



Introduction

Welcome to the “*The Program Handbook: Guidance and Instructions for Accredited Certifying Agents and Certified Operations.*” The goal of the Program Handbook is to provide those who own, manage, or certify organic operations with guidance, instructions, and policy memos that can assist them in complying with the National Organic Program (NOP) regulations.

The NOP is issuing this Program Handbook under the auspices of the Office of Management and Budget (OMB) Bulletin on Agency Good Guidance Practices (GGPs) published January 25, 2007 (72 FR 3432-3440). The purpose of the OMB’s GGPs is to help ensure that program guidance documents are developed with adequate public participation, are readily available to the public, and are not applied as binding requirements. The OMB further requires agencies to maintain a current electronic list of all guidance documents as defined in the Bulletin.

The NOP strives to ensure uniformity in the development, issuance, and use of guidance, instruction, and policy memo documents related to NOP’s regulatory, accreditation, and enforcement activities. The use of such documents to assist in developing uniform regulatory decisions is a standard government practice. This introduction provides an overview of the types of documents included in this Program Handbook, and outlines their purpose, legal effect, and the process by which they are authorized, reviewed, revised and disseminated to the public.

Handbook Overview

There are three parts to the Program Handbook. The first part is comprised of Level 1 Guidance Documents. Level 1 Guidance Documents set forth interpretations of NOP statutory or regulatory requirements, changes in interpretation or policy, or address unusually complex or highly controversial issues.

The second part is comprised of Level 2 Instruction Documents. Level 2 Instruction Documents set forth or clarify existing NOP procedures. Level 2 Instructions are meant to inform certifying agents and certified operations about best practices for conducting business related to certification, accreditation, international activities, and compliance and enforcement. Unless otherwise noted, Level 2 Instruction documents are effective immediately upon their issuance and publication in the Program Handbook.

The third part is comprised of NOP Policy Memos. A policy memo is a document that provides formal communication to public audiences on NOP policy regarding a specific regulatory requirement. Policy memos are valid until revised or archived. Beginning in January 2011, all current and valid NOP policy memos will be included in the Program Handbook.

The term "guidance, instruction, and policy memo documents" collectively refers to documents prepared by the NOP, for certifying agents, certified organic operations, and the public that:

1. Relate to the production, handling, processing, labeling and marketing of organic food products;



2. Relate to the accreditation of certifying agents and the certification of organic producers and handlers;
3. Relate to the National List of Allowed and Prohibited Substances, State Organic Programs, fees, compliance, inspection and testing, reporting and exclusion from sale, compliance, adverse action appeals process and enforcement policies regarding agricultural products regulated under 7 CFR Part 205;
4. Establish policies and procedures or describe the program's policy and regulatory approach to an issue.

Guidance, Instruction, and Policy Memo Documents do not include documents relating to program reports, general information documents provided to consumers, speeches, journal articles and editorials, media interviews, press materials, letters addressing enforcement or compliance actions, or other communications directed to individual persons or firms. Correspondence, including public notices (time sensitive communication on a specific topic) are not part of the Program Handbook and are posted on a separate webpage (www.ams.usda.gov/NOPCorrespondence).

The purpose of issuing the documents in this Handbook is to:

1. Provide assistance to the regulated industry by clarifying requirements that have been imposed by the Act or its implementing regulations and by explaining how industry may comply with those statutory and regulatory requirements, and
2. Provide standard operating procedures and specific review and enforcement approaches to help ensure that all parties implement the program's mandate in an effective, fair, and consistent manner.

The NOP will solicit public input through a notice in the Federal Register prior to finalizing new Level 1 Guidance Documents for inclusion in this Program Handbook, *unless*:

1. There are significant regulatory justifications for immediate implementation;
2. There is a new statutory requirement, executive order, or court order that requires immediate implementation, and guidance is needed to help effect such implementation;
3. The guidance presents a less burdensome policy that is consistent with the purposes of the Act and implementing regulations; or
4. The guidance was issued prior to NOP's publication of this Handbook. Five guidance documents (NOP 5006, NOP 5008, NOP 5012, NOP 5014, NOP 5016, and 5017 series) meet this criterion. These are republished "as is" in the first part of this Handbook.

The NOP recognizes that, in the past, informal communication sent by the program may have been interpreted as official NOP positions, policy or guidance. To prevent misunderstanding in the future and to ensure that all stakeholders are operating from a common baseline, only final regulations/rules and the NOP Handbook represent official NOP policy or guidance.

The NOP continues to develop guidance that will be incorporated into the NOP Handbook, and new rules are being worked on as well. Effective immediately, NOP will point to these Regulations and the Handbook as the definitive source of available information.



Legal Effect

Guidance, Instruction, and Policy Memo Documents do not themselves establish legally enforceable rights or responsibilities and are not legally binding on the public or the program. Rather, the documents explain how the Organic Foods Production Act (OFPA) of 1990 (7 U.S.C 6501-6522) and its implementing regulations (7 CFR part 205) apply to certain regulated activities. In addition, because these documents represent the program's current thinking on the subject addressed in the document, the NOP will take steps to ensure that the program does not deviate from the document without appropriate justification and appropriate supervisory concurrence.

The documents contained in the Program Handbook provide a uniform method for operations to comply that can reduce the burden of developing their own methods and simplify audits and inspections. Alternative methods that comply with the Act and its implementing regulations are acceptable. The NOP strongly encourages accredited certifying agents and certified operations to discuss alternative approaches with the NOP before implementing them to avoid unnecessary or wasteful expenditures of resources and to ensure the proposed alternative approach complies with OFPA and its implementing regulations.

Authorization Policy

All drafts of Level 1 Guidance Documents, Level 2 instructions, and Policy Memos will be reviewed and approved by the Deputy Administrator of the National Organic Program prior to their publication.

Review and Revision

The NOP intends to review existing Guidance, Instruction, and Policy Memo Documents on a regular basis. The NOP will, when appropriate, update or revise these documents in accordance with OMB's Good Guidance Practices. In addition, when significant changes are made to an applicable statute or regulation, the NOP will, on its own initiative, review and, as appropriate, revise documents relating to that changed statute or regulation.

Document Archiving

When a Guidance, Instruction or Policy Memo document is no longer needed or applicable for the conduct of day-to-day activities, the document is archived. Archived documents are identified by placing the word 'Archived' at the end of the file name and an 'Archived' watermark on the document. A list of archived documents is available in Appendix A of the Program Handbook. Archived documents are available on request.

Public Dissemination

The most recent edition of the Program Handbook is available for viewing and downloading through the NOP web site (www.ams.usda.gov/nop). The NOP will also make the Program Handbook available in hard copy, upon request to: Standards Division, National Organic Program, 1400 Independence Ave., SW., Room 2646-S, Ag Stop 0268, Washington, D.C. 20250-0268. Telephone: (202) 720-3252; Fax



(202) 205-7808. The public will be notified when new draft guidance is available for public comment through a notice in the Federal Register.

Updates to the Program Handbook

The NOP envisions publishing new editions of this Handbook as the NOP develops additional guidance, instructions, and policy memos on topics that require clarification. If necessary, the full Program Handbook will be released four times each year: Fall (October), Winter (January), Spring (April), and Summer (July). Each edition will include a detailed Summary of Changes from the previous edition. Updates to the Program Handbook that occur between editions will be handled as follows:

1. The NOP will notify the public via announcements on the NOP web site and on the NOP Newsroom web page.
2. At all times, the most up-to-date Table of Contents, Summary of Changes, and individual documents comprising the Program Handbook will be available for download on the NOP Program Handbook web page <http://www.ams.usda.gov/NOPProgramHandbook>.
3. Updates to all documents will be reflected in the following ways:
 - a. Next to the document name in the Table of Contents (e.g. Processed Animal Manure in Organic Crop Production (*Updated 10.28.10*)).
 - b. In the document's effective date.

Contact Information

Members of the public who wish to request that the agency issue, reconsider, modify, or rescind a guidance document, or to complain that the agency is not following the procedures in OMB's Bulletin on Good Guidance Practices or is improperly treating a guidance document as a binding requirement, may do so by sending an email to NOP.Guidance@ams.usda.gov.

Or by mailing a letter to the following office:

Standards Division
National Organic Program
U.S. Department of Agriculture
Room 2646-So. (Stop 0268)
1400 Independence Ave SW
Washington, DC 20250-0268