# The regulatory process

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The regulatory process in laboratory animal science is a participatory one that allows the regulated community to provide expertise as regulations are being developed. By law, experts must be consulted when promulgating and enforcing the regulations and standards[1].

The Animal Welfare Act (AWA) aims to ensure the humane treatment of animals that are intended for research, bred for commercial sale, exhibited to the public or commercially transported. The AWA authorizes the Secretary of Agriculture to develop regulations and standards to implement the intent of Congress[1]. Like other federal laws, the AWA can be amended through the normal legislative process by the successful passage of legislation by both the US House of Representatives and the US Senate and signature by the President of the US. Such legislation could be introduced at any time, but major amendments to the AWA are usually included in the reauthorization of the Farm Bill, an omnibus bill governing federal farm and food policy that covers a wide range of programs and provisions. The Farm Bill is an authorization bill and is reauthorized approximately every five years. The Farm Bill was last updated in 2008 and included an amendment to the AWA that increased the maximum allowable fine for violations from $2,500 to $10,000 per animal per day[2].

The US Department of Agriculture (USDA), as the Executive Agency responsible for the enforcement of the AWA, promulgates regulations to implement the requirements of the AWA. In addition to regulations that are developed as a result of changes to the AWA, the Secretary may change or add to the existing regulations through the federal rulemaking process, which is governed by the Administrative Procedures Act (APA)[3]. A rule is any agency statement of general or particular applicability and future effect designed to implement, interpret or prescribe law or policy. An agency may issue rules only within the scope of its authorizing legislation, and rules generally carry the weight of law. The USDA Animal and Plant Health Inspection Service (APHIS) must engage in the rulemaking process whenever it wishes to establish a new rule. The APA requires that the proposed rule be published in the *Federal Register* to provide the public an opportunity to submit written comments. The final rule must also be published in the *Federal Register*, along with an explanation of any changes that the agency has made and a response to the public comments. The effective date for the final rule to become a regulation must be at least 30 days after publication, unless the rule relieves restrictions or there is other good cause for making the rule effective earlier. The most recent changes to the regulations impacting the biomedical research community involved the requirement for registrants and licensees to have contingency plans.

The rulemaking process as described above involves many time-consuming steps, designed to ensure that the public and regulated community have an adequate opportunity to express their opinions about the proposed rule. It may take years from the time the need for a change in regulations is identified to the actual implementation of new regulations. Once the need is identified, an analysis of the proposed rule and its impact must be prepared along with a work plan. The proposed rule is drafted, and any analyses that will be included must be completed and reviewed by USDA attorneys (and by OMB if it is considered to be a "significant" rule[4]). Once this is done, it is published in the *Federal Register* with a minimum comment period of 60 days.

The Animal Welfare Regulations are included in Title 9 of the Code of Federal Regulations[5]. Part 1 is the Definition of Terms, which contains key definitions used in the Regulations and Standards. Part 2 contains the Regulations, which include subparts for Licensing, Registration, Research Facilities, Adequate Veterinary Care, Identification of Animals, Stolen Animals, Records, Compliance with Standards and Miscellaneous. Part 3 contains the Standards for the day-to-day care in Subparts for the species covered under the AWA. Part 4 is Rules of Practice Governing Proceedings under the AWA. It describes the scope and applicability of the rules of practice, summary action that can be taken to suspend a license and the stipulation process.

Responsibility for administering the AWA is delegated within the USDA to the Administrator of APHIS. Enforcement duties are the responsibility of the APHIS Deputy Administrator for Animal Care (AC). Inspections of research facilities are conducted by Veterinary Medical Officers working under one of the AC Regional Supervisors. They identify and report Non-compliant Items. Any subsequent enforcement actions are handled by the Investigative and Enforcement Services division of the USDA.

In addition to the Regulation and Standards, the USDA also publishes the *Animal Care Resource Guide Policies* document[6]. Agency policies are considered guidance documents or interpretative rules. Policies do not carry the same weight of law as rules and regulations may and do change between Administrations. Because policies are not laws or regulations, they cannot be used as the basis for citations and should not be referred to in an inspection report.

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1. Animal Welfare Act. <http://www.aphis.usda.gov/animal_welfare/downloads/awa/awa.pdf>
2. Animal Welfare Act. Public Law 110-246 (approved 18 June 2008).
3. Administrative Procedures Act as Amended. 5 USC § 553(d) (2006).
4. Executive Order 12866. Regulatory Planning and Review. *Fed. Reg.* **58**, 51735 (1993).
5. Code of Federal Regulations. 9 CFR.
6. US Department of Agriculture. *Animal Care Policy Manual* (USDA, Riverdale, MD, 2011). <http://www.aphis.usda.gov/animal_welfare/policy.php>