



BEYOND PESTICIDES

701 E Street, SE ■ Washington DC 20003
202-543-5450 phone ■ 202-543-4791 fax
info@beyondpesticides.org ■ www.beyondpesticides.org

October 2, 2015

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Ave. SW.,
Room 2648-S, Mail Stop 0268
Washington, DC 20250-0268

Re. PDS: Policy and Procedures Manual

These comments to the National Organic Standards Board (NOSB) on its Fall 2015 agenda are submitted on behalf of Beyond Pesticides. Founded in 1981 as a national, grassroots, membership organization that represents community-based organizations and a range of people seeking to bridge the interests of consumers, farmers and farmworkers, Beyond Pesticides advances improved protections from pesticides and alternative pest management strategies that reduce or eliminate a reliance on pesticides. Our membership and network span the 50 states and the world.

Revision Process

Given the format of the proposed changes to the Policy and Procedures Manual (PPM), it is difficult to determine what changes are being proposed or announced. Since the PPM serves as the NOSB's bylaws, this difficulty is no small matter for the public and board members who have not participated in the process of writing the actual and detailed changes. In addition, with the extensive reorganization, it is often difficult to determine whether a section has been moved or deleted.

What makes this especially important is the fact that buried in this difficult to read rewrite of the NOSB's bylaws several substantial changes are being announced. It does not appear that the NOSB will have an opportunity to vote on the changes, as past boards have done in carrying out their functions under the Organic Foods Production Act (OFPA). To announce such changes without justification –or even identifying them– is far from the transparent process that is required under OFPA and the Federal Advisory Committee Act (FACA). NOSB members should seek public input and seek a vote on the changes before they go into effect. Before moving forward, the board and the public should have access to:

1. A redlined version, such as one produced using “track changes” in Word;

2. An annotated table of contents that indicates which sections have been moved or changed; and
3. An explanation and justification of each change.

In addition, future editions of the PPM should annotate amendments with notes –for example, if a section is added, it should note, “Added October 2015.” If it was amended in April 2010, it should note, “Amended in April 2010 to add section on xxx.” We note that some sections are annotated in this way.

Comments on Specific “Updates”

Beyond Pesticides opposes several changes that reduce the role of the NOSB and increase the role of the NOP.

1. In the Introduction/Purpose, the “updates” delete “New policies and revisions to existing policies and procedures will be incorporated into the NOSB Policy and Procedures Manual from time to time, as determined by the Board.”

The PPM is a living document that serves as bylaws for the NOSB. The NOSB should, as this sentence indicates, have the authority to propose and vote on new policies and revisions to existing policies. **This sentence should be restored.** To the extent that USDA would like to usurp board authority to establish procedures to carry out its unique authorities under OFPA, it will erode the good will and confidence that it has built with consumers and farmers at a critical period in the development of the organic market.

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

The current version stresses a commonality of goals, cooperation, and two-way feedback. The “update” creates a mechanical version of “collaboration” involving participation of NOP staff in calls and provision of technical, legal, and logistical support. The current version establishes a framework for NOSB-NOP interaction based on the statutory duties of the NOSB. Historically, the PPM has created a framework for collaborative decision making between the NOSB and the NOP.

3. Neither version, however, addresses the provision of §6518(j) of OFPA, “The Secretary shall authorize the Board to hire a staff director.”

The above provision establishes a relationship between the NOSB and NOP that has been routinely violated by the NOP. The fact that the law requires the board to be able to hire a staff director for the Program implies that Congress intended that the NOSB, and not the NOP, should be setting the direction and priorities for the board, given authorities that exceed the advisory duties in FACA. FACA, however, recognizes that boards established by statute, like the NOSB, may have authorities that exceed those outlined in FACA, such as the NOSB’s authority to recommend materials on the National List that the Secretary may not embellish with additional uses. Furthermore, the direction is meant to come from the organic community as a whole, since OFPA §6518(c) requires that board appointments originate “from nominations

received from organic certifying organizations, States, and other interested persons and organizations.” The appointment process should also be much more transparent.

4. The section on NOSB work agendas (formerly work plans) removes from the NOSB the authority to initiate agenda items.

As stated above, OFPA gives the leadership role to the NOSB, not the NOP. **Authority over work agendas must be restored to the NOSB.** This is an example of where collaboration on issues and priorities has been important to the board carrying out its statutory duty.

5. 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.”

The deleted sentence recognized the role of the NOSB in setting the direction for the National Organic Program. It should be restored.

6. 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.

Deleted:

The Policy Development Committee makes draft recommendations for consideration by the Board to provide guidance, clarification or proposed standards of Board operations, policies and procedures. The PDC maintains the content and updates to the NOSB Policy and Procedures Manual (in collaboration with the NOSB Vice Chair) and New Member Guide. The PDC occasionally works with other committees to develop joint recommendations where policy issues are involved.

Added:

The Policy Development Subcommittee provides guidance, clarification or proposed standards on NOSB operations, policies, and procedures as needed, in collaboration with the NOP.

This section should be restored in order to restore the authority of the NOSB to establish procedures necessary to carry out its unique statutory responsibilities, in recognition of the role of the NOSB in setting the direction of the NOSB and NOP.

Beyond Pesticides opposes provisions that decrease public involvement and transparency.

1. In the section on Additional Administrative Items, the “update” provides for public access to documents and communications according to the provisions of FOIA instead of FACA:

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 are subject to these requests, with some exemptions. Some 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.

However, FACA requires much prompter response to public requests, and the PPM should cite FACA instead. We recommend including the following guidance. According to a General Services Administration memo to Committee Management Officers:¹

Section 10(b) of the Federal Advisory Committee Act (FACA), as amended, (Public Law 92-463, 5 U.S.C. App.) provides that:

"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."

The purpose of section 10(b) is provide for the contemporaneous availability of advisory committee records that, when taken in conjunction with the ability to attend committee meetings, provide a meaningful opportunity to fully comprehend the work undertaken by the committee. Records covered by the exemptions set forth in section 552(b) of FOIA may generally be withheld. However, it should be noted that FOIA Exemption 5 cannot be used to withhold documents reflecting an advisory committee's internal deliberations.

The memo also states,

Although advisory committee records may be withheld under FOIA's provisions if there is a *reasonable expectation* that the records sought fall within the exemptions contained in section 552(b), agencies may not require members of the public or other interested parties to file requests for non-exempt committee records under the request and review process established by FOIA section 552(a)(3). [Emphasis in original.]

... Accordingly, agencies may not delay making available non-exempt records to interested parties under FOIA procedures as an administrative convenience, or for other reasons.

... Given the plain and unambiguous language contained in section 10(b) of FACA, coupled with controlling case law and DOJ's FOIA guidance, I am encouraging each Committee Management Officer (CMO) to assure the maximum timely availability of covered advisory committee records. If you have not already done so, you should consider:

¹Public Access to Records (FACA), Memorandum for Committee Management Officers. March 14, 2000. From: James L. Dean, Director, Committee Management Secretariat, Subject: Public Access to Advisory Committee Records <http://www.gsa.gov/portal/content/100785>.

Amending agency procedures to facilitate the timely release of requested information and materials;
Segregating information and materials that must be released under FACA section 10(b) from those that must be processed under FOIA; and,
Expediting requests for release of information and materials that must be legitimately processed under FOIA, including the provision of timely explanations for unanticipated delays to interested parties.

It is simply outrageous that USDA would seek to make the work of the incredibly important NOSB stakeholder group, whose operations are vital to public trust in the organic food label and the growth of the organic market, less transparent and take steps that will suggest that organic decision making is cloaked in secrecy and backroom collusion. How is that good for the growth of the organic market? And, 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?

2. "Nonpublic information" has been redefined to include information that is public according to FACA.

The current version defines it:

Nonpublic information is defined as information that the 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. This includes information that is "routinely exempt from disclosure in 5 U.S.C. 552 (Freedom of Information Act) 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."

The "update" defines it:

Nonpublic information is 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.

The new definition is much broader and includes information that is public according to FACA.

3. Changes to the requirements for minority reports decrease the full understanding of the NOSB and the public.

Subcommittees do not make decisions on behalf of the full Board. They digest information and present it in a way that the NOSB and the public can understand it. A minority position is no less important than the position of the majority, and must be accorded equal status by the subcommittee. The "update" adds new requirements for minority reports:

- They should not include any data or information not introduced on a Subcommittee call; and

- They should be submitted in a timely manner, and will not be accepted after the Subcommittee has voted on its recommendation.

The second of these requirements is impossible to implement, since it could not be determined which is the “minority” opinion until after the vote. The first also does not make sense because the voting process may clarify issues that were not obvious before the vote –or the agenda may not have permitted full discussion– though it is obviously in the interest of each subcommittee member with an opinion on the issue to bring forward relevant information as early in the process as possible.

The “update” also says, “The minority report is presented for information purposes only, and it cannot be acted upon unless there is a motion to substitute it for the report of the Subcommittee.” This needs to clarify when such a motion can be made and ensure that an opportunity exists to make such a motion. The NOP may either facilitate the views of all the stakeholders being articulated and presented to the public as part of a robust consideration of issues, or stifle the rich discussion that has helped grow the organic market. Inviting those discussions and opinions into the NOSB process will ensure that the board is in touch with the range of views that make up the organic community and industry. To do otherwise, will be to stifle the process and undermine the statutory responsibility of the board.

The process for NOSB resignations, particularly forced resignations, should be better defined.

The “update” adds the following:

The NOSB typically has a heavy work load and thus active participation by all 15 members is essential to carry out the mandates in OFPA. When one or more members fail to actively participate in Board work the entire NOSB and the organic community is negatively impacted. If a Board member finds that s/he cannot consistently attend Subcommittee meetings, take on work assignments, complete Subcommittee work in a timely manner, or cannot attend the twice-yearly public meetings and public comment listening sessions, the NOSB Chair shall discuss the matter with the Board member, bring the concerns to the attention of the Executive Subcommittee, and if necessary encourage the Board member to resign.

We support the concept of ensuring that all 15 members of the NOSB are actively contributing. However, this proposal requires improvement in two respects: it should be specific about the situations that trigger the Chair or Executive Subcommittee to “encourage” a resignation, and it should provide a process for NOSB members to correct conditions that might be leading to a lack of participation.

We would not dictate these conditions for the board, but a reasonable condition would establish some standard for reporting a reason if a board member misses some number of meetings. This would prevent the provision from being used arbitrarily to push someone off the board.

Secondly, it is possible that the failure of a board member to participate arises from problems within the NOSB, NOP, or NOP-NOSB collaborative process that can be corrected. Therefore, a grievance procedure should be established. If a board member believes that s/he has a grievance with the way the NOSB is being managed, s/he should be able to file a grievance with AMS and receive a response within 30 days.

Conflict of interest (COI) policies.

A basic tenet of democracy is that decisions are made in an open fashion, based on rules known to all. This contrasts dramatically with dictatorial forms of government all over the world that have thrived on enforcement of rules known only to the enforcers. In that respect, this proposal seems to establish a system that enforces rules without clearly stated criteria and does so out of the public's eye.

The NOSB, being a Federal Advisory Committee established under FACA (though with additional authority) and composed of "representatives" is not subject to the same legal requirements that apply to a board composed of government employees or special government employees. The fact that the NOSB is not subject to those rules does not mean that no rules apply to them. There are "applicable COI statutes and regulations" that apply to the board. But we believe it is arbitrary and capricious for the NOP to act on the authority of statutes and regulations that are presumed and not specifically stated and referenced.

We support the efforts of the NOSB to write policies governing conflict of interest of its members, but those policies should remain the board's policies and not become the NOP's policies. The board should not abdicate responsibility for the enforcement of any policies that it establishes for itself in this area. It is very important that the NOSB operate, as it was intended by Congress, with independent authority in this and other areas as it collaborates with the NOP.

At the same time, we recognize that NOP may seek to adopt policies that it believes is under its legal authority and should do that with complete clarity and complete citation of applicable laws.

So, there may be two sets of COI rules applicable to the NOSB –those created by Congress and agencies of the federal government in statutes and regulations, and those created by the NOSB and codified as policies in the Policy and Procedures Manual. The NOP is responsible for enforcing the first, and the NOSB is responsible for enforcing the second. Insofar as this proposal seeks to establish procedures for enforcing applicable COI statutes and regulations, it totally fails to be transparent because the applicable statutes and regulations are never named. With regard to the establishment of NOSB policies and procedures, the proposal lacks transparency because conflicts are not disclosed to the public, and may not be disclosed to the full board itself.

COI policies for TR and TAP contractors are missing.

NOSB decisions are based to a large extent on information provided by Technical Reviews and Technical Advisory Panels. Part of the reason that TRs and TAP reviews are so widely used is that compared to research undertaken by individual NOSB members, these reviews are assumed to be more neutral. But this is not always the case. Contracted reviewers may also have conflicts of interest, and their interests are not disclosed to the NOSB or the public. Therefore, we suggest that another point be added in the following sections

On Third Party Technical Reviews:

Potential contractors will provide a disclosure of interest statement for both the company and individuals who will be doing the work. This disclosure will be included on the first page of the report. Such disclosure will include any financial interests that he or she has that can be reasonably assumed to influence his or her presentation or content.

On Technical Review Sufficiency Determination:

The subcommittee will review the disclosure of interests submitted by the contractor to determine that no conflict exists that would interfere with the ability to fully evaluate the material without bias.

The Sunset Review policy unilaterally imposed by the NOP should not replace the policy adopted by the NOSB.

The change in the sunset policy imposed by the NOP has never been proposed for public comment.² To bury it in changes to the PPM without opportunity for public debate is a further violation of public process, as well as the board's right to set its own policies for determining the content of the National List.

We have submitted elsewhere extensive comments on the NOP sunset process. (See attachment.) In short, recent NOP policy changes regarding sunset are contrary to OFPA and interfere with the rational functioning of the National List process.

- Every dictionary and other laws define "sunset" so that the default is that the provision ceases to be in effect at sunset unless deliberately renewed. NOP has reversed this commonsense and legal interpretation of the word, and the rules requiring a vote to delist, rather than to relist, with a two-thirds majority should be reversed.
- OFPA requires that every exception to the general rule that natural materials are allowed and synthetic materials are prohibited be listed "by specific use or application." When the required annotation is not present, or found to be inadequate, the annotation should be changed at sunset.
- NOP rules allow a subcommittee to decide to relist a material, by failing to bring forward a motion to delist. This rule must be eliminated because a subcommittee may not decide for the full board.
- NOP rules declare that information brought forward at the second sunset meeting "will be considered untimely for purposes of the Sunset Review process" if the subcommittee

² See attached transcript of hearing: Center for Environmental Health et al v Vilsack for the court's view on USDA's process.

believes the evidence “merits reconsideration of the conclusions presented in the preliminary review.” This makes the submission of substantive evidence at the second sunset meeting pointless unless it confirms the position of the subcommittee. This rule should be revoked.

- All of the above NOP rules on sunset were promulgated without the benefit of public notice and comment. NOP should revoke them and revert to the former process until new rules are adopted through a notice-and-comment process.

Changes regarding how meetings are held need to be debated, not quietly made in the confusion of a new and drastically rearranged document.

The “update” removes, “At this time, full Board conference calls or full Board assembly via electronic bulletin board are not permitted.” It adds, under quorum: “In cases of a medical situation preventing attendance in person, a virtual presence is permitted.” It deletes, under election of officers, “Only NOSB Board Members present are eligible to vote for nominated officers. Absent NOSB members will not be eligible to vote.”

Before electronic participation in NOSB meetings is allowed, the PPM must clarify the situations, medical or otherwise, in which it would be allowed. What if a board member can’t attend because of a funeral of a family member or a sick child? How much of that benefit is lost if one, two, or fifteen members participate remotely? The NOSB must discuss the benefits of in-person meetings to the NOSB, NOP, and the public and discuss the range of possibilities, should electronic participation be established. It sounds again like policy is being crafted by NOP in response to a specific incident, at its whim, rather than as comprehensive policies are required to be established –with full consideration, public hearing, and public input.

The “update” also adds, under public comment,

The NOP and NOSB encourage public comment and work collaboratively to increase opportunities for greater participation by a broad range of people, employing various modes of communication and modern technology whenever possible. Individuals may present oral comment at either a pre-meeting electronic webinar or at the in-person NOSB meeting.

Oral comments: May be received via a virtual meeting/webinar. Public notice of such electronic meetings will be included in the Federal Register notice announcing the public meeting. Such electronic pre-meetings may allow individuals more time to present their data or information, reduce the need to attend the public meeting in person, reduce our carbon footprint, and give the NOSB more time to absorb the information. Such electronic meetings shall be recorded and made available to the public and to NOSB members.

We encourage the NOSB and NOP to expand opportunities for public comment. However, we ask why this form of public comment is being promoted when the open public docket unanimously approved by the NOSB in April 2013 has not been implemented yet.

Thank you for your consideration of these comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Terry Shistar". The signature is fluid and cursive, with a long horizontal stroke at the end.

Terry Shistar, Ph.D.
Board of Directors

Attachments:

Beyond Pesticides comments on NOP sunset process

Transcript of hearing: Center for Environmental Health et al v Vilsack



BEYOND PESTICIDES

701 E Street, SE ■ Washington DC 20003
202-543-5450 phone ■ 202-543-4791 fax
info@beyondpesticides.org ■ www.beyondpesticides.org

March 27, 2014

National Organic Standards Board
Spring 2014 Meeting
San Antonio, TX

Re. CS, LS, HS: Sunset

These comments are submitted on behalf of Beyond Pesticides. Beyond Pesticides, founded in 1981 as a national, grassroots, membership organization that represents community-based organizations and a range of people seeking to bridge the interests of consumers, farmers and farmworkers, advances improved protections from pesticides and alternative pest management strategies that reduce or eliminate a reliance on pesticides. Our membership and network span the 50 states and groups around the world.

These comments will address the sunset policy, actions by the National Organic Program (NOP), and sunset materials.

1. Sunset Policy

a. History

7 USC §6517(e) of the Organic Foods Production Act (OFPA) states,
(e) Sunset provision

No exemption or prohibition contained 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 or reviewed and the Secretary has renewed such exemption or prohibition.

The Preamble to the NOP Final Rule published December 21, 2000 states:

(12) National List Petition Process as Part of the Final Rule. Commenters have requested that the National List Petition Process, approved by the NOSB at its June 2000 meeting (and published in the Federal Register on July 13, 2000), be included in the final rule. We do not agree with the commenters, and we have retained the National List Petition Process regulation language from the proposed rule.

Sunset review is not mentioned in the preamble or the Final Rule.

In June 2005, the Advanced Notice of Proposed Rulemaking for the first sunset says comments should present clear reasons, citing OFPA criteria, especially if the comments oppose relisting.

In a March 4, 2010 memorandum, the NOP stated, “The NOSB has the responsibility and authority to add substances to the National List...The NOSB is responsible for making a recommendation regarding whether the listing should be renewed or removed during the sunset review. In the absence of a recommendation, the NOP will initiate rulemaking to remove the substance from the National List.”

On the topic of annotations during sunset, the memo said, “There is nothing in OFPA to prevent the NOSB from making a recommendation to modify or amend an annotation during the sunset process. However, the NOSB Policy Manual states in the sunset review procedures that amending or creating new annotations is not part of the sunset review process.”

The NOSB policy was amended in October 2010. The sunset review policy and procedures can be found in the Policy and Procedures Manual (PPM), April 2012 edition, starting on page 56.

The prescribed steps in the sunset review process as adopted by the NOSB are the following:

1. A public notice is placed in the Federal register (Advance Notice of Proposed Rule Making or ANPR of the pending sunset of the listed materials. The public has 60 days after the publication date to provide written comment (see Chart 1 below). The committee may request a third party technical review in anticipation of scientific evidence and claims likely to be made during public comment to the ANPR.
2. Public comments are collected and forward to the NOSB (see Chart 2).
3. The appropriate NOSB committee begins review of the material with the intent of providing a recommendation to the entire Board for the material’s removal, renewal, or renewal with the addition of an annotation. The review is conducted based on “Force of Evidence” as presented by Board members, public comments, and scientific data from other sources (see Chart 3). This includes the original recommendation from the Board to list. The committee may request a third party technical review, if needed, to verify scientific evidence and claims made during public comment to the ANPR.
4. The reviewing NOSB committee provides its recommendation to the full Board and the public no less than 60 days prior to the Board Meeting which would include the following:
 - (i) Simple motion to remove, add, or amend an annotation, resulting in the restriction or clarification of the use of a material (if applicable).
 - (ii) Simple motion to renew the existing listing.
5. At the public NOSB business meeting, the NOSB hears additional public comment, discusses the force of evidence, and votes on the committee’s recommendation.
6. The NOP reviews the NOSB recommendation and accompanying documentation and publishes a proposed rule to review the National List. The public has 90 days after the publication date to comment. All comments are made available on the NOP website. The NOP will review public comment and draft the final rule. The final rule will proceed through interagency (i.e. OGC, OMB, and departmental) and congressional review, and upon receiving clearance from the appropriate parties, the NOP will publish the final rule in the Federal Register.

In addition, the PPM states, “As a norm, a motion for a petitioned material or sunset review should always be presented in the affirmative.” The PPM provisions addressing the process for voting on annotations during sunset was adopted at the October 2010 meeting of the NOSB in Madison, WI. These PPM provisions, as adopted, contain a primary and backup motion. There was an extensive discussion leading up to and at the Madison meeting on the purpose of the backup motion, developed in collaboration with Deputy Administrator Miles McEvoy and NOP staff, and taking into account the regulatory time requirements.

The written record on the backup motion from the Madison meeting demonstrates that in the case where a sunset material is renewed with an annotation, the backup motion is intended to allow NOP the time necessary for a continuation of the current use of a substance if it is not possible to amend the annotation during the normal sunset rulemaking deadline.

On September 27, 2012, Mr. McEvoy sent a memo to the NOSB that confirmed the NOSB sunset process that was adopted by the Board at its October 2010 meeting:

The NOSB recommended amending annotations for three of the six substances (summarized in Table 1.) For each of these three substances, the NOSB also recommended to renew the existing listing. The NOSB recommendations to renew listings are provided to the NOP to allow for a continuation of the current use of a substance if it is not possible to amend the annotation during the sunset rulemaking.

At the April 2013 NOSB meeting, the Deputy Administrator stated,

I just wanted to clarify our thinking around the annotations in sunset, kind of add a little bit to that. There have been a number of annotation changes that have been recommended during the sunset process and we have found that that has been incredibly difficult to meet the deadlines, the time frames of sunset, when we're making annotation changes because it complicates the rulemaking process.

So what we're requesting is to move forward with these reviews and making recommendations about the annotation changes, but to have any rulemaking that we conduct to make annotation changes be separate some sunset so that we don't run into these very difficult deadline problems, and that the annotation changes could be made through a separate rulemaking process.¹

b. May 3 Federal Register Notice

In its proposed rule of May 3, 2013 (78 FR 25879), the Agricultural Marketing Service (AMS) proposed adoption of the backup motion and rejected the NOSB’s primary motion and reasoning for changing the annotation to carrageenan, and similarly proposed adoption of backup motions only for List 3 inerts and cellulose for reasons other than those allowed.

¹ April 2013 NOSB meeting transcript, page 1087, lines 3-21.

c. Issues Concerning the May 3, 2013 Federal Register Notice

i. NOP's proposed rule contradicts the intent and recommendation of the NOSB concerning National List materials and thus ignores OFPA and is a breach of trust with the NOSB and the public.

The Organic Foods Production Act §6517(d) states,

(d) Procedure for establishing National List

(1) In general

The National List established by the Secretary shall be based upon a proposed national list or proposed amendments to the National List developed by the National Organic Standards Board.

(2) No additions

The Secretary may not include exemptions for the use of specific synthetic substances in the National List other than those exemptions contained in the Proposed National List or Proposed Amendments to the National List.

The NOP proposal to adopt the “second recommendation” for carrageenan, cellulose, and List 3 inerts contradicts the clear intent of the NOSB concerning National List materials. In doing so, it violates the standards that have established a collaborative process between the NOSB and NOP, consistent with OFPA and the Federal Advisory Committee Act. NOP's proposal is also a breach of trust with the NOSB and the public. It is a violation comparable to the proposal in USDA's original draft regulations to allow sewage sludge, genetically engineered organisms, and radiation. In addition, in making this proposal, NOP ignores OFPA standards.

In these three cases, the NOSB proposed restrictive annotations to materials being considered under Sunset. NOSB policy calls for backup motions in these cases to allow the material to be continued to be used when the bureaucracy is unable to process a change in the listing in the timeframe before the material sunsets. There was an extensive discussion at the 2010 NOSB meeting of the purpose of the backup motion and Deputy Administrator Miles McEvoy, along with other NOP staff participated in that conversation. Although the purpose of the “second motion” did not, make its way into the final recommendation as printed, the record from the Madison meeting makes it very clear that the backup motion was not designed to give USDA the option of ignoring the NOSB action or choosing which motion to enforce --only to fill the time that it takes the action to be implemented.² In addition, there is nothing in the record from the Albuquerque NOSB meeting that indicates that the Board was giving the NOP the option of not enforcing the Board's decisions.³

Furthermore, in the NOP response to the NOSB meeting, NOP acknowledges the purpose of the second sunset vote. In its September, 27, 2012, Memorandum to the National Organic Standards Board, the NOP states: "For each of these three substances the NOSB also recommended to renew the existing listing. The NOSB recommendations to renew the listings

² Transcript of October 2010 NOSB meeting, October 26 pages 450-485 and October 28 pages 314-348.

³ Transcript of May 2012 NOSB meeting, pages 152-185; 290-384; 386-422.

are provided to the NOP to allow for a continuation of the current use of a substance if it is not possible to amend the annotation during the sunset rulemaking."⁴

However, instead of honoring the NOSB decision to phase-out certain uses (e.g. carrageenan in infant formula, and microcrystalline cellulose) and establish a rigorous timeframe for reviewing List 3 "inerts," NOP made the following statement: "AMS is accepting NOSB's second recommendations rather than the NOSB's first recommendations to add or amend restrictive annotations for the following substances under Sunset review: EPA List 3 Inerts, carrageenan, and cellulose."

The reasons given by the Program for adopting the "second" (that is, backup) motions, as quoted below, are not consistent with the intent of the NOSB or PPM, as recognized by Mr. McEvoy in the memo cited above. They also raise concerns because in the organic program, the NOP/USDA should not rely on standards of safety that are contained under other statutes, such as the Federal Food, Drug and Cosmetic Act, as the basis for meeting the standards under OFPA. Those concerns will be addressed below.

Carrageenan

"Because the NOSB's sole justification for restricting the allowance of carrageenan was on the basis of food safety concerns, despite the fact that FDA regulations provide for its use as a safe food additive when used in accordance with 21 CFR 172.5, 21 CFR 172.620 and 21 CFR 172.626, AMS is renewing carrageenan as codified based on the NOSB's second recommendation."

Cellulose

"The NOSB. . . recommended changing the annotation to explicitly state which forms are allowed, thereby prohibiting the use of the microcrystalline form. Concurrent with Sunset Review policy, the NOSB also issued a second recommendation to renew the existing listing for cellulose. . . However, AMS needs more information from the industry to confirm that the microcrystalline form of cellulose is not currently in use in organic processed products. Therefore, through this proposed rule, AMS is proposing to address the NOSB's second recommendation to renew the exemption for cellulose as currently listed at section 205.605(b) and is seeking public comments on the NOSB's first recommendation to restrict its use in organic processed products. This approach would meet the timeframe required by the Sunset provision of OFPA and, based on the public comment, enable AMS to consider a restriction on its use for a future rulemaking."

List 3 Inerts

"AMS recognizes the recommendation's intent to address the complex challenges presented by the out-of date listings in a timely manner. However, a rulemaking action to add an expiration date at this time may be problematic in the event that the timeline for inerts review takes longer than the projected four years; therefore, we are not proposing the addition of an expiration date to the exemption for EPA List 3 Inerts."

⁴ Miles McEvoy, September 27, 2012 "Memorandum to the National Organic Standards Board."

In none of the explanations quoted above, does the NOP recognize the underlying requirement that adoption of the second recommendation is only a place-holder while recommended annotations are implemented, as cited by Mr. McEvoy in his September 27, 2012 memo. Because each backup motion effectively includes the assumed conditional, “if it is not possible to amend the annotation during rulemaking,” the NOP action would, if promulgated, be an exemption not proposed by the NOSB, and therefore a violation of OFPA for the two synthetics (cellulose and List 3 inerts). In addition, this action is a breach of the trust that must be present if the NOSB and NOP are to work cooperatively to carry out the Organic Program and promote organic production. It is also a breach of trust with the public, which relies on the collaborative efforts of the NOSB and NOP to deliver food meeting consumer expectations of the organic label. Ultimately, the failure of NOP to follow agreed upon and legal process requirements only serves to undermine the value of the USDA organic label.

ii. The NOP proposal improperly applies weaker standards in violation of OFPA.

In each of the cases, the NOP cites reasons for adopting the backup resolution that are not compatible with OFPA criteria. The statements on carrageenan provide a clear example.

Carrageenan

The NOP states, “The NOSB’s recommendation to prohibit the use of carrageenan in infant formula was based solely on food safety concerns despite carrageenan’s status as a safe food additive when used as specified by FDA regulations and despite FDA’s review of carrageenan in infant formula formulations under the FFDCFA. Therefore, AMS is not implementing this recommendation.”

The NOSB received extensive comments about the health effects of carrageenan and debated them at length. OFPA was created because other environmental and health standards were not seen as adequate for organic food. The fact that the NOSB cited food safety concerns does not mean that those concerns were limited to those addressed by other statutes, or that the Board saw the standards of those statutes as being adequate. In the case of natural materials, the NOP must base its decision on NOSB recommendations regarding any prohibited uses. NOP technical staff attended every meeting of the Handling Committee, attended the NOSB meeting, had access to the Technical Review, and never questioned the ability of the Board to make its determination, let alone disclose that it intended to overrule the NOSB’s determination on the acceptability of a National List material. Although carrageenan is classified as nonsynthetic and therefore not subject to the “no additions” clause of OFPA⁵, the NOP must still base the National List and its amendment on NOSB recommendations.⁶

Cellulose

The NOP says it needs more time to determine whether microcrystalline cellulose is currently in use in organic processed products. The concerns raised to the board related to the health and

⁵ 7 U.S.C. § 6517(d)(2).

⁶ 7 U.S.C. § 6517(d)(1).

environmental impacts of microcrystalline cellulose, and its incompatibility with organic production.⁷ OMRI's opinion is that microcrystalline cellulose is not allowed under the current listing. Industry speakers supported the annotation prohibiting microcrystalline cellulose. Under the circumstances, the question that NOP needs to investigate seems irrelevant to the board decision. Again, the NOSB made a finding after a lengthy review process in compliance with NOP rules and under NOP's oversight, and the NOP needs to respect the NOSB decision and the reasons behind it.

But perhaps the NOP is attempting, in this case, to use the backup vote for its intended purpose. If that is the case, it has not been done correctly. Instead of proposing the backup motion and asking for comments on the NOSB proposal, the NOP should have proposed the NOSB proposal with the amended annotation, giving the justification for that proposal. Then the NOP should have said something like, "The NOSB also passed a backup recommendation renewing the existing listing. NOSB's backup recommendations to renew listings are provided to the NOP to allow for a continuation of the current use of a substance if it is not possible to amend the annotation during sunset rulemaking. In order to meet its obligations to the Office of Management and Budget, NOP needs more information from the industry to confirm that the microcrystalline form of cellulose is not currently in use in organic processed products. Therefore, in the event that the NOP cannot obtain the needed information in time, the final rule will contain the backup renewal language, which will be replaced by the NOSB proposal when the required clearances are obtained."

List 3 "Inerts"

NOP says, "[A] rulemaking action to add an expiration date at this time may be problematic in the event that the timeline for inerts review takes longer than the projected four years; therefore, we are not proposing the addition of an expiration date to the exemption for EPA List 3 Inerts." In making this statement, the Program ignores some important facts: (1) There are only four materials formerly listed as List 3 "inerts," and (2) the NOP controls the subcommittee workplan. If the NOP wants those four materials to have high priority, all it needs to do is make them a high priority. In fact, the NOP should make the consideration of all "inerts" a priority. When this motion was passed, the NOP was asked to respond to the first motion contained in the recommendation, "Be it Resolved, It is the understanding of the NOSB that the NOP is committed to expediting the review of all inert ingredients as soon as possible and will support the NOSB in creating a plan for inerts review and accompanying workplan for the crops committee to complete this work." The NOP responded:⁸

Melissa Bailey: Okay, so I think what we, our understanding, if I could restate it back, is that the, the Program agrees to support the, the Inerts Working Group process to move forward on inerts review. That may, depending on what kind of proposal the Working Group comes out with, the individual, any individual review of List 3 inerts may not actually occur first. It could occur later on in the process because of prioritizing inerts in

⁷ See the transcript of May 2012 meeting, p. 303, and comments submitted by Beyond Pesticides and Cornucopia Institute.

⁸ Transcript of May 2012 meeting, p. 180.

however those maybe reviewed, according to the Working Group for List 4. So, that we certainly support and would provide the, the resources and support to get there. That is my understanding. ...

Miles McEvoy: Yeah. Just to clarify, we definitely can commit that, that this is important and we will move that forward. In context of all of the other things that we are moving forward as well. So, is a lot on our work plan, a lot on your work plan, you know what is important, we will move it forward.

The proposed action is a renegeing of that commitment to move ahead with the consideration of individual inert ingredients.

iii. Conclusion

The language in the proposed rule regarding use of the "second recommendation" betrays the intent of the NOSB and undermines the NOP's credibility and by association organic integrity and people's trust in the process. Is NOP saying, and does it really believe, that it was the intent of the sunset policy and the NOSB decision making process to offer the NOP two choices (by identifying the "two recommendations"), rather than a mechanism to facilitate a process for implementing the NOSB's authority to authorize and deauthorize materials on the National List?

d. September 16, 2013 Declaration of Sunset Policy

On September 16, 2013, the NOP issued a statement in the Federal Register⁹ of its sunset policy. This policy superseded and reversed the collaborative policy and process developed between NOP and NOSB. Elements of the unilateral NOP sunset policy include:

- The NOSB will vote on sunset motions only if a motion opposing relisting is proposed by the subcommittee. If the subcommittee does not want to oppose relisting, then no motion will come from the subcommittee, and the NOSB will not vote.
- A motion opposing relisting will require a 2/3 majority to pass.
- The NOSB may not add annotations to a listing during sunset.
- The NOP will act to relist in the absence of any board action.

e. Issues Concerning September 16 Declaration of Sunset Policy

NOP's sunset policy statement has a number of implications that threaten the integrity of the organic program and undermine the standards established in OFPA:

- Because a subcommittee will be allowed to decide to relist a material in sunset –if the subcommittee does not produce a proposal opposing relisting, it is deciding to relist— subcommittee meetings must be open to the public under FACA.
- The announcement states that NOP will, on its own, without consideration of the material by the full board have the authority to relist a material. This is contrary to OFPA §6517(d)(2), which states, “The Secretary may not include exemptions for the use of

⁹ 78 FR 56811.

specific synthetic substances in the National List other than those exemptions contained in the Proposed National List or Proposed Amendments to the National List.”

- The requirement that a 2/3 majority (a decisive vote under OFPA) is required to prevent relisting, rather than to allow relisting, during sunset is a complete reversal of the statutory standard and intent of OFPA. It conflicts with the meaning of sunset, “a provision of a law that it will automatically be terminated after a fixed period unless it is extended by law.”¹⁰ The NOP analogy equating sunset with a petition to remove a substance from the National List is therefore backwards, since a sunset requires action to keep it in effect. In both cases, re-listing at sunset and listing in response to a petition, a decisive or 2/3’s vote is required of the NOSB.
- NOP’s sunset policy unilaterally confounds the collaborative policy-making process between the NOSB and NOP concerning annotations during sunset review and further erodes faith and confidence in the NOP’s dedication to organic integrity. The NOSB-passed policy allowing annotation during sunset was supported by the NOP when it was passed. The NOP has recently raised issues with annotation during sunset, mostly involving timing (which was set in collaboration with the NOP), but has not tried to work with the NOSB to resolve the difficulties.
- Annotations during sunset enable the NOSB to respond to specific concerns and fine tune listings without removing materials from the National List.

f. Recommendations to NOSB and NOP

i. To the NOSB

OFPA gives the NOSB responsibility for managing the National List. The NOP has usurped that authority. The NOSB should use every opportunity to assert its authority. This includes refusing to approve petitions because they may prove to be irrevocable and unmodifiable in the near future.

ii. To the NOP

The NOP’s actions clearly violate the standards and practices of OFPA. The NOP and USDA should consider the impact of their actions on the organic marketplace. Trusting USDA to regulate organic production has been an issue since a national organic label was envisioned. The credibility of the organic label depends on the existence and functioning of an independent board that makes decisions concerning the materials allowed to be used in organic production and advises the Secretary of Agriculture on all issues regarding the implementation of OFPA. The board was given clear statutory authority beyond a typical board organized under the Federal Advisory Committee Act (FACA). In fact, under FACA, the underlying principle of an appointing agency not influencing the advice of the advisory board is being violated by the NOP, which has stifled and undermined the board process of bringing concerns of the organic community to the Secretary. Without the NOSB performing its prescribed functions at its intended level, standards are called into question, public trust is violated, and there can be no national organic marketplace.

¹⁰ *Collins English Dictionary*, <http://www.collinsdictionary.com/dictionary/english/sunset-clause> We consulted several other legal and plain language dictionaries, and all gave similar definitions.

We ask that the NOP place a moratorium on changes announced in the September 16, 2013 Federal Register until the changes are announced with an opportunity for public comment.

2. Sunset Materials

We address sunset materials in separate comments. However, we urge NOSB subcommittees to pass motions supporting removal from the National List because under the new policies, that is the only way that the full NOSB may perform its mandated duty to review all materials at sunset.

Thank you for your consideration of these comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Terry Shistar". The signature is fluid and cursive, with a long horizontal stroke at the end.

Terry Shistar, Ph.D.
Board of Directors

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

Before The Honorable Jacqueline Scott Corley, Magistrate Judge

CENTER FOR ENVIRONMENTAL)
HEALTH, et al.,)
)
Plaintiffs,)

VS.)

NO. C 15-01690 JSC

TOM VILSACK, SECRETARY OF THE)
UNITED STATES DEPARTMENT OF)
AGRICULTURE, et al.,)
)
Defendants.)

San Francisco, California
Thursday, September 10, 2015

TRANSCRIPT OF PROCEEDINGS

APPEARANCES:

For Plaintiffs:

CENTER FOR FOOD SAFETY
917 SW Oak Street, Ste. 300
Portland, OR 97205
**BY: GEORGE A. KIMBRELL
PAIGE M. TOMASELLI
MAURA FAHEY
ATTORNEYS AT LAW**

For Defendant:

UNITED STATES DEPARTMENT OF JUSTICE
Federal Programs Branch
20 Massachusetts Ave., NW
Washington, D.C. 20530
**BY: ARJUN GARG
ATTORNEY AT LAW**

Reported By: Rhonda L. Aquilina, CSR #9956, RMR, CRR
Official Court Reporter

1 Thursday - September 10, 2015

9:07 a.m.

2 P R O C E E D I N G S

3 ---000---

4 **THE CLERK:** Calling civil action C-15-1690, Center for
5 Environmental Health, et al. versus Vilsack, et al.

6 Counsel, please come up to the podium to state your
7 appearances.

8 **MR. KIMBRELL:** Good morning, Your Honor. May it
9 please the Court, George Kimbrell on behalf of the plaintiffs
10 Center for Environmental Health.

11 **THE COURT:** Good morning.

12 **MR. GARG:** Good morning, Your Honor. Arjun Garg on
13 behalf of the defendants.

14 **THE COURT:** Good morning.

15 All right. So we're here on defendant's motion to
16 dismiss, and they've made two arguments, a 12(b)(6) and a
17 12(b)(1).

18 I think we should start with the 12(b)(6), because I think
19 it relates to the 12(b)(1), and your argument is that this
20 wasn't a legislative rule, therefore no notice and comment was
21 required, because it's an interpretive rule, or it's a
22 guidance; correct?

23 **MR. GARG:** Correct, Your Honor.

24 **THE COURT:** And on an interpretive rule, it's not
25 interpretive, according to the Ninth Circuit, it's if any of

1 three factors are met, the third one being that it effectively
2 amends a prior legislative rule.

3 **MR. GARG:** Correct.

4 **THE COURT:** And we would agree that 7 C.F.R.
5 205.203(e)(1) is a prior legislative rule. That was adopted
6 after notice and comment.

7 **MR. GARG:** Yes, Your Honor, that's correct.

8 **THE COURT:** And that rule says that compost -- that a
9 product cannot be labeled as organic if the compost used,
10 right, in the production of that product contains a synthetic
11 substance not included on the National List of permissible
12 synthetic substances.

13 **MR. GARG:** Yes, Your Honor.

14 **THE COURT:** And there's no other exception. It
15 doesn't say anything else. It just says it may not contain a
16 synthetic substance unless it's on that National List, period;
17 right?

18 **MR. GARG:** Correct.

19 **THE COURT:** Now, the guidance actually adds two
20 additional substances. In other words, it's kind of that you
21 would read it -- and this is a 12(b)(6), so I have to draw
22 inferences in the plaintiff's favor -- that the rule could be
23 read -- it now reads you cannot use compost that contains a
24 synthetic substance or in which the synthetic substance is not
25 directly -- no, no, not or -- no or, and the synthetic

1 substance is not directly applied during the composting
2 process.

3 **MR. GARG:** Correct, that's one prong.

4 **THE COURT:** Or, or is it *and*, does not affect or
5 contaminate the water or soil?

6 **MR. GARG:** I think the way Your Honor phrased it is an
7 *or*, if you're saying what they cannot do --

8 **THE COURT:** Yeah.

9 **MR. GARG:** They cannot -- it cannot be directly
10 applied during the composting process *or* --

11 **THE COURT:** Right.

12 **MR. GARG:** -- cause onward contamination to crops,
13 soil or water.

14 **THE COURT:** So even if it's not applied during the
15 compositing process, if it contaminates the soil or water,
16 although we don't know what that means, then it also can't be
17 used.

18 **MR. GARG:** Correct.

19 **THE COURT:** Right. But why isn't that amending the
20 rule? I mean, the rule was very clear. You can't use compost
21 that contains a synthetic substance unless it's on this list.
22 Now you've added another exception: Or if the synthetic
23 substance isn't applied directly during the composting process.
24 I mean, that's just adding -- now it's one, two, three.

25 **MR. GARG:** Your Honor, I would respectfully say that

1 under the concepts that exist in the statutory and regulatory
2 scheme as a whole, the word "contains," which we're looking at
3 here, is open to different interpretations than the one Your
4 Honor just stated and the one that the plaintiffs are pursuing
5 here where yes, under a dictionary definition of the word
6 "contains," it can be read to categorically forbid any
7 scintilla of any synthetic substance not on the National List
8 no matter where it came from, no matter how it got in there, no
9 matter what amount that is in there. That is a possible
10 reading.

11 What defendants argue is another possible reading,
12 consistent with the way the Supreme Court has said you should
13 do canons of construction, is that the dictionary definition is
14 not the only possible one you have to follow. A word can take
15 on other meanings based on what the statutory and regulatory
16 scheme around it provides in terms of context.

17 And here, the context of the statutory regulatory scheme
18 is not on all fours with this idea that we categorically forbid
19 any synthetic substance whatsoever in organic production.

20 **THE COURT:** No, no, no, that's correct, in compost, in
21 the compost. This rule is about compost.

22 **MR. GARG:** Correct.

23 **THE COURT:** There's nothing inconsistent with the
24 whole statutory scheme that you say if you're buying an organic
25 product, organic compost was used to make it. There's nothing.

1 Now maybe -- I'm not saying you couldn't adopt a rule that
2 said that compost used doesn't have to be organic if it has
3 some minimal amount; right? So here, it's not that you
4 can't -- it's correct, under the unavoidable whatever,
5 whatever; right?

6 **MR. GARG:** Correct.

7 **THE COURT:** In the -- what is it, the unavoidable --

8 **MR. GARG:** Unavoidable residual environmental
9 contamination, UREC.

10 **THE COURT:** Yes. I'll just call it the unavoidable
11 thing.

12 A product may have some residue in there, a product, but
13 that has to do with the soil that it's planted in or the
14 product itself. The soil, we know, sometimes if -- because the
15 farmer before you or you used to use pesticides, there might be
16 some residue in there, so it's unavoidable. There's nothing
17 you can do. The only way to avoid it would be to not plant
18 there; right?

19 **MR. GARG:** Right.

20 **THE COURT:** But that's not here. You can avoid it by
21 using organic compost.

22 **MR. GARG:** Right. Well, Your Honor, I don't think --
23 and the plaintiffs have argued this -- that NOP 5016 is a
24 misapplication of UREC or is trying to expand on this UREC
25 concept. I don't think that's correct at all.

1 UREC -- NOP 5016 does not purport to be an application of
2 UREC. As Your Honor just stated, UREC applies to soil and the
3 food products, not to compost. The regulation that governs
4 compost is 205.203(e)(1). I think where UREC comes into play
5 is showing that contextually in the overall regulatory scheme,
6 there is an idea that, as stated in NOP 5016, the regulations
7 and the standards for organic production practices are
8 processed-based, and there isn't an idea of zero tolerance
9 whatsoever for any synthetic residue without any attention to
10 well, how did that residue get into the production process, and
11 is it there in a way that's material that we really care about.

12 **THE COURT:** So let me ask you this, since we're
13 talking about the word "contained," and you say dictionary, I
14 say common sense definition.

15 How does whether something contains a substance, how does
16 that depend on how it gets there? I mean, like why is how it
17 gets there make a difference as to whether it contains it?

18 **MR. GARG:** Your Honor, I would again say that the
19 interpretation you're pushing towards with that question is a
20 valid possible interpretation.

21 **THE COURT:** Plausible.

22 **MR. GARG:** Plausible, sure.

23 **THE COURT:** Doesn't that mean I have to deny your
24 motion, because this is a 12(b)(6) motion, and the question is
25 whether their interpretation is plausible? I would say it's

1 plausible, and I in fact say it's more plausible than your
2 interpretation. Maybe you would argue if they're equally
3 plausible, you win. They're not equally plausible. You're
4 arguing for a definition of "contained," which is not the
5 dictionary, you would admit, though it's not common sense
6 either.

7 I mean, just answer this, because you're saying that it
8 doesn't contain a synthetic substance if the substance wasn't
9 added during the composting process, so how is that? How is
10 that consistent with any normal, understandable use of the word
11 "contained." Either something contains it or it doesn't. Now,
12 it may have gotten there through various means, but whatever
13 means it got there, it still contains it.

14 **MR. GARG:** Your Honor, I would submit that we're not
15 dealing here in the realm of -- this is a highly technical
16 regulatory provision. We're not dealing here necessarily in
17 the sense of common sense interpretation of the word
18 "contains."

19 And I'll just compare it to the *Dolan* case in the Supreme
20 Court. The language at issue there was negligent transmission,
21 and the question was when the Postal Service drops off a
22 package at the door and they put it somewhere where somebody
23 comes and slips on it and falls, does that qualify as negligent
24 transmission by the Postal Service. And the Supreme Court said
25 well, look, the definition of "transmission" probably includes

1 the act of you leaving it on the doorstep. But, in the context
2 of what we're talking about here, negligent transmission means
3 we delivered your mail to the wrong address or we delivered it
4 late. It doesn't mean the act of leaving it on your doorstep.
5 And the act of leaving it on the doorstep would be a common
6 sense understanding of yes, that's part of the transmission,
7 but that wasn't how the Supreme Court read the word.

8 So I don't -- you know, taking that as a precedent of what
9 the Supreme Court has done, I don't think it's unreasonable or
10 implausible to read the word "contains" the way that defendants
11 are reading it.

12 And I would back up to one point --

13 **THE COURT:** But as a matter of law, I have to read it
14 that way. That's what your motion is, is that as a matter of
15 law -- was the Supreme Court in *Dolan*, did that case -- did it
16 get there on a 12(b)(6)?

17 **MR. GARG:** Your Honor, I can't say that for sure.

18 But on this point of us arguing you have to read it our
19 way, that is not what the defendants are stating. That would
20 be the determination the Court needed to make if the plaintiffs
21 had made a substantive challenge to the validity of the reading
22 of 205.203(e)(1). That is not what they've done. Their claim
23 solely -- their sole claim in this case is that it is a
24 procedural rule that required notice and comment. And there,
25 the inquiry the Court is making is just a little different.

1 I don't have -- I don't think it's the defendant's burden
2 here to show that ours is the best interpretation, the only
3 interpretation, a better interpretation than the one they've
4 offered. All the defendants need to show is that it is a
5 possible interpretation.

6 **THE COURT:** Why do you win then if that's the case?
7 Why do you win? No, don't I have to find that it could not
8 possibly have amended the rule? Don't I have to find that that
9 is the interpretation, that "contains" is -- that that's what
10 they were doing, was actually interpreting "contains" as
11 opposed to amending the rule?

12 **MR. GARG:** Your Honor, again, I think that would be --
13 if that was a theory the plaintiffs wanted to pursue, the claim
14 would need to be a little different, that this is a substantive
15 challenge that your interpretation, no matter what deference it
16 may or may not be entitled to, is not a plausible reading of
17 the -- of the regulation.

18 **THE COURT:** But your argument is that it didn't amend
19 the rule, because we were interpreting "contains;" right?

20 **MR. GARG:** Correct.

21 **THE COURT:** Their argument is that no, you amended the
22 rule because "contains" can't be interpreted that way, so
23 they're completely intertwined, at least with respect to this.
24 Otherwise, are you saying that whenever the Government comes in
25 here and says we're interpreting the rule, the Court just has

1 to accept it, case over?

2 **MR. GARG:** I think as long as it is a possible
3 interpretation that the agency took of its own rule, yes.
4 Under the circumstances of the claim here --

5 **THE COURT:** On a 12(b)(6) what case do I look at for
6 that, because if I recall, almost all your cases were summary
7 judgment cases.

8 **MR. GARG:** Your Honor, on a 12(b)(6), let me look
9 through the papers and find you exactly a case that's on a
10 12(b)(6) dealing with this notice and comment issue. There
11 certainly are 12(b)(6) cases on the standing issue, but I'll go
12 through all the papers and get back to you if I have a case on
13 that, or submit a supplemental --

14 **THE COURT:** Well, if you have to get back, this is the
15 time.

16 **MR. GARG:** I understand.

17 **THE COURT:** So you don't. All right.

18 **MR. KIMBRELL:** Can I respond briefly, Your Honor?

19 **THE COURT:** Of course.

20 **MR. KIMBRELL:** I think the best case here is what we
21 cited in our briefs, the *Hemp Industries* case, and in this case
22 the Ninth Circuit decision there, you had a longstanding Drug
23 Enforcement Agency rule that defined THC to be just synthetic
24 THC, and then they changed it without notice and comment
25 expanding the definition to include natural sources of THC, and

1 the Hemp Industries oil and seed producers challenged that
2 successfully, that it was a legislative rule, because it had
3 changed the meaning of the regulation and had the force of law.

4 And the Ninth Circuit said:

5 (reading) An agency is not allowed to change a
6 legislative rule retroactively through the process of
7 disingenuous interpretation of a rule to mean something
8 other than its original meaning. To quote 'interpret' the
9 regulation, the DEA rule must be consistent with the
10 regulation.

11 So I think Your Honor has it exactly right, to interpret
12 "contains" to mean not contains is not consistent with the
13 existing regulation, and effectively amends it.

14 **THE COURT:** All right. So let's go to the argument
15 then that it's -- I can't -- you lose on that one. I can't
16 find on this, that it's interpretive rule as a matter of law.

17 So your other argument is that it's just guidance, and
18 that it has no binding effect, and for that you say all I have
19 to do is look at the document itself that says this guidance
20 provides clarification; right? Now, I can take judicial notice
21 of this document, that it exists and what it says, but I can't
22 take judicial notice for the truth of the matter asserted.

23 **MR. GARG:** I think if Your Honor is stating that you
24 don't have to accept it face value, the agency's claim that
25 this does not create binding legal obligations, then I think

1 that's an accurate statement of law. I also don't think that
2 it should be ignored, that the agency's own statements, before
3 this litigation ever occurred, or that this document that we've
4 issued does not create legal obligations.

5 **THE COURT:** So the certifier -- so if a certifier
6 tests a product and it finds some residue pesticide in it and
7 says to the farmer *What compost are you using? I'm using X*
8 *compost*, and it's the compost that was banned by California, at
9 least for OFPA, and the certifier then tests that compost or
10 explores it, investigates it, and finds that the pesticide
11 that's in that compost was not applied during the compositing
12 process, the leaves that were in there, whatever, weren't
13 organic, but it was not applied during the compost process, and
14 it's of such, in the certifier's mind, based on whatever
15 standards the certifier comes up with, it does not contaminate
16 the soil, and that kind of thing. The certifier can still
17 nonetheless order the producer to not be able to use the
18 organic label. They can say you *can't* use the organic label.

19 **MR. GARG:** There's -- I want to make sure I'm not
20 getting the double negatives wrong there, but I think you're
21 right. Yes, the organic -- the certifying agent in that
22 situation would not have authority to say even though you've
23 met what NOP 5016 says you're allowed to do, I'm still going to
24 say that you can't label your product as organic.

25 **THE COURT:** Could or could not do that?

1 **MR. GARG:** Could not do that.

2 **THE COURT:** Okay. Then it's binding. That's not
3 guidance.

4 **MR. GARG:** Your Honor, I don't think that's accurate,
5 because USDA -- so I would analogize it this way, and I think
6 the cases support this, USDA is allowed to be let's call it the
7 judge that says here is the principles of law that need to
8 guide your determination. The certifying agent is let's say
9 the jury, it's the fact-finder that says yes or no, this did
10 exist prior to the composting process, or yes or no this does
11 contaminate surrounding crops, soil or water.

12 I don't think that fact-finding process is a rogue thing
13 that has no discretion involved in it. That is a very
14 important and, as the plaintiffs have conceded, non-obvious
15 determination to make. So there is quite a large amount of
16 discretion still available to certifying agents. I don't think
17 agencies are prohibited from giving guidance to their agents in
18 the field of -- as a matter of policy of here's how we want you
19 to operate under our rules, and the cases support that. I
20 mean --

21 **THE COURT:** No, no, no, that's fine. But, actually,
22 what you're saying is we've now amended the rule, because the
23 rules say that you cannot have compost that contains a
24 synthetic substance, and you're now telling your certifiers,
25 no, it's okay if it contains a synthetic substance, as long as

1 it meets these two criteria, and by the way, not only is it
2 okay, you have no authority under (e) (1), it doesn't mean what
3 it says now, it means something else. It's not just guidance,
4 it's binding on them. You said they can't decertify.

5 **MR. GARG:** Well, I think the question as phrased by
6 the Court might be blending the interpretive rule and general
7 policy arguments with each other. I mean, if you've
8 accepted -- and you told me that you rejected this argument.
9 The USDA would say that no, the regulation always meant this,
10 it's not that we changed it, this is what it always meant. But
11 I understand Your Honor is not going to accept that.

12 **THE COURT:** They may say that on summary judgment, but
13 this is a 12(b) (6).

14 **MR. GARG:** I understand Your Honor is not accepting
15 that today.

16 On the general statement of policy argument then, what
17 we're talking about is a little different. Okay. Maybe 203.--
18 205.203(e) (1) says what the plaintiffs -- it means what the
19 plaintiffs think it means; however, in our discretion as an
20 agency, here's how we're going to enforce it. Even when
21 statutes are on the book, agencies or regulations are on the
22 book, agencies have discretion not to enforce it to maximum
23 level; right? That's a standard tool of discretion idea that
24 agencies have a good idea of what's practical and what makes
25 sense, in terms of allocation of resources, and where they want

1 to focus their attention.

2 So I think this would be saying, as a statement of policy,
3 we're not going to in all cases enforce this regulation to the
4 maximal level possible.

5 Here, we've carved out a narrow area where we think we're
6 better off not pursuing this, as far as we conceivably could.
7 And I don't think agencies are forbidden from issuing a policy
8 to their certifying agents in the field that says here's how we
9 want our discretion applied. You are still free to make fact
10 findings and determine where to go from there, but we want you
11 not to pursue these kinds of cases.

12 **THE COURT:** But isn't that just changing the rule? I
13 mean, I don't understand. That's just a way of getting around
14 why -- I mean, they could just -- they could add a million
15 exceptions then to (e)(1), right, and say -- actually, why
16 couldn't they just say we're not going to enforce it at all?
17 Could they do that? Could they say that? Could they issue a
18 guidance document that said to the certifiers that, you know
19 what, it can contain any synthetic -- compost can contain any
20 amount. We're not going to -- if the compost contains a
21 synthetic pesticide of any amount, we're not going to enforce,
22 we just don't care about that; could they do that? We're not
23 going to enforce it.

24 **MR. GARG:** Your Honor, short of an argument that that
25 would be a total abdication of their statutorily commanded

1 duty, yes, I think the agency could say that, you know, based
2 on the circumstances that are confronting us as an agency, this
3 is not where we want to focus our resources right now in
4 bringing enforcement actions.

5 **THE COURT:** Okay. So then what's the difference
6 between that and amending a rule? So then when do they ever
7 have to amend a rule? Under your argument they never have to
8 amend a rule. They can just say they're not going to enforce
9 it, though they have a rule out there, and then they could just
10 say they're not going to enforce it, and then they can just do
11 that.

12 **MR. GARG:** Your Honor, it gets to a tricky issue that,
13 you know, at some point you blend into well, when did they
14 change the rule?

15 **THE COURT:** Yes.

16 **MR. GARG:** I don't think this case is to that level of
17 a total abdication of any -- I mean, still, in the vast
18 majority of cases, USDA is saying you cannot use compost that
19 contains synthetic substances. This is a very narrow carve-out
20 that USDA is allowing here. I just don't think that it rises
21 to the level --

22 **THE COURT:** Well, when do we get to the line -- see,
23 now it's like law school, right, where you have that discussion
24 all the time.

25 All right. Let me hear from the plaintiff.

1 **MR. KIMBRELL:** Your Honor, just to respond briefly, I
2 would say on the binding norm issue, the best case is the
3 *Community Nutrition Institute* case from the D.C. Circuit where
4 the FDA did something similar, set allowances for contaminants
5 in food products there, corn, and said it wasn't going to
6 enforce below that and didn't do notice and comment, called it
7 a guidance, and consumer groups successfully challenged that.
8 And the D.C. Circuit said exactly as Your Honor did, you've
9 bound your own enforcement discretion, and that's a rule.

10 And I would also add that to be a general statement of
11 policy, there are two prongs that the cases talk about, one
12 being the binding norm, the other being that the action
13 challenged by the agency must be only prospective in nature.
14 And our allegation here is that this is definitively not
15 prospective in nature, but, rather, expressly retroactive, and
16 that's the history of this --

17 **THE COURT:** How is it retroactive?

18 **MR. KIMBRELL:** Well, if you look at the guidance
19 itself and the history of this litigation, as Your Honor noted
20 first, organic regulators in California applying the then
21 existing USDA standard, the one that you've quoted, banned
22 several compost products that were contaminated with the
23 insecticide bifenthrin, and then the USDA came back and issued
24 this decision.

25 And in the guidance itself, it goes through -- it recounts

1 as a background, on the first page, what happened in California
2 here, and then it said this is our new decision. At the end,
3 it says that it's -- now this type of compost, assuming that
4 these two new factors are met, it is acceptable.

5 So it overruled that decision, and in that way it's
6 retroactive. We have not heard from the Government that those
7 products, by the way, are still banned. They did not say that
8 in their reply briefs, so our allegation is that it's been
9 retroactive here, and if it's retroactive, setting aside the
10 binding question, independently it can't be a guidance.

11 **THE COURT:** I'm not -- so wait, so California banned
12 it in California.

13 **MR. KIMBRELL:** Yes, Your Honor.

14 **THE COURT:** But so I still don't understand. When
15 they issued this guidance then, they would say that applied
16 going forward. How does that change what happened before?

17 **MR. KIMBRELL:** Well, they had to withdraw the notices,
18 the notices from the organic regulators banning the previous
19 products.

20 **THE COURT:** All right. Well, what about that?

21 **MR. GARG:** Well, Your Honor, first of all, we are
22 under 12(b)(6), as the Court has made clear. I believe
23 plaintiffs' counsel might have just introduced a lot of facts
24 that are not in the complaint, for one thing; but secondly, I
25 think the idea that California -- first of all, California had

1 made a decision about this, not the USDA. NOP 5016 is the
2 first time USDA has addressed this issue of synthetic residues
3 in green waste compost. But even if --

4 **THE COURT:** No, no, no, it's not the first time, it
5 was addressed in 205.203(e)(1).

6 **MR. GARG:** All right, Your Honor, we'll agree to
7 disagree on that one.

8 But, on the -- on the point that, well, California had to
9 withdraw notices, that doesn't affect, you know, what
10 California notices were still valid and out there under
11 California's authority for however long they existed before
12 they got withdrawn, so it doesn't retroactively go back and
13 change determinations California had made during that time. It
14 says going forward, California, the policy you've been applying
15 is no longer consistent with what USDA is saying.

16 **THE COURT:** And what case would I look to that on a
17 12(b)(6), this argument that it's guidance as a matter of law
18 has been accepted, what case would I look to?

19 **MR. GARG:** So you're asking me to identify a 12(b)(6)
20 case.

21 **THE COURT:** Yes, this is a 12(b)(6) motion.

22 **MR. GARG:** Your Honor, I would again want to -- I'll
23 take a peek through the cases, but --

24 **THE COURT:** I don't know how you could get there on a
25 12(b)(6). I don't know how you could get there; right?

1 Because I have their allegations in the complaint. You want me
2 to reject their allegation and say no, you have to find that
3 this is just guidance, and that it doesn't -- you want me to
4 find that it's just minimal, that it doesn't cross that line -
5 all those things involve some development that I can't find on
6 a 12(b)(6). You're asking me, actually, to draw all the
7 inferences in your favor and not the plaintiffs' favor.

8 **MR. GARG:** Your Honor, I don't think so. I think
9 we're saying all their factual allegations can be true, that
10 they've said, you know, all the certifying agent has left to do
11 on the ground is make these fact determinations of, well, did
12 it preexist the composting process and does it contaminate
13 crops, soil or water. That can be entirely true. And I think,
14 under just the statements of law that are out there, numerous
15 circuit cases, that does not overly cabin administrative
16 discretion in a way that's inconsistent with a general
17 statement of policy.

18 And just a recent quote: Agency instructions that the
19 agency offers are not legislative rules. An agency action that
20 merely explains how the agency will enforce a statute or
21 regulation, how it will exercise its broad enforcement
22 discretion is a general statement of policy. That's a 2014
23 D.C. Circuit case.

24 **THE COURT:** But doesn't that depend on a finding that
25 it doesn't amend the existing rule? I mean, I've already told

1 you that just a common sense reading of it, and I draw the
2 inference favor, it amends it. There's one exception to
3 synthetics materials when you're filing compost, under that
4 legislative rule that was adopted by the USDA, and that is that
5 it's on the National List. You've now added two other
6 exceptions. That's a plausible interpretation of it. You
7 would agree with, that that that's a plausible interpretation?

8 **MR. GARG:** It is a possible interpretation, yes.

9 **THE COURT:** Okay. No, I want you to say or not say,
10 and if it's not plausible, tell me why it's not plausible,
11 because that I find hard to believe.

12 **MR. GARG:** I don't think the agency would say that it
13 is the most plausible interpretation.

14 **THE COURT:** No, no, I'm asking you as an advocate
15 standing here, as an attorney, as an officer of the Court, is
16 it a plausible interpretation. You went to law school. You
17 did those things. You're at the DOJ, so you obviously did
18 well. Is that a plausible interpretation of when it says any
19 compost that contains a synthetic substance -- cannot be
20 organic, any compost that contains a synthetic substance cannot
21 be on the National List; isn't it a plausible interpretation of
22 that, that it?

23 **MR. GARG:** Your Honor, taking into account the overall
24 regulatory scheme outside of that one narrow provision that
25 we're talking about, I don't think that's a plausible

1 interpretation.

2 **THE COURT:** Okay. All right. I don't -- okay.
3 That's your argument. I have to find -- I don't find that a
4 credible argument at all, and so when you take those kinds of
5 positions, then that carries over.

6 So I don't -- I can't grant the 12(b)(6) on either, so
7 let's talk about standing then.

8 So they've stated a claim. So the question -- so they've
9 argued, and there's lots of cases on standing, that they're
10 harmed by the fact that now -- or they say some of the
11 plaintiff members are harmed by the fact when they go to the
12 store, they have to do additional research to figure out if the
13 product before this guidance was adopted. And by the way,
14 there's nothing in the record in front of me that shows that
15 prior to the adoption of this guidance, compost that contained
16 synthetic materials other than -- not on those lists were
17 allowed to be certified as organic, in fact.

18 The only thing in front of me is the fact that when
19 California learned of compost that did not, they actually
20 banned it, so the inference goes the other way; that prior to
21 the adoption of this guidance, it was being enforced in such a
22 way that it would not be labeled organic if it was using
23 compost that was not organic as well.

24 So now they say so now if I go to the store and I'm buying
25 something, I have to do all this research if I want to be sure

1 that I'm buying products that were not produced with
2 non-organic compost. Why isn't that an injury?

3 **MR. GARG:** Your Honor, I don't think -- I think that's
4 not an injury, because there's no ability to connect this
5 policy preference of I don't like the fact that synthetic
6 pesticides are used generally. There's no ability to connect
7 that to an actual effect on the food that's purchased, because
8 NOP 5016 by its nature doesn't allow contamination of the food,
9 it doesn't permit that, it says it only allows introduction of
10 synthetic residues where it does not cause onward contamination
11 of crops, soil or water, and crops being what becomes the
12 foods. So as a consumer, if you have that personal preference
13 of I don't want -- I generally don't like the idea of synthetic
14 pesticides anywhere in my food production, that's fine,
15 obviously, you're perfectly entitled to have that view. I
16 don't think that view by itself gives you a right to come into
17 federal court based on a concrete --

18 **THE COURT:** Why not?

19 **MR. GARG:** Because there's no concrete personal harm
20 that the food I bought actually now is people -- farmers
21 complying with NOP 5016 are going to have introduced actual
22 synthetic residues into the food I'm purchasing. That's not
23 true. That can't be true under the guidance itself.

24 **THE COURT:** I'll accept that, but why doesn't my
25 preference to not eat food, because maybe I don't believe the

1 USDA, maybe I'm irrational whatever, but I actually think I am
2 harmed or I care about harm to the environment if pesticide is
3 being used, and I want to buy food that's produced in such a
4 way that reduces the amount of pesticides just being introduced
5 into the environment in general. Why isn't that a harm, and
6 what case would I look at? Because there's lots of cases that
7 show simply just aesthetic, right, the environmental cases,
8 simply aesthetic harm is enough.

9 **MR. GARG:** Well, so I would say that as taking the
10 aesthetic harm point, first of all, you know, even on that kind
11 of idea, you need to show a direct connection to aesthetically
12 here is an area where I know these synthetic residues are being
13 used, or I'm alleging that these synthetic residues are being
14 used, I visit that area and I go there and it's less pretty or
15 less nice a place to visit, and that upsets me. You at least
16 have to make that much an allegation, and that's not in the
17 papers the plaintiffs have submitted.

18 As to the broader point, I think that the argument that,
19 well, there's something about this that I don't like, and even
20 though it doesn't actually affect directly the product I'm
21 buying, I have a right to come into court and complain about
22 it, that just becomes a staggeringly broad thing that basically
23 nullifies the injury-in-fact requirement. I mean, you could
24 carry that on indefinitely that I don't like the Department of
25 Labor's regulations about union issues.

1 **THE COURT:** That's not even close. Who would have
2 standing then to challenge this action? Who?

3 **MR. GARG:** Your Honor, as I stand here now, I'm not
4 sure who would.

5 **THE COURT:** Of course that's the argument USDA is
6 going to make, that we can do this, and nobody can challenge
7 it. We're insulated from any review whatsoever, because you
8 have to accept the results. That's -- come on. Is that the
9 argument? No one -- no one would have standing to come in and
10 challenge it.

11 **MR. GARG:** Your Honor, the nature of the -- it's as I
12 stated, it's a very, very narrow policy exception here. This
13 is not a broad, huge impact where the quality of the organic
14 food itself physically gets degraded; right?

15 **THE COURT:** That's your argument. The problem is, is
16 the Department didn't want to open it up to notice and comment
17 so they could actually have a robust discussion about whether
18 that would be the case. I mean, why not -- that's what I don't
19 get, is why not just do that? What are they afraid of?

20 **MR. GARG:** Your Honor, I mean, these exceptions in the
21 APA are there for A reason. Congress thought the agency
22 shouldn't always have to do that. Notice and comment is not
23 always required.

24 So I don't think that -- you know, it's not the role of
25 the courts to go beyond what Congress stated the agency needs

1 to do under the APA.

2 **THE COURT:** No.

3 **MR. GARG:** And I understand Your Honor might disagree
4 with that.

5 **THE COURT:** Right. It is the role of the courts to
6 make sure that the agency doesn't hide and insulate what it
7 does from public reviewing by calling it things that it's not,
8 by amending the rule and then saying, oh, we're not amending
9 the rule, we're just interpreting the word "contained" to not
10 be what the dictionary definition is or even a common sense
11 definition, it's something else. Maybe you're right, and maybe
12 it has the ability to do so, but this is on a 12(b)(6) that
13 you're saying they don't even get past go. They don't even get
14 past go. And I'm a little -- I'm always a little skeptical
15 when the response is, well, no one would have standing,
16 especially when at least I found they have a plausible argument
17 here, their definition of the statute, and the fact that what
18 the agency has done amended it is completely plausible. It may
19 not in the end be right, I don't know, but it's plausible. But
20 to say that no one would have the right to do that -- let me
21 hear from the plaintiff.

22 **MR. KIMBRELL:** Thank you, Your Honor.

23 A few points in response to opposing counsel.

24 With regards to the exceptions, I would just respond that
25 those exceptions are to be narrowly construed, and that's from

1 the *Hemp Industries* case and others of when a notice and
2 comment is not required.

3 But to get to the standing issue, I think Your Honor has
4 it exactly right. The fundamental injury here is that a new
5 loophole has been created that previously didn't exist that
6 allows a new source of synthetic substances, including
7 pesticides, into the organic production stream. And for our
8 members and for organic consumers generally, they buy organic
9 not because only it's not going to be on their food, they buy
10 it because they don't want to harm bees, they don't want to
11 harm the environment. They know it to be an environmentally
12 beneficial way of producing food.

13 In fact, the very definition of "organic production" at 7
14 C.F.R. 205.2 is a type of production that, quote, promotes
15 ecological balance and conserves biodiversity. So they buy it
16 for many reasons, including environmental ones. And I think
17 Your Honor has it exactly right here, that the injury here is
18 this new introduction to the food stream.

19 **THE COURT:** Well, so point to me where in the
20 complaint that's alleged, because what counsel says is that's
21 not alleged in the complaint.

22 **MR. KIMBRELL:** Sure. I think we have sufficiently
23 pled standing at our paragraphs for standing -- I'll just find
24 them here. It's going to be -- I have them listed. Ah,
25 paragraphs 15, 18 through 20 and 60 through 63, those would be

1 the standing paragraphs, first describing our members, and then
2 later the injury to the plaintiffs. And we did file some
3 illustrative standing declarations as well with the Court in
4 support of our allegations.

5 But certainly there are several ways to talk about the
6 injury, and certainly I think when you talk about standing
7 injury, you have to take into account the statutory source.
8 And here it's not this free-floating concern. Really, there's
9 this fundamental tenant, in fact *the* fundamental tenet from the
10 statute itself, about the prohibition generally on the use of
11 synthetic substances. It's at 7 CFS 6504, and it says organic
12 foods, quote, must be produced and handled without the use of
13 synthetic substances, except as otherwise provided by the
14 Organic Food Production Act. So it doesn't say they're going
15 to be produced so it's not on the food. It says they're not
16 going to be produced using these substances unless you go
17 through the National List.

18 So standing injury, as Your Honor noted, it could be
19 aesthetic, it can be recreational, in environmental cases it's
20 oftentimes enjoyment of the forest.

21 And by the way, to respond to the cite-specific argument,
22 the case we cited in our brief, *Citizens for Better Forestry*
23 dispatches that argument and says that when you are dealing
24 with a programmatic nationwide approval, it's sufficient if you
25 have members that use the forest, in that case the forest

1 system generally, like we have members here that buy organic
2 foods.

3 But setting aside the environmental harm, the other way of
4 thinking about this is the economic harm of it. Essentially,
5 you have consumers that are paying a premium for a product for
6 a reason, and they're not getting what they're paying for, and
7 that's fundamental. And you can look at class action cases
8 like natural cases where somebody is buying natural cosmetics
9 or cooking oil, and it's not natural, it has some synthetic
10 substance in it. It doesn't matter if that's actually in the
11 product at the end of the day, what matters is that it's
12 produced in a way that's contrary to what's being purported to
13 be done. And that's the very same here, and that's the
14 economic side of this injury.

15 And I would just say that the *Harvey* case is right on
16 point. It's the exact injury that we allege, and it's the only
17 court of appeal case out there dealing with standing under the
18 Organic Food Production Act. That's a First Circuit case from
19 2004, and in that case Mr. Harvey was an organic consumer and
20 farmer just like our members, and he challenged eight different
21 regulations of OFPA, as contrary to the statute, and he said it
22 undermines their integrity, which is exactly what we say. And
23 one of his arguments, his third claim, I would like to point
24 the Court correctly to especially, I was rereading it last
25 night, and he alleged successfully in that case that the

1 regulations had unlawfully allowed synthetic substances in
2 production and handling of organic foods, and that the law --
3 the statute didn't allow that. And so that's very much akin to
4 what we're saying, instead of production and handling, we're
5 saying inputs, namely compost. But the same thing, you can't
6 impermissibly allow synthetic substances in this loophole. The
7 First Circuit had no problem finding standing for Mr. Harvey in
8 that case.

9 **THE COURT:** But here is a little different, because
10 you're arguing notice and comment, so really what you're
11 arguing is the injury is the inability for -- to be denied the
12 opportunity to make your argument to the USDA as to why they
13 should not adopt such a loophole; right?

14 **MR. KIMBRELL:** Yes, Your Honor, absolutely. But make
15 no mistake, we believe that what they've done here is contrary
16 to the statute.

17 **THE COURT:** No, no, I understand that, but why isn't
18 that in itself just an injury, I mean, when you're dealing with
19 notice and comment. See, they've stated a claim, so then why
20 isn't that an injury? I mean, that seems to me that the most
21 obvious injury is all, is they're being denied the opportunity
22 to persuade the USDA that the path they're taking is not -- I
23 mean, the whole point of the whole notice and comment process.

24 **MR. GARG:** Your Honor, I think the Supreme Court spoke
25 directly to that in the *Summers* case where -- which also is a

1 notice and comment case, I believe not under the APA, but
2 similar statute that provided notice and comments rights. The
3 procedural of injury alone of being deprived an opportunity of
4 notice and comment is not itself sufficient to confer standing
5 without attachment to some concrete interest underlying it.

6 And you know, they call it a procedural right in vacuo.
7 That's exactly what *Summers* says. That's not enough to get
8 standing.

9 **THE COURT:** All right. But here, they argue they have
10 more, and they do allege more, I think in paragraph -- the
11 earlier ones, their level of value, but in paragraph 62, they
12 allege that they pay a premium for organic. They needn't rely
13 on the rule that was out there, that no compost with any
14 synthetic material would be used in the process, and that's not
15 the rule anymore.

16 **MR. GARG:** Your Honor, I would say that, again, I
17 think it's -- that is divorcing a little bit. They relied on
18 the organic -- you know, so just to distinguish it and the
19 natural line of cases that plaintiffs' counsel is discussing,
20 that's a case where the food producer is saying I as the food
21 producer certify that the product is natural, and natural has
22 these meanings or it doesn't have this meaning.

23 Organic doesn't have a fixed, you know, meaning that way
24 outside of the regulations that USDA is putting in place. So I
25 think it's just a distinguishable situation where, under the

1 argument plaintiffs' counsel is making, USDA could never change
2 the argument -- change the meaning of what it is to be organic,
3 even if it went through formal rule making, without causing
4 injury to some consumer who says, well, I thought organic meant
5 something different, now you change what it means, and I get to
6 challenge that now, just because I used to rely on what it
7 meant before and now you changed it. I mean, what's wrong with
8 that? All we're talking about is standing, all we're talking
9 about is for the ability for the USDA's actions to be reviewed,
10 not whether they're lawful or not. I mean, it may be in fact
11 that the change in regulation may be entirely lawful and
12 consistent with the Organic Act, but why is it such a horrible
13 thing that someone would have standing to challenge it?

14 **MR. GARG:** I think it veers very much towards the
15 generalized grievance idea. I think smart plaintiffs lawyers
16 would drive a truck right through that exception. You can
17 characterize almost anything as I used to rely on what I
18 thought this meant, and now I can't rely on it anymore, and
19 that caused me an economic injury.

20 Take the *Schmier* case --

21 **THE COURT:** Doesn't have to be economic.

22 **MR. GARG:** Correct. Take the *Schmier* case, for
23 example. That's a case where a lawyer came into the Court and
24 said I believe the Ninth Circuit's rule is not allowing me to
25 cite their unpublished decision are illegal, and that's a case

1 where the district court found no standing, and the Ninth
2 Circuit affirmed no standing, and also it dismissed -- the
3 Ninth Circuit affirmed dismissal with prejudice, saying there's
4 no way you could ever show standing in this scenario.

5 That's a scenario where the lawyer could easily have come
6 in and said I practice law, my clients depend on a stable body
7 of law that makes sense and is rational and is dependable, and
8 the Ninth Circuit, by not allowing citations on unpublished
9 decisions, has some injury to my ability to tell my clients
10 that here is what the law is, and it always works out this way,
11 and that has damaged my brand as a lawyer, it damaged what I
12 used to be able to rely on, and I get to have standing because
13 of that.

14 I think it's very similar argument to one the plaintiffs
15 are trying to make here, and the Ninth Circuit in that case
16 said there is no circumstances where you could show standing in
17 that kind of scenario.

18 **MR. KIMBRELL:** Can I respond, Your Honor?

19 So the *Schmier* case, the unpublished decisions case, the
20 lawyer had no case. It wasn't if he had had, I think, an
21 unpublished decision, he might have had standing, but that's
22 totally inapposite to what we have here. We have numerous
23 consumers and members of ours, clients that have provided
24 declarations that they buy and continue to buy organic
25 products, and they're injured by this rule.

1 We also have farmers, which we haven't talked about yet,
2 and this new rule provides new risks for them. How do they
3 comply with this amorphous do-not-contaminate standard? What
4 if they don't want to use compost, are they put at an economic
5 disadvantage? Those are the allegations that we've provided
6 and provided an independent source of standing.

7 **THE COURT:** All right. Anything further?

8 **MR. GARG:** Unless Your Honor has further questions...

9 **THE COURT:** No. I mean, I'll write something, but
10 I'm -- I'll go back and look, but I'm inclined to find standing
11 as well. I mean, standing is there not to protect the
12 Government from being sued, but to ensure that those plaintiffs
13 who sue have a concrete interest so they actually represent and
14 have an injury, and that they're pursuing the interests of
15 everyone, but it's not there to protect the Government from
16 suits. So I think I'm inclined to find standing. But I'll
17 write something, so -- and then when I do so, I'll set a date
18 for a CMC.

19 How much time do you think you would need in between my
20 order and the CMC?

21 **MR. KIMBRELL:** It would depend on when the Government
22 could produce the record, I think, or --

23 **THE COURT:** So that what you're going to produce -- so
24 then you have to produce the administrative record. So I guess
25 maybe what I'll do is I'll suggest that you meet and confer and

1 come up with a schedule for production of the record and
2 briefing, and all that kind of thing.

3 And the last thing I would say is these cases the judges
4 often -- I did one the other day, not in a USDA case, entirely
5 different agency -- send to someone for settlement and then
6 it's totally pointless. So what I want to know would that be
7 pointless here or not, and if it is, that's completely fine. I
8 understand when you're dealing with the Government it's
9 different than in other cases. Or is that something -- you
10 don't have to answer me right now, I guess. Why don't you meet
11 and confer on that, and then when you submit your schedule, if
12 you would want, for example, a referral to a magistrate judge,
13 I would be happy to do so, but if you don't, I'm not going to
14 force you to do that at all.

15 **MR. GARG:** Thank you, Your Honor.

16 **MR. KIMBRELL:** Thank you, Your Honor.

17 **THE COURT:** Okay. Thank you.

18 (Proceedings adjourned at 9:51 a.m.)

19 ---oOo---

20

21

22

23

24

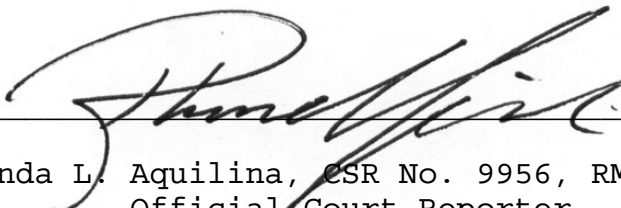
25

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

CERTIFICATE OF REPORTER

I certify that the foregoing is a correct transcript
from the record of proceedings in the above-entitled matter.

DATE: Wednesday, September 16, 2015


Rhonda L. Aquilina, CSR No. 9956, RMR, CRR
Official Court Reporter