

**OVERVIEW OF U.S. STANDARDS-MAKING
AND REGULATORY PROCEDURES**

Development and Enforcement of Government Regulations

Submission by the United States at the Meeting of 29-30 March 1995

Transparency and Non-Discrimination

1. In the United States, the promulgation of technical regulations by federal agencies is governed by various statutes and executive orders. These statutes and executive orders impose procedural requirements which serve to insure that technical regulations adopted by government agencies are necessary for the fulfilment of objectives for the public good such as protecting health, safety, essential security, the environment, or consumers. The U.S. regulatory process is transparent from proposed rule to final rule making, and in the implementation or application of such rules.

2. Either the Executive Branch or the Congress (either the Senate or House of Representatives) may initiate new legislation or amendments to existing legislation. Even if there is an Administration proposal, drafting is often done by Congressional staff, with varying amounts of consultation with the Executive Branch agency responsible for implementing the law. The process is an iterative one, involving extensive negotiation and compromise within the legislative bodies. The process can frequently result in a final statute that is significantly different from the original proposals. All statutes are subject to Congressional approval and are forwarded to the President of the United States for enactment.

3. The Administrative Procedure Act (APA) sets forth the general procedures for rulemaking to be followed by agencies of the United States Government (5 U.S.C. section 551 et seq.) At a minimum, the APA requires that for the issuance of a substantive rule (as distinguished from a procedural rule or a statement of policy), an agency must:

(1) Publish a notice of proposed rulemaking in the Federal Register. This notice must set forth the text or the substance of the proposed rule, the legal authority for the rulemaking proceeding, and applicable times and places for public participation.

(2) Provide all interested persons - nationals and non-nationals alike - an adequate opportunity for submission of written comments on the proposed rule. This public comment process serves a number of purposes, including giving interested persons the opportunity to provide the agency with information that will enhance the agency's knowledge of the subject matter of the rulemaking. The public comment process also provides interested persons with the opportunity to challenge the factual assumptions on which the agency is proceeding, and to show in what respect such assumptions are in error.

- (3) Publish a notice of final rulemaking at least thirty days before the effective date of the rule which includes a statement of the basis and purpose of the rule, and responds to all substantive comments received. The APA makes an exception from the requirement for publication of the final rule thirty days before its effective date if the rule makes an exemption or relieves a restriction, or if the agency makes and publishes a finding that an earlier effective date is required "for good cause".
4. Usually, rulemaking proceedings are commenced by an agency at its own initiative. However, the APA provides that each agency of the United States Government shall afford interested persons the right to petition for the issuance, amendment, or repeal of a rule. According to law, agencies must respond to the request. If the request is meritorious, work will commence on developing a proposed rule. In some cases, Congress by statute directs an agency to begin a rulemaking proceeding.
5. The APA also contains provisions for advance notice of proposed rulemaking. This allows agencies to seek general comments on issues prior to developing the specific regulatory proposal. Often agencies will provide sixty days or more for public comment in an advance notice of rulemaking.
6. The adjustment period allowed for affected industries to meet the new regulatory requirements will vary with the economic impact and the reasons for the new requirements, e.g., the effective date of new labelling requirements may be delayed for a year or more to permit inventories of existing labels to be depleted.
7. There are only limited exceptions to requirements for notice and comment on rulemaking. For example, agencies are not required to publish in advance for public comment their general statements of policy, or rules concerning their agency's organization, procedure or practice.
8. From start to finish, a simple or high priority rulemaking may take as much as a year to complete. Regulations for controversial and complicated issues will take much longer. Everyone has an equal opportunity to comment on proposed rules during the specified comment period. This includes commercial representatives and Embassies of foreign countries. According to U.S. law, public comments have to be reviewed and assessed, and then addressed in the final rule.
9. In addition to providing for public participation in the rulemaking process, the APA subjects all final rules to judicial review (e.g., United States District Court). In particular, a reviewing court must set aside a rule if the court finds that the agency's actions were "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law". In certain cases, a court must invalidate a rule if its provisions are "unsupported by substantial evidence" (5 U.S.C. section 706(2)). Thus, at a minimum, technical regulations promulgated by a U.S. Government agency must meet one of the two aforementioned legal standards.
10. The Office of Management and Budget (OMB) publishes a Unified Agenda of Federal Regulations in the Federal Register each April and October. This publication contains a brief description of each activity of each agency that is likely to result in the issuance of a proposed or final rule within the next twelve months. This publication is in addition to the notices published by agencies in the Federal Register to initiate a rulemaking proceeding.
11. Specific administrative and procedural requirements and, in some instances, different procedures and a more stringent standard for judicial review, may be incorporated into a particular agency's authorizing statutes in addition to the APA requirements. These additional requirements provide further assurance that technical regulations are necessary to fulfil government objectives for the public good. For example, provisions of the Consumer Product Safety Act [15 U.S.C. section 2058(a)], the Federal Hazardous Substances Act [15 U.S. C. section 1262(f)], and the Flammable Fabrics Act [15 U.S.C.

section 1193(g)], require the publication of an advance notice of proposed rulemaking as the first step in a proceeding for the issuance of certain kinds of standards and banning rules. All three of these statutes require the Consumer Product Safety Commission to provide opportunity for oral presentations concerning certain types of proposed rules at a public hearing, and these acts provide for judicial review of certain rules by a United States Court of Appeals rather than by a United States District Court. Additionally, the Consumer Product Safety Act provides that in reviewing a consumer product safety standard or banning rule, the court shall not sustain the rule unless its provisions are supported by "substantial evidence on the record taken as a whole".

12. Specific regulations and enforcement responsibilities for all products, new or used, are codified in the Code of Federal Regulations (CFR). It is divided into 50 titles which represent broad sectoral areas subject to federal regulation. Each title is further divided into chapters, which usually bear the name of the issuing agency. Each chapter is subdivided into parts covering specific regulatory areas. The index refers users to the appropriate titles and chapters affecting specific areas. The CFR also contains Federal requirements for packaging and shipping. The CFR is updated annually, usually in the Spring. Individual states or local jurisdictions (cities or counties) may impose additional special requirements for specific products (e.g., building and construction products and materials, automobiles) entering their state boundaries. All U.S. agencies maintain the same regulations for domestic and imported merchandise and agricultural products. Thus, products made in the United States are subject to the same requirements as imported products.

13. Statutes and regulations may be subject to interpretation by agency-developed policies or guidelines. Within the framework of the statute or regulation an agency has the administrative flexibility to modify policies and guidelines to reflect current conditions, e.g. new scientific information, advances in processing technologies, or less frequently to bring policies into alignment with broader USG policy positions. Guidelines also are used internally to ensure that regulations are interpreted and applied uniformly by an agency's employees throughout the country.