



United States
Department of
Agriculture

Agricultural
Marketing
Service

STOP 0268 Room 4008-S
1400 Independence Avenue, SW.
Washington, D.C. 20250-0200

USDA REVIEW OF APEDA – GOVERNMENT OF INDIA RECOGNITION AGREEMENT
DATES OF REVIEW – DECEMBER 18-22, 2006

REVIEW TEAM: Mark Bradley, Agricultural Marketing Service
Gerald Smith, Foreign Agricultural Service

1. INTRODUCTION

- 1.1. On February 16, 2006, the U.S. Department of Agriculture (USDA) recognized the Government of India's Agricultural and Processed Foods Export Development Authority (APEDA) as a competent body for the accreditation of organic certification bodies under the U.S. National Organic Program (NOP). Pursuant to the recognition agreement representatives of the NOP conducted an onsite review of APEDA's recognition program in India on December 18-22, 2006.
- 1.2. At the time of the audit, APEDA had accredited ten organic certification bodies to certify to the NOP standards.

2. OBJECTIVES OF AUDIT

- 2.1. This audit was a quality system and compliance audit. The objective of the audit was to evaluate the system capabilities and performance of APEDA in controlling the proper application and enforcement of the NOP technical and conformity assessment standards for organic products labeled and exported to the United States.

3. LEGAL BASIS FOR THE AUDIT

- 3.1. The audit was conducted pursuant to a recognition agreement between the Agricultural Marketing Service (AMS) and APEDA completed by the AMS Administrator on February 16, 2006. The agreement provides for USDA to conduct onsite reviews of the APEDA conformity assessment system when properly notified of the review by USDA. Recognition agreements are provided for pursuant to NOP regulations at 7CFR 205.500 (c) (1).
- 3.2. The following statutes, regulations, and standards were considered in the review:
 - 3.2.1. Organic Foods Production Act of 1990

3.2.2. U.S. Code of Federal Regulations (CFR) Title 7 – Agriculture, Part 205, National Organic Program

3.2.3. ISO/IEC 17011:2004(E) Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies.

4. PROTOCOL

- 4.1. The assessment was accomplished in three parts; a review of operations at the APEDA headquarters office in New Delhi; a review of certification bodies accredited by APEDA to apply the NOP standards; and a review of four certified organic operations.
- 4.2. In selecting certifiers and operations to be reviewed, the audit team worked with APEDA officials to determine a representative sampling of operations according to size (large, medium, and small) and type (production or handling).
- 4.3. The auditors reviewed each phase of the Indian production, certification, and accreditation system to determine if the competent authority had the necessary controls in place to ensure traceability and compliance with the NOP regulations.
- 4.4. The auditors interviewed APEDA personnel at the headquarters offices in New Delhi and observed procedures and records related to the operation of the program.
- 4.5. At each certification agency reviewed, the auditors reviewed procedures and sampled records relating to the certification of organic operations in order to determine compliance with the NOP regulations. The auditors also interviewed certification body personnel to determine their knowledge of the NOP regulations and their qualifications with respect to their duties and responsibilities.
- 4.6. The audit team visited four organic production and handling operations to observe production, handling and labeling practices in order to determine the level of compliance accomplished by the certified operations. The auditors reviewed available records, interviewed farmers or other responsible parties at each site, and participated in a witness audit conducted by one certifying body.
- 4.7. The audit team was accompanied by a representative of APEDA throughout the audit. At each of the certified operations visited, the team was also accompanied by a representative of the respective certifying body. Any instances of concern or perceived noncompliances were immediately brought to the attention of the accompanying APEDA official.

- 4.8. Unless otherwise noted in this report, conformity assessment practices and technical performance observed was considered to be in compliance with the NOP regulations.
5. Summary of Previous Audits
- 5.1. This was the initial onsite audit of the India government program. There were no previous onsite audit findings to consider for corrective actions.
6. Observations
- 6.1. Qualifications of accrediting body personnel. Review of qualifications of accrediting body personnel revealed substantial education, training and experience relevant to the certification of organic production. Many personnel had advanced degrees in the life sciences and key management personnel had specialized training in quality systems management or assessment.
- 6.2. Qualifications of certifying body personnel. All inspectors had secondary education or higher and all had received training on the NOP standards. All certifying body managers receive mandatory training from APEDA in the proper application of the NOP regulations as part of the APEDA accreditation process.
- 6.3. Quality system management. A review of the quality management system in place at APEDA with regards to application of the NOP technical standards revealed a detailed system in place addressing all NOP technical program and conformity assessment system requirements. Document control is closely observed by the APEDA staff person responsible for maintaining the system. The documented quality management system in place at APEDA, including the qualifications of management and staff, provide confidence in the system of controls in place for organic certification.
- 6.4. APEDA officials should continue to maintain their strict adherence to established procedures and only accredit certifying bodies once they have demonstrated their ability to comply with NOP requirements.
- 6.5. Any noncompliances identified at certifying body offices during the course of this review should be addressed both as discrete issues to be corrected and from a quality system approach in order to prevent further noncompliance.
7. Main Findings
- 7.1. Quality System

7.1.1. No noncompliances were observed during the review with regard to APEDA's processes for quality system management.

7.2. Conformity Assessment

7.2.1. Requirement for review and approval of technical processes for organic systems plans. Review of organic systems plans at one certification body office revealed that certification had been issued to a spice extract manufacturer without receiving complete information on materials used as solvents in the extraction process. Further review of the file indicated that the certifying body had issued a notice requiring the extract manufacturer to provide the missing information within a specified time period. At the time of the USDA review, the time frame for providing the missing information had expired without the manufacturer's compliance with the request. Further review of records of certified operations maintained by the certifier showed that two of three records sampled were missing information in the organic systems plans regarding inputs used in manufacturing. [Citation: 7CFR 205.201 (a) Organic production and handling plan]

7.2.2. Grower group certification. Grower group certification is a recognized practice among certifiers accredited to the NOP by APEDA and the certification bodies observed each practiced certification of grower groups. A review of grower group certification practices revealed that certification decisions are based on a sample of the production sites included in the grower group. Only a percentage of production units receive onsite inspections by the certifying body each year. The number of production sites in the sample is based on risk with respect to the performance history of the grower group. NOP regulations require that all production sites receive an annual onsite inspection by the certifying body. [Citation: 7CFR 205.403 Onsite inspections] However, pursuant to a May 2, 2007 interim policy published by NOP on the USDA website (attached), the NOP will not take enforcement action against certifiers who conduct grower group certification using percentage sampling methods as long provisions of the October 20, 2002 National Organic Standards Board (NOSB) recommendation Criteria for Certification of Grower Groups (attached) are met.

7.2.3. Requirement for each certified operation to maintain records. A review of one certified operation, a member of a grower group, revealed that the operator did not maintain records of application of materials used on his farm. It was further observed that this deficiency was not due to a lack of literacy on the part of the grower and that the absence of records had not been detected by the certifying body. NOP regulations require that all certified operations maintain records concerning the production, harvesting, and handling of agricultural products. [Citation: 7CFR 205.103 Recordkeeping by certified operations.]

7.3. Application of NOP Technical Standards

7.3.1. Use of cow urine in organic production. A review of production operations and interviews with certifiers and producers revealed that foliar application of cow urine is a common practice in Indian organic production. APEDA officials were advised that under the NOP regulations, urine is included in the regulatory definition of manure and must be used according to NOP regulations [Citation: 7CFR 205.2 Definitions: Manure and 205.203(c)]

8. Closing Meeting

8.1. The audit team conducted a closing meeting with APEDA officials in Delhi on December 22, 2006.

9. Attachments

9.1. NOSB recommendation: Criteria for Certification of Grower Groups – December 20, 2002.

9.2. Grower Group Letter – May 2, 2007

Control File:

N:\NOP\INTERNATIONAL\INDIA\Recognition Report APEDA 2006 mab final 051407.doc