National Organic Standards Board
Materials Subcommittee
Proposal
Process for Limited Scope Technical Reviews

February 12, 2013

Background

The Policy and Procedures Manual (PPM) currently allows considerable flexibility in topics/questions to be considered in a technical review (TR). If the reason the petitioner is petitioning is to get a National Organic Standards Board (NOSB) finding on classification, and it is controversial because Material Review Organizations (MROs) are in disagreement or a MRO changed its determination on synthetic non-synthetic, then a truncated TR would be helpful before launching into a full blown review. Since the determination of category compliance is left to the NOSB, not National Organic Program (NOP), a truncated TR can provide an important third-party assessment.

The PPM describes the process for determining whether a TR is needed, and if so, what the scope should be in “Phase 2: Determine if a Third Party Technical Review is required” (PPM, p.35) and “Procedures for Handling Technical Reviews” (PPM, p.37). The former section says:

> The NOSB committee assigned for the review (as identified by the Materials Committee Chair) must decide whether
> a) there is sufficient information in the petition,
> b) the committee can reasonably research any pending technical information, or
> c) there is the need to secure a technical review from a third party expert (see section titled Procedures for Handling Technical Reviews)

The latter section provides more detail concerning the scope of the TR:

> 3. When requesting the assistance of a third party expert to evaluate a material, a committee must identify the main technical issues needed to be addressed including, but not limited to:
> a. All uses of the petitioned material beyond what the petitioner has requested
> b. All uses of the petitioned material in combination with other material(s) that have been already approved on the same section of the National List
> c. Interactions of the petitioned material, not addressed by the petitioner, and that may involve materials currently on the same section of the National List.
> d. All possible manufacturing methods for a petitioned material.
> e. Potential effects on public health and biodiversity
> f. Environmental risks and hazards including, but not limited to potential for developing pesticide resistance, or long-term effects on sustainability.

Since the three criteria of environmental and health effects, essentiality, and compatibility with organic production practices, all must be met in order for the material to be listed, there really is no need for a full Technical Review if certain threshold issues, such as synthetic/nonsynthetic and compatibility with organic, are not met during the review process. Should those threshold issues not be met, considerable resources of time and money could be saved by conducting a first-stage TR that would only be followed by a complete TR if necessary.

Proposal

Revise the Petition Checklist Protocol to establish a more streamlined process for review of certain petitions.

The following process applies in those cases in which the NOP's review of the petition is unable to assign the substance petitioned for a crop or livestock use to an OFPA category (6517 (c)(1)(B)(i) or 6517(c)(1)(B)(ii)) or when the material comes to the NOSB because of a question of its synthetic/nonsynthetic classification, usually identified as "TBD." Before requesting a complete TR, the review subcommittee receives a more limited review that would answer the questions below. If these questions are answered satisfactorily, the subcommittee conducting the material review could proceed to a full TR. The following checklist questions will be considered by a limited scope TR.

> Evaluation Question #1: What category in OFPA does this substance fall under? (A) Does the substance contain an active ingredient in any of the following categories: copper and sulfur compounds, toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers? (B) Is the substance a synthetic inert or other ingredient that has not been classified by the EPA as inerts of toxicological concern (i.e., EPA List 4 inerts) (7 U.S.C. 6517(c)(1)(B)(ii)) and otherwise complies with the material review criteria? Is the synthetic substance an inert ingredient which was not on EPA List 4, but is exempt from a requirement of a tolerance, per 40 CFR part 180?
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> Evaluation Question #2: Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Further, describe any chemical change that may occur during manufacture or formulation of the petitioned substance when this substance is extracted from naturally occurring plant, animal, or mineral sources (7 U.S.C. 6502 (21)).
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> Evaluation Question #3: Is the substance synthetic? Discuss whether the petitioned substance is formulated or manufactured by a chemical process, or created by naturally occurring biological processes (7 U.S.C. 6502 (21)).

Subcommittee Vote:
Motion: The Materials Subcommittee moves to accept the proposal to establish a process for limited scope technical reviews as described above.

Moved: Tracy Favre Second: Jay Feldman

Yes: 5 No: 0 Abstain: 0 Absent: 2 Recuse: 0