

NOSB Presentation

Thank you for the invitation

History and Mission of CFNP

The Center for Food and Nutrition Policy of Virginia Tech (CFNP) is an independent, non-partisan, academic research center in the College of Agriculture and Life Sciences (CALS). The mission of the center is to advance rational, science-based food and nutrition policy. CFNP is recognized as a center of excellence in food and nutrition policy by the Food and Agriculture Organization of the United Nations. Our areas of focus are food safety and nutrition. We conduct research, outreach, communication, and education on a variety of issues within our areas of expertise.

All of the activities of the center eventually come back to policy issues. We believe that better analysis leads to better policy. Eventually.

CFNP conducts original research to address questions that are relevant to current food and nutrition policy. We communicate our research through peer-reviewed publications, scientific conferences, and comments to national and international policymakers. We host conferences, roundtables, and lectures to bring together scientists, policymakers, and stakeholders and foster better communication. And we provide policy analysis through comments, essays, and presentations. However, CFNP does not make policy.

We help all of the stakeholders understand the issues and consequences of policy alternatives.

How NOP fits into mission of CFNP

Providing TAP reports for the NOP and NOSB fits very well with the overall mission of CFNP. This project is about implementing an important food law in a manner that is faithful to the legislation in order to provide useful information to consumers and an objective and transparent process for stakeholders. In our view, the role of CFNP as a TAP reviewer is to provide factual and scientific answers in an objective manner so that NOSB and NOP can make informed judgments on the petitions they receive for the National List. We do not believe that it is appropriate for CFNP, or any TAP reviewer, to make value judgments on either specific substances or the philosophy of organic farming. The role of TAP reviewers, in our opinion, is to facilitate the implementation of OFPA based on the legislation and the regulatory guidance provided by the USDA.

CFNP's activity on qualified health claims

CFNP is active on other issues involving the implementation of regulatory policy and food labeling. We are currently preparing an evidence-based summary of the scientific literature for a qualified health claim. The evidence-based summary will be included in a petition for a health claim that a coalition will present to the FDA before the end of the year.

As part of the qualified health claim project, we developed a rigorous method for conducting an evidence-based summary of the scientific literature that conformed to the interim regulatory guidance provided by the FDA. We presented our approach to a panel of external experts for validation, and included extensive internal and external quality control at all stages of the procedure.

Our experience with qualified health claims is relevant to today's discussion in two ways. First, it has provided us with first-hand experience in how petitions are put together in other regulatory contexts. Second, it provides a useful example of how regulatory guidance, even interim guidance, can put "flesh on the bones" of legislation in order to improve the consistency, objectivity, and transparency of a regulatory review process.

The petitions for qualified health claims are expected to be much more detailed than those that have been used to date in the TAP review process. The petitions for a qualified health claim essentially represent the petitioner's best attempt to address all of the standards set forth in the interim guidance. This includes, among other things, a summary of the scientific evidence, evidence summary tables, and copies of all the relevant scientific articles. The FDA has an initial screening process to ensure that petitions are complete, and they have defined explicit criteria that they will use to prioritize the review of petitions.

The FDA's interim guidance for qualified health claims is also quite extensive.

SHOW STACK OF GUIDANCE NOW.

It provides detailed guidance on what criteria will be used to evaluate a petition for a qualified health claim as well as information on the standards that will be used to determine whether a criterion has been satisfied.

Based on our experience with the TAP review process, the qualified health claim regulatory guidelines, and other regulatory policy issues, CFNP respectfully offers the following suggestions for petitions, the statement of work, and regulatory guidance.

General comments on regulatory process

- We need more regulatory guidance to make the process more consistent and transparent.
- TAP reports should provide concrete, objective information and avoid value judgments.
- Each of the criteria need regulatory guidance that establishes clear, objective standards
- TAP reviewers need guidance on expectations for reports and a way to clearly establish what constitutes a complete and satisfactory report. Guidance to

“answer the seven questions” is not sufficient because the questions have not been clearly defined.

- Lines of communication need to be clearly defined and consistently maintained. There has been some confusion over whether communication should come to the TAP reviewers through NOP or NOSB. The communication has not always been timely. The communication sometimes consists of forwarded email that contains a complicated mix of messages that does not include clear direction.
- TAP reviewers need more consistency in the timing and quantity of reports in order to maintain proper staffing levels and quality control. CFNP can plan to do about ten TAP reports a year or about twenty a year, but we cannot plan for twenty and only receive five. We recognize that some of the issues regarding the timing and quantity of TAP reports is outside the control of either NOP or NOSB, and we are happy to work to manage the situation as efficiently as possible. For example, all faculty and staff that work on the TAP reports have other projects that support a percentage of their effort, and we do utilize some temporary staffing when we receive high volumes of TAP reports. However, we believe it is essential to maintain some expertise and continuity on the faculty and staff.
- TAP reviewers need to be given as much time as possible to prepare the reports. CFNP has never had the 262 days that is stipulated in the Statement of Work in which to complete an assigned TAP report. CFNP is very willing to work to meet the needs of our partners, but we need as much time as possible to produce a high-quality product.

Specific comments on the petitions

- Petitions need to be more detailed and consistent
 - Compare to qualified health claim process
 - Ideally should address each criteria and provide evidence supporting claim
- Different petitions formats for crops, livestock, and processing
- Confidential information is a serious problem
 - Need to develop a systematic way of handling confidential manufacturing information
 - TAP reviewers should document attempts to obtain information (where, when, who, etc.) and flag report as incomplete if confidential information cannot be obtained.
- More information on uses of substance
 - Specific uses envisioned by petition
 - Other uses of the substance
 - Examples of uses
- A screening process by NOSB/NOP to determine that petitions are complete and that the proposed substance and use do not violate federal law. We understand that this is being implemented currently.

Specific comments on the statement of work

- The terms used in the criteria need to be clearly defined and objective standards need to be established on which to judge whether each criteria is met. The standards need to be established so that value judgments and personal opinions are irrelevant. The standards need to be clear to all stakeholders. They should be designed to be more defensible in the event of legal challenges.
- Separate and distinct regulatory guidance needs to be issued for crops, livestock, and processing. The issues in the three areas are very different, and the TAP reviewers need guidance on each one.
- A system should be established to provide more consistent and constructive feedback to improve future reports. We understand the NOP and NOSB are developing forms and procedures that should improve the feedback provided to TAP reviewers.
- The lines of communication need to be clearly established and maintained. TAP reviewers need to know whether the assignment of petitions will come through NOP or NOSB and whose direction to follow.

Seven Criteria (crop and livestock):

1. The potential of the substance for detrimental chemical interactions with other materials used in organic farming systems;

Impossible to address every possible interaction. Guidance on how to focus or limit the search would be useful. Objective standards on the amount of

detrimental chemical interactions that would be allowed under the criterion.

None? A little? It depends?

2. The toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence in the environment;

We can report on the chemical and environmental properties of a substance, but the criterion currently does not provide any guidance about what level is allowable.

3. The **probability** of environmental contamination during manufacture, use, **misuse** or disposal of the substance;
4. Its effects on human health;

Under what conditions? Proper use? Improper use? Accidental release?

What level is allowable?

5. The effects of the substance on biological and chemical interactions in the agroecosystem;
6. The alternatives to using the substance: and,

7. The compatibility of the substance with a system of sustainable agriculture.

Seven Criteria (processing):

1. That processing aid or adjuvant cannot be produced from a natural source and has no organic ingredients as substitutes;
2. If manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling as described in section 6513 of the OFPA;
3. The nutritional quality of the food is maintained and the material itself or its breakdown products do not have adverse effects on human health as defined by applicable Federal regulations;
4. Its primary purpose is not as a preservative or used only to recreate/improve flavors, colors, textures, or nutritive value lost during processing except in the latter case as required by law;
5. It is GRAS by FDA when used in accordance with GMP and contains no residues of heavy metals or other contaminants in excess of FDA tolerances;

6. Its use is compatible with the principles of organic handling; and,
7. There is no other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.

CFNP looks forward to working with NOSB and NOP to improve the process of evaluating TAP petitions and implementing the OFPA. OFPA is an important tool to provide consumers with consistent information about products that meet the federal organic standards, and we hope to make the implementation of the law as consistent, objective, and transparent as possible.

CFNP is committed to making the TAP review process successful. We have gained valuable experience from our previous reports, and we have just brought on an additional project manager to assist with the TAP reports. Ms. Gayle Hein has several years of experience with environmental chemistry and EPA regulations as well as an undergraduate degree in human nutrition. Combined with the rest of CFNP's experience and knowledgebase in food safety, nutrition, and animal health, we believe we can provide an excellent breadth of knowledge.

Thank you once again for the opportunity to share our thoughts with you.