



Recommendation 78-4

Federal Agency Interaction with Private Standard-Setting Organizations in Health and Safety Regulation

(Adopted December 14-15, 1978)

(a) Many federal agencies have authority to issue mandatory health or safety regulations relating to products, materials, processes, practices or services that may be the subjects of voluntary standards prepared by non-governmental organizations. Non-governmental standards, though not legally enforceable, have in fact gained wide acceptance and a high degree of observance. Many voluntary standards are developed, reviewed, and periodically revised by technical committees of such non-governmental organizations that follow open and regular procedures, including a process for considering and attempting to resolve negative comments. Membership on technical committees may be broadly based and "balanced" in an effort to assure representation of varying points of view and avoidance of domination by a single interest. Some standards-developing organizations provide a review mechanism to assure compliance with prescribed procedures and an appropriately balanced membership. Standards developed by private organizations that generally observe such procedures, or under the Department of Commerce voluntary standards program, are frequently referred to as "voluntary consensus standards," and are the subject of this recommendation. This recommendation is directed toward the manner in which agencies should interact with non-governmental organizations that develop voluntary consensus standards and the manner in which agencies should utilize such standards for health and safety regulation.

(b) Not all voluntary standards are developed through the consensus process just outlined. Other kinds of voluntary standards—for example, those developed by trade associations or other organizations through non-consensus procedures—may be valuable for regulatory use by federal agencies, but are not treated by this recommendation. Also, the recommendation does not address the development of international standards.

(c) Members of technical committees that develop voluntary consensus standards often have a wealth of technical knowledge and expertise that agency staffs do not possess. Agency participation in or cooperation with those technical committees may result in the development of standards that adequately address considerations of health or safety more efficiently and



ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

effectively than if the agency seeks independently to formulate standards. The fact that a standard has been developed by an organization that uses consensus processes, however, does not of itself assure that it is appropriate for regulatory use. For example, some standards were developed at a time when less open procedures were followed, or when the state of relevant knowledge was less advanced, than at present. Some standards were developed without relevant accident and injury information. Some organizations and committees preparing voluntary consensus standards may not always have an adequate representation of varying interests; in particular, there are problems in obtaining effective representation of and participation by certain significant interests, especially consumers, employees, small business, and certain noneconomic interests that agencies may be charged with protecting.¹ Moreover, the process of seeking consensus followed by some standards-developing organizations often may create standards that are acceptable for business interests but may not be suitable for regulatory use.

(d) Consequently, the appropriateness of particular voluntary consensus standards for use by an agency in the development of mandatory health or safety regulations should be determined on a case-by-case basis. Of course, before adopting any mandatory standard, the agency should identify a need for doing so.

(e) Questions have been raised as to the possible applicability of the Federal Advisory Committee Act to technical committees and standards-developing organizations. The FACA should not apply to the technical committees and standards-developing organizations contemplated by this recommendation, which ordinarily are privately organized and operated primarily for purposes independent of advising the federal government. It would be injurious to the operation of such organizations, and to their willingness to cooperate with federal agencies, to apply to them certain provisions of the FACA which assume federal sponsorship and control of committees subject to the Act. Examples include the vesting of authority in federal employees to approve and terminate meetings and to approve the agenda of meetings, and of authority in the General Services Administration to conduct annual reviews which can result in recommendations to restructure or even abolish committees. The recommendation calls upon Congress to amend the FACA to make explicit that it does not govern the technical committees

¹The Conference is aware that the concept of representing identified "interests" in private standards-developing organizations is a complex one, involving considerations such as what may be identifiable as an interest, its relevancy, its internal homogeneity, its capacity to be represented by knowledgeable spokesmen, and its political strength.



ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

and standards-developing organizations here addressed. Of course, several principles reflected in the FACA—such as balanced membership and open decisionmaking— represent important criteria for agencies to take into account when considering the use of standards developed by such organizations (see paragraph 6(c)).

(f) The recommendation that follows is limited to agency interaction with standards-developing organizations and use of voluntary consensus standards in the context of regulation of health or safety.² The recommendation may nevertheless be significant in relation to setting standards for other purposes: For example, in conservation of energy and resources, environmental issues, and formulation of test methods and definitions. Agencies that use voluntary consensus standards in contexts other than health or safety regulation are urged to consider the recommended measures set forth below and to follow them to the extent appropriate. However, the recommendation is not intended to have application to the use of voluntary standards in government procurement, as to which less elaborate procedures may be appropriate in many cases.

Recommendation

Coordination and Cooperation with Standards-Developing Organizations

1. An agency having authority to issue mandatory health or safety regulations should draw on the knowledge and information available in active technical committees that develop relevant voluntary consensus standards, and should interact in accordance with this recommendation with technical committees that follow procedures that are substantially in accord with the criteria of paragraph 6(c).

(a) To the extent that staff resources permit, the agency should arrange for an appropriately qualified employee to serve on each technical committee in which the agency has a significant interest. An employee so serving should serve as a representative of the agency rather than in an individual capacity or as a representative of some other designated

² The concept of "regulation of health or safety" for purposes of this recommendation is not intended to encompass all agency functions aimed at health and safety concerns. For example, the recommendation does not deal with requirements relating directly to the qualifications or conduct of individuals engaged in the performance of professional services in areas of health or safety, or regulations that impose preconditions on eligibility for federal funding programs.



ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

"interest."³ Where separate representatives of several agencies may result in an imbalance on the committee, the agencies should seek to agree on a common representative or on the attendance of some agency personnel as observers. The representative's function should be to act as liaison to the committee, to monitor and participate in its standards-writing activities, and to provide information and communicate the views of the agency relative to the standards being developed and the procedures followed by the technical committee. The representative should have no authority to vote or to bind the agency to any specific proposal. An agency employee who has participated in a technical committee's development of a standard may thereafter participate in the agency's decisionmaking process by providing information and advice, but should not otherwise participate in making the agency's decision on whether to adopt or to revise that standard unless the agency has no other personnel with the requisite knowledge and expertise.

(b) When considering whether to modify an existing mandatory health or safety standard or to develop a new mandatory standard, the agency should normally ask an appropriate technical committee, if an active one exists, to consider the matter and the data bearing on the possible need for a modification or a new standard. This should be done before the agency independently publishes a modification or new standard as a proposed regulation. The agency should announce the referral in an advance notice of proposed rulemaking which describes the interaction between the agency and the technical committee and explains how the views of the interested public may be communicated to the committee. If the technical committee promptly takes steps to develop an appropriate new voluntary consensus standard or to modify a relevant voluntary consensus standard in a manner acceptable to the agency, or presents an appropriate existing standard, the agency may incorporate the standard into its regulations, or may determine that governmental action is not needed (see paragraph 7). If, however, the committee does not respond promptly or adequately and the agency determines that regulatory action is needed, the agency should proceed independently to develop a mandatory standard. In determining whether to request the assistance of a technical committee or to defer development of a regulation pending action by a technical committee, the agency should take into account the need for prompt development of the standard and whether committee consideration may be obtained promptly.

³ This paragraph should not be construed as indicating disapproval of the common present practice of permitting agency employees serving with the consent of their agencies on technical committees in their individual capacities or as representatives of some other designated "interest" rather than as agency representatives.



ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

(c) The relationship between the agency and the technical committee should be a cooperative one, and the agency should not seek to dominate the committee.

(d) In their published rulemaking notices relating to voluntary consensus standards, agencies should describe their interactions with the technical committees involved.

(e) Congress should amend the Federal Advisory Committee Act to state explicitly that the technical committees and standards-developing organizations of the sort addressed by this recommendation, which are privately organized and operated primarily for purposes independent of advising federal agencies, are not within the definition of "advisory committee" for purposes of that Act.

2. In appropriate cases the agency should provide its available technical information, data on health or safety concerns, and other relevant material and information to the technical committee. The agency may also provide financial and other support for the committee when such action is legally permissible and is in furtherance of the agency's mission and responsibility.

3. If an active relevant technical committee exists, an agency undertaking to develop standards "in-house" should coordinate its efforts with the committee as outlined in paragraphs 1 and 2, unless the agency has strong reasons to believe the committee can make no useful or timely contribution to the development of an adequate standard.

4. Each agency should, as a matter of general policy, regularly review standards or revisions proposed by technical committees active in the areas of regulatory concern of the agency, and should advise such committees on a regular and informal basis whether the proposed standards and revisions appear to be consonant with the agency's regulatory responsibilities.

5. Agencies should adopt and publish regulations or policy statements implementing the procedures outlined in paragraphs 1 through 4 and describing the manner in which agency representatives are to be designated and the authority they are to possess.

Use of Existing Voluntary Consensus Standards in Regulation

6. Agencies with authority to issue health or safety regulations should consider the use of existing relevant voluntary consensus standards in developing mandatory standards. Voluntary consensus standards should be considered with due caution and on a case-by-case



ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

basis. Ordinarily, standards which embody judgmental factors should receive greater scrutiny when being considered by agencies for adoption into regulations than standards which specify nomenclature, basic reference units, or methods of measurement or testing, and which are primarily empirical in their formulation. In evaluating a voluntary consensus standard each agency should consider the following factors:

(a) The apparent suitability of the voluntary consensus standard for use as a mandatory standard, including:

(i) The problems addressed by the standard and changes in the state of knowledge since the standard was prepared or last revised;

(ii) The extent to which the standard has been complied with, and the reasons for any noncompliance;

(iii) The extent of injury, accident, or illness known to have resulted from products, materials, processes, practices or services that have conformed with the standard;

(iv) The clarity and detail of the standard's language;⁴

(v) The extent to which the standard establishes performance rather than design criteria, where feasible;

(vi) The extent to which a newly developed standard, under which little experience exists, appears adequately to address the hazards considered by the developers of the standard or known to the agency; and

(vii) The enforceability of the standard.

(b) The nature of the agency's statutory mandate to develop health or safety regulations and the consistency of the provisions of the voluntary consensus standard with that mandate.

(c) The adequacy of the procedures followed by the organization preparing the standard to assure that:

(i) The membership of the technical committee represents a broadly based and balanced array of relevant interests, including, where appropriate, representatives of

⁴ The wording of a standard may contain too much detail as well as too little.



ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

consumers, labor, small business, and other affected groups, and no single interest has a dominating influence on the committee;

(ii) Reasonable notice that a proposed standard is being considered is given to interested persons and groups;

(iii) Interested persons and groups have an opportunity to participate in the deliberations and discussions relating to the standard;

(iv) Prompt and careful consideration is given to minority points of view and objections to the standard;

(v) Standards are approved by considerably more than a simple majority vote of the technical committee, although unanimity is not necessarily required;

(vi) An adequate opportunity for review is afforded to assure that fairness is protected and that dissenting views are given full consideration;

(vii) Adequate records are maintained to document that the established procedures were actually followed and that the views presented were duly considered in accordance with those procedures; and

(viii) The entire process is open to public scrutiny and review.

(d) The availability of documentation adequately describing the costs and benefits, the rationale for and method of arriving at the critical requirements of the standard, and other factors actually considered by the technical committee in developing or revising the voluntary consensus standard.

(e) The number of negative voters and the interests they represent.

(f) Possible anti-competitive effects that may arise from the use of the voluntary consensus standard.

7. Subject to the procedural requirements of 5 U.S.C. 553 or other relevant statutes, a voluntary consensus standard that appears to be partially or wholly suitable for use as a regulation may be adapted by an agency in various ways:

(a) If the voluntary consensus standard adequately addresses the questions of health or safety and is being substantially complied with by the affected industry, the agency may decide



ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

to take no further regulatory steps, or, alternatively, to adopt the standard into its regulations (see paragraph (f) below), and direct its primary regulatory efforts elsewhere. If, under these circumstances, the agency decides to take no further regulatory steps, it should publish that decision and the reasons therefor in the Federal Register. The agency should thereafter review periodically the continued adequacy of the standard and the extent of compliance with it by the affected industry.

(b) If the voluntary consensus standard adequately addresses the questions of health or safety, but there has not been substantial compliance with the standard by the affected industry, or if the industry is so scattered and diffuse that it is difficult to ascertain compliance, then the agency should adopt the standard into its regulations. Where the standard is new, the agency may defer a decision for a reasonable period to observe the effects of the standard.

(c) If the voluntary consensus standard adequately addresses the questions of health or safety but the language of the standard lacks the clarity or detail appropriate for a regulatory standard, then the agency should accept the substantive provisions of the voluntary consensus standard and seek to develop the needed clarity or detail by working with the technical committee. Only if this is unsuccessful or impractical should the agency alone reformulate the standard. In evaluating whether a voluntary consensus standard is appropriately detailed, the agency should consider the extent to which other regulatory authorities have adopted the standard and have then succeeded in enforcing it.

(d) If the voluntary consensus standard does not adequately address the pertinent questions of health or safety, the agency should seek to develop an adequate standard with the assistance of the relevant technical committee by following the procedures described in paragraph 1(b).

(e) Agencies should consider the "regulatory guide" approach as a means of effectively making use of voluntary consensus standards. A "regulatory guide" is a formal declaration by the agency that compliance with designated portions, or all, of a voluntary consensus standard will be considered an acceptable method of compliance with a general mandatory standard appearing in either the governing statute or the agency's regulations. When taking this approach, the agency should suitably publicize its decision and reasons therefor.

(f) The agency may adopt a voluntary standard into its regulations either by placing the text of the standard in the regulations, or, preferably, by incorporating the standard by reference pursuant to 1 CFR part 51.



ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

8. Each regulatory agency must take special care to avoid needless inconsistencies between voluntary and mandatory standards, as well as to remain abreast of technological change. An agency that has adopted a voluntary consensus standard into its regulations must therefore be aware of and must promptly review all later revisions initiated by the technical committees. If a revision is consistent with the agency's regulatory responsibilities, the agency should promptly proceed under its rulemaking authority to amend its prior standard by adopting the latest revision. Such procedures should provide for coordinated consideration by all agencies that have adopted the standard.

Revisions of Standards That Have Been Incorporated by Reference by More Than One Agency

9. Where a voluntary consensus standard has been incorporated by reference by two or more agencies, the Office of the Federal Register should develop, and implement in the form of a regulation, a procedure by which such agencies may elect in advance to have all proposed changes in such voluntary consensus standard reviewed pursuant to the following procedure:

(a) A notice of proposed rulemaking, prepared by or under the direction of the Office of the Federal Register, should be published under the name of each electing agency in accordance with the notice and comment requirements of 5 U.S.C. 553, so that each agency's standard can be revised promptly in accord with revisions subsequently approved by the promulgating organizations. The notice should also direct that all comments on the proposed revision be sent to each electing agency as well as to the promulgating organization. The Office of the Federal Register should coordinate the distribution of comments if the number of electing agencies is large.

(b) Each electing agency should promptly review each proposed revision to the referenced standard in the light of the comments received, and should then determine whether or not to adopt the revision when it has been finally approved by the promulgating organization. Adoption of the revised standard should be formally announced and should be officially published, without further public opportunity to comment.

10. In order to implement paragraph 9, the Office of the Federal Register should promptly ascertain all incorporations by reference of voluntary standards that have been made in the Code of Federal Regulations and are currently in effect.



ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

Citations:

44 FR 1357 (January 5, 1979)

___ FR ___ (2012)

1978 ACUS 13