

## Questions and Answers: The Rulemaking Process

### Q. What is a rule or regulation?

**A.** A rule or regulation is a set of requirements that has the force and effect of law. Federal agencies issue rules or regulations to implement laws passed by Congress that authorize or direct the agency to take certain actions. These laws are often referred to as an agency's statutory authority.

Federal agencies may issue regulations only within the scope of their statutory authority. The U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) has authority under a number of laws, but our primary statutory authorities include: the Animal Health Protection Act (AHPA), the Animal Welfare Act (AWA), the Horse Protection Act (HPA) and the Plant Protection Act (PPA).

- The AHPA, passed in 2002, authorizes APHIS to regulate the importation and interstate movement of animals and animal products to prevent livestock pests and diseases from being introduced into or spreading within the United States.
- The AWA requires that basic standards of care and treatment be provided for certain animals bred and sold for use as pets, used in research, transported commercially, or exhibited to the public. The AWA became law in 1966 and has been strengthened several times by amendments.
- The HPA prohibits horses subjected to a practice called *soring* from participating in shows, sales, exhibitions, or auctions. Congress passed the HPA in 1970 with the goal of eliminating this cruel and inhumane practice that is used to accentuate a horse's gait (i.e., *soring*).
- The PPA became law in 2000 as part of the Agricultural Risk Protection Act. It authorizes APHIS to regulate the importation and interstate movement of plants, plant products, biological control organisms, noxious weeds, and plant

pests to prevent plant pests or noxious weeds from being introduced into or spreading within the United States.

### Q. What is rulemaking and what steps are involved in it?

**A.** Rulemaking is a thorough process that provides opportunity for the public to provide input on regulations before they are finalized. The process includes various steps to ensure that regulations are sound and consistent with applicable laws and policies. While the steps may vary, at APHIS they generally involve:

- Conducting risk, economic, and/or environmental analyses, as appropriate, and drafting a proposed rule.
- Reviewing the draft proposed rule within USDA to ensure technical accuracy, legal sufficiency, and consistency with policy. In certain cases, a rule may also be reviewed by the Office of Management and Budget (OMB), an office within the Executive Office of the President of the United States.
- Publishing the proposed rule in the *Federal Register*, a daily publication of the U.S. Government.
- Accepting written comments on the proposed rule from the public.
- Reviewing the public comments and determining what changes, if any, should be made to the proposed rule in response to the comments.
- Drafting, reviewing, and publishing a final rule in the *Federal Register* that summarizes and responds to the public comments, makes any necessary changes to the proposed rule, and sets a date for when the rule will take effect.

### Q. How long does rulemaking take?

**A.** Rulemaking can take from several months to several years, depending on a number of factors. These factors include the complexity of the issues involved; the availability of data needed for economic, risk, or environmental analyses; the extent of public participation in the rulemaking, and the number and nature of comments received; the priority of the rulemaking relative to other agency rulemakings under development at the same time; and whether the rule requires OMB review. Some rulemakings also require consultations with State and local governments and Indian tribes.

## The Typical Rulemaking Process in APHIS

### Step 1: The Proposed Rule

#### Q. What is a proposed rule?

A. A proposed rule is a document that sets out potential new regulations or changes to existing regulations that an agency is considering under its statutory authority, along with an explanation of why the new or revised regulations are appropriate. A proposed rule may be accompanied by analyses that examine the risks the rule is intended to address, the likely economic effects of the rule, and any environmental impacts associated with the rule. A proposed rule does *not* have the force of law. It may be changed in response to public comments and must be published as a final rule before any changes to the regulations can become effective and be enforced.

#### Q. Why does APHIS prepare risk assessments and what types of things do they assess?

A. APHIS' statutory authority is often tied to risk. For example, under the PPA, APHIS can prohibit or restrict the importation or movement in interstate commerce of any plant or plant product if we determine that the prohibition or restriction is necessary to prevent the introduction or dissemination of a plant pest or noxious weed into or within the United States. Similarly, under the AHPA, we can prohibit or restrict the importation or movement in interstate commerce of any animal or other article if we determine that the prohibition or restriction is necessary to prevent the introduction or dissemination of any livestock pest or disease.

APHIS conducts risk assessments as necessary to determine whether movement of an article presents a risk of introducing or disseminating a plant pest, noxious weed, or livestock pest or disease. APHIS may also conduct risk assessments to examine the efficacy of measures that could be applied to mitigate that risk.

#### Q. Why does APHIS conduct environmental analyses?

A. The National Environmental Protection Act (NEPA) requires all Federal agencies to consider whether any of its actions, including regulations, may significantly affect the quality of the human environment. APHIS' NEPA process is a separate decisionmaking process that is done in conjunction with rulemaking. APHIS and other agencies may need to prepare an environmental analysis to determine the overall level of environmental impacts from its actions.

#### Q. What kinds of environmental analyses might APHIS prepare?

A. Many rulemaking actions by APHIS pose no significant environmental impacts and are, therefore, categorically excluded from further environmental analysis. APHIS usually prepares an environmental assessment (EA) to comply with NEPA when agency actions require more in-depth environmental review. EAs usually provide a basis for determining whether an action is likely to have any significant impacts on the environment. If we determine that significant impacts to the environment are likely to occur, we prepare an environmental impact statement, which involves a more comprehensive analysis.

#### Q. Why does APHIS conduct economic analyses?

A. APHIS conducts economic analyses because Presidential Executive Orders 12866 and 13563 require Federal agencies to assess the costs and benefits of certain rules and to select an approach that maximizes benefits. In addition, the Regulatory Flexibility Act requires agencies to examine the potential economic effects of rules on small businesses, nonprofit organizations, and small governmental jurisdictions.

#### Q. What rules does OMB review?

A. OMB reviews all rules that it designates as "significant" in accordance with Executive Order 12866. Significant rules are those that may have a high economic impact, conflict with the actions of another agency, alter the budgetary impact of Government programs, or raise novel legal or policy issues. For most rules, OMB has 90 days to conduct its review.

### Step 2: The Comment Period

#### Q. How is the public informed of the rulemaking process?

A. APHIS publishes proposed rules in the *Federal Register*, which are available to the public online at [www.regulations.gov](http://www.regulations.gov). We also use a variety of other means to inform the public, such as the APHIS Web site, press releases, stakeholder registries, email listserves, and, in some cases, public meetings.

#### Q. What is the comment period for a proposed rule?

A. The comment period is the duration of time—starting with the date a proposed rule is published in the *Federal Register*—during which anyone may comment on a rule. Comment periods are typically 60 days, but they may be longer or shorter as circumstances warrant. Any comments received during the comment period are considered

part of the legal record for the rule and will be reviewed and considered by APHIS prior to finalizing the rule. APHIS accepts written comments submitted electronically through [www.regulations.gov](http://www.regulations.gov) and via postal mail.

In some cases, APHIS may also hold public hearings on proposed rules. Oral comments made at those hearings are transcribed and made part of the formal rulemaking record, along with all written comments received.

**Q. Do I have to formally submit my comments during the comment period or can I just call APHIS to talk about the proposed rule?**

**A.** You must submit comments to APHIS through the formal process described above. You may speak with APHIS officials to ask factual questions about a proposed rule (for example, does the proposed rule apply to all parts of this plant or only to fruit?). However, in order to ensure fairness and transparency in the rulemaking process, USDA prohibits private written and oral communication between USDA officials and outside parties regarding the merits of a proposed rule between the time a proposed rule and final rule are published. Comments supporting a rule, objecting to a rule, or requesting changes to a rule must be submitted through the formal process.

**Q. What type of comment is likely to result in changes to a proposed rule?**

**A.** There is no formula for drafting a comment that will result in changes to a proposed rule. However, comments that identify specific concerns and explain the reasons for those concerns are useful to APHIS and are more likely than unsupported objections to result in changes. The following are examples of the types of comments that may result in changes:

- Comments providing specific reasons why provisions of the proposed rule will be difficult to comply with or implement.
- Comments proposing alternatives that will be easier to implement or comply with or that will be at least equally effective but less costly.
- Comments indicating how provisions of the proposed rule substantively duplicate or conflict with existing regulations.
- Comments providing scientific evidence that raises questions about the basis for certain provisions of the rule.

Comments that object to provisions of a proposed rule without explaining why the provisions should be changed or removed do not provide APHIS a basis for changing a proposed rule.

### **Step 3: The Final Rule**

**Q. What is a final rule?**

**A.** A final rule finalizes all or some of the provisions of a proposed rule. It also summarizes and responds to issues raised by commenters during the comment period and indicates whether and how the agency is changing the proposed rule in response to comments. The final rule may differ significantly from the proposed rule or may not differ at all. Final rules have the force of law.

It is worth noting that not all proposed rules result in final rules. An agency may withdraw a proposed rule and either take no further action or issue a new, revised proposed rule for public comment.

**Q. When do final rules take effect?**

**A.** When publishing a final rule, agencies must specify the date it will become effective. Typically, final rules take effect 30 days after publication. That being said, some final rules—such as those likely to have significant economic effects or require significant changes to procedures or practices within an industry or regulated community—may be made effective more than 30 days after publication to allow sufficient time to prepare for implementation. In addition, final rules may take effect less than 30 days after publication if they relieve restrictions or the agency otherwise finds good cause and states its reason in the final rule.

### **Other Types of Rulemaking Documents**

**Q. What is an interim rule?**

**A.** An interim rule is a rule that is effective and has the force of law before an agency has considered public comments regarding its requirements. In APHIS, most interim rules are effective on the date they are published in the *Federal Register*. Unlike a final rule, an interim rule is not preceded by a proposed rule.

Because an interim rule goes into effect before we consider public comment on it, APHIS may issue an interim rule only when there is good cause for us to determine that providing this prior opportunity for public comment is impracticable, unnecessary, or contrary to the public interest. For example, APHIS may need to issue regulations effective immediately to quickly respond to an outbreak of a plant pest or livestock disease.

All interim rules have comment periods that begin on the publication date and typically last for 60 days.

An agency may make changes to an interim rule based on public comments. Such changes are typically made in a follow-up final rule. If APHIS determines that an interim rule should remain in effect without change following the comment period, we will publish a document affirming the interim rule without change. We call this document an affirmation of interim rule. Like a final rule, an affirmation of interim rule summarizes and responds to issues raised during the comment period.

**Q. What is an advance notice of proposed rulemaking?**

**A.** An advance notice of proposed rulemaking (ANPR) is a regulatory document that APHIS prepares and publishes in the *Federal Register* when we want to obtain additional, preliminary information before beginning rulemaking. ANPRs usually describe the nature of the issue that a proposed rule would seek to address and may include a description of regulatory options the agency is considering. ANPRs often contain specific questions APHIS would like the public to answer. ANPRs can help the agency determine whether rulemaking is appropriate and identify specific issues or concerns that may need to be addressed in developing a rule. APHIS may or may not initiate rulemaking following an ANPR.

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