

Organic Materials Review Institute
Improvements to the TAP Process

NOSB Meeting
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OMRI's Mission

- ◆ To provide professional, independent, and transparent review of materials and compatible processes allowed to produce, process, and handle organic food and fiber.



OMRI's Structure

- ◆ A non-profit, non-governmental research & education organization.



OMRI Services

- Publishes a Generic Materials List cross-referenced to the National Organic Program Rule
- Reviews specific inputs and ingredients to determine compliance with USDA NOP Rule
- Publishes a list of approved Brand Name products
- Provides technical consulting to certification bodies, government agencies, and international organizations

Enhancing the Petition Process

- Petition
- Handling and screening petitions
- TAP contractors
- Guidance for TAP contractors
- Decision making process

The Petition Guidelines

- FR notice of July 2000 needs updating
 - Should refer to the final regulation
 - Should reference OFPA prohibitions
 - Should reference OFPA permitted categories

The Petition Guidelines

- FR notice of July 2000 needs updating
 - Processing criteria should be included
 - Livestock criteria - include guidance from NOSB recommendation
 - Justification statements should be tied to criteria
 - *National List* annotations can be amended
 - Amend language on 'handling' substances
 - "Non-agricultural" substances need justification

Guidance for Petitioners

- Define and distinguish
 - Synthetic vs. Non-synthetic
 - Agricultural vs. Non-agricultural
- Categories of permitted substances
- Substances prohibited by statute and regulation
- Reference to previous NOSB decision making



Guidance for Petitioners

- Confidential Business Information
 - Explain the process to petitioners
 - Possible delays, limitations created
- Need to know regulatory status
 - EPA, FDA compliance



Importance of Screening

- Maintains the transparency of the process
- Assures that all petitions meet basic requirements of OFPA
- Enables better TAP reviews

Screening of Petitions

Step 1. Received by NOP

- Completeness – send back if not

Step 2. NOP & NOSB review to OFPA criteria

- Prohibited substances
- Permitted categories



Step 2- Screening of Petitions

NOP & NOSB review to OFPA criteria

- Natural vs. synthetic? Is it permitted already?
- Agricultural or Not? Does it need to go in §205.606?
- Might require technical support to decide

Step 2- Screening of Petitions

Handling substances prohibited by OFPA

- Sulfites, nitrites, and nitrates
- Packaging materials containing synthetic fungicides, preservatives or fumigants
- Ingredient known to contain levels of nitrates, heavy metals, or toxic residues

(7 USC 6510)

Step 2- Screening of Petitions

OFPA Permitted Categories- in production

- Copper and sulfur compounds
- Toxins derived from bacteria
- Pheromones
- Soaps
- Horticultural oils
- Fish emulsions,
- Treated seed
- Vitamins and minerals
- Livestock parasiticides and medicines
- Production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and
- Equipment cleansers

7 USC 6517(e)

Step 3 Screening of Petitions

Regulatory status

- Should be clear in petition - status under
 - FDA
 - Food Drug and Cosmetic Act
 - FSIS
 - Federal Meat Inspection Act
 - Poultry Products Inspection Act
 - Egg Products Inspection Act
 - EPA- FIFRA
- Verify petitioner's compliance claim with agency

Step 4 Screening of Petitions

Public record

- Provide public record on rejected materials
- Document the reasons for rejection

Statement of Work - Contractors

- Contract requires bimonthly reporting
- Qualifications of personnel should be required
- Timeline and progress report keyed to the assignment of each petitioned substance
- Minimum of 120 days from assignment of each petition to when a draft is sent to TAP reviewers

Statement of Work - Contractors

- Scope of review
 - Alternatives to using the substance
 - Should provide from literature, plus historical methods
 - Include also biological, cultural, mechanical, and physical alternatives
 - availability or economic feasibility of stated alternatives is beyond scope
 - NOSB can solicit economic impact from public

NOSB Decision Process

- Must be transparent
- All petitions posted
- All TAP reviews posted
- Committee recommendations posted before the meetings
- Supplemental information provided to NOSB should be posted

NOSB Decision Process

- Develop standard procedures to be followed at meetings
- Suggest decision tree model for crops, livestock, processing
- Supporting documentation for decisions
- Call for more information if not sufficient
- Adequate time for public comment

Policy issues in need of guidance

- Agricultural or non-agricultural determination
- Synthetic or non-synthetic
- What is an antibiotic?
- Commercial availability of non-organic agricultural commodities used in processing.

Getting quality TAP reviews

Getting quality TAP reviews

- Consider a wider pool of contractors
 - Organizational competence in all three categories of 'materials' is rare.
 - Operational and real-life experience with the three material categories improves the quality of a review.

Getting quality TAP reviews

- Utilize competent investigators . . .
 - It takes time to develop competence.
 - Contractors need a program to train investigators. Current contracts do not fund training.
- with sufficient time to do quality work
 - The contractor should receive petitions at as steady a rate as possible.

Getting quality TAP reviews

- Provide a complete petition.

Getting quality TAP reviews

- Provide TAP Review templates.
 - Templates need to be updated as criteria change (e.g., 2002 livestock criteria).
 - Templates need to be specific for crop, livestock and processing materials.
 - OMRI created specific templates and guidance documents for TAP reviewers.

Getting quality TAP reviews

- Provide Exemplary TAP reviews.
 - New contractors need a blueprint for success.
 - Exemplary TAP reviews in the three material areas would be most helpful.
 - NOSB should provide detailed comments on why these TAP reviews are exemplary.

Getting quality TAP reviews

- Find competent TAP Reviewers.
 - Finding competent TAP Reviewers with operational experience can be difficult.
 - NOSB and NOP should consider maintaining a roster of TAP Reviewers.

Getting quality TAP reviews

- Keep competent TAP Reviewers.
 - Competent reviews of complete petitions are the best way of retaining TAP Reviewers.
 - A mechanism is needed to pay TAP reviewers when their scope of work expands for reasons beyond their control.

OMRI

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