
**Comments Submitted to Docket No. TMD-94-00-2
USDA's Proposed National Organic Program**

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Submitted to:

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Introduction.

The following material is being submitted by the International Center for Technology Assessment ("CTA") as comment to the United States Department of Agriculture ("USDA"), Agricultural Marketing Service's, "National Organic Program; Proposed Rule" found at 62 Federal Register 65850 (December 16, 1997).

General Considerations.

I. USDA's Proposal Ignores the Actions of the National Organic Standards Board. (Comment Topic Heading: General). The National Organic Standards Board ("NOSB") is a federal advisory committee created by the Secretary of Agriculture pursuant to the Organic Food Production Act[1] ("OFPA") and the Federal Advisory Committee Act ("FACA").[2] The NOSB serves as an advisory board to the Secretary of Agriculture. The Board is generally responsible for advising the Secretary on all aspects of the implementation of the OFPA. Specifically, the Board is responsible for evaluating substances for inclusion on the Proposed National List.[3] The purpose of the Board is to assist in the development of standards for substances to be used in organic production and

to advise the Secretary on any other aspects of the implementation of the OFPA.[4] The role of the NOSB is to recommend organic standards and provide public input to help the Secretary shape the policies and regulations that will govern the national organic certification program.[5] Thus, the NOSB has two distinct roles: (1) to provide the Secretary of Agriculture with recommendations regarding the implementation of the OFPA; and (2) to develop the Proposed National List or amendments to the National List for submission to the Secretary.[6]

The NOSB has fulfilled this statutory role by providing the USDA with extensive, consensus recommendations on the acceptable practices governing virtually all aspects of organic farming, processing, handling and labeling. As directed by the OFPA, the NOSB compiled the final, initial National List of Allowed and Prohibited Substances. Despite these efforts, the USDA has significantly altered the majority of the NOSB's recommended practices, directly altered the NOSB's National List, removed the NOSB's annotations and restrictions on use that accompanied the National List, and attempted to change the NOSB's future governance of the National List process. Such an explicit challenge to the NOSB's statutory authority is contrary to the OFPA and violative of the public/private partnership that supported Congressional passage of the OFPA.

II. The Proposes Rule Should Be Reframed Strictly as a Process Standard. (Comment Topic Heading: General). The NOSB focus, and that of other organic standards, has been to establish acceptable processes by which organic foods can be grown, handled, marketed, etc. In this regard, the NOSB recommendations were designed to create a national system outlining how to farm, process and handle organically. However, the USDA has attempted to alter this approach to the organic rule through the introduction of "performance" standards. In describing these standards USDA states, "Performance standards are generally written in terms of the results expected." 62 Federal Register 65869 (emphasis added). As a result, USDA has attempted to change the overarching philosophy of the rule from one of "processes" (process standards) to one of "end results" (performance standards or product standards). This philosophical shift informs the entire proposed rule and provides USDA with its basis for creating a number of large, vague exemptions from the organic processes recommended by the NOSB.

In addition, the USDA has made numerous changes in definitions that serve as the basis of the proposed national organic program. USDA has altered a number of definitions (e.g., organic, unavoidable residual environmental contamination) and added new, previously undiscussed definitions (e.g., non-active synthetic, cytotoxic mode of action). These definitional changes inform USDA's attempt to change the National Organic Program ("NOP") into a performance-based program allowing for new exemptions from required organic processes and standards. See generally, § 205.1 & 205.2; 62 Federal Register 65865-65867. In general, CTA believes that any national organic program must be reframed exclusively as a process standard.

Specific Considerations.

I. Alterations to the NOSB's National List. (Comment Topic Heading: National List. Proposed Section 205.20-205.28)

Under the OFPA the NOSB performs functions of a unique nature which require powers beyond those of a typical federal advisory committee. This is particularly true of its role in developing the National List.[7] Premised on the fundamental principle that synthetic chemicals should not be used in the production or handling of organic food product, the OFPA prohibits the use of synthetic chemicals and natural chemicals that are dangerous to human health or the environment in organic products. The National List is a procedural mechanism for establishing exceptions to this general principal. The OFPA specifically enumerates the NOSB's expanded role in establishing the National List:

- (D) Procedure for establishing National List. (1) In general - The National List established by the Secretary shall be based on a proposed national list or proposed amendments to the National List that is developed by NOSB. (2) No additions. The Secretary may not include exemptions for synthetic substances in the National List other than those exemptions contained in the Proposed National List or Proposed Amendments to the National List.[8]

Specifically, Congress delegated responsibility to the NOSB to develop the proposed National List.[9] Accordingly, the NOSB through its committee structure has developed a proposed National List of both natural substances whose use is not allowed under the OFPA and synthetic substances allowed to be used pursuant to the OFPA.[10] In addition to creating this list, the NOSB may allow the proposed approved synthetics and prohibited natural substances to be listed only after the NOSB consults a technical advisory panel and the Secretary consults with the Secretary of Health and Human Services and the Administrator of the Environmental Protection Agency.[11] Thus, the OFPA places specific duties upon the NOSB when developing its Proposed National List that go well beyond the traditional role of an advisory committee. This NOSB review activity in regard to the development of the National List is an example of the NOSB's extra advisory committee powers.

The USDA's proposed rule explicitly challenges and takes away the NOSB's statutory power to establish the National List of Allowed and Prohibited Substances. Some specific examples of USDA's illegal alterations include, but are not limited to, the following:

- (1). ***"Killed B.t."*** November 1, 1995, the NOSB listed genetically engineered *Pseudomonas fluorescens* with a B.t. gene ("***Killed B.t.***") as synthetic and non-approved. USDA ignored the NOSB and proposes that toxins derived from genetically engineered bacteria be placed on the National List of Active Synthetic Substances Allowed "so that [the agency] can receive comments on the proper classification of these substances, and whether they should be allowed, prohibited or allowed on a case-by-case basis" (Proposed § 205.20; 62 Federal Register 65889) and specifically lists "***Killed B.t.***" as an allowed active synthetic (Proposed § 205.22(d); 62 Federal Register 65891).

(2). **Piperonyl Butoxide.** On October 14, 1994, the NOSB rejected a motion to add Piperonyl Butoxide to the National List as an approved synthetic. See, NOSB, Final Recommendation, Addendum 2, “Botanical Pesticides Policy.” USDA ignored the NOSB finding and proposes that Piperonyl Butoxide be included on the National List of Active Synthetic Substances Allowed. (Proposed § 205.22(c)(9); 62 Federal Register 65891).

(3). **Chymosin.** On September 20, 1996, the NOSB determined genetically engineered chymosin to be an unacceptable synthetic. See, “Summary of NOSB Recommendation for Materials Considered at Indianapolis, IN.” USDA ignored the NOSB finding and proposes that genetically engineere