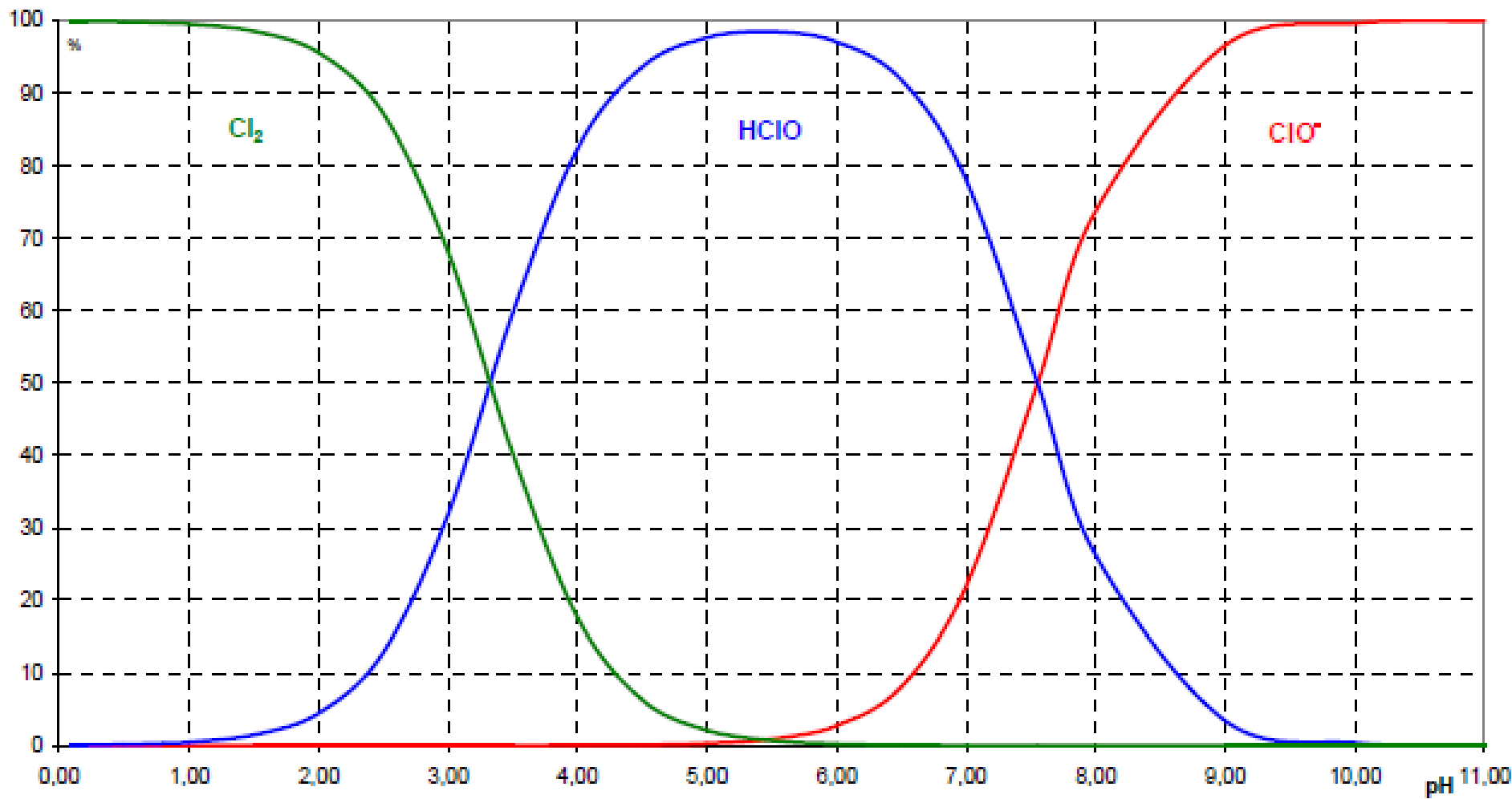


Fig. 1. Schematics of electrolyzed water generator and produced compounds.

# Hypochlorite / Hypochlorous acid / Chlorine as a function of pH



# 2017 Sunset Timeline Reorganization

- ▶ Unity and Alignment across the community, Industry, certifiers, Interest groups , trade associations - Just Do It.
- ▶ Support was given to groups of like substances - along the lines of proposals B and C.
- ▶ Materials need to be reviewed prior to their 5 year requirement
- ▶ Those reviewed and voted for removal will be removed on their original sunset date
- ▶ Decisions should be made on current information, not future potential information
- ▶ Suggestions for additional groupings

The background features abstract, overlapping geometric shapes in various shades of green, ranging from light lime to dark forest green. The shapes are primarily triangles and polygons, creating a dynamic, layered effect. The central text is positioned on a white background that is partially framed by these green shapes.

# PDS Proposal: NOSB Policy and Procedures Manual (PPM)

# Background



# Q. Why Revise the PPM?

A.

- ▶ Current version woefully out of date almost to the point of being irrelevant - has not been updated since 2012 (4 years)
- ▶ Does not reflect the current operating practices of the board.
- ▶ PPM conflicts with FACA
- ▶ Current PPM is confusing - Lots of new NOSB members need on-boarding (4 in 2015, 6 in 2016, 5 in 2017).
- ▶ Want to preserve good policies.

# Q. Who initiated this revision on the PPM?

## A. The NOSB

-----Original Message-----

From: Jean Richardson [mailto:(b) (6)]

Sent: Friday, September 12, 2014 4:39 PM

To: McEvoy, Miles - AMS

Cc: John Foster (jfoster@ebfarm.com); Mac Stone (mac@elmwoodstockfarm.com); Nick Maravell; Jay Feldman; Tracy Favre; Harold Austin; Carmela Beck; Calvin Walker; COLEHOUR BONDERA; Arsenault, Michelle - AMS; Brown Rosen, Emily - AMS

Subject: request to reactivate the PDS

Hi Miles: attached please find a request from the PDS to re-activate the Policy Development subcommittee, meet by teleconference call on October 14, and place on the Workplan the PPM.

Thank you

Jean

# NOP agreed to PDS leadership on revisions

**From:** [McEvoy, Miles - AMS](#)  
**To:** [Jean Richardson](#)  
**Cc:** [John Foster \(jfoster@ebfarm.com\)](#); [Mac Stone \(mac@elmwoodstockfarm.com\)](#); [Nick Maravell](#); [Jay Feldman](#); [Tracy Favre](#); [Tucker, Jennifer - AMS](#); [Harold Austin](#); [Carmela Beck](#); [Calvin Walker](#); [COLEHOUR BONDERA](#); [Arsenault, Michelle - AMS](#); [Brown Rosen, Emily - AMS](#)  
**Subject:** RE: request to reactivate the PDS  
**Date:** Thursday, September 18, 2014 7:20:26 AM

---

Hi Jean,

We agree that the NOSB PPM needs revision and we look forward to supporting the work of the NOSB Policy Development Subcommittee in updating/revising the PPM. We look forward to discussing in more detail on October 14. We will provide some additional background material prior to the meeting on the 14th.

Miles V McEvoy  
Deputy Administrator  
National Organic Program



# Q. What was the starting place for the proposed PPM?

## A. Work of previous PDS

**From:** [Jean Richardson](#)  
**To:** [Zea Sonnabend](#); [Mac Stone](#); [John Foster](#); [Harold Austin](#); [Tracy Favre](#); [Carmela Beck](#); [Calvin Walker](#); [Arsenault, Michelle - AMS](#); [McEvoy, Miles - AMS](#); [Bailey, Melissa - AMS](#)  
**Subject:** Move Exec till next week?  
**Date:** Wednesday, May 07, 2014 4:43:32 PM

---

Hi Executive team:

•••

I have asked Miles to get to work as quickly as possible to bring the PPM up to date, including role of NOSB Chair. We need clarity on what in the PPM is acceptable to NOP/AMS and which parts are not. Presently we seem to work on a mix of the outdated PPM, FACA, tradition and Roberts Rules in varying combinations. John, Michelle, and Colehour's PDS did a lot of work on proposed edits over the last year or so, so there is a foundation document to work from. I would ask that the edited PPM and related document if any be brought to the Exec. when ready to review.

# Q. What was the NOP's involvement?

## A. Supportive in nature: administrative assistance, review, compliance

On Jul 11, 2015, at 11:58 AM, Brown Rosen, Emily - AMS wrote:

Hi all,  
Here is the revised PPM draft based on changes made during 6-30 meeting. We stopped on page 21. I have inserted additional comments from Jean and Colehour in track changes mode also, hopefully I got them all,  
Regards,  
Emily

On Jun 10, 2015, at 10:13 AM, Brown Rosen, Emily - AMS wrote:

Hi all,  
Here is the long awaited revision of the PPM, incorporating comments from the earlier meeting and those sent in by Jean and Tracy. I have left these changes in track changes mode.

I think this list below includes the significant changes that need discussion.

1. Section III D3 -Role of Secretary - page 8
2. Work agendas , Section III F Page 9
3. Standards of Conduct, Sect III J -1-2 page 14
4. Task force – Section IV C page 19

# Q. What was the NOSB's involvement?

## A. Proposed, discussed, and approved changes. Considered public input.

- **Notes of January 12, 2016** were approved with no changes.
- **PPM revisions (ALL).**
- **FOIA changes.** The AMS's Office of General Council (OGC) provided some clarifying guidance about FACA vs FOIA, which the members will incorporate into the document. The members asked that this section be highlighted during new member training.
- **Policy Development Subcommittee description.** The paragraph was modified to indicate that

### Discussion

### Discussion

- **Notes of July 14, 2015** were approved with no changes
- **PPM revisions:** The group discussed various changes proposed by each of the members and will send some follow up language to the NOP for inclusion in the next draft version of the PPM. August 11 will be the last meeting before the proposal deadline and the PDS will submit what they have at that time.
- **The meeting was adjourned**

the fall 2015 NOSB meeting.

regulations. The PDS feels that the COL document is robust and is supportive of it in

# Q. Who has authority over PPM?

- ▶ By Law? The USDA -
- ▶ OFPA - § 6518 - National Organic Standards Board (a) In general. The Secretary shall establish a National Organic Standards Board (**in accordance with the Federal Advisory Committee Act**) (hereafter referred to in this section as the “Board”) to assist...
- ▶ FACA 8 (b) The head of each agency which has an advisory committee shall designate an **Advisory Committee Management Officer who shall—**
  - (1) **exercise control and supervision over the establishment, procedures, and accomplishments of advisory committees established by that agency;**
- ▶ By Tradition? The NOSB

Q. Do the PPM revisions reduce NOSB authority and independence?

A.

- ▶ Brings PPM into compliance with FACA and OFPA.
- ▶ PPM only authoritative on the NOSB, putting verbiage in the PPM does not make it binding on the NOP.
- ▶ Retains NOSB authority and sets collaborative nature with NOP based on mutual respect for each others roles.

# Tensions/Balancing

- ▶ Tradition vs compliance with OFPA/FACA
- ▶ Current wording vs current operations
- ▶ Accuracy vs aspirations
- ▶ Independence vs collaboration
- ▶ Protest vs compromise

## ▶ OBJECTIVE

- ▶ PPM that complies with OFPA
- ▶ PPM that complies with FACA
- ▶ PPM that is approved by the NOSB and NOP/AMS
- ▶ PPM that accurately reflects current operating procedures
- ▶ PPM that fosters transparency and public participation in NOSB decision making process
- ▶ PPM that respects and builds on past NOSB Policy where it does not conflict with the above points
- ▶ PPM with a logical structure and with proper grammar
- ▶ Continuous Improvement

# Public Comment Review





# NOSB/PDS ability to approve/revise PPM

## Public Input

- ▶ “The role of the Policy Development Subcommittee has been redefined in a way that diminishes the ability of the NOSB to establish its own procedures.”
- ▶ “Taken together, OFPA and FACA imply that NOP must recognize NOSB authority to develop its own operating principles.”

# NOSB/PDS ability to approve/revise PPM

## PPM Proposal

### IX. REVISIONS TO THE POLICY AND PROCEDURES MANUAL

- The PDS will review the PPM each year and, working in collaboration with the NOP, determine if any updates are necessary.
- Proposed changes will be subject to review and approval by the NOP and the full NOSB.

# NOSB/PDS ability to approve/revise PPM

## OFPA/FACA

- ▶ OFPA - § 6518 - National Organic Standards Board (a) In general. The Secretary shall establish a National Organic Standards Board (**in accordance with the Federal Advisory Committee Act**) (hereafter referred to in this section as the “Board”) to assist...
- ▶ FACA 8 (b) The head of each agency which has an advisory committee shall designate an **Advisory Committee Management Officer who shall—**
  - (1) **exercise control and supervision over the establishment, procedures, and accomplishments of advisory committees established by that agency;**

# The section on NOP-NOSB Collaboration has become less collaborative

## Public Input

- ▶ “The separation of the board’s responsibility to carry out its statutory authority should not be confused with **bureaucratic constraints** that preemptively restrain board function.”
- ▶ ‘OFPA mandates this independent authority, independence is not foreign to FACA. Section 5.b.3 of FACA requires that, “the advice and recommendations of the advisory committee will not be inappropriately influenced by the appointing authority..., but will instead be the result of the advisory committee's independent judgment.” **We interpret this to mean that you either seek advice or you do not seek advice. Once you seek advice (in the case of the NOSB, the agency is not seeking advice by Congress had mandated independent outside advice with line item authorities), you do not seek to influence that advice. A serious form of influence is a government official preemptively telling advisors that they may not offer advice because of the associated costs.**”
- ▶ “OFPA, as pointed out above, requires NOP to consult with the NOSB on a number of issues, including **‘developing the program.’**”

# The section on NOP-NOSB Collaboration has become less collaborative.

## Public Input

- ▶ “At the same time, less emphasis is placed on *true collaboration*. It is essential that the NOSB police itself and adapt to changing circumstances from the NOSB. This self-regulation cannot occur if the NOSB does not have the ability to change its own official policies, with the appropriate public comment.”
- ▶ “In addition, the requirement in OFPA for the Secretary to authorize the board to hire a staff director is a clear statutory direction that the NOSB must lead the way. Taken together, these two statutes conflict with parts of the statement in the proposal that ‘the NOSB cannot direct USDA or bind the Secretary through its actions; for example, it cannot obligate funds, contract, make NOP staffing decisions, or initiate policies of its own accord.’”

# The section on NOP-NOSB Collaboration has become less collaborative.

## PPM Proposal

### NOSB-NOP COLLABORATION

In 1990, [the Organic Foods Production Act \(OFPA: 7 U.S.C. 6518 \(a\)\)](#) directed the Secretary of Agriculture to “establish a National Organic Standards Board (in accordance with the [Federal Advisory Committee Act \(FACA\)](#)) ... 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 the Act. Section 6503 (a) of the OFPA requires that the Secretary “[shall establish an organic certification program ... and shall consult with the NOSB](#)” (6503(c)). The National Organic Program (NOP) is the governmental institution responsible for implementing the OFPA and is the means through which the NOSB provides advice and assistance to the Secretary of Agriculture. The NOSB, as a FACA advisory committee, must conduct business in the open, under the requirements of P.L. 94-409, also known as “[Government in the Sunshine Act](#)” (5 U.S.C.552b).

The section on NOP-NOSB Collaboration has become less collaborative.

## PPM Proposal

The USDA cannot delegate its authority as a regulatory body to private citizens, even when those private citizens are appointed by the Secretary to provide advice. Therefore, the [NOSB cannot direct USDA or bind the Secretary through its actions; for example, it cannot obligate funds, contract, make NOP staffing decisions, or initiate policies of its own accord.](#)

However, the NOSB has unique statutory authority related to the recommendation of materials as approved or prohibited substances for inclusion on the National List.

The unique nature of the NOSB and its relationship with the NOP, as established through OFPA, requires that the volunteer Board, which regularly receives stakeholder input through public comment, must work collaboratively with the NOP.

[Similarly the NOP, as required through OFPA, must consult and collaborate with the NOSB](#)

# The section on NOP-NOSB Collaboration has become less collaborative.

## PPM Proposal

Team work and collaboration between the NOSB and the NOP, as well as others in the organic community, is needed to maintain, enhance and promote the integrity of organic principles and products. Successful collaboration is dependent on effective communication and constructive feedback.

Communication is facilitated by the Advisory Committee Specialist, who participates in all NOSB calls. Additionally, the NOP Deputy Administrator or designee will participate in all ES calls, and in other standing Subcommittee calls upon request and mutual agreement. In addition, each standing Subcommittee will be assigned an NOP staff person to provide technical, legal, and logistical support.

The work of the NOP and NOSB since the 1990 passage of the OFPA clearly demonstrates the need for the high level of collaboration and consultation described above. NOP, NOSB and its associated stakeholders must continuously work to seek common ground, collaborate and consult in order to build organics and maintain organic integrity. Every aspect of this work must take place in a manner which clearly demonstrates mutual respect and positive intent.



# The section on NOP-NOSB Collaboration has become less collaborative.

## OFPA/FACA

- ▶ OFPA • § 6503 - National organic production program (c) Consultation. In developing the program under subsection (a), and the National List under section 6517 of this title, the Secretary **shall consult with the National Organic Standards Board** established under section 6518 of this title.
- ▶ OFPA - § 6518 - The Secretary shall establish a National Organic Standards Board (in accordance with the Federal Advisory Committee Act) (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 chapter.
- ▶ (j) Other terms and conditions. The Secretary shall authorize the Board to hire a staff director and **shall detail staff of the Department of Agriculture or allow for the hiring of staff** and may, **subject to necessary appropriations, pay necessary expenses incurred by such Board in carrying out the provisions of this chapter, as determined appropriate by the Secretary.**

The section on NOP-NOSB Collaboration has become less collaborative.

## OFPA/FACA

- ▶ FACA 7. (c) The Administrator shall prescribe administrative guidelines and management controls applicable to advisory committees, and, to the maximum extent feasible, provide advice, assistance, and guidance to advisory committees to improve their performance. In carrying out his functions under this subsection, the Administrator shall consider the recommendations of each agency head with respect to means of improving the performance of advisory committees whose duties are related to such agency
- ▶ FACA 8 (b) The head of each agency which has an advisory committee shall designate an Advisory Committee Management Officer who shall—
  - (1) exercise control and supervision over the establishment, procedures, and accomplishments of advisory committees established by that agency;

# Work Agendas

## Public Input

- ▶ “The section on NOSB work agendas (formerly workplans) removes from the NOSB the authority to initiate agenda items.”
- ▶ “OFPA gives the leadership role to the NOSB, not the NOP. Authority over work agendas must be restored to the NOSB.”
- ▶ “The NOSB should be allowed unequivocally to retain control of its own administrative work plans and agendas dictated and specified by the Organic Food Production Act.”

# Work Agendas

## OFPA/FACA

- ▶ OFPA - § 6518 - National Organic Standards Board (a) In general. The Secretary shall establish a National Organic Standards Board (**in accordance with the Federal Advisory Committee Act**) (hereafter referred to in this section as the “Board”) to assist...
- ▶ FACA 8 (b) The head of each agency which has an advisory committee shall designate an **Advisory Committee Management Officer who shall—**
  - (1) **exercise control and supervision over the establishment, procedures, and accomplishments of advisory committees** established by that agency;
- ▶ FACA 10. Advisory committee procedures; meetings; notice, publication in Federal Register; regulations; minutes; certification; annual report; Federal officer or employee, attendance
  - (f) **Advisory committees shall not hold any meetings except at the call of, or with the advance approval of, a designated officer or employee of the Federal Government, and in the case of advisory committees (other than Presidential advisory committees), with an agenda approved by such officer or employee.**

# Work Agenda

## PPM Proposal

The NOSB Work agenda is a list of projects for the upcoming semester or year for each of the Subcommittees. Agendas are developed via collaboration between the NOSB and the NOP and are revised based on AMS-NOP requests, NOSB priorities, and public comment.

Work agendas are developed based on the following criteria:

- **Within Scope:** Item must be within the scope of OFPA. NOP must have a clear sense of the intent and scope of the work agenda item. The public may petition additions or deletions from the National List that will be added to the work agenda. In addition, the public may submit comments to the NOSB or write to the NOP for potential additions to the work agenda. For the NOSB, work agenda items may emerge from discussions on current issues.
- **USDA and NOP Priority:** Item must be a priority for the USDA/NOP; something that the NOP is able to implement in a reasonable timeframe.
- **Clear Need:** Item must reflect a clear need for the NOP and/or organic community, for which new or additional information or advice is needed.

# Work Agenda

## PPM Proposal

The NOSB work agenda establishes Subcommittee work for the upcoming semester or year, and is developed through the following process:

1. NOSB Subcommittees submit to the Executive Subcommittee draft work agenda items based on AMS-NOP requests, NOSB priorities, and requests from public comment.
2. The NOP and Executive Subcommittee review the draft NOSB work agenda. The content and schedule will be reviewed on an ongoing, as needed basis.
3. NOP confirms the final NOSB work agenda, and provides written confirmation.

Work agenda items should be prioritized accordingly:

1. Substance evaluations (e.g., 5-year sunset review, petitions)
2. NOP requests to the NOSB
3. NOSB requests to NOP
4. Other projects

# Work Agenda

## PPM Proposal

Below are descriptions of common NOSB work agenda items and the corresponding NOP and NOSB responsibilities.

- Review of materials proposed to be added to or removed from the National List

The NOSB has the statutory authority to consider and recommend materials for addition to, or deletion from, the National List of Approved and Prohibited Substances. The NOSB may also make recommendations to add, remove, or modify annotations restricting the use of such listed materials.

- Changes to annotation or classification of materials

The NOSB may request to review an existing substance on the National List without a new petition when they have justification to support a revision of the annotation or reclassification of the substance. This may happen as a result of the sunset review process, or as new information is provided in a Technical Review, or from public comment.

# Work Agenda

## PPM Proposal

Below are descriptions of common NOSB work agenda items and the corresponding NOP and NOSB responsibilities.

- **Recommendation for modification of existing standards or new standards**

The NOP may request that the NOSB develop recommendations for new or existing standards. The request should be in writing and include a statement of the problem to be addressed, background, including the current policy or situation, statutory/regulatory authority, legal context, and desired timeframe for receiving the recommendation. The request will be posted on the NOP web site.

- **Advice on NOP policy and interpretation of standards**

The NOSB may provide comments on guidance or policy memos included in the Program Handbook, or may also make recommendations for new guidance or policies.



# Work Agenda

## PPM Proposal

Below are descriptions of common NOSB work agenda items and the corresponding NOP and NOSB responsibilities.

- **Compliance and Enforcement**

The NOP is responsible for compliance and enforcement. The NOP welcomes NOSB input on standards, but NOSB involvement in active investigations or enforcement actions is not appropriate. When timely and appropriate, the NOP reports to the NOSB the status of enforcement actions and also posts the status on the NOP web site.

- **Management Review**

The NOSB may review the quality management system and internal audits to ensure that the NOP is managed effectively and efficiently. For example, the NOSB may be asked for informal feedback or to work on specific work agenda items that relate to the development or implementation of audit corrective actions.

# Conflict of Interest

## Public Input

- ▶ “The proposal incorporates the NOP changes that are not publicly transparent, but divulge potential conflicts only to the NOP. The NOP changes also do not divulge the **statutory basis of the criteria**, nor the particular bases for decisions. **They allow for arbitrary decisions based on vague, nonpublic criteria.** The COI policies in the current PPM are clear, and allow for a public application by the NOSB itself. **If the NOP has additional criteria that it thinks should be applied, it should state them publicly and apply them publicly.** “Taken together, OFPA and FACA imply that NOP must recognize NOSB authority to develop its own operating principles.”

# Conflict of Interest

## Public Input

- ▶ “Discussion of potential conflicts that might exist for board members should be discussed in public not in private conversation with NOP. In this sense, these guidelines overstep the NOP’s authority to control the process, since the board has historically conducted potential conflicts in public with the board making a determination in public.”

# Conflict of Interest

## OFPA/FACA

- ▶ OFPA - § 6518 - National Organic Standards Board (a) In general. The Secretary shall establish a National Organic Standards Board (**in accordance with the Federal Advisory Committee Act**) (hereafter referred to in this section as the “Board”) to assist...
- ▶ FACA 7 (c) The **Administrator shall prescribe administrative guidelines and management controls applicable to advisory committees, and, to the maximum extent feasible, provide advice, assistance, and guidance to advisory committees to improve their performance.**
- ▶ FACA 8 (b) The **head of each agency** which has an advisory committee shall designate an Advisory Committee Management Officer who shall—
  - (1) **exercise control and supervision over the establishment, procedures, and accomplishments of advisory committees established by that agency;**

# Conflict of Interest

## OFPA/FACA - GSA Guidance

FACA ADVISORY COMMITTEE MEMBERS APPLICABLE ETHICS STATUTES AND REGULATIONS

SGE - Special Government Employee (a person who serves not more than 130 days out of a 365 day period)

FTE - Full-time regular government employees

REP - Representative of particular interest group

I. Executive Orders apply to SGEs and FTEs **but not to REPs**

II. Standards of Conduct apply to SGEs and FTEs **but not to REPs except as noted below.\***

III. **Conflicts of Interest apply to SGEs except as noted below\*\* and FTEs but not to REPs.**

IV. Ethics in Government Act including both the A. Public Financial Form and B. Confidential apply to SGEs and FTEs but not to REPs.

**\* Representative commission members would only be bound by the standards of conduct if the commission as a body made it applicable to all members. Representative members are reminded that nonpublic information should not be released to the public without permission.**

**\*\* SGE's are treated less restrictively on a number of conflicts of interest laws.**

# Conflict of Interest

## PPM Proposal

### K. DECLARATION OF INTERESTS/Conflict of Interest

NOSB members are classified as representatives under the Federal Advisory Committee Act (FACA). Each representative is appointed to articulate the viewpoints and interests of a particular interest group. The Organic Foods Production Act (OFPA) prescribes these interest groups, which include farmers/growers, handlers, certifiers, environmentalists/conservationists, scientists, consumers and public interest groups, and retailers. Representatives are appointed to speak in “we” terms, serving as the voice of the group represented (e.g., “we farmers/growers believe...”). As such, NOSB members are not expected to provide independent expert advice, but rather advice based on the interests of the groups served.

NOSB members represent the interests of a particular group. As such, many of the interests are acceptable interests. **An interest is acceptable if it is carried out on behalf of a represented group, and if a Board member receives no disproportionate benefit from expressing the interest. True conflicts of interest arise when an interest:**

- **Directly and disproportionately benefits you or a person associated with that member;**
- **Could impair your objectivity in representing your group; or**
- **Has the potential to create an unfair competitive advantage.**

The appearance of a personal conflict and loss of impartiality, while not a true conflict, must be considered when conducting NOSB business.

# Conflict of Interest

## PPM Proposal

### Declarations of Interest/Conflicts of Interest Procedures

**Board members are appointed in part because of their interests.** As such, each NOSB member needs to actively consider their interests with respect to topics being considered by the Board, and identify whether these interests would create appearance problems. This consideration should occur at two specific points during the Board's work on a particular topic. The first consideration should occur at the Subcommittee level, when a Subcommittee begins work on material or topic. The second is when a discussion document or proposal advances from the Subcommittee to the full Board for consideration.

#### At the Subcommittee Level

**NOSB members represent the diverse interests of a broad stakeholder community, and make recommendations that may have wide-reaching regulatory impacts across all of these interest groups.** As such, NOSB member actions are carefully scrutinized.

Given this, the NOP has provided the following guidelines for NOSB members working at the **Subcommittee level:**

- Avoid leading projects for which you could reasonably be viewed by others as having a particular interest that would hinder your ability to objectively and fairly represent broader group interests, and to allow other members to represent theirs. If leading a project would likely lead others to believe you are “self-dealing” to benefit yourself or someone close to you, you should refrain from leading.

# Conflict of Interest

## PPM Proposal

- If you feel you may have an appearance problem or conflict of interest, you should inform the DFO that a conflict may exist, and describe the nature of that conflict. **You should also tell the subcommittee impacted that you may have a conflict; sharing as much or as little about the nature of the conflict with other board members as you wish.** After this declaration, you may continue to contribute to the discussion on the topic. As long as it is known there is a conflict of interest, the conflict does not preclude the member from contributing his or her input to the subcommittee.
- **If you are uncertain as to whether an interest constitutes an appearance problem or a true conflict, then contact the DFO to discuss it. In this case, the NOP, working with the USDA office of ethics as needed, will make the determination about whether a problem exists.**

### At the Full Board Level

Once discussion documents and proposals are posted for public comment, each NOSB member is to review the documents across all Subcommittees, and research any potential conflicts of interest due to organizational affiliation or relationships.

The following procedures will take place at the Board level:

1. Approximately **2-4 weeks before the meeting**, the NOP's DFO will provide a matrix to all NOSB members that lists the items being considered at the meeting.
2. **If you determine that you do have a conflict of interest, use the matrix to disclose that information and to declare a recusal from voting on the item(s).**



# Conflict of Interest

## PPM Proposal

3. If you are not sure whether an interest is acceptable or poses a problem, or if you are uncertain whether recusal is needed, contact the NOP DFO to discuss. The NOP - working with the USDA office of ethics as needed - will make the determination about whether a conflict of interest exists, and will instruct the member accordingly as to whether to vote or not.
4. Return your completed matrix approximately one week before the board meeting. The NOP will then use these to compile a list of all recusals for the meeting.
5. At the meeting, at the beginning of each subcommittee session or at a time designated at the discretion of the board chair, the DFO will state: “the following board members have a conflict of interest with the following documents, and will not be voting: e.g. Bob has a conflict and will recuse himself from the proposals CleanGreenA and GreatChemB (etcetera).”
6. Once the DFO completes listing the recusals, the NOSB Subcommittee chair leading the session may invite additional information from members on a voluntary basis, with a statement such as: “if Board members wish to disclose information about their conflict, or any other information about their interests, they are welcome to do so at this time.” This is to be stated as a general and voluntary invitation; no specific NOSB member is to be called on.
7. For any documents deferred to the last day of the meeting, the DFO will repeat the declaration of statement above at the start of the voting session for each subcommittee. When it is time to vote, the NOSB member recusing her/his self should state “recuse” when it is his or her time to vote.

# Advisory Committee Specialist/Staff Director

## Public Input

- ▶ “Neither version addresses the provision of §6518(j) of OFPA, “The Secretary shall authorize the Board to hire a staff director.”
- ▶ “The section on the Advisory Committee Specialist (formerly Executive Director) deletes this sentence: “The most important function of the ED is to facilitate the operation of the Board, while helping to maintain and strengthen its independence.”

# Advisory Committee Specialist/Staff Director

## OFPA/FACA

- ▶ OFPA - § 6518 - **The Secretary shall authorize the Board to hire a staff director** and shall detail staff of the Department of Agriculture or allow for the hiring of staff and may, subject to necessary appropriations, pay necessary expenses incurred by such Board in carrying out the provisions of this chapter, as determined appropriate by the Secretary.

# Advisory Committee Specialist/Staff Director

## History from NOSB minutes

- ▶ May 1993 - Hal Ricker referred to as Staff Director, not hired by NOSB
- ▶ April 1995 - Hal Ricker referred to as Program leader
- ▶ April 1996 - Hal Ricker referred to as Program Manager
- ▶ May 2002 - Public calls for the hiring of a staff director in public comment
- ▶ 2004 - Appropriations made and NOSB FACA budget enlarged for hiring of a staff director
- ▶ October 2004 - Barbra Robinson AMS Deputy Administrator talks about hiring of a Staff Director
  - ▶ Must be a federal employee supervised by a federal employee
  - ▶ They cannot work at the direction of the Board.
  - ▶ Staff director to fulfill the Board's expectations. This staff director, the duties and the responsibilities of this staff member will be to work with the Board
  - ▶ Combined NOSB draft job description with USDA job description for Board Specialist
  - ▶ Need for collaboration between NOSB/NOP on this role was noted

# Advisory Committee Specialist/Staff Director History

- ▶ August 2005 - Job description posted for Executive Director
- ▶ April 2006 - Valerie Frances announced as Executive Director, Katherine Benham hired as Advisory Board Specialist
- ▶ October 2010 - Lisa Ahramjian announced as replacement for Valerie
- ▶ 2011 Katherine Benham transfers out of AMS and position is not refilled; Lisa A transitions roles in NOP
- ▶ November 2011 - Lorraine Coke fills Board Specialist/Executive Director role temporarily
- ▶ May 2012 - Michelle A announced as Advisory Board Specialist USDA title for the Executive Director job description
- ▶ April 2013 - New calls from Public for hiring of Staff Director by the NOSB, asserts position is Deputy Administrator

# Advisory Committee Specialist/Staff Director

## PPM Proposal

### H. Advisory Committee Specialist

The Advisory Committee Specialist (ACS) is an NOP staff member who is assigned to support the NOSB. The Advisory Committee Specialist prepares the Advisory Committee's and Subcommittees' meeting agendas and notes, and attends all meetings. [The position of Advisory Committee Specialist \(formerly called Executive Director\) was added in 2005 to facilitate communication and collaboration between the NOP and the NOSB.](#) Advisory Committee Specialist duties include but are not limited to:

- [Ensuring that all FACA and OFPA requirements are implemented](#)
- Managing calendars and work agendas to facilitate Subcommittee and NOSB activities
- Arranging, facilitating, and documenting the NOSB Subcommittee conference calls
- Ensuring NOSB members have all necessary materials and information to provide informed, structured and timely recommendations to the NOP
- Conducting meeting planning activities for the semi-annual NOSB meetings, including preparation of Federal Register notices and press releases, and facilitation of public comments
- Coordinating the NOSB nomination and chartering process
- Facilitating training of NOSB members
- Managing information reporting and communication between the NOSB and NOP

# Public Information

## Public Input

- ▶ “if NOP wants to constantly stress the importance of FACA in issuing directives to the NOSB, why isn’t it following FACA when it comes to public disclosure and true transparency? The fact that USDA regards responding to requests as such a low priority indicates contempt for the law (FACA) and public participation in making decision.”
- ▶ “As such, any restriction to public access, beyond what FOIA provides for, is contrary to FACA.”

# Public Information

## OFPA/FACA

- ▶ OFPA - § 6518 - National Organic Standards Board (a) In general. The Secretary shall establish a National Organic Standards Board (**in accordance with the Federal Advisory Committee Act**) (hereafter referred to in this section as the “Board”) to assist...
- ▶ FACA § 10. (b) Subject to section 552 of title 5, United States Code, the records, reports, transcripts, minutes, appendixes, working papers, drafts, studies, agenda, or other documents which were made available to or prepared for or by each advisory committee **shall be available for public inspection and copying at a single location in the offices of the advisory committee or the agency to which the advisory committee reports until the advisory committee ceases to exist.**



# Public Information

## OFPA/FACA and GSA guidance

- ▶ FACA § 8 (b) The head of each agency which has an advisory committee shall **designate an Advisory Committee Management Officer who shall—**
  - (3) **carry out, on behalf of that agency, the provisions of section 552 of title 5, United States Code, with respect to such reports, records, and other papers.**
- ▶ **FACA Guidance GSA:** Representative commission members would only be bound by the standards of conduct if the commission as a body made it applicable to all members. **Representative members are reminded that nonpublic information should not be released to the public without permission.**

# Public Information

## PPM Proposal

- Recordkeeping

Records of the NOSB shall be handled in accordance with General Records Schedule 26, Item 2 or other approved agency records disposition schedule. These records shall be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. 552. Information about the NOSB is available online at: <http://www.ams.usda.gov/rules-regulations/organic/nosb>

While meeting transcripts are not required under FACA, the **NOP provides transcripts or meeting notes to support the transparency of NOSB meetings and to support subsequent rulemaking activities.** Minutes of each NOSB meeting, as approved by the DFO and the NOSB Chair and Secretary, shall contain a record of the persons present, a complete and accurate description of matters discussed and conclusions , and the outcome of voting.

# Public Information

## PPM Proposal

- **FACA requires (5 U.S.C. App. Section 10 (b) ):** “Subject to section 552 of title 5, United States Code, the records, reports, transcripts, minutes, appendixes, working papers, drafts, studies, agenda, or other documents which were made available to or prepared for or by each advisory committee shall be available for public inspection and copying at a single location in the offices of the advisory committee or the agency to which the advisory committee reports until the advisory committee ceases to exist.”

Any request for FACA records must be made to the NOP.

- While requests for FACA Board records do not have to go through the formal FOIA request process, those records must be reviewed by AMS/NOP before release, to determine whether any FOIA exemptions apply (e.g., personal information, business proprietary information). In addition, OFPA itself requires that no confidential business information be released, so emails and documents need to be reviewed before release to ensure that this requirement is met.

# Public Information

## PPM Proposal

- [Freedom of Information Act \(FOIA; 5 U.S.C. 552\)](#). Under this Act, the public may request documents and other information pertaining to USDA actions. NOSB communications with USDA (including email) are subject to these requests, with limited exemptions. Some USDA information is routinely exempt from disclosure in or otherwise protected from disclosure by statute, Executive Order or regulation; is designated as confidential by the agency or program; or has not actually been disseminated to the general public and is not authorized to be made available to the public upon request. When there is a FOIA request for information, the USDA will review all relevant information and determine what qualifies for release, then provide it to the requestor.

# Public Information

## PPM Proposal

### 2) Additional Standards of Conduct

NOSB members **should adhere** to the following basic “standards of conduct” while in government service:

- Refrain from sharing working documents with the public. Working documents are defined as information that a board member gains by reason of participation in the NOSB and that he/she knows, or reasonably should know, has not been made available to the general public: e.g. is not on the NOP or other public websites, or is a draft document under development by an NOSB Subcommittee.
- Do not circulate draft Subcommittee documents until they are finalized and publicly available to all on the AMS/NOP website.

# Sunset Voting Procedures

## Public Input

- ▶ “The most disturbing change found in the draft proposal PPM and in NOSB policy in general is the complete reversal of the material Sunset Review process. This change was made without proper notice and public comment in 2013.”
- ▶ At a minimum, the results of this lawsuit should be realized before the Sunset policy is revisited with proper attention to public comment and debate (as claimed by the legal challenges).

# Sunset Voting Procedures

## PPM Proposal

### VII. Sunset Review Process

The Organic Foods Production Act of 1990 (OFPA) authorizes a National List of Allowed and Prohibited Substances (7 U.S. C. Section 6517). Section 6517 (e) mandates a Sunset Provision as follows:

“No exception or prohibition in the National list shall be valid unless the National Organic Standards Board has reviewed such exemption or prohibition as provided in this section within 5 years of such exemption or prohibition being adopted and the Secretary has renewed such exemption or prohibition.”

The [NOP published a Federal Register notice on Sept. 16, 2013 \(78 FR 56811\) describing current procedures for sunset review.](#) Through the sunset review process, the NOSB can recommend to USDA the removal of substances based on adverse impact on human health, the environment, or other criteria under the Organic Foods Production Act (OFPA). If upon review the NOSB believes the substance no longer fits the criteria for an exemption or prohibition, the NOSB can recommend (by a decisive two-thirds vote, 7 USC Section 6158 (i)) to remove the substance from the National List. After the NOSB has completed this "sunset" review, the USDA must renew or remove the substances on the National List to complete the process. All substances under sunset review will be considered over two NOSB meetings, to provide ample opportunity for public notice and comment. [The NOSB observes the following procedure.](#)

# Sunset Voting Procedures

## PPM Proposal

The NOSB **observes** the following procedure.

Definition:

Observe: to fulfill or **comply with** (a social, legal, ethical, or religious) **obligation**

Does not say:

Accept

Approve

Support



# Sunset Voting Procedures

## PPM Proposal

A. Steps in the Sunset Review Process (See Member Guide for forms used in these steps.)

Step 1: The NOSB Subcommittees submit the initial Sunset List Summary for posting which may include requests for specific information. The NOP posts the list as well as the NOSB Meeting Announcement in the Federal Register which invites comments, at least 30 days prior to the first public meeting on these sunset substances.

Step 2: The public submits written comments, which are analyzed by Subcommittees.

Step 3 (Public Meeting #1): Subcommittees summarize background and public comment & receive oral comment.

Step 4: Subcommittees analyze written and oral comments from Meeting #1 and prepare a Preliminary Review that includes a motion to remove the substance from the National List. The NOP publishes the next meeting announcement in the Federal Register, inviting comment on the Preliminary Reviews, which are posted on the NOP website.

Step 5: Written public comments submitted and analyzed by Subcommittees.

# Sunset Voting Procedures

## PPM Proposal

Step 6 (Public Meeting #2): Subcommittees present Preliminary Review, receive oral comment, and discuss the proposal with the full Board. When presented to the full NOSB, reviews will contain a motion and second taken in Subcommittee. Motions for removal based on the Preliminary Review are voted on by the full Board, and require a decisive two-thirds (2/3) majority to pass.

- o At Meeting #2, the NOSB completes the Sunset Review and submits the final documents to the NOP.

Step 7: AMS reviews the NOSB Sunset Review and considers rulemaking action for any recommended removals. This will include a proposed rule open for public comment before a final rule amendment is published.

Step 8: AMS issues Federal Register Notice announcing renewal of applicable substances.

# Minority View/Opinion

## Public Input

- ▶ “Keeping a record of minority opinions is essential for the NOSB’s operation at both the subcommittee and whole-board level.”
- ▶ The new draft deletes the inclusion of the minority opinion as a separate document (when it’s applicable at all). These changes to the text have the effect of silencing the minority opinion and must be changed.
- ▶ A view cannot be determined a “minority” view until after a vote is taken. It is also contrary to the purpose of an advisory committee to set a deadline dictating when new information may be introduced, particularly when a vote crystallizes the minority view.

# Minority View/Opinion

## PPM Proposal

•When it is not possible for a Subcommittee, during its regular deliberations on conference calls, to reach consensus on a proposed document/recommendation as it is being reviewed, and there are substantive irreconcilable differences, a minority of the Subcommittee may develop a written minority view for review by all members of the Subcommittee. The Subcommittee Chair has the responsibility to facilitate the process for the minority view.

A minority view should:

- o Be short and concise, and include reasons for opposing the Subcommittees recommendation;
- o Should not include any data or information not introduced on a Subcommittee call;
- o Should be submitted in a timely manner, and will not be accepted after the Subcommittee has voted on its recommendation;
- o Will be included as a separate section at the end of the recommendation.

The NOSB was carefully chartered by Congress to facilitate both a **valid consensus among very diverse stakeholders** on the numerous questions of interpretation, as well as provide the special –“gatekeeper” function with respect to substances that the Secretary would allow for use in organic production and processing.

-Kathleen Merrigan

# Conflict of Interest for Technical Reviews

## Public Input

- ▶ “As part of these policies and procedures, the authors of the Technical Reviews and/or parties to a Technical Advisory Panel should be public knowledge. This transparency is a necessary part of the political process and cannot be ignored. Luckily, the PDS responded favorably to public comment and added that contractors will now be named on Technical Reviews. However, it is imperative that the authors - the scientists and technical experts themselves - are also identified to NOSB members and the public on any Technical Reviews or Technical Advisory Panels in which they participate.”

# Conflict of Interest for Technical Reviews

## PPM Proposal

The NOP will seek Technical Reviews from a range of experts. The name of the contracted party will appear on the Technical Review. All Federal contracts, including those issued by USDA/NOP to Technical Report contractors, are governed by the Federal Acquisition Regulations (FAR). The FAR includes a “Subpart 3.11— Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions,” which requires contractors to identify and prevent personal conflicts of interest for their covered employees. “Personal conflict of interest” means a situation in which a covered employee has a financial interest, personal activity, or relationship that could impair the employee’s ability to act impartially and in the best interest of the Government when performing under the contract. Link: <https://www.acquisition.gov/far/current/pdf/FAR.pdf>

# Conflict of Interest for Technical Reviews

## FAR

- ▶ FAR - 3.1101 “Personal conflict of interest” means a situation in which a covered employee has a financial interest, personal activity, or relationship that could impair the employee’s ability to act impartially and in the best interest of the Government when performing under the contract. (A de minimis interest that would not “impair the employee’s ability to act impartially and in the best interest of the Government” is not covered under this definition.)
  - (1) Among the sources of personal conflicts of interest are—
    - (i) Financial interests of the covered employee, of close family members, or of other members of the covered employee’s household;



# Conflict of Interest for Technical Reviews

## FAR

- (ii) Other employment or financial relationships (including seeking or negotiating for prospective employment or business); and
  - (iii) Gifts, including travel.
- (2) For example, financial interests referred to in paragraph (1) of this definition may arise from—
- (i) Compensation, including wages, salaries, commissions, professional fees, or fees for business referrals;
  - (ii) Consulting relationships (including commercial and professional consulting and service arrangements, scientific and technical advisory board memberships, or serving as an expert witness in litigation);
  - (iii) Services provided in exchange for honorariums or travel expense reimbursements;

# Conflict of Interest for Technical Reviews

## FAR

- (iv) **Research funding** or other forms of research support;
- (v) **Investment** in the form of stock or bond ownership or partnership interest (excluding diversified mutual fund investments);
- (vi) **Real estate** investments;
- (vii) **Patents, copyrights, and other intellectual property interests**; or
- (viii) **Business ownership** and investment interests.

## Public Comment:

### ► Electronic Participation

Presence at a Meeting the PPM must be specific regarding **the conditions under which electronic participation** will be allowed and what mechanisms will be used to approve such participation

### PPM Proposal

Quorum: As specified in OFPA, a majority of the members of the NOSB shall constitute a quorum for the purpose of conducting business. (7 USC 6518 (h)). **In cases of a medical situation preventing attendance in person, a virtual presence is permitted.**

## Public Comment:

### ► NOSB authority over National List not clearly stated

#### Proposed PPM

I. The primary roles and duties of the National Organic Standards Board (NOSB):

- Propose amendments to the National List of Allowed and Prohibited Substances

I.C Mission: Key activities of the Board include:

- Reviewing petitioned materials for inclusion on or removal from the National List of Approved and Prohibited Substances (National List)
- Recommending changes to the National List

III.E. However, the NOSB has unique statutory authority related to the recommendation of materials as approved or prohibited substances for inclusion on the National List.

III.F The NOSB has the statutory authority to consider and recommend materials for addition to, or deletion from, the National List of Approved and Prohibited Substances. The NOSB may also make recommendations to add, remove, or modify annotations restricting the use of such listed materials.

## Public Comment:

- ▶ Unclear if Robert's Rules is used:

## PPM Proposal

### C. PARLIAMENTARY PROCEDURES

The NOSB adopted the use of Robert's Rules of Order in March 1992, but modified its use as only a non-mandatory guide in May 1993. Roberts Rules may be adapted to meet the special requirements of a group. Because the NOSB is also subject to the OFPA, FACA and USDA, a designated NOP staff member may act as an informal Parliamentarian to advise the Chair.

# Public Comment:

## ► Roll call voting

## PPM Proposal

Voting may be by show of hands, roll call, or by use of modern voting devices.

Barry Flamm: We are ready to vote. I believe, believe we did the conflict of interest earlier. So, proceed with Jean please.

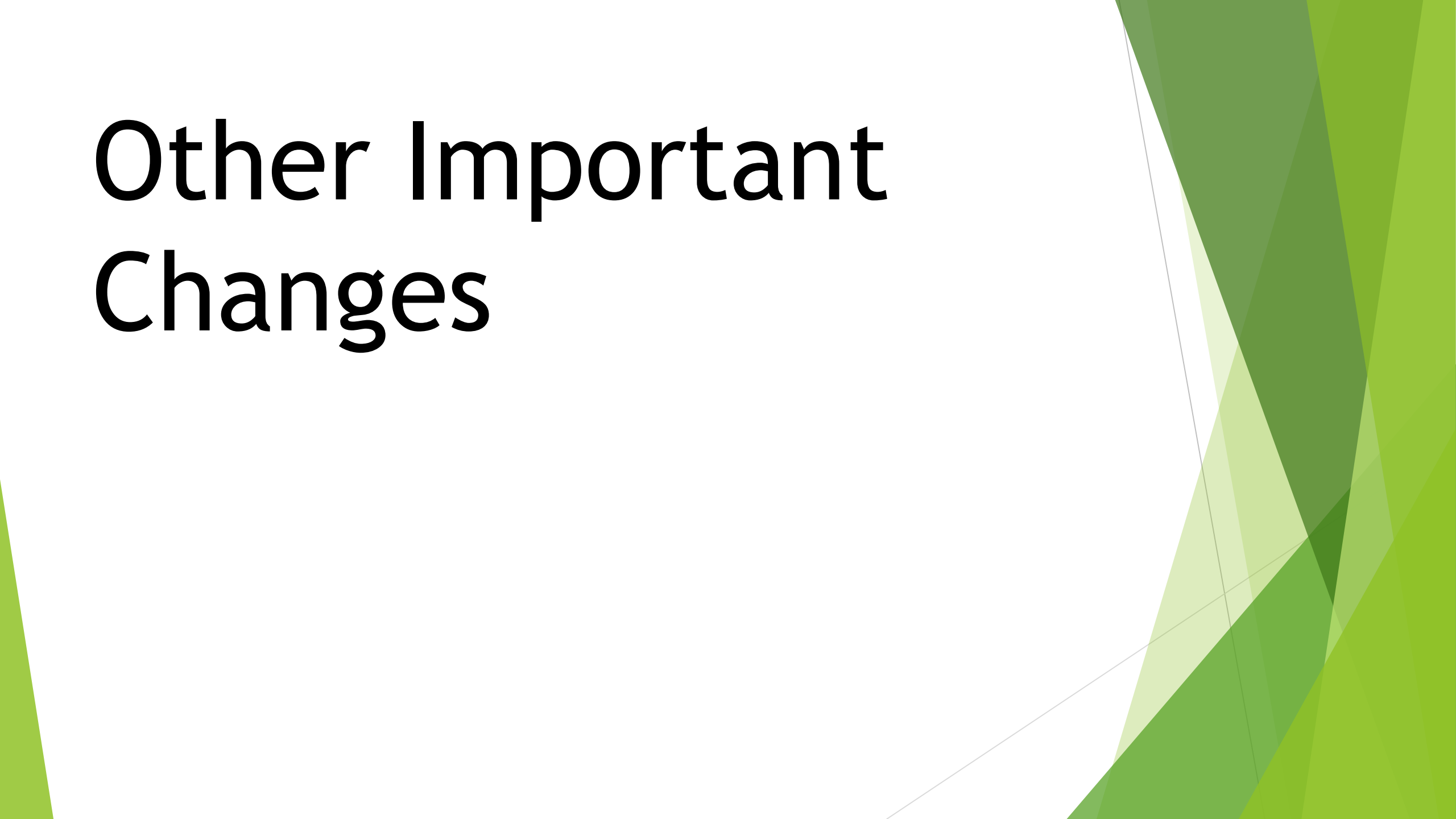
Jean Richardson: No.

The Entire NOSB Board: Yes. No, sir. Yes. No. No. No. No. No. No. No. No. Yes. No.

Barry Flamm: The chair votes no. Three yes, 12 no, the motion fails. We will take a 15 minute break at this time.

NOSB Fall 2015 Proposals and Discussion Documents				Present	Motion by	Seconded	Schroeder	Ross	Walter	de Leo	Bonders	Chapman	Richardson	Fawn	Stephens	Beck	Taylor	Marshall	Thicke	Austin	Yes (y)	No (n)	Abstain (a)	Recuse (r)	Absent (b)	Pass/Fail
CS	Motion to change the annotation for Micronutrients	205.801	Proposal	Zee	Francis		Y	Y	Y	Y	A	Y	Y	Y	Y	Y	N	Y	Y	Y	12	1	1	0	0	PASS
CS	Motion to change the annotation EPA List 4 - Inerts of Minimal Concern:			Zee	Harold		Y	Y	Y	Y	N	Y	Y	Y	Y	Y	N	N	N	Y	10	4	0	0	0	PASS
CS	Laminaria Petition to classify as petitioned as synthetic.	205.801	Petition	Zee	Harold																0	0	0	0	0	
CS	Motion to remove Lignin Sulfonate from 205.801(f)(1) of the National List for use as a floating agent in postharvest handling.	205.801(f)	Petition	Zee	Collette																0	0	0	0	0	N/A REMOVED DU
CS	Motion to classify sulfuric acid as petitioned as synthetic.	205.801	Petition	Francis	Harold		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	14	0	0	0	0	PASS
	Motion to list sulfuric acid, as petitioned			Francis	Harold		N	N	N	N	N	N	N	N	N	N	N	N	N	N	0	14	0	0	0	FAIL
CS	Motion to classify Brown Seaweed Extracts as petitioned as synthetic.	205.801	Petition	Carmela	Harold		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	14	0	0	0	0	PASS
CS	Motion to add Seaweed Extracts as	205.801	Petition	Carmela	Harold		N	N	N	N	N	N	N	N	N	N	N	N	N	N	0	14	0	0	0	FAIL

# Other Important Changes



- ▶ Webinars for Public Comment
- ▶ Prohibition on withdrawal of petitions already reviewed by Subcommittee
- ▶ Establishment of COI procedures for Technical Reviews
- ▶ Description of roles of subcommittee
- ▶ Establishment of GMOs as a standing purpose for the Materials Subcommittee
- ▶ Establishment of research priorities as a standing purpose for the Materials Subcommittee
- ▶ Creates a document that flows logically, grammatically correct



Public Comment,  
to be reviewed by  
PDS for future  
revisions

## Public Comment:

- ▶ Make it clear order of precedence of rules (ie, OFPA, FACA, Charter, other laws/regulations, PPM, RONR)
- ▶ Guidance on detail level and timeliness of subcommittee notes
- ▶ Review Public communications policy from 2012 for inclusion
- ▶ Definitions for certain terms
- ▶ Guidance to the Secretary on Appointments
- ▶ Voting for election of officers
- ▶ Voting record is part of the minutes

## Public Comment:

- ▶ Clarification on roles of the USDA DFO and USDA CMO
- ▶ Publication of voting records with meeting transcripts
- ▶ Minutes from the Administrative team
- ▶ Meeting Minutes - documents provided to the committee
- ▶ Add The General Services Administration memo to Committee Management Officers on FACA public information access should be included in the PPM
- ▶ Timing of public comments and publications
- ▶ Hiring of the Staff Director

**In summary -**

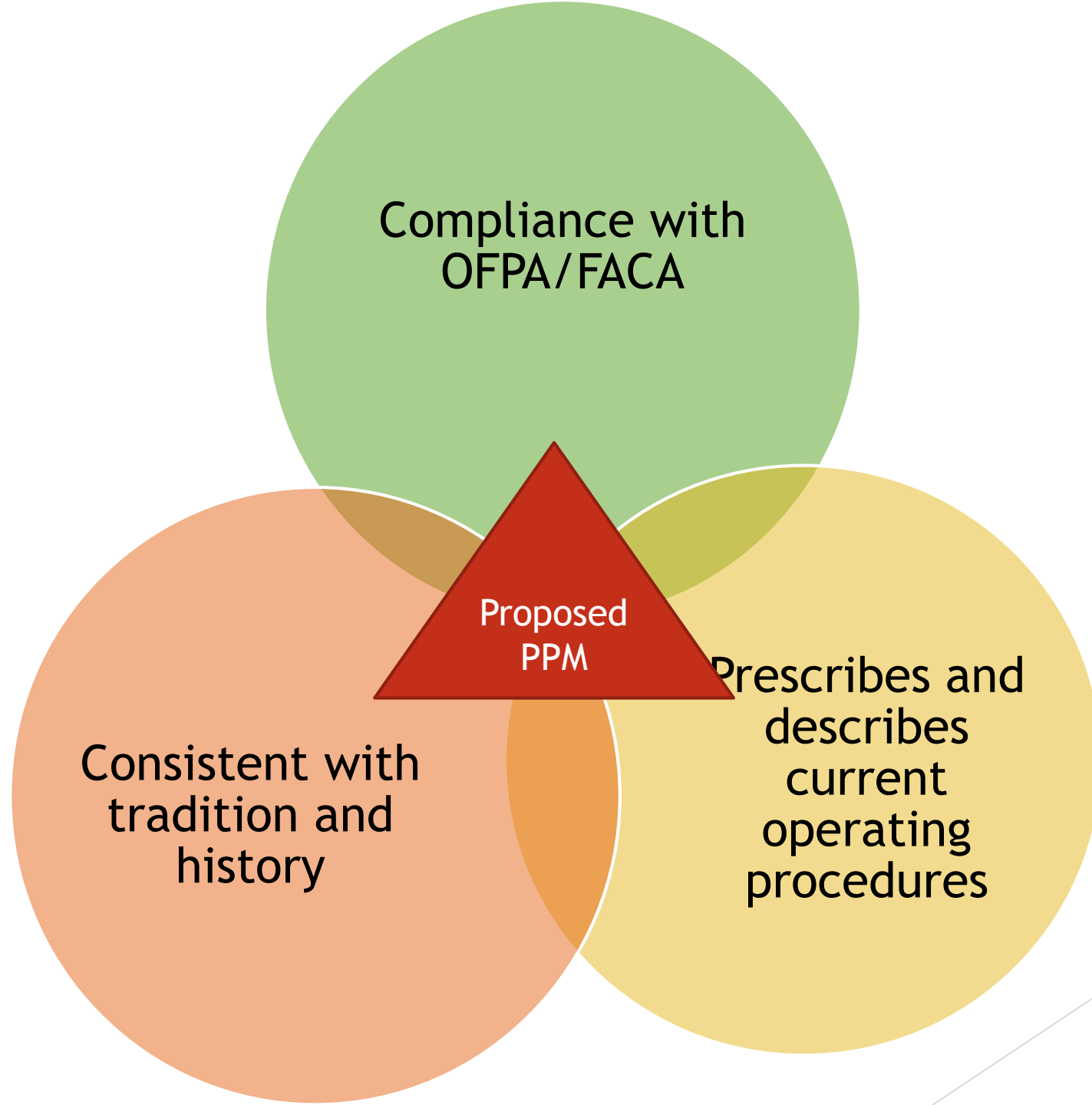
**...80 slides later**

# Tensions

- ▶ Tradition vs compliance with OFPA/FACA
- ▶ Historic wording vs current operations
- ▶ Accuracy vs aspirations
- ▶ Independence vs collaboration
- ▶ Protest vs compromise

## ▶ OBJECTIVE

- ▶ PPM that complies with OFPA
- ▶ PPM that complies with FACA
- ▶ PPM that is approved by the NOSB and NOP/AMS
- ▶ PPM that accurately reflects current operating procedures
- ▶ PPM that fosters transparency and public participation in NOSB decision making process
- ▶ PPM that respects and builds on past NOSB Policy where it does not conflict with the above points
- ▶ PPM with a logical structure and with proper grammar
- ▶ Continuous Improvement



# Ancillary Substance Review Flow Chart



1. Petition comes in or Sunset process starts

2. Technical Report (TR) is commissioned

- 2a. TR will have chart of ancillary substances in use organized by functional class

- 2b. TR will evaluate ancillaries along with substance for each OFPA and Handling criteria.

- 2c. Any that could be used that do not meet criteria will be flagged.

- 2d. Any on the lists (IARC or NTP) of problematic ones will be flagged.

**EXAMPLE:****Identity of Ancillary Substances Permitted for use in Microorganisms and Dairy Cultures**

<b>Functional class</b>	<b>Substance name</b>
Anti-caking & anti-stick agents	magnesium stearate, calcium silicate, silicon dioxide
Carriers and fillers, agricultural or nonsynthetic	lactose, maltodextrins, sucrose, dextrose, potato starch, non-GMO soy oil, rice protein, grain (rice, wheat, corn, barley) flour, milk, autolyzed yeast, inulin, cornstarch, sucrose.
Carriers and fillers, synthetic	micro-crystalline cellulose, propylene glycol, stearic acid, dicalcium phosphate. potassium phosphate, potassium sulfate, tricalcium phosphate.
Preservatives	sodium benzoate, potassium sorbate, ascorbic acid, sodium formate
Stabilizers	maltodextrin
Cryoprotectants used to freeze-dry (& freeze) micro-organisms and Dairy Cultures	liquid nitrogen, maltodextrin, magnesium sulfate, dimethyl sulfoxide, sodium aspartate, mannitol, sorbitol , polysorbate
Substrate that may remain in final product	milk, lactose, grain (rice, barley, wheat) flour, brewed black tea and sugar, soy

### 3. NOSB reviews TR

3a. All information in the TR is evaluated, including the use of Ancillaries. The criteria in the Ancillary Substance Framework document (baseline) are used by the NOSB.

3b. Any that are flagged in the process above will be in the proposal or posting for public comment.

3c. NOSB prepares proposal (for petitions) or first posting (for sunset) with the list of proposed ancillaries.

### 4. Posted for public comment

4a. Public offers comments about chart of ancillary substances used. Additions of new ones and concerns about any that have been reviewed may be raised.

5. NOSB passes proposal or completes Sunset Review with accepted ancillary substances along with it, and indicate which substances are prohibited. For sunset review, any that are expressly to be prohibited will have another proposal for prohibition.

6. NOP publishes rule with those actions above.

7. ACA responsibilities once rulemaking is complete:

7a. Consult chart of ancillaries associated with a substance.

7b. Anything on the chart is allowed.

7c. If a new ancillary appears, the criteria and template suggested in the current proposal can be used to collect the required information. The template is optional.

7d. Information received must then be screened against the IARC and NTP lists.

# Carrageenan

National Organic Standards Board

April 2016

Analysis of Issues & Input

# Carrageenan

- Classification & Environmental Criteria
- Bias and Expertise
- Science related to Human Health
  - Experimental Methods
  - Degradation
  - Inflammation
  - “Sensitivity”
- Alternatives
- Next Steps for Handling Subcommittee

## Carrageenan – Classification

In the 2012 NOSB review, it was stated that we would wait to address classification until the Final Guidance on Classification of Materials is published. This is still our position.

If it is available before the fall meeting posting deadline, we will address classification.

Public comment indicates that there is more than 1 method used to extract and purify carrageenan and some methods may be synthetic while others are non-synthetic.

## Carrageenan – Environmental Criteria

A separate Technical Report (TR) has been commissioned to address the impacts on the environment of the production and harvest of all types of marine plants used in agriculture and processed food. If that report is received on time, we will use the information in our second Sunset posting. If not, the issue will be taken up separately in regard to all marine plant products on the National List.

# Carrageenan – Bias and Expertise

A significant amount of comment is related to the issue of bias in the scientific literature over who conducts and funds experimental studies and who reviews them.

Both sides publish in peer reviewed journals, including:

<b>Challenging Carrageenan</b>	<b>Supporting Carrageenan</b>
<i>Journal of Diabetes Research (2015)</i>	<i>Food and Chemical Toxicology (2016)</i>
<i>Diabetes (1991)</i>	<i>FAO JECFA Monographs (2014)</i>
<i>Environ Health Perspectives (2001)</i>	<i>Food Additives Contamination (2014)</i>
<i>Food and Cosmetics Toxicology (1976)</i>	<i>Journal of Pharmacy and Pharmacology (2008)</i>
<i>Food Hydrocolloids (1996)</i>	<i>Critical Reviews in Toxicology (2002, 2014)</i>
<i>Journal of Biological Chemistry (2010, 2015)</i>	<i>Journal of Applied Microbiology (1996)</i>
<i>Journal of Allergy and Clinical Immunology (2015)</i>	<i>The Toxicologist: Supplement to Toxicological Sciences (2016)</i>
<i>Biochim Biophys Acta (2014)</i>	<i>Journal of Food Chemistry (2001)</i>



# Carrageenan – Bias and Expertise

## ANNEX 3

### Joint FAO/WHO Expert Committee on Food Additives

Geneva, 17–26 June 2014

#### Members

Dr J.R. Bend, Distinguished University Professor, Emeritus, Department of Pathology, Schulich Medicine & Dentistry, Western University, London, Ontario, Canada

Dr D. Benford, Chemical Risk Assessment Unit, Chemical Safety Division, Food Standards Agency, London, England, United Kingdom

Dr M. DiNovi, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition, United States Food and Drug Administration, College Park, MD, USA

Dr D. Folmer, Center for Food Safety and Applied Nutrition, United States Food and Drug Administration, College Park, MD, USA

Dr Y. Kawamura, Division of Food Additives, National Institute of Health Sciences, Tokyo, Japan

Dr A. Mattia, Division of Biotechnology and GRAS Notice Review, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition, United States Food and Drug Administration, College Park, MD, USA (*Chairperson*)

Mrs I. Meyland, Birkerød, Denmark (*Vice-Chairperson*)

Dr U. Mueller, Food Standards Australia New Zealand, Barton, ACT, Australia (*Joint Rapporteur*)

Dr G. Pascal, Le Breuil, Saint Alyre d'Arlanc, France

Dr J. Schlatter, Zurich, Switzerland

Dr M. Veerabhadra Rao, Quality Control Department, Department of the President's Affairs, Al Ain, United Arab Emirates

Mrs H. Wallin, Helsinki, Finland (*Joint Rapporteur*)

To the left are the members of the JECFA Expert Committee who reviewed the status of Carrageenan for the WHO. Below are the authors of the review report.

### Carrageenan (addendum)

#### First draft prepared by

**Susan M. Barlow,<sup>1</sup> Gérard Pascal,<sup>2</sup> Peter Cressey,<sup>3</sup> Daniel Folmer<sup>4</sup> and Jim Smith<sup>5</sup>**

<sup>1</sup> Brighton, East Sussex, England, United Kingdom

<sup>2</sup> Saint Alyre d'Arlanc, Puy-de-Dôme, France

<sup>3</sup> Food Programme, Institute of Environmental Science and Research, Christchurch, New Zealand

<sup>4</sup> Food and Drug Administration, College Park, Maryland, United States of America (USA)

<sup>5</sup> Bio|Food|Tech, Charlottetown, Prince Edward Island, Canada

## Carrageenan – Science: Experimental Method

- Older studies did not distinguish between degraded and undegraded carrageenan.
- Carrageenan is a substance that binds tightly to protein and passes through the digestive system. Studies in which it is administered in water without protein, injected, or introduced artificially into tissues that are not part of the digestive system are questionable.
- *In vitro* studies have been challenged because the behavior of cells in test tubes may not be comparable to *in vivo* digestive systems.
- Scientist disagree over which animals are appropriate test subjects. Rats and mice have different digestive systems than humans. Piglet studies have been challenged and primate studies are few.
- A key tenet of the scientific method is that a result from one lab should be able to be replicated by other labs using the same experimental parameters. So far this has not been directly done and published, particularly on the glucose intolerance issue.

## Carrageenan – Science: Degradation

- Undegraded, or native, carrageenan (CAS#9000-07-1) is the type that is used in food. It has an average molecular weight of 200 to 800 kDa. A substance called poligeenan (CAS #53973-98-1) is a degraded form that has been treated with a strong acid to create a low molecular weight substance with industrial uses. It has an average molecular weight of 10 – 20 kDa.
- Native carrageenan may partially degrade in digestion, but it will be in a full range of molecular weights from 200 kDa downwards. This is very hard to measure.
- A key question is how much the native carrageenan breaks down and what level of degradation could be harmful.
- Studies have indicated that most of the carrageenan ingested is excreted in feces.
- The hypothesis of the degraded carrageenan being absorbed into tissue or causing harm has not been proven. Some studies are published showing inflammation and other problems, while other studies have not shown problems.

## Carrageenan – Science: Inflammation

- A series of studies has shown that carrageenan can induce a complex inflammatory cascade in human intestinal epithelial cells (TR 2015) These studies were *in vitro* using cells from one individual.
- Other studies did not associate food-grade carrageenan with inflammation.
- Results are mixed in animal studies that administered carrageenan through drinking water. (TR 2015)
- The ability for carrageenan to bind to TLR4 and trigger the inflammatory cascade has been challenged in the literature.
- The NOSB Technical Report states, “Definitive conclusions regarding the varying degrees of human susceptibility to inflammation effects of carrageenan cannot be made from the available literature.”
- The NOSB previously looked at an article published in 2015 by Chassaing et. al. regarding potential for all dietary emulsifiers to impact the gut microbiota of mice promoting inflammation and colitis. These issues may not be unique to carrageenan.

## Carrageenan – Science: Sensitivity

- In the 2012 Sunset Review we received public comment from at least 7 individuals who described themselves as sensitive to carrageenan who experienced adverse effects that stopped when they removed carrageenan from their diet. In this batch of public comment we received more of these experiences.
- One of these commenters searched the medical literature and only found one report of adverse reactions.
- Many public commenters this time denied the reality of these complaints because they are anecdotal and not backed by scientific literature.
- However, it appears that this is not in the literature because it has not been studied. No commenter on either side brought a population study on whether these concerns are attributable to carrageenan, nor is there any type of study that proves that all humans are subject to inflammation caused by carrageenan.
- Carrageenan is required to be on food labels with a few exceptions, including beer. Therefore those wishing to avoid it have the ability to do so.

## Carrageenan – Alternatives – 1

<u>Food Product</u>	<u>Made without carrageenan?</u>
Chocolate Milk	yes and no
Whipping and heavy cream	yes
Protein shakes (with milk proteins)	no
Milk Powders	no
Yogurt, sour cream, and cottage cheese	no comments received.
sugar free spreads - gelling agent	yes and no
puddings	no
fruit fillings	no
gummi bears	yes
Vegan marshmallows	no

## Carrageenan – Alternatives – 2

<u>Food Product</u>	<u>Made without carrageenan?</u>
frozen soy dessert	no
Soy milk	Yes and no
capsules for supplements, vegetarian	no
Infant formula	no
Processed meats	yes and no
non-dairy beverages (nut and grain milks)	yes and no
beer	no

## Carrageenan – Next Steps

The NOSB Handling Subcommittee will fully evaluate all the public comment received between now and the fall meeting.

Any new published research studies between now and then should be sent to Michelle Arsenault. Please provide actual text and not just abstracts or links to articles that require payment.

There will be another comment period open in October before the fall meeting. We encourage more comments at that time regarding alternatives to the use of carrageenan.