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# Rulemaking at APHIS

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Rulemaking is one of many tools we use to achieve our broad mission of protecting the health and value of America's agricultural and natural resources. It is the process for issuing, changing, or removing Federal regulations.

These regulations help us carry out the many [laws we enforce](#).

## Public Participation in Rulemaking

The [Administrative Procedure Act](#) sets the basic requirements for Federal rulemaking. One key requirement is that agencies must follow an open public process when they issue regulations. For most rulemaking, this includes publication in the [Federal Register](#) and an opportunity for—and agency response to—public comments.

Other laws and executive orders also apply to Federal rulemaking (such as [Executive Order 12866](#) and the [Regulatory Flexibility Act](#)). But the opportunity for public participation is one of the most fundamental requirements.

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## Our Process

In most cases, rulemaking at APHIS involves the steps below.

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## **Step 1: Identify a Need**

Any number of factors may prompt the need for a new or revised regulation (rule). Here are a few:

- New technologies or new data on existing issues
- Recommendations from Congressional committees or Federal advisory committees
- Petitions from interest groups, corporations, or members of the public
- Studies and recommendations from other agencies or our own agency staff

## **Step 2: Plan**

We assess the possible impacts of the rule by preparing risk, environmental, or other analyses as needed. We then prepare a regulatory work plan, clear it within APHIS and USDA, and submit it to the Office of Management and Budget (OMB) so they can designate it as "significant" or "not significant" as described under [Executive Order 12866](#).

The term "not significant" has nothing to do with an action's importance or priority; it just means OMB has decided not to review the docket.

## **Step 3: Draft**

APHIS staff work to draft a proposed rule and clear it with our technical experts, USDA attorneys, and policy officials (plus OMB if "significant").

## **Step 4: Publish Proposed Rule**

Our next step is to publish the proposed rule in the [Federal Register](#). This document must have a summary that includes:

- An explanation of the proposed rule
- An analysis of its expected economic effects
- A description of any information collection requirements
- An invitation to the public to submit comments by a set date (usually 60 days after publication)
- The proposed rule itself (as it would appear in the [Code of Federal Regulations](#))

## **Step 5: Review Public Comments**

We consider all public comments on the proposed rule and prepare responses. We make decisions on how to proceed, including any revisions needed to the rule. We prepare a regulatory worksheet for the final rule, clear it within APHIS and USDA, and submit it to OMB for designation.

## **Step 6: Finalize**

We draft a final rule and clear it with our technical experts, USDA attorneys, and policy officials (plus OMB if “significant”).

## **Step 7: Publish Final Rule**

We publish the final rule in the Federal Register. This document must have a summary that includes:

- A response to issues raised by the public comments
- An analysis of the expected economic effects
- A statement about any information collection requirements
- An effective date for the rule (at least 30 days after publication, in most cases)
- The final rule itself (as it will appear in the Code of Federal Regulations)

## Timeline

From start to finish, the rulemaking process can be lengthy-anywhere from one to several years. The timeline depends on a number of factors, including the complexity of the rule, the number and nature of comments received, the priority assigned by the agency, and the designation assigned by OMB. Rules designated “significant” take longer than rules designated “not significant,” for example.

## Types of Rules

A **proposed rule** and a **final rule** are the most common types of rulemaking at APHIS. However, we may publish several other types of rules, depending on the situation. A brief description of each is below.

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### Interim Rule

We may issue an interim rule instead of a proposed rule when there is good cause for making a rule effective before the public has an opportunity to comment on it. For example, APHIS may need to put immediate restrictions in place after an outbreak of an animal disease to prevent the spread of that disease.

An interim rule may be followed by a final rule; this could contain changes to the interim rule based on public comments. If the final rule doesn't make any changes to the interim rule, we call the final rule an affirmation of the interim rule.

### Advance Notice of Proposed Rulemaking

Another type of rulemaking document is the advance notice of proposed rulemaking. We may use this type of document when APHIS needs preliminary information before issuing a proposed rule-or even deciding whether to issue a proposed rule.

# Non-Regulatory Documents

APHIS publishes a number of other documents in the [Federal Register](#) that are **not** rules. These may be supporting materials for a specific rule, or they may be unrelated to any regulatory action. Below are the most common types of non-regulatory documents we publish.

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## Notices of Availability of Environmental Documents

This includes notices that make environmental assessments, environmental impact statements, and related documents that fall under the National Environmental Policy Act (NEPA) available to the public. [Learn about NEPA compliance.](#)

## Notices of Availability of Risk or Economic Analyses

This includes notices making available a variety of documents, such as pest risk assessments, risk management documents, risk analyses, evaluations of foreign regions with regard to their status for a pest or disease of livestock, reviews of the regulatory status of certain products of genetic engineering, and evaluations of the quarantine significance of certain plant pests.

## General Notices

These documents vary in purpose. We may publish a notice to share information or seek input on agency actions that are of public interest, but don't have broad national impact or legal effects. Some examples include advisory committee meeting notices, administrative orders, or notice of decisions that impact specific groups.

# Commenting Opportunities

Now that you know how the rulemaking process works, see what APHIS has available for public comment.

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- [Animal Health Commenting Opportunities](#)
- [Animal Welfare Commenting Opportunities](#)
- [Biotechnology Commenting Opportunities](#)
- [Plant Health Commenting Opportunities](#)
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