National Organic Standards Board Meeting

Hotel Albuquerque | Albuquerque, New Mexico

May 22, 2012 – May 25, 2012

National Organic Standards Board Meeting

Albuquerque, New Mexico, May 22-25, 2012

AGENDA

Schedule at a Glance

	Tuesday, May 22	*Wednesday, May 23*	*Thursday, May 24*	*Friday, May 25*
AM	- Call to Order and Secretary's Report - NOP Update - Open Public Comment	- Materials Subcommittee - Crops Subcommittee	- Policy Development Subcommittee - Handling Subcommittee	- Deferred Items - Final Votes - Subcommittee Work Plans - Other Business and Closing Remarks
PM	- Compliance, Accreditation & Certification Subcommittee - GMO ad-hoc Subcommittee	- Livestock Subcommittee	- Handling Subcommittee	

Meeting Format

- USDA National Organic Program (NOP) National List Manager presents overview of sunset substances, petitioned substances and Technical Reports in consistent format. NOSB members present Subcommittee proposals on petitioned substances and sunset substances.
- Public comments are segmented to correspond with each Subcommittee.
- The agenda has been revised to account for the number of oral public comments that will be made for each Subcommittee.
- Each Subcommittee's proposals are discussed and voted on before moving to the next Subcommittee.
- Board votes on Subcommittee proposals can be deferred to Friday for final vote if more deliberation is needed.
- Final recommendations are completed during the meeting so that they can be posted on the NOP website immediately following the meeting.

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
- Persons must give their names and affiliations for the record at the beginning of their public comment.
- Each person is provided a 3 minute comment period.
- Each person may sign up for only one comment period.

Tuesday, May 22, 2012

8:00 AM	***Call to Order*** **Barry Flamm, Chairperson** – Announcements – Introductions – NOSB Mission
8:15 AM	***Secretary's Report*** **Wendy Fulwider, Secretary** – Acceptance of December 2011 Meeting Transcripts and Voting Results as Official Record
8:30 AM	***National Organic Program Update*** **Miles McEvoy, Deputy Administrator** **National Organic Program**
10:00 AM	***BREAK***
10:15 AM	***Open Public Comment*** – Public comments that are not specific to a particular Subcommittee
12:30 PM	***LUNCH***
1:30 PM	***Compliance, Accreditation and Certification Subcommittee*** **Joe Dickson, Chairperson** - Present Subcommittee proposals and summarize written comments ***Topics:*** - Discussion paper - Sanitizers and "100% organic" products - Proposal - Material Review Organizations review criteria
2:00 PM	– Public comments related to CAC Subcommittee
2:30 PM	– Subcommittee modifies proposals as needed – Board votes
3:15 PM	***BREAK***

3:30 PM	***GMO ad-hoc Subcommittee*** **Zea Sonnabend, Chairperson** – Present Subcommittee proposals and summarize written comments – NOP presentation on NOP GMO policy ***Topics:*** – Proposal - Letter to Secretary Vilsack
4:10 PM	– Public comments related to GMO Subcommittee proposals
4:45 PM	– Subcommittee modifies proposals as needed – Board votes
5:30 PM	***RECESS***

Wednesday, May 23, 2012

8:00 AM	***National Organic Program- Materials Classification Overview*** **Dr. Lisa M. Brines, NOP National List Manager**
8:30 AM	***Materials Subcommittee*** **Jennifer Taylor, Chairperson** – Present Subcommittee proposals and summarize written comments ***Topics:*** – Aquaculture petition update – for use of vitamins (no document) – Proposal - Research Priorities Framework – Discussion paper – Extractants and solvents – Discussion paper – Significant residues and classification of materials
9:30 AM	– Public comments related to Materials Subcommittee proposals
10:15 AM	***BREAK***
10:30 AM	– Subcommittee modifies proposals as needed – Board votes
11:00 AM	***Crops Subcommittee*** **Jay Feldman, Chairperson** – Present Subcommittee proposals and summarize written comments – Report from Inerts working group

	Crops Subcommittee Topics: ***Sunset 2013 Recommendations on § 205.601*** – EPA list 3 (Inerts)
11:20 AM	– Public comments related to Crops Subcommittee proposals
11:50 AM	– Subcommittee modifies proposals as needed – Board votes
12:30 PM	***LUNCH***
1:30 PM	***Livestock Subcommittee*** **Wendy Fulwider, Chairperson** – Present Subcommittee proposals and summarize written comments ***Topics:*** – Proposal - GMO vaccines – Discussion paper - Species specific guidance – Discussion paper - Dairy auditor score sheet – Discussion paper - Dairy score card – Discussion paper - Guidance for Assessing Welfare: Bison – Discussion paper - Guidance for Assessing Welfare: Poultry – Discussion paper - Guidance for Assessing Welfare: Sheep – Discussion paper - Outcome score tally sheet for Animal Welfare
2:30 PM	– Public comments related to Livestock Subcommittee proposals
3:30 PM	***BREAK***
3:45 PM	– Public comments related to Livestock Subcommittee proposals
4:45 PM	***Livestock Subcommittee continued*** – Subcommittee modifies proposals as needed – Board votes
5:30PM	***RECESS***

Thursday, May 24, 2012

8:00 AM	***Policy Development Subcommittee*** **Colehour Bondera, Chairperson** – Present Subcommittee proposals and summarize written comments

	Policy Development Subcommittee Topics: – Proposal - Conflict of Interest – Proposal - Public Comment Procedures – Proposal – Public Communications
8:45 AM	– Public comments related to Policy Subcommittee proposals
9:15 AM	– Subcommittee modifies proposals as needed – Board votes
10:00 AM	***BREAK***
10:15 AM	***Handling Subcommittee*** **John Foster, Chairperson** – Present Subcommittee proposals and summarize written comments – Update on ancillary and other ingredients ***Topics:*** ***Petitioned Materials Proposals*** – Choline – Curry leaf – Gibberellic acid – Inositol – Citrus hystrix ***Sunset 2013 Proposals on § 205.605(a)*** – Agar-agar – Calcium sulfate – Carrageenan – Glucono delta-lactone ***Sunset 2013 Proposals on § 205.605(b)*** – Cellulose
12:00 PM	***LUNCH***
1:00 PM	***Handling Subcommittee, continued*** – Public comments related to Handling Subcommittee proposals
3:00 PM	***BREAK***
3:15 PM	– Subcommittee modifies proposals as needed – Board votes
5:00 PM	***RECESS***

Friday, May 25, 2012

8:00 AM	***Deferred Proposals*** ***Final Votes***
10:00 AM	***BREAK***
10:15 AM	***Deferred Proposals/Final Votes, continued***
11:00 AM	***Subcommittee Workplans***
11:30 AM	***Other Business and Closing Remarks***
12:00 PM	***ADJOURN***

National Organic Standards Board
Compliance, Accreditation and Certification Committee
Proposal
Criteria for Material Review by Material Review Organizations

March 29, 2012

Introduction

The assessment of specific substances for compliance with the National Organic Standards – known as "Materials Review" – is a foundational element in the organic supply chain. Certifiers and other materials review organizations regularly review materials as a service to their clients, and these decisions directly impact the organic integrity of growing, livestock and handling operations and ultimately the integrity of the USDA Organic label. The uniformity, consistency and integrity of materials review decisions is of paramount importance to the integrity of the entire organic supply chain, and the National Organic Program must play a primary role in supervising and monitoring these activities.

Following the NOP's request for NOSB advice on this issue, the CACC prepared a discussion document for the April, 2011 NOSB meeting in Seattle. This document summarized the issue and the NOP request, and posed a number of specific questions about specific facets of this complex subject. The board received written and oral public comment from numerous stakeholders, including certifiers, materials review organizations, input manufacturers and others. The CACC presented a recommendation on the topic at the November, 2011 NOSB meeting in Savannah. This recommendation described specific criteria to be used by the NOP in evaluation and oversight Materials Review Organizations. During and following the Savannah NOSB meeting, a number of stakeholders pointed out that the recommendation failed to address *the specific criteria and procedures to be used by MROs in evaluating materials*. The present recommendation addresses those concerns by detailing such procedures.

Background

On January 18, 2011, the NOP Deputy Administrator requested the participation of the NOSB in developing a clearer NOP policy on the oversight of materials review organizations:

> The NOP is interested in developing a more uniform and consistent procedure for evaluating the competency and quality of material evaluation programs, as approved by accredited certification agencies or by other third party organizations.
>
> The NOP is requesting that the National Organic Standards Board (NOSB) develop a recommendation that delineates the criteria that should be used by certifying agents and third party organizations to evaluate materials used in

organic production and handling. The recommendation should include the criteria and process that should be used to determine the approval of input substances used in crop production (e.g. fertilizers, pest control materials, soil amendments, crop production aids), livestock production (e.g. feed supplements, feed additives, medications and livestock production aids), post-harvest handling and food processing (e.g. processing aids, sanitizers, facility pest control materials).

A number of organizations currently provide materials review services to producers and certifiers. At least one of those organizations is an independent organization that is not an Accredited Certifying Agent or under any NOP oversight. At least one other materials review organization is a formal subdivision of an ACA, and many ACAs provide some material review services to clients on a formal or informal basis. The CACC agrees with the NOP that there is a clear need for more uniform and consistent policies governing material review services, and we believe that all organic stakeholders would benefit from a clearly defined NOP guidance around the qualification and activities of these organizations.

Challenges

1. All certifying agents review input materials for compliance with the NOP regulations. Most certifying agents do not publish their list of approved inputs. This leads to a lack of transparency of what materials have been approved for use in organic production and handling.
2. There are numerous organizations reviewing materials for compliance with the NOP regulations. On numerous occasions a material that is allowed by one certifying agent is prohibited by another. This lack of consistency in what materials are approved creates an uneven regulatory landscape, is unfair to organic producers and handlers, and leads to certifier shopping to find the certifying agent that allows more materials.
3. There have been situations where the NOP has disallowed the continued use of materials and material review organizations continue to list/register these materials as approved for use in organic production/handling.
4. A universal list of approved substances is not currently available to organic producers and handlers. It is difficult for many organic producers and handlers to understand what materials are allowed and which materials are prohibited. This regulatory uncertainty causes reluctance by many potential organic producers and handlers to enter the organic trade.
5. OMRI and WSDA maintain a publically available list of approved materials. The process for removing substances from these approved lists is not consistent. There is not a consistent process for material input manufacturers to appeal decisions made by OMRI, WSDA or certifying agents.
6. The NOP does not have direct regulatory authority over material manufacturers. If material manufacturers violate the organic standards or fraudulently represent their product as approved for organic use the NOP does not have authority to

issue civil penalties or propose adverse actions. Currently organic producers and handlers bear the risk of using substances that may not comply with the NOP regulations.

The CACC's November 2011 recommendation presented a framework for NOP oversight and evaluation of MROs. The present recommendation will set out specific review criteria to be used by such organizations (both independent MROs and ACAs performing materials review activities) in reviewing materials.

Relevant Areas in the Rule

While both OFPA and the Rule deal extensively with the review of materials as performed by NOSB, NOP and ACAs, neither provides any language that relates directly the work or oversight of materials review organizations.

Discussion

The NOSB's fall 2011 Recommendation detailed specific criteria to be used by the NOP in evaluation and oversight Materials Review Organizations. A number of commenters, including MROs and ACAs, noted that the CACC's recommendation failed to provide a concrete framework for the NOP to use in creating guidance for such organizations in the short term. This recommendation addresses that deficiency by adding a number of specific criteria and procedures to be used by such organizations in the evaluation of specific materials. A number of issues were discussed, including the following:

Depth of materials review.

At what depth should an input be reviewed (i.e. ingredients within ingredients OR ingredients within ingredients within ingredients)

Evaluation of synthetic/non-synthetic and agricultural/non-agricultural status of materials.

How should MROs make these determinations in a way that ensures consistency with NOP policy and consistency across MROs?

Duration and expiration of materials review determinations.

How long is a material review decision valid? How often must a substance or input be re-reviewed?

Procedures for monitoring ongoing compliance of approved products.

What are guidelines for surveillance, removal of noncompliant products from the list, documentation of formula changes, etc.?

Evaluation of potential use of prohibited methods.

What level of verification is necessary for prohibited methods, especially GMO sourced inputs like corn gluten meal or soy meal.

Substantiation of label claims and other requirements.

i.e. pH in stabilized fish, purchase records to prove formulas, records for compost production, NPK label claims

Recommendation

In its November 2011 recommendation, the NOSB asked that the National Organic Program require that MROs become accredited or formally recognized under a newly formed Material Review scope, in order to facilitate adequate oversight and enforcement of the activities of MROs. The recommendation advocated that Materials review activities should ultimately only be allowed by NOP accredited entities.

Since the creation of a new accreditation scope is a complicated and potentially long-term undertaking, the NOSB also recommends a number of short term measures to support the consistency of decisions currently being made by MROs. On an immediate basis, NOP should provide detailed guidance and criteria on the material review process in order to promoted consistency and uniformity among currently operating MROs while longer term regulatory changes are undertaken.

We ask that the NOP provide detailed guidance to MROs and ACAs to ensure the consistency and integrity of materials review decisions. Such guidance should:

- Establish that material review organizations may not make synthetic vs. non-synthetic or agricultural vs. non-agricultural determinations except when made in strict compliance with NOP guidance. We urge the NOP to expedite the publication of clear guidance for making such determinations, based on earlier recommendations of the NOSB. The classification of materials is of foundational importance to the integrity of organic products, and such guidance is extremely critical, given the thousands of synthetic vs. non-synthetic and agricultural vs. non-agricultural determinations made by certifiers each year.

- Require that MROs obtain and maintain ISO 65 accreditation, which will ensure MROs are meeting these strict guidelines regarding consistency and transparency.

- Require that MROs provide a clear and publically available description of its review criteria and decision-making procedures.

- Establish appropriate education, training, and experience levels for personnel conducting material review.

- Establish appropriate levels of personnel, resources, infrastructure, and documentation to engage in on-site inspections where needed. Establish need, frequency, and type of on-site inspections.

- Create clear expectations about the depth of the review, providing clear direction for the evaluation of ingredients, sub ingredients, and processing aids at various levels within a formulation.

- Create clear expectations for the frequency of material review, establishing how often and under what conditions approved products must be re-reviewed.

- Contain a mechanism to ensure consistency in decisions across MROs. Specifically, it should give direction to MROs about what action, if any, should be taken when making a decision it knows conflicts with another MRO's decision.

- Establish criteria for determining the acceptability of documentation for verifying compliance with certain material annotations or required conditions (e.g. pH in stabilized fish, purchase records to prove formulas, records for compost production, NPK labels claims).

- Give direction to MROs on verification of products derived from GMO risk crops (e.g. corn gluten meal, soy meal). What type of substantiation is sufficient to verify that an input has been produced without excluded methods?

- Provide procedures for ongoing monitoring of approved products, including market surveillance, testing, removal of noncompliant products from lists, etc.

- Give direction to MROs about what action should be taken when the NOP issues guidance or policy which contradicts an MRO's listing of an input or material, including the expected timeframe for the MRO's listing to be changed.

- Be developed with the input and participation of current MROs and ACAs, through the Accredited Certifiers Association, the Organic Materials Review Institute, and others, to draw on the considerable material review expertise of those organizations currently making such decisions. The NOP has noted that its 2012 accreditation audits of ACAs will include materials review processes as a focus; we hope that the NOP will use this information to inform the development of a policy which incorporates the best practices being currently used.

- Provide clear definitions of key terms, including the use of the term "certification" with regard to materials review activities.

Committee Vote

Motion by: Joe Dickson Second: Barry Flamm

Yes: 7 No: 0 Absent: 1 Abstain: 0 Recuse: 0

National Organic Standards Board
Certification, Accreditation & Compliance Committee
Discussion Document Proposal
Use of Sanitizers on Eligibility for 100% Organic Claims

March 29, 2012

Introduction & Background

Four labeling categories have been established for products intended for human consumption under the National Organic Program (7 CFR Part 205.301). From lowest to highest organic composition they are:

Products comprised of less than 70% organic ingredients
Products comprised of at least 70% organic ingredients (“made with”)
Products comprised of 95% or more organic ingredients
Products comprised of 100% organic ingredients.

All four categories may be produced using processing aids which are either removed prior to packaging or remain behind in “insignificant amounts,” and which do not have to be identified on the ingredient statement. (FDA regulations in 21 CFR Subpart F) However, under the NOP the use of such processing aids is restricted in the three highest categories:

At least 70% - processing aids must be on National List
95% or more - processing aids must be on National List
100% - processing aids must be organic

From the beginning of NOP implementation, the use of food contact sanitizers did not impede a producers or handlers ability to make a 100% organic label claim on products coming in contact with them. This changed in early 2007, when certifiers were advised during ACA trainings that the use of these substances voided 100% organic label claims on processed products, but this was later retracted (though not formally) by NOP staff at that time, but in any event formal written guidance affirming the loss of 100% organic claim eligibility emerged from the NOP and continues in force presently. It is worth noting that several companies were forced to change packaging claims as a result to reflect the downgraded organic status.

In 2010 the NOSB deliberated on the use of inert gases in the packaging of organic products and how such use should or should not affect the eligibility for 100% Organic claims.

The 100% category has been marked by confusion since its inception by certifiers, consumers, producers, manufacturers, and by NOP staff at times. This category is not allowed by U.S. major trading partners the E.U. and Canada and the U.S. is the only jurisdiction to define it

Relevant areas in the Rule

There are no references to processing aids in OFPA. Potentially relevant statutory citations pertain to use of synthetic ingredients are found in Sec 2111 - 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 during the processing or any postharvest handling of the product:…

(4) Add any ingredients that are not organically produced in accordance with this title and the applicable organic certification program, unless such ingredients are included on the National List and represent not more than 5 percent of the weight of the total finished product.

In NOP 205.2 Terms Defined, the following distinct definitions can be found for “ingredient” and “processing aid:”
“*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.*

(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 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.”

7 CFR 205.301 (f) (4) states:
“All products labeled as “100 percent organic” or “organic” ……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% organic,” if processed, must be processed using organically produced processing aids;
The definition of “processing aid” in the Rule is taken verbatim from the FDA definition found in 21 CFR Subpart F, below:
21 CFR Subpart F- Exemptions from Food Labeling Requirements comprehensively describes those things which do not need not appear on a product ingredient statement. Section 100.101 (a) (3) (i) and (ii).
§ 101.100 – Food; exemptions from labeling.
(a) the following foods are exempt from compliance with the requirements of section 403(i) (2) of the act (requiring a declaration on the label of the common or usual name of each ingredient when food is fabricated from two or more ingredients)…….(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 purpose of this paragraph (a) (3), incidental additives are:…..
(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 food during processing, are converted into constituents normally present in the food, and do not significantly increase the amount of those constituents naturally found in the food.

(c) Substances that are added to a food for their 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 pursuant to section 409 of the act. ("Food and Drugs Sub Chapter B-Food for Human Consumption")

The definition of "processing aid" found in 7 CFR Part 205 is taken directly from the FDA definition of "processing aid," which, in turn, makes a clear distinction between "processing aids" and substances such as some specific atmospheric gases which have no functional effect in the food or the processing of that food, but merely modify the environment in which the food is packaged. The Organic Rule – 7 CFR Part 205, by including separate definitions for "processing aid" and "ingredient" allows that not everything in a package labeled and sold as "organic" is an ingredient.

Sanitizers are defined and regulated by FDA (21 CFR Part 178) as "substances used to control the growth of microorganisms." According to the FDA, these substances are classified as Food Contact Substances, not processing aids.

Discussion

CACC members discussed the background and prior activity around this subject, referencing especially the 2009-2010 NOSB discussions around inert gas packaging aid use and the 100% Organic claim.

The current guidance from the NOP disallows using the 100% Organic label claim when organic goods come into contact with food contact or food contact surface sanitizers, even when the sanitizer is no longer present in the finished product prior to sale. This is consistent with the loss of 100% Organic eligibility when non-organic (but organic -compliant) processing aids are used in otherwise organic products. Of course, any such sanitizers or processing aids used must be included on the appropriate section of the National List, included as part of each operator's Organic System Plan, and approved by the operator's Accredited Certifying Agent (ACA).

This guidance leads to some interesting outcomes. For example, organic oranges are harvested into bins in the field and may be labeled with a 100% Organic claim. If and when those oranges are deposited into a wash tank at the pack shed and that tank has added chlorine in it, the oranges lose their 100% organic status. The chlorine is there to keep the water from becoming contaminated with pathogens or spoilage organisms. To think of an unprocessed orange as anything other than 100% is confusing for some consumers.

Beyond that, if and when that orange is sold, for juicing for example, the juice that comes from that orange cannot make a 100% Organic claim since the oranges it came from can't either. For the sake of example, assume that no filtering agents are used in the juicing process. If a beverage maker wants to use that organic juice in a 100% juice beverage, that operator would have to default to allowing only 95% of the orange juice to contribute to the organic percentage of the beverage as a whole. This can occur unless the organic certifier of the juice is willing and able to issue a letter of some sort to clarify the amount of the juice that may be used in excess of 95% toward finished goods percentage calculations.

Another example of confusion occurs when produce is field packed, such as celery hearts, which are typically cut, trimmed and placed on a mobile harvest machine in the field. The belt which conveys the produce to those who pack it into cartons is typically sprayed with chlorinated water to reduce the likelihood of contamination by pathogens or spoilage organisms. Once again, those celery hearts, 100% Organic after being cut from the stem and trimmed, are relegated to Organic status (with a presumptive 95% organic percentage) once hey touch that belt.

Other options the Committee discussed were the concept of recommending the removal of the 100% Organic claim altogether and the concept of recommending the removal of the requirement that processing aids used in products making a 100% Organic claim be themselves organic. These concepts are more complicated and have intricate ramifications for the regulation and industry as a whole, and the Committee is not prepared to focus on those options at this time.

It is worth noting, as did the NOSB in 2008, that "sanitizers are defined and regulated by FDA (21 CFR Part 178) as "substances used to control the growth of microorganisms." As such these substances are classified as Food Contact Substances, are not processing aids, and do not have to be reviewed and approved by NOSB to be placed on the National List to for use in organic products."

The CACC believes that this issue deserves additional attention and community deliberation. The Committee does not feel that adequate information or dialogue has been had on the subject to propose a recommendation about guidance on the matter at this time, and we would like to promote community discussion. Accordingly, we ask for public comments in response to the questions posed below.

Requested Input from NOSB, NOP and Public Comment

The CACC proposes to put forward the following questions to the NOSB and the organic community regarding the use of food contact or food contact surface sanitizers and the resultant ability to use labeling claims of "100% Organic":

1. Does the 100% Organic label claim hold value for you?
2. Do you feel that contact with a non-organic processing aid should prevent an item from being 100% organic and why?
3. Do you feel that contact with a non-organic food contact sanitizer should prevent an item from being 100% organic and why?
4. How do you distinguish a processing aid from a food contact sanitizer?

5. Does your organic certifier provide guidance on what is a processing aid versus a food contact sanitizer? If so, what is that guidance?
6. If your certifier allows you to use a processing aid, how do you show that the processing aid “is present in the finished food at insignificant levels and does not have any technical or functional effect in that food?”
7. Should there be a category/list of NOP allowed food contact sanitizers and non-organic processing aids that are approved to be used in the 100% organic category? (e.g. Chlorine, peracetic acid, diatomaceous earth, etc.)
8. At what concentration, if any, do you consider a sanitizer/disinfectant to have disqualified an item from the 100% organic category?
9. Should food contact sanitizers be allowed in the 100% organic category if it is proven that no residue from the treatment remains in the finished good?
10. Do you certify items to the 100% organic category? If so, how many?
11. Do you feel that food contact sanitizers are necessary for food safety concerns?
12. If food contact sanitizers could be used while still allowing for a 100% organic claim would you certify more products with the organic claim? If not, why not?
13. Do you have customer requests/demand for products in the 100% organic category?

The CACC also welcomes comments and input in addition to answers to the questions above.

Committee Vote

Motion: The CACC moves to accept this document and present it for full board discussion at the Spring 2012 NOSB meeting

Motion by: John Foster Second: Calvin Walker
Yes: 7 No: 0 Absent: 1 Abstain: 0 Recuse: 0

National Organic Standards Board
Ad hoc GMO Committee
Proposal
Letter to the Secretary on GMOs

March 28, 2012

March 28, 2012

The Honorable Tom Vilsack
Secretary of Agriculture
US Department of Agriculture
Washington, DC 20250

Dear Honorable Secretary Vilsack:

The National Organic Standards Board (NOSB) members appreciate the opportunity to carry out our authority under the Organic Foods Production Act (OFPA) to provide advice on the development of organic standards and to determine substances for the National List.

The NOSB accepts responsibility for making recommendations that pertain to "excluded methods" to ensure that GMOs (genetically modified organisms) are prohibited in organic production and handling. To do this we have established an Ad Hoc Committee on GMOs. The NOSB, speaking for the organic community, believes the USDA's actions on genetically engineered crops have been insufficient to protect the organic industry.

Unsolicited public comments at many NOSB meetings since the rule came out in 2002 have illustrated the extreme concern about the impact that continued deregulation of new genetically engineered crops has had on our community of organic farmers, handlers and consumers.

The NOSB ad hoc GMO committee will examine all the areas where GMO contamination poses a threat to organics and will provide leadership in clarifying what excluded methods actually are, and how compliance to the provisions of the rule can be monitored. We see the potential of contamination by genetically engineered crops as a critical issue for organic agricultural producers and the consumers of their products. There are significant costs to organic producers and handlers associated with preventing this contamination and market loss arising from it.

Organic farmers must no longer be held solely responsible to prevent contamination from practices outside their control. We feel the developers of the GMO technology should share the burden that organic farmers now assume in mitigating the gene flow between farms and should compensate organic farmers for genetic drift.

We intend to keep you informed of our recommendations on this issue. We would like to open the door to continued dialogue with the USDA so that the responsibility to prevent GMO contamination of organics is shared by those who develop, use, and regulate this technology. USDA actions are critical to the integrity of the organic seal and consumer confidence.

Sincerely,

Barry Flamm
Chair of the National Organic Standards Board
c/o NOP office

Moved: Colehour Bondera Second Mac Stone
Yes 6 No 0 Abstain 0 Absent 0 Recuse 0

National Organic Standards Board
Materials Committee
Proposal for
Research Priorities Framework

March 27, 2012

Introduction

A discussion document on a Research Priorities Framework was circulated at the last National Organic Standards Board (NOSB) meeting in November 2011. Relatively little public comment was received but much of the public comment on the other issues on the agenda brought up the ongoing need for research on many topics that come before the NOSB. We are therefore proceeding to adopt criteria and a process for making the research priorities of the NOSB known to researchers, funders, and the public.

Background

Please refer to the previous (September 27, 2011) Proposed Discussion Document for most of the background about why there is a need for this recommendation.

The discussion document was generally viewed favorably by the commenters with the primary constructive points being fleshing out how the information is prioritized and disseminated and the suggested addition of one criterion about need for alternatives to materials on the National List.

Relevant areas in the Rule

The very definition of Organic Production implies a positive approach to farming and handling that would benefit from research into the integration of cultural, biological and mechanical practices:

> "§ 205.2 Terms defined.
> *Organic production.* A production system that is managed in accordance with the Act and regulations in this part to respond to site-specific conditions by integrating cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity."

The National List section requires the NOSB to evaluate a variety of criteria. In doing so, the NOSB often finds gaps in the research that would be relevant to making an informed decision on whether to add a substance to the National List.

> "§ 205.600 Evaluation criteria for allowed and prohibited substances, methods, and ingredients
>
> The following criteria will be utilized in the evaluation of substances or ingredients for the organic production and handling sections of the National List:
> ....."

Discussion

Much discussion of this topic occurred in the Discussion document from fall 2011. The goals of this recommendation are worth repeating here, with a little streamlining.

The primary goal of this framework is for the NOSB to align on criteria for prioritizing research needs and recommend a process for collecting and communicating research needs. Additional benefits include:

- Influencing where research dollars are directed and increasing the amount of research being done related to organic agriculture.
- Allowing the NOSB to be more proactive with regards to problematic or controversial National List substances by creating a mechanism to advocate for primary research ahead of material review dates
- Reducing disagreement within the organic community by increasing the amount of primary research on which decisions could be based, while satisfying many different stakeholders that the criteria have been met.
- Making the research community aware of the research needs of organic producers and handlers. Awareness could allow for USDA funding of primary research in these top priority areas and provide support for researchers submitting grants requests these research areas.

It has been recognized through the process of reviewing materials by the NOSB that it is important not only to identify the research topic, but to ask the specific questions on a topic around which research is needed.

As a recent example, oxytetracycline, indicates, the topic may be "Alternatives to Antibiotics in Organic Fruit Production", but then the supplemental research questions could include *(these are only examples)*:

- Are there common elements, such as cultural or biological methods, that should be incorporated into any Organic System Plan for prevention of fireblight?
- What are the region-specific limitations of resistance to fireblight for both rootstocks and varieties?
- What strategies and characteristics can make a fireblight resistant apple or pear variety acceptable to consumers?
- Are any of the alternative materials and methods named in the TR effective in all areas of the country?
- Are there other alternative materials that have not yet been investigated?

Each one of these questions may take a considerable time to research, but each of them are important and may fit into different areas of expertise from different researchers. Therefore, the committee feels that at least some questions should be associated with each of the top group of research priorities chosen. By doing this, aspiring organic researchers from among plant breeders, laboratory scientists, livestock nutritionists, pesticide toxicologists and more can have some guidance on what is needed and justification to put into research proposals.

Recommendation

This recommendation consists of criteria for identifying research needs, a process for the NOSB to use in developing a yearly recommendation on research needs, including making the public aware of the research recommendations.

Criteria

The criteria for prioritization are for those topics that the NOSB believes will have the largest long-term impact on growth and integrity of organic agriculture. These criteria are not presented in order of importance, but will be evaluated by the Materials Committee in selecting the top research needs.
Criteria for research topics are:

- Persistent and chronic (i.e., perennial topics of debate and need)
- Challenging
- Controversial (i.e., topics on which there are widely differing perspectives or for which there have been close NOSB votes)
- Nebulous (i.e., the research need is hard to identify but the organic agriculture need is clear). For example, improved methods of weed control.
- Lacking in primary research. That is, topics for which there is no active research being conducted, primarily relating to the criteria in OFPA for review of materials..
- Relevant to assessing the need for alternative cultural, biological, and mechanical methods to materials on the National List.

Process Framework

1. The Materials Committee will collect research topics from public comment, NOP and NOSB committees on an on-going basis. Specifically, the Materials committee should review research topic needs after every NOSB meeting to ensure that public comment and NOSB discussion on new research needs are added to a 'running' list.
2. Each NOSB Committee will address the question of research priorities that have been uncovered in the course of Committee business. Committees shall identify the specific research need(s), background on the problem(s), and a description of how the research will contribute to the ability of the NOSB to carry out its function of reviewing materials in an organic systems framework. They shall submit their committee list to the Materials Committee after each NOSB meeting.
3. Research topics will be kept by the Materials committee on an all-inclusive 'running' list. The list would include a description of the research questions that need to be addressed, and how the research methods need to be applied in an organic context. It can include a preliminary list of what entities are involved in that type of research and an evaluation of funding opportunities, collaborations and endorsements.
4. On an annual basis, the committee will review the list and based on the criteria adopted above sort the list into two groups: the top research priorities for NOSB review as a recommendation, and the rest of the research suggestions to remain on an on-going list. The top priorities will not be ranked, but will have descriptions of the key questions that the NOSB wishes to see researched about each topic.
5. The Materials Committee will present the recommendation of the top research priorities to the full NOSB each year at the fall meeting. At this time public comment can be sought about the priorities and the research questions, as well as unbiased entities or individuals who may be able to conduct pressing organic research activities. The list of remaining items that the Materials Committee has chosen not to bring forward to the full Board will also be made available to the public, so that individuals with desire to research specific subjects can know what some of the broader topics are.
6. After a recommendation is finalized by the NOSB each fall the Chair of the Board will make sure it is sent to the primary organic research funders such as NIFA, ARS, NRCS,

OFRF, and private foundations and other funders that may be identified. In addition all NOP staff, NOSB members and stakeholders can use the list for inspiring appropriate research.

Committee Vote

Motion to adopt the proposed recommendation on Research Priority Criteria and Process.

Motion by: Zea Sonnabend Second: Calvin Walker
Yes: 5 No: 0 Absent: 1 Abstain: 0 Recuse: 0

National Organic Standards Board
Materials Committee
Extractants and Solvents Discussion Paper
March 21, 2012

Background

Extractants or solvents are used to produce materials used in crops, livestock, and processing. There are limitations on the use of certain extractants, but they are not uniform or consistent. There are numerous places in the rule where solvents are prohibited generally and specifically by name of chemical, or “water process only.” The lack of consistency leads to problems in deciding on classification and listing issues. The Materials Committee seeks to clarify the issues around the use of extractants and solvents to ensure more informed and logical decision making across numerous NOSB committees and material reviews.

Extractants and Solvents in OFPA and Regulations

The Organic Foods Production Act (OFPA) mentions extracting as a means of processing. The only other mention of solvents or extraction is in the definition of “synthetic”:

> **§.2103 [7 U.S.C. 6502] Definitions**(21) The term "synthetic" means a substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes.

Several definitions in the regulations mention extraction or solvents, including the definition of “synthetic” repeated from OFPA:

> **§ 205.2 Definitions.**
> *Excipients*. Any ingredients that are intentionally added to livestock medications but do not exert therapeutic or diagnostic effects at the intended dosage, although they may act to improve product delivery (e.g., enhancing absorption or controlling release of the drug substance). Examples of such ingredients include fillers, extenders, diluents, wetting agents, solvents, emulsifiers, preservatives, flavors, absorption enhancers, sustained-release matrices, and coloring agents.
>
> *Nonagricultural substance.* A substance that is not a product of agriculture, such as a mineral or a bacterial culture, which is used as an ingredient in an agricultural product. For the purposes of this part, a nonagricultural ingredient also includes any substance, such as gums, citric acid, or pectin, that is extracted from, isolated from, or a fraction of an agricultural product so that the identity of the agricultural product is unrecognizable in the extract, isolate, or fraction.

> *Processing.* Cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, extracting, slaughtering, cutting, fermenting, distilling, eviscerating, preserving, dehydrating, freezing, chilling, or otherwise manufacturing and includes the packaging, canning, jarring, or otherwise enclosing food in a container.

"Extracting" is mentioned as an allowed processing method in § 205.270(a). § 205.270 (c) prohibits the use of "volatile synthetic solvents" in organic handling of agricultural products:

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

There are a few more specific prohibitions on solvents:

> §205.601(j) As plant or soil amendments.
> (1) Aquatic plant extracts (other than hydrolyzed)—Extraction process is limited to the use of potassium hydroxide or sodium hydroxide; solvent amount used is limited to that amount necessary for extraction.
> (3) Humic acids—naturally occurring deposits, water and alkali extracts only.
>
> §205.606(k) Gums—water extracted only (Arabic; Guar; Locust bean; and Carob bean).
>
> §205.605(a) Nonsynthetics allowed:… Flavors, nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.

At its November 2011 meeting, the NOSB recommended the approval of a petition for Docosahexaenoic acid (DHA) algal oil petition with the following annotation: DHA from Algal Oil, not hexane extracted; other ingredients that are agricultural must be organic" to the National List at 7 CFR, §205.605(a)

Issues and Discussion

1. **What is a volatile synthetic solvent?**

A volatile synthetic solvent is, first of all, synthetic. This is important to keep in mind, since many natural substances otherwise meet the definition –water, for example.

There are many definitions of volatile in the context of "volatile organic chemical," which is a regulated class of chemicals. Some focus on specific regulatory aspects (such as

EPA's definition for air pollution purposes, any organic compound that participates in a photoreaction.) For our purposes, however, the crucial aspect is volatility. Volatility is most precisely defined in terms of vapor pressure, which is not very intuitive to most people. Equivalent definitions can be expressed in terms of boiling point, which is more intuitive and is a commonly reported property of chemicals. The most commonly used definition is a chemical with boiling point between 69 and 287 degrees Celsius, and very volatile is defined as having a boiling point below 69 degrees Celsius.[1] For our purposes, very volatile and volatile should be combined.

A solvent is a chemical capable of dissolving another substance.

Thus, a volatile synthetic solvent is a synthetic chemical with boiling point less than 287 degrees Celsius that can dissolve another substance.

Some examples of volatile synthetic solvents and their boiling points in degrees Celsius:

Ethanol (may be nonsynthetic)	15.8
Dichloromethane	40
Acetone	56
Chloroform	61
Hexane	69
Benzene	80
Isopropyl alcohol	82
Toluene	111
Super critical carbon dioxide	[2]

2. When does the use of a synthetic solvent change the classification of the material?

Agricultural -> Nonagricultural

A nonagricultural substance is defined as:

> A substance that is not a product of agriculture, such as a mineral or a bacterial culture, that is used as an ingredient in an agricultural product. For the purposes of this part, a nonagricultural ingredient also includes any substance, such as gums, citric acid, or pectin, that is extracted from, isolated from, or a fraction of an agricultural product so that the identity of the agricultural product is unrecognizable in the extract, isolate, or fraction. (**§ 205.2)**

In November 2009, the Board approved a revised definition of nonagricultural, which has so far not been written into regulation: "A product, such as a mineral or atmospheric

[1] Eurofins Product Testing –What means VOC? http://www.eurofins.com/voc.aspx

[2] Carbon dioxide usually behaves as a gas in air at standard temperature and pressure (STP), or as a solid called dry ice when frozen. If the temperature and pressure are both increased from STP to be at or above the critical point for carbon dioxide, it can adopt properties midway between a gas and a liquid. More specifically, it behaves as a supercritical fluid above its critical temperature (31.1 °C) and critical pressure (72.9 atm/7.39 MPa), expanding to fill its container like a gas but with a density like that of a liquid.

gas, that does not originate from agriculture. For the purposes of this part agricultural refers to the production or handling of crops or livestock." The NOP stated,[3] "The NOP does not object to the above definition, but proposes that some ambiguity remains. For example, does the removal of the example of 'bacterial culture' mean that microorganisms, dairy cultures, and their products are considered agricultural? The NOSB has indicated they will be determining this on a case by case basis. If so, it would be useful to develop criteria for this review of microorganisms and their products. The NOP acknowledges that the current definition, which includes pectins and gums as nonagricultural conflicts with the present listings at 205.606."

Thus, the use of a solvent –synthetic or nonsynthetic—may result in production of a nonagricultural product from an agricultural substance under the current definition, though if the revised definition were written into the regulations, it would not. It is not clear whether the definition in the regulations will be changed. The definition is pertinent because, as noted below, the prohibition against extraction with a volatile synthetic solvent in §205.270(c) applies only to agricultural substances.

Nonsynthetic -> Synthetic

The issue of when the use of a synthetic solvent changes the classification from nonsynthetic to synthetic has been addressed in the Recommendation on Classification of Materials, adopted by the Board in November 2009:

> It is our intent through this recommendation that a material would be classified as synthetic when:
>
> - The source of the material is not "from mineral, plant, or animal matter" (from the definition of nonsynthetic) and is not a "substance created by naturally occurring biological processes" (from the definition of synthetic) or;
> - The process used to manufacture the material is synthetic (per the definition of synthetic and clarifying definitions in our recommendation) or;
> - The material contains, at a significant level, a synthetic substance not on the National List of allowed synthetics. (p5)

Thus, there are two cases in which the use of a synthetic solvent can change the classification of a material from nonsynthetic to synthetic:

a. If the addition of the synthetic solvent results in chemical change, then the resulting substance is synthetic, and
b. If the material contains a significant level of the synthetic solvent, then it is synthetic**.**

[3] Miles McEvoy, September 30, 2010. Memorandum for the chairman of the National Organic Standards Board, p. 15.

The definition of “chemical change” approved by the NOSB in November 2009 (and amended slightly in April 2011 in Update and Proposed Guidance Document, Classification of Materials) is:

> *Chemical Change* An occurrence whereby the identity of a substance is modified, such that the resulting substance possesses a different distinct identity (see related definition of “substance”)

The definition of “substance” included in the November 2009 guidance is:

> *Substance* An element, molecular species, or chemical compound that possesses a distinct identity (For example, a distinct identity may be demonstrated through the material having a separate Chemical Abstract Service (CAS) number (in some cases the same material may have multiple CAS numbers), Codex International Numbering System (INS) number, or FDA or other agency standard of identity).

The latest April 2011 recommendation to define a significant residue in the classification of materials policy was unsuccessful. At the April 2011 meeting, the motion was made to accept the proposed guidance that a significant level of a synthetic substance in the final material means a level exceeding any applicable regulatory limits, where in effect for the material being classified, and a level without any technical and functional effects in the final material. The vote was 8 yes and 6 no. Since the vote was not decisive, the motion failed and the proposed guidance was sent back to the Materials Committee for further refinement.

The other approach that was supported by a minority of the committee and considered, as documented in the proposed guidance document was that, “[A]ny known level of a synthetic substance in the final material or in the environment, as a result of the substance’s manufacture, use and disposal would be a significant level…. Proponents believe this standard of review requires a determination as to whether there is harm associated with the use of the synthetic substance, and therefore subject to the National List review process. Under this approach, all synthetic inputs or residues must be examined to determine their associated health and environmental impacts.”

The question as to what level of synthetic residue would result in the change in classification of a nonsynthetic material to synthetic therefore awaits clarification by the NOSB.

3. **Does the use of a volatile synthetic solvent in an ingredient mean that the ingredient is not permitted in organic food? This has to do with the heritage of an input—does a prohibition against its use carry back to the origin of the ingredients?**

§205.270(c) of the regulations states, “(c) The handler of an organic handling operation must not use in or on agricultural products intended to be sold, labeled, or represented

as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” or in or on any ingredients labeled as organic:… (2) A volatile synthetic solvent or other synthetic processing aid not allowed under §205.605: *Except,* that, nonorganic ingredients in products labeled “made with organic (specified ingredients or food group(s))” are not subject to this requirement.

It is not clear whether the use of a volatile synthetic solvent in an ingredient that is subsequently used in another product disqualifies the second product as being labeled organic. On one hand, one could argue that it makes the ingredient nonorganic, but the ingredient could be used as part of the 5% in an organic product, but not used in a 100% organic product. But that would make the exception unnecessary.

The alternative interpretation is that by using an ingredient that has been produced using a volatile synthetic solvent, one is adding the solvent to the final product as well. Since the prohibition is absolute, it may be proper to disallow ingredients made using volatile synthetic solvents anywhere in their history.

Other Issues Concerning Solvents

Regardless of whether the material being extracted is synthetic or nonsynthetic, if the material is being considered for use in organic production –for example, as a crop input to be listed on §205.601– the impacts of the extractant need to be considered as part of the review of the material. These impacts are not limited to the impacts of the residues in the material, but also include the impacts of the manufacture, use, and disposal of the solvent material. Questions that need to be asked include:

1. Is the site where the solvent is manufactured at a site where there is contamination, such as a Superfund site?
2. Is solvent released into the air or water during or following the extraction process?
3. What happens to waste solvent?

Comments Requested

The Committee requests public comments on the following questions:

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

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

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

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

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

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

7. What is a significant residue of a synthetic solvent? Should the prohibition on the use of volatile synthetic solvents include the use in any ingredient in the history of the product?

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

Committee Vote:
The Materials Committee moves to accept this document and present it for full Board discussion at the spring 2012 NOSB meeting:

Moved: Jay Feldman Second: C. Reuben Walker

Yes: 5 No: 0 Abstain: 0 Absent: 1 Recuse: 0

National Organic Standards Board
Materials Committee
Discussion Document
Significant Residues Definition in Classification of Materials Policy
March 27, 2012

This discussion paper addresses a key issue left unresolved in the Materials Classification Policy adopted by the Board. The Addendum to November 6, 2009 Recommendation on Classification of Materials states that, "It is our intent through this recommendation that a material would be classified as synthetic when: . . . The material contains, at a significant level, a synthetic substance not on the National List of allowed synthetics." However, the Board did not clarify this guidance by defining "significant" in this context.

The dictionary defines "significant" as "important" or "of consequence." However, the question that remains is what level of a synthetic impurity found in a material under review is determined to be "of consequence" under the Organic Foods Production Act (OFPA). This discussion paper asks how the NOSB should apply the framework of OFPA to the definition of "significant." Three different approaches are presented, and input is sought on the broad approach as well as details.

Materials Classification Policy

At the November 2009 National Organic Standards Board (NOSB) meeting, the NOSB passed a recommendation on Classification of Materials. The recommendation included several "Next Steps" that the NOSB felt are required in order to implement the recommendation. In passing the recommendation, the NOSB indicated that further work is required of the Board to develop a Guidance Document that the various stakeholders (e.g., Accredited Certifying Agents, committees of the NOSB, National Organic Program personnel) could use when classifying materials.

At the April 2010 NOSB meeting, the Joint Materials and Handling Committee presented a draft Guidance Document for public input. It was clear from that public input that the guidance document needed more work. A key topic left unresolved was the question, "What is a significant amount/level of a synthetic input to the process remaining in the final material?" Prior to the April 2011 meeting, the Materials Committee evaluated two different approaches in the context of work on a classification of materials worksheet. They are discussed, along with a third approach, in "Issues and Discussion" section below.

OFPA and the Rule

The underlying statutory standard in the Organic Foods Production Act with regard to synthetic agents and their allowance is found in Sec. 2118 [7 U.S.C. 6517] National List, (c) Guidelines for Prohibitions on Exemptions.– (1) Exemption from Prohibited

Substances in Organic Production and Handling Operations.– The National List may provide for the use of substances in an organic farming or handling operation that are otherwise prohibited under this title only if– (A) the Secretary determines, in consultation with the Secretary of Health and Human Services and the Administrator of the Environmental Protection Agency, that the use of such substances– (i) would not be harmful to human health or the environment…" The list criteria provide the mechanism for evaluating harm for all substances by weighing information from the other agencies along with the unique organic considerations.

This statutory intent is captured in the "Evaluation Criteria for Substances Added to the National List" with the questions, "Is there any harmful effect on human health? [§6517 (c)(1)(A)(i); 6517(c)(2)(A)(i); §6518(m)(4)]" and, "Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]" The scope of the possible harm that OFPA requires the NOSB to examine is identified in the question, "Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518(m)(3)]"

Issues and Discussion

In the context of OFPA and materials classification, a level of a synthetic impurity is "significant" when it is "of consequence" to materials classification and review. A major issue in defining "significant" is the degree to which harm must be identified before deciding the residue is significant. We also understand that decisions about significant residues are made not only by the Board, but also by materials review organizations (MROs) and certifiers, and that a definition of "significant synthetic residue" must allow MROs and certifiers to act on the information available to them. Two of the three approaches outlined below were discussed in the April 2011 Materials Committee Recommendation.

The first approach is the one proposed by the Materials Committee in the April 2011 recommendation, which failed to pass the Board by the required 2/3 margin. This approach says that an insignificant level of a synthetic substance in the final material means a level below any applicable regulatory limits for the type of substance and without any technical and functional effects in the final material. Proponents of this approach believe this approach is more consistent with past NOSB practices, is consistent with the recommendation of the Materials Working Group and reflects the bulk of the public comment received on this topic. Additionally, the majority of the Materials Committee was concerned with using an approach of "any known level" knowing that technology allows the detection of ever-decreasing amounts of material. So a material that today has no known level of synthetic input in it may very well tomorrow have a detectable level. The majority of the committee felt that using the "any known level" approach would be disruptive to the industry as it differs from past practice and would lead to an on-going reevaluation of materials on a perpetual basis as detection levels change. As this approach was discussed, it was acknowledged that a given material may not have any applicable regulatory limits or may have several. In the case where no regulatory limit is available, technical and functional effects of any remaining synthetic would need to be evaluated. In the case where multiple regulatory

limits exist, the reviewer would evaluate which best applies for the classification. For example, for a synthetic solvent used to extract a natural sourced material there may be an OSHA inhalation limit and EPA residue limit. Since the synthetic is present in a material to be used in crops, the EPA limit is most appropriate.

The second approach was supported by a minority of the Materials Committee in April 2011. It would characterize any known or detectable level of a synthetic substance in the final material or in the environment, as a result of the substance's manufacture, use, and disposal as a significant level triggering NOSB review. Proponents of this approach point to the statutory standard in OFPA §6517(c)(1) with regard to synthetic agents and their allowance. Proponents believe this standard of review requires a determination as to whether there is harm associated with the use of the synthetic substance, analogous to the standard of review used in the process of allowing synthetic substances on the National List. The minority felt that citing regulatory standards set under different statutory criteria does not meet the OFPA intent or standards, but, like all other regulatory standards, we must be prepared to adjust regulatory action to advances in good laboratory practices as they improve. Finally, proponents believe that the quantity of synthetic residue is not the sole determinant of "harm" in the end product. The minimal residue that causes harm may not be known, and harm may be more dependent on other factors, like timing of exposure, than dose. Furthermore, OFPA requires consideration of the material's residual harm from manufacture to disposal, including its use in organic agriculture or processing.

A third approach acknowledges that MROs and certifiers have to make frequent evaluations of a variety of residues that occur in both food processing and crop inputs that do not always come to the attention of the NOSB because they are not petitioned or may change frequently. Therefore, the NOSB would need to offer guidelines to screen these potential synthetic residues rather than review each one. What would emerge would be a screen for all synthetic residues by evaluating them against a list of known harmful chemicals created by governmental and international organizations to determine whether they are significant. This process might be applied in field situations by Material Review Organization (MROs) and certifiers when a full NOSB review is not practical. Slightly different screens for crop inputs and food ingredients may be used because there are different sources of information on them and they are handled differently in the regulation. The first two steps in the screening process would be, "What chemical is it?" "Is it measurable?" Then, it would be compared to lists of known harmful materials. If the chemical is found on one of the lists of known harmful materials, then the residues would be considered significant and this would trigger a full NOSB review. In this scenario the guidelines would appear in the NOP Program Handbook or in guidelines for MROs and the individual impurity chemicals would not have to appear on the National List.

Comments Requested

The Committee requests comments on the following questions:

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

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

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

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

5. When residues of a certain synthetic impurity are identified as significant, how should the review proceed (a) if the material containing the impurity is under review by a MRO prior to use, (b) if the significant residues are discovered by a MRO/ACA when the material is in use, (c) if the material is under review by the NOSB?

Committee Vote:
The Materials Committee moves to accept this document and present it for full Board discussion at the spring 2012 NOSB meeting:

Moved: __Jay Feldman__ Second: __Jennifer Taylor__

Yes: __5__ No: __0__ Abstain: __0__ Absent: __1__

National Organic Standards Board
Crops Committee
2012 Sunset Recommendation
List 3 Inert Ingredients in Passive Pheromone Dispensers
March 20, 2012

List: 205.601 Synthetic substances allowed for use in organic crop production.
(m) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

(2) EPA List 3—Inerts of unknown toxicity—for use only in passive pheromone dispensers.

Background

Inert ingredients are defined in the National Organic Program (NOP) regulations, with reference to the Environmental Protection Agency (EPA) definition, to include any ingredient other than active ingredients used in pesticide products. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides that inert ingredients used in pesticides do not require disclosure on product labels.

> NOP 7 CFR §205.2 Terms Defined
> *Inert ingredient*. Any substance (or group of substances with similar chemical structures if designated by the Environmental Protection Agency) other than an active ingredient which is intentionally included in any pesticide product (40 CFR 152.3(m)).
>
> EPA 40 CFR 152.3 Definitions
> *Active ingredient* means any substance (or group of structurally similar substances if specified by the Agency) that will prevent, destroy, repel or mitigate any pest, or that functions as a plant regulator, desiccant, or defoliant within the meaning of FIFRA sec. 2(a), except as provided in §174.3 of this chapter

Section 6517(c)(1)(B)(ii) of the Organic Foods Production Act of 1990 (OFPA) authorizes the National Organic Standards Board (NOSB) to establish a National List of approved and prohibited substances that may include synthetic inert ingredients that are not classified by the Administrator of the EPA as “inerts of toxicological concern.”

> **OFPA**
> 7 USC 6517(c)(1) Exemption for Prohibited Substances.
> 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

… (ii) is used in production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern;

Summary

OFPA, Regulations, and Previous NOSB Action

OFPA, in establishing the National List (§2118, 7 U.S.C. 6517), creates a list of exemptions for prohibited substances in organic production and handling and in so doing lists the categories of substances that must be reviewed by the NOSB if they are to be listed: "(B) the substance (i) is used in production and contains an active synthetic ingredient in the following categories: .....; (ii) is used in production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern; or…" Tracking the U.S. Environmental Protection Agency (EPA) categorization of active and inert ingredients in pesticide formulations, OFPA subjects all allowed substances to the underlying statutory standards of health and safety, essentiality, and compatibility in this section of the law. Section 2118(c)(1)(B)(i) creates a category of **active ingredients** that may be allowed, which is parallel to Section 2118(c)(1)(B)(ii) creating the category of **inerts** that may be allowed --those found by EPA to not be "inerts of toxicological concern." In summary, the categories of active and inert ingredients in Section 2118 establish an NOSB duty to review these substances.

The fact that OFPA uses the language the "substance…contains synthetic inert ingredients…" is somewhat confusing. The confusion is amplified by the fact that inert ingredients are themselves "substances."[1] The language in OFPA is clarified in the Conference Report, which states: "The Conference substitute adopts the House provision with an amendment that adds production aids to the category of synthetic active ingredients and the category of synthetic inert ingredients not of toxicological concern to the Administrator of EPA *as possible exemptions* on the National List." [Emphasis added.]

The language of the Conference Report thus makes it clear that "synthetic inert ingredients not of toxicological concern to the Administrator of EPA" is a category of substances that may be considered for listing on the National List.

[1] §205.2
Inert ingredient. Any substance (or group of substances with similar chemical structures if designated by the Environmental Protection Agency) other than an active ingredient which is intentionally included in any pesticide product (40 CFR 152.3(m)).
Classification of Materials November 2009: "*Substance"*: "An element, molecular species, or chemical compound that possesses a distinct identity (For example, a distinct identity may be demonstrated through the material having a separate Chemical Abstract Service (CAS) number (in some cases the same material may have multiple CAS numbers), Codex International Numbering System (INS) number, or FDA or other agency standard of identity)."

However, even if we take the interpretation that it is “substances *containing* synthetic inert ingredients not of toxicological concern to the Administrator of EPA” that may be listed on the National List, §6517(c)(1)(B) only allows such substances to be listed on the National List if the requirements of §6517(b), §6517(c)(1)(A), and §6517(d) are met. This requires that the “substance” undergo review according to the criteria of OFPA. If the inert is regarded as a component of the substance and not a substance itself, it still must be reviewed as part of the review of the substance.

The NOSB responsibility has its roots in both the Senate Report and the Preamble to OFPA and the subsequent action by the NOSB.

The Senate Report makes it clear that inert ingredient review was to be subject to the National List process:

> Until such time as FIFRA is altered to require the full disclosure of inert ingredients, organic farmers should be allowed to continue using compounded substances if the active ingredient is natural and if use of the substance is recommended by the National Organic Standards Board and approved by the Secretary for inclusion on the National List. However, in order for the National Organic Standards Board to evaluate whether certain compounds should be listed, the Board will need some information about the inert ingredients in question. The Committee directs the Board to seek the advice of the Administrator of the EPA, who has information on inert ingredients submitted as part of registration, as to whether such inert material would be appropriate for organic production. EPA's response will not limit its regulatory responsibility for such material.

In the Preamble to the Final Rule, December 21, 2000, USDA said,

> In this final rule, only EPA List 4 Inerts are allowed as ingredients in formulated pesticide products used in organic crop and livestock production. The allowance for EPA List 4 Inerts only applies to pesticide formulations. Synthetic ingredients in any formulated products used as organic production inputs, including pesticides, fertilizers, animal drugs, and feeds, must be included on the National List. As sanctioned by OFPA, synthetic substances can be used in organic production and handling as long as they appear on the National List. The organic industry should clearly understand that NOSB evaluation of the wide variety of inert ingredients and other nonactive substances will require considerable coordination between the NOP, the NOSB, and industry.

In February, 1999, the NOSB recommended:

> Inert ingredients on EPA Lists 1 and 2 shall be prohibited for use in organic production and handling effective on the date of implementation of the final rule of NOP. Synthetic inerts on EPA List 3 shall be prohibited if not specifically approved by the NOSB. This approval process will be completed and published

> by January 1, 2002. Any inert currently in use in organic production that is not approved by the NOSB will be banned within 18 months after the review is completed and published. To that goal, inerts on EPA List 3 used in products that have active ingredients approved for organic production shall be reviewed by the NOSB on a case-by-case basis for possible inclusion on the National List.

Thus, the board voted that the consideration of individual List 3 materials was to be completed by January 1, 2002 –more than 10 years ago.

In October 2002, the Board passed the motion to list pheromones, which resulted in the current listing for List 3 inerts.

> Pheromones—includes only EPA-exempt pheromone products, EPA registered pheromone products with no additional synthetic toxicants unless listed in this section and any inert ingredients used in such pheromone formulations that are not on EPA List 1, that is inerts of toxicological concern or EPA List 2, that is potentially toxic inerts, provided the pheromone products are limited to passive dispensers, pheromone products containing only pheromone active ingredients listed in this section and List 4 inerts may be applied without restriction.

At the same meeting, the Board also passed a motion *temporarily* allowing the continued listing of certain List 3 inerts:

> The NOSB recommends that any list 3 inert material forwarded for a technical review be allowed for use until that material is approved or prohibited by the Secretary of Agriculture.

When the List 3 inerts came up for sunset in November 2007, the summary of the recommendation said,

> Future petitions to add, remove or renew an inert ingredient to the National List will need to reference a specific inert ingredient. A petition may be submitted to the NOSB using the National List petition procedures. Individually petitioned substances must be recommended by the NOSB and added to the National List through notice and comment rulemaking before use in organic agriculture.

That recommendation was reaffirmed in February 2008. And, in presenting the discussion paper on List 4 inerts in November 2008, Gerald Davis said, “[Discussion paper point number] Five concerns the list 3 inerts currently used in passive pheromone dispensers. The current policy is that they need to be petitioned individually and are subject to regular sunset reevaluations, that that has already been in place as an NOP policy for a couple years now, since we were first notified about the EPA change.”

Consultations with USDA and EPA

The NOSB, in conjunction with USDA, consulted with EPA during the development and subsequent amendments of the National List. The NOSB recommended in 1999

prohibiting List 1 and 2 inerts, and List 3 inerts that are not specifically approved by the NOSB, in spite of the fact that the EPA had by that time distinguished Lists 4A and 4B as those ingredients that were not of toxicological concern (4A), and those regarded as not causing adverse effects based on their use patterns (4B).[2]

In 2006, EPA reassessed all inert ingredients used in pesticide formulations allowed on food crops, including former Lists 3, 4A, and 4B inerts, to ensure that they met the tolerance reassessment requirements of the Food Quality Protection Act. Inerts allowed for use in EPA registered pesticides applied to food now must either have a residue tolerance level or an exemption from tolerance level codified at 40 CFR Part 180. As a result of this reclassification, NOP regulations concerning allowed inert ingredients are out-of-date when compared with current EPA regulations, since EPA eliminated its list categories when it completed its tolerance reassessment. The NOSB recommended in April 2010 that NOP establish a task force in collaboration with EPA to examine this problem and provide a recommendation to the board for re-evaluation of former List 3 and List 4 inerts. In October 2010, the NOSB recommended that the current exemption on the National List that permits former List 4 inerts through October 2012 should be renewed "pending review by the program of inerts individually and as a class of materials".[3] The current exemption that permits former List 3 inerts in passive pheromone dispensers only is scheduled to sunset November 3, 2013.

An NOSB-NOP-EPA working group was established in June 2010. Current members include: Jay Feldman (NOSB), Zea Sonnabend (NOSB), Chris Pfeifer (EPA Biopesticides and Pollution Prevention Division), Kerry Leifer (EPA Registration Division), Emily Brown Rosen (NOP), and Lisa Brines (NOP). The group has collected information regarding current classification of the former List 3 and 4 inerts and presented a discussion document at the November 2011 NOSB meeting.[4]

This NOSB policy recommendation phases out former EPA List 3 inerts in passive pheromone dispensers from a general approval provision to full review under the National List standards. Currently, based on information from EPA, OMRI, and WSDA, we believe that there are three formerly List 3 inerts in use under this provision, three of which were the subject of petitions filed to the NOSB. It is understood that the former List 3 inerts requiring review are limited to the following substances: (i) Butylated

[2] In the notice 54 FR 48314 (11/22/89), EPA said (emphasis added),
"To accommodate revision of the lists, EPA has decided to subdivide List 4 into two parts. The previous list 4, representing inerts generally recorded as safe, has become List 4A, and a new List 4B has been created. List 4B is composed of inerts for which EPA has sufficient information to reasonably conclude that *the current use patterns* in pesticide products will not adversely affect public health and the environment. List 4B inerts in formulations proposed for new use patterns which cause significant increases in exposure will receive further scrutiny." In notice 59 FR 49400 (6/28/94), EPA said, "In reviewing List 4 inert ingredients for the proposed section 25(b) rule, many inerts on the original List 4 were moved from List 4A to List 4B. In particular, acutely toxic inerts were moved to 4B because, although the testing of products for acute toxicity ensures low concern for these inerts in registered products, without such regulatory oversight there may be unacceptable acute risks."
[3] October 28, 2010 recommendation available at http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5087999&acct=nosb
[4] Available at http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5094901&acct=nosb

hydroxytoluene (CAS # 128-37-0); (ii) 2-Hydroxy-4-n-octyloxybenzophenone (CAS # 1843-05-6); (iii) 2-(2-Hydroxy-3-tert-butyl-5-methylphenyl)-chlorobenzotriazole (CAS #3896-11-5)]. It is also understood that there may be a fourth inert in this category that has been identified by the Washington State Department of Agriculture.

The proposed annotation creates a timeframe for evaluation of these formerly List 3 inerts in passive pheromone dispensers: a review and board action is set for Dec. 31, 2015. This gives the board two years to review the petitions and act, and it provides the NOP a year to go to rulemaking. If for some reason the timeframes are delayed, the backup sunset provision allows the former List 3 uses to continue until Board action and rulemaking are complete. If the NOP adopts a policy by December 31, 2015 that covers former List 3 as well as other inerts, then that policy will prevail.

Committee Recommendation

The italicized text is new proposed language. Deleted text is indicated with a strike-through line.

List: 205.601 Synthetic substances allowed for use in organic crop production.
(m) As synthetic ~~inert~~ *other* ingredients *not* ~~as~~ classified by the Environmental Protection Agency (EPA) *as active ingredients*, for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

2) Inert ingredients exempt from the requirement of a tolerance under 40 CFR 180.1122 that were formerly on EPA List 3 in passive polymeric dispenser products may be used until December 31, 2015, after which point they are subject to individual review under 205.601, unless already covered by a policy adopted by the NOP for all other inert ingredients.

Committee Vote
Moved: Jay Feldman Second: Nick Maravell
Yes__8___ No__0__ Abstain__0__ Absent__0__ Recuse__0__

Committee Backup Vote to Relist:
List: 205.601 Synthetic substances allowed for use in organic crop production.
(m) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

(2) EPA List 3—Inerts of unknown toxicity—for use only in passive pheromone dispensers.

Committee Vote:
Moved: Zea Sonnabend Second: Jay Feldman
Yes__8__ No__0__ Abstain__0__ Absent__0__ Recuse___0___

§ 205.2 Terms defined.
Passive polymeric dispenser products. *Solid matrix dispensers delivering pheromones through volatilization only at rates less than or equal to 150 grams active ingredient (AI)/acre/year that is placed by hand in the field and is of such size and construction that it is readily recognized and retrievable. [59 FR 7368, March 30, 1994.] To be removed as a definition when 205.601(m)2(a) and (b) expire.]*

Moved: Jay Feldman Second: Zea Sonnabend
Yes__8___ No__0___ Abstain__0__ Absent__0___ Recuse ___0__

National Organic Standards Board
Livestock Committee
National List Proposal
Vaccines from Excluded Methods

April 3, 2012

Summary of Proposed Action:
See attached document Recommendation of Livestock Committee, on Vaccines derived from Excluded Methods, dated March 24, 2012
This recommendation concerns the class of livestock vaccines derived from excluded methods, commonly called GMO vaccines. There are approximately 73 registered animal vaccines, of which 13 are GMO. Only 2 vaccines, Bovine and Avian Salmonellosis, appear to be presently available only as GMO. At present livestock producers use all vaccines and are not required to determine if they are using non-GMO (conventional) or GMO derived vaccines. GMO vaccines are not legally allowed in organic production. This recommendation proposes a change which will allow GMO vaccines only in a declared emergency and, further, that at such time producers could use GMO vaccines without losing organic status of livestock. The recommendation also proposes changes to the definition of "emergency treatment program". The entire recommendation applies to the class of vaccines derived from excluded methods, but does not foreclose petitions for individual vaccines or a class of vaccines to treat specific diseases.

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: [1, 2, 3] **Comments:** 1. and 2. fail because of the necessity to evaluate individual vaccines on a case by case basis. 3 fails because vaccines derived from excluded methods are not consistent with organic agriculture

Proposed Annotation (if any): Modify language in 205.603(a)(4) as follows: Biologics—Vaccines*, provided, with regard to vaccines produced with excluded methods, the requirements of 205.105(e) are satisfied*.

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

Recommended Committee Action & Vote, including classification recommendation (state actual motion):
1. Modify language in 205.238(a) (6) as follows, change shown in italics.
Administration of vaccines and other veterinary biologics, *provided, vaccines produced with excluded methods, can only be administered in accordance with §205.105(e).*

2. Modify 205.105 (e) as follows: Excluded methods, except for vaccines: Provided*,*

(1) *such vaccines are administered only due to a Federal or State emergency pest or disease treatment program, and*

(2) such vaccines are approved in accordance with §205.600(a);

3. Modify language in 205.603(a)(4) as follows: Biologics—Vaccines*, provided, with regard to vaccines produced with excluded methods, the requirements of 205.105(e) are satisfied*.

Classification Motion: Vaccines are already classified as synthetic on the National List at section 205.603, Synthetic substances allowed for use in organic livestock production. The Committee did not propose to reclassify the substance.
Motion by: N/A Seconded by: N/A
Yes: # No: # Absent: # Abstain: # Recuse: #

Listing Motion: To accept the recommendations of the committee for listing, as above:
Motion by: Colehour Bondera Seconded by: Jean Richardson
Yes: # 5 No: # 0 Absent: # 3 Abstain: # 0 Recuse: # 0

4. Change the Definition of "Emergency pest or disease treatment program*"* in section 205.2 with the additions shown in italics.

Emergency pest or disease treatment program: A mandatory program authorized by a Federal, State or local agency for the purpose of controlling or eradicating a pest or disease*, except for a program requiring substances described in section 205.105(e) regarding only vaccines produced with excluded methods, in which case such program is defined as a mandatory treatment program authorized by a declared Federal or State emergency for the purpose of controlling a pest or disease.*

Refine definition of Emergency pest, disease, and treatment program Motion:
Motion by: Nick Maravell Seconded by: Jean Richardson
Yes: # 8 No: # 0 Absent: # 0 Abstain: # 0 Recuse: # 0

Crops	☐	**Agricultural**	☐	**Allowed[1]**	**X**
Livestock	**X**	**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 § 205.603 with Annotation (if any): Biologics—Vaccines*, provided, with regard to vaccines produced with excluded methods, the requirements of 205.105(e) are satisfied*.

[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 Committee Chair to Transmit to NOSB

Wendy Fulwider, Committee Chair **April 3, 2012**

NOSB Evaluation Criteria for Substances Added To the National List

Category 1. Adverse impacts on humans or the environment? Substance: Class of vaccines derived from excluded methods

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 248-255) finds that any effects would be similar to conventional, non-GMO vaccines. The impact of any environmental contamination will be specific to each individual vaccine and difficult to address for a whole class.
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		This is difficult to address since this review addresses a broad class of materials, but the TR at line 217 finds that GMO vaccines are not expected to persist in the environment any longer than traditional vaccines.
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		Generally any vaccines causing adverse reactions would not be allowed on the market unless risks were mitigated (TR at lines 263-264)
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		X		GMO and conventional vaccines are evaluated for side effects by manufacturers and results are similar (TR at lines 287-290). It is difficult to answer such question for a class as a whole.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		X		As cited above, and it is difficult to answer this except on a case by case basis rather than as a whole class.
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		As cited above, and it is difficult to answer this except on a case by case basis rather than as a whole class
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]		X		Vaccines, both conventional and GMO, are short lived in the environment (TR)

10. Is there any harmful effect on human health? [§6517 c (1)(A)(i); 6517 c(2)(A)i; §6518 m.4]		X		The TR (lines 307-323) finds that all vaccines are evaluated for potential risk to human health risk before being licensed; such risk is minimal. It is difficult to conclusively answer this with reference to an entire class of vaccines.
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: class of vaccines derived from excluded methods

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			All vaccines, both conventional and GMO, are formulated by a chemical process (discussion with manufacturers)
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			All vaccines, both conventional and GMO, are manufactured or extracted from naturally occurring sources (discussion with manufacturers, and TR)
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		X		GMO vaccines are derived from excluded methods, not created by naturally occurring biological processes (TR and discussions with manufacturers.)
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	X		At present conventional vaccines are available for all but 2 diseases, avian and bovine salmonellosis (TR line 416 Table 1.)
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		At present conventional vaccines are available for all but 2 diseases, avian and bovine salmonellosis (TR line 416 Table 1.) In addition there are homeopathic substances available (TR)
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X	X		Depending upon each vaccination on a case by case basis. Management practices might have an influence on whether the substance is necessary.

[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: class of vaccines derived from excluded methods

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		Based on extensive comments received during the formulation of the NOP regulations in 2000 and in response to USDA's questions posed to the public, excluded methods, also known as GMOs, were not considered consistent with an organic production and handling system.
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]	X	X		This would have to be determined on a case by case basis.
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 categories: a. copper and sulfur compounds;		X		
b. toxins derived from bacteria;	X	X		Generally No (discussion with manufacturer), but this would need to be determined on a case by case basis
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		X		

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: vaccines derived from excluded methods**

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.

Livestock Committee Proposal
Expanded narrative on Vaccines derived from Excluded Methods
March 24, 2012

SUMMARY
This recommendation concerns the class of livestock vaccines derived from excluded methods, commonly called GMO vaccines. There are approximately 73 registered animal vaccines, of which 13 are GMO. Only 2 vaccines, Bovine and Avian Salmonellosis, appear to be presently available only as GMO. At present livestock producers use all vaccines and are not required to determine if they are using non-GMO or GMO vaccines. GMO vaccines are not legally allowed in organic production. This recommendation proposes a change which will allow GMO vaccines only in a declared emergency and, further, that at such time producers could use GMO vaccines without losing organic status of livestock. The recommendation also proposes changes to the definition of "emergency treatment program". The entire recommendation applies to vaccines as a class but does not foreclose petitions for individual vaccines or a class of vaccines to treat specific diseases.

I Introduction
At the present time organic livestock producers are allowed to use all vaccines as provided in 205.105 (e) and 205.603 (a)(4). Genetically Modified Organism (GMO) vaccines, also referred to as vaccines derived from "excluded methods" in regulation, are not currently allowed in organic production. The National Organic Progam (NOP) received advice from the USDA General Counsel that GMO vaccines could only be allowed if specifically added to the National List. Currently, GMO vaccines are not on the National List.

II Background
Vaccines are used by a majority of organic livestock producers throughout the various geographic regions of the U.S. The use of vaccines is considered critical to disease prevention. A significant number of organic livestock producers do not routinely use vaccines, especially for smaller poultry flocks and for closed herds.

"All vaccines" includes, de facto, both GMO and non-GMO derived vaccines.

The use of genetic engineering is prohibited in organic production and handling under the NOP regulations. However, on most organic farms the producer does not ask if the vaccine to be administered is GMO or Non-GMO.

Producers are presently not required to ask to document use of GMO vaccines.

Since implementation of the NOP regulations in 2002, certifiers were routinely allowing all vaccines. Thus, in November 2009 the NOSB recommended that if non-GMO vaccines were not commercially available, then a GMO vaccine would be allowed, as practiced at that time.

Nonetheless, consumers continue to assume that all organic products reaching market are Non-GMO in production and handling.

III Relevant Areas of the Rule
Section 6509 (d)(1)(C) of the Organic Food Production Act (OFPA) of 1990, authorizes the use of vaccinations as an allowed healthcare practice in the production of organic livestock.

This authorization was implemented in Section 205.238(a)(6) “Livestock health care practice standard” which requires that “producers must establish and maintain preventive livestock healthcare practices including: …(6) the administration of vaccines and other veterinary biologics”.

In 2002 the NOP implemented Section 205.603(a)(4) “Synthetic substances allowed for use in livestock production.” This section lists without annotation, “Biologics-Vaccines.”

Section 205.105 – “Allowed and prohibited substances, methods and ingredients in organic production and handling,” states, in part, as follows:
“To be sold or labeled as “100% organic”, “organic”, or “made with organic”... the product must be produced and handled without the use of :....(e) Excluded methods, except for vaccines: Provided, that the vaccines are approved in accordance with 205.600(a).”

The phrase “excluded methods” is defined in section 205.2 as:

A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions and 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 positions of genes when achieved by recombinant DNA technology). Such methods do not include traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.

The relevant Section 205.600(a)“Evaluation criteria for allowed and prohibited substances, methods and ingredients” states: “The following criteria will be utilized in the evaluation of substances or ingredients for the organic production and handling sections of the National List: 205.600(a) Synthetic and nonsynthetic substances considered for inclusion on, or deletion from, the National List of allowed and prohibited substances will be evaluated using the criteria specified in the Act (7 U.S.C. 6517 and 6518)”.

A Technical Report (TR), dated November 29, 2011, entitled “ Vaccines Made from Genetically Modified Organisms - Livestock” utilizing the criteria as specified in the Act (7 USC 6517 and 6518) has been submitted to the NOSB.

Thus the NOSB is now in a position to clarify whether the use of GMO vaccines as a class of substances is allowed or prohibited under the requirements stipulated in 205.105(e), and 205.600 (a).

IV Discussion

1. Should the present practice allowing use of all livestock vaccines, whether GMO or Non-GMO, continue?
The current regulation has a provision for a Federal or Sate emergency pest or disease treatment program (section 205.672). Plants and animals treated with a prohibited substance are taken off the market--plants and meat animals may not be sold as organic. Milk animals must wait one year before the milk can be labeled organic. For mammalian brood stock, newborns must be from livestock under continuous organic management from the last third of gestation to be labeled organic. The organic operation does not loose it certification, but the loss of certified organic plants and animals for sale could lead to immediate economic ruin.

Previous NOSB Action in 2009

The text of the Livestock Committee recommendation adopted by the NOSB on November 5 2009 is in italics:

> §205.105 Allowed and prohibited substances, methods, and ingredients in organic production and handling.
>
> To be sold or labeled as "100 percent organic", "organic", or "made with organic" the product must be produced and handled without the use of:
>
> (e) Excluded methods, except for vaccines***, Provided, that, vaccines made from non-excluded methods are used if commercially available.***

The livestock committee summary rationale in 2009 was:

> Previously, vaccines made by excluded methods were to be individually petitioned to the Board for allowance or prohibition for use. In reality since implementation of the Rule, certifiers have routinely allowed all vaccines, since they are used to prevent disease and needless suffering of animals. This recommendation will more closely align what has been occurring in the field since 2002. However, it will actually make it encumbent[sic] upon the producers and certifiers that vaccines made by non-excluded methods are located and used before those made by excluded methods can be used.

NOP 2010 Response to the NOSB 2009 Action

The NOP responded to this NOSB recommendation on September 30, 2010, in part, as follows:

> The preamble to the National Organic Program final rule (FR Vol. 65, No. 246, page 80554) states:
>
> > The Act allows use of animal vaccines in organic livestock production. Given the general prohibition on the use of excluded methods, however, we believe that animal vaccines produced using excluded methods should not be allowed without an explicit consideration of such materials by the NOSB and without an affirmative determination from the NOSB that they meet the criteria for inclusion on the National List. It is for that reason that we have not granted this request of commenters but, rather, provided an opportunity for review of this narrow range of materials produced using excluded methods through the National List process.
>
> The NOP's understanding is that excluded methods are prohibited under Section 205.105(e) *except for* vaccines. Further, this exception applies to vaccines that are produced through excluded methods only if those GMO vaccines are approved according to 205.600(a). Vaccines are listed under 205.603(a)(4) under —Biologics-Vaccines‖. The NOSB has not reviewed vaccines in accordance with 205.600(a). The listing under 205.603(a)(4) of Biologics-Vaccines does not include the allowance of GMO vaccines. The NOP requested a legal review from USDA's Office of General Counsel (OGC) to determine whether vaccines produced through excluded methods are currently allowed under 205.603(a)(4). The OGC opinion supports the position that GMO vaccines are allowed only if they are approved according to 205.600(a).
>
> The NOP recommends that the NOSB review GMO vaccines under the provisions of 205.600(a).

2.If GMO vaccines are allowed ONLY if non-GMO vaccines are unavailable, or commercially unavailable, how can vaccines be identified by GMO content or origin.?

APHIS List
The Animal and Plant Health Inspection Service (APHIS) maintains a periodically updated list of all registered vaccines with coded alpha-numeric annotations that could allow a certifier or a producer to identify which individual vaccines are produced with GMO methods. Most producers are not aware of this list and the coding on the list requires some skill to use properly. In addition, most vaccines are given as combinations of vaccines which makes cross checking with the APHIS list a complex process.

Direct Inquiry
Some large livestock producers, such as Albert Straus of Straus Family Creamery in California, currently take on the responsibility of asking the manufacturer for a letter of non-GMO origin for vaccines. This approach may be less feasible for small producers: will manufacturers want to answer hundreds of inquiries? Also, could a certifier verify the information, and how "current" or up-to-date does the manufacture's letter have to be? Vaccines change on a constant basis to reflect new strains of disease and other factors. These are issues that might be addressed in guidance by the NOP.

Combinations of Vaccines
Because multiple vaccines are often combined into one dosage, a single GMO vaccine could rule out the administration of 6 other non-GMO vaccines, if the non-GMO vaccines were not available in singular or non-GMO formulations. The TR did not identify vaccines that would be unavailable in non-GMO form due to the combination of vaccines.

3. Should GMO vaccines be allowed ONLY in “extraordinary” circumstances?

Relieving economic hardship in the event of emergency treatment programs
The option of allowing GMOs in emergency treatment programs would change current policy. Under current policy, GMO vaccines are not permitted at all, as the NOP outlined. If they were required as part of an emergency treatment program, then organic producers would be penalized by having the affected products taken out of organic status, creating economic hardship beyond the control of the organic livestock producer, but in the furtherance of a larger public policy goal for all livestock producers. Creating an exception to allow GMO vaccines in organic production in cases of an emergency treatment program, and allow livestock to retain their organic status would relieve the economic hardship or the prospect of destroying entire organic herds or flocks if non-GMO vaccines were not located in time.

Use of GMO vaccines if non-GMO vaccines are not commercially available
In the alternative, the proposal put forward by the NOSB in 2009 would allow GMO vaccines if non-GMO vaccines were simply not commercially available. Under this scenario also, there would be no penalty to the organic product. The use of GMO vaccines would be permitted in the absence of either 1) a declared emergency treatment program, or 2) an indication that a specific vaccine was needed.

Commercial Availability
Commercially available also presents some issues because many “off-the-shelf” and prescribed commercially available vaccines are not effective or not as effective as desired because diseases evolve new strains. It is also difficult to tell whether two vaccines, one GMO and one non-GMO, are functionally equivalent for a specific livestock operation.

Autogenous, or customized, vaccines are prepared from microorganisms which have been freshly isolated from the lesion of the animal which is to be treated with it. These vaccines are

not “commercially available’ in the sense that they are already developed and ready for administration for any given livestock population.

Autogenous vaccines do not appear on the APHIS list. They are subject to different USDA licensing requirements. Autogenous vaccine regulations do not require confirmation of 1) efficacy, 2) potency correlated to efficacy; or 3) host-animal safety data submitted to the USDA prior to product licensure and use.

Variances
A variance cannot be granted for a prohibited substance, ingredient, or method (excluded methods). The current regulations contemplate a possible exemption for GMO vaccines from being an excluded method--hence no variance would be needed. However, GMO vaccines would have to be added to the National List, which they currently are not.

4. Should GMO vaccines be prohibited in livestock production and handling?
The Livestock Committee has concluded that at this point in time there is not enough evidence of essential need to allow GMO vaccines as a class of substances for all diseases in livestock production, except in cases of a declared emergency. A declared emergency may emanate from acts of bio-terrorism or from outbreaks of diseases of major significance or foreign animal diseases. Nothing in the Committee recommendation is intended to preclude the possibility of successful future petitions to the NOSB for specific GMO vaccines or for GMO vaccines as a class for specific animal diseases.

The NOSB should recommend policy based on what is consistent with an organic system of production rather than administrative and enforcement exigencies.

A key factor regarding GMO vaccines is: are we making the decision based on the proper considerations. The NOSB is a policy body, not an administrative or enforcement body. The NOP is responsible for administering and enforcing policy related to GMO vaccine use.

It is the NOSB responsibility to consider, among other things, whether the use of GMO vaccines would be consistent with an organic system of production or considered essential to organic production. In general, GMOs are considered “excluded methods” and not consistent with organic production. In addition information in the TR and information received from other sources in the field did not indicate that GMO vaccines were essential to organic production at this time.

Any recommendation providing an exception to the general policy should not be unduly influenced by administrative and marketplace factors such as 1) currently many certifiers and producers do not know which vaccines are derived from excluded methods 2) current public policy chooses not to identify by label which vaccines contain GMOs or are derived from excluded methods, 3) the larger marketplace may not take GMO status into account in deciding how to produce and market vaccines, and 4) speculatively, some future unknown diseases of non-emergency proportions or new strains of diseases may be addressed by manufacturers with GMO only vaccines.

Further, NOSB recommendations should not be limited by current USDA and FDA discretionary policy that does not require labeling of GMO content because GMOs are considered "functionally equivalent" to non-GMOs. It is clear GMOs are not functionally equivalent in the eyes of the consumer in the organic marketplace and in the legal interpretation of NOP

regulations.

Difficulties in enforcement
The Livestock Committee recognizes several administrative factors making it difficult to manage and enforce a non-GMO vaccine policy, including: 1) a lack of access to an easily identified and up-to-date list of which vaccines are of GMO origin, and 2) a lack of access to an easily identified and up-to-date list of the availability of non-GMO vaccines for all livestock diseases. Given that there are approximately 73 APHIS registered animal vaccines (livestock, feral animals and pets) and only 13 (or 18 %) are thought to be livestock GMO vaccines, the construction of a usable list of GMO and non-GMO livestock vaccines is quite possible. The basic data should be in the APHIS list.

In addition, the TR describes the current state of GMO vaccine use in organic production as follows:

> Because organic certifying agents generally do not consider GMO status, no data are available on how many GMO vaccines are being used in organic production at this time.

Determination of Excluded Method
Because the NOP regulations do not use the words genetically modified organism(GMO) or "genetically engineered"(GE), we are concerned with "excluded methods." A method is usually a process rather than a material or product. As such, how do we evaluate excluded methods when looking at vaccines? Are we looking at the entire method of producing a vaccine? Does the method include all of the materials and steps necessary to produce the vaccine? If any of those methods, steps, or materials resulted from excluded methods (such as a GMO produced substrate that does not remain in the final product or is not the "active" ingredient), then do we conclude the vaccine is a GMO--a result of a process that used excluded methods?

From a purely policy perspective, it would seem that any use of excluded methods could be interpreted to mean that a vaccine is of GMO origin. This interpretation would mean that if a vaccine were only grown in a substrate from a GMO product (e.g. corn), it would be classified as a GMO vaccine even though no GMO substance remained in the finished vaccine. It is highly unlikely that the APHIS list would ever be detailed and precise enough to make these distinctions, since APHIS is not tasked with administering or enforcing organic certification. This conclusion could also lead to an unknown GMO status for a large number of vaccines. The committee recommends that NOP guidance specify that the information from the APHIS list of registered vaccines be used to determine GMO or non-GMO status.

Definition of emergency treatment program.
Background

Organic Foods Production Act of 1990 (OFPA)
OFPA 7 U.S.C. 6506 (b)(2) only confers on the Secretary the power to

"provide for reasonable exemptions from specific requirements of this title … on certified organic farms if such farms are subject to a Federal or Sate emergency pest or disease treatment program." (Complete quotation is included below) No mention is made of "local" or "eradication" programs.

Maryland Department of Agriculture

Committee research indicates that Maryland and most states have very broad powers to enforce eradication programs without ever declaring a state of emergency. If the intent of a recommendation for GMO vaccines in organic production were to limit their use to major outbreaks and to diseases of major significance or foreign animal diseases, such as hoof and mouth disease, then it would be appropriate to require a declared state of emergency. Requiring a declared state of emergency would definitely limit the use of GMO vaccines to major events.

In Maryland and other states, the Secretary of Agriculture would have to go the Governor to declare a state of emergency because only the Governor has such authority. In some states the chief agricultural officer may be able to make a declaration of emergency. A local agency would be unlikely to have the authority to declare an emergency, and in Maryland no local agencies have that authority.

The Secretary of Agriculture in Maryland could not recall a case of a vaccine ever being required within the Maryland. However, they have the authority to investigate outbreaks and to require treatment as necessary without declaring an emergency. It is also possible that they could require animals entering the State to have been vaccinated for a specific disease known to be a problem from the livestock's point of origin, although they were not sure that situation had ever occurred.

National Organic Program
The NOP currently administers the emergency treatment program provision in the regulations, responding to declared emergencies by an appropriate State official, and all products which are touched by or which received a prohibited substance are no longer eligible to be sold as organic, although the organic operation did not lose its certification.

It was noted that there is a discrepancy between section 205.672 "Emergency pest or disease treatment" and 205.2 "Definitions—Emergency pest or disease treatment program." This is a potential legal ambiguity. Which provision would be controlling, since they say different things?

It is advisable to change the Definition, section 205.2, "Emergency pest or disease treatment program:" (see language in recommendation section at end of document).

1) to comply with the statutory authority in 7 U.S.C. 6506 (b)(2);

2) to clarify any potential legal ambiguity in the reading of 7 CFR 205.672 "Emergency pest or disease treatment" with 7 CFR 205.2 "Definitions-- Emergency pest or disease treatment program;"

3) to reflect what appears to be the current NOP practice and ;

4) to accurately reflect the intent of the NOSB Livestock Committee recommendation on the use of vaccines derived from excluded methods.

Some central questions not completely addressed by the TR

1)WHAT SPECIFIC DISEASE PROBLEM(S) CAN ONLY BE ADDRESSED WITH A GMO VACCINE?
The TR does not point to a single or narrow group of problem diseases in organic livestock that

are creating hardship and urgently need to be addressed with GMO vaccines. Rather than addressing specific vaccines for specific diseases, we are addressing vaccines as a class of substances used in an organic livestock healthcare program. The TR seems to identify two diseases for which a GMO only vaccine is available: 1) Avian Salmonellosis and 2) Bovine Salmonellosis. For salmonella, improved management practices are often the first line of defense, with vaccination as an option if the disease cannot be controlled by management practices alone. Due to the changeable nature of Salmonella, finding an effective vaccination for a specific herd or flock may be challenging and may require customizing the vaccine.

2)WILL CREATING A GMO EXCEPTION LEAD TO LEGAL AMBIGUITY, PERCEPTIONS OF UNFAIRNESS, OR SUCH FREQUENT USE THAT IT LEADS TO POTENTIAL ABUSE?
The exception(s) created are to be narrowly construed and not used as a precedent for allowing excluded methods (GMOs) elsewhere in organic production or handling, unless specifically authorized, vigorously reviewed by the NOSB and NOP, and subject to public comment.

The intention with regard to organic use of GMO vaccines is that they should be legal, fair, and rare. The Committee feels its recommendation meets these tests.

Legality
The use of GMO vaccines, to the extent allowed in organic in emergency treatment programs, has to be clearly and understandably legal--a producer/consumer/certifier/public agency must be able to read and understand the policy easily and not have it subject to questions that could lead to legal challenges.

Fairness
The GMO exception policy must be fair to accommodate both the organic producer's ideals and livelihood and the organic consumer's expectations.

Rareness
GMO vaccine use in organics should be so rare (i.e. emergency use only). The rarity of GMO use should be an accepted outcome with regard to legality--everyone agrees to the ground rules (Federal vs. State authority, for emergency use, etc) and GMO vaccine use does not lead to abuses.

Additionally, the rarity should be recognized as fair and the rationale for the GMO vaccine use should meet the concerns of both producers and consumers, i.e. all livestock producers, both organic and conventional, must take concerted action in the face of a publicly declared emergency to safeguard livestock production for all concerned.

3)HAS THERE EVER BEEN AN EMERGENCY TREATMENT PROGRAM DECLARED BY THE FEDRAL OR STATE LEVEL IN RECENT MEMORY, AND HAS IT LEAD TO TREATMENT WITH GMO VACCINES?
This is a factual question not addressed by the TR because it was never posed.

4) DOES THE CURRENT REQUIREMENT TO USE NON-GMO VACCINES IN ORGANIC LIVESTOCK PRODUCTION LEAD TO UNACCEPTABLE ANIMAL DISEASE AND SUFFERING?
This is not a question that was explicitly posed or addressed in the TR with regard to organic production. The following information that has some bearing on a response to this question was presented to the committee from the TR and other sources.

Number of GMO vaccines
GMO vaccines became available in the early 1980s. Of the approximately 73 vaccines licensed for use in wild and domesticated animals, 28 are GMO and 13 (about 18%) are given to livestock animals.

Choice of vaccines
In summary, organic producers have choices of non-GMO vaccines in many cases, and only two cases of individual vaccines only available in GMO form were identified in the TR. Combination vaccines were identified as a problem, but often the individual non-GMO components were available, and no specific case was identified when they were not available.

Advantages of GMO vaccines
From the information presented in the TR and other sources, it would appear that GMO vaccines are sometimes, but not always, faster to develop, more quickly targeted to the specific disease, safer and cheaper than their counterparts, and may have advantages for efficacy, lower production costs, better storage and transportation, and ability to track which animals have been vaccinated. In general it was not possible to make broad conclusive generalizations regarding the advantages of GMO vaccines. Non-GMO vaccines generally can more quickly meet Federal registration criteria.

Types and Use of Vaccines
Non-GMO live bacterial vaccines are still used extensively and GMO live bacterial vaccines are still very rare. GM viral vaccines are more prevalent than GM bacterial vaccines, although there are many conventional viral vaccines.

Concerns about GMO vaccines
With bacterial GMO vaccines (which are predominantly administered via the mouth), there are concerns that the engineered bacteria may recombine with natural bacteria in the gastrointestinal tract. Furthermore, it is unclear how long the altered virus/bacteria will remain in the vaccinated animal.

Vaccines manufactured from artificial DNA created by combining several sequences of DNA are not used livestock. DNA from these types of vaccines may integrate into a host's chromosomes and initiate a cancer-initiating event, although results have been negative in experiments thus far. In addition, the modified DNA could theoretically integrate into the sperm or egg cells and be passed on to future generations.

Market for non-GMO vaccines for organic production
While the TR is not explicit about whether organic livestock production is too small to warrant attention from manufacturers to produce non-GMO vaccines, it presents evidence that organic represents a very small percentage of total livestock production. The clear implication is that the organic market does not command enough demand for independent non-GMO vaccine development. Organic poultry production is seen as the largest potential livestock market. Autogenous vaccine development was not specifically addressed.

Findings

1. Section 205.238 (a) (6) requires that producers must establish and maintain preventive healthcare practices, including administration of vaccines and other veterinary biologics, thus to deny use of a vaccine because it is ONLY available as GMO could be construed, incorrectly, by certifying agency as a non-compliance with the Rule.

2. Withholding treatment to an animal to maintain organic status is prohibited. Administering a GMO vaccine would prevent the animal or animal products and some mammalian offspring from being sold as organic.

3. A review of commonly administered livestock vaccines suggests that routine vaccinations are relatively common, and that they tend to be given as combinations of vaccines in single delivery format.

4 A review the USDA's APHIS list of Livestock Vaccines, regulated by the Center for Veterinary Biologics, suggest that there are non-GMO vaccines available for virtually all common potential livestock sicknesses. However there is presently no list which easily allows identification of GMO status.

5. Presently there is no requirement that a producer make inquiries of the veterinarian or pharmaceutical company as to the GMO or recombinant nature of vaccines to be administered.

6. Canada does not allow GMO vaccines (CGSB, 2009)

7. Europe allows GMO vaccines: Council Reg EC No 834/2007, Article 4 , Overall Principles: Organic production shall be based on the following principles: (iii) exclude the use of GMO's and products produced from or by GMO's with the exception of veterinary medicinal products.

8. The WHO, OIE and FAO clarified the difference between GM foods and use of GMO vaccines. With engineered foods the intention is to introduce a new trait into a food; this trait will be present in the food eaten by the consumer. On the other hand, the intention of genetically modified vaccines is to introduce into food animals "a protective immune response by means of an immunogen that is often no longer itself present at the time the animal is slaughtered."

V Recommendations

1. Modify language in 205.238 (6) as follows, change shown in italics.
Administration of vaccines and other veterinary biologics, *provided, vaccines produced with excluded methods, can only be administered in accordance with §205.105(e).*

2. Modify 205.105 (e) as follows: Excluded methods, except for vaccines: Provided*,*

(1) *such vaccines are administered only due to a Federal or State emergency pest or disease treatment program, and*

(2) such vaccines are approved in accordance with §205.600(a);

3. Modify language in 205.603(a)(4) as follows: Biologics—Vaccines*, provided, with regard to vaccines produced with excluded methods, the requirements of 205.105(e) are satisfied*.

4. Change the Definition of "Emergency pest or disease treatment program*"* in section 205.2 with the additions shown in italics.

Emergency pest or disease treatment program. *A mandatory program authorized by a Federal, State or local agency for the purpose of controlling or eradicating a pest or disease, except for a program requiring substances described in section 205.105(e) regarding only vaccines produced with excluded methods, in which case such program is defined as a mandatory treatment program authorized by a declared Federal or State emergency for the purpose of controlling a pest or disease.*

VI Committee Vote on Main Motion: Motion : Nick Maravell

Second : Jean Richardson

Yes 5 No 0 Abstain 0 Recuse 0 Absent 3

Committee Vote on Motion to Amend emergency treatment program: Motion: Colehour Bondera

Second: Calvin Walker

Yes 8 No 0 Abstain 0 Recuse 0 Absent 0

National Organic Standards Board
Livestock Committee
Proposed Discussion Document
March 28, 2012

Introduction

Animal welfare is a basic principle of organic production. As the number of farmers in the United States decline, consumer concerns for farm animal care have increased. There are numerous animal welfare organizations and methods to verify animal welfare. The Livestock Committee wishes to provide guidance that will assist producers and certifiers to improve and assess welfare on farm and assure consumers that animals are well cared for and that the organic community is leading with a focus on continuous improvement.

Background

The United States Congress anticipated the need to elaborate livestock standards in 1990 when the Organic Foods Production Act was passed. The Humane Society of the United States played a central role in advocating for the passage of OFPA. It was understood at that time that animal welfare standards would eventually be developed. Several animal health and welfare practices were described in the Preamble accompanying the NOP Final Rule. An organic livestock farmer must conform to the following list according to the Description of Regulations:

- select species and types of livestock with regard to suitability for site-specific conditions and resistance to prevalent diseases and parasites
- provide a feed ration including vitamins, minerals, protein, and/or amino acids, energy sources, and, for ruminants, fiber.
- establish appropriate housing, pasture conditions and sanitation practices to minimize the occurrence and spread of diseases and parasites.
- maintain animals under conditions which provide for exercise, freedom of movement, and reduction of stress appropriate to the species.
- conduct all physical alterations to promote the animals' welfare and in a manner that minimizes stress and pain.
- establish and maintain livestock living conditions which accommodate the health and natural behavior of the livestock.
- provide access to the outdoors, shade, shelter, exercise areas, fresh air, and direct sunlight suitable to the species, its stage of production, the climate, and the environment.
- provide shelter designed to allow for the natural maintenance, comfort level, and opportunity to exercise appropriate to the species

The NOSB was further tasked in the Preamble with creating species specific guidelines. These were to include specifics on temporary confinement, space requirements, and management guidance. The current Livestock Committee has worked with Temple Grandin, the Livestock Issues Working Group, and other individuals with specific areas of expertise toward completing this task. The Livestock Committee feels that outcome based standards best measure the health and well-being of livestock and will continue to work on those documents. The guidance documents are intended to help the program, certifiers and producers to understand and meet the regulations. These documents were written to enhance the regulations, clarify the expectation for animal welfare on organic farms and minimize the need for increased regulations.

Proposed Materials

The Livestock Committee intends to develop species specific guidance for all species. To date, the Livestock Committee has worked with members of the organic community, certifiers, animal welfare specialists, and previous NOSB members to develop the following four species specific guidance pieces.

Guidance for Assessing Animal Welfare on Organic Bison

Guidance for Assessing Animal Welfare on Organic Poultry Operations

Guidance for Assessing Animal Welfare on Organic Sheep Operations

Committee Vote

Motion: Wendy Fulwider Second: Colehour Bondera

Yes: 8 No: 0 Absent: 0 Abstain: 0 Recuse: 0

Overview of livestock health and conditions:

Extremely thin 1	Frame obvious 2	**Body condition** 3 Good fat cover	Well covered 4	Obese 5

Very clean 1	**Hygiene** 2 Manure stains	Wet or dry manure 3 On legs udder	Extremely dirty 4

Normal 1	**Locomotion** 2 Slightly affected	3 Cannot keep up with herd	Limping 4	Can't bear weight 5

Hock condition 1 May have hair loss	Swelling 2

Number of cows missing patches of hair due to mange or lice	Number of cows with broken tails	Ammonia odor present

Housing type: Milking herd _____Dry cows _____

Heifers _____ Calves _____

Three items done well at this farm:

Three items that may need attention at this farm:

Locomotion Scoring

Score 1 Normal Stands and walks normally. Her back is level. She makes long confident strides.

Score 2 Slightly affected - Stands with flat back and arches when she walks. Gait is slightly off.

Score 3 Cannot keep up with the grazing herd. Stands and walks with an arched back. Makes short strides and favors one or more legs.

Score 4 Lame - Arched back standing and walking. Favoring one or more limbs but can bear some weight on affected limb(s).

Score 5 Severely Lame - Pronounced arching of the back. Reluctant to move, with almost complete weight transfer off the affected limb.

Body Condition Scoring

Score 1 Extremely thin

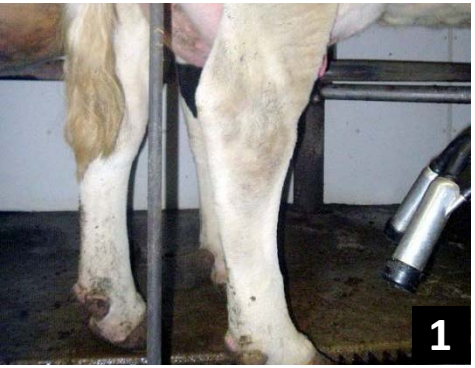
Score 2 Frame obvious

Score 3 Frame and covering well balanced

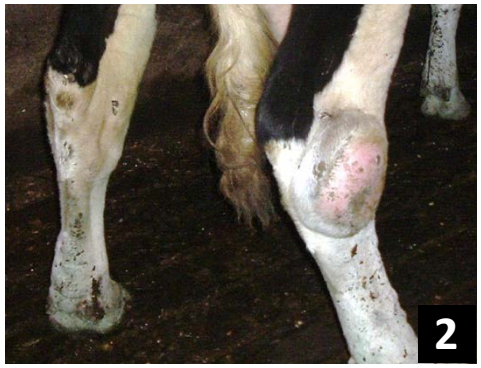
Score 4 Frame not as visible as covering

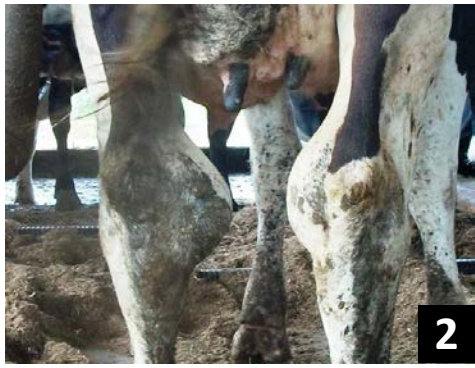
Score 5 Obese

Hock Lesions



Score 1 No damage or may have patches of hair loss on the hock





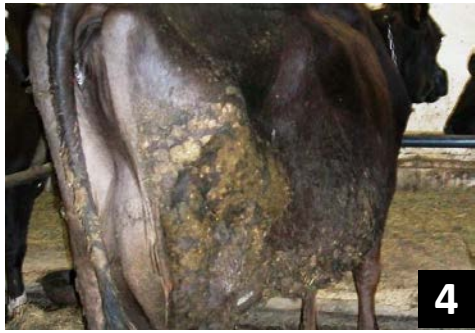
Score 2 Swellings at the hock may be extensive, bleeding, or draining

Cow Cleanliness

Score 1 No manure stains or dried manure attached to cow.

Score 2 Manure stains but no dried manure attached to cow.

Score 3 Dried or wet manure on legs or udder.



Score 4 Cows with wet or dried manure on legs, udder, and ventral abdomen.

National Organic Standards Board
Livestock Committee
Proposed Discussion Document
Guidance for Assessing Animal Welfare on Organic Bison Operations

March 28, 2012

The following is provided to aid in assessment of whether or not the requirements of **§ 205.238-241** are being met sufficiently to demonstrate adequate animal welfare conditions on organic bison operations.

Contents

Introduction

The North American Bison has undergone little modification through domestication or selective breeding. Consequently, it is still possible to compare the characteristics of today's bison to what was historically roaming the North American continent to identify the similarities to what is called typical for this animal.

Because bison remain largely undomesticated, the optimal nutritional requirements, and body conditioning will vary significantly on a seasonal basis. In addition, humane handling procedures are crucial to minimizing stress on the animals. We attempt to address those factors in this guidance document.

Bison Nutrition

General Guidance

Because bison are grazing ruminants with a four chambered stomach for feed digestion, it is easy to assume that the feed requirements for bison are similar to cattle. However, there are some significant differences in the species that require an understanding of the nutritional needs of bison.

A bison's rumen is very structured, ensuring that forage based feeds are retained for long periods of time. Bison retain feed in their digestive system longer than cattle. Longer feed retention means that bison have more time to digest the fiber in feeds such as sedges and grasses. However, when consuming alfalfa or alfalfa brome hay, there is virtually no difference in digestibility between bison and cattle because the fiber level in alfalfa based forages is typically lower than in grasses and sedges. Forages with lower fiber levels do not need to stay in the digestive tract as long to be fully digested as compared to forages with higher fiber levels.

Comparison of total tract retention time and dry matter digestibility of forages between bison and cattle

	Bison	Cattle
Total Tract Retention Time (h)	78.8	68.7
Dry Matter Digestibility (%)		
Sedge hay	64	58
Grass hay	74	62
Alfalfa/brome hay	50	52

SOURCE: Schaefer, A. L., Young, B. A. and Chimwano, A. M. 1978

Bison seem to naturally self-limit intake with less dry matter consumed per unit body weight than bovines. Bison also consume feed in several small meals throughout the day vs. fewer large meals observed in bovines. This habit maintains a more uniform ruminal environment and may contribute to more complete nutrient extraction by bison vs. bovines.

Protein needs to be treated entirely different in bison diets than bovines. Bison recycle nitrogen efficiently, an evolutionary response to very low protein diets from mature grasses during several months of the year. This recycling may cause high blood urea nitrogen levels from modestly high protein levels in the diet. In some areas, many feeds contain protein

levels higher than many bison producers consider optimum making it difficult to formulate diets. Eleven or 12% protein is considered the maximum from anecdotal experience.

Animals given too high protein and feed have produced rapid growth and resulted in horn, hoof and kidney problems that lead to other problems. The over-feeding of high-nutrient feed may lead to lethargic animals that have trouble moving about, and could lead to calving problems. A cow needs nine percent protein just to maintain her condition over winter and try to develop her calf. Less than that amount of protein or severe winter could result in pulling her down physically, and thus would take more time to bring her back into condition prior to breeding. The result is a late calf or no calf the following year.

Forage samples alone would indicate that the forage or feed is sufficient for the bison's need, but examining the water could show that a critical element like copper is tied up by iron and manganese and thus causes a deficiency. Molybdenum, sulfate, nitrate, calcium and sodium can also cause mineral deficiencies due to interference.

Many producers experiencing cold winter climates realize that they need to supplement with more of an energy supplement to insure that their animals have the energy to eat and be active.

Seasonal Considerations

Bison have a strong anabolic/catabolic cycle based on day length (anabolic means build up – catabolic means to tear down). All wildlife species in the northern hemispheres require this cycle for survival. It relies on the animal's ability to have a strong anabolic cycle in spring, summer, and early fall and survive nutritional deficiencies in the winter with the nutrients they stored during the anabolic cycle.

Summer grazing usually meets most bison nutrient requirements so long as carrying capacity is not exceeded and minerals are supplemented. If pasture quality and quantity is low, supplementation with hay or grains may be necessary.

It is not uncommon for bison older than 18 months of age to lose 10 to 15% of pre-winter body weight from December to April. Dry matter intake during the winter period tends to range from 1.4 to 1.8% of body weight depending on forage quality, fiber levels, metabolism and total tract retention time. In the spring to autumn, dry matter intake can be expected to range from 2.0 to 3.0% of body weight.

Nutrition and Bison Reproduction

Heifers/Cows

Bison typically mature at two years of age for both male and females. Some yearling females will breed at one year of age and give birth to a calf as they turn two years of age, but this is an exception. The nutrient intake during the pregnancy of first and second calf heifers is significantly higher than a mature cow, especially during the third trimester. These young females must have sufficient nutrient intake to finish growing their own body in addition to finish growing a calf.

This nutrient demand will continue after the calf is born and taper off some as the calf forages on grass. Her ability to seek sufficient nutrition to grow and come into cycle during the normal breeding period is dependent on the quality of food available to her. The result is that calves are then born 45 days following the spring equinox. Normal practice is to breed females at age two with bulls that are two years or older. If a heifer does not attain sufficient size, it may be difficult for her to stand up under the weight of large mature bulls. A key concern for first and second calf heifers is to grow them to sufficient size prior to being bred to insure pregnancy each year of their lives.

A critical issue affecting pregnancy is the ability of a female to flush on highly nutrient forage or feed. Spring time usually brings forth lush vegetation that is high in nutrients. Having this available to females that have recovered from previous pregnancies will help insure a high calving percentage the following year.

Drought and high temperatures prior to and during the normal rut (breeding) period can have a negative effect on pregnancy rate. Often times, a fall green up will cause a flush in the cows that did not breed or take during the normal rut period, and the result is a late calf the next year.

Bulls

A bison male at 18 months of age will begin a lifetime cycle of winter weight loss followed by spring/summer weight gain. Mature bulls will also lose weight during the breeding season, followed by a final period in the fall to allow for weight gain.

Much like mature females, bison bulls can lose 10 to 15% of their pre-winter body weight from December to April due to a slower metabolism. During this winter period, dry matter intake will range from 1.4 to 1.8% of body weight. If grass hay diets are supplemented with grain, winter weight loss will be minimized, but compensatory gains in the spring and summer will not be as great.

During the breeding season, bulls can potentially lose 10 to 15% of body weight again. Therefore, it may be necessary to provide extra energy through supplementation to prevent too much loss of body condition. Excessive loss of body weight during breeding makes it more difficult for the bulls to regain a proper weight status prior to the start of the wintering period. It is important to ensure the bulls are of adequate body condition prior to the winter and breeding seasons. Much like the cows, thin or poorly conditioned bulls entering the winter will still lose weight and be more expensive to feed.

Body Condition and Scoring

As mentioned above, the idea body condition for bison is based upon the attributes that the animal carries in nature. Survivability and low management requirements are important characteristics.

Even though bison in commercial organic operations are selected for the meat marketplace, it is important that the commercial characteristics (size, yield, etc.) are not accomplished at the expense of sacrificing the unique genetic characteristics that allow

bison to survive in a wide variety of conditions, and to calve easily. In other words, bison producers must avoid an attitude of “screw the hump, and build the rump.”

Bison characteristics are usually developed and identifiable by the time they mature at two years of age. The characteristics become more pronounced with age such as the horn growth and overall size. Calves start exhibiting typical bison characteristics late in their first year of life. The more angular and triangle shaped heads, greater horn bases and growth are found on the males, while the females have smaller horns both in diameter and length.

Female bison heads are longer and narrower than the male. Female horns are typically more curved and possess less circumference and more curvature, with the horn tips curved up and inward and often times pointing at each other.

Typical bison characteristics of the Plains bison, (*Bison, bison, bison*), include long hair under the chin forming a large rounded beard, long hair on the front legs forming leggings, and a raised pelage of usually longer and lighter colored hair located over the front shoulder. The pelage extends along the back to just behind the front shoulders. The raised hump is a distinguishing characteristic as well. Calves should exhibit the development of the hump as they approach one year of age.

Wood bison, normally associated with the Canadian provinces, (*Bison, bison athabascae*) tend to have less developed beard, leggings, and an incomplete pelage. The structure of the Wood bison is taller, more moose-like in form. The incomplete development of the beard, leggings and raised pelage, and the body higher off the ground is an advantage for Wood bison, who have to endure the deep snow and ice conditions found in Canada.

The head and neck projection of the Plains bison favored grazing of the plains in more mild climates. The Plains bison’s highest point is typically found by extending a line straight up the center of the leg to a point on the back. The highest point on a Wood bison is also the hump, but it is typically projected as much as one foot forward from a line extending up the middle of the front leg to a point on the back.

Bulls that have to compete within a herd for breeding rights need to have size, muscling and strength less they be overpowered by a bull having more strength. Bison strength is a result of a wide and deep body conformation. The lack of muscle development may be attributed in part to nutrition and exercise.

Female bison need to have sufficient “spring of rib” (width and depth to provide for room for an unborn calf to grow, develop and be born). Pelvic structure is important. Females possessing a narrow pelvis or a serious drop in the top line in the last foot before the tail could very easily develop calving problems due to restriction of the birthing canal. A high tail head can also produce a problem, due to narrowing of the birthing canal to compensate for the projected high tail head.

Bison are seldom caught in a squeeze to allow a “hands on” body condition scoring system so most of the criteria used to assess the animal are visual clues.
A body condition score (BCS) of 1 indicates that the animal is very thin. A BCS of 5 indicates that it is very fat. Alberta Agriculture has developed a comprehensive guide for body conditioning scoring for bison. The table below is excerpted from that guide. The entire guide is available at:
http://www1.agric.gov.ab.ca/$department/deptdocs.nsf/all/agdex9622/$FILE/bcs-bison.pdf. The guide can also be obtained through the National Bison Association at www.bisoncentral.com.

BODY CONDITION SCORING GUIDE FOR BISON

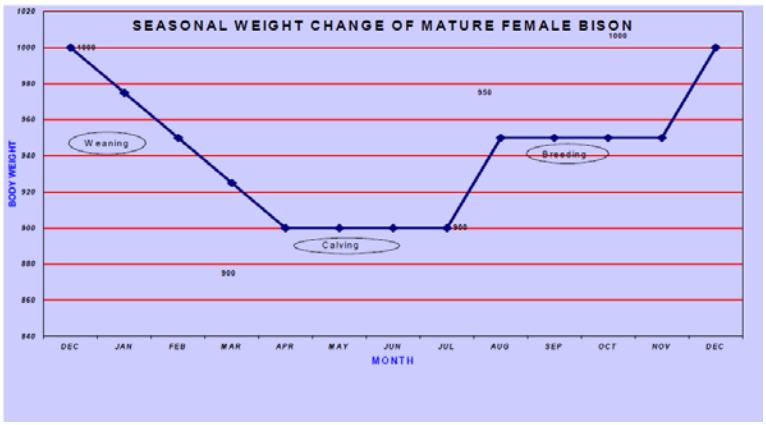
This table can be used to score bison in the field.

BCS	RIBS	SPINE (backbone)	HIP BONE	TAIL HEAD	HUMP
1 very thin	prominent in summer; many ribs visible; in winter, visible but less distinct	very sharp; angle of muscle is steep	prominent and edges are very sharp; rump muscles are caved in	devoid of fat; deep sunken depressions on either side of the tailhead; no fat palpable if bison is in a squeeze	sharp topline; narrow with flat sides when viewed from the front; sharp contrast between the hump and shoulder when viewed from the side
2 moderately thin	some ribs visible in summer and winter	evident but not sharp; angle of muscle is steep	readily seen and edges are sharp; rump muscles cave in slightly	sunken depressions on both sides of the tailhead; small amount of fat palpable if bison is in a squeeze	hump is narrow but not sharp; sides are flat when viewed from the front; distinct contrast between the hump and the shoulder
3 moderate	may be visible in summer but not sharp or distinct; edges round and covered in flesh; not visible in winter	not prominent but can be seen; angle of the muscle has a moderate slope similar to the roof of a tent	visible but not sharp; rump muscles are flat and angular	slight hollowing on either side of the tailhead; some fat palpable if bison is in a squeeze	well developed but not bulging; noticeable distinction between the hump and shoulder
4 moderately fat	may be visible in summer but not sharp or distinct; edges round and covered in flesh; not visible in winter	not readily seen; angle of the muscle has a gentle slope	barely visible; muscles are full but not bulging	slight depression in bulls and no depression in cows	full hump when viewed from the front but not round and bulging; little distinction between the hump and shoulder when viewed from the side.
5 very fat	not visible in winter or summer; covered in fat	not visible and is buried in fat; angle of muscle has little slope and is flat	covered in fat and is not seen; rump is rounded out and full	no depression (bulls) or bulging with fat (cows) on both sides of the tailhead	thick with rounded top when viewed from the front; blends into the should when viewed from the side

Source: Alberta Agriculture, "What's the Score; Bison"
http://www1.agric.gov.ab.ca/$department/deptdocs.nsf/all/agdex9622/$FILE/bcs-bison.pdf

Optimal body condition for bison varies with the seasonal weight fluctuations of the animals.

For example, the weight of mature females will vary up to 15% throughout the year. The animals' typically achieve top weight in the late fall as they graze to store fat to provide energy for both mother and unborn calf to overwinter. The females will lose up to 100 lbs. from December to April, when calving season typically begins.



Source: USDA NRCS Grazing Lands Technology Institute

The chart at right illustrates a typical weight change for mature female bison.

Most people aim to have their bison fat in the fall so that they do not require as much feed over the winter. Most experienced producers aim to have their bison lean in the spring because excess fat may lead to calving problems.

By the beginning of breeding season, the cows should be back to a moderate to good body condition to ensure optimal conceptions rates.

The best indication of overall bison health and condition throughout the season is the hair. Healthy animals have a good hair coat that is full of life that may give a producer an indication of proper nutrition.

TIME OF YEAR	IDEAL SCORE	RANGE
November	4	3-4+
April	2+	2-3
July	3+	3-3+

Bison Health

Bison are not cattle. Differences include the age to breeding (2.5 years), nutritional requirements over winter, nutrition for slaughter animals, social structure, and longevity. Bison have a relatively good resistance to many pathogens that affect cattle.

The two primary factors affecting the health of bison are environmental/nutritional considerations, and chronic stress. Paying attention to these two areas is critical

because typical livestock therapeutic drugs are not as effective in bison as in cattle. In fact, one saying in the bison business is: “A sick bison is a dead bison.”
Because bison still carry the prey/predator instinct, they will mask a sickness until seriously ill (why let the predators know your sick?). At that point, antibiotics and other therapeutic remedies will have only limited efficacy. In addition, the added stress induced to administer the treatment is so great that it often pushes the animal over the edge. This stress can be effectively eliminated by using one of the modern air-powered dart guns.

Poor environmental and feed conditions will weaken the animal’s natural immune system, and increase susceptibility for disease. A successful organic systems plan for bison must focus heavily on the ecosystem and developing systems that will provide optimal nourishment for the bison while sustaining the natural environment.

Chronic stress will have the same effect as more environmental and nutritional conditions. Bison can readily handle the acute stress that comes from a short-term perceived threat. That is the “fight or flight” response to a stimulus. They can fight or run from grizzlies or humans and when all threats are passed, go back to grazing and the adrenalin and steroid levels return to normal. However, they react poorly to extended or continuous (chronic) stress. That stress can be minimized through humane handling procedures (discussed later).

Pathogens

Bison have a strong resistance to many pathogens prevalent in other livestock. Much of this resistance is the result of the “bottleneck” that the species passed through roughly 110 years ago.

In the 1850’s, the bison population was estimated to be somewhere between 30 and 60 million animals. The domesticated livestock species introduced to the West allowed the pathogens these species carried to adapt to these new and different species. BVD, IBR, PI3, BRSV, TB, Johne’s, mycoplasma, leptosirosis, clostridia, Staph, Strep, internal and external parasites and probably pasteurella found a plethora of new ways to reproduce and spread their DNA (genes) to the demise of these native ungulates.

In the late 1800’s, bison were driven to the brink of extinction because of market hunting, war tactics against the Native Americans, and because of the introduced pathogens. Fewer than 1,000 bison survived this onslaught. The surviving animals were those bison that had a genetic resistance to these new pathogens. Testing of wild ungulate species has been undertaken for the past several decades across the western states. All wild populations show exposure to these introduced pathogens without large detrimental effects - yet these same pathogens remain of utmost importance to the livestock industry.

Today, the primary diseases affecting bison are Bovine TB, brucellosis, Bovine Virus Diarrhea (BVD) and Malignant Catarrhal Fever (MCF).

Bovine Tuberculosis (TB)

Bovine Tuberculosis (TB) is a slow, progressive bacterial disease that is difficult to diagnose in the early stages. As the disease progresses, animals may exhibit emaciation, lethargy, weakness, anorexia, low-grade fever, and pneumonia with a chronic, moist cough. It usually is transmitted through contact with respiratory secretions from an infected animal. TB is a zoonotic disease meaning it can be transferred to other species, including man.

Free-ranging and privately owned bison in the U.S. have been free of TB for several decades. TB testing in bison has proven to be effective in diagnosing infected animals. If you are buying animals to start or augment your herd, have the bison over 12 months old tested. Many states are TB free and testing is not required, but as a precautionary measure require TB testing before purchasing.

Brucellosis

Brucellosis is a disease that has strong regulatory and economic guidelines for all states. A majority of states have been brucellosis free in livestock for many years.

The notable exceptions are the states that border Yellowstone National Park. State and federal regulatory agencies consider the Greater Yellowstone Area (GYA) an area of interaction with these wildlife species the last nidus of infection in the U.S. Brucellosis was introduced into bison and elk in the early 20th century. Once the organism was in these wildlife populations it became problematic to control. To this day 20 to 40 percent of the bison and elk in the GYA have been proven to harbor titers from exposure or infection.

Abortion is the most obvious indication of the disease in a herd. Brucellosis is a disease not spread from cow to cow, but from a birthing or abortive event where the abortive event including the aborted, stillborn, newborn calf and afterbirth are exposed to other animals. There are several tests to determine if bison are infected or exposed. These tests are, for the most part, accurate. There are cross-reactions with other organisms that can create suspects in your bison. Regulators are working on being able to identify these other organisms and incorporate them in the battery of tests for brucellosis "suspect" bison.

Calfhood vaccination for brucellosis (Bang's vaccinations) is not mandatory in many states. The vaccine (RB51) is safe for use in bison. It is not as protective against abortion or infection as in cattle, but does offer limited protection. Brucellosis is also a zoonotic disease and can be transmitted to other species including man.

Bovine Virus Diarrhea (BVD)

Anywhere in the world there are cattle, there is Bovine Virus Diarrhea (BVD). This worldwide distribution makes this disease important to cattle producers. BVD is a complicated disease to discuss as it can result in a wide variety of disease problems from very mild to very severe. BVD can be one of the most devastating diseases cattle

encounter and one of the hardest to get rid of when it attacks a herd. The viruses that cause BVD have been grouped into two genotypes, Type I and Type II. The disease syndrome caused by the two genotypes is basically the same. However, disease caused by Type II infection is often more severe in cattle. The various disease syndromes noted in cattle infected with BVD virus are mainly attributed to the age of the animal when it became infected and to certain characteristics of the virus involved.

As mentioned earlier, bison appear to be resistant to clinical manifestations from exposure. BVD has been incriminated in losses of bison placed in feedlots in conjunction with cattle. Vaccinations for BVD Type I and Type II are effective in preventing the disease in bison. I have never seen the disease in free-ranging or any captive herd.

Malignant Catarrhal Fever (MCF)

Malignant Catarrhal Fever (MCF) is a generally fatal disease of cattle, bison, true buffalo species, and deer. It is caused by viruses belonging to the Herpesvirus family. MCF occurs worldwide and is a serious problem, particularly for bison in the United States and Canada.

MCF in bison is caused by a virus called ovine herpesvirus-2 (OvHV-2). Most infections are characterized by depression, separation from the rest of the herd, loss of appetite, and in many bloody diarrhea. Unlike MCF in cattle, discharge from the eyes and nasal passages of affected bison is minimal. Animals develop a fever and may pass bloody urine. The clinical course is generally 1-7 days. Most animals die within three days of developing clinical signs. There is no effective treatment for MCF in bison. Bison older than six months, particularly if stressed by bad weather, transportation and handling are the most susceptible to infection. Large outbreaks occur in feedlots, where stress due to crowding is likely.

Studies of field outbreaks strongly suggest that sheep infected with OvHV-2 are the principal source of MCF outbreaks in bison. A strong association between outbreaks in bison and recent exposure to sheep has been documented repeatedly since 1929. In some outbreaks, however, no sheep were in the vicinity immediately prior to the first case being identified. There is no evidence that transmission occurs horizontally from one bison to another. Currently there is a study supported in part by the National Bison Association to establish whether bison-to-bison transmission is a factor in natural outbreaks.

Internal parasites

It is necessary for special attention to be given to managing internal parasites on organic bison operations. Each parasite's life cycle is different and many cycles can be interrupted by changes in management. Sometimes small changes in the way the producer pastures or feed bison may slow or stop the future spread of the parasite based on the available facilities.

If breed selection, pasture management, supplements and allowed treatments are not successful in keeping sheep parasite loads from impacting well-being, individual animals need to be given conventional treatments.

External Parasites

Ticks and lice have been identified on bison and could potentially be detrimental. Bison have a thicker hair coat and identification of lice in bison is rare. Ticks have been found on bison around the tail head. In many areas where elk and deer are infested with ticks, bison sharing the same habitat are tick free.

Physical Alterations

Consistent with the low-management approach to bison, bulls are not castrated. Nor is there any need to dehorn bison.

Bison Handling

The primary objective of any handling program is to reduce stress on the animals while assuring the safety of handlers. A bison organic systems plan must discuss how the producer will handle or move bison; how they manage them on range; how they confine and feed them; as well as how they are worked in the corral.

It is important to recognize that bison are an extremely social animal with strong matriarchal divisions. Establishing a herd with the correct social balance, and the ability for animals to express their natural behavior, is the first step in reducing stress.

Bison have a very intact social structure that has definite spacing requirements between individuals and family groups. This spacing requirement may be different for different sexes and ages of animals throughout various times of the year. Herds that generate their own replacements from offspring will develop family groups between related individuals.

The pasture environment includes the size and shape of the pastures, forage quantities and qualities available, watering sources, spatial requirements for individuals and/or family groups as well as a myriad of other considerations. Social stress will become a factor if pasture size is too small to give adequate spatial requirements for individuals or family groups for large herds. This causes discontent and disharmony within the herd, causing animals to breach fences and become difficult to handle.

Bulls will separate from the herds after breeding and only young bulls are allowed to stay with the cows and calves. Post-breeding, the bulls have been nutritionally and physically stressed and should be checked for wounds or other forms of trauma.

Corrals

Corrals and working facilities should be designed to minimize the stress on animals, and to facilitate the ability of handlers to gently apply and release pressure. The amount of space allowed for each individual animal depends upon the amount of time that the animal will be maintained in the corral. When animals are introduced into a new herd, is advisable to house those animals in the corral for several days so that the animal s can adjust to their new environment. The producer should allow a minimum of 250 sq. /ft. (preferably 400 sq. ft.) per adult animal in this type of confined situation.

Never place just one bison in a corral or pasture for extended periods. Because they are extremely social, they will experience chronic stress when isolated from the herd.

When handling bison, the producer should strive for a gentle "dance" of applying pressure, the animal moving away from the pressure and then releasing the pressure. The fact that we move into an animal's flight zone giving it pressure and when it moves away from us, we release the pressure by either not moving with them in the same direction (by stopping) or we move in a different direction. This sets up a positive cause and effect relationship – that is we get into their flight zone putting pressure on them, and they, by moving away from us get released from the pressure.

The National Bison Association—in cooperation with Dr. Temple Grandin of Colorado State University—developed has developed a bison welfare audit form to measure several areas of working bison in the corral. That audit form is included as an attachment at the end of the Guidance Document.

Inside housing is rarely used for bison. These animals are adapted for extreme weather conditions in the outdoors. Bringing the animals inside actually increases stress.

Calving

Human interaction with calving bison should be held to a minimum. Because bison have not been bred to produce calves larger than nature intended, cows rarely need assistance in calving.

One of the most important things a bison cow needs at calving time is peace. There is no fixed rule regarding amount of space a calving bison cow needs. However, the producer can judge that space by monitoring the cow's behavior: If she changes her behavior with the producer's presence (such as standing up, running off or her labor arrests) she needs more space. If the other bison pester her and she cannot get away, then she needs more room.

Nature also needs the cow to be leaner to give birth effectively. A fat bison cow will have trouble giving birth, and the calf from such a cow will likely be too big and too hard to birth.

Reference Material:

Alberta Agriculture (2007) "What's the Score: Bison" Body Condition Scoring Guide.

Anderson, Vern PhD (____) “perspectives on Nutritional Management of Bison Bulls Fed for Meat, Carrington Research Extension Center, North Dakota State University.

Feist, Murray (2000)”Basic Nutrition of Bison,” Saskatchewan Agriculture, Agriculture Knowledge Centre, Saskatoon, Saskatchewan, CA

National Bison Association (2010) The Bison Producers’ Handbook, A Complete Guide to Production and Marketing, Westminster, CO.

USDA NRCS (2006) “Bison Body Condition.” Grazing Lands Technology Institute, Fort Worth, TX

Attachment -- Bison Welfare Audit

The National Bison Association—in cooperation with Dr. Temple Grandin of Colorado State University—developed the following bison welfare audit to measure several areas of working bison in the corral.

Bison Welfare Audit

ranch _____ auditor _____ date _____

class of animals_____ time of day _____ total time_____

(score 50 consecutive head - score each animal individually - repeat audit as necessary)

a) ELECTRIC PROD usage ---- Circle number if prod is USED --- Slash otherwise

(The goal is to not carry a Hot-Shot in hand - even a touch without the shock counts as usage.)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50

note where usage took place-

b) COLLISION with HEAD GATE ---- Circle number IF HARD HIT occurred --- Slash otherwise

(use your best judgment here - If the bison hits hard enough to cause a bad headache, count it)

(moving further from the chute, or enclosing the sides and/or front of the chute are common solutions)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50

c) CHUTE EXIT SPEED ---- Circle number if the bison FELL exiting the chute --- Slash otherwise

(a rubber mat for footing, or a visual barrier in front of the chute will help this problem)

(a knee hitting the ground, or worse, constitutes a fall)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50

d) INJURY ---- Circle number, if at any time, recent injuries are apparent --- slash otherwise

(broken legs, broken horns, broken ribs, puncture wounds, etc.)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50

b) CROWDING ---- Circle number if any bison climbs on another --- slash otherwise

(position in the stack does not matter, count all involved; also include bison that turn over backwards)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50

note where crowding occurred -

Questions: (to assist in improvement - check appropriate box)	yes	no	?
1) Bison were gathered from the pasture into a holding area at a slow pace			
2) Bison were moved into the corral system at a reasonably slow pace			
3) The bison were generally relaxed while in the corral system before processing			
4) Bison flowed through the corral system to the tub smoothly with minimal effort			
5) Personnel moved slowly without making excessive noise (yelling, slamming gates, etc.)			
6) Bison were moved easily through the corral with one or two people			
7) Post processing, bison receive ample space, water, and feed			
8) Weaning pens have adequate space, water and bunks, and dust is minimal			
9) Panting was observed in some animals in the corral			
10) Dust was a problem during processing			
11) Excessive poking, beating on, or multiple electric prod use on animals occurred			
12) Old bulls were a problem when gathering and/or processing			
13) Too many serious bison injuries occur during processing			
14) The corral system needs significant modifications			

Additional comments:

Committee vote:

Motion: Wendy Fulwider Second: Colehour Bondera

Yes: 8 No: 0 Absent: 0 Abstain: 0 Recuse: 0

National Organic Standards Board
Livestock Committee
Proposed Discussion Document

March 28, 2012

Guidance for Assessing Animal Welfare on Organic Poultry Operations

The following is provided to aid in assessment of whether or not the requirements of **§ 205.238-241** are being met sufficiently to demonstrate adequate animal welfare conditions on organic poultry operations. In addition, this document provides further guidance to producers for improving poultry welfare. The internationally recognized "five freedoms" (freedom from hunger, thirst and malnutrition; freedom from fear and distress; freedom from physical and thermal discomfort; freedom from pain, injury and disease; and freedom to express normal patterns of behavior) promulgated by the Farm Animal Welfare Council are a useful framework for considering animal welfare.

Nutritional requirements

Poultry must be fed a wholesome diet that meets their nutritional needs and promotes optimal health. Feed should be formulated to meet or exceed the National Research Council's *Nutrient Requirements of Poultry,* and adjusted with bird age and stage of production. Feed and water should be palatable and free from contaminants. Unless using a commercially prepared complete feed, laying hens must have access to a course calcium source, such as ground limestone. Water should be fresh, potable, and clean. Feed and water delivery systems should be checked daily and kept clean and in good working order. Birds must be provided with feed on a daily basis and water should be available continuously, with the rare exception of withholding for medical treatment under the advice of a veterinarian.

There should be enough feed and water space to prevent competition between birds. In double sided liner feed track, there should be at least 2 inches of feed space per bird, and 4 inches per bird for single sided feed track. Circular feeders should provide at least 1.5 inches of feeding space per bird.

Adjust the height of drinkers for easy access at each bird age and so that droppings do not fall into the water supply. There should be at least 1 bell-type drinker for every 100 hens and 1 nipple drinker per 12 hens. In small flocks, there should be a minimum of two drinkers.

Physical alterations

Management methods should be implemented to reduce feather pecking and cannibalism (see "preventing injurious pecking" below). If these management strategies fail, therapeutic beak trimming using the infrared laser method should be considered for subsequent flocks. This amputation must be performed on chicks no later than 10 days of age, and is commonly carried out at the hatchery.

While not pain-free, infrared laser beak trimming is superior to the conventional hot blade trimming in that open wounds are eliminated and the method is more precise, minimizing error and inconsistency. It also leaves a greater proportion of the beak intact.[1]

With the exception of toe trimming of turkey poults at the hatchery using infrared laser, other alterations including de-snooding, caponization, dubbing and toe clipping of birds are not permitted.

Force molting

Forced molting by feed withdrawal is not permitted under the National Organic Program, as it causes hunger and distress. If force molting is practiced, a molt ration should be supplied that is palatable and acceptable to the birds. A molt diet is acceptable to the birds if, on average, the total amount of feed consumed per day does not differ during the molting and non-molting period. Flocks should be carefully monitored during a molt, and individual hens that are not faring well should be separated into a designated sick pen and provided with a non-molt diet. Water should never be withheld for molting purposes.

Poultry health

Poultry should be monitored for signs of stress and disease. Birds should have a healthy body condition, have good feather cover for their stage of life, and no more than 2% should have poor hygiene, lesions or other injuries. Sick or injured birds must be treated without delay or, if suffering and unlikely to recover, euthanized humanely. Producers must not withhold medical treatment from a sick animal in an effort to preserve its organic status.

Animal health plan

All poultry farms should draft and follow an animal health plan that covers the specific circumstances unique to each farm. The plan should include, at a minimum, the disease prevention strategy (such as vaccination schedules and biosecurity protocols), contingency plans for emergency situations (including failure of the power or water supply), predator exclusion steps, veterinary contacts and emergency euthanasia procedures.

Sick pens

A designated area for the treatment of injured or moribund birds should be prepared to aid recovery, by preventing competition between birds and allowing a greater level of individual care. Sick pens should be arranged for the comfort and safety of the birds during convalescence. Feed and water must be provided, with the rare exception of withholding for medical treatment under the advice of a veterinarian.

Lameness

Broiler chickens, turkeys and ducks are prone to leg problems, including angular deformities, tibial dyschondroplasia (TD), and in severe cases, ruptured tendons. These may manifest as lameness or more severe mobility impairment.

Gait scoring is a tool that can be used to assess the degree of lameness in a broiler chicken flock.[2,3,4] Randomly score 100 birds individually by viewing their walking ability using the following scale:

Score 0. No detectable gait impairment
Score 1. Slight gait defect. Wobbling or uneven gait.
Score 2. Gait abnormality. Bird has impairment, but will move away from handler when approached.

Score 3. Gait abnormality that impairs function. Bird has a limp, jerky or unsteady gait and moves away from the observer when approached, but squats again within 15 seconds. Bird prefers to squat when not coerced by handler.
Score 4. Severe gait defect. Bird remains sitting when approached or nudged, but can stand or walk when placed in a standing position by a handler.
Score 5. The bird is completely lame and cannot walk. The bird may shuffle along on its hocks.

Gait score tends to worsen as birds age.[5] Birds that are suffering or are too crippled to reach feed and water should be humanely euthanized. Birds at gait score 3 and above are probably experiencing pain,[6,7] so ideally no birds should reach this level. However, a reasonable place to set the target for lameness is that 95% of the birds should be gait score 2 or less at seven weeks of age or older.

Broiler chickens, turkeys and ducks are also prone to contact dermatitis. When heavy birds spend excessive time lying down in wet or soiled litter, they are prone to skin lesions on the feet, legs and breast.[8, 9,10] Focal ulcerative dermatitis is small skin lesions (commonly called "breast buttons") that develop on the keel bone of turkeys.[11] A reasonable place to set target levels is that no more than 5% of birds should show hock burn, breast blisters or foot pad dermatitis.

Additional producer guidance on preventing leg problems

While dietary deficiencies are one factor that can lead to skeletal deformities,[12] genetic selection for rapid early growth rate is the major contributing factor. Rapid growth is also implicated in metabolic disorders, including ascites and Sudden Death Syndrome.[13] Some commercial broiler crosses are more susceptible to leg problems than others,[14] but slow growing broiler strains are generally less prone to these weaknesses. They are also less prone to heart and circulatory problems.[15] The use of slow growing breeds is therefore recommended. Broiler growth should be limited to no more than 45g per day and should be achieved without feed restriction.

Other factors that can improve gait score include: increasing the daily period of darkness, lowering the stocking density, and adding whole wheat to an otherwise balanced diet. Increasing the daily period of darkness allows chickens more time to rest and less time to feed. Feeding whole wheat is thought to be effective though slowing the rate of digestion. Both of these interventions work through reducing growth rate.[16] The reason that higher stocking densities can lead to lameness is more complex, involving both lack of room available for exercise and movement, as well as factors such as additional ammonia and litter moisture.[17,18,19]

Additional producer guidance on preventing dermatitis

Dermatitis lesions are painful and create a gateway for bacterial infection. Avoid them by preventing wet, sticky, or compact litter. Use bedding with good moisture holding capacity, such as wood shavings, and keep litter dry (but not dusty), with good ventilation. Drinkers should be monitored to ensure they are not spilling over and causing wet areas in the litter. Water nipples with drip cups can reduce water spillage.[20] Moisture and temperature of the

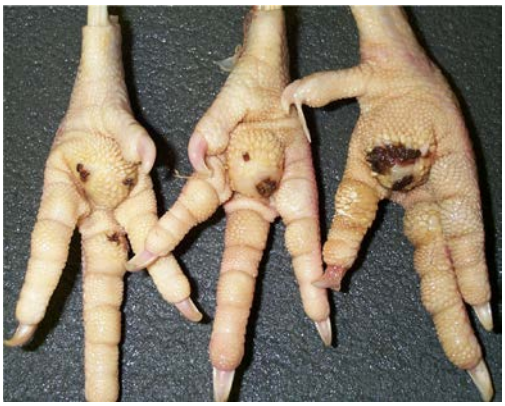
litter increase with stocking density, so if these variables become problematic, it may be necessary to raise fewer birds in the allotted space.[21] Manually turning the litter can help. Floor heating systems have also been found to improve litter quality.[22]

Conversely, well-managed litter is a soft substrate, while outdoor environments can cause abrasion and foot-pad dermatitis if not carefully managed.[23] Birds should be kept on cushioned, dry, clean surfaces outdoors. Rotate or move birds onto fresh pasture often enough to prevent the build up of droppings and damage to the protective vegetative cover.

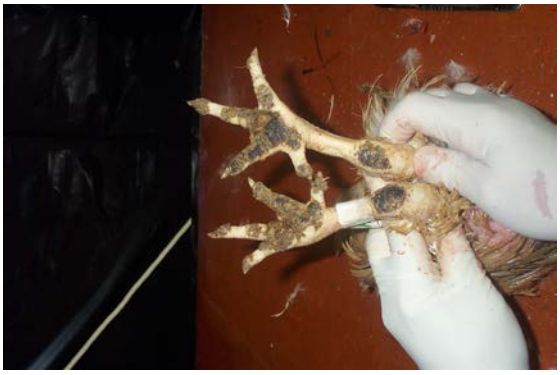
Feed composition affects the consistency and composition of bird droppings, and is therefore a factor influencing irritant qualities of litter. Protein, fat and salt content can all affect the levels of contact dermatitis, as can the source and type of raw ingredients. Within the limits of meeting nutritional requirements, adjustments to the diet may help improve litter quality.[24]

For ducks, bell-type drinkers and open water troughs have been correlated with low levels of foot pad dermatitis. Conversely, foot pad dermatitis tends to worsen in houses with nipple drinkers. There is also evidence that increasing relative humidity and ammonia levels are associated with foot pad dermatitis of ducks.[25]

The health status of the flock will also affect the prevalence of contact dermatitis. Intestinal parasites, infectious disease, and poor feed quality can cause diarrhea, which will negatively impact litter friability (looseness and dryness). Prevent coccidiosis and other enteric diseases and feed good quality feed. Also strive to reduce leg problems, as lame birds will sit for longer periods of time in contact with litter.[26]



Varying degrees of foot pad dermatitis on the feet of turkeys



Foot pad dermatitis and hock burns on a broiler chicken

Disease

Disease incidence is a welfare indicator. Respiratory disease may indicate poor air quality. Incidence of internal parasites can indicate management issues such as lack of sanitation and failure to rotate outdoor areas often enough.

Poultry houses must be cleaned out completely between flocks if there have been adverse health issues with the previous flock; in other cases, the addition of a clean layer of litter will help maintain a sanitary environment.

If there is a documented occurrence of a disease outbreak in the region or relevant migratory pathway, or state or federal advisory order to confine birds, then poultry must be kept indoors to reduce the likelihood of pathogen transmission.

Any dead birds must be removed daily and disposed of in accordance with state and local laws.

Additional producer guidance on management of disease risk

Disease risk should be managed by using multiple approaches, including attention to outdoor range area, good litter management indoors, adherence to an effective biosecurity plan and ensuring clean, hygienic facilities.

Overcrowded and unsanitary outdoor environments are a disease hazard. Providing a rest period in-between flocks reduces the buildup of infectious organisms and allows the regeneration of vegetation and soil. Where stocking density is high, the environmental pathogen load may be correspondingly heavy, and bird-to-bird contact will be more frequent. Providing as much space as possible is therefore important, and the stocking density guidelines set out in the organic rule are minimum space allowances—where conditions permit, the aim should be to lower stocking densities and provide as much space as possible, while balancing freedom of movement with safety of the flock, including protection from predators.

Disease risk can be reduced in barn housing by removing droppings (e.g., via a belt in aviary systems, for example) or by preventing birds from accessing heavily soiled areas (e.g., by

placing drinkers on a raised, slatted platform above a manure pit). Contact with droppings—exacerbated by high stocking density and wet, cool conditions—is a risk factor for enteric disease.[27] Litter that "stops working", leaking drinkers, and an inadequate ventilation system (to remove water vapor) may all increase disease risk.[28,29] Maintain litter in friable condition.[30,31] Introduce only healthy young birds from genetic lines resistant to intestinal parasites.[32]

The build up of parasites around the barn can be avoided with the use of mobile housing,[33] pasture rotation, reduced stocking density, and by using land with good drainage.[34,35] Other methods that are helpful include regularly mowing or grazing to keep vegetation short on pasture, and removing heavily contaminated soil around the barn before introducing a new flock.[36] Gravel around the outside of permanent housing structures, by the exits where birds tend to congregate, can prevent muddy conditions in wet weather and provide additional drainage.

Biosecurity is a strategic plan to prevent the introduction of harmful pathogens. A good biosecurity plan will minimize disease risks and protect flocks. To prevent the spread of disease, limit movement between flocks and outside visitors. Always start with the youngest birds on the farm when doing daily chores and inspections to avoid carrying pathogens from older flocks to younger flocks. Microorganisms, such as coccidiosis for example, can be spread on vehicles and equipment, so designate specific tools and equipment for each poultry house or farm area. Transport crates should be cleaned between uses. Visitors should not enter a poultry farm if they have recently visited other flocks, unless they wear protective, disposable outerwear at both locations and ideally change clothes and shoes and shower between farms.

Mortality rates (deaths, culls)
Mortality rate is a key indicator of poultry welfare. Low mortality is also important for the economic viability of a poultry or egg production enterprise. A reasonable place to set the target for mortality is 3-5%. Birds must be protected from predators.

Additional producer guidance on lowering mortality rates

A low mortality rate is the hallmark of a well-managed poultry farm. Mortality spikes can be caused by a number of different problems, including disease outbreaks, cannibalism, and excessive losses due to predation. It is vital that producers take steps to prevent each of these outcomes, as they are all serious welfare and economic problems.

When poultry are given outdoor access, they become targets for many types of predators including coyotes, opossums, hawks, owls, and domestic dogs, to name a few. Predation is a welfare issue, as birds may suffer when attacked, are not necessarily killed quickly, and flocks can become fearful and reluctant to use outdoor areas if they are threatened by repeated attacks. To protect free-range flocks from nocturnal predators, birds must be secured in a fully enclosed coop, barn, mobile chicken house or other safe facility at night, *without fail*. Depending on the predator pressure at individual farm sites, further steps may be necessary; perimeter fences can be dug deep in the ground to prevent predators from digging underneath, and an overhang at the top of the fence will help prevent animals from climbing over. Electric fencing can further discourage ground predators, and overhead

netting may be necessary to protect hens from aerial predators. Do not permit repeated heavy losses.

Preventing injurious pecking

Injurious pecking, including feather pecking and cannibalism should be managed so that severe outbreaks do not occur.

Additional producer guidance on management of injurious pecking

Feather pecking and cannibalism are common behavioral abnormalities of poultry, usually most problematic in large flocks of laying hens, but also sometimes seen in other poultry such as turkeys, ducks and pheasants. Severe feather pecking can lead to denuded plumage and eventually to cannibalism.[37,38] Outbreaks of cannibalism are unpredictable, and once they begin, are very difficult to stop. Prevention is the best approach.

Beak trimming is commonly used as a prophylactic measure to prevent feather pecking and cannibalism. Beak trimming is usually effective in significantly reducing cannibalism and subsequent mortality,[39,40] although occasional outbreaks do occur in beak trimmed flocks. Beak trimming as a solution is not ideal though, as it is a painful procedure. Further, the beak tip is highly innervated and contains abundant sensory receptors;[41,42] cutting off the beak tip thus impairs sensory function. Welfare can be improved by controlling cannibalism using alternative means.

Dietary deficiencies have been linked to increased incidence of pecking damage,[43] especially protein deficiencies,[44,45] so the first step in preventing injurious pecking is to ensure that the feed is nutritionally complete. However, outbreaks of feather pecking still often occur in flocks that are fed to their nutritional requirements. There are a variety of other factors involved.

Successful control of feather pecking and cannibalism requires an integrated approach that includes consideration of three main factors: early-life experiences, the environment and genetics.[46]

Feather pecking and cannibalism are not aggressive acts—rather, science demonstrates that these are foraging pecks that have been re-directed toward feathers.[47,48,49] In natural conditions, domestic fowl spend over 50% of their active time in foraging related activity.[50,51] Studies have shown that hens will choose to forage for feed on the ground in loose substrate rather than eat identical food freely available from a feeder.[52,53] Thus, the natural urge to forage remains strong, even when full feed is provided. The acquisition process itself—including seeking, investigating, and manipulating feed items—is nearly as important as the act of consuming the feed itself.[54]

Pecking preferences are formed early in life, and these are learned through experience.[55] Therefore, providing appropriate pecking and foraging substrate from day one[56,57] is a critical factor shaping adult pecking preferences. Scientific research has demonstrated that early access to loose litter—such as wood shavings, sand and straw—is an important first step in reducing feather pecking, cannibalism and subsequent mortality.[58,59,60, 61,62,63] Conversely, studies also show that the absence of loose-litter[64] and poor litter quality are risk factors for

plumage deterioration due to feather pecking.[65] Scattering grain or feed into loose litter for young chicks can also be beneficial.[66]

Lack of perches during early rearing is another important risk factor for feather pecking on organic farms.[67] Early access to perches can decrease cloacal cannibalism by giving potential victims a safe place to avoid hens who would peck them from the floor.[68,69,70] Young birds must learn how to successfully navigate perches by gaining experience with them from a young age, which shapes their cognitive spatial abilities.[71] Pullets should have access to perches elevated above 35 centimeters at no later than four weeks of age.[72,73] Higher perches are generally better, [74] although they must be constructed and arranged in a way that allows easy access, or else hens can miss a landing, fall and become injured (see section on providing perches for laying hens in indoor housing below).

Feather pecking often begins to appear in affected flocks shortly after moving pullets from the rearing to the laying house. When transferring pullets, there are many potential stressors including changes in light intensity, diet, house layout and access to the outdoors. Stress can be partially alleviated by matching the rearing and laying environments as closely as possible.[75] Do not change the feed or lighting program at the same time pullets are moved into the laying house.

Since cannibalism is thought to have a hormonal basis, the risk of cannibalism may be reduced by using lighting programs that delay the age at which hens first begin to lay eggs to after 20 weeks of age.[76] Flocks that begin laying eggs before 20 weeks of age have approximately four times the risk for vent pecking as compared with flocks that begin laying at a later age.[77]

When feather pecking outbreaks occur in adult hens, lowering the light level is a commonly used intervention. While somewhat effective, the problem with dimming the light is that, like beak trimming, the underlying cause of the problem is not addressed. To truly attend to the welfare issue, the natural early motivation of a hen to forage and peck should be channeled appropriately into desirable adult pecking behavior, as discussed above.

Feed form is also important for attracting and sustaining foraging related pecks and regulating appetite. Studies show that a mash diet is better than pelleted feed for reducing feather pecking and cannibalism.[78,79] The small particle form takes longer to consume, sustaining foraging related pecking behavior for a longer period of time as birds pick out individual feed particles.[80] A diet high in insoluble fiber has also been shown to help to reduce and control cannibalism,[81] and millrun, oat hulls, rice hulls, and lucerne meal are effective sources.[82] Additional foraging enrichments such as maize, barley-pea silage, carrots,[83] straw[84,85] seeds in suet, and cabbage leaves[86] have been shown to attract interest and reduce the tendency to perform injurious pecking.

Most importantly, it has been repeatedly demonstrated in scientific studies that flocks making good use of an outdoor range area (where more foraging and exploring opportunities are provided for them) are significantly less likely to feather peck and cannibalize flock mates.[87,88,89,90,91,92,93] One study found that when at least half the flock was observed outdoors during good weather, there was a five-fold decrease in the risk of feather pecking. On these farms, it is likely that hens are directing their pecking behavior at appropriate

foraging substrate, rather than at each other.[94] Therefore it is essential to provide attractive outdoor areas and encourage hens to go outside (see section on outdoor access below).

If possible, time the introduction of pullets into the laying house so that they will have good weather when the doors are first opened to permit outdoor access. If inclement weather prevents them from using the range area when they are young, it may be difficult to encourage them out when they grow older.[95]

Other risk factors that have been associated with injurious pecking include:
- Restricting access to portions of the indoor litter area;[96]
- Restricting access to the outside range area;[97]
- Changing the diet three or more times during the laying period;[98,99]
- Using lights inside the nest boxes;[100]
- Use of bell drinkers;[101,102]
- Inadequate number of drinking places;[103]
- Reduced indoor temperature (below 68º F);[104]
- Not keeping cockerels with the hen flock;[105] and
- Dietary deficiencies.[106]

Feather pecking, cannibalism, and the associated mortality have genetic components, which means that these traits can be selected against in breeding programs.[107,108,109,110] Different hen strains vary in their propensity to exhibit injurious pecking behavior.[111] It is therefore critical to source hens that exhibit low levels of feather pecking behavior. Because breeding efforts to control cannibalism are ongoing, it is difficult to pinpoint lasting recommendations on specific genetic lines. If a severe outbreak occurs, consider using a different supplier, switch to a different hen strain, or use a different breed or hybrid altogether.

For more information on managing feather pecking without beak trimming see:

"A guide to the practical management of feather pecking & cannibalism in free range laying hens" at:
www.defra.gov.uk/publications/files/pb10596-feather-pecking-050309.pdf

Newberry RC. 2003. Cannibalism. In: Perry GC (ed.), Welfare of the Laying Hen, Poultry Science Symposium Series, 27 (Wallingford, U.K.: CABI Publishing, pp. 239-58).

Indoor living conditions

Housing must protect birds from the elements, maintain a comfortable temperature, provide ventilation and allow birds to exercise and conduct natural behavior. Cages are not permitted. Bedding indoors provides comfort, insulation, and pecking and scratching opportunity. However, it must be maintained in clean, dry condition. Slatted-floor systems are useful under watering areas to prevent wet litter.

The indoor climate must be modulated for light, temperature, and air quality to provide a comfortable environment for the birds. Lighting should provide for an 8 hour rest period daily. Indoor temperatures must not be so warm that birds pant or so cold that they huddle together. Ventilation must be adequate to prevent the buildup of ammonia. Ammonia levels should generally be less than 10 ppm. Ammonia level testing must be documented and

ammonia levels must be at or below 25ppm. General levels can be tested using ammonia test strips and if excessive ammonia is noted a second test using passive dosimeter or gas detection tubes should be conducted. Dust should also be kept to a minimum.

Layers should be provided with nest boxes—at least one box per 5 birds is recommended. If community nest boxes are provided, there should be at least 9 square feet of nesting space for every 100 hens.

Laying hens must also be provided with perches—at least 6 inches of elevated perch space per hen is suggested. There must be enough perch and/or flat roost space for all hens to simultaneously rest off of the floor at night. Turkeys can be provided with elevated platforms and ramps in addition to or instead of perches.[112]

Poultry must be provided with dustbathing areas. Preferred substrates include sand, wood shavings and peat. On outdoor range areas, chickens usually create their own preferred dustbathing locations in loose, dry dirt. Dustbathing balances oil levels in the feathers,[113,114,115] and helps keep the plumage in good condition.

Ducks should have access to water for bathing and head dunking in addition to water for drinking. Water related activity is part of the natural behavior of waterfowl. At a minimum, ducks should be able to dip their heads and splash their feathers with water. This behavior will help keep their nostrils, eyes and feathers clean.[116,117] Troughs are often used to provide an open water source and these can be situated on grids or slats over a drainage channel to prevent adjacent litter from becoming wet. Nipple drinkers do not permit ducks to wet their eyes or feathers, and can lead to poor eye and plumage cleanliness.[118] Open water sources should be cleaned daily.

Additional producer guidance on providing perches for laying hens in indoor housing

Perches are an important enrichment in indoor housing for laying hens. The foot of a hen is anatomically adapted to close around a perch,[119,120] and this is the natural resting position for chickens. Perch use maintains bone volume and bone strength,[121,122,123] and can serve as a refuge for subordinate hens to avoid aggressive interactions with more dominant hens.[124] Research demonstrates that hens are highly motivated to perch at night.[125,126,127] When given a choice, hens often prefer to roost on higher perches as opposed to those that are closer to the floor.[128,129]

Bumblefoot is a bulbous swelling of the footpad caused by a localized infection.[130] Some hen breeds are more susceptible than others, and the condition is associated with poor hygiene and poor perch design.[131,132] The use of plastic perches or the commonly used soft wooden perches measuring 25 mm (0.98 in) in width are thought to contribute to poor foot health, as manure and moisture are able to accumulate on the structure's top where the birds' feet rest.[133] Incidence of bumblefoot can be reduced by providing hens with hardwood perches that are approximately 1.5 inches in diameter with a flattened top[134,135] and by limiting walking exposure to mud and manure.[136]

Hens selected for egg production are prone to osteoporosis and subsequent bone fractures.[137,138,139] These often go undetected unless hens are palpated by an experienced

veterinarian. The way perches are arranged inside the poultry house can have an effect on the incidence of bone fractures. Research suggests that the upper limit on a hen's ability to jump from one perch to another is about three feet,[140] and angles greater than approximately 45º can be difficult to navigate.[141] At a minimum, hens need approximately 6 inches of perch space to take-off, and 6-9 inches to land.[142] Perches should be large enough for hens to maintain stable footing, about 1.5 inches in diameter.[143,144] These general requirements may differ depending on the size and previous experience of the hen, so adjustments may be necessary for individual flocks. Injuries are more likely to occur if perch design and layout require hens to jump beyond their natural capabilities.[145]

Providing perches at a young age can also help reduce the risk of floor eggs,[146] as pullets must be skilled at flying up and down in order to access elevated nest boxes.[147]

Outdoor access and living conditions

Outdoor access must be provided to all poultry, with the following exceptions:

- Pullets younger than 16 weeks of age.
- Broiler chickens younger than 4 weeks of age.
- Outdoor temperatures below 50ºF.
- Other inclement weather such as heavy snow, sleet, rain, wind or extreme heat that would endanger the health or welfare of the animals.

Pullets must be provided outdoor access by 16 weeks of age, when weather permits. As a guide, doors for outdoor access should be at least 14 inches high, spaced uniformly and provide direct access to the outdoors. Total door opening should be at least 6 feet/1000 birds.[148] Once layers are accustomed to going outdoors, a brief confinement period of no more than 5 weeks to allow for nest box training is permitted. Broiler chickens must be provided outdoor access by 4 weeks of age, provided that they are fully feathered and weather permits.

Enclosed spaces that have a solid roof overhead (sometimes called "porches" or "winter gardens") do not meet the definition of outdoor access and cannot be included in the space calculation of outdoor access.

Additional producer guidance on outdoor access

Outdoor areas for poultry should be fully vegetated, where possible. Grasses, legumes, and other forage provide interest and enrichment to poultry, who consume not only greens, but also insects, grubs, and seeds. However, high traffic areas tend to become denuded of vegetation, so steps must be taken to keep outdoor areas in good condition. Rotate the use of range areas by taking flocks off of pasture to prevent the buildup of infectious organisms and allow the re-growth of vegetation. Fields can also be rotated between species with different parasite spectrums, such as cattle and poultry. Harvested crop fields also make good poultry runs.

Layout is important for attracting hens to use outdoor space. There should be plenty of exits from the hen house, and they should be easily accessible and large enough for several hens to pass through simultaneously. Since hens are prey animals, they are naturally wary of overhead predators, and will sometimes avoid open range if some sort of cover is not provided. Cover, either artificial or natural structures, should therefore be provided.[149] Natural cover can take many forms, including tall plantings of vegetation, bushes, and trees,[150] however, large swaths of thick undergrowth can actually attract ground predators if fences don't exclude them. Maize plantings and low pollard willows (*Salix*), for example, have worked on organic farms to attract hens outdoors.[151] In "tree-range" production, the outdoor area is planted with short trees, such as orchard varieties. Flocks with canopy cover from trees are more likely to have better plumage condition at the end of lay than those without canopy cover.[152]

Artificial structures that provide shelter, shade, and security can also be constructed.[153,154] Cover made from a wide variety of wood, plastic or recycled materials, in designs both low to the ground and high enough to include perches, have been innovated by producers with success. Camouflage nets are another option.[155] If artificial cover is portable, it can be moved to different range areas to encourage more even distribution of the flock, preventing buildup of contamination over highly frequented areas.

For more information see: Fanatico, A. 2006. Alternative poultry production systems and outdoor access. Available through the National Sustainable Agriculture Information Service at: www.attra.ncat.org

Space allowances

Poultry housing must be sufficiently spacious to allow all birds to move freely, stretch their wings and engage in natural behavior. Perching areas and nest boxes may not be used in the calculation of floor space. Slatted/grated floors may be considered floor space. Mobile poultry units require the same amount of indoor space per bird but allow the house to be moved so birds always have access to fresh vegetation.

Livestock Species	**Indoor Space**	**Outdoor Runs and Pens**
Chickens		
Laying hens and breeders	2.0 sq ft / bird	2.0-5.0 sq ft / bird
Pullets	2.0 to 3.0 lbs / sq ft	2.0-3.0 lbs / sq ft
Broilers	1.0 to 5.0 lbs / sq ft	2.0 to 5.0 lbs / sq ft
Other poultry		
Turkeys and	7.5 lbs / sq ft	2 lbs / sq ft

Geese—breeding, laying, or meat birds (pounds)		
Ducks-meat	5 lbs / sq ft	2 lbs / sq ft
Ducks-laying hen	2 lbs / sq ft	1 lbs / sq ft
Ducks—breeder	3.3 lbs / sq ft	1 lbs / sq ft

Humane handling of poultry

Poultry should be handled quietly and firmly, with care taken to avoid unnecessary distress and dislocated or broken bones during catching and loading for transport. Poultry catching should be scheduled to minimize the time to slaughter as well as climatic stress during catching, transport and holding. Birds should not be picked up by the neck or wings.

Transport is a stressful experience,[156,157] as birds are subjected to noise, vibration, motion, overcrowding, feed and water deprivation, social disruption, and potential temperature extremes.[158,159,160] Aim to reduce these stressors and comfort the birds wherever possible. Transportation units should provide space enough that all birds can lie down at the same time and none are on top of each other. Birds must be protected from heat and cold. Delivery of poultry for slaughter should be scheduled such that they are not deprived of water for longer than 12 hours.

Birds must be fit for transport before being loaded for slaughter. Due to the stress involved, animals must be healthy enough to withstand the rigors of the journey. Birds exhibiting obvious signs of poor health, weakness or injury are not fit for transport. These birds should be euthanized using the most humane method available.

Inspectors should discuss procedures for poultry catching and loading with the producer and must observe poultry being caught and loaded for slaughter at the annual inspection and note percentage of birds with broken/dislocated legs/wings.

Additional producer guidance on humane handling of poultry

Low-stress handling is as important for poultry as it is for livestock. Although commonly carried this way, research shows that birds react with a significant stress response when picked up and held upside-down by the legs, as this is a physiologically abnormal posture for chickens.[161] Handling, crating and loading for transportation, have been identified by researchers as major sources of stress and trauma.[162] Bruising and injuries are well-documented, and these are not only welfare problems, but can also result in carcass downgrading and economic loss to producers.[163, 164,165,166,167] Ideally, all poultry should be handled individually, upright, and carried gently using two hands.

Catching and carrying turkeys can also cause bruises and injuries. Turkeys can be driven or herded into transport crates instead, which reduces stress levels.[168]

Euthanasia and depopulation
Individual birds who are ill or injured, are suffering, and are unlikely to recover, should be euthanized without delay. All euthanized and depopulated birds must be confirmed dead before disposal. No live birds should be found on dead piles.

Permitted methods include:
- Hand held electrical or percussive stunning using an instrument designed for the specific size/age of the species, followed by neck cutting;
- Cervical dislocation by stretching the neck to sever the spinal cord and cause extensive damage to the major blood vessels.
- Barbiturate overdose administered by a licensed veterinarian (with special considerations noted below)
- Decapitation
- Carbon dioxide or a mixture of nitrogen and argon gases, delivered in an appropriate container at acceptable concentrations.

Acceptable gas mixtures include:
- a minimum of 2 minutes exposure to any mixture of argon, nitrogen or other inert gases with atmospheric air and carbon dioxide, provided that the carbon dioxide concentration does not exceed 30 percent by volume and the residual oxygen concentration does not exceed 2 percent by volume; or
- a minimum of 2 minutes exposure to argon, nitrogen, other inert gases or any mixture of these gases in atmospheric air with a maximum of 2 percent residual oxygen by volume.

Methods that are not permitted include, but are not limited to:
- Suffocation
- Blow to the head by blunt instrument
- Equipment that crushes the neck including killing pliers or burdizzo clamps
- Carbon monoxide
- Neck wringing (holding the head while swinging the body in a circular motion)
- Maceration in a wood chipper

Additional producer guidance on euthanasia and depopulation

The term euthanasia is derived from Greek words meaning “good death” and is applied to the killing of an animal with minimal pain and distress.[169] Animals that are suffering must be euthanized in a timely manner, and should not be left for extensive periods, over a weekend, for example.

Barbiturate injection or inhalant anesthetics administered by a veterinarian are the ideal methods for a limited numbers of hens, as they most closely meet the goals of killing with minimal pain and distress. However, these methods have not been widely used on farm settings due to cost and convince issues associated with culling large numbers of birds. Producers should also be aware that drug residues associated with the use of barbiturate injections will prevent the use of carcasses for human consumption, and dead birds must be disposed of carefully, because residues could also be unwittingly consumed by other animals

eating the carcass or could become an environmental pollutant. Dead poultry should be disposed of in a way that does not attract wildlife.

Research demonstrates that inhalation of an inert gas (including argon and nitrogen) is probably painless, as they are colorless, odorless gases and birds do not demonstrate aversive reactions with initial exposure. In carefully controlled behavior experiments, turkeys and chickens are willing to enter a chamber filled with inert gas in order to access food.[170,171] Argon and nitrogen can be used to kill chickens on the farm. Containerized gas killing systems have been developed for culling large numbers of birds,[172] and these can be built on either a large or small scale, depending on the needs of individual producers. Such a system is the most humane method for killing large numbers of chickens on the farm that researchers have identified to date.

The use of CO_2 is problematic as there are both physiological and behavioral lines of scientific evidence suggesting that CO_2 may be unpleasant and possibly very distressing to inhale, as it is an acidic gas, pungent at high concentrations.[173,174]

Exhaust fumes from an idling car engine are an unacceptable source of carbon monoxide, due to problems with production of other gases, inadequate gas concentration, and gas temperature.

While purpose-build macerators are sometimes used to kill unwanted chicks at hatcheries, using a wood chipper to dispose of a spent laying-hen flock is never acceptable.

It is extremely important to confirm that all animals are dead before disposal. When depopulation is performed on large flocks, depending on the methods used, it can be difficult to ensure that birds are actually dead and not simply lying still or unconscious. There is a very high potential for birds that are not dead, but are severely injured, to suffer greatly. Each bird must be methodically checked, and dead piles must be examined carefully for any sign of movement. A backup method of euthanasia must be in place to kill any birds that recover. Careful attention to this step in the euthanasia process is essential to ensuring a humane end for farmed poultry.

Slaughter of poultry

All slaughter facilities must be audited yearly. Organic certifiers can use documentation from other third-party animal welfare audits that have been performed and should do additional auditing as necessary.

Slaughter establishments must also perform self-audits on a weekly basis. Self-audits ensure that animal welfare standards are being upheld, identify problems that may arise within the facility or with individual staff members, and identify specific farms that may be shipping problematic animals to the slaughter plant. These problems may be due to animals' genetics or handling; slaughter facilities are encouraged to contact the producers of problematic animals so that these problems can be addressed in the future.

In electrical water-bath stunning systems, birds must be shackled by both legs. Birds with broken or dislocated wings should be humanely killed before being shackled.

Stunning

Poultry must be rendered unconscious by stunning, or killed before being bled by simultaneous severance of both carotid arteries or by decapitation. Bleeding without stunning requires a high level of operator competency to avoid causing pain and missing cutting of both carotid arteries. A very sharp blade or knife of sufficient length is needed so that the point of the knife remains outside the incision during the cut; the point of the knife should not be used to make the incision. The incision should not close over the knife during the throat cut. Decapitation may be achieved by manual or automatic means.

Decapitation must be performed using a sharp instrument which achieves the complete severance of the head from the body by cutting all the major vessels of the neck and the spinal cord with a sharp instrument. All mechanical and automatic instruments used in this method shall be sharp and inspected frequently for sharpness. The poultry slaughter establishment shall ensure that all instruments and equipment are maintained so that they function effectively. All birds (100%) should be dead before they enter the scald tank.

For inspector assessment, 99% of the birds must be rendered insensible by the stunning method chosen. Arched neck and wings tucked in are visible signs of effective stunning.

Additional producer/processor guidance on stunning for slaughter

Electric stunning: The disadvantage of electric stunning for poultry is that birds must be shackled and hung upside-down before they enter the stunner. Care must be taken to avoid pre-stun electrical shocks. Amperage must be high enough that birds lose consciousness and are not merely paralyzed. The electric current shall be administered so as to produce effective surgical anesthesia or death with a minimum of excitement and discomfort. The current necessary to produce an effective stun changes depending the species and electrical frequency. These are outlined in the World Organization for Animal Health, Terrestrial Animal Health Guide, Chapter 7.5, Slaughter of animals (available at: www.oie.int/index.php?id=169&L=0&htmfile=chapitre_1.7.5.htm), and the minimum currents are as follows:

- Broiler chickens and spent laying hens, 100 milliamperes per bird
- Turkeys, 150 milliamperes per bird
- Ducks and geese, 130 milliamperes per bird

For high frequency settings of 200-400 Hz, the minimum current needed to stun chickens is 150 milliamperes. For frequency settings of 400-1500 Hz, the minimum current is 200 milliamperes. For turkeys, frequency settings of 200-1500 Hz require a 400 milliampere currency setting.

These are minimal settings, and higher current levels better ensure that more birds will be effectively rendered unconscious.[175]

Gas stunning: Acceptable gas mixtures include argon, nitrogen, and low initial levels of CO_2 in one of the following combinations, as described by the World Organization for Animal Health:

- a minimum of 2 minutes exposure to 40 percent carbon dioxide, 30 percent oxygen and 30 percent nitrogen, followed by a minimum of one minute exposure to 80 percent carbon dioxide in air; or
- a minimum of 2 minutes exposure to any mixture of argon, nitrogen or other inert gases with atmospheric air and carbon dioxide, provided that the carbon dioxide concentration does not exceed 30 percent by volume and the residual oxygen concentration does not exceed 2 percent by volume; or
- a minimum of 2 minutes exposure to argon, nitrogen, other inert gases or any mixture of these gases in atmospheric air with a maximum of 2 percent residual oxygen by volume.

To avoid unnecessary stress and trauma due to handling, chickens should remain in their transport crates while being conveyed through the gas tunnels. Gas concentrations must be monitored for precision at all times. An alarm system is necessary to indicate malfunctions.

Bleeding

Once stunned, birds should be bled without delay to ensure that consciousness is not regained. Bleeding shall be accomplished by severing both carotid arteries or by decapitation. Sufficient bleeding time (at lest 30 seconds, 60 seconds for gas stunning, and approximately 2 to 3 minutes for electric stunning resulting in cardiac arrest) shall be allowed to prevent the unacceptable condition known as “red skins” or “cadavers” which may occur with insufficient bleeding. For inspector assessment, 99% must be effectively cut by hand or by the bleed machine. Remaining birds must be cut by a backup person.

The inspector will monitor condition of carcasses exiting the scald tank. Birds exiting the scald tank should not show signs that they entered it alive. “Red skins” with uncut throats indicate that they entered the scalding water alive, and those with cut throats could possibly have entered before becoming unconscious.

For poultry, the percentage of chickens with broken or dislocated wings should not exceed 2%, with zero being the goal. No broken legs should be noted.

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Committee vote:

Motion: Wendy Fulwider Second: Colehour Bondera

Yes: 8 No: 0 Absent: 0 Abstain: 0 Recuse: 0

National Organic Standards Board
Livestock Committee
Proposed Discussion Document

March 28, 2012

Guidance for Assessing Animal Welfare on Organic Sheep Operations

The following is provided to aid in assessment of whether or not the requirements of **§ 205.238-241** are being met sufficiently to demonstrate adequate animal welfare conditions on organic sheep operations.

Nutritional requirements

Body condition scoring of sheep

Because wool covering makes visual examination of sheep body condition more difficult than with other species of livestock, body condition scoring may be helpful in determining whether the nutritional requirements of the ewe flock are being met and also in assessing the health status of sheep.

Estimated external fat cover is used as a base for estimating body condition. The fingertips are used to palpate fat cover over and around the vertebrae in the loin region. The best area to palpate is just behind the last rib. The spinal column has a vertical process at the midpoint of the back and a transverse process horizontal to the back and just below the loin. The prominence of these two points, or their lack of prominence due to fat cover, is helpful when estimating body condition. The recommended scoring system uses body condition scores ranging from 0 to 5. A condition score of 0 indicates extreme emaciation; a score of 5 represents excessive obesity. A condition score of 2.5-3 is considered as a medium fat-condition score for a healthy ewe at breeding and starting into the late gestation stage of pregnancy. If, within a "uniform" group or flock, several or more ewes differ from the majority in body condition score it may mean they are parasitized, diseased, aged (lacking teeth) or have other non-nutritional problems. As a rule, no more than 5% of the ewe flock should be below target body condition scores for the stage of production.

Scoring:

1. Feel for fullness of muscle and fat cover. (illustration)
2. Feel for the spine in the center of the sheep's back behind the last rib and anterior to the hipbone. (illustration)
3. Feel for the tips of the transverse processes. (illustration)

Target body condition scores based on stage of production

Dry Ewe	1.5-2.0
Breeding	2.5-3.0
Early Gestation	2.0-2.5
Late Gestation*	2.5-3.0
Early Lactation*	3.0-3.5

Late Lactation, Weaning 2.0-2.5
*Add .5 to the target score for ewes expecting or nursing twins.

Body Condition Score 0: Sheep is extremely thin, unthrifty and weak. Skeletal features, such as backbone, shoulder blades and ribs, very prominent. Wasted muscle tissue evident. Eye socket is prominent and sunken. May be humped back and isolates self from flock (illustration)
Body Condition Score 1: Sheep is extremely thin, unthrifty but agile. Skeletal features are prominent with no fat cover. No apparent muscle tissue degeneration. Has strength to remain with the flock (illustration)
Body Condition Score 2: Sheep is thin but strong and thrifty with no apparent muscle structure wasting. No evident fat cover over the backbone, rum and ribs, but skeletal features do not protrude (illustration)
Body Condition Score 3: Sheep are thrifty with evidence of limited fat deposits in fore rib, over top of shoulder, backbone, and tail head. Hipbone remains visible (illustration)
Body Condition Score 4: Moderate fat deposits give the sheep a smooth external appearance over the shoulder, back, rump, and fore rib. Hipbone is not visible. Firm fat deposition becomes evident in brisket and around the tail head (illustration)
Body Condition Score 5: Sheep are extremely fat with the excess detectable over the shoulder, backbone, rump, and fore rib. Excess fat deposits in brisket, flank, and tail head regions lack firmness. Sheep appear uncomfortable and reluctant to move about. Quality fleeces are generally found (illustration)

Other areas of importance in providing adequate nutrition to sheep:

- Sheep need to be provided with enough roughage in the diet to ensure proper rumen function. After weaning, 70% of daily dry matter fed should be long fiber roughage/forage.
- There should be sufficient access to forage when fed that all sheep have sufficient access to meet their nutritional requirements within 24 hours.
- If supplementary concentrates are fed, all animals in a group should be able to eat at the same time.
- Ewe lambs should not be bred unless they have reached 70% of their mature body weight. If ewe lambs are bred to lamb before they are 18 months of age, they may need to be fed separately from the ewe flock to ensure adequate nutrition during gestation.
- Lambs should not be weaned before 5 weeks of age. Early weaned lambs need a high-protein ration and should not be put on forage only.
- If culling does not remove older sheep with damaged or missing teeth from the flock, attention should be given to providing sufficient feed of a type these sheep can eat and digest.

Sheep health

When managed in a pasture-based or range system as required by organic production, with attention to suitability of species, and selective breeding for desirable traits, sheep can require few health inputs, require little lambing intervention, operator- or veterinary-provided health treatment and yet display optimal health.

Internal parasites

It is necessary for special attention to be given to managing internal parasites on organic sheep operations. If breed selection, pasture management, supplements and allowed treatments are not successful in keeping sheep parasite loads from impacting well-being, individual animals need to be given conventional treatments. Lambs are more susceptible to parasites than ewes.

Lameness

Sheep hooves should be examined periodically or at least once yearly, and trimmed if necessary. 95% of the sheep should walk with no obvious limp. Animals with chronic or infrequent trimming management will be seen grazing on their knees and often will have grass stains on their knees. To simplify assessment, sheep can be classified as either lame or not lame. On a 5 point lameness scoring system, sheep that score as 3, 4, or 5 would be classified as lame.

Score 1. Completely normal walking
Score 2. No obvious limp, but may have slight gait abnormalities.
Score 3. All sheep that walk with an obvious limp. Sheep with a score 3 are able to keep up with their flock mates when the group is walking.
Score 4. All sheep that walk with an obvious limp and refuse to bear their full weight on one or more legs. Score 4 animals are not able to keep up with their flock mates when the group is walking.
Score 5. All sheep that have great difficulty walking. Score 5 sheep are barely able to walk.

Physical alterations

Tail docking should only be done if needed for prevention of fly strike. When necessary, tail docking should be performed by suitably trained and competent individuals on lambs that are between 24 hours and 14 days old. Tails should not be docked shorter than the distal end of the caudal tail fold.

If castration is necessary to avoid breeding by ram lambs, banding should be done by suitably trained and competent individuals on lambs that are between 24 hours and no more than 30 days old.

Sheep living conditions

Flocks may be managed with only natural shelter, depending upon climate, breed and lambing season. If sheep are housed or fed in lots, conditions should be such to maintain a cleanliness score or 1 or 2 for 95% of the flock.

Cleanliness Scoring

Fleece maintenance is necessary to prevent manure from accumulating on the back end, rear legs and tail if present. The presence of manure in the fleece is an indicator of poor management that can lead to low conception rates and harbor external parasites. Messy rear ends may be due to washy forage growth or may be from untreated internal parasite loads. Excessive wool growth is problematic for newborn lambs to find the nipple and receive the valuable colostrum.

Score 1. The entire sheep is clean except its feet and lower half of the legs. Animals on lush green pastures may have some soiling of the rear legs.

Score 2. Both the upper and lower legs are soiled and the body/breast and sides are clean.

Score 3. Both the legs and belly are soiled.

Score 4. The legs, belly and sides of the body are soiled.

95% of the sheep should have a cleanliness score of 1 or 2.

Space allowances

If sheep are confined in buildings or lots during the non-grazing season, the following minimum space allowances should be met. Because the standards require outdoor access for organic livestock unless weather conditions would be injurious to animal health, and because sheep tend towards respiratory difficulties when confined unless ventilation and moisture control is optimum, it is important than confinement of sheep to buildings be of a temporary nature—for treatment of illness, or shelter due to inclement weather, winter lambing or post-shearing—and that outdoor access be provided as soon as possible.

Livestock	**Indoor Floor Space**	**Outdoor Space**
Sheep and goats (pounds)	**Square feet / animal**	**Square feet / animal**
Sheep and Goats	16.0	30.0
Nursing lamb or kid	4.0	8.0

For ewes with lambs add 5 square feet for lambing percentages over 170%. Ewes lambing in confinement should be provided with a dry, bedded area for lambing and should be checked at least 3 times daily during lambing time for lambing difficulties or unclaimed lambs. Lambing jugs (pens) as small as 16 square feet in area may be used for up to three days for a ewe and her lamb(s) to separate them from the rest of the flock for a period of bonding and observation.

Pasturing sheep

Important factors in managing sheep on pasture:

- Pastures need to be rotated and rested to minimize parasite infestation.
- Sheep need to be protected from predation.
- If electronet fencing is used, it should be kept properly energized.
- Sheep on pasture should be checked at least twice/day during lambing, once/day otherwise.

Humane handling of sheep

Sheep should be handled quietly and firmly, with care taken to avoid unnecessary pain or distress. Sheep should not be caught by the fleece, or lifted or dragged by fleece, limbs, ears or tail. Electric prods should not be used on sheep.

Mortality rates in sheep production

In assessing the level of animal welfare that is met on an organic sheep operation, mortality rates and causes should be examined and considered. Mortality in sheep production is generally looked at in terms of lamb mortality before and after weaning and ewe mortality.

Lamb mortality rates are impacted by the prolificacy of the ewe breed (multiple births=higher mortality rate) and lambing conditions. The primary causes of neonatal lamb death are starvation and hypothermia. A lamb survival rate of 95% at weaning is considered to be a goal by many sheep producers.

Similarly, a death loss of 5% or less in weaned lambs or ewes is considered to be indicative of good management. Weaned lambs in organic systems are impacted most greatly by parasites or predation. The mortality rate of ewes is affected by culling rate; if older ewes are kept on the farm, the mortality rate could be higher.

Committee vote:

Motion: Wendy Second: Colehour

Yes: 8 No: 0 Absent: 0 Abstain: 0 Recuse: 0

National Organic Standards Board
Livestock Committee
Proposed Discussion Document
March 28, 2012

Introduction

Animal welfare is a basic principle of organic production. As the number of farmers in the United States decline, consumer concerns for farm animal care have increased. There are numerous animal welfare organizations and methods to verify animal welfare. The Livestock Committee believes that outcome based scores are the best measure of farm animal welfare.

Background

The United States Congress anticipated the need to elaborate livestock standards in 1990 when the Organic Foods Production Act was passed. The Humane Society of the United States played a central role in advocating for the passage of OFPA. It was understood at that time that animal welfare standards would eventually be developed. Several animal health and welfare practices were described in the Preamble accompanying the NOP Final Rule that organic livestock farmers must adhere to.

Discussion

The Livestock Committee feels that outcome based standards are the best measure for assessing the health and well-being of livestock. The four major concerns for dairy cattle are:

- Body condition
- Locomotion
- Cleanliness
- Injury and lesions

These measures are currently in use and have been well documented as welfare indicators in the livestock industry. Body condition is affected by stage of lactation and diet. Cows generally score less than 2 only if they are ill. Locomotion score may be 2 or greater if there is an injury. When cattle have a clean, dry place to lie down the majority of the herd will be clean. Grazing cattle generally have safe and spacious environments which minimize injuries and lesions. The Livestock Committee will discuss what is considered normal and acceptable for each of these measures in the future. Other welfare measures on the tally sheet include:

- Cattle affected with mange or lice
- Cattle with broken tails
- Ammonia concentration in buildings
- Other items that may need attention

Cattle may be affected with mange and lice during the winter months. This is an uncomfortable condition and requires immediate treatment. Broken tails are uncommon and are generally the result of an accident. High numbers indicate a problem with animal handling or the farm environment. Ammonia smell in buildings may indicate a lack of ventilation.

The photographs and descriptions on the dairy score card clearly show the difference between scores and have a corresponding spot on the tally sheet. The shaded boxes on the tally sheet represent areas of concern. Inspectors should view all of the cows and young stock but tally only the animals that would score in a shaded box. This identifies any issues that may need to be addressed and minimizes the amount of additional inspection time.

Proposed Materials

I. Dairy auditor tally sheet

II. Dairy Scorecard

Committee Vote

Motion: Wendy Fulwider Second: Colehour Bondera

Yes: 8 No: 0 Absent: 0 Abstain: 0 Recuse: 0

National Organic Standards Board
Policy Development Committee
Proposal
Conflict of Interest

March 29, 2012

I. Introduction

The National Organic Standards Board (NOSB) is seeking to enhance the NOSB's conflict of interest (COI) policy by providing two definitions and outlining general procedures for declaring, evaluating, and acting upon a COI. The recommendations are responsive to a number of requests by stakeholders to improve the NOSB COI policy. The proposed additions should provide greater transparency of and expectations around NOSB members' work on behalf of the organic community.

NOSB's Policy Development Committee (PDC) initially presented a version of this recommendation at the November, 2011 NOSB meeting. Based on feedback from the National Organic Program, the NOSB and the public, the PDC chose to retract the recommendation and make substantial revisions.

II. Background

The NOSB recognizes that members have been specifically appointed to the NOSB to provide advice and counsel to the Secretary of Agriculture concerning policies related to the development of organic standards and the creation of amendments to the National Organic Program's National List. NOSB members have been appointed because they represent various interests involved in the organic community, enabling them to advise the Secretary of Agriculture on the implementation of the Organic Foods Production Act (OFPA). The statutory composition of NOSB is composed of 15 members. OFPA describes the composition of the NOSB as follows:

- four (4) members who own or operate an organic farming operation;
- three (3) members with expertise in areas of environmental protection and resource conservation;
- three (3) members who represent the public interest or consumer interest groups;
- two (2) members who own or operate an organic handling operation;
- one (1) member who owns or operates a retail establishment with significant trade in organic products;
- one (1) member with expertise in the fields of toxicology, ecology, or biochemistry; and
- one (1) member who is a certifying agent.

NOSB members – like most federal advisory board members - are chosen specifically because of their professional expertise within a given area. Especially since NOSB members represent sectors of the industry directly impacted by the board's decisions, it

is necessary to maintain a clear and detailed NOSB COI policy. To prevent overt advocacy for direct financial gain and the appearance of self-interest or the appearance of wrongful activity, the NOSB has adopted a COI policy (NOSB, Policy & Procedures Manual (2011, pg. 9). At this time, the PDC of the NOSB seeks to update the Board's policy and procedures on COI.

The proposed COI policy will enhance and build upon the existing NOSB's COI policy. The recommendations include definitions of key terms and guidance on the procedural steps to be followed in declaring and acting upon a COI.

III. Relevant Areas of the Rule

The OFPA establishes the NOSB at §2119 (7 U.S.C. 6518) (a). It reads, "The Secretary shall establish a NOSB (in accordance with the Federal Advisory Committee Act (5 U.S.C. App. 2 et seq.) (hereafter referred to in this section as the "Board") to assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of this title." The 2011 NOSB Revised Policy and Procedures Manual (PPM) dated April 29, 2011 on page 9 sets forth the current NOSB's COI policy. The professional conduct of NOSB members are alluded to in the PPM on page 8. Therefore, action and activities of the NOSB members on matters pertaining to organic should be in the best interest of the organic community as a whole.

IV. Discussion

The benefits of the proposed recommendations include providing clear definitions of key terms and providing procedural steps for managing a COI in the course of the NOSB's business. The updated COI policy will provide greater transparency and confidence in Board decisions by the organic community.

An alternative approach would be to keep the current COI policy. However, an enhanced COI policy should help the Board's in its continued responsiveness to the organic community's feedback and address a number of opportunities for enhanced clarity, particularly with regard to the specific procedures to be followed in declaring, evaluating, and acting upon a COI.

Previously, the June, 1999 NOSB Procedures Taskforce Report to the Board on COI was approved. The Board's COI policy was updated to read:

> *Members of the Board shall refrain from taking any official Board action from which that Board member is or would derive direct financial gain. Board members shall disclose their interest to the Board and the public, when they or their affiliated business stand to gain from a vote, which they cast in the course of Board business. Under certain circumstances, the Board may determine whether it is appropriate for the member to vote.*

That members of the Board shall refrain from promoting for consideration any material, process or practice for which the member is or would derive direct financial gain arising out of such Board action. The act of promoting such material, process or practice shall include private discussion with members of the Board advocating the value of the material, public discussion and/or written advocacy.

A "direct financial gain" is defined as monetary consideration, contractual benefit or the expectation of future monetary gain to a Board member, including but not limited to, financial gain from a party who manufactures, distributes or holds exclusive title to a formula for a material or product, process or practice. [NOSB's PPM, 2011, page 9.]

The current document seeks to enhance the existing COI policy. It attempts to do so by, (1) proposing clear definitions for "conflict of interest," and "immediate family member," and (2) suggesting procedural steps for dealing with a declared COI.

V. Recommendations

Recommendation #1

The first three paragraphs shown below are on page 9 of the 2011 PPM and will remain the same.

The NOSB recognizes that members have been specifically appointed to the NOSB to provide advice and counsel to the Secretary concerning policies related to the development of organic standards and the creation and amendment of the National List. NOSB members have been appointed because they have professional expertise which enables them to advise the Secretary. This professional expertise may, at times, present an inherent COI. To prevent overt advocacy for direct financial gain and the appearance of self-interest or the appearance of wrongful activity, the NOSB has adopted an updated COI policy.

Members of the Board shall refrain from taking any official Board action from which that Board member is or would derive direct financial gain. Board members shall disclose their interest to the Board and the public, when they or their affiliated business stand to gain from a vote, which they cast in the course of Board business. Under certain circumstances, the Board may determine whether it is appropriate for the member to vote.

That members of the Board shall refrain from promoting for consideration any material, process or practice for which the member is or would derive direct financial gain arising out of such Board action. The act of promoting such material, process or practice shall include private discussion with members of the Board advocating the value of the material, public discussion and/or written advocacy.

Recommendation #2

The definitions below are to be inserted before paragraph #4 on page 9 of the 2011 PPM.

The term "conflict of interest" is defined as a situation in which there is an actual or potential direct financial interest of a Board member which could impair the individual's objectivity or which has the potential to create an unfair competitive advantage for said Board member, board member's immediate family member, or Board member's organization or affiliated business.

An "immediate family member" includes a Board member's relative by blood or marriage who may be a spouse or partner, children or step children, parents or step-parents, brother or sister.

A "direct financial gain" is defined as a monetary consideration, contractual benefit or the expectation of future monetary gain to a Board member, including but not limited to, financial gain from a party who manufacture distributes or holds exclusive title to a formula for a material or product, process or practice.

Recommendation #3

We recommend the added section below.

Procedural Steps for a COI Determination and Resolution

1. *Each Board member is responsible for declaring his/her COI when an issue is first being discussed, to include one's participation on a committee, task force, or full NOSB meeting.*
2. *In opening the discussion of each issue and prior to each vote, the chair will ask all Board or committee members to raise any COI or potential COI in that particular matter.*
3. *Upon such declaration, the member may voluntarily refrain from participating, or may request that the Board or committee decide whether the conflict warrants said Board member abstaining from participating in the discussion in said matter and from voting on said matter.*
4. *The chair will ask the Board or committee for any objections to the Board member participating in said discussion or voting on said matter. If no member(s) object, then said Board member may participate in said discussion and vote on said matter. If any member(s) do object, then said matter will be subject to a full Board or committee vote. The motion requires a simple majority to pass.*
5. *The Board's or committee's final decision on all COI must be clearly recorded in the minutes.*

VI. Summary

NOSB members with diverse backgrounds are recruited to provide balance to the NOSB. While individual NOSB members represent the segments of the population from which they were selected, they also represent the greater good of the population as a whole. The revised COI policy and procedures are an attempt to address several stakeholders' request for updating the Board's COI policy and provide for a greater level of transparency in the deliberation, discussion, and voting on matters pertaining to the Board authority for the benefit of the organic community.

VII. Committee Vote:

Moved: Barry Flamm Second: Jean Richardson
Yes: 8 No: 0 Abstain: 0 Absent: 0 Recusals: 0

National Organic Standards Board
Policy Development Committee
Proposal
NOSB Meeting Public Comment Procedures

March 29, 2012

I. Introduction

Public input and transparency are central to the effective functioning of the NOSB. The proposed amendments to the Policy and Procedures Manual are intended to improve the ability of the NOSB to receive public comment.

II. Background

The six NOSB committees meet using teleconference calls on a regular, typically twice a month basis, sharing information received from the public, actively seeking further information and data as they review an ever increasing range of complex substantive issues and develop recommendations. Twice a year the full NOSB physically meets together at a location within the U.S. These public meetings take place at different geographic locations in order to ensure that those who cannot travel long distances for reason of cost or time are more likely to have their voices heard, and assumes that more regional members of the public will attend in person, and also that regional differences in agriculture will thus be better understood by the Board as it develops recommendations to forward to the NOP.

For anyone involved in public policy it is well understood that input through public comment at open public meetings provides both challenges and opportunities. There is a delicate balance between letting everyone speak for as long as they want to, while allowing time for everyone present to be heard, and then time for their comments to be digested by those who listen and pose questions. In addition the public needs to feel confident that their views have been heard and taken into consideration before decisions are voted on. Well run and effective Public Meetings require clear rules and leadership. Over the last five years there has been an increasing interest by the public to attend the semi-annual meetings to provide public comment, and increasing mutual desire by the public and the Board to clarify and improve procedures for taking public comment. Thus, in October - November 2011 the NOSB sought public input to clarify policy and procedures for receiving public comment specifically with reference to public meetings.

III. Relevant Areas of the Rule

The Organic Foods Production Act (OFPA) establishes the National Organic Standards Board at Section 2119 (7 U.S.C. 6518), “(a) The Secretary shall establish a National Organic Standards Board (in accordance with the Federal Advisory Committee Act (5 U.S.C. app. 2et seq.) [hereafter referred to as the “Board”] to assist in the development of standards for substances to be used in

organic production and to advise the Secretary on any other aspects of the implementation of this title."
The Policy Procedures Manual (PPM), Section VI "Policy for Public Comment at NOSB Meetings" lays out the process and the time designations of public comment and further provides for "Other suggestions that would be appreciated by NOSB members".

IV. Discussion
It is clear that many members of the public are frustrated by the procedures for public comment at the national meetings and they seek clarification and a desire for greater confidence that the Board members have heard what they have to say, and have seriously considered their input. Comments also requested flexibility with public involvement.

Following are some of the issues raised:
Length of time to speak
With an increased interest in public comment at meetings, there are typically many more speakers for time allotted. While 10 minutes is too long to permit, it is clear that for many even 5 minutes is a short time to speak given the complexity of issues and range of topics covered in one meeting. Requiring a 3 minute time limit forces speakers to be concise and prioritize topics covered in verbal presentation. In addition speakers need to be reminded that they can also submit an expanded written version of their comments during the meeting.

One comment stated" the length of time is not as important as that the designation of a time be regarded as a commitment."

While it may seem that speakers have travelled long distances, incurring expense and taking time to speak for only 3 minutes, it is obvious that attending the meeting allows face to face exchange of data, information and policy concerns throughout the week.

Several organizations requested that length of time be set at 5 minutes and decreased to 3 minutes if too many presenters for time period allotted, with flexibility being provided by the Chair.

Time allotted on agenda for public comment
There is widespread concern that there is not enough time on the week's agenda for public comment. While this is probably a normal perception by the public for any national board, it is nonetheless an important issue to address. In past years public comment extended into evening hours and the Board may wish to seriously consider returning to this option.

One comment suggested extending time allotted for public comment by one hour.

Another stated “we may reach a point when comments need to be prioritized, either on a first come first served, or randomized basis in order to ensure equity and diverse public input”.

Another comment suggested maintaining a waiting list for public comment.

Board Questions to Public speakers
There is a perception that Board members are not listening to the speakers because they do not ask many questions. And it is a perception that not all Board members are knowledgeable on the subject at hand because they do not ask questions. Thus it would seem counterproductive to consider “limiting Board questions” as a way to allow more public input, and none of the comments received suggested limiting Board questions.

Two organizations wanted it to be clear that Board question time was not considered part of the 3 minutes of public comment, while being sure that Board members ask questions to clarify issues under consideration.

Board members should be encouraged by the Chair to ask questions that are relevant and required to assist the Board in reaching decisions on substantive issues, and to be active listeners. Further, there needs to be far greater public understanding of the inordinate number of hours every week that individual board members in fact spend on reviewing TR, public input, committee meetings, e-mail exchanges and phone calls.

Public Comment impact on board decisions.
There is a perception that the Board does not take the time to adequately review and apply public input prior to making their decision. In order to address this very real concern the Board should always have time to recess following a public comment period prior to making a public decision on an agenda item.

Use of Proxy speakers
There is a mix of public perception on use of proxy speakers. One organization suggested continued use of proxy presentations, but stated that the information could also be achieved through written testimony. Three other comments suggested refined limitations to monitor implementation.

There is a public perception that those who turn up and speak at the meeting will have a more direct impact on the immediate decisions of the board. However there is the counter argument that the proxy is not in fact the originator of the input and cannot really answer any board question, and such information could simply be provided in writing prior to the meeting. Eliminating proxy speakers will allow more time for those who are present in person.

Use of electronic participation in lieu of physical presence
This is not an easy issue to address. On the one hand, attending the meeting is expensive and time consuming, limiting those who may attend, and there are a number of electronic means for communicating, such as via skype, or conference speaker phone, constant tweet inputs or other social networking tools, or by having a room full of people at a distant location with a TV type satellite connection. Any one of these or a combination could allow for increased input during the hours allotted to public comment.

Indeed one might envisage a national meeting where committee members are scattered at various regional geographical locations nationwide using TV "classroom" connections, a teaching tool which University and other teachers have been using for years to teach at diverse locations simultaneously. All input would thus be essentially electronic. This would be an improvement over the faceless nature of the phone conference calls, but would be complex to set in place and would increase participation which would in turn require more time allotment.

Conversely interested members of the public can submit public comment in writing, and public meetings rotate geographically around the US, allowing for greater regional participation over time. Further there are already many people who physically attend and not enough time to allow everyone to comment on everything that they would like to comment on.

Based on comments reviewed and experience, the use of electronic communication is not recommended presently.

V. Recommendations
Amend SECTION VI of the PPM, entitled NOSB Policy for Public Comment at NOSB Meetings, as follows:

NOSB Policy for Public Comment at NOSB Meetings:

1. All persons wishing to comment at NOSB meetings during public comment periods must sign up in advance per the instructions in the Federal Register Notice for the Meeting.

2. All presenters are encouraged to submit public comment in writing according to the Federal
Register Notice. Advance submissions allow NOSB members the opportunity to read comments in advance electronically, and decrease the need for paper copies to be distributed during the meeting.

3. Persons will be called upon to speak in the order they sign up. Persons called upon who are absent from the room could potentially miss their opportunity for

4. Time allotment for public comment per person will be 3 minutes with the option of extending to a maximum of 5 minutes at discretion of Chair during meeting

5. Persons must give their names and affiliations for the record at the beginning of their public comment.

6. Proxy speakers are not permitted.

7. Public comment requests may be scheduled by the Board by major topics under consideration.

8. Individuals providing public comment will refrain from any personal attacks and from remarks that otherwise impugn the character of any individual.

Other suggestions that would be appreciated by NOSB members:

- The NOSB will attempt to accommodate all persons requesting public comment time, however, persons requesting time after the closing date in the Meeting Notice, or during last minute sign-up at the meeting, will be placed on a waiting list and will be considered at the discretion of the NOSB Chair depending on availability of time.
- Members of the public are asked to define clearly and succinctly the issues they wish to present before the Board. This will give NOSB members a comprehensible understanding of the speaker's concerns.

VI Committee Vote:
Moved: Jean Richardson Second: Calvin Walker
Yes 6 No 0 Abstain 0 Absent 2 Recuse

National Organic Standards Board
Policy Development Committee
Proposal
Public Communications
March 29, 2012

I. Introduction

A primary role of the National Organic Standards Board (NOSB) is to advise and counsel the Secretary, to represent the segments of the population from which they were selected, and to treat the business of the Board as fiduciaries for all members of the organic community and public at large (NOSB Policy and Procedures Manual, pp4-8).

The Federal Advisory Committee Act (FACA) Meeting Obligations to the Public (41 CFR 102-3.140) suggest that, “Any member of the public is permitted to file a written statement with the advisory committee during meetings.”

In addition, the NOSB infrequently receives public communications outside of the designated public comment period. These communications include verbal and written information.

II. Background

The Organic Foods Production Act (OFPA), enacted under Title 21 of the 1990 Farm Bill, serves to establish uniform national standards for the production and handling of foods labeled as “organic.” The Act authorized a new USDA National Organic Program (NOP) to set national standards for the production, handling, and processing of organically grown agricultural products. In addition, the Program oversees mandatory certification of organic production. The Act also established the National Organic Standards Board (NOSB), which advises the Secretary of Agriculture in setting the standards upon which the NOP is based.
http://www.nal.usda.gov/afsic/pubs/ofp/ofp.shtml

Sec.2119 [7 U.S.C. 6518] states that the NOSB consist of four individuals who own or operate an organic farming operation; two individuals who own or operate an organic handling operation, one individual who own or operates a retail establishment with significant trade in organic products; three individuals with expertise in areas of environmental protection and resource conservation; three individuals who represent public interests or consumer interest groups; one individual with expertise in the fields of toxicology, ecology or biochemistry, and one individual who is a certifying agent.

The statutory mission in OFPA states:

> "To assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of this title." (OFPA, Sec 2119 (a))

As stated in the NOSB Policy and Procedures Manual (PPM, p5), the NOSB Mission Statement is:

> "To provide effective and constructive advice, clarification and guidance to the Secretary of Agriculture concerning the National Organic Program (NOP), and the consensus of the organic community.

In carrying out the mission, key activities of the Board include:

- "Assist in the development and maintenance of organic standards and regulations;
- Review petitioned materials for inclusion on or deletion from the National List of Approved and Prohibited Substances (National List); Recommend changes to the National List;
- Communicate with the organic community, including conducting public meetings, soliciting and taking public comments, provide timely information and education on the NOP, making reasonable use of a variety of communication channels.
- Communicate, support and coordinate with the NOP staff.
  The PPM (p8) states that NOSB members shall act impartially and not give preferential treatment to any organization or individual.

The PPM indicates (p6) that,

> "To fulfill their responsibilities, Board members agree to adhere to three duties: Duty of Care, Duty of Loyalty, and Duty of Obedience (p6).

The PPM continues,

> "The Duty of Care calls upon a member to participate in the decisions of the Board and to be informed as to the data relevant to such decisions. In essence, the Duty of Care requires that a member:
>
> Be reasonably informed—It is the duty of all Board members to seek and study the information needed to make a reasoned decision and/or recommendation on all business brought before the Board. The NOP will provide some of that information, but other information must be developed from independent sources."
>
> The National Organic Standards Board members study and evaluate all public communications, written and verbal communications, as a function of the NOSB role and duties, in order to benefit the organic community. In so doing, National

Organic Standards Board members are able to provide effective and constructive advice, clarification and guidance to the Secretary of Agriculture and the NOP.

NOP said in the *National Organic Program Newsletter*, December 11, 2011:

> The members of the National Organic Standards Board (NOSB) and the National Organic Program (NOP) often receive letters and requests from people interested in our upcoming regulatory activities and meetings. In this note, we summarize the best way to direct your letters and requests.
>
> As a Federal Advisory Committee, the NOSB has a well-defined scope of activity. If you have opinions and requests to share with the Board, please use the public comment period that is open before each NOSB meeting to submit your thoughts. Or, submit a formal National List petition for consideration using the guidelines provided in the link below.
>
> The NOP is the best place to send your letters outside the NOSB public comment and petition process. In addition to formal public comment periods on specific regulatory actions, we are always open to comments on a variety of topics related to organic agriculture. While we cannot guarantee that every letter will receive a direct response, your letters do get an audience and help us identify and prioritize needs. We look forward to hearing from you!

This explanation by NOP describes the current official means of communication outlined in the PPM, which does not prohibit other forms of communication between the public and NOSB members. The NOP statement, however, suggests a need to clarify the ability of the public to communicate with NOSB members outside of Board meetings and the public comment period to inform the ongoing deliberations of committee work.

III. Summary

The National Organic Standards Board through it Policy and Procedures Manual establishes procedures for its activities. The Manual, “is designed to assist the Board in its responsibilities” (PPM, p4), and establish procedures for carrying out its responsibilities in accordance with its advisory mission.

Because of the opportunities that the Board has to hear from the organic community in the course of fulfilling its mission, it has both an opportunity and responsibility to bring to the Secretary of Agriculture information that it believes may impact on the implementation of OFPA. This communication may, by necessity, extend to organic standards and practices as well as related issues that may affect those standards and practices. Therefore, based on the communications and input it receives from the public the National Organic Standards Board may provide effective and constructive advice, clarification, and written information, as it deems necessary, directly to the Secretary of Agriculture after each of its Board meetings.

Additionally, and 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 and the community decision making process. The procedures of the Board should facilitate public communication with Board members in the course of those deliberations.

IV. Recommendations

PPM, Section VI, Miscellaneous Policies, page 26 is amended by adding a new subcategory (in italics):

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

PPM, Section VI, Miscellaneous Policies (page 27), is amended by adding a new subcategory (in italics).

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

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

Receive and maintain an archival record of all communications submitted by the public to the National Organic Standards Board and make communications available to the Board members.

Maintain a public listing posted on the NOP website of contact information for NOSB members, including an email address or other points of contact.

V. Committee Vote

Moved: Jean Richardson Second: Jennifer Taylor

Yes 6 No 0 Abstain 0 Absent 2 Recuse 0

National Organic Standards Board
Handling Committee
Petitioned Material Proposal
Choline

March 20, 2012

Summary of Proposed Action:
Choline is a synthetically made nutrient that also occurs naturally in food. It is considered by most regulatory bodies to be essential in non-milk-based infant formula and is required by the FDA for this purpose. It is permitted but not required to be added to milk-based infant formulas. All the organic infant formula brands that could be found through an internet search contain added choline, both milk-based and non-milk-based.

Choline has been petitioned for addition to adult food items as well as infant formula. There is no compelling reason to think that this is essential to handling organic food, although it is not harmful either. Therefore there are 2 proposed actions on choline. First, to add it to the National List for use in infant formula labeled organic or made with organic ( ). Second, to add it to the National List for use only in agricultural products other than infant formula labeled "made with organic (specified ingredients or food group(s))" and prohibited in agricultural products labeled "organic".

Allowing it in adult foods that are in the Made with organic category would allow such foods to highlight the fact they are fortified, while at the same time limiting the number of non-essential synthetics in organic processing.

Evaluation Criteria

(Applicability noted for each category; Documentation attached)	**Criteria Satisfied? (see "B" below)**
1. Impact on Humans and Environment	☒ Yes ☐ No ☐ N/A
2. Essential & Availability Criteria	☒ Yes ☒ No ☐ N/A
3. Compatibility & Consistency	☒ Yes ☐ 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: Essential **Comments:**
The substance is deemed essential in infant formula by regulating authorities but the NOSB committee does not feel it is essential to supplement it for adults.

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: Move that Choline as petitioned is synthetic.
Motion by: Zea Sonnabend Seconded by: Harold Austin
Yes: # 5 No: # 0 Absent: # 1 Abstain: # 0 Recuse: # 0

Listing Motion: **1**. Move to add Choline to the National List 205.605(b) for use in infant formula labeled organic or made with organic (specified ingredients or food group(s))
Motion by: Zea Sonnabend Seconded by: Harold Austin
Yes: # 5 No: # 0 Absent: # 1 Abstain: # Recuse: #

Listing Motion: **2**. Move to add Choline to the National List 205.605(b) for use only in agricultural products other than infant formula labeled "made with organic (specified ingredients or food group(s))" and prohibited in agricultural products labeled "organic".
Motion by: Zea Sonnabend Seconded by: Tracy Favre
Yes: # 5 No: # 0 Absent: # 1 Abstain: # 0 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 Committee Chair to Transmit to NOSB

John Foster, Committee Chair M**arch 20, 2012**

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		
3. Is the substance harmful to the environment and biodiversity?		X		

[§6517c(1)(A)(i);6517(c)(2)(A)i]				
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 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:

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			food sources are abundant, such as eggs, liver, wheat germ, lecithin, human milk.
5. Is there an organic substitute? [§205.600 b.1]	X	X		food sources can be organic but are not strictly substitutes in infant formula.
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]		X		all the products in the petition can be made without this substance, although it is required by the FDA in non-milk-based infant formula.
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	X			For uses in adult food, the food is a substitute. In infant formula there is no natural substitute.
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			breastfeeding. However in some circumstances breastfeeding is not feasible.

[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		
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			nutritional quality is improved.
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		It is required by law for non-milk-based infant formula only.
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	Although this is considered a vitamin on product labels, it is not considered a vitamin by other entities.
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		Other than for infant formula, there seems no compelling justification as to why choline should not be obtained from organic food sources.
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		same as above.
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			X	

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
***Murraya koenigii* (curry leaves)**
March 31, 2012

Summary of Proposed Action:

A petition has been received to add *Murraya koenigii* (curry leaves) to be added to §205.606-Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic." *Murraya koenigii* (more commonly known as curry leaves or sweet neem leaves) is an extremely fragrant leaf commonly used for Indian cuisine.

Discussion

Since curry leaves are natural, not reported to be toxic or dangerous and are in fact a common condiment or ingredient in human diets, the Handling Committee chose not to request a TR.

Searches of the NOP database and two major organic certifiers' online databases (QAI) and directories (CCOF) have yielded only three suppliers of organic curry leaves. The NOP's database lists two distinct suppliers of curry leaves, both located in Sri Lanka while the CCOF directory lists one domestic source. QAI's product listing database did not return any results. Since curry leaves are an important ingredient in numerous Indian recipes, and it is reported that no common ingredient substitution exists, this agricultural item appears to meet the requirements defined for "commercially available" in §205.2 in the NOP regulation (appropriate form, quality, quantity). As a result, curry leaves are a candidate for listing on §205.606.

The petitioner indicated that a pest species quarantined in the United States, the Asian citrus psyllid, is commonly found on curry leaves in common countries of origin; as a result, imported organic curry leaves are not reliably available. A simple internet search for the pest yields numerous reliable stories on the quarantines in place. Additionally, the single domestic supplier has limited quantities available, well under the quantity claimed to be needed by the petitioner.

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, including classification recommendation (state actual motion):

Classification Motion: Motion to determine substance as non-synthetic.
Motion by: John Foster Seconded by: Harold Austin
Yes: 5 No: 0 Absent: 1 Abstain: 0 Recuse: 0

Listing Motion: Motion to add *Murraya koenigii* (curry leaves) to §205.606- Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."
Motion by: John Foster Seconded by: Joe Dickson
Yes: 5 No: 0 Absent: 1 Abstain: 0 Recuse: 0

Crops	☐	**Agricultural**	☐	**Allowed[1]**	**x**
Livestock	☐	**Non-synthetic**	**x**	**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):

[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 Committee Chair to Transmit to NOSB

John Foster, Committee Chair 3/31/12

NOSB Evaluation Criteria for Substances Added To the National List

Category 1. Adverse impacts on humans or the environment?
Substance: *Murraya koenigii* (Curry Leaves)

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		x		

or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]				
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 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. Substance Essential for Organic Production?
Substance: *Murraya koenigii* (Curry Leaves)

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			
5. Is there an organic substitute? [§205.600 b.1]	x			But limited and uncertain supply
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]	x			For those foods needing the profile the ingredient imparts
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		
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. Substance compatible with organic production practices?
Substance: *Murraya koenigii* (Curry Leaves)

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			Petition
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			
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 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:** *Murraya koenigii* (Curry Leaves)

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
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	x			

temporarily restrict supplies; or				
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
Giberellic Acid

March 20, 2012

Summary of Proposed Action:
This is a non-synthetic material that is allowed already for crop production and is being petitioned for post-harvest use to delay ripening of bananas, citrus, and pineapple. The need for it in bananas is also partially to delay or prevent development of the disease Black Sigatoka during transport to market.

Two issues are of concern to the Handling Committee that we are seeking public comment on. The first is whether there are cultural practices that would serve the same function in bananas to reduce the disease pressure after harvest. The second is the effect of post-harvest treatment on the nutritional content of the fruit. For this reason, it is being recommended for bananas, where the nutritional profile remains the same, and not recommended for other uses.

Evaluation Criteria

(Applicability noted for each category; Documentation attached)	**Criteria Satisfied? (see "B" below)**
1. Impact on Humans and Environment	☒ Yes ☐ No ☐ N/A
2. Essential & Availability Criteria	☒ Yes ☒ No ☐ N/A
3. Compatibility & Consistency	☒ Yes ☒ 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: Essential and Compatible **Comments:**
The Handling committee recognizes the lack of alternatives in bananas and acknowledges that the research that its use does not harm nutrition of bananas. But for citrus there is evidence that it harms the nutritive value and its essentiality was not shown convincingly. Very little support was provided for the use in pineapple.

Proposed Annotation (if any): for post-harvest use on bananas only.

Basis for annotation: ☐ To meet criteria above ☐ Other regulatory criteria ☐ Citation
Notes: There was not sufficient evidence in either the petition or the TR that the material is necessary for citrus and pineapple. Furthermore, there is some evidence that the use in citrus can decrease nutritional content.

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

Classification Motion: Move to determine that Giberellic Acid is non-synthetic
Motion by: Zea Sonnabend Seconded by: Harold Austin
Yes: # 5 No: # 0 Absent: # 1 Abstain: # 0 Recuse: # 0

Listing Motion: Move that Giberellic Acid be added to the National List section 205.605(a) for post-harvest use on bananas only.

Motion by: Zea Sonnabend Seconded by: Tracy Favre
Yes: # 5 No: # 0 Absent: # 1 Abstain: # Recuse: #

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 Committee Chair to Transmit to NOSB

John Foster, Committee Chair M**arch 20, 2012**

NOSB Evaluation Criteria for Substances Added To the National List

Category 1. Adverse impacts on humans or the environment? Substance: Gibberellic 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		
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		active ingredient only under consideration. Formulations are unknown.
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		X		
6. Are there adverse biological and		X		

chemical interactions in agro-ecosystem? [§6518 m.5]				
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]			X	does not come in contact with soil, crop or livestock.
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		it is unclear whether the FDA regulates this as post-harvest material. The TR states it is not GRAS but it is an approved food additive used in malting barley. (TR, 2011, page 4)
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:

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 fungus *Gibberella fujikuroi* is the source.
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	X		it does seem essential for bananas to prevent large amounts of loss in shipping. Sufficient evidence was not shown for essentiality for citrus or pineapple. (petition, 2011)
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]				maybe waxes are alternative substances for citrus. No alternatives in bananas.
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]				Perhaps there are cultural practices for bananas that would reduce the disease incidence and thus make the substance less necessary. The Handling committee seeks input on this issue.

[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			
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		while the TR states that bananas will ripen to their full nutritional profile, in other fruits (including citrus) there is some evidence that GA treatment can decrease flavonoids and polyphenols. (TR, Evaluation Question #7, 2011)
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 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			Non-agricultural
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			X	

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
Inositol

April 1, 2012

Summary of Proposed Action:
Inositol is an important biologic compound that serves numerous biologic functions/roles including but not limited to the following: a structural component of cell membranes, messenger molecules in reactions/processes, assist in overall muscle function and cell growth. Inositol may be formed endogenously using glucose as a substrate or it may be obtained by the human body through dietary sources. In addition to the aforementioned roles, inositol has been found to influence fat accumulation within the liver/intestines, control triacyglycerol and esterified cholesterol levels, and impact insulin resistance. Due to its association with these biologic processes/conditions, inositol is often marketed as a dietary supplement for those with these afflictions. The category of dietary supplements in the United States are not required to be regulated by the FDA in order to assure the validity and safety of using a substance to treat conditions, and as long as no health claims are made on the supplement they may be sold to American consumers without restrictions.

Inositol is found naturally in many foods which include fruits, beans, grains, seeds, and nuts. Another notable source of inositol is human breast milk which has been found to contain high concentrations of inositol (1500- 4000 mM/L) as stated in the March 2012 Tap review. The FDA list inositol as Generally Recognized as Safe (GRAS) for human consumption by the under 21 CFR 184.1370 and also mandates that all infant formulas sold in the United States must contain a minimum 4mg/ 100 kilocalories of inositol in order to assure infants fed solely on formula sources acquire adequate nutrition to grow as successfully as breast-fed infants.

Commercial production of inositol is often obtained from hydrolysis and acidification that begins from the corn/rice steeping process by using the phytic acid extracted from the corn/rice, and then using this phytic acid in one of several different chemical processes that ultimately results in isolating inositol. Additional methods also include utilization of microbial byproducts and processes (yeast); however these reactions are also dependent on synthetic reactions, or reactions that would not normally occur in nature to produce the final product of isolated inositol. Therefore, while inositol is a natural compound, the methods by which we can obtain commercial quantities of inositol are synthetic.

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)	☐ Yes ☐ No X N/A

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

Proposed Annotation (if any):

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

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

Classification Motion: Move that inositol as petitioned is synthetic.
Motion by: John Foster Seconded by: Joe Dickson
Yes: # 5 No: # 0 Absent: # 1 Abstain: # 0 Recuse: # 0

Listing Motion: **1**. Move to add inositol to the National List 205.605(b) for use in infant formula labeled organic or made with organic (specified ingredients or food group(s))
Motion by: John Foster Seconded by: Joe Dickson
Yes: # 5 No: # 0 Absent: # 1 Abstain: # 0 Recuse: # 0

Listing Motion: **2**. Move to add inositol to the National List 205.605(b) for use only in agricultural products other than infant formula labeled "made with organic (specified ingredients or food group(s))" and prohibited in agricultural products labeled "organic".
Motion by: John Foster Seconded by: Joe Dickson
Yes: # 5 No: # 0 Absent: # 1 Abstain: # 0 Recuse: # 0

Crops	☐	**Agricultural**	☐	**Allowed[1]**	**X**
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 § 205.605 with Annotation (if any):

As noted above.

[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 Committee Chair to Transmit to NOSB

John Foster, Committee Chair **April 2, 2012**

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		TR 3/9/12
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		x		TR 3/9/12
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]		x		TR 3/9/12
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 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:

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			May be obtained through yeast hydrolysis
3. Is the substance created by naturally occurring biological processes? [6502 (21)]	x			Yes, but can also be made synthetically
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			Yes, but only for infant formula as req in 21 CFR 107.100
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		Mass production is via synthetic pathways. Could be produced using organic yeast to provide organic inositol
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:

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			
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		Nutritive, but not replacing nutrients
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			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
Petition Proposal
***Citrus hystrix* leaves and fruit**

March 31, 2012

Introduction

A petition has been received to add the leaves and fruit of *Citrus hystrix* to §205.606- Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic." The species is also known by several common names including kieffer lime, kaffir lime, and makrut lime.

Background

Citrus hystrix leaves and fruit are traditional ingredients in Lao and Thai cuisine/curries. The ingredient is known for its "bumpy" skin and for imparting a unique intense flavor and aroma in foods (particularly curries) due to its high concentration of essential oils. *Citrus hystrix* is not a common crop in the United States; and is limited in its potential to be cultivated in that there a plant quarantine exists from the USDA due to citrus greening disease (Asian citrus psyllid) and the threat of spreading this debilitating plant disease throughout the country. Citrus greening disease is not limited to *Citrus hystrix* and it may be spread to other varieties of citrus. Due to this threat of disease, and the relatively unknown status of the ingredient in cuisines most common in the United States, this plant and its products are currently not well known or propagated.

Relevant areas in the Rule

§ 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."

Discussion

Searches of the NOP database and two major organic certifiers' online databases (QAI) and directories (CCOF) have yielded exceedingly few suppliers for *Citrus hystrix* fruit or its products. The NOP database was the only source that identified a supplier (two distinct organic certificates but one farm name) that has these items listed in the NOP database. Given the limited supply availability, and the threat of spreading the area afflicted by citrus greening disease, there appears to be little likelihood of procuring organic *Citrus hystrix* leaves and fruit in the immediate future in any significant quantity. With this knowledge, and the considerations of commercial availability as defined in under §205.2 (appropriate form, quality, quantity) it seems that *Citrus hystrix* is not commercially available for organic producers in the quantity that is required and should be listed on §205.606.

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, including classification recommendation (state actual motion):

Classification Motion: Motion to determine substance as non-synthetic.
Motion by: John Foster Seconded by: Harold Austin
Yes: 5 No: 0 Absent: 1 Abstain: 0 Recuse: 0

Listing Motion: Motion to add *Citrus hystrix* leaves and fruit to §205.606- Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."
Motion by: John Foster Seconded by: Joe Dickson
Yes: 5 No: 0 Absent: 1 Abstain: 0 Recuse: 0

Crops	☐	**Agricultural**	☐	**Allowed[1]**	**x**
Livestock	☐	**Non-synthetic**	**x**	**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):
[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 Committee Chair to Transmit to NOSB

John Foster, Committee Chair 3/31/12

NOSB Evaluation Criteria for Substances Added To the National List

Category 1. Adverse impacts on humans or the environment?
Substance: *Citrus hystrix* leaves and fruit

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?		x		

[§6517c(1)(A)(i);6517(c)(2)(A)i]				
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 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. Substance Essential for Organic Production?
Substance: ***Citrus hystrix*** leaves and fruit

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			
5. Is there an organic substitute? [§205.600 b.1]	x			But limited and uncertain supply
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]	x			For those foods needing the profile the ingredient imparts
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		
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. Substance compatible with organic production practices?
Substance: ***Citrus hystrix*** leaves and fruit

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			Petition
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			
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 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: ***Citrus hystrix*** leaves and fruit

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
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	x			

barriers, or civil unrest that may temporarily restrict supplies; or				
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
Sunset 2013 Proposal
Agar- Agar on 205.605(a)
February 21, 2012

List: 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)).”

(a) Non-synthetics allowed

Committee Summary:

Federal register notice of the sunset of this material elicited several public comments in favor of its re-listing. There were no comments against re-listing of it.

Review of the original TAP, the original recommendation to list, historical documents and public comments does not reveal any unacceptable risks to the environment, human, or animal health as a result of the use or manufacture of this material, at this time.

Upon review of the Technical Evaluation Report submitted on October 3, 2011, there does appear to be a question as to whether two forms of agar-agar being used exists. While there are extraction processes that are natural, without chemical modifications or non-synthetic, there are others that can be considered synthetic. An example of the synthetic method would be when the Graciliara species of algae are subjected to an alkaline pretreatment (heated in sodium hydroxide solution) to modify the polysaccharides in the algae. This process brings about a chemical change in the polysaccharides (L-galactose-6-sulfate groups are converted to 3,6-anhydro-L-galactose), increasing the gel strength of the agar-agar. Data would indicate that without this treatment the gel extracted would be too weak for most food applications.

While the Technical Review does list several methods of extraction, it does state that only 1 -2 % of the Agar- Agar supply is from the natural form of extraction. Furthermore, the product from the natural extraction method does not appear to be readily available in the U.S. market, or at least on a very limited basis.

The Technical Evaluation Report submitted on October3, 2011, under Evaluation Question #9: (which pertains to possible harmful effects on the environment or biodiversity) states that the current world demand for agar-agar is increasing and has the potential for over harvesting of these natural resources, which would affect

biodiversity of nearby beaches and the algae beds themselves. There were no studies found to indicate whether or not the harvesting of agarophytes, in particular, is harmful to the biodiversity on nearby beaches or in the algae beds at this time. There are alkaline waste waters that result from the manufacture of agar-agar, but there were no documents found that show this to be a problem to the environment, at this time. Based off of the information provided in the Technical Evaluation Report we are making the following recommendations, but we do think that continued review of this material and these areas of possible concerns should be duly noted in this recommendation.

Recommendation:

At this time we would recommend the relisting of Agar- Agar as it is currently listed on the National List : 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)).”

(a) Nonsynthetics allowed

We would also recommend an additional listing of Agar- Agar under:

(b) Synthetics allowed

This recommendation would be based from information presented in the October 3, 2011 Technical Evaluation Report. The NOSB Classification Guidance of 11/05/2009 was also considered for making this recommendation.

We would propose to list both with the following Annotations:

(a) Non-synthetic allowed
(b) Synthetics allowed

We would also recommend that this listing be revisited once the NOP has finalized the Draft Guidance for Materials Classifications (agricultural, nonagricultural substances). This would help to ensure that the materials have been properly classified and thus remove any further confusion from their status and help during future reviews.

Agar continues to be an important material used by the organic community.

Committee Vote

5 – yes 0 – no 1- absent 0-recused 0- abstain

National Organic Standards Board
Handling Committee
2013 Sunset Proposal
Calcium Sulfate on § 205.605(a)

March 20, 2012

Current National List Citation

List: 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))."

(a) Nonsynthetics allowed

Calcium sulfate—mined.

Committee Summary

Calcium sulfate can be chemically synthesized, or mined as gypsum. As a food additive, it is used as a coagulant in tofu production (the original petitioned use), and also as a nutrient, dough conditioner, sequestrant, jelling aid, firming agent, leavening agent, and pH buffer, among other uses. The use of gypsum as a tofu coagulant can be traced back at least 2000 years, according to the 2001 Technical Advisory Panel (TAP) review, which considered all food additive uses of this substance. The panel also found that the use of calcium sulfate was necessary for the production of certain types of tofu.

Processing of mined gypsum deposits into food grade calcium sulfate is minimal; mined deposits are crushed, screened, milled, graded and packaged in food grade facilities. The current annotation restricts the use of calcium sulfate to that from mined sources only.

Review of the original recommendation, the 2001 TAP review, historical documents, the 2007 sunset recommendation, and public comments does not reveal unacceptable risks to the environment, human, or animal health as a result of the use or manufacture of this material. There is no new information contradicting the original recommendation which was the basis for the previous NOSB decisions to list and again re-list this material.

Committee Recommendation(s)

The handling committee recommends the renewal of the following substance in this use category as published in the final rule:

Calcium sulfate – mined.

Committee Vote

Motion: Tracy Favre Second: Harold Austin
Yes: 5 No: 0 Abstain: 0 Recuse: 0 Absent: 1

National Organic Standards Board
Handling Committee
Sunset 2013 Proposal
Carrageenan on 205.605(a)
February 21, 2012

List: 205.605 Nonagricultural (non-organic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

(a) Non-synthetics allowed

Committee Summary:

Federal register notice of the sunset of this material elicited several public comments in favor of its re-listing. There were no comments against the re-listing of it.

Review of the Technical Evaluation Report of October 3, 2011 showed that while new uses are being explored for Carrageenan in the food industry as protective coatings, the food uses of it have not changed substantially since the original TAP review was conducted in 1995.

The FDA says that carrageenan may be safely used as a food additive for human consumption as long as its use is in accordance with 21 CFR 172.620. This regulation specifies that carrageenan should be prepared by aqueous extraction from any of the following eight species of *Rodophyceae* seaweeds: *Chondrus crispus, Chondrus ocellatus, Eucheuma cottonii, Gigartina acicularis, Gigartina pistillata, Gigartina radula, and Gigartina stellata.*

There are three primary extraction methods used to produce Carrageenan from its seaweed source: alcohol preparation (which is the most traditional method), gel press, and semi-refined or PES extraction. While Carrageenan is a naturally occurring polysaccharide extracted from seaweed and considered non-synthetic, the extraction process used, may in most instances, alter it. The Technical Evaluation Report of October 3, 2011 makes point of the fact that when industrial extraction methods using alcohol or alkali are used that modifications of the chemical structure of the polysaccharides occur. The predominant carrageenan present (i.e., kappa, iota, or lamda) and the resulting properties of the final product, are determined by the amount of time and the type of alkali used for the alkali treatment (all three extraction processes use a form of alkali as part of the aqueous extraction process). Examples: kappa carrangeenans are modified in a way that allows adjacent chains to form helical structures, resulting in firm, brittle gels. Iota carrageenans are modified to form weak, elastic gels and lamda carrageenans do not gel but rather form high viscosity liquids. This would appear to show that alkali treatments are used to promote structural

changes to carrageenan to acquire the specifically desired gel strength or textures. Thus, Carrageenan produced using these types of methods should be considered to be synthetic rather than non-synthetic, according to the information provided in the TR. This would be true for all three types of commercial extraction, currently being used by the industry to produce Carrageenan.

The Technical Evaluation Report of October 3, 2011 states that there were no other means of extraction currently being used.

Carrageenan continues to be an important material used by the organic community.

Recommendations:

At this time we would recommend the relisting of Carrageenan on the National List: 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food groups(s)). We are going to make the following recommendations to allow the current listing to sunset 605(a) and then move to relist it under 605(b). We are hoping that there will not be any disruption in the current use of Carrageenan, since this should hopefully occur at the same time.

We recommend allowing this current listing to sunset 605(a)

(a) Nonsynthetics allowed

We recommend then relisting under 605(b)

(b) Synthetics allowed

These recommendations are based from information presented in the October 3, 2011 Technical Evaluation Report. The NOSB Classification “draft” Guidance of 11/05/2009 was also considered for the making of this recommendation.

We would also recommend that this listing be revisited once the NOP has finalized the Draft Guidance submitted by the NOSB on November 5, 2009. Re-evaluation of the materials classification (agricultural, nonagricultural substances) should be considered to ensure that the listed materials have been properly classified and thus remove any further confusion from their status and help during future reviews.

Committee Vote:
5 – yes 0 – no 1 – absent 0-resused 0- abstain

National Organic Standards Board
Handling Committee
2013 Sunset Proposal
Glucono Delta-Lactone on § 205.605(a)

March 20, 2012

Current National List Citation

List: 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))."

(a) Nonsynthetics allowed

Glucono delta-lactone—production by the oxidation of D-glucose with bromine water is prohibited.

Committee Summary

Glucono delta-lactone (GDL) is used as a coagulant in tofu production, and also as an acidulant, leavening agent and sequestrant in food. It is produced by the oxidization of gluconic acid by a number of methods. The petition focused on the use of the substance as a tofu coagulant, and delineated a number of key advantages which make the use of this substance necessary relative to other coagulants. Because of the slow speed at which hydrolyzes back to gluconic acid, it results in tofu products with preferable texture and consistency. It also imparts a far less sour taste than other available coagulants.

The substance was reviewed by a Technical Advisory Panel (TAP) in 2002 at the request of the NOSB. The TAP found that the substance can be either synthetic or non-synthetic depending on the production method, and the current annotation prohibits its production using bromine water, which would render it synthetic. The other methods of GDL production – oxidation of gluconic acid with microorganisms, or oxidation with enzymes derived from those microorganisms – result in a non-synthetic form of GDL.

Review of the original recommendation, the 2002 TAP review, historical documents, the 2007 sunset recommendation, and public comments does not reveal unacceptable risks to the environment, human, or animal health as a result of the use or manufacture of this material. There is no new information contradicting the original recommendation which was the basis for the previous NOSB decisions to list and again re-list this material.

Committee Recommendation

The handling committee recommends the renewal of the following substance in this use category as published in the final rule:

> Glucono delta-lactone—production by the oxidation of D-glucose with bromine water is prohibited.

Committee Vote

Motion: John Foster Second: Tracy Favre
Yes: 5 No: 0 Abstain: 0 Recuse: 0 Absent: 1

National Organic Standards Board
Handling Committee
2013 Sunset Proposal
Cellulose on § 205.605(b)

March 20, 2012

List: 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))."

(b) Synthetics allowed

Cellulose—for use in regenerative casings, as an anti-caking agent (non-chlorine bleached) and filtering aid.

Committee Summary

Cellulose, in its natural form, is the main component of plant cell wells and one of the most abundant organic substances on earth. However, most commercially available cellulose is produced from wood pulp or other plant sources through a delignification process that results in sufficient chemical change to render the substance synthetic. While there are many uses for cellulose in food production, the 2002 Technical Advisory Panel (TAP) report focused on the petitioned uses for and forms of the substance – as a filtering aid, as a component of processed meat casings, and as an anti-caking agent. The current annotation restricts the substances use to these specific areas. While the production of non-synthetic (and even organic) cellulose is technically possible, no commercial sources of non-synthetic cellulose are currently known.

Review of the original recommendation, the 2001 TAP review, historical documents, the 2007 sunset recommendation, and public comments does not reveal unacceptable risks to the environment, human, or animal health as a result of the use or manufacture of this material. There is no new information contradicting the original recommendation which was the basis for the previous NOSB decisions to list and again re-list this material.

Committee Recommendation(s)

The handling committee recommends the renewal of the following substance in this use category as published in the final rule:

> Cellulose—for use in regenerative casings, as an anti-caking agent (non-chlorine bleached) and filtering aid.

Committee Vote

Motion: Harold Austin Second: Zea Sonnabend
Yes: 5 No: 0 Abstain: 0 Recuse: 0 Absent: 1