials or as a form of *nanotechnology*. Micro- and macroencapsulation appear to be cellular packaging mechanisms for engineered genes, food additives, or pesticides rather than a form of genetic engineering (see selected citations B). Specifying them as excluded methods is questionable and has been ridiculed by at least one academic commenter (Eisen 2012).

4. and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology).

DNA, Recombinant
Biologically active DNA which has been formed by the in vitro joining of segments of DNA from different sources. It includes the recombination joint or edge of a heteroduplex region where two recombining DNA molecules are connected.
Year introduced: 1977 (MeSH)

Gene Deletion

A genetic rearrangement through loss of segments of DNA or RNA, bringing sequences which are normally separated into close proximity. This deletion may be detected using cytogenetic techniques and can also be inferred from the phenotype, indicating a deletion at one specific locus. Year introduced: 1993. (MeSH)

Genetic engineering
Changes in the genetic constitution of cells resulting from the introduction or elimination of specific genes via molecular biology (i.e., recombinant DNA) techniques. (National Academies 2004 glossary)

Recombinant DNA techniques
Procedures used to join together DNA segments. Under appropriate conditions, a recombinant DNA molecule can enter a cell and replicate there. (National Academies 2004 glossary)

Recombination naturally occurs between chromosomes during the process of meiosis to form gametes for sexual propagation, in plants, animals and other organisms. Recombination naturally occurs during high frequency recombinant (Hfr) conjugation in which part of the chromosome from one bacterium is transferred to another bacterium, resulting in homologous recombination which genetically modifies the target bacteria. These are just two examples of genetic modifications through recombination events which may be allowed by the current definition of excluded methods.

This language seems valid and on point in addressing the main concerns most organic stakeholders have with transgenic technologies; however, the specifics could probably be updated to include other recombinant technologies and to remove phrasing that is not in common usage. For example, “gene doubling” is not often found in the literature.

Such methods do not include the use of

5. traditional breeding,

This term is assumed to include breeding methods that have been used prior to the emergence of transgenic technologies. It is not clear at which point traditional breeding techniques are divided from modern or non-traditional breeding techniques. Is there a time point at which all techniques before that time are considered traditional and all new techniques developed after that time are not considered traditional? The use of transposons (see below Part B) since the 1930's or chemical, physical, and biological mutagens since the 1940's are blurring the distinction between traditional breeding and biotechnology.

One form of traditional breeding that has not been formally defined and has been called into question is *mutagenesis.*

Mutagenesis (or mutation breeding)
A process whereby the genetic information of an organism is changed in a stable, heritable manner, either in nature or induced experimentally via the use of chemicals or radiation. In

agriculture, these genetic changes are used to improve agronomically useful traits. (National Academies 2004 glossary)

The “problem” with mutagenesis as an acceptable practice in organic breeding is that it sometimes relies on processes that would not occur naturally, but sometimes does involve naturally derived substances and processes. Additionally, some mutagenesis is now accomplished by inserting DNA or other genetic material into a cell (*insertional mutagenesis).* Because of its widespread usage in plant breeding since the 1940s, however, there may be a need to clarify which types of mutagenesis are acceptable under the organic standards. See selected citations C.

6. conjugation,

Conjugation, Genetic: A parasexual process in BACTERIA; ALGAE; FUNGI; and ciliate EUKARYOTA for achieving exchange of chromosome material during fusion of two cells. In bacteria, this is a uni-directional transfer of genetic material; in protozoa it is a bi-directional exchange. In algae and fungi, it is a form of sexual reproduction, with the union of male and female gametes. Year introduced: 1968 (MeSH)

Conjugation can be used to transfer genetic information (via plasmids) between different genera of bacteria. Might this violate the guiding principle of not crossing taxonomic lines? (See Jones and Woods 1986 for background.)

7. fermentation,

Fermentation: Anaerobic degradation of GLUCOSE or other organic nutrients to gain energy in the form of ATP. End products vary depending on organisms, substrates, and enzymatic pathways. Common fermentation products include ETHANOL and LACTIC ACID. (MeSH)

Should inclusion of fermentation on this list be reconsidered? While the process of fermentation can be used to multiply transgenic organisms and some fermentation processes are done with transgenic organisms, it is not a breeding technology. (See Jones and Woods 1986 for background on the use of microbes to manufacture solvents via fermentation.)

8. hybridization,

Hybridization, Genetic: The genetic process of crossbreeding between genetically dissimilar parents to produce a hybrid. (MeSH)

Hybrid
Progeny of genetically different parents, usually of the same species, that has enhanced productivity over either parent. Generally, the more genetically diverse the parent lines, the more hybrid vigor, or heterosis, is observed in the hybrid progeny. (National Academies 2004 glossary)

Here are some other types of hybridization defined on the MeSH site for reference.

Nucleic Acid Hybridization: Widely used technique which exploits the ability of complementary sequences in single-stranded DNAs or RNAs to pair with each other to form a double helix. Hybridization can take place between two complimentary DNA sequences, between a single-stranded DNA and a complementary RNA, or between two RNA sequences. The technique is used to detect and isolate specific sequences, measure homology, or define other characteristics of one or both strands. (Kendrew, Encyclopedia of Molecular Biology, 1994, p503). Year introduced: 1972(1971) (MeSH)

In Situ Hybridization
A technique that localizes specific nucleic acid sequences within intact chromosomes, eukaryotic cells, or bacterial cells through the use of specific nucleic acid-labeled probes. Year introduced: 1993. (MeSH)

9. in vitro fertilization,

Fertilization in Vitro
An assisted reproductive technique that includes the direct handling and manipulation of oocytes and sperm to achieve fertilization in vitro. Year introduced: 1979. (MeSH)

10. tissue culture

Tissue Culture Techniques
A technique for maintaining or growing TISSUE in vitro, usually by DIFFUSION, perifusion, or PERFUSION. The tissue is cultured directly after removal from the host without being dispersed for cell culture. Year introduced: 2005. (MeSH)
Another one that was defined long before the "year introduced"

Tissue culture does not "disperse the tissue for cell culture." But cell culture is used in breeding and the process of culturing cells can stimulate genetic variability that can provide further breeding material. Cell culture can be a means of generating "natural" genetic variability under "unnatural" conditions along the lines of mutagenesis. See selected citations D. Here are related definitions.

Cell Culture Techniques
Methods for maintaining or growing CELLS in vitro.Year introduced: 2005 (1996) (MeSH)

Primary Cell Culture
The initial culturing of cells derived directly from fresh TISSUES. Year introduced: 2012 (MeSH)

Batch Cell Culture Techniques
Methods for cultivation of cells, usually on a large-scale, in a closed system for the purpose of producing cells or cellular products to harvest. Year introduced: 2012. (MeSH)

Part B
Contemporary breeding methods that may be candidates as "excluded methods", but may not be.

This section was compiled by looking through critiques of the current organic standards regarding transgenic technologies and from there following the discussions on the internet. A couple of other terms are relevant to the work of the Vaccines Working Group. One science blogger in particular (von Mogel 2010) dissects the rationale Jim Riddle presented in 2010 for why genetic engineering is incompatible with organic farming. Von Mogel includes a figure that purports to show relative risks of unintended consequences by breeding method (National Academies 2004). The figure is shown in Appendix II.

This is a list of other emerging breeding strategies that may need to be included in the recitation of "excluded methods." These are:

- Gene silencing—occurs naturally and may also be engineered

Silencing
Shutdown of transcription of a gene, usually by methylation of C residues. (National Academies 2004 glossary)

- Embryo rescue

Embryo rescue
A sequence of tissue culture techniques used to enable a fertilized immature embryo resulting from an interspecific cross to continue growth and development, until it can be regenerated into an adult plant. (National Academies 2004 glossary)

This fairly common technique is used to clean plant tissue from viruses (such as potatoes) and is quite beneficial to organic agriculture.

- Microinjection—clearly an excluded method. Need to be specified?

Microinjection
Introduction of DNA into a cell by injection through a very fine needle. (National Academies 2004 glossary)

- Biolistic transfer—already covered in the definition of excluded methods. Need to be specific? Also known as *microprojectile bombardment.*

Biolistic device
A device that bombards target cells with microscopic DNA-coated particles. Familiarly known as the Gene Gun, it was first developed in the early 1980s. (National Academies 2004 glossary)

- Somaclonal variation (analogous to mutagenesis in that it is a form of natural genetic variation forced by unnatural conditions [cell culture])

Somaclonal variation
Epigenetic or genetic changes, sometimes expressed as a new trait, resulting from in vitro culture of higher plants. (National Academies 2004 glossary)

- Transposons — naturally occurring, double stranded DNA sequences with a defined structure. They are present in plant, animal and bacterial species.

Transposons

Each end of the transposon includes inverted repeats. In prokaryotes, the internal structure includes at least one gene for transposase and may contain many more depending upon the type of transposon. When the transposase gene is expressed, the protein binds to the inverted repeats of the transposon, cleaves the genomic DNA and excises the transposon. Transposase can then cleave the genomic DNA at another spot and recombine the transposon into a new position in the genome. By moving from one location to another in the genome, transposons can cause gene deletions or change expression patterns through gene deletion, resulting in changed phenotypes. (Ivics, Z. and Z. Ivsvak. 2010; MeSH)

Transposons were initially identified as jumping genes by Barbara McClintock in research on variegation of corn kernels in the 1930's (Pray & Zhaurova, 2008). More recently researchers have used transposons as a vector for inserting specific foreign genes into the genomes of various species. The transposon system called "Sleeping Beauty" was used to genetically modify swine cells with genes from rice (Carlson et. al., 2011). The Vaccine Working Group has more detail on transposons as used to produce vaccines.

- Transduction— while this theoretically could occur in nature, the specific purpose of its intentional use is in biotechnology applications.

Transduction
The process through which the genomes of bacteria can be modified with the use of bacterial virus, called a phage. Some types of phage attach to the bacterial cell wall and insert the viral genome into the cell. The viral genome may then be inserted into the bacterial genome through a recombination event which is part of the lysogenic cycle. After receiving a trigger, the viral genome will be excised and the lytic cycle will be triggered (MeSH).

This method can stably introduce genetic mutations into the new bacteria. This technique is widely used to create gene deleted vaccine products.

Discussion Questions
The GMO ad hoc Subcommittee is seeking response from the organic community on the issues presented in this discussion. A few of the questions to be addressed are:

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.

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"?

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

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

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?

Subcommittee Vote
Motion to adopt the proposed Discussion Document on Excluded Methods

Motion by: Jean Richardson Second: Colehour Bondera
Yes:7 No:0 Absent:0 Abstain:0 Recuse:0

Appendix I. Other GE and GMO definitions

USDA Advisory Committee on Biotechnology and 21st Century Agriculture (AC21)
http://www.usda.gov/documents/ac21_report-enhancing-coexistence.pdf

—**Genetically Engineered** is meant to include biotechnology-derived organisms produced through the application of 1) *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles or 2) fusion cells beyond the taxonomic family, that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection.

Codex Alimentarius Commission, International Food Standards
http://www.codexalimentarius.org/standards/list-of-standards/en/

CAC/GL 44-2003
PRINCIPLES FOR THE RISK ANALYSIS OF FOODS DERIVED FROM MODERN BIOTECHNOLOGY
Adopted in 2003. Amendments 2008, 2011

SECTION 2 – SCOPE AND DEFINITIONS

7. The purpose of these Principles is to provide a framework for undertaking risk analysis on the safety and nutritional aspects of foods derived from modern biotechnology. This document does not address environmental, ethical, moral and socio-economic aspects of the research, development, production and marketing of these foods3.

8. The definitions below apply to these Principles:

"Modern Biotechnology" means the application of:

i) *In vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

ii) Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection[4].

[3] This document does not address animal feed and animals fed such feed except insofar as these animals have been developed by using modern biotechnology.

[4] This definition is taken from the Cartagena Biosafety Protocol under the Convention on Biological Diversity.

European Union
Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 Deliberate Releases into the Environment of Genetically Modified Organisms
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2001L0018:20080321:EN:PDF

Article 2

Definitions - (2) ‘genetically modified organism (GMO)’ means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination;
Within the terms of this definition:
(a) genetic modification occurs at least through the use of the techniques listed in Annex I A, part 1;
(b) the techniques listed in Annex I A, part 2, are not considered to result in genetic modification;

ANNEX I A
TECHNIQUES REFERRED TO IN ARTICLE 2(2)
Techniques of genetic modification referred to in Article 2(2)(a) are inter alia:

(1) recombinant nucleic acid techniques involving the formation of new combi- nations of genetic material by the insertion of nucleic acid molecules produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation;
(2) techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro- injection and micro-encapsulation;
(3) cell fusion (including protoplast fusion) or hybridisation techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

PART 2
Techniques referred to in Article 2(2)(b) which are not considered to result in genetic modification, on condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms made by techniques/methods other than those excluded by Annex I B:

(1) in vitro fertilization,
(2) natural processes such as: conjugation, transduction, transformation,
(3) polyploidy induction.

ANNEX I B
TECHNIQUES REFERRED TO IN ARTICLE 3
Techniques/methods of genetic modification yielding organisms to be excluded from the Directive, on the condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms other than those produced by one or more of the techniques/methods listed below are:
(1) mutagenesis,
(2) cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods.

Canadian Standards:

CAN/CGSB-32.315-2004, Voluntary Labelling And Advertising of Foods That Are and Are Not Products of Genetic Engineering
http://www.tpsgc-pwgsc.gc.ca/ongc-cgsb/programme-program/normes-standards/internet/032-0315/index-eng.html

Genetic engineering (Génie génétique): Refers to techniques by which the genetic material of an organism is changed in a way that does not occur naturally by multiplication and/or natural recombination. Examples of the techniques used in genetic engineering include but are not limited to the following:

1. recombinant DNA (rDNA) techniques that use vector systems
2. techniques involving the direct introduction into the organism of hereditary materials prepared outside the organism
3. cell fusion (including protoplast fusion) or hybridization techniques that overcome natural physiological, reproductive, or recombination barriers, where the donor cells/protoplasts do not fall within the same taxonomic family

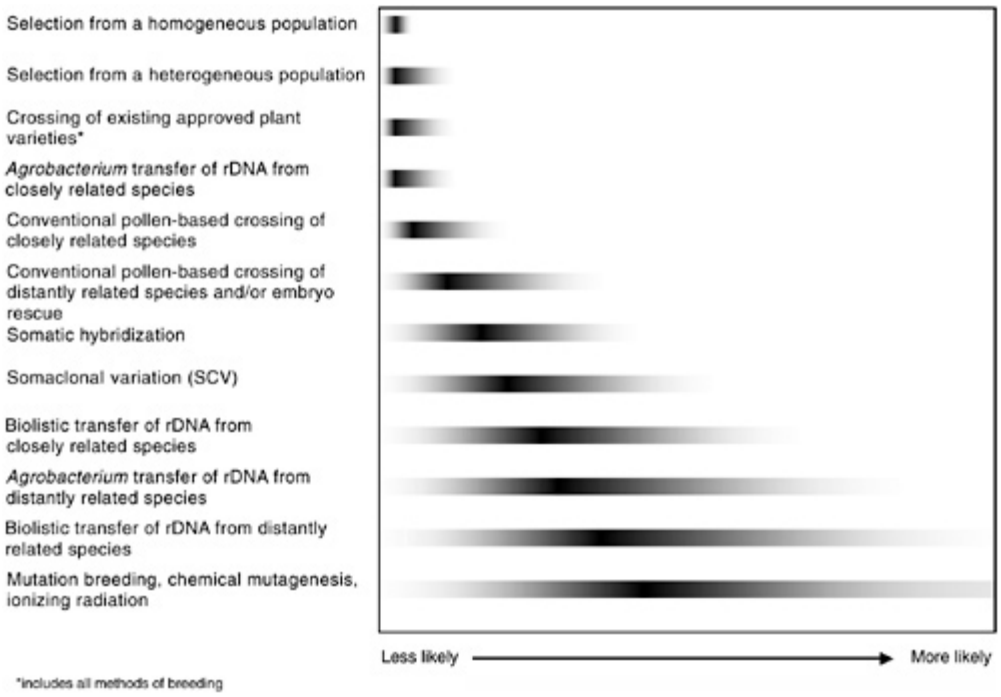
Unless the donor/recipient organism is derived from any of the above techniques, examples of excluded techniques include but are not limited to the following:

1. in vitro fertilization
2. conjugation, transduction, transformation, or any other natural process
3. polyploidy induction
4. mutagenesis
5. cell fusion (including protoplast fusion) or hybridization techniques where the donor cells/protoplasts fall within the same taxonomic family.

Note: (Descriptions of most of these techniques are found in Appendix A.)
Appendix A
Cell fusion (Fusion cellulaire): The fusing of two cells to form a single cell.
Macroinjection (Macro-injection): The introduction of larger molecules into single cells.
Microencapsulation (Micro-encapsulation): The enclosure of small DNA molecules into a capsule, which could be any fatty, fibrous, or membranous structure.
Microinjection (Micro-injection): The introduction of DNA or other compounds into single cells with a microscopic needle.
Mutagenesis (Mutagenése): The induction of genetic mutation through chemical, physical, or radiation treatment, causing nucleotide(s) of the exposed organism's DNA to be altered. This occurs naturally at a very low rate of occurrence, or can be accelerated with in vitro methods.
Plasmid (Plasmide): A circular DNA molecule found in bacteria. Plasmids can transfer genes between bacteria and are important transformation tools.
Polyploidy (PolyploÏdie): The condition where more than two copies of chromosomes are present within a cell - this is caused either by the prevention of cell division or by reproduction of extra copies of chromosomes.
Protoplast fusion (Fusion de protoplastes): The fusing of two protoplasts (a bacterial or plant cell deprived of its cell wall but having an intact plasma membrane).
Recombinant DNA (rDNA) techniques (Techniques de l'ADN recombinant): The transfer, in vitro, of spliced genes between different organisms of the same or different species, or the transfer of synthetic genes, which in turn changes the heritable traits of the organism. Such transfer of genes can be accomplished using vector systems or by direct introduction using a number of techniques including but not limited to chemoporation, electroporation, liposome fusion, macroinjection, microencapsulation, microinjection, and transduction.
Taxonomic family (Famille taxonomique): An orderly classification of living organisms according to their presumed natural relationships, in which a group of related living organisms form a category ranking above a genus and below an order, and usually comprising several to many genera.

Transduction (Transduction): The transfer of DNA from one micro-organism to another via a virus that infects bacteria.
Transformation (Transformation): A process whereby a cell incorporates foreign DNA into its genome.
Vector (Vecteur): An organism, plasmid, or virus that is used to deliver selected foreign DNA into a host cell.

Appendix II. Graph from National Academies study assessing the safety of genetically engineered foods, p. 64. (National Academies 2004).



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Jones, D.T., and D.R. Woods. 1986. Acetone-Butanol Fermentation Revisited. MICROBIOLOGICAL REVIEWS, Dec. 1986, p. 484-524. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC373084/pdf/microrev00055-0136.pdf

Lammerts van Bueren, E.T., P.C. Struik, M. Tiemens-Hulscher, and E. Jacobsen. 2003. The concepts of intrinsic value and integrity of plants in organic plant breeding and propagation. Crop Sci. 43:1922-1929.

MeSH (Medical Subject Headings), the NLM [National Library of Medicine] controlled vocabulary thesaurus used for indexing articles for PubMed.

http://www.ncbi.nlm.nih.gov/mesh

National Academies Committee on Identifying and Assessing Unintended Effects of Genetically Engineered Foods on Human Health, National Research Council. "3. Unintended Effects from Breeding." Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects. Washington, DC: The National Academies Press, 2004. http://www.nap.edu/openbook.php?record_id=10977&page=1

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Selected citations and abstracts
A. cell fusion, somatic cell hybridization, somatic hybridization, protoplast fusion

“Arabidobrassica”: A novel plant obtained by protoplast fusion. Yury Yu. Gleba, Franz Hoffmann. Planta July 1980, Volume 149, Issue 2, pp 112-117. http://link.springer.com/article/10.1007%2FBF00380870?LI=true#page-1
“The results represent the first case of intergeneric-intertribal hybridization of flowering plants.”

Protoplast Fusion Technology and Its Biotechnological Applications. (India) http://www.aidic.it/IBIC2008/webpapers/96Verma.pdf

Somatic hybrids produced by protoplast fusion between S. tuberosum and S. brevidens: phenotypic variation under field conditions. S. Austin, M. K. Ehlenfeldt, M. A. Baer and J. P. Heigeson. Theor Appl Genet (1986) 71:682-690. http://download.springer.com/static/pdf/805/art%253A10.1007%252FBF00263264.pdf?auth66=1354679330_b79ef433d91a5620b0caed8b8612b6fd&ext=.pdf

Somatic hybrids between Solarium brevidens and Solarium tuberosum: Expression of a late blight resistance gene and potato leaf roll resistance. (USA 1986) http://download.springer.com/static/pdf/146/art%253A10.1007%252FBF00269122.pdf?auth66=1354678213_aa1aef7574f60c3e2fecc6febb8df18b&ext=.pdf

Somatic hybridization in citrus: An effective tool to facilitate variety improvement. J. W. Grosser, P. Ollitrault, O. Olivares-Fuster. In Vitro Cellular & Developmental Biology - Plant November–December 2000, Volume 36, Issue 6, pp 434-449
Download PDF (354 KB)
Summary: **Citrus somatic hybridization and cybridization via protoplast fusion has become an integral part of citrus variety improvement programs worldwide.** Citrus somatic hybrid plants have been regenerated from more than 200 parental combinations, and several cybrid combinations have also been produced. Applications of somatic hybridization to citrus scion improvement include the production of quality tetraploid

breeding parents that can be used in interploid crosses to generate seedless triploids, and the direct production of triploids by haploid + diploid fusion. ....Several allotetraploid somatic hybrid rootstocks are performing well in commercial field trials, and show great promise for tree size control. Seed trees of most of these somatic hybrid rootstocks are producing adequate nucellar seed for standard propagation. Somatic hybridization is expected to have a positive impact on citrus cultivar improvement efforts.

B. microencapsulation, macroencapsulation

Microencapsulation: Methods and Industrial Applications. By Simon Benita.
http://books.google.com/books?hl=en&lr=&id=sz-669oFo6AC&oi=fnd&pg=PP1&dq=pesticide+microencapsulation&ots=_x0RTSoIAI&sig=mJQZ6Ox-CfpRkBpASH8YzS6CJ90#v=onepage&q=pesticide%20microencapsulation&f=false
Chapter 2. Advances in the Technology for Controlled-Release Pesticide Formulations

Microencapsulation: Is listed under Drug Compounding (MeSH)
The preparation, mixing, and assembling of a drug. (From Remington, The Science and Practice of Pharmacy, 19th ed, p1814)

Sher et al. 1999. Microencapsulation of pesticides by interfacial polymerization utilizing isocyanate or aminoplast chemistry.http://onlinelibrary.wiley.com/doi/10.1002/%28SICI%291096-9063%28199812%2954:4%3C394::AID-PS829%3E3.0.CO;2-S/abstract - fn1
Summary: Interfacial polymerization microcapsulation processes based on isocyanate or aminoplast chemistry, where all wall-forming reactants are placed in the dispersed oil phase are described.
Pesticide microcapsule formulations can be used to reduce mammalian toxicity and extend activity, to control evaporation, to reduce phytotoxicity, to protect pesticide from rapid environmental degradation, to reduce leaching and to reduce pesticide levels in the environment.
http://onlinelibrary.wiley.com/doi/10.1002/(SICI)1096-9063(199812)54:4%3C394::AID-PS829%3E3.0.CO;2-S/abstract

Microencapsulation is a cell-based method of gene therapy, using genetically-modified cells to provide a novel protein for the treatment of various inherited or somatic diseases. In contrast to conventional gene therapy using viruses to transfer therapeutic genes into the patients' own cells, this method uses universal cell lines genetically engineered to secrete high levels of the therapeutic gene product. These cells are implanted within immuno-protective microcapsules into patients to act as a continuous source of the desired gene product, thus providing a potentially safer, reversible and more economic treatment than viral gene therapy. http://fhs.mcmaster.ca/gene/

The in vivo delivery of heterologous proteins by microencapsulated recombinant cells. Trends Biotechnol. 1999 Feb;17(2):78-83.
http://www.ncbi.nlm.nih.gov/pubmed/10087608?ordinalpos=2&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_RVDocSum

Macroencapsulation—MeSH search gives no results

Patrick Aebischer (http://len.epfl.ch/) is cited as the developer of macroencapsulation, which appears to be a packaging technology for genetic therapies. From Neuronal Degeneration and Regeneration: From Basic Mechanisms to Prospects. By F W Van Leeuwen.
http://books.google.com/books?id=516KNxhxd8UC&pg=PA518&lpg=PA518&dq=Macroencapsulation+genetic&source=bl&ots=eoaX_4ZZv7&sig=nqahF3GMkDNcpOXNk6tedviHcXE&hl=en&sa=X&ei=qki8UKPCJ6mu0AGgrYDwDg&ved=0CE4Q6AEwBDgU#v=onepage&q=Macroencapsulation%20genetic&f=false

C. Mutagenesis

Wieczorek, A. M. & Wright, M. G. (2012) History of Agricultural Biotechnology: How Crop Development has Evolved. Nature Education Knowledge 3(10):9. Cites FAO as stating that "More than 2,500 plant varieties (including rice, wheat, grapefruit, lettuce and many fruits) have been developed using radiation mutagenesis."
http://www.nature.com/scitable/knowledge/library/history-of-agricultural-biotechnology-how-crop-development-25885295

Falk, R. 2010. Mutagenesis as a Genetic Research Strategy. Genetics. August; 185(4): 1135–1139. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2927745/

Alonso et al. 2003. Genome-Wide Insertional Mutagenesis of Arabidopsis thaliana. Science 301 (5633): 653-657. Abstract online at
http://stke.sciencemag.org/cgi/content/abstract/sci;301/5633/653

D. cell culture, somaclonal variation

Somaclonal variation — a novel source of variability from cell cultures for plant improvement. P. J. Larkin, W. R. Scowcroft. Theoretical and Applied Genetics 16. X. 1981, Volume 60, Issue 4, pp 197-214.
Abstract: It is concluded from a review of the literature that **plant cell culture itself generates genetic variability (somaclonal variation).** Extensive examples are discussed of such variation in culture subclones and in regenerated plants (somaclones). A number of possible mechanisms for the origin of this phenomenon are considered. The phenomenon may be employed to enhance the exchange required in sexual hybrids for the introgression of desirable alien genes into a crop species. It may also be used to generate variants of a commercial cultivar in high frequency without hybridizing to other genotypes.
http://link.springer.com/article/10.1007%2FBF02342540?LI=true

Somaclonal variation - Genetic basis and breeding applications. David A. Evans.
Somaclonal variation, the recovery of genetic changes in plants regenerated from tissue culture, offers an opportunity to uncover natural variability and to use this variability for the development of new varieties. This review focuses on the unique variation generated by this technique and the current use of somaclonal variation to develop new plant varieties.
Abstract—pay for full text.
http://www.sciencedirect.com/science/article/pii/0168952589900218

Somaclonal variation as a tool for crop improvement. Angela Karp. Euphytica

February 1995, Volume 85, Issue 1-3, pp 295-302. Abstract: Somaclonal variation is a tool that can be used by plant breeders. The review examines where this tool can be applied most effectively and the factors that limit or improve its chances of success.... Somaclonal variation is cheaper than other methods of genetic manipulation. At the present time, it is also more universally applicable and does not require 'containment' procedures. It has been most successful in crops with limited genetic systems and/or narrow genetic bases, where it can provide a rapid source of variability for crop improvement.
Full article online at http://link.springer.com/article/10.1007%2FBF00023959?LI=true

National Organic Standards Board
Policy Development Subcommittee
Proposal
New Member Guide Updates

February 4, 2013

I. Introduction

The National Organic Program (NOP) and the National Organic Standards Board (NOSB) seek to provide a guide for new members to the NOSB. The NOSB's New Member Guide (NMG) helps provide guidance and resources to new members and to ease their transition to the NOSB.

II. Background

The NOSB New Member Guide (NMG) was first adopted on March 29, 2007. The NMG was updated once in 2007. In 2008, the NMG was updated twice. In 2009, 2010, and 2012 the NMG were update once. The NMG includes (1) the authorization of NOSB, (2) mission of NOSB, (3) listing of the various subcommittees, (4) outlining the importance of public comment and the process, (5) the do's and don'ts of traveling to NOSB biannual meetings, (6) listing of current NOSB members, (7) contact information of the personnel in the Office of the Deputy Director of NOP, (8) personnel in the Standards Division, (9) personnel in the Accreditation & International Activities Division, (10) personnel in the Compliance & Enforcement Division, (11) personnel in the listing of critical non-NOP staff, and the (12) importance of the Board's Policy and Procedures Manual (PPM).

III. Discussion

The NMG is an excellent guidance and resource document for new members. The guide is updated yearly. The frequent updates are due in part to policy changes, subcommittee membership changes, NOP staffing changes, and personnel additions. The NMG provides guidance for new members before attending their first meeting. The NMG provides a listings of subcommittees from which a new member can choose.

IV. Recommendation

The recommendation is to accept the revised 2013 NOSB New Member Guide attached.

V. Committee Vote

Moved: Calvin Rueben Walker Second: Jennifer Taylor

Yes: 6 No: 0 Abstain: 0 Absent: 0 Recuse: 0

National Organic Standards Board

New Member Guide

2 0 1 3

Adopted: March 29, 2007 | Updated November 30, 2007 | Updated: May 22, 2008
Updated: November 19, 2008 | Updated: May 6, 2009 | Updated: October 28, 2010 |
Updated: January 23, 2012| February 1, 2013

Table of Contents

Welcome New NOSB Members

Congratulations and welcome to the National Organic Standards Board (NOSB)! We look forward to working with you over the next five years to advance organic regulations as defined by the Organic Food Production Act (OFPA) and the USDA National Organic Program (NOP). This guide provides guidance and resources to new members to ease their transition to the NOSB.

Soon after joining the NOSB, you need to read and be familiar with the following materials:

Organic Food Production Act of 1990 (OFPA)
USDA Organic Regulations at 7 CFR 205 Final Rule
NOSB Policy and Procedure Manual (PPM)
NOP Federal Advisory Committee Act (FACA) Training Power Point

The first three documents listed are available at **http://www.ams.usda.gov/NOP**; brief summaries are provided below. The NOP FACA Training Power Point will be sent to all NOSB members as reference following the annual January FACA training session for NOSB members.

Questions?

Count on it. The Board Chairperson will assign you an NOSB mentor prior to your first official meeting to help you transition onto the Board. Your NOSB mentor will be available to you by phone or email to answer questions as they arise. The NOSB Chairperson or the Designated Federal Officer (DFO) can also be reached at any point to assist you. Contact information can be found at the end of this document or by contacting Michelle Arsenault at Michelle.Arsenault@ams.usda.gov.

Federal Organic Regulations & Entities: A Primer

Organic Food Production Act (OFPA)

Title XXI of the 1990 Farm Bill, known as the OFPA, established the NOP within the Agriculture Marketing Service (AMS) of the USDA. It also established the NOSB, an advisory body to the NOP.

Federal Register Final Rule Establishes the NOP

The December 21, 2000 final rule established the NOP within the AMS, an arm of the U.S. Department of Agriculture (USDA). NOP facilitates domestic and international marketing of fresh and processed food that is organically produced and assures consumers that such products meet consistent, uniform standards. NOP is required to establish national standards for the production and handling of organically produced products, including a National List of substances approved for and prohibited from use in organic production and handling. The final rule also established a national-level accreditation program, labeling requirements, and foreign organic program equivalency requirements.

National Organic Standards Board (NOSB)

OFPA authorized the Secretary of Agriculture to appoint a 15-member National Organic Standards Board (NOSB). The NOSB has the sole authority granted through OFPA to recommend additions to the National List of Allowed and Prohibited Substances. Further, the NOSB drafts recommendations based on needs of the industry with public and industry input. The Board's main mission is to make recommendations about whether a substance should be allowed or prohibited in organic production or handling, to assist in the development of standards for substances to be used in organic production, and to advise the Secretary on other aspects of OFPA implementation. Members come from all four U.S. regions.

The first NOSB was appointed by then Secretary Edward Madigan in January, 1992. Members of the initial board served staggered terms of 3, 4, or 5 years; all subsequent board appointees serve 5-year terms. Per OFPA, the board must consist of 15 members:

- Four farmers/growers
- Two handlers/processors
- One retailer
- Three environmentalists / resource conservationists
- Three consumer/public interest advocates
- One scientist (toxicology, ecology, or biochemistry)
- One USDA accredited certifying agent.

National List of Allowed and Prohibited Substances

Through OFPA, the NOSB has the sole authority to recommend adding materials to or removing materials from the National List. The Secretary of Agriculture has limited authority with regard to NOSB recommendations for additions to the National List; the Secretary of Agriculture may deny the listing of a material, but may not add a material that was not previously recommended by the Board.

Technical Information

To help NOSB members assess whether materials should be added or removed from the National List, the NOSB is authorized to request technical information on materials from internal and external sources. See The Final Rule Subpart G 205.600 and the NOSB Policy and Procedures Manual, Section VIII Materials Review Process, for additional information.

NOSB Policy and Procedure Manual (PPM)

The PPM outlines all general procedures followed by members of the NOSB. The manual is designed to assist the Board in its responsibilities and is considered mandatory reading for all members. The PPM covers many important issues such as the NOSB Vision Statement, Duties of the Board and Officers, NOSB job descriptions, NOSB Principals to Production and Handling, Materials Review Process, Technical Advisory Panel (TAP), Sunset Review Process, and other critical information. Policies and revisions are incorporated periodically, and since the PPM guides you on how to craft your documents and recommendations, it is essential to refer to it to make sure you are following the process.

Additional Helpful Reading

NOSB Website | **www.ams.usda.gov/nosb**
The website includes access to NOSB meeting transcripts, NOSB executive subcommittee notes, and previous NOSB recommendations.

NOP Website | **www.ams.usda.gov/nop**
The website includes access to NOP Newsroom, organic regulations, and resources for various stakeholder groups.

From the Margins to the Mainstream, Advancing Organic Agriculture in the United States: National Organic Action Plan | **http://www.rafiusa.org/docs/noap.pdf**
The website provides a portal to access a document on the growth of organic agriculture in the United States.

Selecting NOSB Subcommittees

You will work with the NOSB chairperson to select 2-4 standing Subcommittees from the following on which to participate

1. Compliance, Accreditation, & Certification Subcommittee
2. Crops Subcommittee
3. Handling Subcommittee
4. Livestock Subcommittee
5. Materials Subcommittee
6. Policy Development Subcommittee

New members may also have the option to join a currently-existing ad hoc subcommittee. Additional information on the different Subcommittees is available in the PPM. Generally, it is best to select a Subcommittee for which you have experience. New members are also encouraged to seek guidance from the NOSB Chairperson or the Advisory Board Specialist to best utilize your skills and experience. Subcommittee Chairpersons can update you on current topics under consideration and provide you with recent meeting notes.

Demystifying the Federal Register

The Federal Register is the official daily publication for rules, proposed rules, and notices of federal agencies and organizations, as well as executive orders and other presidential documents. The Federal Register has format and public notice rules that have to be followed.

Public comment periods are generally a minimum of 30 days, but since the organic community believes strongly in collaboration and public comment, NOP strives to allow 45 days for public comment on their notices. "If you intend to bind the public, you have to provide actual and timely notice." Several types of Federal Register notices are used at different rulemaking stages:

Advanced Notice of Proposed Rule (ANPR)

Optional – Involves proposing an idea and formally asking for public comment ***before*** you draft the proposed rule. This is strictly an idea and data collecting process that discourages back-room idea and data collection.

Notice of Proposed Rule (NPR)

Required – Provides Background, Intent, Objectives via the Preamble, Proposes specific rule language, and is Open to Public Comment.

Interim Final Rule (IFR)

Optional – Very similar to the Final Rule – still open to some public comment, used primarily when issues are controversial and some tweaking of the final rule language may be required.

Supplemental Notice of Proposed Rule (SNPR)

Optional – open to public comment on an newly proposed areas that came up during NPR that were not foreseen, but also includes some areas that are more decided and not as open to comment.

Direct Final Rule (DFR)

Special Circumstances – usually not a controversial issue and requires immediate action (good cause criteria have to be met), risky because if one commenter objects, then they have to resubmit as an NPR which costs money – and allow public comment. i.e. the banning of dangerous toys for small children.

Final Rule: 30 days before effective date

Required – Provides Background, Intent, and Objectives via the Preamble, Proposes specific rule language, and is not open to Public Comment as all public commenting time periods have either been met through the above required and optional steps, *with the exception of rules being modified to respond to court actions and deadlines*.

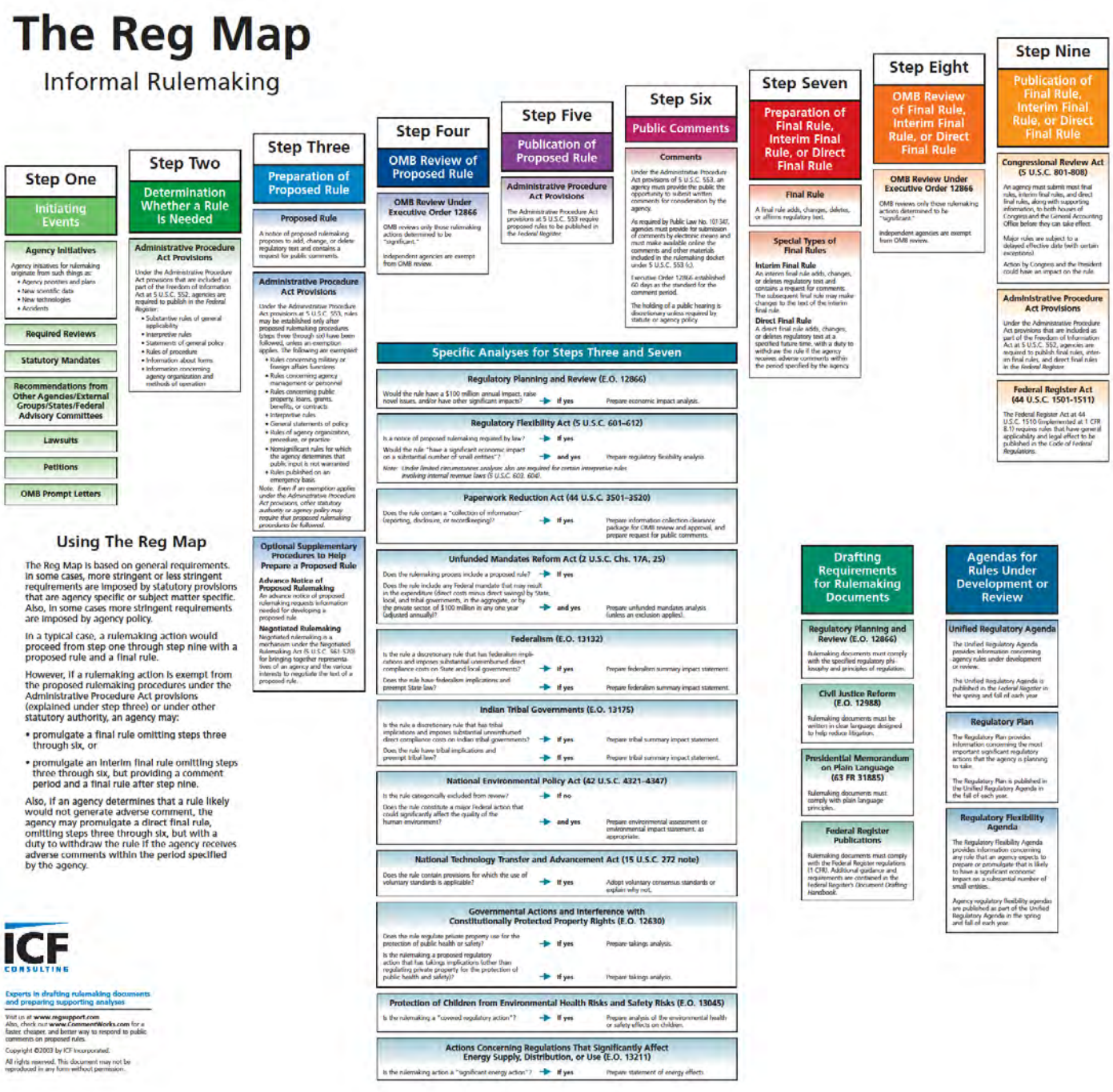
Any further changes to these regulations would be made through petition: "Petition for Reconsideration", and would essentially be re-run through the Federal Register process as described above.

Rulemaking 101

Commonly, laws do not contain a level of detail for their practical implementation. Rather, agencies of the Executive branch have to establish rules, or regulations, to serve as guides in the implementation of laws. The rule development process can be described in five steps:

1. **Framework for establishing rulemaking authority**
   In NOSB's case, per OFPA
2. **Publish proposed rule with request for public comments**
   Rule is subject to Office of Management and Budget review
3. **Publish final rule addressing public comments; set effective date**
   Rule is subject to Office of Management and Budget review
4. **Congressional review**
   Congress or the Government Accountability Office has the ability to nullify rules
5. **Effective date**
   Rules go into effect after a 30-day minimum; 60-days for major rules. Agencies may delay or withdraw rules before they become effective

The diagram below provides additional details on the rulemaking process; this resource is also available at **http://www.reginfo.gov/public/reginfo/Regmap/index.jsp**.



Public Comment

Refer to the PPM for detailed policy & procedures on the public comment process.

NOSB's Unique Role

Organic stakeholders are extremely engaged in the activities of both the NOP and the NOSB. Both groups receive an unprecedented amount of public input from farmers, businesses and consumers during every step of their decision-making process—from a draft NOSB discussion document or proposal, to a final rule. Refer to Section V of the PPM for writing a recommendation. After considering the recommendations of the NOSB, the NOP reviews public comments and industry analysis before proposing a final recommendation. However, the Secretary of Agriculture has final authority in determining all regulations.

NOSB members are in the unique position of not only representing their sector, but also representing the USDA and the public. It is therefore especially important for NOSB members to weigh public comments to help guide us towards what the public wants to see in organic regulations. The public comment process is in place to insure timely notice and to avoid back room decision-making; the NOSB process must be transparent per the Sunshine Act. The following activities require public comment:

- Approving/removing materials for use in the organic industry
- Evaluating a specific Rule
- Providing clarifications
- Discussion documents
- Proposals

Comment Mechanisms

NOP is responsible for receiving and posting all petitions and formal public comments related to NOSB meeting activities and rulemaking. On an informal level, NOSB members are encouraged to maintain and expand their contact base in order to maintain an open line of communication with the organic community. On a formal level, NOSB members request input from the public in two main ways: during formal NOSB meetings and in response to Federal Register notices, either electronically or via mail.

During Formal NOSB Meetings

The public is invited to sign up on a first-come, first-served basis to address the Board about identified topics during the public comment sessions. Commenters typically have 3-5 minutes, not including questions from Board members (NOSB members are encouraged to ask questions at the end). Refer to the PPM for additional details on public commenters' time allocation and process. Please remember to listen, let the speaker finish, and make eye contact as much as possible. The public deserves our respect and attention; they rely on NOSB members to consider their comments. When commenting during meetings remember to be respectful, professional, patient, informed, and concise. The public is encouraged to provide written testimony to facilitate NOSB's consideration.

In Response to Federal Register Notices

The NOP is responsible for publishing Federal Register notices, including those that identify the NOSB's draft recommendation proposals in advance of NOSB meetings. In these notices, the public is directed on how to submit public comments: either electronically (preferred) or via mail. NOP is responsible for reviewing and posting these comments for NOSB's (and the public's) review.

Incorporating Public Comments

The review and implementation of public input takes place at the Subcommittee level. Subcommittee members are expected to review all petitions and comments from the public before providing a recommendation to the Chairperson and members of the Board. Currently, a Subcommittee member is assigned to review, classify, and summarize all data received by NOP, but all Subcommittee members are expected to review the data individually before making a final recommendation.

Separation of Powers

As a member of the NOSB, you are working within the Executive Branch of government. In this capacity, you are not permitted to work in the other branches while on the NOSB because of the required separation of powers.

Confidentiality

While Board members are volunteer, private citizens, and not employed by the government, the Board itself is a government entity. As such, here are some points to be aware of in your communications on NOSB Topics:

- NOSB Subcommittee calls are not recorded or open to anyone besides the NOP and NOSB unless an expert is specifically invited to attend. However, summary notes are developed for each NOSB subcommittee call and are posted on the NOP website.
- Formal transcripts are recorded for NOSB public meetings – whatever you say at a public meeting is on the record.
- Any email or written communication you send that includes a government employee, or that gets forwarded to a government employee, may be releasable to a member of the public in response to a Freedom of Information Act (FOIA) request. (Example: Board members send emails to each other and cc the DFO. This email may be subject to FOIA if a specific request is received that includes that email's topic in its scope).

It is your duty to respect and follow a foundational level of trust and not share internal discussion and deliberative information until it is officially made public. As mentioned in the PPM, a Board member's loyalty is to the organic community and the public at large; however the information should be accurate and agreed upon before being shared with the public.

Best Practices to Optimize Productivity

Staying Organized

NOSB members receive a lot of materials, both electronically and in hard copy; staying organized can be a challenge. Members may want to create a file cabinet specifically for the NOSB, with files created yearly for each Subcommittee. Subcommittee Chairpersons and Vice Chairpersons should save all versions and file them, while Subcommittee members can just save the final copy. Public comments that you receive at the meetings can be filed, or you can find them archived on the NOP web site.

Optimizing Conference Calls and Meetings

Because members are based in all regions of the country, a great deal of the work of the NOSB is conducted over the phone. Subcommittees are encouraged to develop the agenda together with key Subcommittee members, provide ample notice of the date and time of the meeting/conference calls, review the agenda and all documents related to agenda items, start and finish on time, and review action items. The DFO will take notes at all conference calls and will send out periodic updates to a master calendar of the scheduled Subcommittee conference calls with phone-in numbers and pass codes (required to access calls). Executive Subcommittee calls are scheduled the second Friday of each month and consist of only the NOSB officers, Subcommittee Chairpersons, and NOP personnel. NOSB members are welcome to listen in, but are not permitted to vote. All Subcommittee meeting notes are posted on the NOP website for public access.

Organizing Email

To help optimize NOSB productivity, it is important to consistently organize and respond to emails. You are encouraged to create specific folders for each Subcommittee and utilize a filing system that works for you, keeping in mind that you don't need to save every email you receive from NOP or NOSB members.

Tips for Success:

- Check your inbox on a daily basis.
- Use a clear subject line, noting NOSB and the appropriate Subcommittee
- Be concise and answer all questions within 24-48 hours.
- Do not attach unnecessary files.
- Do not overuse Reply to All.
- Try not to write with abbreviations.

Tracking Changes in Word Documents

Drafting and revising NOSB discussion documents and proposals require combining feedback from multiple people at multiple steps. The Microsoft Word track changes feature can help facilitate this, allowing you to merge all versions and view all edits at once. You are then able to accept or reject edits, resulting in a final version. A few tips are included below; a full demo is found in **http://office.microsoft.com/training**.

Turning on Track Changes

After opening your document:

Word 1997-2003:

- Go to Tools, select Track Changes.
- The review toolbar will appear at the top
  "TRK" will show on the status bar (bottom of the screen)
-

Word 2007 and 2010:

- Select the Review tab
- Click Track Changes

All edits will be shown in the document in colored font. If you find it distracting to view the edits, you can select to view "Final" instead of "Final Showing Markup". If you no longer need to track changes, you can click on Track Changes to turn it off.

Reviewing Documents with Track Changes

To determine who proposed a given change, hold your curser over the change. The review toolbars allow you to approve, reject, or edit in two simple steps. First, place your cursor over the edited text. Second, click the  button to accept the edit. This will delete the track change and restore your document without showing edits. To reject the change, click the  button. This will reject the suggested edit and return your document to its original state. The **Next**  and **Previous**  buttons allow you to navigate through the document quickly. Using the drop down list on the  and  buttons, allows you to accept or reject all changes in the document at once.

There are two features in TRK that help in the review process, the **Reviewing** and **Show** toolbars. The drop-down arrow in the **Reviewing** toolbar, allows you to view the document at different stages of editing. For example, the **Original Showing Markup** selection displays all edits from all contributors highlighted in different colors. The **Original** selection presents the document prior to any edits. The **Show** toolbar allows you to select edits by type such as comments, insertions and formats. This toolbar also allows you to isolate edits by reviewer name. To print a list of changes made in a document, select Print (Word 1997-2003: File, Print; Word 2007: Microsoft Office button (top left), Print); in the Print what box, click "List of markup; Word 2010: Microsoft Office button (top left), Print); Under Settings, click the Print what box, click "List of markup."

Traveling to NOSB Meetings

Airline Reservations

The USDA Travel Coordinator will provide each person with an approved authorization number that will be provided to the USDA's Travel Service. The authorization will be sent to each Board member via email. USDA is responsible for paying all airline costs. However, members are responsible for arranging their own airline reservations. Each Board member must contact Michele Green or Kim Webster, at Boersman Travel 888-291-6705, and identify themselves as USDA/Agricultural Marketing Service (AMS). The travel service is aware that they should obtain the best Federal government rate when possible; however, if your airline rate is over $800, please contact the Advisory Board Specialist, National Organic Program (NOP), for approval. Boersman emergency assistance is provided outside of normal business hours by calling 866-648-7861.

After scheduling your airline reservations with Boersman, you will receive an email acknowledgement from Virtually There at www.virtuallythere.com detailing your reservations and flight information. If you reserve a refundable government ticket, you could receive your tickets approximately one week prior to travel. If you reserve a non-refundable restricted ticket, you will be ticketed within 48 hours.

Reminder: When traveling to attend an NOSB meeting, members are not authorized to use personal credit cards to pay for airline tickets or utilize another travel service on behalf of USDA/AMS. You will not be reimbursed. Please note that USDA is responsible for paying all airline costs.

It is important to notify your travel coordinator if you plan to arrive or depart outside of the intended travel dates authorized. Also, provide notification if you plan to combine personal or business travel to attend the NOSB meeting.

Personal Owned Vehicles (POV)

If you need to travel using your own POV, please notify the travel coordinator via email, and provide mileage to/from the meeting, and dates of arrival and departure to/from residence.

Rental Car and Train Reservations

If there are no flights to/from an airport or other modes of transportation available, and your only option is to use a rental car or train to/from a meeting, you must state why it would be advantageous to the Federal government. If the cost of a rental car (including gas), or a train ticket is less than the cost of an airline ticket this would be advantageous to the Federal government. USDA will reimburse you. However, if the rental car or train cost is more than the airline, then you are responsible for paying the difference.

To reserve a rental car or train, you must obtain prior approval at least two weeks before a meeting. Submit to the travel coordinator a written justification stating your need, and include a cost comparison for the rental car, train and airline outlay. You can either locate a local rental car or train service and make your own reservation or submit your request to Boersman Travel service. Members are not allowed to use a rental car for travel to/from hotel to obtain dinner. You will not be reimbursed.

Meeting Space and Lodging Accommodations

USDA/NOP is responsible for reserving and paying all expenses for the meeting space and lodging. Members should not make their own hotel reservations as we will have a special block reserved. However, if you plan to modify your arrival/departure travel dates for personal reasons, please contact the hotel and travel coordinator. To avoid "no show" charges, it's important that the hotel is aware of travel date modifications. Personal travel is non-reimbursable.

Post-Travel Document

After each meeting, the travel coordinator will forward to all members a post-travel document that should be completed and signed as soon as possible. Submit all applicable receipts (with the exception of meals) to the travel coordinator for reimbursement. Travel documentation can be faxed, emailed or mailed to the attention of Travel Coordinator.

Travel reimbursement will include the following

- Rental Car or Train expense (if applicable)
- Location per diem (meals + incidentals)
- POV mileage to/from airport or meeting at the current GSA per diem rate
- Roundtrip tolls
- Airport parking
- Local Transportation: Taxi cab fares to/from airport to hotel, or residence; tips not to exceed 15% of the fare, Shuttle services to/from airport to hotel, or residence
- Airline baggage fees

Submit your travel voucher information to:

Special Assistant to the Board
USDA/National Organic Program
1400 Independence Avenue, SW
Washington, D.C. 20250
(202) 720-3252, Fax: (202) 205-7808

What to Pack?

The dress code at NOSB meetings is business casual. It's suggested you bring some casual attire as well. Most of the hotels also have work-out rooms and pools. For the most part, dress is not too important as long as you are representing the NOSB professionally.

The agenda, proposals and any supporting documents will all be available prior to meetings at **www.ams.usda.gov/nosb/meetings/meetings.html**. Materials will be provided to you before or at the meetings in hard copy or on a thumb drive or CD. Other useful documents include a copy of OFPA and the Federal Register Regulation, which will be provided upon request and are also available electronically. If you have a travel mug, please bring it along. It doesn't make a very good impression if we are all using non-recyclable cups.

List of Common Technical Sources Used by NOSB Members

Very often during the review process and discussions, NOSB members need to consult various sources of information. The following is a general list of common technical sources.

Accredited Certification Agencies

The function of the Accredited Certification Agencies (ACAs) is to certify, on behalf of USDA, that producers and handlers comply with approved organic practices. An ACA is accredited by the NOP. They operate in all regions of the United States and selected countries, and include private companies, not-for-profit organizations and several state government agencies.

For a comprehensive list of ACAs: **http://www.ams.usda.gov/NOPACAs**

Federal Agencies

U.S. Department of Agriculture/Marketing Service
http://www.ams.usda.gov/

U.S. Department of Agriculture Research Service
http://www.ars.usda.gov

U.S. Department of Agriculture/Food and Nutrition Service
http://www.fns.usda.gov/fns/

U.S. Department of Agriculture/Food Safety and Inspection Service
http://www.fsis.usda.gov

U.S. Department of Agriculture/National Agricultural Library Alternative Farming Systems Information Center
http://www.nalusda.gov/afsic/ofp/susagrsch.htm

U.S. Department of Agriculture/National Institute of Food and Agriculture
http://www.csrees.usda.gov

U.S. Environmental Protection Agency Integrated Risk Information System
http://www.epa.gov/iris

U.S. Department of Agriculture/National Organic Program
http://www.ams.usda.gov/nop

U.S. Department of Agriculture/Sustainable Agriculture Research and Education Program
http://www.sare.org/index.htm

U.S. Environmental Protection Agency Inert Ingredients Permitted in Pesticide Products
http://www.epa.gov/opprd001/inerts/lists.html

U.S. Environmental Protection Agency Organic Agriculture Page
http://www.epa.gov/oecaagct/torg.html#National%20Organic%20Standards
U.S. Environmental Protection Agency Water
http://www.epa.gov/ow/

U.S. Environmental Protection Agency Water Science
http://www.epa.gov/waterscience/

U.S. Department of Health and Human Services Agency for Toxic Substances and Disease Registry
http://www.atsdr.cdc.gov/atsdrhome.html

U.S. Food and Drug Administration's Center for Food Safety and Applied Nutrition
http://www.cfsan.fda.gov/list.html

U.S. Food and Drug Administration's Center for Food Safety and Applied Nutrition - Food Ingredients and Packaging Terms
http://www.cfsan.fda.gov/~dms/opa-def.html

U.S. Food and Drug Administration's Center for Food Safety and Applied Nutrition Indirect" Additives Used in Food Contact Substances
http://www.cfsan.fda.gov/~dms/opa-indt.html

U.S. Food and Drug Administration's Center for Food Safety and Applied Nutrition Inventory of Effective Food Contact Substance Notifications **http://www.cfsan.fda.gov/~dms/opa-fcn.html**

U.S. Food and Drug Administration's Center for Veterinary Medicine
http://www.fda.gov/cvm

U.S. Food and Drug Administration's Food Safety Risk Analysis Clearinghouse
http://www.foodriskclearinghouse.umd.edu/

U.S. Food and Drug Administration's Numerical Listing of GRAS Notices
http://www.cfsan.fda.gov/~rdb/opa-gras.html

U.S. National Institute of Health's National Institute of Environmental Health Sciences
http://www.niehs.nih.gov/centers/res-core/iowares2.htm.

U.S. Occupational Safety and Health Administration
http://www.osha.gov

Other Sources

Appropriate Technology Transfer to Rural Areas
http://www.attra.org

Organic Materials Review Institute
http://www.omri.org

The National Sustainable Agriculture Information Service
http://www.attra.org

Glossary of Acronyms

ACA	Accredited Certifiers Association
AMS	Agricultural Marketing Service (home of NOP)
EPA	Environmental Protection Agency
FACA	Federal Advisory Committee Act
FDA	Food and Drug Administration
NOP	National Organic Program
OFPA	Organic Foods Production Act of 1990 (Title XXI of the 1990 Farm Bill)
OMRI	Organic Materials Review Institute
TAP	Technical Advisory Panel
USDA	United States Department of Agriculture

National Organic Standards Board Subcommittees

NOSB Officers (2013)

Robert (Mac) Stone	Chairperson
John Foster	Vice Chairperson
C. Reuben (Calvin) Walker	Secretary

Executive Subcommittee Representatives (2013)

Jay Feldman, Chairperson	Crops
Joe Dickson, Chairperson	Compliance, Accreditation & Certification
John Foster, Chairperson	Handling
Tracy Favre, Chairperson	Livestock
Zea Sonnabend, Chairperson	Materials
Colehour Bondera, Chairperson	Policy Development
Jennifer Taylor, Chairperson	GMO ad hoc

CROPS

Jay Feldman, Chairperson
Nick Maravell, Vice Chairperson
Harold Austin
Carmela Beck
Colehour Bondera
John Foster
Zea Sonnabend
Mac Stone (unofficial, non-voting)
Francis Thicke

COMPLIANCE, ACCREDITATION, CERTIFICATION

Joe Dickson, Chairperson
Jean Richardson, Vice Chairperson
Harold Austin
Carmela Beck
Tracy Favre
John Foster
Mac Stone
C. Reuben (Calvin) Walker

HANDLING

John Foster, Chairperson
Harold Austin, Vice Chairperson
Carmela Beck
Joe Dickson
Tracy Favre
Nick Maravell
Jean Richardson
Zea Sonnabend

GMO ad hoc

Jennifer Taylor, Chairperson
Zea Sonnabend, Vice Chairperson
Colehour Bondera
Jay Feldman
Jean Richardson
Mac Stone
Francis Thicke
C. Reuben (Calvin) Walker

LIVESTOCK

Tracy Favre, Chairperson
Wendy Fulwider, Vice Chairperson
Colehour Bondera
Joe Dickson
Nick Maravell
Jean Richardson
Mac Stone
Francis Thicke
C. Reuben (Calvin) Walker

MATERIALS

Zea Sonnabend, Chairperson
Jennifer Taylor, Vice Chairperson
Joe Dickson
Tracy Favre
Jay Feldman
Wendy Fulwider
C. Reuben (Calvin) Walker

POLICY DEVELOPMENT
Colehour Bondera, Chairperson
C. Reuben (Calvin) Walker, Vice Chairperson
Jay Feldman
John Foster
Nick Maravell
Jennifer Taylor

INERTS WORKING GROUP
Jay Feldman
Zea Sonnabend

VACCINES MADE WITH EXCLUDED METHODS WORKING GROUP (Vaccines MWEM)
Jean Richardson
Nick Maravell

National Organic Program – Contact Information

This directory is updated fairly often, and can be found here:
http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5086703

National Organic Standards Board
Policy Development Subcommittee
Proposal
Public Communications

January 22, 2013

I. Introduction

The National Organic Standards Board (NOSB) recognizes that members have been specifically appointed to NOSB to provide advice and counsel to the Secretary concerning policies related to the development of organic standards and the creation and amendments to the National List (NOSB Policy and Procedures Manual, pg. 9). A part of the NOSB's responsibility is to communicate with the organic community pertaining to the implementation of Organic Foods Production Act (OFPA); the NOSB must receive and review information from USDA's National Organic Program (NOP) and other sources during its deliberations. The input from the organic community is valuable in the deliberations of NOSB, the NOP, and the community decision-making process. NOSB recommends that the NOP establish a year-around online communication mechanism(s) for stakeholders to communicate with NOSB and the NOP on matters of interest and concern.

II. Background

The Federal Advisory Committee Act (FACA) regulations on "Meeting Obligations to the Public" (41 CFR 102-3.140) states that, "Any member of the public is permitted to file a written statement with the advisory committee during meetings." A written statement received during the comment period for scheduled NOSB meetings has been the primary method by which the public communicates with the Board.

Nevertheless, NOSB members also receive public communications outside of the designated public comment period. These communications include verbal and written information. In response to a previous public communications proposal, the NOSB received public comments that overwhelmingly supported the establishment of a mechanism that would provide for a central location for all public communications to the NOSB and NOP, enable transparency in public communications, and provide access to information from the organic community.

III. Discussion

The NOSB through its Policy and Procedures Manual establishes procedures for its activities. The manual "is designed to assist NOSB in its responsibilities" (PPM, p4) and establish procedures for carrying out its responsibilities in accordance with its advisory mission.

As a part of its responsibility to communicate with the organic community pertaining to the implementation of OFPA, the Board must receive and review information from the

NOP and other sources during its deliberations. As a stakeholder Board, the input from the organic community is valuable in the deliberations of the Board, the NOP, and the community decision-making process. The procedures of the Board and NOP should facilitate public communication to inform these deliberations.

Providing an online mechanism that allows the public to share information between official comment periods will help to facilitate public communication that informs the Board's and NOP's deliberations in several ways. The online system is intended to:

1. Inform discussions early in the materials or policy review process through the collection of complete background and perspectives;
2. Reduce the amount of new information coming to the Board and NOP late in its deliberations on an issue without adequate time to verify or fully assess it;
3. Increase transparency for the NOSB, NOP, and the public itself to ensure that everyone has access to the same information in a timely fashion;
4. Help the Board and NOP to become aware of issues that may not be on the work plan or may not have been generated internal to the NOP and NOSB process, but are important based on the experience and expertise of those in the organic community.

Thus, an online public communication mechanism can help board members to discharge their "Duty of Care," which "calls upon a member to participate in the decisions of the Board and to be informed as to the data relevant to such decisions." (PPM, p. 6)

IV. Recommendation

1. *The NOSB proposes amending* PPM Section VI, Miscellaneous Policies (page 27) to add a new subcategory (in italics).

Policy for Public Communication between NOSB Meetings.

The NOSB and NOP seek public communication outside of Board biannual meetings and public comment periods to inform the NOSB and NOP of stakeholders' interests, and to comment on the NOSB's and NOP's work activities year around.

PPM Section II (page 13) adds a phrase to the Role of an Advisory Board Specialist to include the following language (in italics):

With support from NOP, identify, implement, administer and maintain a year-round public communication mechanism (Internet and other means) by which public feedback can be received, posted, and archived online for viewing by the NOSB, the NOP, and the public.

V. Committee Vote
Moved: Jay Feldman Second: Jennifer Taylor

Yes: 6 No: 0 Abstain: 0 Absent: 2 Recuse: 0

National Organic Standards Board
Policy Development Subcommittee
Discussion Document
NOSB Initiation of Materials Review

February 12, 2013

Background

It may be necessary to clarify in the Policy and Procedures Manual (PPM) of the National Organic Standards Board (NOSB) the process by which material review requests may be initiated. This process may be distinct from the normal public petition process. Examples of situations in which this process may arise are when the NOSB or NOP is notified that:

(1) a nonsynthetic material appears not to meet the criteria of the Organic Foods Production Act (OFPA), resulting in confusion by growers;
(2) there has been a reevaluation of a substance's classification by a review organization, calling into question its existing use; and,
(3) new information that requires prompt revisiting of a recent decision.

The basis for the review process flows from the NOSB's responsibility to propose amendments to the National List and the procedures by which it considers these amendments. The NOSB's authority to make these proposed amendments stems from the Organic Foods Production Act (OFPA):

SEC. 2118 [7 U.S.C. 6517] NATIONAL LIST
(d) PROCEDURE FOR ESTABLISHING NATIONAL LIST. –
(1) IN GENERAL.- The National List established by the Secretary shall be based upon a proposed national list or proposed amendments to the National List developed by the National Organic Standards Board.
(2) NO ADDITIONS.- The Secretary may not include exemptions for the use of specific synthetic substances in the National List other than those exemptions contained in the Proposed National List or Proposed Amendments to the National List.

The PPM contains policy dealing with NOP requests for modified or new standards in the NOSB-NOP Collaboration section of the PPM (p25), #2:

> **Recommendation for modification of existing standards or new standards.** The NOSB will use the decision making procedures outlined in Section VIII to justify modifying existing standards or proposing new standards. 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 receiving the recommendation. The request will be posted on the NOP web site.

Issue and Discussion

The process of identifying issues is outlined under Step 1 of the Procedures of the NOSB, section on Committee Work Plans. “Step 1, Identifying all issues” is outlined on p. 33 of the Policy and Procedures Manual (December 2011.) It is stated there:

> The committee work plan rises out of these main situations:
>
> - Items committed, or assigned to a subcommittee, by the Board during an official session.
> - Items that are reviewed by a subcommittee on a regular basis such as materials sunset review or petitions submitted by members of the public.
> - Requests or suggestions from the National Organic Program such as clarifications on a particular issue or guidance on enforcement.
> - Proposals stemming from the subcommittee members’ contact with the organic community.

Under the last bullet above, it is clear that the subcommittee members may initiate a “proposal.” Assuming that these proposals may include materials review, the process for initiating that review appears to need clarification. This section is followed by the Materials Review Process (p. 34), which then references a “receipt” of petition. It is that part of the process that may need clarification.

OFPA §6518(n) states, “The Board shall establish procedures under which persons may petition the Board for the purpose of evaluating substances for inclusion on the National List.” The law does not make distinctions based on the “persons” who may petition the board—, the NOP, NOSB, commercial interests, and the general public are all included. Therefore, it is the board’s responsibility to establish procedures for any situations that do not fit the currently established petition procedures. This may include the situations outlined above or others.

Priority. The PPM assigns levels of priority to different types of petitions (p. 49). That is,

1. Reviews to Remove a Material From the National List:

a. A proposal to **remove** a material presently on the National list that raises serious health, environmental, or regulatory concerns, including petitions to reconsider previous decisions, will be given the highest priority - **Priority 1,** above all other petitions in the queue of the reviewing committee (Crops, Handling, or Livestock).

b. A proposal to **remove** a material presently on the National list not based on serious health, environmental, or regulatory concerns, but based on other new information, such as commercial availability status, would be assigned a **Priority 2,** behind Priority 1 petitions, but above any petitions to list materials that are in the queue of the reviewing

committee (Crops, Handling, or Livestock). This priority assignment would include any removal proposals requesting reconsideration of previous board decisions, if the proposal contains substantive new information to warrant reconsideration. [The process also includes reconsideration of the classification of materials currently considered nonsynthetic because that is a *de facto* delisting of the material.]

2. Petitions to Add a Material to the National List: Proposals to add materials to the National List of allowed synthetics might arise from reconsideration of the classification. A proposal to **add** a material to the National List will be considered by the reviewing committee (Crops, Handling, or Livestock) in the chronological order it is received, and will be designated as **Priority 3**. [The process also includes reconsideration of the classification of materials currently considered synthetic.]

3. Petitions to Reconsider a Material for Addition to the National List: A proposal to **reconsider** adding a material that had previously been rejected by a board vote would be given the lowest priority - **Priority 4**, and would go to the bottom of the committee (Crops, Handling, or Livestock) queue of petitioned materials. Proposals for listing a substance that had been previously rejected by the board must contain substantive new information to warrant reconsideration.

Public participation. When a material is petitioned, the petition becomes available on the NOP website. Technical reviews are also posted when finalized. The public needs to have similar access to information involving reviews that do not arise from the normal petition process.

Comments Requested

Clarify the process to initiate reviews for annotation of materials by the NOSB, the public, and NOP.

1. Should an NOSB subcommittee utilize the public petition process when proposing changes to the National List?
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?
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?
4. How and when should the public be notified that the NOSB has initiated a review if it is added to the work plan?
5. Is it reasonable to interpret the NOSB-NOP Collaboration section of the PPM (p25), #2 **Recommendation for modification of existing standards or new standards,** as quoted above, to include the listing, delisting, or annotating National List materials?
6. Is the current system for determining the priority of reviews (PPM, p.49) acceptable? If not, please list any concerns?

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

Subcommittee Vote:
The Policy Development Subcommittee moves to accept this document and present it for full Board discussion at the spring 2013 NOSB meeting:

Moved: Jay Feldman Second: Nick Maravell

Yes: 6 No: 0 Abstain: 0 Absent: 0 Recuse: 0

National Organic Standards Board
Livestock Subcommittee
Petitioned Material Proposal
Required Synthetic Amino Acids for Pet Foods

February 5, 2013

Summary of Proposed Action:
Thirteen synthetic amino acids were petitioned for use in organic pet foods. The Subcommittee evaluated the petition and 2012 technical report (TR), and had discussions with State Feed Control Officials. Based on this information, the Subcommittee concluded that only Taurine for cats was deemed necessary as a synthetic additive to meet nutritional requirements and thus should be allowed in organic pet food. The Subcommittee determined that the manufacturers could meet the required levels of Arginine, DL-Methionine, Cysteine, L-Lysine, Tryptophan, Threonine, Histidine, Isoleucine, Leucine, Phenylalanine, Tyrosine, and Valine to meet the criteria for "complete and balanced" as required by American Association of Feed Control Officials (AAFCO) with organic agricultural ingredients.

Evaluation Criteria

(Applicability noted for each category; Documentation attached)	**Criteria Satisfied?**		
Impact on Humans and Environment	☒ Yes	☐ No	☐ N/A
1. Essential & Availability Criteria	☒ Yes	☐ No	☐ N/A
2. Compatibility & Consistency	☒ Yes	☐ No	☐ N/A
3. Commercial Supply is Fragile or Potentially Unavailable	☐ Yes	☐ No	
☒ N/A as Organic (only for § 205.606)			

Substance Fails Criteria Category: [ ] **Comments:**

Proposed Annotation (if any): 205.603(d)(4) Taurine (CAS 107-35-7) for use in cat food only

Basis for annotation: ☒ To meet criteria above ☐ Other regulatory criteria ☐ Citation
Notes: The other 12 petitioned Amino Acids failed to meet the necessity criteria as manufacturers should be able to meet the required AAFCO levels through use of organic agricultural ingredients.

Recommended Committee Action & Vote, including classification recommendation (state actual motion):

Classification Motion: Motion to classify amino acids (Arginine, Methionine, Cystine, Lysine, Taurine, Tryptophan, Threonine, Histidine, Isoleucine, Leucine, Phenylalanine, Tyrosine, and Valine) as synthetic.

Motion by: Mac Stone Seconded by: Jean Richardson
Yes: # 9 No: # 0 Absent: # 0 Abstain: # 0 Recuse: # 0

Listing Motion: Motion to list amino acids (Arginine, Methionine, Cystine, Lysine, Tryptophan, Threonine, Histidine, Isoleucine, Leucine, Phenylalanine, Tyrosine, and Valine) on section 205.603 for use in organic pet food.
Motion by: Mac Stone Seconded by: Colehour Bondera
Yes: # 0 No: # 9 Absent: # 0 Abstain: # 0 Recuse: # 0

Listing Motion: Motion to list taurine CAS (107-35-7) at 205.603(d), as a feed additive, for use in cat food only
Motion by: Mac Stone Seconded by: Jean Richardson
Yes: # 8 No: # 0 Absent: # 0 Abstain: # 1 Recuse: # 0

Crops	☐	**Agricultural**	☐	**Allowed[1]**	☒
Livestock	☒	**Non-synthetic**	☐	**Prohibited[2]**	☐
Handling	☐	**Synthetic**	☒	**Rejected[3]**	☐
No restriction	☐	**Commercial unavailable as organic**	☐	**Deferred[4]**	☐

[1]Substance voted to be added as "allowed" on National List to § 205.603 with Annotation (if any): Taurine (CAS 107-35-7) on 206.603(d)(4) for use in cat food only

[2]Substance to be added as "prohibited" on National List to § 205. with Annotation (if any):
Describe why a prohibited substance:

[3]Substance was rejected by vote for amending National List to § 205.603 .
Describe why material was rejected: NOTE: 12 petitioned amino acids were rejected for lack of necessity to formulate complete and balanced feeds for cats and dogs. The Subcommittee determined that manufacturers should be able to meet the AAFCO required levels through use of agricultural ingredients.

[4]Substance was recommended to be deferred because

Approved by Subcommittee Chair to Transmit to NOSB
Tracy Favre February 5, 2013

NOSB Evaluation Criteria for Substances Added To the National List

Category 1. Adverse impacts on humans or the environment?
Substance: Amino Acids for Pet Food

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]		x		
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		x		
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]		x		
4. Does the substance contain List 1, 2 or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]		x		
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		x		
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		x		
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		x		
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		x		
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]		x		
10. Are there any harmful effects on human health? [§6517 c (1)(A)(i); 6517 c(2)(A)i; §6518 m.4]		x		
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]			x	
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]			x	
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		x		

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB Evaluation Criteria for Substances Added To the National List

Category 2. Is the Substance Essential for Organic Production?
Substance: Amino Acids for Pet Food

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]	x			
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]	x			
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		x		
4. Is there a natural source of the substance? [§205.600 b.1]	X			The petition states the plant and animal sources of each AA.
5. Is there an organic substitute? [§205.600 b.1]	x			From the listed sources of AA in the petition, some of these agricultural ingredients may be organic.
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]	X Taurine	Arginine, DL-Methionine, Cysteine, L-Lysine, Tryptophan, Threonine, Histidine, Isoleucine, Leucine, Phenylalanine, Tyrosine, Valine		From the TR and petition and discussions with Feed Control Officials, only Taurine was determined absolutely necessary for cats, for diet formulators to meet AAFCO guidelines. The other twelve amino acids can be provided through use of agricultural ingredients.
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	X	Not for taurine		The TR indicates that natural forms of taurine are less available in agricultural products and degraded during commercial processing to the point the nutritional

				requirements of cats cannot be maintained.
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]		x		
9. Is there any alternative substances? [§6518 m.6]	Yes for other amino acids	Not for taurine		The petition and TR indicate the non-synthetic forms of taurine from any source are degraded during processing moreso than the other AA.
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	Yes for other amino acids	Not for taurine		The TR describes how raw food diets of organ meats, bone, fat, and meat are a substitute, with risk to nutritional imbalance and bacterial contamination

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB Evaluation Criteria for Substances Added To the National List

Category 3. Is the substance compatible with organic production practices?
Substance: Amino Acids for Pet Food

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]	X - Taurine only			Synthetic vitamins and minerals are allowed in organic foods and livestock feeds to maintain the nutritional quality. 205.603(d)(2)(3)
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]	X - Taurine only			The petition describes which organic agricultural products and by-products are used in the production of pet foods. Taurine is not readily available in these products. Providing optimum nutrition to animals under our care is a tenant of organic farming.
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]	x			
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]	X – Taurine			Consultation with AAFCO officials confirm our ingredient panel surveys that to meet the nutritional requirements for cats can only be accomplished with synthetic form supplementation.
5. Is the primary use as a		x		

preservative? [§205.600 b.4]				
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]	X Taurine			Due to the degradation during heat processing and preservation required for pet food manufacture as stated in the petition and TR.
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: a. copper and sulfur compounds;		x		Numerous synthetic amino acids are added during processing of commercial pet foods is common in the manufacture of pet foods as stated in the petition and TR.
b. toxins derived from bacteria;		x		
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?		x		
d. livestock parasiticides and medicines?		x		
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?			x	

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB Evaluation Criteria for Substances Added To the National List

Category 4. Is the commercial supply of an agricultural substance as organic, fragile or potentially unavailable? [§6610, 6518, 6519, 205.2, 205.105 (d), 205.600 (c) 205.2, 205.105 (d), 205.600 (c)] **Substance: Amino Acids in Pet Food**

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the comparative description provided as to why the non-organic form of the material /substance is necessary for use in organic handling?			X	
2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **form** to fulfill an essential function in a system of organic handling?			X	
3. Does the current and historical industry information, research, or evidence provided explain how or			X	

why the material /substance cannot be obtained organically in the appropriate **quality** to fulfill an essential function in a system of organic handling?				
4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quantity** to fulfill an essential function in a system of organic handling?			X	
5. Does the industry information provided on material / substance non-availability as organic, include (but not limited to) the following: a. Regions of production (including factors such as climate and number of regions);			X	
b. Number of suppliers and amount produced;			X	
c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;			X	
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or			X	
e. Are there other issues which may present a challenge to a consistent supply?			X	

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

National Organics Standard Board
Livestock Subcommittee
Proposal: Required Synthetic Amino Acids for Pet Foods
February 5, 2013

Introduction

The growth of the organic food sector extends into the pet food market. Consumers are looking for organic alternatives for their pets because they understand the strict policies behind the organic seal and it corresponds with their values in terms of no Genetically Modified Organisms (GMOs), transparent sourcing of ingredients, and lessened environmental impact of production. Certifiers currently certify pet food products by following relevant sections of the USDA organic regulations as it pertains to livestock feed, processed products, and associated labeling requirements. Specific organic pet food standards are not currently part of these regulations; however, the National Organic Program (NOP) is currently drafting a Proposed Rule to regulate organic pet food based on the 2008 NOSB recommendation.

In some cases, synthetic amino acids, like vitamins and minerals, have been allowed for organic pet food, if required by the U.S. Food and Drug Administration. However, the NOP recently reviewed the allowance for nutrients, including amino acids, for use in organic processed products such as organic pet food, and determined that the NOSB should review these nutrients through the petition process. Therefore, the Pet Food Institute has petitioned the NOSB to place the 13 essential synthetic amino acids for dogs and cats on the National List. Sourcing organic ingredients to meet the amino acid needs of pets and achieve “organic” or “made with organic” status is challenging in terms of seasonal and geographic constraints on availability of feedstuffs. Dogs, cats, and specialty pets that live in tanks or cages, have dietary demands that must be met with a sole source feed formulation specific to their species and stage of life.

Background

Meeting the nutritional needs of pets with a single source of feed requires manufacturers to follow strict dietary guidelines. These guidelines are regulated by a series of regulators and scientific communities. The Food and Drug Administration (FDA) regulates pet food under the Federal Food, Drug, and Cosmetic Act that requires all animal feeds, like human foods, to be safe to eat, produced under sanitary conditions, contain no harmful substances, and be truthfully labeled. The FDA Center for Veterinary Medicine (CVM), that manages the non-human aspect of the regulation for the agency, accepts the determination of an *ad hoc* expert nutrition committee under the Committee on Animal Nutrition for the National Research Council (NRC) in the National Academy of Sciences to establish nutrient requirements for dogs, cats, and all other species of animals. For dogs and cats, the required essential nutrients are listed and described in the *NRC 2006 edition of Nutrient Requirements of Dogs and Cats.* The 2006 edition is the standard State Feed Control Officials use when evaluating diet formulations and to verify labels as sufficient for use in their state. These State Feed Officials have formed the Association of American Feed Control Officials (AAFCO) to act as a forum and clearinghouse for developing an overall regulatory structure that is consistent across the country for continuity of interstate commerce. FDA officials sit on the standing committees of this organization to ensure

compliance with the regulations. The State Feed Control Officials implement the regulatory process through their legislative system.

Through this system, for a pet food to make the label claim “complete and balanced,” it must meet the standards in the NRC 2006 edition of Nutrient Requirements for Dogs and Cats.

The current AAFCO standard classifies 13 amino acids (AA) as essential for dogs and cats (Appendix). This means they cannot be synthesized by the body and must be supplied by the feed. All of these AA are naturally occurring in nature. Prior to domestication, these animals sought out food sources to supply these AA in the correct balance to meet their needs. With domestication came the need to supply the animals a complete and balanced diet with the correct food sources. It can be difficult to achieve the required balance of AA given access to ingredients and the processing requirements for preserving and packaging them for market. These AA are also manufactured by chemical synthesis, fermentation, and enzymatic synthesis to supplement diets that may be deficient in one or more of them. The AA produced from each of these processes would be considered synthetic under the working definition of the NOSB. The fermentation process could use excluded methods.

Some pet foods on the market are certified organic without the use of synthetic AA and meet the complete and balanced claim, albeit a very small segment of the market. Some are certified with the understanding that synthetic nutrients, including synthetic AA are allowed, along with vitamins and minerals, without regard to source and “other ingredients” under the livestock feed standards. Certifiers, to date, are using the livestock feed standards at 7 CFR 205.237 for processing and handling; and label standards at section 205.301 to certify these products.

In 2012, the NOP notified the industry that these amino acids must be petitioned individually, as they do not fall under the current allowance for vitamins and minerals on the National List. In 2005, a Pet Food Task Force (PFTF) was formed by the NOSB and NOP to advise the NOSB on future recommendations to implement pet food standards. This led to the NOSB making recommendations to the NOP in fall 2008 on numerous changes to regulate pet foods in the USDA organic regulations. These recommendations included the use of mammalian and poultry products and by-products as allowed since pets are not part of the food chain. This point is the fundamental reason pet foods must be distinguished from livestock feeds. It also clarified labeling requirements, and the need for additions to the National List. Currently the NOP intends to announce proposed rulemaking on this topic in 2013. When the rulemaking process is complete, only approved synthetic AA will be allowed in organic pet foods.

Discussion

The Pet Food Institute has petitioned the NOSB to place Arginine, Methionine, Cystine, Lysine, Taurine, Tryptophan, Threonine, Histidine, Isoleucine, Leucine, Phenylalanine, Tyrosine, and Valine, as synthetic AA, on the National List. These AA, must be supplied by the feed, in some form, at minimum levels, for the feed to meet the AAFCO standards of complete and balanced. However, the petition states that

Threonine, Histidine, Isoleucine, Leucine, Phenylalinine, and Valine are available in agricultural products used as feedstuffs and will not need to be utilized in synthetic form. Therefore, the committee focused its work on Arginine, Methionine, Cystine, Lysine, Taurine, and Tryptophan, the AA listed on the 2008 NOSB pet food recommendation as potentially necessary in synthetic form. Carnitine was also on the 2008 recommendation however, it is not part of this petition.

Dog foods must be at least 22% protein, however, some go much higher to mimic natural diets. The higher protein (meat based) diets may require less AA supplementation, yet be more expensive to produce. Many commercial dog food formulations have synthetic Taurine, DL-Methionine, L-Lysine and Carnitine listed on the ingredient panel. In addition, there are many dog foods on the market with no added synthetic AA.

Virtually all cat foods have synthetic Taurine because of the relatively high requirement for cats, and degradation during processing no matter the protein percentage. Many cat foods also list synthetic Methionine and Lysine on their labels. The Technical Report states several pet food brands are on the market as complete and balanced without the use of synthetic AA.

There is no mention of “other ingredients” such as anti-oxidants, carriers, etc. associated with these AA. The committee would like to know more about other ingredients associated with these products. Those derived from fermentation would have to document no excluded methods are used in the process. It is reported that Taurine is particularly sensitive to heating and is severely degraded in the manufacturing process.

The use of synthetic AA in pet foods is based on the ability of the manufacturer to formulate a diet that supplies the correct balance of AA to meet AAFCO standards of “complete and balanced”. 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. It is unclear from the information at hand that the allowance of synthetic AA will foster the expanded use of organic by-products and other organic inputs because manufacturers will be have these limiting AA at their disposal. It is also unclear that if these synthetic AA are available to manufacturers, if it will allow the use of lower quality ingredients, supplemented with these AA, to be more competitive in the market place.

Relevant Areas of the Rule

The 2008 NOSB recommendation proposed a change to the organic regulations to support labeling of organic pet food and provide clarity where any conflicts may have existed between organic labeling claims and the existing state requirements for pet food labeling. The intent of the proposed regulation was to create a pet food label that is consistent with labeling for human food.

Appendix

	AAFCO Dog Food Nutrient Profiles			
		Growth	Adult	
	Units	Reproduct	Maintena	
	Basis	Minimu	Minimu	Maximum
Arginine	%	0.62	0.51	
Histidine	%	0.22	0.18	
Isoleucine	%	0.45	0.37	
Leucine	%	0.72	0.59	
Lysine	%	0.77	0.63	
Methionine-	%	0.53	0.43	
Phenlyalanine-	%	0.89	0.73	
Threonine	%	0.58	0.48	
Tryptophan	%	0.20	0.16	
Valine	%	0.48	0.39	

	AAFCO Dog Food Nutrient Profiles			
	Units	Growth &	Adu	
	1000	Reproduct	Maintenan	
	M	Minimum	Minimum	Maximum
Arginine	g	1.77	1.46	
Histidine	g	0.63	0.51	
Isoleucine	g	1.29	1.06	
Leucine	g	2.06	1.69	
Lysine	g	2.20	1.80	
Methionine-	g	1.51	1.23	
Phenlyalanine-	g	2.54	2.09	
Threonine	g	1.66	1.37	
Tryptophan	g	0.57	0.46	
Valine	g	1.37	1.11	

	AAFCO Cat Food Nutrient Profiles			
		Growth &	Adu	
	Units	Reproduct	Maintenan	
	Basis	Minimum	Minimum	Maximu
Arginine	%	1.25	1.04	
Histidine	%	0.31	0.31	
Isoleucine	%	0.52	0.52	
Leucine	%	1.25	1.25	
Lysine	%	1.20	0.83	
Methionine-	%	1.10	1.10	

Methionine	%	0.62	0.62	1.50
Phenlyalanine-tryosine	%	0.88	0.88	
Phenylalanine	%	0.42	0.42	
Threonine	%	0.73	0.73	
Tryptophan	%	0.25	0.16	
Valine	%	0.62	0.62	
Taurine (Dry	%	0.10	0.10	
Taurine (Wet	%	0.20	0.20	

	AAFCO Cat Food Nutrient Profiles			
	Units	Growth &	Adu	
	1000	Reproduct	Maintenan	
	M	Minimum	Minimum	Maximum
Arginine	g	3.10	2.60	
Histidine	g	0.78	0.78	
Isoleucine	g	1.30	1.30	
Leucine	g	3.10	3.10	
Lysine	g	3.00	2.08	
Methionine-	g	2.75	2.75	
Methionine	g	1.55	1.55	3.75
Phenlyalanine-	g	2.20	2.20	
Phenylalanine	g	1.05	1.05	
Threonine	g	1.83	1.83	
Tryptophan	g	0.63	0.40	
Valine	g	1.55	1.55	
Taurine (Dry	g	0.25	0.25	
Taurine (Wet Food)	g	0.50	0.50	

Common Name	Chemical Name	CAS Number	Trade Names	Other Codes
Arginine	(S)-2-Amino-5-guanidinopentanoic acid	74-79-3	Arginine (L-)	EINECS: 230-571-3
Methionine	2-amino-4-(methylthio)butanoic acid	63-68-3 (L-); 59-51-8 (DL-)	Mepron®; Alimet®	EINECS: 200-432-1
Cysteine	2-amino-3-sulfanylpropanoic acid	52-90-4; 3374-22-9 (DL-)	L-Cysteine; L-Cysteine Hydrochloride Monohydrate	EINECS: 222-160-2
Lysine	2,6-diaminohexanoic acid	56-87-1 (L-); 70-54-2 (DL-)	VitaLys®; L-Lysine Premium®	EINECS: 200-740-6
Taurine	2-aminoethane sulfonic acid	107-35-7	Taurine: AI3-18307; O-Due; Taurina; Taukard	EINECS: 203-483-8
Tryptophan	(2S)-2-amino-3-(1H-indol-3-yl)propanoic acid	73-22-3 (L-); 54-12-6 (DL-)	TryptoPure®; L-Tryptophan	EINECS: 200-194-9
Threonine	2-Amino-3-hydroxybutanoic acid	72-19-5 (L-); 80-68-2 (DL-)	L-Threonine; DL-Threonine;	EINECS: 201-300-6
Histidine	2-Amino-3-(1*H*-imidazol-4-yl)propanoic acid	71-00-1 (L-); 4998-57-6 (DL-)	L-Histidine	EINECS: 225-660-9
Isoleucine	2-Amino-3-methylpentanoic acid	73-32-5 (L-); 328-39-2 (DL-)	L-Isoleucine	EINECS: 207-139-8
Leucine	2-Amino-4-methylpentanoic acid	61-90-5 (L-); 328-39-2 (DL-)	L-Leucine	EINECS: 206-328-2
Valine	2-Amino-3-phenylpropanoic acid	72-18-4 (L-); 516-06-3 (DL-)	L-Valine	EINECS: 208-220-0
Phenylalanine	2-Amino-3-phenylpropanoic acid	63-91-2 (L-); 150-30-1 (DL-)	L- Phenylalanine	EINECS: 205-756-7
Tyrosine	L-2-Amino-3-(4-hydroxyphenyl)propanoic acid	60-18-4 (L-); 556-03-6 (DL-)	L-Tyrosine	EINECS: 209-113-1

Note

This Interim Report is presented by the National Organic Standards Board Livestock Subcommittee on behalf of the Vaccines Made with Excluded Methods Working Group. This document has **not** been approved by the Livestock Subcommittee, but comments on this document are welcome, and will be supplied to the working group as they develop a final report.

Vaccines Working Group

Interim Report: Identifying Vaccines Made with Excluded Methods

Submitted to the National Organic Standards Board Livestock Subcommittee

February 5, 2013

Working Group Participants:
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Scott Updike, PhD, Agricultural Marketing Specialist, National Organic Program, AMS-USDA
Patricia Foley, DVM, PhD –Center for Veterinary Biologics (CVB), APHIS
Nick Maravell, Organic Producer Representative & NOSB Livestock Subcommittee Member
Jean Richardson, PhD, Consumer/Public Interest Representative & NOSB Livestock Subcommittee Member
(* indicates working group facilitator)

SUMMARY OF FINDINGS:

1. Organic livestock producers, certifiers and material evaluation programs can identify certain vaccines as being produced with excluded methods by the presence of the words “chimera,” “vector,” or “subunit” on the label of the vaccine.

2. The Center for Veterinary Biologics assigns a product code of D to DNA vaccines and R to recombinant vaccines. However, rules on confidential business information and differences in the definitions between the NOP’s “excluded methods” and CVB’s “recombinant” do not allow for the working group to identify these vaccines in the market or to verify that they are made with excluded methods.

3. The definition of excluded methods seems to be a less than ideal fit with vaccine production methods. The vaccines working group has developed two proposals for certifiers and material evaluation programs to sort between various vaccine products which have publicly described development methodologies. Under the first proposal, all technologies that could be used to create a targeted change or mutation in a genome would be considered excluded methods. The second proposal would take every technology on a case by case basis so that if a given technology can induce genetic mutations randomly or targeted, that technology would be allowed if mutations were random for the material in question.

FURTHER INVESTIGATION NEEDED

The working group suggests seeking comment on a number of issues:

1. The definition of "excluded methods" under the USDA organic regulations excludes "the use of traditional breeding" (emphasis added). However, the regulations do not give more detail on what is included in "traditional breeding". Therefore, it is difficult to determine what techniques used in vaccine development would be considered "traditional breeding", and, thus allowed under the regulations, versus those that would be considered "excluded". How should traditional breeding techniques be divided from modern breeding techniques as it pertains to vaccine production? Should the definition of excluded methods be changed or clarified specifically towards vaccine production?

2. The definition of excluded methods includes the use of methods that are not possible under natural conditions such as the use of recombinant DNA technology. However, recombination can be a naturally occurring event in many biological processes, such as occurs every time a plant or animal sexually reproduces. 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. The third criterion proposed to identify vaccines made with excluded methods is for certifiers and MEPs to analyze the methods used to create the vaccine. The working groups proposed two ways for this analysis of methods to be done. Should a given technique be declared excluded or allowed or should the effects of each method be analyzed so that all random genetic modifications be allowed and all targeted genetic modifications be prohibited?

4. If the use of biological mutagens to randomly modify the genome of the targeted pathogen is considered allowed (i.e. not an excluded method), do certifiers and MEPs need to consider whether the biological mutagen was produced through use of an excluded method? For example, if the use of transposons to create random genetic mutations is allowed, can the transposon have been produced using excluded methods? Essentially this question is asking how far back into the development or manufacturing should the excluded method prohibition apply? As a factual matter, how far back in the development process can an accurate assessment be made of the possible use of excluded methods?

INTERIM REPORT

I. Introduction

The NOP (National Organic Program) established the Vaccines Made with Excluded Methods (MWEM) working group in response to a request of the National Organic Standards Board (NOSB) for more information about the use and identification of vaccines MWEM. The working group includes two members of the NOSB, NOP staff, and staff from the Center for Veterinary Biologics (CVB), the division in the Animal Plant and Health Inspection Service (APHIS) that approves and regulates vaccines for use in livestock and pets. The working group prepared this discussion document to summarize its efforts to date for the NOSB Livestock Subcommittee. This document outlines an approach for how certifiers and material evaluation programs (MEPs) can identify some vaccines MWEM (i.e. genetically engineered vaccines and what some people incorrectly refer to as GMO vaccines) and summarizes questions that could be posed to the organic community about whether certain methods used to produce vaccines should be considered excluded or allowed under the USDA organic regulations.

II. Background

The USDA organic regulations at 7 CFR part 205 contain several references that are relevant to the discussion on the use of vaccines in organic livestock production. The first reference, under the "Livestock healthcare practice standard", requires that "the producer must establish and maintain preventative healthcare practices, including…administration of vaccines and other biologics" (205.238(a)(6)). The second reference on the National List of Allowed and Prohibited Substances allows the use of livestock vaccines, which are synthetics as follows: 205.603(a)(4) as follows: "Biologics – vaccines" (205.603(a)(4)) (without annotation). The third reference at 205.672 deals with emergency pest or disease treatment which is defined in 205.2 to include disease eradications programs. In the past, vaccines MWEM have been required as part of disease eradication programs. The working group is unclear as to the effects of these eradication programs on organic livestock producers.

The fourth reference is nested within the section of the USDA organic regulations that details the allowed and prohibited substances, methods, and ingredients in organic production and handling. Under this section (205.105(e)), the use of excluded methods is prohibited in organic production. Excluded methods are defined under the USDA organic regulations (205.2). The methods that are excluded and, thus, prohibited, are those used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. However, there is a specific reference to vaccines in the section on excluded methods. Section 205.105(e) of the organic regulations provides an allowance for vaccines produced through the use of excluded methods if the vaccines are reviewed and recommended for the addition to the National List by the NOSB. The review needs to be conducted in accordance with section 205.600 of the organic regulations. Section 205.600 specifies the evaluation criteria that the NOSB follows in their evaluation of allowed and prohibited substances, methods, and

ingredients. To date the NOSB has not recommended any vaccines made with excluded methods be added to the National List.

The preamble to the final rule (65 FR 80554) in 2000 discussed the NOP's response to comments about use of vaccines MWEM in organic livestock production. Some commenters wanted all vaccines MWEM to be completely prohibited from organic livestock production while others wanted all vaccines to be temporarily allowed until more information could be assembled in the future to determine if any of the vaccines MWEM were necessary for production. At the time, NOP chose to structure the provision so that vaccines MWEM could only be used by organic production if they are affirmatively included on the National List after review by the NOSB. But, with no information or guidance about how to identify vaccines MWEM, many organic livestock producers, with approval from their certifiers, have chosen vaccines based upon disease prevention and not based on whether they are made with excluded methods.

To rectify this divergence between regulatory language and industry practice, the NOSB, in 2009, recommended a change to section 205.105(e) to allow the use of vaccines made with excluded methods if vaccines made without excluded methods were not commercially available[1]. That recommendation stated that such a change would not require individual review of vaccines made with excluded methods. The NOP has not implemented this change into the USDA organic regulations. Therefore, the current exception at section 205.105(e) to allow vaccines made with excluded methods only applies to those that are reviewed according to 205.600. In September 2010, the NOP requested that the NOSB review vaccines made with excluded methods (i.e. GMO vaccines or genetically engineered vaccines) in accordance with section 205.600[2].

In response to the NOP's request, the NOSB began to review vaccines MWEM. The Livestock Subcommittee requested a Technical Review of GMO Vaccines[3], drafted a proposal and submitted the proposal to the full NOSB. The NOSB discussed the proposal pertaining to the use of vaccines MWEM at its May 2012 public meeting[4]. The NOSB received considerable public comment on this issue leading up to and at this public meeting. Comment was split with members of the general public advocating for a prohibition on vaccines MWEM and certifiers and producers asking for more detailed information about current vaccine use and clarification about which vaccines were MWEM. Due to the need for additional technical information before voting, the NOSB decided to table the proposal until a future meeting, but passed a resolution that included a request for more information from USDA[5]. The NOSB requested 1) NOP identify all vaccines registered with USDA as GMO or non GMO 2) Vaccine manufacturers voluntarily and truthfully label vaccines about their absence of GMO content, 3) NOP or other USDA

[1] http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5081499&acct=nosb
[2] http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5090932
[3] The technical review may be viewed at
http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5097326
[4]Information on the May 2012 NOSB meeting may be found at
http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateJ&page=NOSBMeetings
[5]May 25, 2012 NOSB Formal Recommendation on GMO Vaccine Information Request
http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5098924

agency publish a real time tracking system to identify GMO and non GMO vaccines. In response to the NOSB's May 2012 resolution, the NOP convened the Vaccines Made with Excluded Methods Working Group.

The working group first collected information regarding the use of vaccines, government programs that may require the use of vaccines, technical information about how vaccines are made and how vaccines are regulated. In response to requests from the NOP, CVB and Veterinary Services (VS) from APHIS elaborated on regulations that could require livestock producers to use vaccines. The working group's understanding is that the Secretary of Agriculture has the authority to declare emergencies at various levels depending upon the severity of the outbreak. Emergency declarations allow both state and the federal government to require livestock producers to use specific vaccines, including vaccines MWEM. The only regional emergency in the past decade was an Exotic Newcastle outbreak in unvaccinated backyard poultry and game fowl. No vaccination program was used in this emergency because USDA determined that most commercial poultry operations in the area, whether conventional or organic, had already vaccinated their birds for this disease. It is difficult to ascertain whether vaccines MWEM would be needed in future emergencies but VS stated it is likely that most new vaccines would be made with such methods and these could be selected as the most effective option in future disease outbreaks. However, no such forced vaccination program in response to an emergency has occurred recently.

The working group also learned that disease eradication programs authorized by the federal government may include mandated use of vaccines. The two recent eradication programs, Brucellosis in cattle and Pseudorabies in swine both required vaccines. These two eradication programs used vaccines that allow blood tests to differentiate between those animals that have an immune response due to the vaccine and those animals that have an immune response due to the disease. In order to differentiate between vaccinated animals and animals which had the disease, producers must use a modified live vaccine that results in a strong immune response, has mutations that alter at least one epitope and is not virulent. The Brucellosis vaccine was developed using cell culture passages, a presumably allowed technology in organic production. The Pseudorabies vaccines, several vaccines were approved for this eradication program, were developed using excluded methods. Based on our discussions with APHIS, the working group believes that vaccines made with excluded methods may be USDA's preferred vaccine choice in future eradication programs.

APHIS' CVB regulates vaccines and vaccine manufacturers under the Virus-Serum-Toxin Act, CVB's primary role is to review and license vaccines based upon purity, safety, potency, and efficacy. CVB requires certain label terms depending upon specific configurations of the vaccine seed (form of the agent used to create the vaccine). CVB also tracks vaccines that are made through the use of biotechnology. However, CVB's evaluation of whether a vaccine is produced through "biotechnology" does not align with how "excluded methods" is defined under the USDA organic regulations. Because of this lack of alignment, it is difficult to know the extent to which vaccines on CVB's list of biotechnology derived vaccines overlaps with what could be considered produced through an "excluded method". CVB does review the use of biotechnology in manufacturing of the vaccines, e.g. if a vaccine is produced using cells made with excluded methods. However, if only the cell line used to culture the vaccine seed has a genetic insertion, deletion or other mutation, the vaccine itself is not considered to be a

recombinant. [6] Finally, the working group could not identify a comprehensive path of "partial" alignment such that if a vaccine were identified as biotechnology derived by CVB then it is was definitely considered made with "excluded methods" as defined by the NOP.

III. Working Group Deliberations

After considering background research, information from other USDA agencies and public comments, the Working Group came to the conclusion that developing criteria for certifiers and MEPs to use to identify vaccines MWEM would be the only approach to allow the organic industry to determine which, if any, vaccines made with excluded methods are being used and if there are reasonable alternatives to these vaccines. The working group has identified three criteria that could be used by certifiers and MEP's to determine the excluded or not excluded status of vaccines. The working group developed how one of the criteria would be used but requests input from the NOSB and the organic community on clarifying the two other items.

The working group considered creating a list of all vaccines produced with (or without) use of excluded methods. This would be the easiest resource for organic livestock producers and certifiers to use. However, creation of a negative and/or positive list is difficult for a variety reasons, including the lack of precise criteria to decide whether something should be considered produced through excluded methods. Furthermore, for such lists to be useful, the lists would need to specify the branded vaccine products that livestock producers purchase and use, not just generic names of the disease or pathogen that is being used to create the vaccine. Another reason the working group chose not to create a list is that the CVB does not differentiate vaccines based upon excluded methods. USDA is concerned that creating such a list would imply a deficiency of vaccines MWEM, which would not be scientifically accurate within USDA's responsibility to regulate the purity, safety, potency, and efficacy of vaccines. The working group was also concerned 1) with liabilities due to the possibility of inaccurately placing a specific vaccine on a list, and 2) the possibility of not being able to obtain necessary vaccine manufacturing information, which is often submitted as confidential business information to APHIS CVB.

IV. Working Group Proposal

The working group has identified criteria that would allow certifiers and MEPs to identify vaccines MWEM. The three criteria to be used in in conjunction are:

- Label Guidelines
- Product Codes
- Methods of Production Analysis

A. Label Guidelines

[6] European organic standards allow the use of all vaccines if they are needed to prevent a disease in the area. Canadian organic standards forbid genetically engineered vaccines outright. In addition, Canadian organic livestock producers may only use a nongenetically engineered vaccine that was grown in a cell culture system that included genetic modifications if no other vaccine is available.

CVB regulations require that certain vaccine seed configurations have specific terms on the labels of branded vaccine products. These terms are required for a subset of biotechnology derived vaccines. While these terms are not added to the labels because an excluded method was used, CVB states that all such vaccines were created using methods that the NOP would exclude. The terms on labels that identify vaccines were made with excluded method are "Subunit," "Vector," and "Chimera." Because these vaccines are labeled with the identified terms, CVB can disclose a trade names list for all of these vaccines.

Vaccines must be labeled with the term "Subunit" when the vaccine is an extracted or purified protein that was expressed in a recombinant system. These vaccines do not contain any genetic information (DNA). These vaccines only contain the protein antigen that induces an immune response. To create "Subunit" vaccines, the gene for the antigenic protein is inserted into an expression vector or expression system. The gene from the pathogenic organism may be expressed in prokaryotic or eukaryotic cell culture systems. The expressed protein is then extracted or purified and used in the vaccine. Currently there are no active licenses for subunit vaccines.

Certain modified live vaccines must be labeled with the term "Vector" or "Chimera" to denote that the vaccine contains DNA from two pathogens. These vaccines are created by identifying a viral structure that induces a strong immune response. This viral structure is termed the expression vector. In many cases, the expression vector is a virus that in its unaltered form can cause a disease in the target species. The vector will then have at least one gene from another disease causing agent inserted into the viral genome. Vaccines labeled with "Vector" may be efficacious against two diseases, the disease caused by the unaltered vector and the disease caused by the source of the gene that was inserted into the vector or only be efficacious against the disease caused by the source of the gene that was inserted into the vector. Vaccines labeled with "Chimera" are similar to "Vector" labeled vaccines, except that certain genes required for replication competency are supplied by the added genes and not contained in the expression vector.

B. Product Code

The CVB requires that every biologic, including vaccines, produced must have a product code. The CVB guide on true names and product codes[7] notes that the 5th digit of the product code may contain "D" or "R." The letter "D" in the fifth digit signifies that the vaccine is a nucleic acid vaccine. Such vaccines, also called DNA vaccines, are made with excluded methods and depend upon foreign genes being expressed in some of the cells of the vaccinated animals. The letter "R" in the fifth digit signifies the vaccine has a recombinant component or is a subunit protein derived from a recombinant organism. The recombinant designation only applies to components in the vaccine and not to methods used to make the vaccine such as genetically engineered cells that are used for cell culturing the vaccine seed.

In public comments, some certifiers stated that they were aware of the R code in the fifth digit of the product code as designating that a component in the vaccine was recombinant or recombinant-derived. However, these certifiers were not able to translate the product code information to actual vaccines on

[7] http://www.aphis.usda.gov/animal_health/vet_biologics/publications/pel_1_3.pdf

the market. CVB is unable to provide a list of the trade names of the vaccines with a "D" or "R" in the product code because confidential business considerations will not permit discussion of production methods, unless the biologics firm specifically agrees to disclose the information. The working group was unable to develop a method to identify the trade names of vaccines and other biologic products that have a D or R in the product code other than the trade names that are already identified as MWEM, e.g. are labeled as containing a "Vector" or "Chimera." Vaccines that have a "D" or "R" in the product code may or may not be made with excluded methods since the production methods may not be identified for evaluation. The working groups is requesting input from the NOSB and organic community to identify methods of linking product codes to trade names in a manner that clearly identifies whether or not an excluded method was used.

C. Method of Production Analysis

Some firms have waived confidentiality by describing how the vaccines were made in public comment to the NOSB. However, some vaccines were and in the future may be made with methods that are not clearly excluded or allowed in organic production. The working group is requesting input from the NOSB and the organic community to provide comments on this issue.

Modified live vaccines generally have been found to produce greater immune responses in vaccinated animals and have become more common in new vaccines than killed vaccines. Live vaccines require that the genome of the disease causing organism be modified to create a living, but not virulent, pathogen which can be packaged in the vaccine. The excluded methods definition (205.2) includes methods which genetically modify organisms or influence their growth and development by means not possible under natural conditions or processes which are not considered compatible with organic production. The definition identifies some of the methods that are excluded including recombinant DNA technology (gene deletion, gene doubling, introducing a foreign gene and changing the positions of genes when achieved by recombinant DNA technology). The definition states that some methods to genetically modify organisms are allowed, including traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization or tissue culture.

Many of the older non-biotechnology derived modified live vaccines were made by using bacterial culture, cell culture or tissue culture with multiple passages to induce genetic modifications to the disease causing pathogen. The various cultures were then screened to identify a modified version that induced an immune response but that was no longer virulent. This is a process of random genetic modification followed by screening for the desired phenotype. The Brucellosis vaccine that is part of the Brucellosis eradication program was produced by growing the parent strain in various concentrations of an antibiotic cocktail over several passages to induce random mutations in the genome of the bacteria. These random mutations resulted in a non-virulent bacterial strain that did not produce the O-chain component of the lipopolysaccharide that was one of the epitopes for immune response.[8] This change in at least one epitope was required for eradication programs so that vaccinated animals could be differentiated from animals infected by the actual pathogen.

[8] Schurig, G., R.M. Roop, T. Baghi, S. Boyle, D. Buhrman and N. Sriranganathan. 1991. Biological properties of RB51; a stable rough strain of Brucella abortus. Veterinary Microbiology 28: 171.

The working groups assumed other genetic modification methods that would be allowed are exposure to chemical or physical mutagens. Physical mutagens include ionizing radiation, UV radiation and radioactive decay. These mutagens create genetic modifications in a random manner through a variety of ways. Some chemical mutagens break the double stranded DNA, allowing a recombination event to occur which can cause gene deletion and changing the position of genes. Other mutagens cause DNA bases to switch to other bases, errors in DNA repair or errors in replication. These mutagens all genetically modify organisms in a random manner that is not targeted. Generally, the vaccines working group considered chemical and physical mutagens to be traditional breeding techniques.

Biological mutagens are excluded if they are considered to be a recombinant technology. Recombination is the process by which double stranded DNA is broken, rearranged and then rejoined. Recombination naturally occurs between chromosomes during the process of meiosis to form gametes for sexual propagation, in plants, animals and other organisms. Recombination naturally occurs during high frequency recombinant (Hfr) conjugation in which part of the chromosome from one bacterium is transferred to another bacterium, resulting in homologous recombination which genetically modifies the target bacteria. These are just two examples of genetic modifications through recombination events which are allowed by the current definition of excluded methods.

Some biological mutagens are clearly excluded by the current definition. Restriction enzymes are naturally occurring proteins in many bacteria that will cleave DNA at specific sequences. These enzymes are defense against phage (viruses that target bacteria) which insert their genetic material, usually but not always DNA. Restriction enzymes have been used to cleave a gene of interest and then through a targeted recombination event create a specific gene deletion, clone the gene in a vector or cause a changing of positions of genes in a controlled, nonrandom manner.

Other biological mutagens are neither explicitly allowed or excluded and may be allowed when used one way but not when used in a different way. Specifically, the working group discussed the methods used to create a vaccine which the manufacturer has stated, in public comments to the NOSB, was not made with excluded methods. This particular gene-deleted product was created using transposons and phage transduction. Transposons and phage transduction both result in genetic modifications mediated through recombination events. However, the working group was divided as to whether or not these methods were excluded. Are these methods considered traditional breeding techniques? Are these methods considered a technology as techniques that involve recombination are allowed in organic production but recombinant technologies are not allowed? The working group recognized that the definition of excluded methods did not appear to clearly fit with the methods and technologies used to produce vaccines. The working group is requesting input from the organic community in regards to how these biological mutagens should be classified in regards to the definition for excluded methods as well as how to evaluate biological mutagens in general.

Transposons[9], also called transposable elements are naturally occurring, double stranded DNA sequences with a defined structure. Each end of the transposon includes inverted repeats. In prokaryotes, the internal structure includes at least one gene for transposase and may contain many more depending upon the type of transposon. Genes for antibiotic resistance, one example of the types of genes within the transposon occur both naturally and sometimes as a marker in lab modified transposons. When the transposase gene is expressed, the protein binds to the inverted repeats of the transposon, cleaves the genomic DNA and excises the transposon. Transposase can then cleave the genomic DNA at another spot and recombine the transposon into a new position in the genome.

Eukaryotic transposons are more complicated as they are first copied to RNA. The RNA is then converted to cDNA by a reverse transcriptase, which is coded for by a gene on the transposon. Another gene on the transposon is an integrase, which then inserts the transposon cDNA back into the genome at a new position.[10] By moving from one location to another in the genome, transposons can cause gene deletions or change expression patterns through gene deletion, resulting in changed phenotypes.

Transposons have played a large role in the formation of the genomes of many species. Inactivated transposons and transposon repeats are estimated to make up 44% of the human genome, though only a small fraction are still active.[11] Transposons are present in plant, animal and bacterial species. Transposons mediated recombination events from transposon activity will occur in most if not all species used in organic production, including agricultural, handling and lab based species.

In order to evaluate the use of transposons in vaccine production, the working group considered if transposons would fit into the allowance for traditional breeding techniques. The working group was not clear at which point traditional breeding techniques are divided from modern or non-traditional breeding techniques. Is there a time point at which all techniques before that time are considered traditional and all new techniques developed after that time are not considered traditional? The definition of excluded methods allows all traditional breeding techniques, so the distinction is important for organic producers.

Transposons were initially identified as jumping genes by Barbara McClintock in research on variegation in corn kernels which began in the 1930's. [12] As the transposons moved and genetically modified the genome, various genes would be turned on or off, altering the phenotype of the expected breeding. The activity of the transposons was part of the plant breeding resulting in the phenotype. Some of the working group considered the use of transposons to fall under the category of traditional breeding.

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[9] MeSH (Medical Subject Headings), the NLM [National Library of Medicine] controlled vocabulary thesaurus used for indexing articles for PubMed.
http://www.ncbi.nlm.nih.gov/mesh

[10] http://chemistry.umeche.maine.edu/CHY431/Genome4.html

[11] Mills RE, EA Bennet, RC Iskow, and SE Devine. 2007. Which transposable elements are active in the human genome? Trends Genet 23(4): 183

[12] Pray, L. & Zhaurova, K. 2008 Barbara McClintock and the discovery of jumping genes (transposons). Nature Education 1(1)

Others on the working group felt that traditional breeding techniques did not provide a clear demarcation between allowed and excluded methods.

More recently, researchers have used transposons as a vector for inserting specific foreign genes into the genome of various species. One of the more widely cited methods is with a transposon system called "Sleeping Beauty."[13] Transposons have been used to genetically modify a variety of agricultural species from plants such as rice to swine cells. This use of transposons would be excluded in organic production. Figure 1. provides an illustrated explanation of how transposons are now used to insert genes of interest into genomes.

[13] Carlson, DF, JR Garbe, W Tan, MJ Martin, JR Dobrinsky, PB Hackett, KJ Clark and SC Fahrnekrug. 2011. Strategis for selection marker-free swine transgenesis using the Sleeping Beauty transposon system. Transgenic Res 20(5): 1125

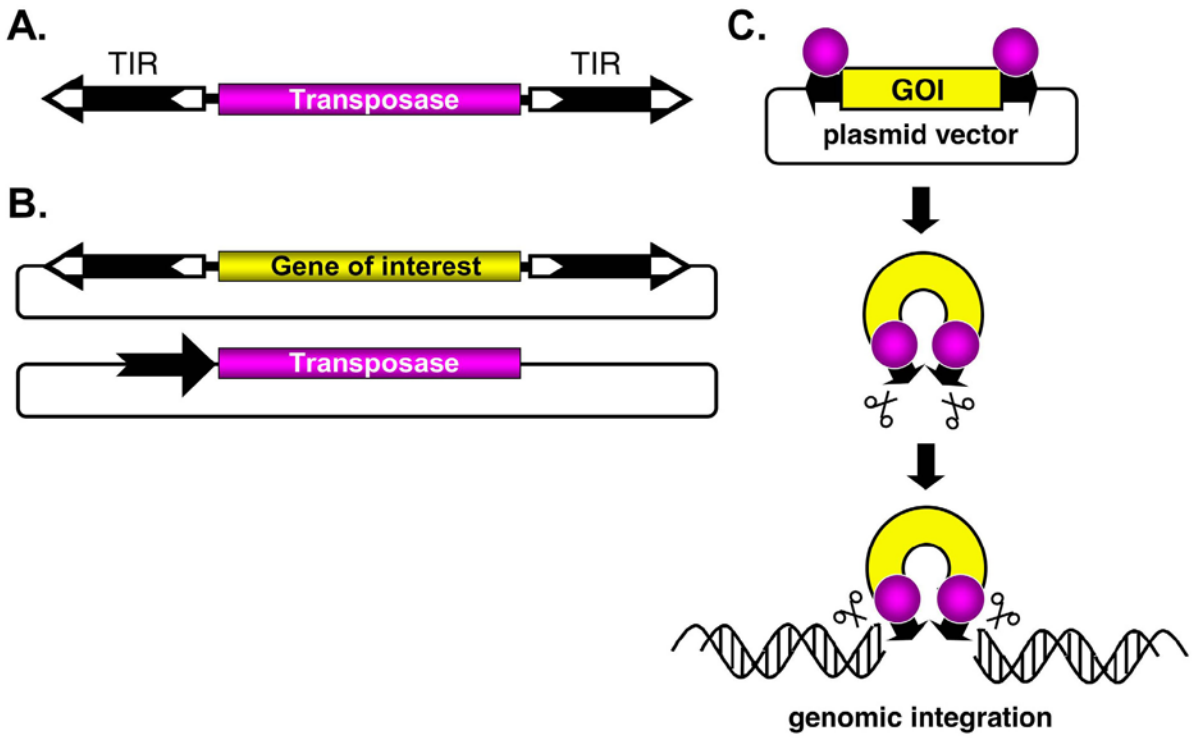

Figure 1.

General organization and use of class II transposable elements as gene vectors.

(A) Autonomous transposable elements consist of terminal inverted repeats (TIR; black arrows) that flank the transposase gene.

(B) Bi-component transposon vector system for delivering transgenes that are maintained in plasmids. One component contains a DNA of interest between the transposon TIRs carried by a plasmid vector, whereas the other component is a transposase expression plasmid, in which the black arrow represents the promoter driving expression of the transposase.

(C) The transposon carrying a DNA of interest is excised from the donor plasmid and is integrated at a chromosomal site by the transposase.[14]

[14] Ivics, Z. and Z. Ivsvak. 2010. The expanding universe of transposon technologies for gene and cell engineering. Mobile DNA. 1:25

The other method used by the vaccine manufacturer under discussion was transduction[15], which is the process through which the genomes of bacteria can be modified with the use of bacterial virus, called a phage. Some types of phage attach to the bacterial cell wall and insert the viral genome into the cell. The viral genome may then be inserted into the bacterial genome through a recombination event which is part of the lysogenic cycle. After receiving a trigger, the viral genome will be excised and the lytic cycle will be triggered. The excision of the viral genome is not perfect and in some cases, parts of the bacterial genome will be excised and packaged into the new phage. These phage can then be used to infect additional bacteria. The bacterial genetic material in the phage will be inserted into the newly infected cell. A homologous recombination event may occur so that some of the genes from the originally infected cell's genome will replace the genes in the newly infect cells. This method can stably introduce genetic mutations into the new bacteria.

These two, briefly described methods of transposons and transduction were used to create a gene deleted vaccine product that the manufacturer has stated is not made with excluded methods. Specifically, the manufacture stated that the transposon Tn10, which codes for tetracycline resistance as well as transposase was used to introduce genetic modifications. The tetracycline resistance gene allows for selection for stable recombination events by adding tetracycline to the media to kill all those bacteria which were not mutated by transposons. Bacteria, which had transposon linked mutations to the genes that needed to be inactivated in order to knock out virulence, then underwent transduction by Phage P22Htint to create the mutated strain used for the vaccine. These methods resulted in bacteria that had stable genetic modifications that rendered the bacteria avirulent, but able to induce a strong immune response in vaccinated animals.[16]

The working group did not come to a decision about the status of vaccines developed using these methods. Certifiers and MEPs who examine vaccines for compatibility with the organic regulations will need guidance on future determinations of other vaccines as well. The working group considered two proposals for methods that could be used for this final determination of methodologies that are not clearly covered in the current definition of excluded methods. While outside the scope of the working group's mandate, a third option briefly discussed is that the definition of excluded methods could be revised to more clearly demarcate technologies used in vaccine production as being allowed or excluded. The vaccines made with excluded methods working group would encourage the GMO Subcommittee to consider changing the definition of excluded methods in 205.2 based on some of the issues addressed in this document.

The first proposal would be technique based. The working group or the NOSB would assess the methods used to genetically modify genomes for vaccine production and then state which methods are excluded. For example, every vaccine that used a transposon or polymerase chain reaction to create the

[15] MeSH (Medical Subject Headings), the NLM [National Library of Medicine] controlled vocabulary thesaurus used for indexing articles for PubMed.
http://www.ncbi.nlm.nih.gov/mesh

[16] Curtis, R. and S Kelly. 1987. Salmonella typhimurium Deletion Mutants Lacking Adenylate Cyclase and Cyclic AMP Receptor Protein Are Avirulent and Immunogenic. Infection and Immunity. 55(12): 3035

vaccine seed would be excluded. This proposal has the limitation of not allowing all uses of a given method, even if only certain uses are excluded. For example, because transposons can be used to create transgenic plants and animals, all use of transposons would be excluded. This proposal would provide greater clarity, but less flexibility.

The second proposal would be based upon how the genetic mutations were introduced to the genome. Most of the allowable mutagens such as chemicals or radiation introduce genetic modifications randomly. Under this proposal, any biological mutagen that created genetic modifications randomly would be allowed and biological mutagens which are targeted (i.e. genetically engineered) to specific places in the genome or specific genes would not be allowed. This proposal would require more work and effort by certifiers to identify not just which method was used, but how that method altered the genome of the pathogen. Restriction enzymes typically cleave DNA at a specific sequence. However that specific sequence may be repeated and randomly distributed across the genome. How should certifiers make a determination when a technique used to mutate or modify a genome should be considered random versus targeted?

National Organic Standards Board
Crops Subcommittee
Petitioned Material Proposal
Oxytetracycline

February 5, 2013

Summary of Proposed Action:

The Crops Subcommittee proposes to:

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 Crops Subcommittee would also like to put forward this resolution:

Resolution: The National Organic Standards Board is committed to the phase out of this material. Between now and 2016 the Board urges growers and certifiers to include in organic systems plans an annual increase in the extent and/or number of alternative practices and materials that are trialed for controlling fire blight. In addition, the board strongly advocates to USDA a high priority for increased support for research into these alternative practices and materials.

Introduction

A Petition to the National Organic Standards Board (NOSB) was received for Removal of the Expiration Date (October 21, 2014) for the Authorized Use of Tetracycline for the Control of Fire Blight in Apples and Pears. It was furthermore requested by the petitioner to reinstate Tetracycline to the sunset process.

Because this subject is complex and there are two different positions to be represented, this recommendation is organized to include a brief history of previous NOSB decisions involving this substance, followed by two separate discussion sections from those for (Majority Position) and against (Minority Position) an extension. These are designed to supplement the points raised in the checklist.

The sub-committee acknowledges the concerns of consumers and previous NOSB members who feel that it is time to phase this material out from organic agriculture. The two positions represented in the discussion section of this document differ on the timing of the phase-out. Additional concerns are being put forward in a separate resolution on the subject.

Background

NOSB History on Tetracycline in Fruit Production

1995- A TAP review on “Antibiotics” was reviewed by the NOSB. All three reviewers thought that tetracycline and streptomycin were non-synthetic. Voted on Nov. 1995 as three separate Listings:

Antibiotics (Avermectin) – failed 3-6-4

Antibiotics (Streptomycin sulfate) – Determined to be synthetic; vote – unanimous. The NOSB's decision is to allow this material for use in organic crop production; vote: 10 aye/3 opposed. Annotation: Permitted for use as a fire blight control in apples and pears only. To be reviewed again in two years.
Antibiotics (Terramycin – Oxytetracycline calcium complex) – Determined to be synthetic; vote – unanimous. The NOSB's decision is to allow this material for use in organic crop production; vote: 10 aye/ 1 opposed/2 abstentions. Annotation: To be reviewed again in two years.

No discussion was given in transcript except that the NOSB was to set up a task force to look further into these materials in the two year time frame.

2006 - A TR commissioned by the NOSB for the sunset review was received in January 2006. Sunset review of Tetracycline and Streptomycin in April 2006. (discussion 4/20/06 pp.41-78) Discussion is worth reading because of the wide variety of concerns raised from the concern of the CDC for antibiotics in the environment to the quantity of pear trees being cut down in Romania and other European Union (EU) countries. Mr Neal from the NOP stated that the board should not be making changes in annotation during sunset especially because nobody presented any economic impact data in the Sunset Federal Register notice for removal of these materials.

The Crops Committee recommends renewing the materials listed in Section (i) as plant disease control. Streptomycin and tetracycline for fire blight control in apples and pears. 7-4-1-2 (p.411)

2007- A petition was received to add Oxytetracycline hydrochloride to the National List. Oxytetracycline calcium complex is the form already on the list and the petitioned form is similar but from a different manufacturer.

2008 - The NOSB reviews the new petition for adding another form of tetracycline (Oxytetracycline hydrochloride) at their public meeting November 19, 2008. The 2006 TR was used for the checklist, with some supplemental references. The committee recommendation to add oxytetracycline hydrochloride for fire blight control only to NL §205.601 (i) failed: 0-6-0-0. The committee recommendation states: "Considering the intense on-going public comment that the committee has been receiving on the negative public health impacts of these materials, the committee anticipates that a petition will be filed for the removal of tetracycline and streptomycin from the National List before their sunset date of October 2012. Adding a new form of tetracycline to the list at this time would be counterproductive".

At the NOSB meeting, Dr. Robinson indicated that adding a new form to the existing listing would "reset the clock" for another 5 years until sunset. The motion to add the Oxytetracycline hydrochloride failed unanimously. However, an NOSB member then moved to reconsider the listing vote because of "new information regarding possible action on this petition….." The NOSB then voted to reconsider the vote before it was stated what the new information was. This passed: 11-0-1-2.

The next motion was "to change….the listing and annotation of tetracycline to read: tetracycline for use only in organic crop production for fire blight control until October 21st, 2012". After an effort to change the date to December 2009, but the NOP stated that they could not get a rule change out by then, this motion was voted with no further public comment. Vote was: 13-0-1-1 to amend the original recommendation. On the motion to add tetracycline for fire blight control only on the National List Section 205.601 (I) until October 21st, 2012. Vote: 13-0-1-1.

2010 – A petition was submitted to remove the Expiration Date for Tetracycline, in accordance with 75 FR38696 where the NOP states: "…*we note the NOSB's recommendation to only allow the continued use of tetracycline for fire blight control until October 21, 2012. Though some commenters have requested the removal of the expiration date from the use of tetracycline, the NOP recommends that such interested parties petition the NOSB using the petition process outlined in 72 FR 2167* (January 18, 2007) *to have the expiration date removed from the authorized use of the substance".*

2011 – Review of Petition to remove Expiration Date for Tetracycline. A new TR was commissioned. The Crops Committee did not receive it before issuing their recommendation, but did review their decision in light of the TR. The TR was posted for public view on the last day of the written comment period.
At the April 2011 meeting the NOSB recommended to:

> "Adopt the petition to amend the listing for tetracycline to remove the expiration date of October 21, 2012 and be annotated as follows:
>
> §205.601 Synthetic substance allowed for use in organic crop production.
> (i) As plant disease control.
> (12) Tetracycline, for fire blight control in apples and pears only until October 21, 2014.
>
> The NOSB expects that members of the industry will collaborate and coordinate efforts in preparing for the eventual removal of this material from the National List, specifically optimizing the use of resistant rootstocks and cultivars, preventive management methods, and the use of alternative, allowed biological and chemical controls, whenever warranted".

Discussion Regarding NOSB History
From the perspective of 2012 looking back on the previous actions of the NOSB and NOP, there are inconsistencies and errors along the way. A few of the most apparent are:

- The task force and two year review was never implemented after the 1995 recommendation.
- The vote to re-list in the first sunset review in 2006 was not a 2/3 majority as is required today.
- The 2008 decision to change from adding another form of tetracycline to the National List to a firm expiration of all forms in 2012 was done without a written public comment period. What happened at the meeting was different from the recommendation on the petition that was posted in advance.
- The proposed rule that followed the 2008 decision received some public comment about economic harm but not enough to trigger a USDA economic impact review, even though the 2006 statement from the NOP indicated such impact must be considered.
- The public did not have access to the TR during the written public comment period prior to the 2011 recommendation, but NOSB members did.
- The 2011 proposed rule to extend the sunset date to 2014 again did not result in an economic impact review by the USDA.

<u>Discussion of the Extension Position</u> (Majority Position)

Because of the very large investment of time and money that establishing an orchard entails, the variety of locations that apples and pears are grown, and the very rudimentary state of research on alternatives to this material in that variety of locations, we are supporting slowing down the removal of tetracycline from the National List.

Since the organic pear industry is more at risk to fire blight than apples (see Pear Perspective later in this document) there is concern that pear research and control measures are lagging behind and that an expanded time frame will be needed.

A slightly extended date of 2016 will benefit consumers and growers alike. The few more seasons of research will enable new products to be tested in both apples and pears in a variety of weather conditions. Allowing the new EPA data to be reviewed will inform many of the unanswered questions stakeholders may have about oxytetracycline.

Because of the need to make sure that this material is phased out, a resolution motion has been added to affirm the commitment by the NOSB to all organic stakeholders. The NOSB must ensure that the decisions made reflect due consideration of the various needs and concerns of the vast array of all our organic stakeholders, especially when dealing with complicated issues, such as this one.

This section focusses on how the material is used in the context of both plant and human health. Specific portions address Checklist categories as noted.

Introduction

In 2009, about 15% of the total apple area and 40% of the pears (organic and conventional) were treated with streptomycin or oxytetracycline for control of fire blight, the disease caused by the bacteria *Erwinia amylovora*.

The core issue here is whether there is a risk of enhancing antibiotic resistance in human pathogens. The most astute and experienced scientists in this area realize that science and medicine have to find a way to co-exist with resistance, including managing reservoirs of resistance in the environment and preventing development of new forms of resistance. (Am. Academy of Microbiology, 2009)

While oxytetracycline is used to treat a wide variety of human bacterial infections and diseases, the 2011 TR (lines 593-597) cites the Centers for Disease Control and Prevention (CDC) as indicating that resistance has not yet occurred for these drugs. Also mentioned is that there are alternative antibiotics to oxytetracycline for human illness.

In fact, the American Academy of Microbiology review of Antibiotic Resistance (2009) states that biocides, such as triclosan or quaternary ammonium compounds, may represent a more important threat to the future of antibiotics than antibiotics themselves. Because they have become so widespread in consumer products at sub-lethal concentrations, they promote the evolution of bacterial resistance. Other environmental factors that can contribute to resistance include the use of sewage sludge and water from sewage facilities, overuse of non-antibiotic drugs, and other chemical stressors that contribute to selective pressure such as heavy metals in animal feeds.

The EPA is reviewing the pesticide registration for oxytetracycline. (US EPA, 2008) Part of this review will include environmental fate data as well as the potential for antibiotic resistance transfer from plant pathogens to human pathogens. The EPA's final registration review decision and information is scheduled for 2014. (TR lines 609 - 612) While the EPA studies only a risk assessment point of view which is not the same as the full spectrum of criteria that the NOSB considers, this review is

particularly important because it is calling for additional ecological data, such as aquatic toxicity to both plants and animals, terrestrial plant toxicity, honeybee toxicity, and avian reproduction studies. They are expecting an immunotoxicity study to determine whether repeated exposure from oxytetracycline will affect the immune system. After the docket closes in June 2014 the EPA will develop a final work plan and schedule for registration review of oxytetracycline, expected in September of 2014.

Quantity and Use Patterns

In 2009 in the US, 16,465 kg (active ingredient) was applied to orchards, which is 0.12% of the total antibiotics used in animal agriculture (Stockwell and Duffy, 2012)

In the USA, the preharvest interval for application of oxytetracycline and streptomycin varies from between 21 and 60 days, depending upon the compound and the crop. (McManus & Stockwell, 2001)

Resistance in *Erwinia amylovora* (Fire Blight)

While there are three major strategies for developing tolerance, efflux pumps, alteration of the ribosome to block binding, and production of enzymes to inactivate the material, resistant strains to tetracyclines have not been detected in orchards in the USA (McManus et al., 2002)

This plant pathogen does not develop resistance in the laboratory during exposure to oxytetracycline. In laboratory experiments, E. amylovora will be resistant to tetracycline if resistance genes are introduced. Nonetheless, there are no examples of acquisition of tetracycline-resistance genes by E. amylovora in orchards. This, in part, may be due to low populations of tetracycline-resistant plant associated bacteria on flowers in fruit orchards that could be a potential source of resistance genes. (Schnabel and Jones, 1999) In orchards treated with antibiotics, only 5% of the bacteria isolated from flowers or leaves was resistant to oxytetracycline (10 µg/ml). (Schnabel and Jones, 1999)

Checklist Discussion:

Category 1, Questions 8 and 9: Mode of Action, Breakdown, and Residues

Mode of Action
Oxytetracycline inhibits the multiplication of bacterial cells by binding reversibly to the bacterial ribosome and blocks proteins while bound. (McManus et al., 2002)

Bacteria from the environment migrate to the flowers over time given favorable environmental conditions. As flowers develop and form fruit tissues, detectable populations of bacteria decrease and are restricted to the stem end and the calyx end of the fruit. Intact waxy surface of the fruit does not support bacterial growth.

Breakdown
Even though they can be detected on plant surfaces for up to a month after application, their capacity to inhibit bacterial growth is lost within a week after application. Oxytetracycline is thermostable on leaves, but rapidly degrades when exposed to natural sunlight. 44% within 1 day, 92% within 4 days, and near the detection limit of 50 ppb by a week after application. (Christiano et al., 2010) It is not rainfast on leaves: 2 minutes of simulated rain reduced residual concentrations by 67% and an hour reduced it near the detection limit. (Christiano et al., 2010)

The 2011 TR points to a study by Chander et al. (2005) that tetracycline remains biologically active even while tightly adsorbed to clay particles in soil. (lines 322 – 323) This is used to bolster the

concern that the residues persist in the environment and may contribute to bacterial resistance. This study however was done in a lab using soil that was centrifuged and innoculated for 24 hours at concentrations many times higher than even a manure application would contribute, much less a foliar spray. This 24 hour time frame tells nothing about persistence in environmental conditions, nor does it acknowledge the role of light in breaking down the material. Other research indicates that the bioavailability of tetracyclines is limited in soil because it forms strong bonds with metals and organic matter. (Lui et al, 2009; Popowska et al, 2012) The relative activity and breakdown is strongly influenced by soil composition, shifts in microbial populations, exposure to light and other environmental factors (TR lines 458- 467).

The petitioner, in their rebuttal to the NOSB 2011 recommendation (submitted with the 2012 petition), states that tetracycline breaks down into 3 by-products found in the soil and much lower levels than the parent compound and with much reduced antibacterial potencies. The tetracycline molecule has a strong affinity to form chelates or complexes with divalent cations. This action reduces the bioavailability of oxytetracycline as well as its antibacterial effects, rendering it inactive in soils through a combination of degradation, absorption, and chelation. (Halling-Sorensen et al., 2002) This research was done on tetracycline being applied in animal manure, at much higher concentrations and with a lot of supplemental nitrogen than would be found in tree fruit applications.

A statement in the NOSB 2011 recommendation checklist (Category 1, Question 9) for tetracycline states that "Tetracycline is taken up by plants and appears in all tissues and exudates." This is not fully borne out in literature. While it has recently been shown that it can be taken up by annual plants from soil after a manure application (Kumar et. al., 2005), it is not always the case for all plants and has not been shown for perennials.

Residue on Fruit
For oxytetracycline the residue tolerance level on tree fruit crops is 0.35 ppm. To date there are no reports of fruit with residues greater than this. In a risk assessment study the EPA states that typical pharmaceutical oxytetracycline exposure to humans would be 50,000 to 200,000 times greater that the theoretical dietary exposure. (US EPA 2008)

Residue data for oxytetracycline were reported by the U.S. EPA (2005) as part of the process to allow the material to be used on apples. Field trials were conducted in various parts of the country. Oxytetracycline was applied at rate from 0.5 to 11 times the proposed seasonal rate of 1.53 lb a.i./acre, and at 49-60 days before harvest. The Limit of Quantification was 0.013 ppm. Most samples were at or below this limit, while the highest residue level detected was 0.252 ppm. There was no dose response to increasing rates in the residue data. No data were reported for trees treated only once or twice during bloom, which is the most common use pattern in the western U.S. (Stockwell and Duffy 2012)

Category 1, Question 10

Potential for Humans to build Resistance to Medical Tetracyclines
There are numerous reports that the use of antibiotics in animal production is associated with increase of antibiotic-resistant bacteria in animals, waste-water, and manure (for some examples see Larsen 2010, Wright 2010). A direct linkage was reported between infection and colonization of humans by antibiotic resistant bacteria from farm animals. (Larsen et al 2010) No direct linkage has been demonstrated between antibiotic resistant bacteria in humans and antibiotic sprays on plants. (Stockwell and Duffy, 2012)

The TR from 2011 cites an article by Rezzonico et al. (2009) that other countries have placed restrictions on antibiotics due to concerns about horizontal transfer of resistance genes from bacterial

in the agricultural setting to clinically relevant bacteria. However such a link has never been documented (2011 TR lines 614 - 616) and this article only referred to streptomycin and not to oxytetracycline.

Models generated by the EPA indicate that the potential for direct exposure of humans and their microflora to antibiotics deployed for crop protection is several thousand-fold less than for the medical use of antibiotics. (US EPA 2006a, 2006b, 2008)

For humans, tetracyclines are administered at doses between 1000 mg to 2000 mg daily for at least a week (http://www.drugs.com/dosage/tetracycline.html) or a minimal exposure of 7,000 to 14,000 mg during a prescribed cycle. To date, there are no reports of fruit with residues at or above the permitted tolerance for oxytetracycline at 0.35 mg/kg fruit.

In the Code of Federal Regulations (21CFR556, Sec. 556.720: Tetracycline), the acceptable daily intake (ADI) for total tetracycline residues (chlortetracycline, oxytetracycline, and tetracycline) is 25 micrograms per kilogram of body weight per day. The ADI is an estimate of the amount of a substance which can be ingested daily over a lifetime by humans without appreciable health risk. For a 100 kg person, the ADI for tetracyclines is 2.5 mg. If a person ate fruit with oxytetracycline residues of 0.35 mg/kg fruit, then they would need to consume 7 kg of fruit daily or 47 apples (150 g) each day to reach the ADI. (Stockwell et al., 2013)

Human pathogens have not been detected in surveys (Pusey et al., 2009) of genera of bacteria on flowers of fruit trees. Given this, direct enrichment of antibiotic-resistant human pathogens from antibiotic sprays on plants is unlikely.

It is well established that bacteria harboring transmissible antibiotic resistance genes are common in the environment, even in environments that have never been exposed to exogenous antibiotics. (Duffy et al., 2011; Popowska, et al., 2012; Sundin and Bender, 1996) Given that human pathogens are not common colonizers of pome fruit flowers, the probability of direct acquisition of antibiotic resistance genes from resident phyllosphere bacteria in the tree canopy is reduced. (Stockwell and Duffy, 2012)

Even those most concerned about spread of antimicrobial resistance state that the molecular details of the emergence of resistance genes "...suggest that an enormous number of encounters between agent and germs have been needed to produce the first emergence of most resistance genes." (O'Brien, 2002) Presumably, this resistance would first be seen in the target organism, *Erwinia amylovora*, since it has far more "encounters" than any human pathogen organism would have in an orchard. Yet this has not been the case. This same article continues that resistance in the bacteria for the first host is key to making it more likely to transfer to a second strain on another host. The implication is that the resistance gene has to come into contact with human or animal pathogenic bacteria in order to move out of the orchard environment. Since plant hosts are not mobile in the way humans or animals are, the chances of this happening mean that the alternate host has to come into the orchard while the material is still active.

During the process of spraying, a portion of the material lands on the orchard floor. The supposition that resistance genes could build up in the soil has not been supported by recent studies. (Duffy et al., 2011; Popowska, et al., 2012; Walsh, et al., 2011) Tetracycline is absorbed onto soil particles and rapidly rendered inactive. (Subbiah et al., 2011) The authors of this study speculate that antibiotic residues from foliar applications would have minor effects, if any, in increasing antibiotic resistance genes in soils.

Conclusion
There is no evidence that applications of antibiotics to orchards during bloom contributes to antibiotic-resistance in human pathogens. Human pathogens have not been found in orchards and would have to be present for the resistance genes to transfer. (Stockwell and Granatstein, 2013) The fire blight organism has not shown any signs of resistance itself, thus negating the first step in the transfer of potential resistance genes. The tetracycline is active for a very short time period on plant tissues and it is long before harvest. (Christiano et al, 2010) Naturally occurring tetracycline resistant bacteria may be minor components of the overall bacterial communities found on apple flowers and in soils, but their presence is independent of the antibiotic application. The amount and timing of the use of this material in an orchard environment does not contribute to any human health concerns.

Checklist Discussion Continued:
Category 2 Questions 9 and 10: The Pear Perspective

Fire blight disease caused by *Erwinia amylovora* poses unique challenges in pears. Because pears bloom earlier than apples in general and the bloom can last for a longer period, they are often more susceptible to fire blight. This discussion focusses on some issues unique to pears because their production will be more challenged by the expiration of oxytetracycline.

Pear growers use integrated management to control fire blight that includes removing infected wood during pruning and spraying copper at early green-tip help to reduce inoculum levels before the growing season. Preventive sprays of oxytetracycline and/or streptomycin are used because applications before infection are known to be more effective than those applied after infection. (Adaskaveg, 2010; Keil & Wilson, 1962) These preventive sprays are based on predicted weather conditions from computer models such as Cougar Blight or Maryblyt Model. However these models are better at predicting high-infection risk from in the primary bloom that is relatively short but not in the secondary (rat tail) bloom that can last two months. (Holtz et al., 1999; Holtz et al., 2002) They also failed to predict warm dew infection periods during rainless weather in the Central Valley of California. (Holtz et al., 2002) The Zoller Degree Hour Model (Zoller, 2000) is widely used in pears and can predict the build-up of the causal bacteria in blossoms, as well as suggesting risk-based changes in treatment frequency needed during rainless infection periods. Refinements of all the models is ongoing, but each pear region needs a model tailored to the local specific growing conditions; something not currently available.

Pear varieties show less variation in resistance than apples and are generally more susceptible to fire blight. (Granatstein et al., 2011) A few "blight resistant" cultivars have been developed but these have not shown full resistance in all locations and have not been popular with consumers.

The alternatives to oxytetracycline and streptomycin are not as well researched in pears as in apples, but some of the same limitations are more pronounced in pears. Coppers are being tested at green-tip stage in pears but cannot be used at bloom or after on clear-skinned fruit because they cause fruit russetting, rendering the fruit unmarketable. The biological antagonists such as *Pseudomonas fluorescens* A506, or *Pantoea agglomerans* strains C9-1 and E25 have either not been tested for as long a period of time in pears and/or the results have been inconsistent. The new yeast product, Blossom Protect, has only been tested for one year in pears. The biological products also must be separated in time from the use of coppers or lime-sulfur, thus possibly interfering with scab treatments. The use of alternative treatments has also resulted in increased russet and loss of fresh market quality. (Zoller, 2011)

In general organic production of pears has lagged behind that of apples largely because of the fire blight problems. Pears take 6 to 7 years to bear their first significant commercial crop and live for 50 to 80 years, so a planting is a larger investment in time and not as easy to replace as apples, which

can produce in 3 to 4 years and live 20 to 50 years. A very limited quantity of pears is now produced without antibiotics for the EU market. These blocks often have to be removed from an EU program periodically to address fire blight infections.

Conclusion for Majority Position

The organic farming sector is committed to developing and implementing a non-antibiotic approach to controlling fire blight in organic apples and pears. Some progress has been made in recent years to identify research needs, secure some research funding, and take an initial look at some promising alternative controls. Because apple and pear growers are spread throughout a majority of the country and are decentralized in organization, the relevant regional research and extension of those results will not reach all the growers by the 2014 expiration date.

Retaining that date could potentially cause immense financial loss for a variety of organic stakeholders and could cause many producers to go out of business. Their fruit could potentially be replaced with organic fruit from Chile, China, and various other countries where there is no fire blight, or with conventionally grown fruit containing a full array of chemicals.

A short extension will benefit organic stakeholders that could be affected by this decision, such as consumers, producers, handlers, and retailers. Giving producers a chance to have good access and experience with other control methods will make sure that consumers have a choice of variety of organic fruit in the marketplace that they have grown accustom to having.

Discussion of the Position to Allow Expiration of Oxytetracycline Listing in October 2014 (Minority Position)

It has been clear for several sunset and expiration reviews that environmental and consumer groups do not support another extension of the listings for antibiotics (oxytetracycline –referred to as tetracycline– and streptomycin) in apple and pear production. This position is based on the analysis that antibiotics for fire blight fail the three NOSB review criteria for materials used in organic production—(i) environmental and health impacts, (ii) compatibility with organic principles, and (iii) essentiality.

Basis for Urgent Action to Remove Antibiotics from Organic Production

There are several principal understandings that form the foundation in science and law for acting to remove antibiotics from organic apple and pear production in an urgent manner:

i. Tetracycline is an antibiotic considered by the World Health Organization to be of critical importance to human medicine.[1]

ii. Tetracycline is used in a way—broadcast spray on trees—that exposes bacteria in the orchard, particularly in the soil, to the antibiotic.[2]

iii. Current science shows that environmental exposure to antibiotic use in the environment is the major cause of development and spread of antibiotic resistance in human pathogens.[3]

iv. The spread of antibiotic resistance does not require contact between the antibiotic and human pathogens because the major means of spreading antibiotic resistance is through the transfer of genes between different bacteria.[4]

vi. Uses resulting in low residues (subtherapeutic or subinhibitory levels) can create a high health risk.[5]

vii. Tetracycline resistance is evident and expected to grow if urgent use precaution is not exercised.[6]

viii. Organic National List standards require adherence to practices and inputs that ensure, "Production practices implemented in accordance with this subpart must maintain or improve the natural resources of the operation, including soil and water quality." (7 CFR §205.200**)**

NOSB Review Criteria

I. Environmental and Health Effects.
Finding: Antibiotic use in organic agriculture —in both animal and plant production— contributes to the spread of antibiotic resistance in human pathogens, while infectious disease are a critical human health issue increasingly uncontrolled. Organic standards are intended, by statute and rulemaking, to lead in the adoption of practices that reverse threats. Several hazards associated with the use of antibiotics in fruit production have been documented in technical reviews.

Summary
Agricultural use of antibiotics—including the spraying of tetracycline in orchards—increases the proportion of antibiotic resistant bacteria through the well-known mechanisms of selection and horizontal gene transfer. [7] This is affirmed in standard scientific texts and is part of the extensive record of NOSB proceedings,[8] which has supported extensive efforts and votes by the NOSB to end the use of antibiotics in organic agriculture. The mechanism of antibiotic resistance –the use of antibiotic anywhere increases the proportion of antibiotic resistant bacteria everywhere– is a fact well-known to all microbiologists and has been crucial to the development of strategies to reduce antibiotic resistance in bacteria that produce human disease.[9] Tetracycline and streptomycin are both considered "critically important antimicrobials"[10] and according to federal guidance, the risk to human health from their use is "high."[11]

Tetracycline Resistance
Resistance to an antimicrobial agent such as tetracycline is promoted when microbes (in this case, bacteria) are exposed to an antimicrobial agent.[12] When bacteria are exposed to tetracycline, two things happen: (1) the bacteria that are susceptible to tetracycline are killed, while those not susceptible survive,[13] and (2) conjugation with other bacteria increases.[14] This conjugation is a sharing of genetic material known as "horizontal gene transfer," and it does not need to be between related bacteria.[15] It can be between an innocuous soil bacterium and *Escherichia coli* (E-coli), for example.[16] Those bacteria receiving genes through conjugation may, in turn, share those genes with other bacteria, including human pathogens not present in the orchard.[17]

Therefore, spraying tetracycline in an orchard will increase the proportion of bacteria that are resistant to tetracycline, and increase the likelihood that human pathogens –which may not be in direct contact with tetracycline, but may be in contact with bacteria that were in direct contact with tetracycline –will end up with genes for tetracycline resistance. This is why the primary strategy for maintaining the effectiveness of antibiotics is to eliminate all non-therapeutic use.[18]

This is not a theoretical issue or a problem of scientific uncertainty. The consequences of spreading genes for resistance to tetracycline are considered severe by the World Health Organization (WHO). WHO has classified tetracycline as a "critically important antimicrobial" because it meets two criteria: (1) it is used as the sole therapy or one of few alternatives to treat serious human disease (limited therapy for infections due to *Brucella*, *Chlamydia* spp. and *Rickettsia* spp.), and (2) it is used to treat

diseases caused either by organisms that may be transmitted via non-human sources or by organisms that may acquire resistance genes from non-human sources (transmission of *Brucella* spp. from non-human sources). [19]

Although the promotion of resistance to tetracycline in human pathogens does not require direct contact between those pathogens and the sprayed tetracycline in the orchard, there is evidence that such direct contact does occur. First of all, tetracycline may be taken up by plants, so that pathogens may be exposed when a person consumes the fruit.[20] Second, there is an EPA food residue tolerance for tetracycline on the fruit, supported by field studies that found residues on fruit after harvest--which is another way for pathogens in a person to be exposed to tetracycline.[21] Finally, tetracycline maintains its antibiotic activity as it is adsorbed to soil particles and later released, allowing direct exposure to tetracycline through soil in air, water, or on fruit.[22] Workers, of course, are at higher risk of direct exposure.[23]

Other Impacts on Human Health

The major impact on human health from tetracycline use is the increase in the pool of antibiotic resistant bacteria that can lead to resistance in human pathogens.[24] However, other health effects are associated with exposure to tetracycline, such as developmental toxicity, and full formulations applied to orchards, which contain the known human carcinogen crystalline silica.[25]

Environmental Contamination and Ecological Impacts

The 2006 TR (TR1) lists a number of substances that may be released in the manufacture of tetracycline, including solvents, detergents, disinfectants, and oxides of nitrogen and sulfur.[26]

Quoting from the 2011 TR (TR2),

> "Thiele-Bruhn (2003) reported that, in general, the effects of an antibiotic on soil organisms are essentially influenced by the bioavailability of the antibiotic, which depends on soil properties, availability of nutrients, and presence of root exudates. Tetracyclines exhibit strong adsorption to soil components such as clay and organic matter and form strong bonds with metals in the soil. These interactions limit the bioavailability of tetracyclines to microorganisms in the soil. (Lui et al., 2009) Tetracycline can persist in soil for long periods of time without showing antimicrobial activity, and high concentrations can be achieved. (Popowska et al., 2010) Upon later release from soil components, it can exhibit antimicrobial activity. Factors that may result in a release of tetracycline from the soil include changes in organic material composition of the soil, shifts in microorganism populations, or changes in soil pH (Aga et al., 2005)."[27] The TR also mentions reductions in fungi, fungal/bacteria biomass, rate of soil nitrification, nodulation of legumes, length of fungal hyphae of mycorrhizal fungi, and bacterial diversity.[28] The TR cites a study that found no direct effects on three species of soil fauna, but "the authors noted that it is not possible to exclude the possibility of indirect effects on soil fauna caused by changes in the microbial community following application of oxytetracycline."[29]

Key Elements of Scientific Understanding

The concerns about the human health impacts of tetracycline use are based on an understanding of the mechanisms by which antibiotic resistance develops and spreads and is directly associated with antibiotic resistance. In this context, the NOSB assesses whether an allowed material in organic production is contributing to an adverse impact even though it may be permitted under statutes other than the Organic Foods Production Act (OFPA). The standard of protection in OFPA and its overriding commitment to sustainability and improvement of the environment means that NOSB decisions must seek to exceed risk minimization standards of other statutes by looking to eliminate dependencies on practices and inputs that cause harm. This is captured in 7 CFR 205.200,

“Production practices implemented in accordance with this subpart must maintain or improve the natural resources of the operation, including soil and water quality.” Thus, it is the intent, spirit, and letter of OFPA that puts organic systems at the forefront of rejecting practices that are not sustainable and puts us on a path detrimental to the environment and health.

(i) Horizontal gene transfer and the American Academy of Microbiology, 2009.[30] The American Academy of Microbiology (AAM) report, cited above in the pro-extension majority position discussion, must be read in full to glean a complete understanding of its position and urging that antibiotic resistance be treated as an urgent matter to prevent the spread of resistance in the environment and preserve the efficacy of antibiotics for human therapeutic use. Therefore the elements of the report are cited here:

- “If science and medicine cannot win a war against antibiotic resistance, what CAN be done? We have to find a way to co-exist with resistance. To minimize the loss of life, we can develop strategies to prevent new resistance from spreading and, where resistance already exists, identify the strains we need to protect against, find ways to treat resistant infections effectively in patients, and manage reservoirs of antibiotic resistant strains in the environment. Preventing development of new forms of resistance should rely, in part, on prudent use of antibiotics with an eye to the ecologies of pathogens and other microorganisms.”[31] (pp.5-6)
- “It is mandatory to prevent the needless use of antibiotics…” (p.2)
- “Horizontal gene transfer, in which genetic information is passed between microbes, allows resistance determinants to spread within harmless environmental or commensal microorganisms and pathogens, thus creating a reservoir of resistance.” (p.1)
- “Horizontal gene transfer—the movement of genetic material from one organism to another—is the primary mechanism by which bacteria acquire antibiotic resistance. Antibiotics promote this genetic exchange by inducing the transfer of conjugative elements.” (p.8)
- “[A]ntibiotics always select naturally resistant bacteria and the strains which have acquired resistance…” (p.3)
- “The rate of antibiotic resistance emergence is related to all uses of these drugs, not just misuse…” (p.4)
- “Most organisms can be sources of resistance genes, but selection for antibiotic resistance most often takes place in non-pathogenic microorganisms, since they comprise the vast majority of the microbial world.” (p.5)
- “Developing resistance to antibiotics increases the cache of genes available to microorganisms and impacts many other genes as well, thereby contributing to the evolutionary possibilities available to them. Once a microorganism derives a genetic tool for resistance, it can pass that gene on to its progeny by clonal replication or to other microbes through horizontal gene transfer…” (p.5)
- “Selection for antibiotic resistance takes place anywhere an antibiotic is present: in the skin, gut, and other areas of the bodies of humans and animals and in the environment…” (p.7)

(ii) Importance of low concentrations of antibiotics to resistance and other factors. While there are certainly many contributory factors to antibiotic resistance, such as widespread use of the antimicrobial triclosan (not allowed in organic systems), this factor does not minimize the critical role that low level concentrations of antibiotics play in enhancing resistance.

The NOSB review process seeks to remove the hazards under assessment, recognizing that there may be other hazards as well, many outside the control of the board. While multiple factors may contribute to the development of resistance, the NOSB considers the various factors individually under the National List review process and assesses whether they contribute to harm individually.

Additionally, the standards of material review require an assessment of harm associated with its manufacture, use, and disposal.

In this regard, AAM says the following:

- The use of sub-inhibitory (or sub-MIC) concentrations of antibiotics plays several important roles in the development of resistance. Like low concentrations of biocides (see *Anti-Infective Strategies and Antimicrobials*, above), low concentrations of antibiotics could enrich for resistance genes in a population while having little effect on overall mortality."[32]
- "The tendency to mutate also increases upon exposure to sub-inhibitory concentrations of antibiotics. Pathogens can initiate an SOS response (a DNA repair pathway) when subjected to low concentrations of antibiotics like quinolones, which affect DNA synthesis. This may make them more prone to develop resistance in the future. Low concentrations of antibiotics can also select for strains that increase expression of their existing resistance genes, further enhancing their resistance.[33]

(iii) Consideration of EPA findings. While regulatory agencies, such as EPA, register materials permitted by National List criteria, the standard by which EPA registers materials that are used in chemical-intensive agricultural production do not necessarily meet the standards of OFPA. EPA has registered tetracycline in fruit production and its ongoing review through its reregistration process (with timelines subject to change) cannot be the basis for delaying NOSB action based on the board's statutory mandated technical review and assessment process. Nor can the NOSB rely on judgments that EPA makes under other statutory standards, including "no unreasonable adverse effects" or "reasonable certainty of no harm," both governed by risk assessments. Therefore, EPA's pesticide registration of tetracycline (2008) and open docket until June 2014, with an expected completion date of September 2014, does not necessarily add additional information beyond the Technical Review and cannot delay action under OFPA.

(iv) Higher exposure to tetracycline in therapeutic context. A higher use rate of tetracycline in a therapeutic context does not justify its allowance in organic agricultural production systems that seek to break the cycle of dependency on inputs and practices known to have deleterious effects on health and the environment. The fact that typical pharmaceutical exposures to humans are 50,000 to 200,000 times greater than the theoretical dietary exposure[34] does not justify an acceptable relative risk standard by which toxic inputs are allowed in organic production. If it were, reduced uses of virtually all hazardous synthetics would be allowed in organic production, based on the assessment that less is used than in chemical-intensive agriculture. Of course, that analysis does not justify the use of National List materials.

Again, as explained above, the issue with respect to antibiotic resistance is <u>not</u> only direct human exposure to tetracycline, but the exposure of bacteria to tetracycline in the environment.[35] And, as explained above, subinhibitory doses lead to increased antibiotic resistance.

(v) Resistance associated with orchard use has been found.
The pro-extension majority position, citing Schnabel and Jones (1999), points out that, "In orchards treated with antibiotics, only 5% of the bacteria isolated from flowers or leaves was resistant to oxytetracycline (10 µg/ml)." Even if this were the only finding in the study, it would be a significant finding, establishing the resistance mechanism and the threat that it presents. However, the authors also found higher levels of tetracycline resistance in the orchard that had a history of five years use of tetracycline before the experiment. In addition, to become problematic, resistance associated with tetracycline use in apple and pear production does not have to start with the fire blight bacterium becoming resistant. There are many bacteria in an orchard environment, including those resident in

orchard workers, which can contribute to the spread of resistance. See discussion of AAM 2009 above.

(vi) Laboratory studies provide useful data in conjunction with field studies, show tetracycline persistence for "long periods"[36] . . .upon later release from soil components."[37] The extension proponents have criticized the TR's treatment of individual studies in the section dealing with the persistence of tetracycline in soils. The complete text from the TR is helpful in understanding both the laboratory and field data:

> Although oxytetracycline, as an antibiotic, is toxic to some microorganisms in the soil, it is already present in soil due to production by naturally occurring bacteria. Thiele-Bruhn (2003) reported that, in general, the effects of an antibiotic on soil organisms are essentially influenced by the bioavailability of the antibiotic, which depends on soil properties, availability of nutrients, and presence of root exudates. Tetracyclines exhibit strong adsorption to soil components such as clay and organic matter and form strong bonds with metals in the soil. These interactions limit the bioavailability of tetracyclines to microorganisms in the soil (Lui et al., 2009). Tetracycline can persist in soil for long periods of time without showing antimicrobial activity, and high concentrations can be achieved (Popowska et al., 2010). Upon later release from soil components, it can exhibit antimicrobial activity. Factors that may result in a release of tetracycline from the soil include changes in organic material composition of the soil, shifts in microorganism populations, or changes in soil pH.[38] (Aga et al., 2005)

Laboratory studies can be helpful, especially in the context of field studies. See 2011 TR lines 502-511:

> Popowska et al. (2010) demonstrated in a laboratory experiment that the presence of tetracycline in three different types of soils affected the ecological balance in the soil, causing the elimination of some bacterial populations. In this study, varying concentrations of tetracycline (1 – 9 ppm) were added to three different soil types in a laboratory setting: forest soil from a pine forest, fertile arable agricultural soil, and garden compost. The soils were then incubated for 14 days. The authors found that 2 ppm and higher concentrations of tetracycline caused a significant reduction in bacterial count and many bacterial species were eliminated from the soils. The eliminated species were described as beneficial bacteria involved in various metabolic processes, mineralization of organic compounds, degradation of toxic compounds, or creating soil structure. This study also isolated from the soils many strains of bacteria demonstrating resistance to tetracycline, including opportunistic pathogens of humans and/or animals.

(vii) Tetracycline has been shown to be taken up by a range of plants, both annual and perennial, and residuals are found in or on fruit. Kong et al. found the uptake of oxytetracycline by alfalfa, a perennial plant.[39] "In an energy-dependent process," Sinha et al. showed that leafhoppers feeding on plants grown in a medium treated with tetracycline also absorbed tetracycline from the plants.[40] Nevertheless, there is agreement that tetracycline residues are found, albeit at low levels, in or on the treated fruit. According to the 2011 TR, "The current tolerance (maximum residue limit) for oxytetracycline on or in apples and pears is 0.35 ppm."[41]

(viii) The linkage of agricultural use to antibiotic resistance is identified by FDA, absent direct exposure to the use pattern. Horizontal gene transfer is the central issue of concern relative to tetracycline use in apple and pear production and antibiotic resistance in humans. As stated earlier, tetracycline is considered a "critically important antimicrobial" by the World Health Organization.[42] FDA's Guidance 152 for evaluating the impact of animal drugs on human health considers the risk to human health to be "high" when an antibiotic is "critically important" even if the probability that the use

of the antimicrobial will result in the emergence or selection of resistant bacteria is low and the probability of direct exposure to humans is low.[43]

Nevertheless, human beings can be found in orchards, and humans carry human pathogens. However, the presence or absence of human pathogens in orchards is not the prime consideration since the primary mechanism of the spread of antibiotic resistance is horizontal gene transfer, and the primary site of development of antibiotic resistance is the "environment."[44]

There is no need for contact with a human or animal pathogen in order for the resistance genes to move out of the orchard environment. As long as the bacteria in the orchard are exposed to tetracycline, the selection for resistance will continue. Those bacteria may move out of the orchard in dust on fruit, airborne dust, dirt attached to workers' shoes, or in many other ways. O'Brien (2002) says, "The abundance of *E. coli* implicates them as the likely predominant vehicles for the spread of resistance genes and vectors, as opposed to the spread of infection, between the bacterial populations of animals and humans…"[45]

(ix) The finding of resistant bacterial in soils is troubling. The focus of mechanism of antibiotic resistance is necessarily focused on the huge number of bacteria in the soil, even though there may be some research showing short tetracycline activity on plant tissue. With a focus on soil tests, such as those conducted by Popowska, it was found that, "Bacteria with the highest MICs [minimum inhibitory concentrations] were detected in manure-amended soils or soils from agricultural systems with a history of antibiotic use."[46] MICs are the indicator that is used to confirm antibiotic resistance. Meanwhile, as indicated in the scientific literature cited in this section, a finding of resistant bacteria in the phylosphere is not required for resistant genes to have adverse impact on human health. And, the existence of naturally occurring tetracycline does not address the effect of additional applied tetracycline and the biological impact that it has on the bacterial resistance to antibiotics. In fact, the fire blight organism is not necessarily the first to develop resistance.

II. The use of antibiotics in organic production is incompatible with organic principles.[47]

Rather than relying on practices central to organic production —such as the choice of resistant cultivars and rootstocks[48]— the antibiotic-dependent system relies on synthetic off-farm inputs.[49] The use of antibiotics to control fire blight is not sustainable[50] and does not promote the long-term viability of organic farm operations because resistance to antibiotics will ultimately develop.[51] This has already been experienced with streptomycin resistance to fire blight in the northwest.[52] The use of antibiotics in organic fruit production is inconsistent with the prohibition against antibiotics in organic livestock production.[53] It is inconsistent with organic standards in the European Union and Canada.[54] The use of antibiotics in organic fruit production does not satisfy consumer expectations regarding the authenticity and integrity of organic products.[55] As reported in "Organic pome and cherry production and marketing issues: Past, present and future," and presented to IFOAM, "Over the last ten years, the Hartman Group (Bellevue, Washington, USA) has studied changes in consumer attitudes, backgrounds, and buying characteristics related to the organic market. The Hartman Group surveyed about two thousand household consumers across four regions of the USA. They found that the 'traditional' properties suggested by 'organic' were no longer the same properties held by the new organic consumer. The survey indicated that traditional properties such as 'locally-grown,' Fair Trade, 'tastes better,' and sustainable production ranked at the bottom. The new organic consumers made it clear that they want, plain and simple, a product centered around the 'absence of all health concerns,' and the absence of pesticides, growth hormones, GMO's, antibiotics, and BSE."[56]

The process surrounding antibiotics since the beginning of the National Organic Program has consisted of repeated acknowledgement of the public health hazard, accompanied by warnings that the tetracycline and streptomycin listings for apple and pear production were phasing out "the next

time."[57] Each time, the use of these materials has been extended with great and increasing reluctance. While the sunset and expiration process has been used as a way of injecting continuous improvement into the organic systems approach to agricultural production and handling, the OFPA process requires that substances meet the three criteria identified at the beginning of this section —(i) environmental and health impacts, (ii) compatibility with organic principles, and (iii) essentiality[58] The OFPA standards require an assessment distinct from pesticide registration process under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and require the prohibition of inputs that cause adverse health and environmental effects, even in the face of production practices that are reliant on the material.

III. The use of antibiotics in organic fruit production is not essential.

Like most challenges in organic production systems, with fire blight there is no one material and no one practice that will eliminate the problem. Fire blight must be met with a truly organic systems approach.

With regard to the "essentiality" of tetracycline, not all organic apple and pear growers depend on antibiotics. In fact, there is a sizeable proportion of growers of both apples and pears who do not use antibiotics. However, many say that large scale, commercial, organic apple and pear production would end without tetracycline. In an organic market where consumers expect no antibiotic use, it is no small point that after years of NOSB debate and votes on discontinuing antibiotic use there is an expectation that the transition to less susceptible varieties and alternative practices would take place by the October 2014 expiration date adopted by the NOSB in 2011.

At the April 2011 meeting of the NOSB in Seattle, Katherine Withey of the Washington State Department of Agriculture's Organic Food Program said in a statement that, "In 2010 WSDA certified 719 producers. Of these producers, 361 were certified for apples and/or pears, and of these 361 producers 136 [38%] used tetracycline and 34 [9%] have used streptomycin."[59] Thus, it appears that a minority of apple and pear producers rely on these antibiotics. As of March 10, 2011, there were 96 businesses certified as EU-compliant organic producers of apples and/or pears in the state of Washington alone, representing about one third of the state's organic apple and one fourth of the state's organic pear production.[60] EU-compliant organic apple and pear growers cannot use antibiotics, and face a three-year ban from selling in the EU if they do. Instead, these growers rely on a number of other practices, allowing them to avoid fire blight damage to susceptible varieties:[61]

- Balancing nutrients and avoiding over-application of nitrogen fertilizers, especially on susceptible varieties of apples or pears;
- Avoidance of over-pruning in the dormant season;
- Use of pre-bloom foliar nutrient sprays even though there is no foliage;
- Use of copper materials on the trees between delayed dormant and tight cluster sages as preventive measures against overwintering FB;
- Use of lime sulfur during bloom to thin apples; and,
- Use of Serenade MAX (in the future, perhaps Blossom Protect) post-bloom and at petal-fall, with good spray coverage.

With some differences for pears:

- For the Bosc, use of low levels of copper only sprayed foliar during bloom and infection periods;

- For pear varieties Bartlett and Anjou which are subject to skin russetting, use of antagonistic bacterial products during bloom, followed by Serenade MAX or Blossom Protect at petal-fall; and,
- Copper and Lime Sulfur with oil.

In addition, Steiner's observations offer insight into how changes in the orchard environment[62] have contributed to epidemics of fire blight.[63] In response, the following is suggested:

- Increase species diversity;
- Decrease tree density;
- Use resistant cultivars and rootstocks;
- Plant a variety of cultivars on a variety of rootstocks.

Evaluation Criteria

(Applicability noted for each category; Documentation attached)	**Criteria Satisfied?**
1. Impact on Humans and Environment	☒Yes x [1]No ☐ N/A
2. Essential & Availability Criteria	☒ Yes x No ☐ N/A
3. Compatibility & Consistency	☒ Yes x No ☐ N/A
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for § 205.606)	☐ Yes ☐ No ☒ N/A

Substance Fails Criteria Category:[ ]**Comments:**

Proposed Annotation (if any):

Basis for annotation:☐To meet criteria above☐Other regulatory criteria ☐Citation

Recommended Committee Action & Vote, including classification recommendation (state actual motion):

Classification Motion: N/A
Motion by: Seconded by:
Yes: No: Absent: Abstain: Recuse:

Listing Motion:

The Crops Sub-Committee recommends amending the listing for tetracycline to remove the expiration date of October 21, 2014 and add the following annotation:
§205.601 Synthetic substances allowed for use in organic crop production
(i)As plant disease control.
(12) Tetracycline, for fire blight control in apples and pears only until October 21, 2016.

Motion by: Nick Maravell Seconded by: Harold Austin
Yes: 5 No: 3 Absent: 0 Abstain: 0 Recuse: 0

Resolution:

[1] "No" check marks indicate minority viewpoint.

The National Organic Standards Board is committed to the phase out of this material. The board urges growers and certifiers between now and the 2016 expiration date to encourage an annual increase in the extent and/or number of alternative practices that are trialed for controlling fire blight. In addition, the board strongly supports increased support for the research into these alternative practices and materials.

Motion by: Nick Maravell Seconded by: Zea Sonnabend
Yes: 7 No: 0 Absent: 1 Abstain: 0 Recuse: 0

Crops	☒	**Agricultural**	☐	**Allowed**[1]	☐
Livestock	☐	**Non-synthetic**	☐	**Prohibited**[2]	☐
Handling	☐	**Synthetic**	**x**	**Rejected**[3]	☐
No restriction	☐	**Commercial unavailable as organic**	☐	**Deferred**[4]	☐

[1]Substance voted to be added as "allowed" on National List to § 205. with Annotation (if any):

[2]Substance to be added as "prohibited" on National List to § 205.with Annotation (if any):

Describe why a prohibited substance:

[3]Substance was rejected by vote for amending National List to § 205. Describe why material was rejected:

[4]Substance was recommended to be deferred because
If follow-up needed, who will follow up:

Approved by Subcommittee Chair to Transmit to NOSB

Jay Feldman Subcommittee Chair February 11, 2013

NOSB Evaluation Criteria for Substances Added To the National List

Category 1. Adverse impacts on humans or the environment? Substance: Oxytetracycline

Question	Yes	No	N/A[1]	Documentation(TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]			x	
2. Is there		x		**[Majority Position]** Line 397 (April1, 2011 TR) states no

environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]				current information can be found on possible contamination from the manufacture of agricultural oxytetracycline products. Lines 398-412 does state that the potential could be there because of the solvents used in the fermentation process. Lines 412-414 state that if the manufacturers comply with the applicable air and water regulations, it is unlikely that environmental contamination will result from fermenting processes. See above – if the label is followed and all applicable air and water regulations followed there should be no environmental contamination, other than from misuse. In the April 2011 Checklist it mentions "treated plants exude tetracycline", the petitioner rebuts this stating that there is no data that they could find that shows apple and pear trees exude tetracycline. WSHA (the petitioner) states that scientific evidence supports the understanding that tetracycline does not freely translocate within an apple or pear tree, nor is it exuded from plants[2]. It is the majority opinion that the papers cited by the minority do not actually support these claims. **[Minority Position]** WSHA does not actually present any citations to support their claim that tetracycline is not translocated in or exuded by plants. Translocation of oxytetracycline is occurring as sprayed material on blossom ends up in fruit. See U.S. 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 "Oxytetracycline tolerances are currently established on peaches and pears at 0.35 ppm in terms of oxytetracycline, only. A tolerance on apple is proposed, also at 0.35 ppm.TR1[3] lines 149-164; TR2 397-426. This is reinforced by label on another oxytetracycline product, Mycoject, while only registered for ornamental, indicates on its label that it is applied by injection and acts by translocation. See Mycoject label, http://www.mauget.com/ProductLabels/AnitiboticLabels/Mycoject.pdf TR1 (lines 149-164); TR2 (lines 397-426): Manufacture may result in discharges of solvents, detergents,

[2] Washington State Horticultural Association, 2011. Comment on the re-listing of tetracycline to docket AMS-NOP-11-0014, page 3.
[3] TR1 is TR dated January 27, 2006.

				disinfectants. Kumar et al, 2005; Kong et al, 2006; Sinha and Peterson, 1972; Daniels, 1982:[4] Treated plants may contain and exude tetracycline. TR2[5] 291-294: "Once released into the soil, oxytetracycline is expected to become strongly adsorbed to soil particles and have moderate to no mobility. (Kumar et al., 2005; HSDB, 2006) This means it can remain in soil for a long time following treatment. Furthermore, it is not likely to leach below the surface soil (Aga et al., 2005); however it can spread by surface run-off of sediment." TR2 322-324: "Chander et al. (2005) demonstrated that even though tetracycline was tightly adsorbed to clay particles in soil, it was still biologically active" following a 24-hour incubation period.
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]	x	x		**[Majority Position]** April 29, 2011 Checklist refers to a report by Thiele-Bruhn and Beck, 2005 on the effects of tetracycline in soil microbial activity. This report is appears to refer to two soil groups representative of European soils. This report does not reflect typical soils or types of soil amendments found in the U.S[6], nor does it reflect the use pattern for this allowed substance as it is listed. **[Minority Position]** See complete reference to TR2 (lines 296-307) that cites scientific literature on limited to no oxytetracyline degradation in U.S. soils: "[T]he extent and kinetics of antibiotic degradation in soil is highly dependent on temperature, soil type, and antibiotic adsorption to soil (Thiele-Bruhn, 2003). One study reported no degradation of oxytetracycline in a soil and manure sample after 180 days (Thiele-Bruhn, 2003). In a field study with silt loam soil, the measured amount of oxytetracycline in the soil declined by 50% in three weeks following application of manure with oxytetracycline, however the amount of total tetracyclines did not significantly decline after 5 months (Aga et al., 2005). Another study showed that oxytetracyline residues were present in agricultural soil 10 months after fertilization with manure containing oxytetracycline (Cengiz et al., 2010). Wang and Yates (2008) found the half-life of

[4] K. Kumar, S.C. Gupta, Y. Chander, and C.J. Rosen, 2005. Antibiotic Uptake by Plants from Soil Fertilized with Animal Manure. J. Environ. Qual. 34:2082–2085 (2005).
W.D. Kong, 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.
RC Sinha and EA Peterson, 1972. Uptake and persistence of oxytetracycline in aster plants and vector leafhoppers in relation to inhibition of clover phyllody agent, Phytopathology 62: 50-56.
MJ Daniels, 1982. Editorial: Possible effects of antibiotic therapy in plants. Reviews of Infectious Diseases 4 (Supp): 167-170.
[5] TR2 is TR dated April 1, 2011.
[6] Washington State Horticultural Association, 2011. Comment on the re-listing of tetracycline to docket AMS-NOP-11-0014, page 4.

				oxytetracycline to be 33 days in manure-amended soil and 56 days in non-amended soil. Yang et al. (2009) reported half-lives for oxytetracycline between 29 and 56 days for non-sterile treatments and 99 to 120 days for sterile treatments (aerobic conditions), and between 43 and 62 days in the non-sterile soil and 69 to 104 days in sterile soil (anaerobic conditions)." Thiele-Bruhn and Beck, 2005:[7] "The antibiotics significantly ($p < 0.05$) reduced numbers of soil bacteria, resulting in dose related shifts in the fungal: bacterial ratio, which increased during 14 d, as determined from analysis of ergosterol and EC. It was concluded that pharmaceutical antibiotics can exert a temporary selective pressure on soil microorganisms even at environmentally relevant concentrations." Aminov, 2011:[8] "There is a substantial body of evidence suggesting that the sub- inhibitory concentrations of antibiotics may significantly increase the frequency of horizontal transfer of many types of MGEs [mobile genetic elements]." See #6 below. TR2 322-324: "Chander et al. (2005) demonstrated that even though tetracycline was tightly adsorbed to clay particles in soil, it was still biologically active" following a 24-hour incubation period. There is a concern that the persistence of oxytetracycline residues in the environment may contribute to the development of bacterial resistance to oxytetracycline and other tetracyclines (Arikan et al., 2007)."
4. Does the substance contain List 1, 2 or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]		x		
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		x		**[Majority Position]** TR 2 (page 9 lines 432-434) states that there is no information available to assess whether spray applications of tetracycline will cause chemical reactions or interaction with other materials used in organic crop production. **[Minority Position]** Burgos et al, 2003:[9] Bacteria with multiple resistances may result from use of oxytetracycline and manure treated with other antibiotics.
6. Are there adverse		x		**[Majority Position]** TR2 (lines 442-453): it was stated

[7] Sören Thiele-Bruhn, and Iris-Constanze Beck, 2005. Effects of sulfonamide and tetracycline antibiotics on soil microbial activity and microbial biomass. **Chemosphere**, Volume 59, Issue 4, April 2005, Pages 457-465
[8] Rustam I. Aminov, 2011. Horizontal gene exchange in environmental microbiota, Front Microbiol. 2011; 2: 158.
[9] Burgos JM, Ellington BA, Varela MF., 2005. Presence of multidrug-resistant enteric bacteria in dairy farm topsoil. J Dairy Sci. 2005 Apr;88(4):1391-8.

biological and chemical interactions in agro-ecosystem? [§6518 m.5]				that there were no available information on the interactions in the agro-ecosystems following the use of oxytetracycline specifically for foliar use to control fire blight in apples and pears. There are studies where tetracycline has been applied directly to the soil and usually are related to manure applications where tetracycline treatments of the animals have been used, or where it has been included in feed stocks. **[Minority Position]** Thiele-Bruhn and Beck, 2005: Oxytetracycline shifts fungal-bacterial balance at environmentally relevant concentrations.TR2 469-511: Application of oxytetracycline changed fungal and bacterial composition of soils and reduced the rate of nitrification.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		x		**[Majority Position]** The TR from 2006 (Lines 210-212): Therefore, it seems unlikely that proper use of calcium oxytetracycline to control fire blight in organic crop production would cause any adverse chemical or biological interactions in the agro-ecosystem. The 2011 TR also indicates no negative interactions could be found in literature (2011 TR lines 432-436. **[Minority Position]** TR2:" No information could be found on interactions in the agro-ecosystem following the use of oxytetracycline specifically for control of fire blight in apples and pears." TR2 does present results of a number of laboratory studies.
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]	x	x		**[Majority Position]** The 2011 Checklist and the petitioner have both combined answers and response to this question (8) and checklist question 10, listed below. (See additional information listed under question 10 of this section.)*See Checklist Discussion, Category1, Question 8 and 9: Mode of Action, Breakdown, and Residues, in the Introduction Document. **[Minority Position]** Mycoshield MSDS: **Other Acute Effects**: Oxytetracycline may cause severe allergic reactions (anaphalactic shock) in sensitive individuals. **Subchronic (Target Organ) Effects**: For oxytetracycline, gastrointestinal irritation with nausea, epigastric pain and burning, vomiting, abdominal pain, transitory yellowish-brown discoloration of the tongue, anorexia and diarrhea. Blood disorders (delay in coagulation) have been reported. Possible hypersensitization and superinfections due to overgrowth of resistant organisms not affected by the antibiotic. Three types of renal diseases are associated with overexposure: Acute Non-Oliguric Renal Failure (individuals with pre-existing pancreatitis or fatty liver); Uremia (individuals with pre-existing impaired renal function) and Reversible Nephrotoxicity (due to outdated or degraded tetracyclines). Inhalation of excessive

				amounts of kaolin dust may produce coughing, sneezing, and nasal irritation Chronic exposure to mica may cause persistent cough, possible difficulty in breathing. **Carcinogenicity/chronic effects**: Prolonged overexposure to oxytetracycline may cause effects to skin and digestive tract. Oxytetracycline did not cause cancer in laboratory animals. Long-term over-exposure to kaolin dust may affect lungs. The diluent as a whole is not listed as a carcinogen. However, it does contain crystalline silica (e.g. Quartz), a natural occurring component. Inhalation of crystalline silica may cause pulmonary fibrosis (silicosis). Crystalline silica has been classified by International Agency for Research on Cancer (IARC) as carcinogenic to humans (Group 1), by the US NTP as a known human carcinogen, and by ACGIH as a suspected human carcinogen (A2). **Developmental Toxicity:** Adverse effects were reported in mother (severe hepatic damage) and fetus (retardation of skeletal development, discoloration of teeth, and enamel hypoplasia.) See also #10 below.
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]		x		**[Majority Position]** The November 2008 recommendation and checklist states degradation half-life varies from 30 days (fresh water) to 10 weeks in pond sediments. It is absorbed and inactivated in dry soils. The 2011 TR (lines 535-543) states that according to EPA's (RED) Pesticides Registration Eligibility Document in 1993 that oxytetracycline products labeled and used according to EPA regulations will not pose unreasonable risks or adverse effects to the environment. Since that time (EPA 2006a &b) the agency noted that new environmental fate studies should be conducted. From the EPA-HQ-OPP-2008-RegReview Summary: "The environmental fate data currently under review, along with the data to be requested, are expected to address some of the uncertainties laid out in the 2006 oxytetracycline TRED regarding the potential for antibiotic resistance resulting from the pesticidal uses." This Re-review by EPA is currently underway and is scheduled to be completed in 2014[10].(also TR lines 542-543) The whole subcommittee recognizes that EPA risk assessments are a different standard than the criteria for the organic regulations, but the majority believes the EPA information will be an important resource contributing to evaluating our criteria. *See Checklist Discussion, Category 1, Questions 8 and 9: Mode of Action, Breakdown, and Residues, in the Introduction Document. **[Minority Position]** OFPA requires Board evaluation of

[10] United States Environmental Protection Agency. 2008. Oxytetracycline summary document registration review: initial docket December 2008. Docket number: EPA-HQ-OPP-2008-0686. Available at: www.regulations.gov

				adverse effects to determine the acceptability of material listing, taking into account compatibility with organic practices. EPA regulates to a different standard of no unreasonable risks, which does not include all OFPA checklist criteria. In this context, the question is whether organic practices should be contributing to antibiotic resistance. Schnabel and Jones, 1999[11]: Resistance to oxytetracycline is associated with use in orchard. To become problematic resistance associated with tetracycline use in apple and pear production does not have to start with the fire blight bacterium becoming resistant. Kumar et al, 2005; Kong et al, 2006; Sinha and Peterson, 1972; Daniels, 1982: Tetracycline may be taken up by plants and appear in all tissues and in exudates. TR2 291-294: Once released into the soil, oxytetracycline is expected to become strongly adsorbed to soil particles and have moderate to no mobility. (Kumar et al., 2005; HSDB, 2006) This means it can remain in soil for a long time following treatment. Furthermore, it is not likely to leach below the surface soil (Aga et al., 2005); however it can spread by surface run-off of sediment. TR2 322-324: "Chander et al. (2005) demonstrated that even though tetracycline was tightly adsorbed to clay particles in soil, it was still biologically active" following a 24-hour incubation period. Halling-Sørensen et al, 2002:[12] Degradation products have same activity as parent. TR2 463-465: Tetracycline can persist in soil for long periods of time without showing antimicrobial activity, and high concentrations can be achieved. (Popowska et al., 2010) Upon later release from soil components, it can exhibit antimicrobial activity.
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i); 6517 c(2)(A)i; §6518 m.4]		x		The 2011 TR (lines 557-559) according to EPA's Tolerance Reassessment Progress and Risk Management Decision (TRED) for oxytetracycline there is reasonable certainty that no harm to any population subgroup will result from exposure to oxytetracycline (EPA, 2006b, p.4) The whole subcommittee recognizes that EPA risk assessment alone is not sufficient to replace the OFPA criteria and that other information must be looked at. However there is no direct evidence of negative human health impacts that have been proven to occur

[11] Elise L. Schnabel and Alan L. Jones, 1999. Distribution of tetracycline resistance genes and transposons among phylloplane bacteria in Michigan apple orchards. Appl. Environ. Microbiol., 65, 4898–4907.

[12] Halling-Sørensen B; Sengeløv G; Tjørnelund J, 2002**.** Toxicity of tetracyclines and tetracycline degradation products to environmentally relevant bacteria, including selected tetracycline-resistant bacteria.
Archives of environmental contamination and toxicology 2002;42(3):263-71.

				solely from the use of oxytetracycline in apples and pears.[13] [14] *See Checklist Discussion, Category 1, and Question 10: Potential for Humans to build Resistance to Medical Tetracyclines, in the Introduction Document. **[Minority Position]** Data submitted in support of EPA's establishment of a tolerance for tetracycline demonstrated residues of tetracycline in apples.[15] Levy, "Antibiotic resistance: an ecological imbalance" (1997) at p6": Dietary exposure of medical concern - "Tetracycline resistance in the faecal flora was high when the volunteers were eating normal, non-sterilized food for 21 days, but dropped dramatically when the diet was shifted to sterilized food for 17 days." TR163-71, 279-293: Workers are at risk of contracting tetracycline-resistant disease and suffering from allergic reactions. Lugo-Melchor et al, 2010:[16] As a consequence of the widespread use of tetracyclines, the emergence and spread of tetracycline-resistant bacterial pathogens, among them the foodborne pathogen Salmonella enterica, has become a serious health hazard worldwide. Levy et al, 1976:[17] Workers who handle feed with tetracycline have tetracycline-resistant flora in their intestines. http://en.wikipedia.org/wiki/Tetracycline_antibioticsTetracyclines remain the treatment of choice for infections caused by chlamydia (trachoma, psittacosis, salpingitis, urethritis, and *L. venereum* infection), Rickettsia (typhus, Rocky Mountain spotted fever), brucellosis, and spirochetal infections (borreliosis, syphilis, and Lyme disease). In addition, they may be used to treat anthrax, plague, tularemia, and Legionnaires' disease. They may have a role in reducing the duration and severity of

[13] Stockwell, V.O., and Duffy, B. 2012. Use of antibiotics in plant agriculture. Rev. Sci. Tech. Off. Int. Epiz., 31:199-210.
[14] Stockwell, V. and Granatstein, D. 2013. Lack of Evidence for Linkage of Plant Agriculture Use of Oxytetracycline to Antibiotic Resistance in Human Pathogens. unpublished report posted to Washington State University Tree Fruit Research and Education Center: http://www.tfrec.wsu.edu/pages/organic/fireblight
[15] 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 "Oxytetracycline tolerances are currently established on peaches and pears at 0.35 ppm in terms of oxytetracycline, only. A tolerance on apple is proposed, also at 0.35 ppm. The crop field trials were conducted from 0.5 to 11.6X the proposed seasonal rate of 1.53 lb ai/A and from 49 to 61 days PHI as compared to the proposed PHI of 60 days. Residues were largely at the limit of quantitation (LOQ) of 0.013 to 0.2 ppm up to 0.252 ppm for a 1X study in Region V [MI]. Adequate storage stability data were presented to indicate that the residues of oxytetracycline were stable for the duration of the residue field trial studies."
[16] Lugo-Melchor, Y., Quinones, B., Amezquita-Lopez, B.A., Leon-Felix, J., Garcia-Estrada, R., Chaidez, C. 2010. Characterization of tetracycline resistance in Salmonella enterica strains recovered from irrigation water in the Culiacan Valley, Mexico. Microbial Drug Resistance. 6(3):185-190.
[17] Stuart B. Levy, M.D., George B. FitzGerald, Ph.D., and Ann B. Macone, B.S., 1976. Changes in Intestinal Flora of Farm Personnel after Introduction of a Tetracycline-Supplemented Feed on a Farm. N Engl J Med 1976; 295:583-588.

				cholera, although drug-resistance is occurring, and their effects on overall mortality is questioned. "Prop 65 list" http://www.oehha.org/prop65/prop65_list/files/P65single3405.pdf Developmental toxin listed by the state of California. TR2 549-551: There is a high probability that oxytetracycline resistant bacteria are present in the environment as a consequence of pesticidal use of oxytetracycline which may have negative health consequences for humans (EPA, 2006). The World Health Organization (WHO) has recently changed its categorization of tetracyclines from "highly important" to "critically important""[18] See also #8 above.
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]			x	
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]			x	
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]			x	

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB Evaluation Criteria for Substances Added To the National List

Category 2. Is the Substance Essential for Organic Production? Substance: Oxytetracycline

Question	Yes	No	N/A[1]	Documentation(TAP; petition; regulatory agency; other)
1. Is the substance formulated or manufactured by a chemical		x		TR2, lines 247-277: Oxytetracycline is a naturally occurring compound produced by the soil bacterium *Streptomyces rimosus.* It is produced on a large scale by aerobic fermentation followed by isolation and purification

[18] WHO, 2009. Report of the First Meeting of the Advisory Group on Integrated Surveillance of Antimicrobial Resistance. CDC, 2010. National Antibiotic Resistance Monitoring System: Enteric Bacteria-- 2010 Human Isolates Final Report.

process? [6502 (21)]				processes. The materials as formulated may or may not have gone through a chemical change during the manufacturing process.
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]	x			See above – question #1. The two forms of tetracycline current on the National List as approved are listed as synthetic substances.
3. Is the substance created by naturally occurring biological processes? [6502 (21)]	x			See above answers to questions #1 & 2.
4. Is there a natural source of the substance? [§205.600 b.1]			x	
5. Is there an organic substitute? [§205.600 b.1]			x	
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]			x	
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]		x		**[Majority Position]** Available natural biological control materials have been proven to not adequately control the serious damage caused by the fire blight organism. (November 2008 recommendation/checklist) There are current trials being conducted on two different strains of yeast *Aureobasidium pullulans* that make up a product from Germany named, Blossom Protect. (2011 TR lines 636-641) (Kunz et al., 2011) TR2 622-725: other products include Bloomtime, Blight Ban A 506, Serenade Max that are listed for use in controlling fire blight. In the April 29, 2011 recommendation/checklist it mentions that there is a natural replacement *Pseudomonas* spp. (Stockwell and Stack, 2007)

				(Phytopathology 97:244-249) The petitioner rebuts this by addressing the inconsistency of control from the use of *Pseudomonas* spp. for control of fire blight in "*real world*" conditions. In the EPA's Oxytetracycline TRED (pages 5 of 15, June 2006) it states that the biological control agent, Blight Ban A506 (a.i. *Pseudomonas flourescens* strain A506) is used to complement an antibiotic pesticide and it is not a replacement for antibiotics. Blight Ban is to be used as part of an integrated control program. Also, there is another product similar to Blight Ban called Bloomtime (*Pantoea agglomerans*). **[Minority Position]** Since Blossom Protect is now available in the U.S.,[19] it should be noted that research reports from Washington state show its efficacy to be equal to or better than that of oxytetracycline.[20] Certainly, research on all of the known products as well as new ones can and should continue, but that should not preclude action by the NOSB. TR2 lines 713-714: "The results are mixed for biological control agents in the suppression of fire blight." Granatstein, 2013[21]: Blossom Protect has given results equal to tetracycline Stockwell and Stack, 2007:[22] BlightBan A506 provides significant control of fire blight caused by *E. amylovora*, russet caused by IAA-producing bacteria, and frost injury due to ice-nucleation active bacteria Glenn et al, 2001:[23] BlightBan A506 provides significant control of fire blight caused by *E. amylovora*, russet caused by IAA-producing bacteria, and frost injury due to ice-nucleation active bacteria
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]			x	
9. Are there any alternative substances? [§6518 m.6]	x			Peracetic acid is now registered for use against fire blight, but the TR2 (lines 747-748) says, "No information could be found on the efficacy of peracetic acid in control of fire blight." There are other products that currently

[19] See label at: http://westbridge.com/products-pdf-documents/BlossomProtectLabel.pdf
[20] Granatstein, 2013. Fire Blight Introduction, OTA Task Force Meeting, January 21, 2013. Powerpoint slides 13-14.

[21] Granatstein, D., 2013. Fire Blight Introduction, OTA Task Force Meeting, January 21, 2013. Powerpoint slides 13-14.
[22] Stockwell, V. O., and Stack, J. P. 2007. Using *Pseudomonas* spp. for integrated biological control. Phytopathology 97:244-249.
[23] Glenn, D. M., van der Zwet, T., Puterka, G., Gundrum, P., Brown. E. 2001. Efficacy of kaolin-based particle films to control apple diseases. Online. Plant Health Progress doi:10.1094/PHP-2001-0823-01-RS. http://ddr.nal.usda.gov/bitstream/10113/12139/1/IND43805958.pdf

				claim or have shown some control: Serenade, lime-sulfur, copper and the biological products. There are currently no stand- alone viable alternatives for reliable control of fire blight on apples and pears in organic production.(2012 Petition last paragraph page 11 of 13) *See Checklist Discussion, Category 2 Questions 9 & 10 for further discussion on Pears, in the Introduction Document. Granatstein, 2013: Blossom Protect has shown comparable efficacy to oxytetracycline in recent trials. However it has been shown to work much better in conjunction with a copper spray ahead of it to remove competing microbes from the flower before introducing the Blossom Protect. And the Blossom Protect does not give immediate results in extreme risk situations. TR1 lines 317-330 Phytotoxicity limits usefulness of copper compounds currently available for use. There are a couple of new copper compounds currently being looked at in research trials that may help to remove that limitation.
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	x	x		**[Majority Position]** There are other practices that could help as part of an integrated systems approach to controlling fire blight that could help to reduce the reliance upon oxytetracycline. But, these practices would not replace oxytetracycline by themselves. The April 1, 2011 TR (lines 757-762) mentions using resistant varieties of apples and pears. (Koski and Jacobi, 2009) There is no cultivar that is completely immune to fire blight. There are some rootstocks (Geneva) coming that are showing good resistance potential, but these are still several years away from being commercially available. (This would also not address the thousands of acres of organic apples and pears currently in production.) This is only the rootstock and not the cropping or cultivar part of the tree. Selection of soils and proper air and water drainage will aid in control. Pruning out cankers will help by removing some of the inoculum from the orchard. Fertility management will also help, by controlling vegetative growth of the tree. There are several detection models that are currently in use to assist in the identification of infection periods and their severity, as well as proper timing of control materials to maximize their efficacy in controlling fire blight. (“Fireblight Management in the Pacific Northwest USA”) http://www.ncw.wsu.edu/treefruit/fireblight/principles.htm Everything listed here would work together as part of an organic systems approach to fire blight control, but not as a stand –alone. *See Checklist Discussion, Category 2 Questions 9 & 10

				for further discussion on Pears, in the Introduction Document. **[Minority Position]** TR1 297-302, 335-343. Resistant cultivars. Proper pruning, fertilization, watering, drainage. Aldwinckle et al, 1998[24]. "Serious fire blight damage can be avoided simply by not planting highly susceptible scion varieties and rootstocks." "Fireblight Management in the Pacific Northwest USA" (http://www.ncw.wsu.edu/treefruit/fireblight/principles.htm) Streptomycin "is no longer adequately effective in most of the Pacific Northwest" Ken Johnson[25]: 'Integrated control': … utilizing delayed dormant copper sanitation … in apples, using bloom thinners to further delay pathogen 'build-up' in flowers As of March 10, 2011, there were 96 businesses certified as EU-compliant organic producers of apples and/or pears in the state of Washington alone, representing about one third of the state's organic apple and one fourth of the state's organic pear production.[26] Testimony of Katherine Withey, Washington State Dept of Agriculture at Seattle NOSB meeting 4/2/2011 p. 380: "In 2010 WSDA certified 719 producers. Of these producers, 361 were certified for apples and/or pears, and of these 361 producers 136 used tetracycline and 34 have used streptomycin."

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB Evaluation Criteria for Substances Added To the National List

Category 3. Is the substance compatible with organic production practices? Substance : Oxytetracycline

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]			x	
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]	x			**[Majority Position]** The substance, oxytetracycline is on the list of allowed exemptions in question 7 below. It is derived from a non-

[24] H. Aldwinckle, J Norelli, and MT Momol, 1998. Fire blight: the search for better control. IDFTA Compact Fruit Tree, Vol. 31, No. 4

[25] Ken Johnson, 2012. Fire Blight Control in Organic Pome Fruit Systems Under the Proposed Non-antibiotic Standard. http://www.extension.org/pages/62448/fire-blight-control-in-organic-pome-fruit-systems-under-the-proposed-non-antibiotic-standard

[26] Washington State Department of Agriculture printout, "International Organic Program—EU Compliant Operations, March 10, 2011.

				synthetic source organism, works in a similar fashion to other biologically based control organisms and has a history of safe use in organic farming systems for more than 20 years. The issues surrounding the use of antibiotics in animal agriculture have not been proven to pose the same threats when used in plants. **[Minority Position]** Ostenson, H.T. 2010, citing Hartman Group[27] study, which says antibiotic use is contrary to consumer expectations. Inconsistent with prohibition on antibiotics in livestock. TR2 lines 226-230: Inconsistent with European requirements.
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]	x			**[Majority Position]** The NOSB recommendation concerning assessing consistency and compatibility[28] lists 12 factors to be considered for determining this and the majority believes that over the time this has been on the National List, some factors have gained priority over others and thus acknowledges the need to phase the material out. However the majority feels that this needs to be done in a way that causes less disruption to the whole industry as alternatives are adopted. **[Minority Position]** Increases likelihood of antibiotic resistance in pathogenic organisms. The use of antibiotics to control fire blight is not sustainable[29]
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]			x	
5. Is the primary use as a preservative? [§205.600 b.4]			x	
6. Is the primary use to recreate or			x	

[27]Ostenson, H.T. 2010. Organic pome and cherry production and marketing issues: Past, present and future. Acta Hort. (ISHS) 873:137-144

[28] NOSB Policy and Procedures Manual p.32.

[29] NOSB Principles of Organic Production and Handling says, "Organic production and handling systems strive to achieve agro-ecosystems that are ecologically, socially, and economically sustainable." AAM, 2009. p.3. "The struggle against antibiotic resistance is a war we will never win."

improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]				
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: a. copper and sulfur compounds;				
b. toxins derived from bacteria;	x			
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?				
d. livestock parasiticides and medicines?				
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?				

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB Evaluation Criteria for Substances Added To the National List

Category 4. Is the commercial supply of an agricultural substance as organic, fragile or potentially unavailable? [§6610, 6518, 6519, 205.2, 205.105 (d), 205.600 (c) 205.2, 205.105 (d), 205.600 (c)]
Substance: Oxytetracycline

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the comparative description provided as to why the non-organic form of the material /substance is necessary for use in organic handling?			x	
2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **form** to fulfill an essential function in a system of organic handling?			x	
3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the			x	

appropriate **quality** to fulfill an essential function in a system of organic handling?				
4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quantity** to fulfill an essential function in a system of organic handling?			x	
5. Does the industry information provided on material / substance non-availability as organic, include (but not limited to) the following: a. Regions of production (including factors such as climate and number of regions);			x	
b. Number of suppliers and amount produced;			x	
c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;			x	
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or			x	
e. Are there other issues which may present a challenge to a consistent supply?			x	

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

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Endnotes for Minority Position

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[2] Tetracycline TR, April 1, 2011. Lines 291-326. Mycoshield label http://www.cdms.net/ldat/ld246008.pdf
[3] American Academy of Microbiology, 2009. Antibiotic Resistance: An Ecological Perspective on an Old Problem. http://academy.asm.org/images/stories/documents/antibioticresistance.pdf (pp.1-5, 10.)
[4] American Academy of Microbiology, 2009. (p.8.)
[5]http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052519.pdf See Table 6, p.22.
[6] 2011 TR lines 549-551: "There is a high probability that oxytetracycline resistant bacteria are present in the environment as a consequence of pesticidal use of oxytetracycline which may have negative health consequences for humans (EPA, 2006)." American Academy of Microbiology, 2009. p.2: "Controlling antibiotic resistant bacteria and subsequent infections more efficiently necessitates the prudent and responsible use of antibiotics. It is mandatory to prevent the needless use of antibiotics…"
[7] T.F. O'Brien, 2002. Emergence, Spread, and Environmental Effect of Antimicrobial Resistance: How Use of an Antimicrobial Anywhere Can Increase Resistance to Any Antimicrobial Anywhere Else, Clin Infect Dis. 34 Suppl 3:S78-84. "Use of an antimicrobial agent selects for overgrowth of a bacterial strain that has a gene expressing resistance to the agent. It also selects for the assembly and evolution of complex genetic vectors encoding, expressing, linking, and spreading that and other resistance genes. Once evolved, a competitive construct of such genetic elements may spread widely through the world's bacterial populations. A bacterial isolate at any place may thus be resistant—not only because nearby use of antimicrobials had amplified such a genetic construct locally, but also because distant use had caused the construct or its components to evolve in the first place and spread there. The levels of resistance at any time and place may therefore reflect in part the total number of bacteria in the world exposed to antimicrobials up until then."
K.M. Shea, 2003. Antibiotic Resistance: What is the Impact of Agricultural Uses of Antibiotics on Children's Health? Pediatrics 112: 253-258. http://pediatrics.aappublications.org/content/112/Supplement_1/253.full.html
[8] One time was in the 2008 testimony of former NOSB member Rebecca Goldburg, writing on behalf of Keep Antibiotics Working. She said, "A first concern is that the use of antibiotics on fruit trees likely makes at least a small contribution to the growing crisis of antibiotic resistance in human medicine. Modern molecular tools for tracking the movement of genes make clear that antibiotic resistance is an ecological and not just a medical problem. The use of antibiotics selects for resistant bacteria, whether in orchards or hospitals. Even if these resistant bacteria are not human pathogens, gene transfer mechanisms special to bacteria allow these microbes to spread their resistance genes to other, unrelated bacteria, including pathogens. Although the odds are very low that resistance genes from any particular orchard bacterium will end up in bacteria harmful to humans, such highly unlikely individual events become probable given the vast numbers of bacteria present in soil, water, and living organisms. In short, the use of antibiotics in orchards increases the load of antibiotic resistance genes in the environment, and thus likely contributes at least modestly to medical problems from resistant bacteria."
[9] American Academy of Microbiology, 2009. "Horizontal gene transfer—the movement of genetic material from one organism to another—is the primary mechanism by which bacteria acquire antibiotic resistance."
[10] WHO, 2009. See Table 1.
[11]http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052519.pdf See Table 6, p.22.
[12] American Academy of Microbiology, 2009. p.10. "Selection takes place anywhere an antibiotic is present, especially in natural environments…"
[13] T.F. O'Brien, 2002. "The basic event in selection is simple. Enough molecules of the antimicrobial agent impinge on a bacterial cell that is about to divide to stop it from doing so, while in its place another cell divides that would not otherwise have divided. The second cell divides either because it was not inhibited by the same exposure (i.e., had some level of resistance) or because it did not quite get that same exposure (e.g., by being a bit away and coming into the space later)."
[14]American Academy of Microbiology, 2009 (p.8): "Horizontal gene transfer—the movement of genetic material from one organism to another—is the primary mechanism by which bacteria acquire antibiotic resistance. Antibiotics promote this genetic exchange by inducing the transfer of conjugative elements." T.F. O'Brien, 2002, p.1: "Use of an antimicrobial agent selects for overgrowth of a bacterial strain that has a gene expressing resistance to the agent. It also selects for the assembly and evolution of complex genetic vectors encoding,

expressing, linking, and spreading that and other resistance genes. Rustam I. Aminov, 2011. Horizontal gene exchange in environmental microbiota, Front Microbiol. 2011; 2: 158: “There is a substantial body of evidence suggesting that the sub-inhibitory concentrations of antibiotics may significantly increase the frequency of horizontal transfer of many types of MGEs [mobile genetic elements].”

[15] American Academy of Microbiology, 2009, p.8: “The transfer of antibiotic resistance genes is evident between bacteria or fungi of the same species, but transfer between organisms that bear limited phylogenetic relatedness, including transfer between gram-negative and gram-positive species, is also possible.”

[16] T.F. O’Brien, 2002 p.5:“The abundance of *E. coli* implicates them as the likely predominant vehicles for the spread of resistance genes and vectors, as opposed to the spread of infection, between the bacterial populations of animals and humans…”

[17] T.F. O’Brien, 2002. p.4: “A resistant strain made prevalent by selection in the bacterial populations of one host is more likely to be among the strains that the host transfers to a second host [15]. Similar selection in the second host would boost the strain’s chances of becoming established, amplified, and then transferred to a third host.”

[18] American Academy of Microbiology, 2009. p.2: “Controlling antibiotic resistant bacteria and subsequent infections more efficiently necessitates the prudent and responsible use of antibiotics. It is mandatory to prevent the needless use of antibiotics…” T.F. O’Brien, 2002. p.6: “Management of such systems necessitates restraint and understanding. The global interdependence of antimicrobial resistance requires that we restrain antimicrobial use to its essential minimum—not just locally, but everywhere in the world.”

[19] WHO, 2009. http://en.wikipedia.org/wiki/Tetracycline_antibiotics “Tetracyclines remain the treatment of choice for infections caused by chlamydia (trachoma, psittacosis, salpingitis, urethritis, and *L. venereum* infection), Rickettsia (typhus, Rocky Mountain spotted fever), brucellosis, and spirochetal infections (borreliosis, syphilis, and Lyme disease). In addition, they may be used to treat anthrax, plague, tularemia, and Legionnaires' disease… They may have a role in reducing the duration and severity of cholera, although drug-resistance is occurring, and their effects on overall mortality is questioned.”

[20] K. Kumar, S.C. Gupta, Y. Chander, and C.J. Rosen, 2005. Antibiotic Uptake by Plants from Soil Fertilized with Animal Manure. J. Environ. Qual. 34:2082–2085 (2005). W.D. Kong, 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. RC Sinha and EA Peterson, 1972. Uptake and persistence of oxytetracycline in aster plants and vector leafhoppers in relation to inhibition of clover phyllody agent, Phytopathology 62: 50-56.

[21] 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 “Oxytetracycline tolerances are currently established on peaches and pears at 0.35 ppm in terms of oxytetracycline, only. A tolerance on apple is proposed, also at 0.35 ppm. The crop field trials were conducted from 0.5 to 11.6X the proposed seasonal rate of 1.53 lb ai/A and from 49 to 61 days PHI as compared to the proposed PHI of 60 days. Residues were largely at the limit of quantitation (LOQ) of 0.013 to 0.2 ppm up to 0.252 ppm for a 1X study in Region V [MI]. Adequate storage stability data were presented to indicate that the residues of oxytetracycline were stable for the duration of the residue field trial studies.”

[22] 2011 TR lines 291-294: “Once released into the soil, oxytetracycline is expected to become strongly adsorbed to soil particles and have moderate to no mobility (Kumar et al., 2005; HSDB, 2006). This means it can remain in soil for a long time following treatment. Furthermore, it is not likely to leach below the surface soil (Aga et al., 2005), however it can spread by surface run-off of sediment.” 2011 TR 322-325: “Chander et al. (2005) demonstrated that even though tetracycline was tightly adsorbed to clay particles in soil, it was still biologically active” following a 24-hour incubation period. There is a concern that the persistence of oxytetracycline residues in the environment may contribute to the development of bacterial resistance to oxytetracycline and other tetracyclines (Arikan et al., 2007).”

[23] Tetracycline TR, January 27, 2006, , lines 279-293: “Workers (pesticide mixers, loaders, and applicators) are likely to be exposed to greater amounts of calcium oxytetracycline than the general public during its application to pears, peaches, and nectarines using foliar application methods; fieldworkers also can be exposed post-application (EPA 1988).” Although EPA at the time judged these exposures to be “negligible”, this is not an appropriate judgment under OFPA, and as we have seen above, no exposure to an antibiotic is negligible. Lugo-Melchor, Y., Quinones, B., Amezquita-Lopez, B.A., Leon-Felix, J., Garcia-Estrada, R.,

Chaidez, C. 2010. Characterization of tetracycline resistance in Salmonella enterica strains recovered from irrigation water in the Culiacan Valley, Mexico. Microbial Drug Resistance. 6(3):185-190. “As a consequence of the widespread use of tetracyclines, the emergence and spread of tetracycline-resistant bacterial pathogens, among them the foodborne pathogen Salmonella enterica, has become a serious health hazard worldwide.”
Stuart B. Levy, M.D., George B. FitzGerald, Ph.D., and Ann B. Macone, B.S., 1976. Changes in Intestinal Flora of Farm Personnel after Introduction of a Tetracycline-Supplemented Feed on a Farm. N Engl J Med 1976; 295:583-588: “Chickens were fed tetracycline-supplemented feed (tet-feed), and, as expected, within one week their intestinal flora contained almost entirely tetracycline-resistant organisms. Increased numbers of resistant intestinal bacteria also appeared, but more slowly, in farm members, but not their neighbors. Within five and six months, 31.3 per cent of weekly fecal samples from farm dwellers contained greater than 80 per cent tetracycline-resistant bacteria as compared to 6.8 per cent of the samples from the neighbors (P less than 0.001).”

[24] 2011 TR lines 549-551: “There is a high probability that oxytetracycline resistant bacteria are present in the environment as a consequence of pesticidal use of oxytetracycline which may have negative health consequences for humans (EPA, 2006).”

[25] See Mycoshield MSDS a: http://www.cdms.net/LDat/mp246000.pdf

[26] 2006 TR Lines 154-162.

[27] Lines 458-467.

[28] Lines 469-511.

[29] Lines 521-522.

[30] American Academy of Microbiology, 2009.

[31] American Academy of Microbiology, 2009, pp.5-6.

[32] American Academy of Microbiology, 2009, p.12.

[33] American Academy of Microbiology, 2009, p.12.

[34] EPA, 2008. Oxytetracycline Summary Document Registration Review: Initial Docket, December 2008, p.8. “The Agency found that the pharmaceutical oxytetracycline exposure a user is expected to receive from a typical therapeutic dose is 50,000 to 200,000 times greater than the estimated dietary exposure from the pesticidal sources of oxytetracycline.”

[35] American Academy of Microbiology, 2009., p.10: “Selection takes place anywhere an antibiotic is present, especially in natural environments…”

[36] 2011 TR line 463.

[37] 2011 TR line 464.

[38] 2011 TR lines 457-467.

[39] W.D. Kong, Y.G. Zhu,, Y.C. Liang, J. Zhang, F.A. Smith, and M. Yang, 2007. Pages 187-193.

[40] RC Sinha and EA Peterson, 1972.

[41] 2011 TR lines 452-453.

[42] WHO, 2009. See Table 1.

[43] http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052519.pdf. See Table 6, p.21.

[44] American Academy of Microbiology, 2009, p.7.

[45] .” T.F. O’Brien, 2002, p.5.

[46] Popowska M., Rzeczycka M., Miernik A., Krawczyk-Balska A., Walsh F. & Duffy B. (2012). – Influence of soil use on prevalence of tetracycline, streptomycin and erythromycin resistance and associated resistance genes. Antimicrob. Agents Chemother., 56 (3), 1434–1443.

[47] See NOSB, 2008. Principles of Organic Production and Handling, adopted by the NOSB October 17, 2001, and NOSB Guidance Document on Compatibility with a System of Sustainable Agriculture and “Consistency with Organic Farming and Handling,” adopted by the NOSB October 24, 2003, revised April 29, 2004.

[48] NOSB Principles of Organic Production and Handling says, “An organic production system is designed to… Utilize production methods and breeds or varieties that are well adapted to the region…”

[49] NOSB Principles of Organic Production and Handling says, “Organic agriculture is an ecological production management system that promotes and enhances biodiversity, biological cycles, and soil biological activity. It emphasizes the use of management practices in preference to the use of off-farm inputs, taking into account that regional conditions require locally adapted systems. These goals are met, where possible, through the use

of cultural, biological, and mechanical methods, as opposed to using synthetic materials to fulfill specific functions within the system."

[50] NOSB Principles of Organic Production and Handling says, "Organic production and handling systems strive to achieve agro-ecosystems that are ecologically, socially, and economically sustainable."

[51] American Academy of Microbiology, 2009, p.3. "The struggle against antibiotic resistance is a war we will never win. The strength of trillions upon trillions of microorganisms, combined with the ancient force of evolution by constant, unrelenting variation, will inevitably overpower our drugs."

[52] Streptomycin TR, March 8, 2011. Lines 506-507.

[53] See comments of former NOSB member Hubert Karreman on antibiotics 4/13/2011. http://www.regulations.gov/?source=govdelivery#!documentDetail;D=AMS-NOP-11-0014-2686 "As a veterinarian you cannot use antibiotics in organic livestock, I see the use of tetracycline and streptomycin as a sick joke. To allow them for use for non-sentient crops and not allow them to relieve pain and suffering in sentient animals is unethical at best and shockingly appalling at least."

[54] See 2011 Tetracycline Technical Report, lines 226-230.

[55] http://www.organicitsworthit.org/quick/antibiotics-101 "Go organic! By law, organic products must be made without the use of antibiotics." http://www.organicvalley.coop/why-organic/antibiotics/ "Organic Means No Antibiotics" http://www.earthsbest.com/products/product/2392320005 (Earth's Best First Pears): "USDA organic: no growth hormones, antibiotics, steroids or potentially harmful pesticides or herbicides." Even USDA expects it: http://www.usda.gov/wps/portal/usda/usdahome?navid=ORGANIC_CERTIFICATIO "U.S. producers are turning to certified organic farming systems as a potential way to lower input costs, decrease reliance on nonrenewable resources, capture high-value markets and premium prices, and boost farm income. Organic farming systems rely on ecologically based practices such as cultural and biological pest management, exclusion of all synthetic chemicals, antibiotics, and hormones in crop and livestock production." (Accessed 1/20/2013.)

NOSB Guidance on Compatibility with a System of Sustainable Agriculture and Consistent with Organic Farming and Handling, question number 5: Does the substance satisfy expectations of organic consumers regarding the authenticity and integrity of organic products?

[56] Ostenson, H.T. 2010. Organic pome and cherry production and marketing issues: Past, present and future. Acta Hort. (ISHS) 873:137-144

[57] In 1995, tetracycline and streptomycin were added to §205.601, but it was to be reviewed again in two years and a taskforce was to be organized to "explore antibiotic use in crop production. (NOSB minutes, Oct-Nov 1995 meeting, lines 594-604.) In 2006, there was much discussion, including presentation of a statement from CDC opposing the use of the antibiotics in crops, and the question, "Is it possible to put forth a recommendation that we would like to have it taken off of the list within two years?" The antibiotics failed to get a two-thirds majority, but were relisted. (Transcript April 20, 2006.) In 2008, board members noted the advantage of the 2012 expiration date as a final end to tetracycline as a reason for supporting the motion to expand the listing to all forms of tetracycline. (Transcript November 19, 2008.) And in 2011, board members expressed frustration, e.g., "feeling the need to see progress," "[T]he fact is that the committee now has twice in the period of time I've been on the Board, expressed itself, the beliefs that the antibiotics ought to come off the list…" "I wouldn't be able to vote for more than a two-year extension at this point." (Transcript April 29, 2011, pp.25, 32, 37.)

[58] §6517(c)(1): "The National List may provide for the use of substances in an organic farming or handling operation that are otherwise prohibited under this chapter only if -

(A) the Secretary determines, in consultation with the Secretary of Health and Human Services and the Administrator of the Environmental Protection Agency, that the use of such substances

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

(ii) is necessary to the production or handling of the agricultural product because of the unavailability of wholly natural substitute products; and

(iii) is consistent with organic farming and handling;

[59] NOSB transcript, April 26, 2011, p.380.

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

[61] Johnson, Ken, Oregon State University, Fire Blight *control in Organic Pome Fruit Systems Under the Proposed Non-antibiotic Standard,* E-Organic Webinar, March 13, 2012. R.D. Koski and W.R. Jacobi *Fire Blight*. Colorado State University Extension. October 2009.
[62] Norelli, John L., Alan L. Jones, and Herb S. Aldwinckle. "Fire blight management in the twenty-first century: using new technologies that enhance host resistance in apple." *Plant Disease* 87.7 (2003): 756-765. “In the twentieth century, fundamental changes in the apple industry resulted in the adoption of high-density orchard systems, and recent planting of susceptible cultivars and rootstocks has increased the danger of fire blight in apple orchards to unprecedented levels.”
[63] Paul W. Steiner, 2000. A Philosophy For Effective Fire Blight Management, Presented at the State Horticultural Association of Pennsylvania Annual Meeting, January 2000. http://www.caf.wvu.edu/kearneysville/articles/PHILOSOPHY2000.html

National Organic Standards Board
Crops Subcommittee
Petitioned Material Proposal
Polyoxin D Zinc Salt

January 29, 2013

Polyoxin D Zinc Salt was petitioned in 2012 as a Synthetic Substance to be Allowed for Use in Organic Crop Production (7CFR 205.601).

Polyoxin D Zinc Salt (EPA Reg. No. 68173-1) is a fungicide derived from *Streptomyces cacaoi* var.asoensis, a soil-borne microorganism, through an aerobic fermentation process. While it appears that the polyoxin D may be a naturally derived material, the added zinc salt may or may not be synthetic. The manufacturer of Polyoxin D Zinc Salt could not confirm the source of the Zinc Salt, as to whether it was “virgin” zinc from a mine or from a recycled zinc source. Thus, it would have to be considered a synthetic material. The zinc salt is added to give the polyoxin D a longer residual time on the plant surface. The manufacturer has chosen to withhold disclosure of its manufacturing process, citing it as proprietary and confidential business information. As stated in the 2012 technical review (TR), which was based on the un-redacted version of the petition, the Zinc Salt appears to be a reaction product and not a naturally occurring form.

The petitioner has submitted several petition amendments that include an expanded tolerance exemption for polyoxin D zinc salt from EPA for use on all food commodities and expanded use allowances for all food and feed crops. This includes both pre-harvest and post-harvest uses. Some examples of plant diseases and pathogens for which its use is intended to control are: Alternaria, Anthracnose, Botrytis, Brown Patch, Downy Mildew, Powdery Mildew, and Rhizoctonia.

Polyoxin D zinc salt is a fungicide labeled for use on an expanded list of crops. It works as a fungistatic material, rather than with fungicidal activity. This means that rather than killing the bacteria or fungi, it inhibits the growth of the fungi colony by inhibiting the chitin growth in the cell walls. Polyoxin D zinc salt is used exclusively on plants. It is not registered for use as an antibiotic in human or veterinary medicine. However, the TR indicates that polyoxin D zinc is a broad spectrum fungicide, raising concerns about its impact on beneficial soil organisms, citing its residual life in soil. While it has impact on non-target beneficial fungi and bacteria in the soil, proponents of this material maintain that it should not have a long lasting effect due to its mode of action and short half-life in water. While there are concerns raised about the effect on beneficial fungi and insects, supplemental data submitted by the petitioner attempts to address the majority of these concerns on an individual basis.

The EPA lists polyoxin D zinc salt (EPA Reg. No. 68173-1) as a Fungicide Resistance Action Committee (FRAC) Code of 19 i.e., the target site of action is a chitin synthestase. This means that it has a unique mode of action, which proponents of its use cite as extremely useful in a rotational fungicide program in organic farming operations as a resistance management tool. The TR listed a number of alternative materials and practices. The majority of the Subcommittee members found this to be incompatible with organic practices.

Evaluation Criteria
(Applicability noted for each category; Documentation attached) **Criteria Satisfied?**

1. Impact on Humans and Environment ☒ Yes ☐ No
   ☐ N/A
   a. Essential & Availability Criteria ☐ Yes ☒ No
   ☐ N/A
2. Compatibility & Consistency ☐ Yes ☒ No
   ☐ N/A
3. Commercial Supply is Fragile or Potentially Unavailable ☐ Yes ☐ No
   ☒ N/A
   as Organic (only for § 205.606)

Substance Fails Criteria Category: [2, 3] **Comments:**

Proposed Annotation (if any):

Basis for annotation: ☐ To meet criteria above ☐ Other regulatory criteria ☐ Citation
Notes:

Recommended Committee Action & Vote, including classification recommendation (state actual motion):

Classification Motion: Motion to classify Polyoxin D Zinc as petitioned as synthetic.
Motion by: Harold Austin Seconded by: Colehour Bondera
Yes: 8 No: 0 Absent: 0 Abstain: 0 Recuse: 0

Listing Motion: To add Polyoxin D Zinc Salt to the National List at § 205.601 as a Synthetic Substance Allowed for Use in Organic Crop Production.
Motion by: Harold Austin Seconded by: Colehour Bondera
Yes: 3 No: 4 Absent: 0 Abstain: 1 Recuse: 0

Crops	☒	**Agricultural**	☐	**Allowed[1]**	☐
Livestock	☐	**Non-synthetic**	☐	**Prohibited[2]**	☐
Handling	☐	**Synthetic**	☒	**Rejected[3]**	☒
No restriction	☐	**Commercial unavailable as organic**	☐	**Deferred[4]**	☐

[1]Substance voted to be added as "allowed" on National List to § 205. with Annotation (if any):

[2]Substance to be added as "prohibited" on National List to § 205. with Annotation (if any):

Describe why a prohibited substance:

[3]Substance was rejected by vote for amending National List to § 205. . Describe why material was rejected:

[4]Substance was recommended to be deferred because
If follow-up needed, who will follow up:

Approved by Subcommittee Chair to Transmit to NOSB

Jay Feldman, Subcommittee Chair **January 29, 2013**

NOSB Evaluation Criteria for Substances Added To the National List

Category 1. Adverse impacts on humans or the environment? Substance:

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]			X	
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]	X			The TR (lines 190-195) states that the EPA considers polyoxin D zinc salt a low environmental risk, listing several reasons for this rationale. Also, included in the supplemental information submitted by the petitioner on October 2, 2012 as part of an EPA posting to the Federal Register on September 12, 2012. The TR does mention (line 194) that failure to follow the product label could result in death of fish and aquatic organisms. In the TR (lines 197-204) states that biopesticides generally pose lower risks than chemically produced pesticides. The manufacturing process is CBI, but the TR states the process would be similar to other antibiotics produced from *Streptomyces.* (TR July 11, 2102) The TR states (lines 190-204) that polyoxin D could get into water if misused by not following the label. Waste may be disposed of on site or at an approved waste facility, but not disposed of in waste water. (TR July 11, 2012)
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]	X	X		Polyoxin D zinc salt is moderately toxic to fish and aquatic invertebrates and should not be discharged into water. (TR lines 279-280). If label instructions followed, those concerns would be mitigated (EPA,

				2001)(TR lines 290-291). Should be considered toxic to various soil fungi and bacteria (TR lines 234-235). However, the TR (lines241-251) does state that alternative fungicides, such as copper or sulfur, may have similar or more severe effects. No documented studies to verify the effects by comparison to other fungicides. In the TR it mentions (TR line 54) Action of Substance: Inhibits cell wall chitin synthesis (Misato, 1977, O'Neill, 2006). It further states (TR lines 257-262) it has been shown to inhibit chitin synthetase in cockroaches, and may therefore affect beneficial insects. EPA: Toxic to Honey Bees. [1][1]Kaken cites EPA [2]"Polyoxin D and its zinc salt do not inhibit the synthesis of chitin in animals that contain chitin, such as for insects and crustaceans that contain chitin in their exoskeletons.
4. Does the substance contain List 1, 2 or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]		?		The TR states that Polyoxin D Zinc Salt is formulated with undisclosed inert ingredients. TR line 58 (TR July 11, 2012) The TR further states that the preferred surfactants used in the dry flowable form are formalin sodium naphthalenesulfonate (inert list 4B) or non-ionic polyoxyethylene alkyl ethers (inert list 4B) (Tokumura, et al.,, 2001). Formulation process is CBI
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]	X	X		Because of its activity as a fungicide, it may have a negative impact on beneficial fungi. Polyoxin D inhibits the germination of *Trichoderma viride* (Benitez, et al., 1976). *T. viride* is closely related to *T.harzianum,* which is used in organic farming under the brand name Root Shield (OMRI, 2012). There are a couple of other fungi used as biological controls in organic farming. (TR lines216-222). However, it has also been shown to promote the biocontrol of Bacillus subtilis, with a strong synergistic effect on Alternaria mali suppression. (TR lines 225-226) (TR July 11, 2012) Also, in the TR (TR lines 220-224) it lists *Gliocladium virens,Paecilomyces fumosoroseus,* and *Streptomyces griseoviridis* as other fungi used as biological control agents in organic

[1] EPA, May 11 ,2012, Science Review of Product Chemistry, Residue Chemistry, Non-Target Organism, and Toxicity Data in Support of Label Amendment for Polyoxin D Zinc Salt. (Included with supplemental petition)

[2] EPA, May 11 ,2012, Science Review of Product Chemistry, Residue Chemistry, Non-Target Organism, and Toxicity Data in Support of Label Amendment for Polyoxin D Zinc Salt. (Included with supplemental petition).

				agriculture. *G virens* is marketed as SoilGard, *P. fumosoroseus* is the active ingredient in PFR-97 and *S.griseoviridis* is sold as Mycostop (OMRI, 2012). (TR line 223) states that polyoxin D zinc salt was found to reduce the efficacy of the virus used to control the black cutwork (sic)(*Agrotis ipsilon)* (Bixby-Brosi and Potter, 2012 In the soil tests, the half-lives were 15.9 days for aerobic soils and 59.2 days for anaerobic soils. (EPA science review, p12). However, in the document provided by the petitioner (January 18,2013 section 5.2) it states that in the presence of sunlight polyoxin D zinc salt degrades by 50% within 0.4 days (9.6 hours) "in sterile natural water, pH 5.0, pH 7.0, and pH 9.0 buffers, respectively." The petitioner says that it inhibits fungi growth but does not kill it, maintain that it would not be a detriment to organic products such as Root Shield, currently used in organic farming (same doc. Pg 24 section 5.5).
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]	X	X		TR 233-237: "As a broad-spectrum antibiotic and fungicide, polyoxin D Zinc Salt is toxic to soil fungi. Polyoxins and other antibiotics were found to increase melanins in *Alternaria kikuchiana* (Kohno, et al., 1983; Butler and Day, 1998). The ecological functions of melanins are still unknown, but they are believed to enhance the phytotoxic and pathogenic properties of plant pathogens (Butler and Day, 1998). Earthworms were shown to have a preference for melanized fungi (Marfenina and Ischenko, 1997; Butler and Day, 1998)." There is some concern that polyoxin D used on turf to have a moderate risk of resistance. (Vincelli and Williams 2012)(TR lines 253-261) Again alternative materials may have similar or worse effects.(TR lines 246-248) (TR July 11, 2012) In the Jan. 18, 2013 (pages 20 -26) document provided by the petitioner it does not actually kill fungi, just inhibits growth. Also is not harmful to beneficial insects. Same report (pages 27-28) also that polyoxin D zinc salt is a FRAC 19 class (Kaken 2008) (EPA Reg. No. 68173-1) of fungicide. It has a unique mode of action that would aid in resistance management

				as part of an IPM disease control program. Only class 19 fungicide currently listed.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]	X			The TR states that there may be adverse effects to beneficial soil organisms when exposed to polyoxin D. TR lines 241-242. It goes on to state that alternative fungicides may have similar or even greater effects on soil ecology, but that no studies could be found that compare the impacts between polyoxin D and other fungicides in organic production, specifically. TR lines 246-251. (TR July 11, 2012) Is not labeled for use on livestock or pastures.
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		The following refers to polyoxin D zinc's use as an antibiotic: Polyoxin D has been shown to be effective as a drug to treat human and animal pathogens *Candida albicans* and *Cryptococcus neoformans* (Becker, et al., 1983: Hilenski, et al., 1986). Polyoxin D also shows some efficacy in the reduction of the protozoan parasite *Encephalitiozoon cuniculi* infecting immune-compromised AIDS patients (Sobottka, et al., 2002). All three of the above mentioned studies were *in vitro* experiments and not substantiated by any *in vivo* claims or studies. Polyoxin D zinc salt in currently not listed for use in human or veterinary medicine. Moderate acute dermal toxicity; moderate toxicity primary eye irritation. (TR Table 2.)
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]		X		The EPA's risk assessment of polyoxin D Zinc Salt to carry a low environmental risk due to its specific mode of action, low toxicity, rapid degradation and low application rate (EPA 2008) TR lines 190-191. "The EPA waived environmental fate and ground water data due to the use pattern, application methods, and mitigation of non-target aquatic organism toxicity with appropriate precautionary label statements under "Environmental Hazards. Failure to follow the label instructions may result in the death of fish and 194 aquatic organisms (EPA, 2001, 2008)." (TR 191-195) Soil half-life from aerobic microbial metabolism is reported to be 15.9 days. Degradation in water and sunlight is reported to be approximately 2.3 days (Smith, 2012). (TR line 153)(July 11, 2012)
10. Is there any harmful	X	X		All polyoxins have shown to have low

effect on human health? [§6517 c (1)(A)(i); 6517 c(2)(A)i; §6518 m.4]				mammalian toxicity.(Copping and Duke, 2007)(TR lines 305-309)). Could case slight skin irritation. Positive benefits for human and animal pathogens Candida albicans and Cryptococcus neoformans (Becker,et al. 1983: Hilenski, et al., 1986) (TR lines 311-314) Polyoxin D Zinc Salt is currently not listed for use for human or veterinary medicinal uses. Also has be shown to have an effect on the protozoan parasite Encephalitozoon cuniculi infecting the immune system in AIDS patients (Sobottka, et al., 2002) (TR lines 311-314) This was the result of one *in vitro* experiment. (TR July 11,2012) EPA: results of the mutagenicity studies indicated Polyoxin D Zinc Salt Technical was weakly mutagenic in an Ames Assay (MRID# 433230-01) and not mutagenic in a host mediated assay (MRID # 432618-36). If a food/feed use is ever sought, the test results will require a review of the mutagenicity data base to determine the need for additional studies.[2]Mammalian chromosome aberration studies with hamster cells showed highly significant increases in chromosomal aberrations over solvent control.[3] However, in view of other studies submitted by the petitioner, EPA decided that the studies indicate that polyoxin D zinc salt is not mutagenic or clastogenic.
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]			X	
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]			X	
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]			X	

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

[2] EPA. Consideration of Eligibility for Registration of the New Pesticide Active Ingredient Polyoxin D Zinc Salt – DECISION MEMORANDUM,p 15.
[3] EPA, May 11, 2012. Science Review of Product Chemistry, Residue Chemistry, Non-Target Organism, and Toxicity Data in Support of Label Amendment for Polyoxin D Zinc Salt. (Included with supplemental petition.)

NOSB Evaluation Criteria for Substances Added To the National List

Category 2. Is the Substance Essential for Organic Production? Substance:

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]	X	X		Included in a new document received on January 18, 2013 from the petitioner it states on page 5 section 1.1, that, polyoxin D is made from an aerobic fermentation process, thus a natural process. However, they do state that they do not know whether the zinc salt is from a mined or from a recycled zinc source. The TR states that the manufacturing process has at least one step that would be similar to other *Streptomyces* products that are classified as synthetic on section 205.601 of the National List: streptomycin and tetracycline (terramycin). Similarly, polyoxin D Zinc Salt may also be classified as a synthetic.TR lines 146-148. It would appear that polyoxin D may be non-synthetic, but it would be assumed that the zinc salt would be synthetic, due to the lack of being able to properly verify its source.
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]	X	X		Refer to the above answer in Category 2, Question 1.
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		X		It is produced from a natural occurring soil microorganism Streptomyces cacaoi by a controlled fermentation process, according to the TR lines 119 – 120. (TR July 11, 21012) The petition states that polyoxin D Zinc Salt is isolated from a broth (extraction media) and then dried.

				Actual process is part of their CBI information. One part of the TR states that a review of all the structural forms of polyoxin does not include the Zinc Salt as a natural product (Worthington, 1988). TR lines 141-142. Also, refer to the answers as stated in Category 2, Question 1 & 2.
4. Is there a natural source of the substance? [§205.600 b.1]		X	X	
5. Is there an organic substitute? [§205.600 b.1]			X	
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]			X	
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	X	X		There is a natural occurring quinone plumbagin, isolated as a botanical that is comparable to polyoxin D (Dekeyser and Downer 1994), but it is not commercially available in the US at this time. There are coppers and sulfur materials currently allowed for use. TR 321-328. (TR July 11, 2012)
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]			X	
9. Are there any alternative substances? [§6518 m.6]	X			There are other alternative substances available. The TR lists several that are currently allowed: JMS Stylet Oil, Dow's M-Pede, Regalia, Sonata, and Kaligreen to name just a few. See TR July 12, 2012 table: Comparison of the Endorse WDG label with Alternative Pesticides., located between lines 355-356. The efficacy of each of these materials is not listed.
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X	X		(TR lines 376-391) The TR lists several possible practices that could be used possibly in place of polyoxin D Zinc Salt. Antibiosis – using the live organisms rather than their extracts. This seems to be more consistent with organic farming principles.(Milner, et al. 1997) Also beneficial antagonistic Streptomyces spp – but commercial development is slow in coming.(Liu, et al., 1997) (TR July 11, 2012) Also, crop rotation, crop nutrient management practices,

				sanitation to remove disease vectors, selection of resistant species and varieties (where applicable) beneficial antagonistic bacteria, monitoring. TR 367-382

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB Evaluation Criteria for Substances Added To the National List

Category 3. Is the substance compatible with organic production practices?
Substance:

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]			X	
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]	X	X		There are concerns with the possible impact on beneficial soil organisms. Toxic to bees. (TR lines 305-309) EPA exempts it from tolerance (40 CFR 180.1285) Also in a petition Addendum dated October 2,2012 the EPA has granted the petitioner an expanded exemption of tolerance to "all food commodities" and given expanded uses for all food and feed crops pre-harvest and post- harvest.
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]	X	X		No, because it is not a unnecessary synthetic input. Also, because it does show toxicity to fungi and bees. However, some felt it was a useful tool as part of a rotational disease control program.
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]			X	
5. Is the primary use as a preservative? [§205.600 b.4]			X	
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]			X	
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following		X		

categories: a. copper and sulfur compounds;				
b. toxins derived from bacteria;	X			According to the TR (TR line 110) polyoxin D is a toxin derived from a bacteria (Streptomyces cacaoi var.asoensis) (TR July 11, 2012)
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?		X		
d. livestock parasiticides and medicines?		X		
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?		X		

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB Evaluation Criteria for Substances Added To the National List

Category 4. Is the commercial supply of an agricultural substance as organic, fragile or potentially unavailable? [§6610, 6518, 6519, 205.2, 205.105 (d), 205.600 (c) 205.2, 205.105 (d), 205.600 (c)] **Substance: Name**

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the comparative description provided as to why the non-organic form of the material /substance is necessary for use in organic handling?			X	
2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **form** to fulfill an essential function in a system of organic handling?			X	
3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quality** to fulfill an essential function in a system of organic handling?			X	

4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quantity** to fulfill an essential function in a system of organic handling?			X	
5. Does the industry information provided on material / substance non-availability as organic, include (but not limited to) the following: a. Regions of production (including factors such as climate and number of regions);			X	
b. Number of suppliers and amount produced;			X	
c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;			X	
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or			X	
e. Are there other issues which may present a challenge to a consistent supply?			X	

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

National Organic Standards Board
Crops Subcommittee
Petitioned Material Proposal
Indole-3-butyric acid (IBA) CAS#133-32-4

January 29, 2013

Summary of Proposed Action:

Indole-3-butyric acid (IBA) CAS#133-32-4 was petitioned in 2009 and was reviewed in 2011 by the NOSB, which voted to not add it to the National List. The petitioner re-petitioned the substance in 2012, this time with a use restriction to rooting cuttings. Besides the use restriction, no new information accompanied the re-petition.

IBA is a plant hormone in the auxin family and is an ingredient in many commercial horticultural plant rooting products. IBA is not soluble in water and it is typically dissolved in 75% or purer alcohol for use in plant rooting, making a solution of between 10,000 to 50,000 ppm. This alcohol solution is then diluted with distilled water to the desired concentration. IBA is also available as a salt, which is soluble in water. This compound had been classified as synthetic; however, it was reported that the compound was isolated from leaves and seeds of maize and other species.

IBA is used to promote strong rooting and root growth, which users say has the benefit of minimizing the period of time in which young planting stock is susceptible to disease and pest pressure, thereby minimizing additional pest and disease control measures and crop losses. It also provides for propagation of seedless annual crops and some perennial crops impossible or nearly so without such support. Additionally, unique flavors of individual plants (e.g. mint, basil) can be precisely propagated whereas propagation by seed creates variability in flavors of sexually propagated stock. Proponents of IBA's inclusion on the National List say it would also allow propagation materials to be sold as organic within a 12-month time frame, thus further developing the supply to build the market for organic perennial planting stock on a regular basis. Its utility in the ornamental crop sector is widespread and may encourage ornamental nurseries to work toward developing organic crop production systems. Five growers provided their written support as part of the petition packet in favor of the including of the material to facilitate the production of organic herbs, strawberries, herb transplants, and other crops, and they appear to have a real interest in the inclusion of IBA on the National List.

IBA's status as a production aid (as opposed to pest control or disinfectant, for example) places it in uncertain territory relative to the National List and makes it difficult to categorize. Additionally, there was little call from organic growers for the material to be placed on the National List and the Crops Subcommittee would like to hear additional comments from the organic growing community as to need and compatibility of the material.

The committee found that it is not essential and is not compatible with organic production.

Evaluation Criteria
(Applicability noted for each category; Documentation attached) **Criteria Satisfied?**

1. Impact on Humans and Environment x Yes ☐ No ☐ N/A
2. Essential & Availability Criteria ☐ Yes x No ☐ N/A
3. Compatibility & Consistency ☐ Yes x No ☐ N/A
4. Commercial Supply is Fragile or Potentially Unavailable ☐ Yes ☐ No x N/A as Organic (only for § 205.606)

Substance Fails Criteria Category: [2, 3] Comments**:** There has not been shown to be a demonstrated need for IBA in organic production. The majority of the subcommittee found that synthetic materials to achieve propagation are inconsistent with organic production. In addition, although #1 is checked yes, environmental impacts may be greater than indicated in the review depending on the raw materials used and the manufacturing process.

Proposed Annotation (if any):

Basis for annotation: ☐ To meet criteria above ☐ Other regulatory criteria ☐ Citation
Notes:

Recommended Committee Action & Vote, including classification recommendation (state actual motion):

Classification Motion: Classify IBA as synthetic.
Motion by: John Foster Seconded by: Harold Austin
Yes: 8 No: 0 Absent: 0 Abstain: 0 Recuse:0

Listing Motion: List IBA (CAS# 133-32-4) as petitioned on §205.601 for the purpose of plant propagation via dipping.
Motion by: John Foster Seconded by: Harold Austin
Yes: 3 No: 5 Absent: 0 Abstain: 0 Recuse:0

Crops	**x**	**Agricultural**	☐	**Allowed[1]**	☐
Livestock	☐	**Non-synthetic**	☐	**Prohibited[2]**	☐
Handling	☐	**Synthetic**	**x**	**Rejected[3]**	**x**
No restriction	☐	**Commercial unavailable as organic**	☐	**Deferred[4]**	☐

[1]Substance voted to be added as “allowed” on National List to § 205. with Annotation (if any):

[2]Substance to be added as “prohibited” on National List to § 205. with Annotation (if any):

Describe why a prohibited substance:

[3]Substance was rejected by vote for amending National List to § 205. . Describe why material was rejected:

[4]Substance was recommended to be deferred because
If follow-up needed, who will follow up:

Approved by Subcommittee Chair to Transmit to NOSB

Jay Feldman, Subcommittee Chair **January 29, 2013**

NOSB Evaluation Criteria for Substances Added To the National List

Category 1. Adverse impacts on humans or the environment? Substance: Indole-3-butyric acid (IBA)

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]			N/A	
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		TR 227- Petitioner stated IBA is a technical grade synthesized substance from many sources.186 products containing IBA are available in US. IBA is manufactured worldwide. Thus, there might be different manufacturing procedures. TR 240 Isopropyl ether is listed as "UN1159 Flammable Liquid" by U.S. DOT. The health effects are listed in 240 OSHA as "Irritation-Eye, Nose, Throat, Skin --- Mild (HE15)."
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		TR 282- IBA is synthesized in natural plants and produced by soil bacteria. It is non-toxic to avian wildlife, plants, but slightly toxic to fish and aquatic, and invertebrates and should not cause adverse effects to mammalian wildlife. EPA says IBA does not persist in the environment. TR 221 EPA also waived most tox requirements. TR 252-255 – IBA has typical hormonal dose-response pattern. TR 287- PAN data base shows no evidence of harmful effects to environment, except slight toxicity to fish.

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
4. Does the substance contain List 1, 2 or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]		X		TR 238- Indole (CAS#120-72-9) butyrolactone (CAS# 96-48-0) and Sodium Hydroxide (CAS# 1310-73-2) were on EPA inerts list 4B.
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		X		TR 246- potentially reacts with strong oxidizers. TR 249- 250: "The stimulating effect of IBA is synergistic with other chemicals and bacteria."
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		X		TR 262-264: The literature about IBA's potentially detrimental chemical interaction with other substances used in organic crop or livestock production is scarce.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		X		TR 272-274: The literature about potential detrimental physiological effects is limited. Instead, indole derivatives including IBA possess fungicidal activity against some plant pathogenic fungi (Abdel-Aty, 2010). (Nothing stated about effects on beneficial fungi.)
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		See # 3 above
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]		X		See # 3 above
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i); 6517 c(2)(A)i; §6518 m.4]		X		TR 303-313: EPA says no known risks to human health and has granted an exemption for tolerance of residue, but has waived many data requirements. IBA is an "acute health hazard" under Section 311/312 Hazard class of SARA Title III Rules (MSDA-IBA,2007)
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]			N/A	
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]			N/A	

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]			N/A	

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB Evaluation Criteria for Substances Added To the National List

Category 2. Is the Substance Essential for Organic Production? Substance: Indole-3-butyric acid (IBA)

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]	X			
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]	X			
3. Is the substance created by naturally occurring biological processes? [6502 (21)]	X			TR 294-296
4. Is there a natural source of the substance? [§205.600 b.1]			N/A	
5. Is there an organic substitute? [§205.600 b.1]			N/A	
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]			N/A	
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	X	X		TR 62, 142-155: IBA occurs naturally, but there is not any commercially available extraction process. The most commonly used auxin for inducing adventitious rooting is IAA, but the availability of natural sources is unclear.
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]			N/A	
9. Are there any alternative substances? [§6518 m.6]	X			TR 314-500 identifies many substances and practices.

10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			TR 314-500 identifies many substances and practices. Successful rooting from stem cuttings depend on many factors: timing, types of cutting, light, temperature, moisture and 10 other factors including plant hormones.(which may be produced naturally by the plant tissues)

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB Evaluation Criteria for Substances Added To the National List

Category 3. Is the substance compatible with organic production practices?
Substance: Indole-3-butyric acid (IBA)

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]			N/A	
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]	X	X		TR 381- European and N. American organic regulations do not allow use of synthetic products forpropagation. It does not fit any of the allowed categories for approving synthetic inputs: 6517c1(B). However, proponents say it does promote healthy plant tissue thereby reducing needs for further intervention measures.
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]		X		IBA is produced in plants and soil bacteria. There is no evidence that chemical properties of synthetic IBA are different from natural sources, but the manufactured IBA contains impurities.
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]			N/A	
5. Is the primary use as a preservative? [§205.600 b.4]			N/A	
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]			N/A	
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following		X		

categories: a. copper and sulfur compounds;				
b. toxins derived from bacteria;		X		
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?		X		
d. livestock parasiticides and medicines?		X		
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?		X		

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB Evaluation Criteria for Substances Added To the National List

Category 4. Is the commercial supply of an agricultural substance as organic, fragile or potentially unavailable? [§6610, 6518, 6519, 205.2, 205.105 (d), 205.600 (c) 205.2, 205.105 (d), 205.600 (c)] **Substance:** Indole-3-butyric acid (IBA)

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the comparative description provided as to why the non-organic form of the material /substance is necessary for use in organic handling?			x	
2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **form** to fulfill an essential function in a system of organic handling?			x	
3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quality** to fulfill an essential function in a system of organic handling?			x	
4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the			x	

appropriate **quantity** to fulfill an essential function in a system of organic handling?				
5. Does the industry information provided on material / substance non-availability as organic, include (but not limited to) the following: a. Regions of production (including factors such as climate and number of regions);			x	
b. Number of suppliers and amount produced;			x	
c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;			x	
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or			x	
e. Are there other issues which may present a challenge to a consistent supply?			x	

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

National Organic Standards Board
Handling Sub Committee
Petitioned Material Proposal
Sulfuric Acid

January 9, 2013

Summary of Proposed Action:
The petition is for the listing of sulfuric acid on 205.605(b) for use as a processing aid in the production of seaweed extract. Sulfuric acid is used as a pH adjuster in the extraction water for the production of seaweed extracts, particularly a class of seaweed extracts called fucoidans, which are largely used as ingredients in dietary supplements.

For a number of reasons, the Handling Subcommittee recommends that sulfuric acid not be added to the national list as petitioned:

- The redaction of substantial amounts of confidential business information (CBI) from the petition makes it impossible to evaluate the use of sulfuric acid in the manufacturing process, and impossible to establish whether the resulting seaweed extract undergoes sufficient chemical change as to render it a synthetic substance.

- The petition and TR fail to demonstrate the essentiality of this substance in the production of organic food, or the absence of viable alternatives. The petition provides little economic data or market narrative to demonstrate that this substance might play a compelling role in the production of organic products, and the redacted CBI makes it impossible to even understand how sulfuric acid is used in seaweed extract production.

- The TR clearly documents negative environmental impacts of the production of this substance, suggests negative health effects in its production and industrial use, and overwhelmingly demonstrates the substance's incompatibility with a system of organic agriculture.

Evaluation Criteria

(Applicability noted for each category; Documentation attached)	**Criteria Satisfied?**
1. Impact on Humans and Environment	☐ Yes X No ☐ N/A
2. Essential & Availability Criteria	☐ Yes X No ☐ N/A
3. Compatibility & Consistency	☐ Yes X No ☐ N/A
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for § 205.606)	☐ Yes ☐ No X N/A

Substance Fails Criteria Category: [1, 2 and 3] **Comments:**

Proposed Annotation (if any):

Basis for annotation: ☐ To meet criteria above ☐ Other regulatory criteria ☐ Citation
Notes:

Recommended Committee Action & Vote, including classification recommendation (state actual motion):

Classification Motion: Motion to classify sulfuric acid (CAS 7664-93-9) as petitioned as synthetic:
Motion by: Joe Dickson
Seconded by: John Foster
No further discussion

Yes: 8 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Listing Motion: List sulfuric acid (CAS 7664-93-9) as petitioned on 205.605(b)
Motion by: Joe Dickson
Seconded by: Tracy Favre
No further discussion
Yes: 0 No: 8 Abstain: 0 Absent: 0 Recuse: 0

Crops	☐	**Agricultural**	☐	**Allowed**[1]	☐
Livestock	☐	**Non-synthetic**	☐	**Prohibited**[2]	☐
Handling	**X**	**Synthetic**	**X**	**Rejected**[3]	**X**
No restriction	☐	**Commercial unavailable as organic**	☐	**Deferred**[4]	☐

[1]Substance voted to be added as "allowed" on National List to § 205. with Annotation (if any):
[2]Substance to be added as "prohibited" on National List to § 205. with Annotation (if any):
Describe why a prohibited substance:
[3]Substance was rejected by vote for amending National List to § 205.605(b). Describe why material was rejected:
[4]Substance was recommended to be deferred because
If follow-up needed, who will follow up:

Approved by Subcommittee Chair to Transmit to NOSB

John Foster, Subcommittee Chair **January 9, 2013**

NOSB Evaluation Criteria for Substances Added To the National List

Category 1. Adverse impacts on humans or the environment? Substance: Sulfuric Acid

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]	x			The TR notes that sulfuric acid is a substantial source of acid rain, and that the manufacture of this material presents adverse environmental impact (lines 327-353)
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]	x			TR lines 327-353
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]	x			TR lines 327-353
4. Does the substance contain List 1, 2 or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]			x	
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]	x			
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]			x	
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]			x	
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]	x			TR lines 327-353
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]	x			TR lines 327-353
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i); 6517 c(2)(A)i; §6518 m.4]	x			While there is no documented detrimental effect on human health from dietary sources of the material as petitioned, the manufacture and industrial use of the material present harmful effects on health. “Sulfuric acid is considered very toxic and may be fatal if inhaled or swallowed. It is corrosive to the eyes, skin, and respiratory tract, and exposure may cause blindness and permanent scarring.” –TR Lines 41-42
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]		x		Not from dietary sources.
12. Is the substance GRAS when used according to FDA’s good manufacturing practices? [§205.600 b.5]	x			It is not clear from the TR that sulfuric acid is GRAS for the petitioned use; the TR does list a number of other GRAS uses (TR Lines 276-282)
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600		x		The petition and TR provide insufficient information to satisfy this criterion. “While residues and impurities (i.e., copper, iron,

b.5]				zinc, arsenic, mercury, lead, and selenium) have been reported in manufactured sulfuric acid product, no information was found to indicate the levels of these substances in sulfuric acid used for pH adjustment. Therefore it is unknown if these contaminants are in excess of FDA tolerances in sulfuric acid. " – TR Lines 318-321

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB Evaluation Criteria for Substances Added To the National List

Category 2. Is the Substance Essential for Organic Production? Substance: Sulfuric Acid

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]	x			TR lines 262-263
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]		x		
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		x		
4. Is there a natural source of the substance? [§205.600 b.1]		x		TR lines 268-269
5. Is there an organic substitute? [§205.600 b.1]		x		Because the manufacturing process is redacted from the petition, it is impossible to determine whether the use of other pH adjusters such as citric or lactic acid is viable or appropriate. TR lines 392-398
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]		x		TR lines 392-398
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]			x	Again, the petition and TR do not provide sufficient information to determine the necessity of the material, or if the resulting seaweed extract has undergone sufficient chemical change to be rendered synthetic.
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]		x		
9. Is there any alternative substances? [§6518 m.6]			x	
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]			x	

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB Evaluation Criteria for Substances Added To the National List

Category 3. Is the substance compatible with organic production practices? Substance: Sulfuric Acid

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]		x		
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]		x		
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]		x		
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]			x	CBI redacted from petition makes it impossible to establish how the substance impacts the food.
5. Is the primary use as a preservative? [§205.600 b.4]		x		It is not clear that the petitioned use is as a preservative per se, but the TR notes a number of preservative uses of the substance (lines 288-298)
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]		x		TR line 305
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: a. copper and sulfur compounds;			x	
b. toxins derived from bacteria;			x	
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?			x	
d. livestock parasiticides and medicines?			x	
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?			x	

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB Evaluation Criteria for Substances Added To the National List
Category 4. Is the commercial supply of an agricultural substance as organic, fragile or potentially unavailable? [§6610, 6518, 6519, 205.2, 205.105 (d), 205.600 (c) 205.2, 205.105 (d), 205.600 (c)]
Substance Name: Sulfuric Acid

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the comparative description provided as to why the non-organic form of the material /substance is necessary for use in organic handling?			x	
2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **form** to fulfill an essential function in a system of organic handling?			x	
3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quality** to fulfill an essential function in a system of organic handling?			x	
4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quantity** to fulfill an essential function in a system of organic handling?			x	
5. Does the industry information provided on material / substance non-availability as organic, include (but not limited to) the following: a. Regions of production (including factors such as climate and number of regions);			x	
b. Number of suppliers and amount produced;			x	
c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;			x	
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or			x	
e. Are there other issues which may present a challenge to a consistent supply?			x	

National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal
Barley betafiber

December 18, 2012

Summary of Proposed Action:

Barley betafiber is described in the petition as a “polysaccharide of unbranched, linear, mixed-linkage ß-glucans” (Kolberg, 2011). Barley betafiber is described at 21 CFR 101.81(c)(2)(ii)(6) as a fraction of cellulase and alpha-amylase hydrolyzed whole grain barley.

Barley betafiber is defined by the FDA as “the ethanol precipitated soluble fraction of cellulase and alpha-amylase hydrolyzed whole grain barley. Barley betafiber is produced by hydrolysis of whole grain barley flour, as defined in paragraph (c)(2)(ii)(A)(5) of this section, with a cellulase and alpha-amylase enzyme preparation, to produce a clear aqueous extract that contains mainly partially hydrolyzed beta-glucan and substantially hydrolyzed starch. The soluble, partially hydrolyzed beta-glucan is separated from the insoluble material by centrifugation, and after removal of the insoluble material, the partially hydrolyzed beta-glucan soluble fiber is separated from the other soluble compounds by precipitation with ethanol. The product is then dried, milled and sifted. Barley betafiber shall have a beta-glucan soluble fiber content of at least 70 percent on a dry weight basis” [21 CFR 101.81(c)(2)(ii)(6)].

Barley ß-glucan isolates such as barley betafiber enable food processors to incorporate the health benefits of barley in various foods without the problems created by whole grain barley in formulation (Fastnaught, 2009). The petition refers to it being used in a juice (Kolberg, 2011). Soluble barley betafiber is possible to use in other beverages (Zheng, et al., 2004). Other foods where barley betafiber has been added, at least experimentally if not commercially, include baked goods, pasta, ready-to-eat cereals, soups, stews, dairy products and meats (Newman and Newman, 2008; Fastnaught, 2009).

Barley is known to be a rich source of ß-glucan. While most other grains have lower fiber in the endosperm than the whole grain, the soluble ß-glucan in barley endosperm is comparable to that of whole grain (Henry, 1987). The variety “Prowashonupana” was identified in the early 1980s as a mutant hull-less waxy barley with a high ß-glucan content (Eslick, 1981). The ß-glucan in Prowashonupana is described as not soluble (WTARC, 2005). Other barley varieties selected for high soluble ß-glucan content are Apollo and Wanubet (Yoon et al., 1995). The petitioned substance is described as new and at this time the only commercial products that use the petitioned substance are processed products that are not certified organic (Kolberg, 2011).

Nutritional fiber has a wide range of technical and functional effects on food (Dreher, 2001; Sharma et al., 2008; Cho, 2009). Naturally occurring β-glucans can be classified as *Soluble Fibers*, while added or isolated β-glucans are potential *Functional Fibers*. Soluble and functional fibers have similar activity, but isolated ß-glucan extracts have a wide range of specific characteristics and functionality. Barley betafiber is distinguished by its low molecular weight (Zheng, et al., 2004). As discussed below, the primary health claim made related to the use of the petitioned substance is its ability to reduce the glycemic index of foods, help to maintain normal blood sugar levels, and lower cholesterol, decrease risk of diabetes, and “(potentially) promoting satiety” (Kolberg, 2011).

Consistent with the literature noted above, the petition claims specific properties of this barley beta fiber that are unique and currently unavailable in organic form to be used as dietary fiber additions in product formulations, specifically that the percentages and ratio of soluble to insoluble fiber are preferable from a product development standpoint. The petition also claims that the variety of barley used for this product is currently not grown in sufficient quantity to satisfy market demand.

The Handling Subcommittee reviewed the petition materials, considered the unique characteristics of the variety and product in the petition and reviewed the TR, which addressed the technical aspects of the material but not the market dynamics. The Subcommittee requests that interested members of the organic community comment on the supply, demand and specific qualities of the petitioned material in an effort to assess the degree to which there is an essential market need.

Evaluation Criteria

(Applicability noted for each category; Documentation attached)	**Criteria Satisfied? (see "B" below)**
1. Impact on Humans and Environment	x Yes ☐ No ☐ N/A
2. Essential & Availability Criteria	x Yes x No ☐ N/A
3. Compatibility & Consistency	x Yes ☐ No ☐ N/A
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for § 205.606)	x Yes ☐ No ☐ N/A

Substance Fails Criteria Category: [ ] **Comments:**

Proposed Annotation (if any): none

Basis for annotation: ☐ To meet criteria above ☐ Other regulatory criteria ☐ Citation
Notes:

Recommended Committee Action & Vote, including classification recommendation (state actual motion):

Classification Motion: Motion to classify barley betafiber as petitioned as agricultural
Motion by: John Foster Seconded by: Joe Dickson
Yes: 8 No: 0 Absent: 0 Abstain: 0 Recuse: 0

Listing Motion:
Motion by: John Foster Seconded by: Joe Dickson
Yes: 7 No: 0 Absent: 0 Abstain: 1 Recuse: 0

Crops	☐	**Agricultural**	**x**	**Allowed**[1]	**x**
Livestock	☐	**Non-synthetic**	☐	**Prohibited**[2]	☐
Handling	**x**	**Synthetic**	☐	**Rejected**[3]	☐
No restriction	☐	**Commercial unavailable as organic**	**x**	**Deferred**[4]	☐

[1]Substance voted to be added as "allowed" on National List to § 205. with Annotation (if any): none

Approved by Subcommittee Chair to Transmit to NOSB
John Foster, Subcommittee Chair December 18, 2012

NOSB Evaluation Criteria for Substances Added To the National List

Category 1. Adverse impacts on humans or the environment? Substance: Barley betafiber

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]		X		See TR-product is agricultural.
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		"
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		"
4. Does the substance contain List 1, 2 or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]			X	
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		X		"
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]			X	
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]			X	
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		"
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]		X		"
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i); 6517 c(2)(A)i; §6518 m.4]		X		"
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]		X		"
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]	X			"
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA	X			Small residual amounts are left in the product. TR states <2ppm lead.

tolerances? [§205.600 b.5]				

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB Evaluation Criteria for Substances Added To the National List

Category 2. Is the Substance Essential for Organic Production? Substance: Barley betafiber

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]	X			Chemical reactions are occurring in the use of enzymes to break bonds. TR.
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]	X			There is a chemical separation of the fiber from the barley; that being said it is a normal component of the barley
3. Is the substance created by naturally occurring biological processes? [6502 (21)]	X			Natural in that it used enzymes; however the enzymes are not endogenous to the barley and are introduces. That being said, it is a normal biologic process.
4. Is there a natural source of the substance? [§205.600 b.1]			X	
5. Is there an organic substitute? [§205.600 b.1]		X		TR states that oat 70% β-glucan is available organically and not mentioned in the petition
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]		X		Not essential; however, it is an ingredient that will assist in providing for the overall health of the consumer.
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]			X	
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]	X			
9. Is there any alternative substances? [§6518 m.6]	X	X		There are other sources of fiber with β-glucans; but these have different properties and are not always functional in some types of products, beverages for example.
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]		X		

NOSB Evaluation Criteria for Substances Added To the National List

Category 3. Is the substance compatible with organic production practices?
Substance: Barley betafiber

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]	X			Consistent with most compatibility criteria
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]	X			Several other materials used in analogous capacities
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]			X	Not used in farming
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]	X			Increased due to the addition of heart healthy fiber
5. Is the primary use as a preservative? [§205.600 b.4]		X		
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]		X		Used for increased dietary fiber in foods
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: a. copper and sulfur compounds;			X	
b. toxins derived from bacteria;			X	
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?			X	
d. livestock parasiticides and medicines?			X	
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?			X	

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB Evaluation Criteria for Substances Added To the National List

Category 4. Is the commercial supply of an agricultural substance as organic, fragile or potentially unavailable? [§6610, 6518, 6519, 205.2, 205.105 (d), 205.600 (c) 205.2, 205.105 (d), 205.600 (c)] **Substance: Barley betafiber**

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the comparative description provided as to why the non-organic form of the material /substance is necessary for use in organic handling?	X			Petition-pg 8
2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **form** to fulfill an essential function in a system of organic handling?	X			Petition Pg. 8—the variety grown for fiber production is not currently in organic production
3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quality** to fulfill an essential function in a system of organic handling?	X			Petition Pg. 8
4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quantity** to fulfill an essential function in a system of organic handling?	X			Petition Pg. 8
5. Does the industry information provided on material / substance non-availability as organic, include (but not limited to) the following: a. Regions of production (including factors such as climate and number of regions);	X			See above
b. Number of suppliers and amount produced;		X		
c. Current and historical supplies related to weather events such as			X	

hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;				
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or			X	
e. Are there other issues which may present a challenge to a consistent supply?	x			

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

National Organic Standards Board
Handling Committee
Petitioned Material Proposal
Sugar beet fiber

December 18, 2012

Summary of Proposed Action:

Sugar beet fiber is the remaining vegetable matter following the sucrose extraction hydrolysis process for sugar beets. This fibrous sugar beet material is composed of hemicellulose, cellulose, and pectin and contains soluble fiber concentrations of 10%-20%. Sugar beet fiber has a large surface area and is able to bind a large volume of water within a product to maintain the product's integrity (moisture) and lower the overall water activity which can lead to a longer shelf-life and minimize microbial concerns. Sugar beet fiber is often added to a food product to provide an increased source of soluble fiber within a food, and it is this function that has been brought forth in the petition for addition to §205.606. The addition of sugar beet fiber in this capacity is due to the fact that it has been found to facilitate better digestion/health in those that consume an adequate amount.

Sugar beet fiber processing may have a negative environmental impact due to the release of wastewater with high biologic oxygen demand (BOD) that can disturb natural ecosystems if not released/treated responsibly. Additionally, the technical review states that sugar beet fiber production often relies upon genetically engineered beets that would are not allowed in organic production since genetic engineering is an excluded method. The extraction process to isolate the sugar from the beet fiber is reliant upon a non-chemical hydrolysis process. However, further sugar beet fiber processing can utilize additional materials to bleach and/or treat the fibers with formaldehyde to produce a uniform color and/or prevent microbial activity which can lead to spoilage and mycotoxin production. Production practices throughout the world for sugar beet production and processing may vary, in some cases, using a variety of organically prohibited materials (pesticides, herbicide, fumigants, fertilizers, preservatives, etc.). These practices, while not allowed for organic production, are consistent with other common crop practices for non-organic ingredients.

The subcommittee discussed concerns over GMOs and the concern over the genetic purity of sugar beets that may be used for sugar production and therefore would be the source material for the fiber in question—either currently or in the future. The subcommittee also had concerns and is seeking comments from the industry regarding the reportedly unique solubility/insolubility ratio and phytic acid levels in the substance and the degree to which these offer specific benefits over other or organically available alternatives.

Evaluation Criteria

(Applicability noted for each category; Documentation attached)	**Criteria Satisfied? (see "B" below)**		
1. Impact on Humans and Environment	x Yes	☐ No	☐ N/A
2. Essential & Availability Criteria	x Yes	☐ No	☐ N/A
3. Compatibility & Consistency	x Yes	☐ No	☐ N/A
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for § 205.606)	x Yes	☐ No	☐ N/A

Substance Fails Criteria Category: [ ] **Comments:**

Proposed Annotation (if any):

Basis for annotation: ☐ To meet criteria above ☐ Other regulatory criteria ☐ Citation
Notes:

Recommended Committee Action & Vote

Classification Motion: Motion to classify sugar beet fiber as agricultural

Motion by: John Foster Seconded by: Joe Dickson
Yes: 8 No: 0 Absent: 0 Abstain: 0 Recuse: 0

Listing Motion: Motion to list sugar beet fiber as petitioned on § 205.606
Motion by: John Foster Seconded by: Joe Dickson
Yes: 7 No: 0 Absent: 0 Abstain: 1 Recuse: 0

Crops	☐	**Agricultural**	**x**	**Allowed[1]**	☐
Livestock	☐	**Non-synthetic**	☐	**Prohibited[2]**	☐
Handling	**x**	**Synthetic**	☐	**Rejected[3]**	☐
No restriction	☐	**Commercial unavailable as organic**	**x**	**Deferred[4]**	☐

[1]Substance voted to be added as "allowed" on National List to § 205.606 without annotation.

Approved by Committee Chair to Transmit to NOSB
John Foster, Committee Chair December 18, 2012.

NOSB Evaluation Criteria for Substances Added To the National List

Category 1. Adverse impacts on humans or the environment? Substance: Sugar beet fiber

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]	X			TR: wastewater can have high BOD and lead to water pollution; growing conventional beets is cited to use a large amount of harmful materials (herbicides, methyl bromide, pesticides); also TR states formaldehyde and sulfur dioxide may be used to bleach and preserve the fiber from microbes/toxin production
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]	X			TR: cites that environmental contamination can happen at processing plants; however, not all plants/production would lead to that pollution since it is practice dependent for different producers worldwide
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		
4. Does the substance contain List 1, 2 or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]			X	
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		X		
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]			X	THIS MATERIAL IS FOR 606
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]			X	
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]		X		
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i); 6517 c(2)(A)i; §6518 m.4]		X		
11. Is there an adverse effect on human health as defined by applicable		X		

Federal regulations? [205.600 b.3]				
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]		X		
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		X		

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB Evaluation Criteria for Substances Added To the National List

Category 2. Is the Substance Essential for Organic Production? Substance: Sugar beet fiber

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]		X		TR-some manufacturers may use some chemicals in bleaching or preventing microbial activity; this would be dependent on the producer and not all sugar beet fiber would have this problem
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]		X		See above
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		X		TR: product is extracted via a physical method using on water and heat
4. Is there a natural source of the substance? [§205.600 b.1]			X	
5. Is there an organic substitute? [§205.600 b.1]	X			TR, PETITION: there is not the quantity of organic to supply the industry
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]		X		TR, PETITION: it is not a requirement for food , but it is a product that can assist in processing and provide additional health benefits to consumers
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]			X	
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]	X			
9. Is there any alternative substances? [§6518 m.6]	X			TR, PETITION: other vegetable fibers can be used instead (oat, pea, etc.) however each has slightly different properties
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			Using another vegetable fiber or not using a fiber at all.

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB Evaluation Criteria for Substances Added To the National List

Category 3. Is the substance compatible with organic production practices? Substance: Sugar beet fiber

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]	X	X		Sugar beet may be grown with GMO sugar beets.
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]			X	
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]			X	
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]	X			TR: no mention or data was presented showing a decrease in the nutritional value due to addition.
5. Is the primary use as a preservative? [§205.600 b.4]		X		TR: sugar beet fiber can bind water and thus act as a preservative
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]		X		Can be used to improve texture but this is not the primary use.
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: a. copper and sulfur compounds;			X	
b. toxins derived from bacteria;			X	
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?			X	
d. livestock parasiticides and medicines?			X	
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?			X	

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB Evaluation Criteria for Substances Added To the National List

Category 4. Is the commercial supply of an agricultural substance as organic, fragile or potentially unavailable? [§6610, 6518, 6519, 205.2, 205.105 (d), 205.600 (c) 205.2, 205.105 (d), 205.600 (c)] **Substance: Sugar beet fiber**

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the comparative description provided as to why the non-organic form of the material /substance is necessary for use in organic handling?	X			Petition: there is not a currently certified source available in large quantity. TR states some suppliers internationally.
2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **form** to fulfill an essential function in a system of organic handling?		X		TR: does mention that production of the crop is challenged by weed pest pressure.
3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quality** to fulfill an essential function in a system of organic handling?		X		
4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quantity** to fulfill an essential function in a system of organic handling?	X			Past suppliers stopped producing it due to lack of purchasing.
5. Does the industry information provided on material / substance non-availability as organic, include (but not limited to) the following: a. Regions of production (including factors such as climate and number of regions);		X		
b. Number of suppliers and amount produced;	X			TR: may be suppliers in the world, but none in the US
c. Current and historical supplies related to weather events such as		X		

hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;				
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or		X		
e. Are there other issues which may present a challenge to a consistent supply?		X		GMO contamination of organic crops/products?

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N /A—not applicable.

National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal
1,3-dibromo-5, 5-dimethylhydantoin (DBDMH) CAS No. 77-48-5

January 14, 2013

Summary of Proposed Action:
1,3-Dibromo-5,5-dimethylhydantoin (DBDMH) is an organic compound and is widely used as a disinfectant used for drinking water purification ,recreational water treatment, as a bleaching agent in pulp and paper mills, and for treating industrial/commercial water cooling systems. 1, 3-Dibromo-5, 5-dimethylhydantoin (DBDMH) is an organic compound with the molecular formula $C_5H_6Br_2N_2O_2$. In water, DBDMH hydrolyzes to form hypobromous acid (HOBr)—a source of bromine and an active antimicrobial agent—and dimethylhydantoin (DMH).

DBDMH has been petitioned for use as an antimicrobial treatment for beef carcasses and parts. The reaction of DBDMH mixed with water leads to the production of HOBr, which is the active antimicrobial (see Action of the Substance). DBDMH has become a favored antimicrobial in beef and poultry disinfection processes because its efficacy is less sensitive to pH than chlorine-based disinfecting agents. DBDMH is also effective in protecting food surfaces against the formation of biofilms (i.e., aggregates of microorganisms in which cells adhere to each other on a surface).

It is not recognized by other organic programs. There are several other materials that are in current use in organic meat handling, this material has the advantage of being less corrosive to concrete and equipment, more cost-effective, and less sensitive to pH variability.

Evaluation Criteria

(Applicability noted for each category; Documentation attached)	**Criteria Satisfied? (see "B" below)**
1. Impact on Humans and Environment	☐ Yes x No ☐ N/A
2. Essential & Availability Criteria	☐ Yes x No ☐ N/A
3. Compatibility & Consistency	☐ Yes x No ☐ N/A
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for § 205.606)	☐ Yes ☐ No x N/A

Substance Fails Criteria Category: [ ] **Comments:**

Proposed Annotation (if any):

Basis for annotation: ☐ To meet criteria above ☐ Other regulatory criteria ☐ Citation
Notes:

Recommended Subcommittee Action & Vote, including classification recommendation (state actual motion):

Classification Motion: Move to classify 1,3-dibromo-5, 5-dimethylhydantoin as synthetic.
Motion by: John Foster Seconded by: Jean Richardson
Yes: 7 No: 0 Absent: 1 Abstain: 0 Recuse: 0

Listing Motion: Move to list 1,3-dibromo-5, 5-dimethylhydantoin as petitioned on section 205.605 (b) of the National List
Motion by: John Foster Seconded by: Harold Austin
Yes: 0 No: 7 Absent: 1 Abstain: 0 Recuse: 0

Crops	☐		☐		
Livestock	☐		☐		

Handling	X		☐		
No restriction	☐		☐		

Approved by Subcommittee Chair to Transmit to NOSB

John Foster, Subcommittee Chair **January 15, 2013**

NOSB Evaluation Criteria for Substances Added To the National List

Category 1. Adverse impacts on humans or the environment? **Substance: DBDMH**

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]		X		TR 344+
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		TR 344+
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		TR 344+
4. Does the substance contain List 1, 2 or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]		X		TR
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]			X	Not for use in farming
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]			X	Not for use in farming
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]			X	Not for use in farming
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		Not applied in environment, None noted, TR 344+
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]		X		Not applied in environment, None noted, TR 344+
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i); 6517 c(2)(A)i; §6518 m.4]		X		DMH may be concerning if inappropriately managed. 361-362
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]		X		Not for petitioned use 79
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]		X		TR 216-218
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		X		TR 271. No identified reports.

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB Evaluation Criteria for Substances Added To the National List

Category 2. Is the Substance Essential for Organic Production? Substance: DBDMH

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]	X			TR 193+
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]		X		TR 193
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		X		TR 193
4. Is there a natural source of the substance? [§205.600 b.1]		X		TR 208
5. Is there an organic substitute? [§205.600 b.1]	X	X		Alcohol may be produced organically, but generally, no, as listed in TR 397-498
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]		X		Some means of microbial control is needed to meet FDA handling standards (even pre-FSMA)
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]		X		TR 193
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]		X		
9. Is there any alternative substances? [§6518 m.6]	X	X		Alcohol, lactic acid, chlorine, ozone, hydrogen peroxide, eperoxyacetic acid, hot water, and others that may be costly due to temp requirements, chemical costs. TR 397-498. however, some forms of chlorine are less effective and are more corrosive than this material. These alternatives are also reported by the petitioner to be less economically feasible.
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			As per TR 397-404 and other practices as noted.

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB Evaluation Criteria for Substances Added To the National List

Category 3. Is the substance compatible with organic production practices? Substance:

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]	X	X		Meets some criteria for compatibility but not others.
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]	X	X		Meets some criteria for compatibility but not others.
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]			X	Not used in farming.
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]	X			TR 240-253 is noncommittal. Alternatives do have negative NQ effects.
5. Is the primary use as a preservative? [§205.600 b.4]		X		TR 47 and 244. Used as an antimicrobial, not a preservative.
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]		X		TR 47 and 244. Used as an antimicrobial, not a preservative.
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: a. copper and sulfur compounds;			X	
b. toxins derived from bacteria;			X	
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?			X	
d. livestock parasiticides and medicines?			X	
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?			X	

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB Evaluation Criteria for Substances Added To the National List

Category 4. Is the commercial supply of an agricultural substance as organic, fragile or potentially unavailable? [§6610, 6518, 6519, 205.2, 205.105 (d), 205.600 (c) 205.2, 205.105 (d), 205.600 (c)]
Substance: Name

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the comparative description provided as to why the non-organic form of the material /substance is necessary for use in organic handling?			X	
2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **form** to fulfill an essential function in a system of organic handling?			X	
3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quality** to fulfill an essential function in a system of organic handling?			X	
4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quantity** to fulfill an essential function in a system of organic handling?			X	
5. Does the industry information provided on material / substance non-availability as organic, include (but not limited to) the following: a. Regions of production (including factors such as climate and number of regions);			X	
b. Number of suppliers and amount produced;			X	
c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;			X	
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or			X	
e. Are there other issues which may present a challenge to a consistent supply?			X	

[1] If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

National Organic Standards Board
Handling Subcommittee
Proposal
Auxiliary/"Other Ingredients"

January 29, 2013

Introduction

On Nov. 23, 2011, National Organic Program (NOP) Deputy Administrator Miles McEvoy sent a Memorandum to the National Organic Standards Board (NOSB) requesting clarification of “other ingredients” contained within handling materials on the National List of Allowed and Prohibited substance used in processed organic products. Since OFPA requires that each non-agricultural ingredient be specifically listed, and because the National List does not specifically list “other ingredients” commonly found in formulated products, the NOP identified the need for clarity and requested that the NOSB develop a policy that specifies whether these “other ingredients” are allowed.

In the memo to NOSB, NOP requested the following:

> The NOP is requesting that the NOSB develop a policy on “other ingredients” in § 205.605 substances that is comparable to the comprehensive policy for crop and livestock materials. From this point forward, NOP is requesting that NOSB consider the presence of any “other ingredients” as part of its processes. As substances on the National List come up for sunset review, or as new petitions are considered, NOP requests that NOSB clarify whether any restrictions are warranted for “other ingredients” in § 205.605 substances. Any third-party technical report that NOP provides will include information on any “other ingredients” commonly found in the substance under review.
>
> NOP is requesting that NOSB specify any allowed “other ingredients” in the background section of its recommendations for substances recommended for listing on § 205.605, so that these allowances are clear to the organic trade, certifying agents, and NOP. Any “other ingredients” not listed on § 205.605 or not referenced in the background section of the recommendation, would not be allowed in formulations of substances on § 205.605 that are used in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

The memo continues:

> NOSB may want to address the subject further in the future with a comprehensive policy for “other ingredients” that may be included in permitted handling materials. Some questions that could be addressed in a future recommendation could include the following:
>
> 1. Should all agricultural ingredients that are “other ingredients” be organically produced?
> 2. Are synthetic preservatives allowed as “other ingredients?

In response to the memo, the NOSB Handling Subcommittee has developed a policy for "other ingredients" that may be included in permitted handling materials. This recommendation defines "other ingredients" and the scope of their review.

Background

The NOP regulations require that all certified organic producers and handlers use materials that comply with the applicable parts of the Standards [7 CFR Part 205]. The Standards include Subpart G (The National List), which specifies allowed and prohibited non-organic inputs for use in organic crop and livestock production and nonorganic substances allowed in organic food processing and handling.

In general, for crop and livestock production, non-synthetic materials are allowed unless prohibited. Synthetic substances may be used provided they are on the National List and used in accordance with any specified restrictions. In contrast, the handling standards require that all non-organic non-agricultural substances, whether synthetic or non-synthetic, be included on the National List. Non-organic agricultural ingredients used in the 5% of an "organic" product must also be on the National List AND commercially unavailable in organic form.

Some items on § 205.605 and on § 205.606, however, are sold as multicomponent substances or mixtures wherein the "active" or listed substance is combined with "other ingredients," (e.g. carriers, stabilizers and antioxidants) to provide a ***necessary*** technical effect on the National List substance. In certain cases, small amounts of standardizing agents may be incorporated to ensure the substance meets the specifications required by their standards of identity. Examples of § 205.605 substances that generally contain "other ingredients" include, but are not limited to, biological substances such as enzymes, dairy cultures and microorganisms; cleaners, sanitizers and disinfectants such as peracetic acid; and nutrient vitamins. Examples of § 205.606 items that generally contain "other ingredients" include, but are not limited to, casings from processed intestines, colors, fish oil, pectin, and whey protein concentrate.

Currently, the allowance of "other ingredients" in substances on the National List used in processed organic products is unclear, particularly in contrast with crop and livestock substances. For organic crop and livestock production, specific categories of "other ingredients" are allowed as inert ingredients in pesticides and excipients in animal drugs.

While inert ingredients used in pesticide products, and excipients used in drugs are addressed, the regulations are silent on "other ingredients" used in ***non***-pesticide and ***non***-drug products. The NOP memo states that for other crop and livestock materials a synthetic "other ingredient" is prohibited unless it appears on the National List and non-synthetic "other ingredients" are allowed unless prohibited by the National List. Livestock vitamins and minerals often include other ingredients, but these may be considered approved by certifiers as part of the vitamin or mineral due to lack of restrictions or further clarification on permitted sources of vitamins and minerals

In contrast, the National List for processed products does not include a provision that provides allowances for any "other ingredients". Instead, certain substances on the National List, such as flavors, colors and fish oil, specify a ***restriction*** on the use of "other

ingredients." This has led some to believe that "other ingredients" used in handling materials are allowed unless specifically prohibited.

Relevant areas in OFPA and Regulations (see **Appendix 1** for full references)
OFPA prohibits a certified handler from adding "any synthetic ***ingredient*** not appearing on the National List during processing or any postharvest handling." The National List heading in the regulations at § 205.605 and § 205.606 also specify the use of non-agricultural substances and agricultural products, respectively, referred to as '***ingredients.'*** While OFPA does not reference processing aids, the regulations under § 205.301(f)(4) prohibit the use of '***processing aids'*** during the handling of an organic product unless they are approved on the National List. Both terms are included under 205.2 (Terms Defined). Furthermore, in the final ruling on the Harvey II case (Nov. 2, 2006, the District Court of Maine[1]) 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 (Memorandum Decision on Motion to Enforce Judgment and Cross Motion for Relief from Judgment, U.S. District Court, District of Maine, Civil Docket 2:02cv216).

There is inconsistent use of the term 'substance' used throughout OFPA and the regulations. OFPA clearly states that other ingredients should be evaluated as part and parcel of the consideration of substances for inclusion on the list. In establishing the criteria for what should be included on the national list and how items on the National List should be evaluated, OFPA uses the term "substance" to describe these items. It does not use terms like "single ingredient" or even "ingredient" in Sections 2118 or 2119 and it does not state that substances with more than one ingredient must be evaluated individually. Indeed, Sec. 2119 (l)(2) makes it clear that it was understood that substances might contain multiple ingredients where it says:

- "Sec. 2119 (l)(2) work with manufacturers of substances considered for inclusion on the National List to obtain a *complete list of ingredients and determine whether such substances* contain inert materials that are synthetically produced;" {emphasis added}

However, the Federal Register Notice on Procedures for Submitting National List Petitions [72 *Federal Register* 2167] has not fostered a clear and consistent approach to the issue. The Notice reads:

> Any person may submit a petition requesting a substance to be reviewed by the NOP and NOSB at any time. Each substance to be evaluated for the National List must be submitted in a separate petition. **Only single substances may be petitioned for evaluation; formulated products cannot appear on the National List.**

[1]OFPA does not refer to 'processing aids.' However, in the final ruling on the Harvey II case Nov. 2, 2006, the District Court of Maine ruled that the OFPA change of 2005 that allowed synthetic "ingredients" also allowed synthetic "processing aids" as long as they appear on the National List. The Court 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 (Memorandum Decision on Motion to Enforce Judgment and Cross Motion for Relief from Judgment, U.S. District Court, District of Maine, Civil Docket 2:02cv216).

Furthermore, the NOSB recommendation of November 2009 in the context of classification of materials uses the following definition for "substance":

> "*Substance.* A generic type of material, such as an element, molecular species, or chemical compound that possesses a distinct identity (e.g. having a separate Chemical Abstracts Service (CAS) number, Codex International Numbering System (INS) number, or FDA or other agency standard of identity)."

Discussion

Defining "other ingredients"

The term "other ingredients," as described in the NOP Memo to NOSB, is not a recognized regulatory term with a legal definition. However since the term was used in the NOP Memo, it will be used throughout this discussion document. For this purpose, "other ingredients" will be defined as additives added during the manufacturing of a non-organic substance and ***not*** removed. They may be considered "incidental additives" by FDA, depending on use and type of end product being considered. . **See Appendix 2** for other relevant FDA Definitions.

"Other Ingredients" have the following characteristics:
• They are added during the manufacturing of a non-organic substance and ***not*** removed.
• They are not added directly by the certified handler.
• They are present in a food at insignificant levels and have no technical or functional effect in that food.
• They are not required by FDA to be listed on the ingredient panel in that food.
• "Other ingredients" are substances that are present because they were incorporated into an allowed substance on the National List.

It should be clear that "other ingredients" discussed in this paper are not the same as "ingredients" or "processing aids" used for a specific purpose ***directly*** by a certified handler in or on processed organic products. The regulations are clear that non-organic 'ingredients' or 'processing aids' used directly by a certified handler in or on a certified organic processed product must be on the National List at § 205.605 or § 205.606.

The NOP memo only requested a policy on § 205.605 listings on the National List. However non-organic ***agricultural*** ingredients or products listed on § 205.606 of the National List often contain "other ingredients" also. The Handling Subcommittee believes it will be more efficient and result in overall better comprehension to address both sections of the National List at the same time.

Baseline Criteria

We believe that baseline criteria should be used for the evaluation of "other ingredients," based on the existing requirements that are already imposed by OFPA and 7 CFR Part 205. As baseline we propose that all "other ingredients" must be legal for use in food in the United States, (appears with a regulated status in the FDA database "Everything Added to Food in the United States" (EAFUS)), or be subject of a FDA "no objections" response in the GRAS Notification Inventory published by FDA. The NOSB is aware that some ingredients are legally used in food products that are deemed GRAS by manufacturers who

do not disclose the safety information by submitting a notification to FDA, but finds that ingredients used in organic food, should at a minimum, be reviewed for safety by the FDA, with such information publicly disclosed.[2]

The **baseline criteria** are as follows:
"Other ingredients" are those that are authorized for use in materials on the National List at § 205.605 and § 205.606 according to the following criteria:

1. Any substance either approved as a food additive or listed or affirmed as GRAS in the FDA Database "Everything Added to Food in the United States (EAFUS)" [http://www.fda.gov/Food/FoodIngredientsPackaging/ucm115326.htm]
2. Any substance listed in the GRAS Notification Inventory published by FDA, with a letter of no objection. [.
(see http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=grasListing] Food/FoodIngredientsPackaging/ucm115326.htm)

AND any component or ingredient would be disallowed if:

3. Prohibited by federal regulatory action [7 U.S.C. § 6517(d)] or;
4. It is required by the FDA to be on an ingredient label for the petitioned substance, and therefore does not meet FDA's definition of an 'incidental additive'.

Recommendation
Policy and Procedure
NOSB currently evaluates materials on a case-by-case basis without an overarching policy for "other ingredients." Additionally, ACAs and MROs have no overall guidance on other ingredients from the NOP, varying capacities for materials review and wide latitude to make decisions unless specific decisions are overruled by the NOP. While the review of materials in general for use in organic production and handling is currently quite rigorous, there is need for improvement and harmonization of the system to assure continued confidence and growth of the industry.

NOP clearly recognizes the need to improve review of non-organic ingredients as reflected by their declaration in the memo that third party technical reviews will include information on "other ingredients" and their request that NOSB consider their presence as part of their review process "from this point forward." This recommendation clarifies the policy to be used for review and sets out a set of procedures to achieve a more consistent and transparent review of these ingredients.

Policy
The NOSB intends to review "other ingredients" found in substances on and petitioned for the National List. Comprehensive review does not require "other ingredients" to be

[2] As FDA notes: "The EAFUS list of substances contains ingredients added directly to food that FDA has either approved as food additives or listed or affirmed as GRAS. Nevertheless, it contains only a partial list of all food ingredients that may in fact be lawfully added to food, because under federal law some ingredients may be added to food under a GRAS determination made independently from the FDA. The list contains many, but not all, of the substances subject to independent GRAS determinations."

individually listed on the National List, however. The Board intends to follow the request by NOP to consider “other ingredients” contained in substances as they come up for sunset review or as new petitions are considered.

In each NOSB review checklist and recommendation cover sheet there will be a clear space to indicate what other ingredients are being reviewed and what restriction if any are placed on them as a result of the review. Restrictions on other ingredients will be included in an annotation and may be for specific individual components, for functional classes of ingredients, or by regulatory reference to another governmental agency such as FDA. If possible the other ingredients restrictions may be incorporated into a permitted substances database for Handling, such as the one that is coming out for crops.

The NOSB recommendation will include a note that the other ingredients were reviewed and accepted. The review of other ingredients will try to distinguish between synthetic and non-synthetic ones, as well as agricultural ingredients that might be able to be organically produced. Any additional restrictions will be specified in an annotation.

Other ingredients in general product categories that are currently on § 205.605 and § 205.606 and currently used in certified organic processed product will continue to be allowed until they go through their next sunset review and subsequent Rule amendment.

Procedure

The following procedure will be used in review of all new petitions to add substances to the National List. It will also be used during the sunset review of existing listings. The sunset process on the more complex groups of substances mentioned below will need to start about six months earlier than normal to allow for stakeholders to submit input on other ingredients before a TR is commissioned.

NOSB Review:

- 1) NOSB identifies “other ingredients” as disclosed in the petition and previous Technical Reports.
- 2) For sunset materials the NOSB will additionally request input from ACAs and MROs on additional other ingredients in a substance before commissioning the TR, so that all can be reviewed at once.
- 3) TR identifies commonly used ‘other ingredients’ and describes them.
- 4) Other ingredients must meet Baseline Criteria (above).
- 5) Special questions on the checklist used by the NOSB will be developed by the fall of 2013 to assess the role, essentiality and viability of alternatives to the "other ingredients" in a substance.
- 6) NOSB may recommend “other ingredients” individually, categorically or a combination of both.
- 7). The NOSB may or may not stipulate in a review that any agricultural "other ingredients" must be organically produced.
- 8). Materials listed on § 205.605(a) and 205.606 may contain synthetic or non-synthetic other ingredients, provided they are specifically acknowledged by NOSB during the review.

The following listings on 205.605 are classes of substances that are known to require the use of "other ingredients". These are recommended for careful review during the sunset period.

- **Nutrient Vitamins/Minerals;** in accordance with 21 CFR 104.20, Nutritional Quality Guidelines For Foods (Sunset 2017)
- **Enzymes;** —must be derived from edible, nontoxic plants, nonpathogenic fungi, or nonpathogenic bacteria (Sunset 2017)
- **Animal enzymes;** Rennet—animals derived; Catalase—bovine liver; Animal lipase; Pancreatin; Pepsin; and Trypsin. (Sunset 2013)
- **Microorganisms;** any food grade bacteria, fungi, and other microorganism (Sunset 2017)
- **Yeast;** nonsynthetic, growth on petrochemical substrate and sulfite waste liquor is prohibited (Autolysate; Bakers; Brewers; Nutritional; and Smoked—nonsynthetic smoke flavoring process must be documented. (Sunset 2017)
- **Dairy Cultures;** (Sunset 2017)
- **Natural Flavors;** must not be produced using synthetic solvents and carrier systems or any artificial preservative. (Sunset 2017)
- **Agricultural Colors;** must not be produced using synthetic solvents and carrier systems or any artificial preservative. (Sunset 2017)
- **Alginates;** (Sunset 2017)
- **Waxes;** Carnauba wax; and Wood resin. (Sunset 2017) Shellac

We hope that during the comment period for this posting more such items can be brought to our attention by commenters.

The Dilemma of Confidential Business Information (CBI)
Some brand name formulations currently used in organic processed products may include other ingredients not reviewed because the manufacturer is unable or unwilling to disclose all of the ingredients. Petitions that contain CBI ingredients run the risk of not having those ingredients reviewed. Please see the NOSB's CBI recommendation.

Other Considerations
In the course of developing policy, several other considerations became apparent. The Handling Sub-Committee hopes to do further work on some of these subjects in the future and brings them up here because they are relevant to reviewing handling materials.

- If a new policy is adopted there will be need for transition time for operators to bring products into compliance. NOP will need to specify this transition or implementation time in their draft and final guidance
- We recommend moving cleaners, sanitizers, disinfectants and other non-food substances such as boiler additives to their own designated section of the National List and develop policy specific to these types of items. This section should apply to Crops, Livestock and Processing materials.
- The Handling Subcommittee recommends that the CACS take up the issue of a standardized template that is required for non-organic ingredient affidavits. The template could include legal language vetted with the NOP that would hold ingredient

manufacturers more accountable about avoiding excluded methods, technical effects of other ingredients and other issues.

Increasing the use of organic ingredients and processing aids has been a very explicit goal of the organic community since early on. The NOSB has already endorsed the concept of a pro-active approach to the development and creation of organic analogs to replace non-organic and synthetic items. By making the policy and procedure clearer for review of minor ingredients there will be more incentive for product development of superior choices within these ingredient categories. This would likely stimulate the use of "other ingredients" in 205.605 substances that are either organic or on the National List.

Subcommittee Vote

Motion: The NOSB Handling Subcommittee moves to adopt this proposal for auxiliary other ingredients.

Motion by: Zea Sonnabend Second: Jean Richardson
Yes: 7 No: 0 Absent: 1 Abstain: 0 Recuse: 0

Appendix 1 – Regulatory References

OFPA
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

SEC. 2118. [7 U.S.C. 6517] NATIONAL LIST.
(a) IN GENERAL.—The Secretary shall establish a National List of approved and prohibited substances that shall be included in the standards for organic production and handling established under this title in order for such products to be sold or labeled as organically produced under this title.
(b) CONTENT OF LIST.—The list established under subsection (a) shall contain an itemization, by specific use or application, of each synthetic substance permitted under subsection (c)(1) or each natural substance prohibited under subsection (c)(2).

NOP Regulations
§ 205.2. Terms Defined.
Ingredient. Any substance used in the preparation of an agricultural product that is still present in the final commercial product as consumed.

Processing aid.
(1) Substance that is added to a food during the processing of such food but is removed in some manner from the food before it is packaged in its finished form;

(2) a substance that is added to a food during processing, is converted into constituents normally present in the food, and does not significantly increase the amount of the constituents naturally found in the food; and

(3) a substance that is added to a food for its technical or functional effect in the processing but is present in the finished food at insignificant levels and does not have any technical or functional effect in that food.

§ 205.301 Product composition.

(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.

(c) *Products sold, labeled, or represented as "made with organic (specified ingredients or food group(s))."* Multi-ingredient agricultural product sold, labeled, or represented as "made with organic (specified ingredients or food group(s))" must contain (by weight or fluid volume, excluding water and salt) at least 70 percent organically produced ingredients which are produced and handled pursuant to requirements in subpart C of this part. No ingredients may be produced using prohibited practices specified in paragraphs (f)(1), (2), and (3) of §205.301. Nonorganic ingredients may be produced without regard to paragraphs (f)(4), (5), (6), and (7) of §205.301. If labeled as containing organically produced ingredients or food groups, such product must be labeled pursuant to §205.304.

(f) All products labeled as "100 percent organic" or "organic" and all ingredients identified as "organic" in the ingredient statement of any product must not:

(4) Be processed using processing aids not approved on the National List of Allowed and Prohibited Substances in subpart G of this part: Except, That, products labeled as "100 percent organic," if processed, must be processed using organically produced processing aids;

§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

The following nonagricultural substances may be used as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))" only in accordance with any restrictions specified in this section.

[Examples of specified restrictions addressing "other ingredients":]

(a) Nonsynthetics allowed:
Flavors, nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.

(b) Synthetics allowed:
Peracetic acid/Peroxyacetic acid (CAS # 79–21–0)—for use in wash and/or rinse water according to FDA limitations. For use as a sanitizer on food contact surfaces.

§ 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."

Only the following nonorganically produced agricultural products may be used as ingredients in or on processed products labeled as "organic," only in accordance with any restrictions specified in this section, and only when the product is not commercially available in organic form.

[Examples of specified restrictions addressing "other ingredients":]

(d) Colors derived from agricultural products—Must not be produced using synthetic solvents and carrier systems or any artificial preservative.

(f) Fish oil (Fatty acid CAS #'s: 10417–94–4, and 25167–62–8)—stabilized with organic ingredients or only with ingredients on the National List, §§205.605 and 205.606.

Appendix 2 – FDA references

Food additive. A substance, the intended use of which results or may reasonably be expected to result, directly or indirectly, either in the substance becoming a component of food or otherwise affecting the characteristics of food. A material used in the production of containers and packages is subject to the definition if it may reasonably be expected to become a component, or to affect the characteristics, directly or indirectly, of food packed in the container. A substance that does not become a component of food, but that is used in preparing an ingredient of the food to give a different flavor, texture, or other characteristic in the food, may be a food additive. 21 CFR § 170.3.

Secondary Direct Food Additive. This term is in the title of 21 CFR 173, which was created during recodification of the food additive regulations in 1977. A secondary direct food additive has a technical effect in food during processing but not in the finished food (e.g., processing aid). Some secondary direct food additives also meet the definition of a food contact substance. For more on food contact substances, consult the Food Contact Substance Notification Program.

Indirect Food Additive - In general, these are food additives that come into contact with food as part of packaging, holding, or processing, but are not intended to be added directly to, become a component, or have a technical effect in or on the food. Indirect food additives mentioned in Title 21 of the U.S. Code of Federal Regulations (21CFR) used in food-contact articles, include adhesives and components of coatings (Part 175), paper and paperboard components (Part 176), polymers (Part 177), and adjuvants and production aids (Part 178). Currently, additional indirect food additives are authorized through the food

contact notification program. In addition, indirect food additives may be authorized through 21 CFR 170.39.

Incidental additive. (3) Incidental additives that are present in a food at insignificant levels and do not have any technical or functional effect in that food. For the purposes of this paragraph (a)(3), incidental additives are:

(i) Substances that have no technical or functional effect but are present in a food by reason of having been incorporated into the food as an ingredient of another food, in which the substance did have a functional or technical effect.

(ii) Processing aids, which are as follows:

(*a*) Substances that are added to a food during the processing of such food but are removed in some manner from the food before it is packaged in its finished form.

(*b*) Substances that are added to a food during processing, are converted into constituents normally present in the food, and do not significantly increase the amount of the constituents naturally found in the food.

(*c*) Substances that are added to a food for their technical or functional effect in the processing but are present in the finished food at insignificant levels and do not have any technical or functional effect in that food.

(iii) Substances migrating to food from equipment or packaging or otherwise affecting food that are not food additives as defined in section 201(s) of the act; or if they are food additives as so defined, they are used in conformity with regulations established pursuant to section 4.

GRAS - "GRAS" is an acronym for the phrase Generally Recognized As Safe. Under sections 201(s) and 409 of the FD&C Act, any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excluded from the definition of a food additive. GRAS substances are distinguished from food additives by the type of information that supports the GRAS determination, that it is publicly available and generally accepted by the scientific community, but should be the same quantity and quality of information that would support the safety of a food additive. Additional information on GRAS can be found on the GRAS Notification Program page.

National Organic Standards Board
Compliance, Accreditation and Certification
Proposal
Calculating Percentage of Organic Ingredients in Multi-ingredient Products

February 12, 2013

I. INTRODUCTION:

The purpose of this document is to propose recommendations on determination of percentage organic ingredients in multi-ingredient products in order to assist the NOP in development of guidance for handlers and certifiers.

Consumers expect that labels on multi-ingredient products sold as “100% organic” or “organic” or “made with organic” reflect an accurate determination of percentage organic ingredients, and that all certifiers have uniformly calculated such percentages.

The integrity of USDA organic products in the USA and throughout the world depends on assurances of consistency and uniformity in interpretation and application of the Rule and associated Regulations, especially when calculating percentage organic ingredients.

II. BACKGROUND:

The Regulation at 205.302(c), under “Calculating the percentage of organically produced ingredients” states:

> “ The percentage must be determined by the handler who affixes the label on the consumer package and verified by the certifying agent of the handler. The handler may use information provided by the certified operation in determining the percentage”.

Thus, when an ingredient has been certified to the “organic” category, the supplier of that ingredient must provide information to the handler making the finished product regarding the actual percentage of organic content of that ingredient.

Over the years this has resulted in a wide variety of mechanisms for determining percentage of organic ingredients, and a wide variety of ways of establishing systems which allow verification by auditors and inspectors.

For example, if the supplier does not provide positive information, verified by the certifier, that the organic ingredient contains more than 95% organic content, then many, BUT NOT ALL certifiers will only allow that ingredient to be calculated at 95% organic content.

With limited guidance, a lack of uniformity in procedures has developed. For example some certifiers may permit handlers to include 100% of the weight/volume of certified ingredients as organic, even if the ingredient is a formulated product and includes other permitted substances and may be in fact be anywhere from 95-100% organic. Chocolate chips for example may be certified organic, and contain 96% organic ingredients, plus 4% permitted substances on 205.605/606. A cookie manufacturer may be considering that the entire weight of the chips counts as organic in the final cookie product.

Many certificates list raw agricultural ingredients as “organic” when in fact they should be listed as “100% organic.” This can have a serious impact in calculating percentage organic in a multi-

ingredient product if the handler must, by default, list those raw agricultural ingredients as 95%. Further, some handlers and certifiers may not be accurately examining the water and salt content for exclusion from the percentage calculation.

There is also a wide array of mechanisms in place amongst handlers as to how processing aids as opposed to additives are recorded or, if necessary calculated as part of the ingredient list. Sub-ingredients are often added to multi-ingredient products, such as spice, oil, sugar, flavor or sauce mixes. Such sub-ingredients may be entirely or partially organic in ingredient make up, and the producer of such sub-ingredient mix may provide a Specification sheet listing ingredients and their organic percentages. In other instances no details are provided on sub-ingredients.

When the percentage of organic ingredients as a percentage of all ingredients is calculated to be close to 95% or close to 70% then the issue of correct labeling of that product becomes difficult for the handler and those who must approve or verify. Standard practice is to calculate ingredients as a percentage *of all ingredients,* although the relevant area of the Rule, as cited below, still states the calculation should be as a percentage *of finished product*.

In October, 2001 the NOSB, recommended[1] to change the regulations at § 205.302(a), to replace the phrase "finished product" with "of all ingredients". The rationale was: Most products lose weight during processing. Dividing the total weight of all combined organic ingredients by the weight of the finished products could easily show that a product contains over 100% organic ingredients. Current practice is to divide the total weight of all combined organic ingredients by the total weight of all ingredients (excluding salt and water). This calculation establishes the total percentage of organic ingredients. The Rule should be changed to correctly calculate the percentage of organic ingredients".

This regulation change has not yet taken place.

III. RELEVANT AREAS OF THE RULE:

NOP Regulation and Policy statements:

§ 205.302 Calculating the percentage of organically produced ingredients.

(a) The percentage of all organically produced ingredients in an agricultural product sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))," or that include organic ingredients must be calculated by:

(1) Dividing the total net weight (excluding water and salt) of combined organic ingredients at formulation by the total weight (excluding water and salt) of the finished product.

(2) Dividing the fluid volume of all organic ingredients (excluding water and salt) by the fluid volume of the finished product (excluding water and salt) if the product and ingredients are liquid. If the liquid product is identified on the principal display panel or information panel as being reconstituted from concentrates, the calculation should be made on the basis of single-strength concentrations of the ingredients and finished product.

(3) For products containing organically produced ingredients in both solid and liquid form, dividing the combined weight of the solid ingredients and the weight of the liquid

[1] http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5100161

ingredients (excluding water and salt) by the total weight (excluding water and salt) of the finished product.
(b) The percentage of all organically produced ingredients in an agricultural product must be rounded down to the nearest whole number.
(c) The percentage must be determined by the handler who affixes the label on the consumer package and verified by the certifying agent of the handler. The handler may use information provided by the certified operation in determining the percentage.

§ 205.2, Terms Defined:

Ingredient: any substance used in the preparation of an agricultural product that is still present in the final commercial product that is consumed

Processing Aid (NOP definition, based on FDA regulation at 21 CFR 100 (a)(3)(ii) Foods Exempt from Labeling):

1. A substance that is added to a food during the processing of such food but is removed in some manner from the food before it is packaged in its final form.
2. A substance that is added during processing, is converted into constituents normally present in the food, and does not significantly increase the amount of the constituents naturally found in the food; and
3. A substance that is added to a food for its technical or functional effect in the processing but is present in the finished food in insignificant levels and does not have any technical or functional effect on that food.

IV. DISCUSSION:
In 2012 the CAC subcommittee discussed this issue in detail and issued a discussion document with a request for public comment prior to the Public Meeting in October 2012. The NOSB received a substantial body of public comment with detailed recommendations for change. These comments came from Accredited Certifying Agencies, non-profit organizations, research groups and trade associations, and they are included in the brief discussion below.

1. Regulatory change:
There is broad consensus that the standard practice is to divide the total net weight (excluding water and salt) of combined organic ingredients at formulation by the total net weight (excluding water and salt) of all ingredients. Thus a simple change to the Regulation at 205.302 is needed to clarify that the calculation of percentage organic ingredients should be made based on “all ingredients” not “finished product” because most products lose weight during processing.

2. Self-calculating Forms:
Formulated multi-ingredient NOP-certified products contain organic ingredients that are either single or multiple-ingredient ingredients. Certified handlers adding an organic ingredient to a formulated product need to understand that the ingredient may contain anywhere between 95% and 100% organic ingredients. For a multi-ingredient certified product used as an ingredient in a multi-ingredient product, the actual organic content must be obtained. Otherwise the ingredient should be calculated at either 95% organic or 70% organic depending on how the product is classified on the certificate.

Thus, to ensure uniformity in making these calculations a number of certifiers use self-calculating forms, samples of which were sent to the NOSB. Certifiers provide these forms to handlers, and there is broad consensus that self-calculating tools are very useful, but one standard NOP generated form is not required.

One certifier noted that being able to provide useful and coherent tools for clients was a point of differentiation for a certifier.

A sample template of a self-calculating form could be included on the NOP website to demonstrate inclusion of all ingredients; show how to exclude water and salt, list supplier of ingredient, percentage organic content of each ingredient, percentage in formulation, and the self-calculating column showing actual organic percentage of each ingredient. Such a sample form should show how to list processing aids separately.

3. Salt Excluded:
Commenters all agree that the only salt which may be excluded is sodium chloride. Potassium chloride is on the National List as an allowed non-synthetic and should be calculated as a non-organic ingredient.

Standard practice is to require any additives, such as anti-caking agents, added to the salt to be on the National List at 205.605 or 205.606. If salt containing an additive on the National List is added to a certified product the additive cannot be excluded. Therefore the product may not be labeled as 100% organic.

4. Water Excluded:
Commenters provided considerable discussion, and raised numerous questions on this complex issue.

In August 2002 the NOP issued a policy memo addressing the exclusion of water when calculating percentage organic ingredients in multi-ingredient food products. This information is incorporated in the NOP Handbook as Policy Memo 11-9.[2] This memo includes reference to 21CFR 131-169 for food and 21CFR 101.30 for vegetable and fruit juices. Several major certifiers find that the FDA is out of date in addressing water content in standardized foods.

Several commenters noted that the lack of a standard of identity for many standardized foods is an impediment to consistency and accuracy in calculating water to be excluded. There is a need for clarification and detailed guidance from the NOP on this topic.

5. Processed single ingredients:
A specification sheet for a product such as “organic” olive oil could be of great assistance to the organic baker making a multi-ingredient product, but this is often not available.

6. Multi-ingredient ingredients:
Several commenters expressed frustration at how to calculate percentage organic when adding a purchased multi-ingredient ingredient, such as chocolate chips to a product and suggested that a specification sheet be provided if requested by handler.

7. Organic label versus organic content:
There were a number of comments related to the fact that the issue of organic **content** contribution versus organic **labeling** claim creates confusion and leads to a lack of consistency in interpretation when formulating multi-ingredient products.

Organic operations want their crops and ingredients to be in the 100% organic category on certificates so that buyers calculate their content at 100% in finished products. If certifiers had clear permission to assume 100% organic content for single-ingredient ingredients and crop

[2] http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5088954

ingredients in the “organic” category this would remove some of the inconsistencies.

Very few products actually make the 100% organic claim on the retail label.

As noted by the range of comments received by the NOSB there is a lack of consistency in determining organic percentages for ingredients treated with processing aids. Often single ingredients such as flour, oil or sugar or crop ingredients such as apples do not meet the 100% organic category due to permitted, but non-organic processing aids (filtration materials in the case of oil, wash water in the case of apples) They will be listed on an organic certificate by the certifier as “organic”. However common sense tells you that they may contribute more than 95% organic content to the finished product formula.

The organic content of a product is based on the percentage of organic ingredients. The use of non-organic processing aids prevents a product being labeled as 100% organic but the product contains 100% organic **ingredients** and can be calculated as such when determining an organic percentage. For Example: Pear Juice Concentrate may be formulated using 100% organic pears, NOP-compliant non-organic enzymes as processing aid, and NOP-compliant non-organic Diatomaceous Earth as a filter aid. For calculation purposes however the pear juice should be calculated at 100% organic in the formulation because all of the ingredients are 100% organic.

8. Raw Agricultural Ingredients:
The lack of a statement of specific percentage of organic content on either the organic certificate or product specification sheet, if one is available, requires additional work for both the certifier and handler. The inclusion of such information on the certificate would be helpful.

Single raw crop ingredients such as carrots or pears, can be listed as “100% organic” on the Certificate (or attached addendum list) issued by the certifier to the Handler. In many cases however the Certificate and attached list simply states “organic”. Thus, when making a multi-ingredient product, those ingredients listed as “organic” on their certificates must be calculated at the default 95% organic calculation. While there may be some instances where a raw crop has been changed, such as adding a wax coating to a cucumber, all commenters agreed that it is reasonable to assume that a single raw crop ingredient should be considered 100%organic for content.

The recommendations following reflect the public comments received prior to the Public Meeting and presented at the Public Meeting.

V. RECOMMENDATIONS:

1. Proposed Regulatory Change
The CACS proposes a change to the regulations at 205.302(a) as follows with proposed deletions with strike through and additions in bold italics:

§ 205.302 Calculating the percentage of organically produced ingredients.

(a) The percentage of all organically produced ingredients in an agricultural product sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” or that include organic ingredients must be calculated by:

(1) Dividing the total net weight (excluding water and salt) of combined organic

ingredients at formulation by the total weight (excluding water and salt) of ~~the finished product~~ all ***ingredients.***

(2) Dividing the fluid volume of all organic ingredients (excluding water and salt) by the fluid volume of ***all ingredients*** ~~the finished product~~ (excluding water and salt) if the product and ingredients are liquid. If the liquid product is identified on the principal display panel or information panel as being reconstituted from concentrates, the calculation should be made on the basis of single-strength concentrations of ***all*** the ingredients. ~~and finished product~~.

(3) For products containing organically produced ingredients in both solid and liquid form, dividing the combined weight of the solid ingredients and the weight of the liquid ingredients (excluding water and salt) by the total weight (excluding water and salt) of ***all ingredients*** ~~the finished product.~~

(b) The percentage of all organically produced ingredients in an agricultural product must be rounded down to the nearest whole number.

2. **Self-Calculating forms**
Section 205.302 (c) states:

(c) The percentage must be determined by the handler who affixes the label on the consumer package and verified by the certifying agent of the handler. The handler may use information provided by the certified operation in determining the percentage.

The CACS proposes that handlers utilize a self-calculating form of their own, or utilize a form provided by their certifier so that a uniform method of calculation is clearly established.

3. **Salt Excluded**.
The CACS proposes that the only salt excluded from the calculation is sodium chloride.

Potassium chloride, listed on 205.605 and any item on the National List such as magnesium chloride or magnesium sulfate used as an ingredient shall be counted in the organic content calculation.

4. **Water Excluded**
Water is excluded from the percentage calculation.

The CACS proposes extensive, detailed and clear NOP guidance to drive consistency among handlers and certifiers to determine how much water should be excluded from certain multi-ingredient formulations that include such ingredients as chicken soup, soy “milk”, almond “milk”, fruit juice, vegetable juice, or ready to drink teas.

5. Processed Single Ingredients.
Handlers or certifiers may request specification sheets from manufacturers of processed single ingredients if they desire more verification that the ingredient was not processed in a way that there would be remaining non-organic components in the single ingredient product. Examples of such ingredients include oil, flour, sugar, and syrup.

6. **Multi-ingredient ingredients**;
For multi-ingredient ingredients, such as chocolate chips, where as much as 5% of the ingredients may be non-organic, the certifier must provide documentation of claims that the

organic content is beyond 95% if requested by another handler or certifier.

7. **Organic Label versus Organic Content**:

As specified in 205.302, the organic content or percentage of a product is based on the percentage of organic ingredients. Sanitizers and processing aids are not ingredients; therefore they should not impact the organic percentage of a product. The use of a non-organic processing aid prevents the single ingredient product from being labeled as 100% organic, but the product continues to contain 100% organic ingredients and can be calculated as such when it is calculated into a multi-ingredient organic product

8. **Raw agricultural and Single-ingredient ingredients** can be assumed by handlers, manufacturers and certifiers to contribute 100% organic content in a multi-ingredient formulation, even if they are listed as “organic” on a certificate, except where it is clear that the ingredient is significantly different from the raw condition.

9. **NOP Guidance**
The NOSB recommends that the NOP establish and maintain an easily accessible website with examples of how to calculate percentage organic ingredients in multi-ingredient products, and related topics such as how to determine when a processing aid becomes an ingredient in calculation, and how to determine excluded water.

Motion to accept and forward to the full Board the proposal on Calculating % of organic ingredients in multi-ingredient products as amended

Subcommittee Vote:
Moved: Jean Richardson Second: Joe Dickson

Yes: 7 No: 0 Absent: 1 Abstain: 0 Recusal: 0