

# Rulemaking

Statutes are laws passed by the California legislature or by the people of California by initiative or referendum. Regulations are rules put into place by state agencies in the executive branch of California government. An agency receives its power to adopt regulations from statutes. Agencies adopt regulations to carry out, interpret or make specific the statutes enforced or administered by it, or to govern its procedures. Properly adopted regulations have the force of law. However, in the event of an inconsistency or conflict, statutes take precedence over regulations. The process of writing and adopting regulations is called rulemaking.

The State Administrative Procedures Act (APA) prescribes procedures designed to ensure proposed regulations are necessary, not duplicative, clear and consistent, go through open public review, and are allowed by law. The APA requires state agencies to give public notice when proposing regulations, to provide the public with a meaningful opportunity to participate, and to consider public comments before making the rules final. Text and notices of proposed regulations and supporting documents must be posted on an agency's Web site. If the agency makes substantial changes in its proposed regulations, the public must again be given an opportunity to comment. Agencies must submit documentation to support the need and authority for the regulation, including a response to public comments to the Office of Administrative Law (OAL) for review to ensure compliance with the APA. After the regulations are adopted by the rulemaking agency, approved by OAL and filed with the Secretary of State, they must be published in the California Code of Regulations (CCR).

OAL's role is to ensure that state agency regulations are authorized by statute and within the agency's conferred authority, consistent with other law, written in an understandable manner, not duplicative of other law, and necessary to accomplish a statutory purpose. OAL also ensures that all APA procedures are followed.

The CCR consists of 28 titles. Title 3, Food and Agriculture, Division 6, Pesticides and Pest Control Operations, contains most pesticide-related regulations. Title 16, Professional and Vocational Regulations, Division 19, contains most Structural Pest Control Board regulations. The CCR is available at offices of county clerks, county law libraries and many public libraries. Regulations overseen by the Department of Pesticide Regulation (DPR) are available on its Web site.

The regulation process typically takes six months to a year to complete. The APA also allows agencies to file emergency regulations without the regular 45-day public notice and comment period provided the agency can show the regulation is necessary to immediately preserve the public peace, health and safety, or general welfare. Unlike permanent regulations, which are in effect until amended or repealed, emergency regulations expire in 180 days. During this time, the rulemaking agency must conduct a regular rulemaking process to permanently adopt the regulation.

## External Scientific Peer Review

The purpose of peer review is to find technical problems or unresolved issues in a draft document so the final publication will reflect sound technical information and analyses.

As a result of a legislative mandate (Chapter 295<sup>1</sup>, Statutes of 1997, SB 1320), no California Environmental Protection Agency (Cal/EPA) board, department or office "shall take any action to adopt the final version of a rule [that establishes a regulatory level, standard, or other requirement for the protection of public health or the environment ... without submitting] ... the scientific portions of the proposed rule, along with a statement of the scientific findings, conclusions, and assumptions on which the scientific portions of the proposed rule are based and the supporting scientific data, studies, and other appropriate materials, to the external scientific peer entity for its evaluation."

The legislatively mandated peer review of the scientific portions of a proposed rule is conducted by a committee comprised of members of the National Academy of Sciences, the University of California (UC), California State University, any similar scientific institution of higher learning, or individual scientists recommended by the UC President.

The Food and Agricultural Code (FAC) mandates that toxic air contaminant (TAC) health evaluation documents be reviewed by the Scientific Review Panel. (*See Chapter 4 for description of DPR's TAC program.*)

External peer review for regulations is in addition to the internal peer review that DPR typically conducts on its scientific documents. In addition, the law directs Cal/EPA's Office of Environmental Health Hazard Assessment to provide scientific peer review of DPR risk assessments (including risk characterization documents and exposure assessment documents). DPR also sends risk assessments to the U.S. Environmental Protection Agency for peer review.

<sup>1</sup> Appendix A lists this and other statutes noted in this chapter and shows the related code section it amended or added. Statutes and related code sections deleted or superseded by later legislation have been omitted.

**Rulemaking Flowchart**

**PREPARATION OF THE PROPOSED ACTION FOR PUBLIC COMMENT**

The Legislature gives limited lawmaking power to a state agency or department when, by passing a statute, it gives the agency a task. An agency or department must have delegated authority from the Legislature to adopt, amend, or repeal a regulation, and must demonstrate the necessity for the proposed regulatory action in the rulemaking record.

**DPR:** Conducts preliminary rulemaking activities, such as research and stakeholder workshops, and prepares proposed action including notice, regulation text, reason for regulation, and costs to state and local government and the economic impact on business.

**Consultation with other agencies:** Depending on the issues addressed in proposed regulations, DPR may consult with the Office of Environmental Health Hazard Assessment, the Air Resources Board, the Department of Food and Agriculture, or other agencies.

**External scientific peer review:** *If the regulations are based on new scientific studies or methodology, that science (not the regulations themselves) must be peer-reviewed by the University of California, National Academy of Sciences or similar approved institutions. Peer review must be completed before adoption of final regulations.*

**DPR:** Submits proposed action to the State Office of Administrative Law (OAL).

**OAL:** Reviews notice for compliance with legal criteria and filing requirements. If approved, notice published in OAL's *California Regulatory Notice Register* and on DPR Web site [www.cdpr.ca.gov], and mailed to interested parties.

**PUBLIC COMMENT PERIOD (45-day minimum)**

**Public Comment:** Begins when proposed action published. All rulemaking documents must be available for public review and comment. Hearings may be scheduled by DPR or by request. Written comments may be submitted via mail and e-mail. DPR must consider public input relevant to the proposal.

**DPR:** Reviews comments, plus any new information from other sources, and decides whether they warrant changes to proposed action.

**FINAL REVIEW AND ADOPTION**

After resolution of public comments and other issues, the regulation is adopted.

*No changes or non-substantive changes*

*Changes to proposed action are necessary*

**DPR:** Changes that are "sufficiently" related require a 15-day notice for public comment on the revised text.

**DPR:** Major changes "not sufficiently" related require a new 45-day notice.

**DPR:** Completes rulemaking record, with extensive documentation, including regulation text, final statement of reasons, and responses to all comments relevant to proposed action. DPR must explain how proposed action was changed to accommodate comments, or reasons for no changes. Rulemaking record must be submitted to OAL within one year of publication of notice or the rulemaking record automatically closes and a new notice of proposed action needs to be issued.

**OAL:** Typically has 30 working days to determine whether to approve proposed action based upon legal criteria and on adequacy of response to comments.

*OAL disapproves*

**DPR:** May be possible to revise and resubmit to OAL. DPR can also abandon proposed action.

*OAL approves*

**Filing:** New regulation is filed with the Secretary of State and printed in California Code of Regulations. Regulation typically goes into effect 30 days after filing.