



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 issued this Program Handbook under current instructions from the Office of Management and Budget.

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. Public notices, including time sensitive communications on specific topics, are not part of the Program Handbook and are posted to the [USDA Organic Insider Archive](#). Additionally, the NOP provides training and educational materials through its [Organic Integrity Learning Center](#) (OILC). OILC courses are not included in the Program Handbook. The OILC is a formal Learning Management System that supports the professional development and continuing education of professionals working to protect organic integrity.

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. Four guidance documents (NOP 5006, NOP 5008, NOP 5012, and NOP 5014) meet this criterion. These are republished "as is" in the first part of this Handbook.

The NOP recognizes that, in the early years of the program, informal communication sent by the program may have been interpreted as official NOP positions, policy or guidance. To prevent misunderstanding 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 will continue to evaluate regulatory priorities and consider the best tools for implementing them. These may include new rules, or new or updated Handbook documents. NOP will continue to point to the Organic Foods Production Act (OFPA), the USDA organic regulations, and the NOP Handbook as the definitive source of available information. Together, these comprise what is known as the organic standards.



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. Chapter 94) 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. A list of archived documents is available in Notice 11-4 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 (<https://www.ams.usda.gov/nop>). The NOP will also make the Program Handbook available in hard copy, upon request to: National Organic Program, 1400 Independence Ave., SW., Room 2642-South, Stop 0268, Washington, D.C. 20250-0268. Telephone: (202) 720-3252. Email: NOP.Guidance@usda.gov. 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

Updates to the Program Handbook will be handled as follows:

1. The NOP will notify the public of updates through the NOP web site, the Federal Register, the Organic Insider email notification service, and/or other means.
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 <https://www.ams.usda.gov/rules-regulations/organic/handbook>.
3. Updates to all documents will be reflected in the following ways:
 - a. Next to the document name in the Table of Contents.
 - 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:

National Organic Program
U.S. Department of Agriculture
1400 Independence Ave., SW
Room 2642-South, Stop 0268
Washington, DC 20250-0268