



United States Department of Agriculture
Office of Inspector General





United States Department of Agriculture
Office of Inspector General
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AUDIT
NUMBER: 01-601-0001-23

TO: David R. Shipman
Administrator
Agricultural Marketing Service

ATTN: Frank Woods
Chief
Internal Controls and Audits Branch

FROM: Gil H. Harden
Assistant Inspector General for Audit

SUBJECT: National Organic Program's National List of Allowed and
Prohibited Substances

Attached is the final report on the subject audit. On June 1, 2012, your office notified us that no exit conference was needed; as a result, we did not issue an official draft or request a formal response. Since the report contains no recommendations, no further response to this office is necessary.

We appreciate the courtesies and cooperation extended to us by members of your staff during our fieldwork.

Attachment

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National Organic Program's List of Allowed and Prohibited Substances

Executive Summary

The Organic Foods Production Act of 1990 (OFPA), as amended, required the Secretary of Agriculture (Secretary) to establish a National List¹ that identifies both synthetic substances which may be used and non-synthetic substances that cannot be used in organic production and handling operations. Any individual, corporation, company, association, partnership, State, municipality, organization, cooperative, group, or tribe can petition the Secretary to have a substance evaluated for inclusion onto or removal from the National List. The Secretary delegated the functions of the Act to the Agricultural Marketing Service AMS and, through regulations effective in October 2002, the National Organic Program (NOP) was created to administer these standards and to require the certification of organic production.

The Act also required the Secretary to establish the National Organic Standards Board (NOSB) 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 Act. The NOSB is appointed by the Secretary and is comprised of 15 members representing the following categories: farmers and growers; handlers and processors; retailers; consumer/public interest advocates; environmentalists; scientists; and certifying agents.

This report presents the results of our audit of the NOP's² National List of Allowed and Prohibited Substances authorized by the OFPA.³ We found that AMS generally had adequate controls over its processes to either allow or prohibit the addition of new substances to the National List, as well as to determine when substances already included in the list need to be removed.

Our audit evaluated NOP's controls and processes to ensure that (1) the guidelines regarding the composition of the NOSB⁴ were followed; (2) petitions for the inclusion of new substances to the National List were complete and met all applicable requirements before approval; (3) the NOSB followed its established procedures for each review of a petitioned substance; and (4) the Sunset Provision process to renew, remove, or change annotations to substances already on the National List was properly followed for each substance we reviewed. This audit was initiated in response to a Congressional request regarding the NOSB's processes for adding new substances to the National List.

Our examination did not disclose any reportable conditions regarding NOP's and NOSB's processes and procedures to allow or prohibit the inclusion of petitioned substances to the National List. We determined that the NOSB's reviews of petitioned substances were adequately documented to establish that the petitions presented to the NOSB were properly evaluated for sufficiency and eligibility. We concluded that the NOSB followed established processes to

¹ 7 CFR §§ 205.600 through 205.607.

² Final regulations implementing NOP were published December 31, 2000, and became effective on October 21, 2002.

³ OFPA as amended through Public Law 109-97, Nov. 10, 2005, Section 2118 7 U.S.C. 6517.

⁴ OFPA as amended through Public Law 109-97, Nov. 10, 2005, Section 2119 7 U.S.C. 6518.

approve or deny petitions with documented and supported research, transparency to the public, and adherence to laws and regulations, including NOSB's Policies and Procedures Manual.⁵ We also evaluated the composition of the 2011 NOSB⁶ by examining the resumes originally submitted by the board members; as part of this we determined whether their education, technical qualifications, organic production work experience, and other documented factors constituted a reasonable basis for their appointments to specific positions on the NOSB. We concluded that the selection process, which was carried out under the requirements of the Federal Advisory Committee Act (FACA),⁷ produced a properly-balanced NOSB membership. We did not attempt to evaluate the accuracy or completeness of any scientific technical reports or petitions. In addition, other than our evaluations of whether the NOSB followed its established processes, we did not reach any conclusions regarding the approval or disapproval of individual petitions by NOSB.

We also assessed the impact of a hotline complaint that was received during our audit, involving the NOSB's approval of a petitioned substance at its November-December 2011 meeting. We evaluated the report of the Technical Advisory Panel for the substance in question, and found that all of the requirements for such a review were followed. Based on our review of the NOSB's minutes for the meeting at which the petition was evaluated, we concluded that the panel's findings were extensively discussed by the board members who were present. Additionally, we reviewed the NOSB's voting record for the questioned substance to verify that the vote was completed according to the NOSB manual. Because we did not interview the complainants, and were not able to perform an in-depth review of the scientific issues raised, we are not reaching any conclusion as to the merits of the complaint itself. However, we did conclude that the NOSB followed its established process for evaluating whether or not the petitioned substance should be added to the National List.

In summary, we determined that AMS has adequate management controls in place for administering the National List of Allowed and Prohibited Substances. We did not identify any significant reportable issues and, as such, are not making any recommendations. Therefore, no further action or response is required by AMS.

⁵ NOSB's Policies and Procedures Manual, updated April 29, 2011.

⁶ Our review was limited to currently-seated board members as of the time of our audit fieldwork.

⁷ Federal Advisory Committee Act (Pub. L. 92-463).

Background and Objectives

Background

In 1990, the Organic Foods Production Act (OFPA) established nationwide standards for the production and handling of organic products and required the Secretary of Agriculture (Secretary) to issue regulations to implement the legislation. The Secretary delegated the functions of the Act to AMS and, through regulations effective in October 2002, the NOP was created to administer these standards and to require the certification of organic production. The Act also required the Secretary to establish the NOSB to assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects involving the implementation of the Act. The 15 members of the NOSB – who are appointed by the Secretary following a review of their qualifications by the management of NOP – represent various interest groups including: farmers and growers; handlers and processors; retailers; consumer/public interest advocates; environmentalists; scientists; and certifying agents.

After the Act was implemented, the Secretary was required to establish the National List,⁸ which can only be amended through the National List Petition Process.⁹ Any individual, corporation, company, association, partnership, State, municipality, organization, cooperative, group, or tribe is qualified to petition to have a substance evaluated for inclusion in or removal from the National List. The National List identifies synthetic substances that are allowed in organic production and non-synthetic substances that are prohibited in organic crop and livestock production. It also identifies non-agricultural non-synthetic, non-agricultural synthetic, and non-organic agricultural substances that may be used in organic handling.

The National List was implemented on October 21, 2002, and initially included over 200 substances. When a substance is added to the National List, it remains there for 5 years after the final rule allowing its inclusion becomes effective. Then, as required by the Sunset Provision in OFPA,¹⁰ the NOSB must publicly review the substance at least once every 5 years thereafter to either reaffirm or reject its continued inclusion on the National List. The first of these Sunset Provision reviews was completed in October 2007. Decisions made under the Sunset Provision must be transparent, non-arbitrary, based on the best current information, and in the interest of the organic community and of the public at large.

Members of the NOSB represent various sectors of the organic community, and some hold advanced degrees in one or more scientific areas. However, due to the wide range of substances or topics that can be involved in any given petition, the members may require outside expertise to make informed decisions. In such cases, the NOSB has the option of requesting assistance from third-party experts to obtain a written technical review regarding the petitioned substance. When NOSB recommends that third-party experts be brought in, NOP contracts out the services of a Technical Advisory Panel (TAP) to evaluate the scientific and technical issues associated with the use of the substance in organic production.

⁸ 7 CFR §§ 205.600 through 205.607.

⁹ 7 CFR § 205.

¹⁰ OFPA (7 U.S.C. 6517 (e)).

The NOSB reviews information from various sources to evaluate substances for inclusion or removal from the National List. Evaluation sources used by the NOSB include the TAP¹¹ evaluations, the Environmental Protection Agency, the Food and Drug Administration, the National Institute of Environmental Health Studies, and comments from the public. The NOSB submits its recommendations, the TAP evaluation, and any other evaluations, to the Secretary for consideration.¹² Upon receipt of the recommendation, the Secretary evaluates the NOSB's recommendation and makes the final decision regarding the approval or disapproval of a petition, or for the retention or removal of a substance reviewed under the Sunset Provision.

Objectives

Our audit objective was to evaluate the controls and processes governing the National List of Allowed and Prohibited Substances. Specifically, we evaluated the processes used by NOP and the NOSB to review and approve petitions for the inclusion of new substances to the National List, and for evaluating existing substances under the Sunset Provision.

¹¹ National Organic Standards Board Policy and Procedure Manual, revised October 28, 2010, pg 5 - TAPs "provide scientific evaluation of the materials considered for inclusion in the National List. Such panels may include experts in agronomy, entomology, health sciences and other relevant disciplines."

¹² Section 2118(d) of the OFPA (7 U.S.C. 6517(d)).

Scope and Methodology

We performed our audit at AMS Headquarters in Washington, D.C. We evaluated the NOP and NOSB processes to either approve or deny petitions to add new substances to the National List. We reviewed 12 of 405 substances that were petitioned for inclusion on the National List from the time of its inception in FY 2002 through November 2011. Additionally, we verified 12 substances that were already on the National List, to ensure that they were reviewed every 5 years under the Sunset Provision. The scope of our audit was FYs 2002 to 2010 to evaluate initial substances as well as substances added in later years to the National List. However, our evaluation of the processes used to fill NOSB vacancies concentrated on current operations only, and was therefore limited to the board membership as it existed at the time of our audit. We conducted our fieldwork from October 2011 through February 2012.

To accomplish our objectives we performed the following:

- Interviewed NOP officials to gain an understanding of laws and regulations for approving or denying the addition of petitioned substances to the National List.
- Reviewed documentation detailing the qualifications of all current NOSB members in terms of education, technical qualifications, and experience in organic food production and handling operations.
- Examined and tested 12 petitioned substances to evaluate whether the NOSB followed its established processes when determining whether to recommend substances for inclusion on the National List. We judgmentally selected petitions from FYs 2002-2010, including petitions both with and without third party technical reviews.
- Verified the documentation of technical reports used by the NOSB to allow or prohibit substances to the National List.
- Assessed NOP's review of petitioned substances for sufficiency and eligibility.
- Verified the accuracy of the NOSB voting process.
- Assessed and tested 12 substances reviewed under the Sunset Provision. We judgmentally selected these from the group of substances that were incorporated into the initial version of the National List, which came up for their Sunset reviews in FY 2008.
- Verified that the NOP properly applied the proposed and final rulemaking process to substances in our judgmental sample.

We conducted this audit in accordance with Generally Accepted Government Auditing Standards. Those standards require that we plan and perform the audit to obtain sufficient and appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our conclusions based on our audit objectives.

Abbreviations

AMS.....	Agricultural Marketing Service
FACA.....	Federal Advisory Committee Act
FY	Fiscal Year
NOP.....	National Organic Program
NOSB.....	National Organic Standards Board
OFPA	Organic Foods Production Act
OIG	Office of Inspector General
TAP.....	Technical Advisory Panel
USDA.....	United States Department of Agriculture

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