

AMERICAN BAR ASSOCIATION

**SECTION OF ADMINISTRATIVE LAW AND REGULATORY PRACTICE
SECTION OF INTERNATIONAL LAW AND PRACTICE
GOVERNMENT AND PUBLIC SECTOR LAWYERS DIVISION**

RECOMMENDATION

1 **RESOLVED**, that the American Bar Association recommends, with respect to significant agency
2 efforts to harmonize domestic and foreign regulations through international negotiations that may
3 require new regulations or the amendment of existing regulations, that:

4 (1) the President seek to ensure effective public participation by encouraging federal
5 agencies to:

6 (a) list at an appropriate time significant proposed and ongoing harmonization
7 activities in their annual regulatory agendas or equally widely available
8 medium; and

9 (b) prepare impact statements already required by statute or executive order as
10 near as is practical to the time of the agency's consideration of a decision to
11 engage in negotiation of significant harmonization, and

12 (2) federal agencies consider public input concerning significant agency efforts to
13 harmonize domestic and foreign regulations through international negotiations by:

14 (a) inviting the public periodically to comment on new and ongoing significant
15 harmonization activities and to attend public meetings concerning such
16 activities;

17 (b) referring significant harmonization issues to advisory committees where
18 appropriate and possible; and

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- (c) establishing a public docket of documents and studies available under the Freedom of Information Act (FOIA) pertaining to each significant harmonization activity.

REPORT

Global efforts to “harmonize” government regulation have increased in recent years. "Harmonization" is the name given to efforts to conform domestic regulations with uniform international standards. In response to federal law and policies that encourage harmonization efforts,¹ harmonization activities are underway at most federal agencies. The movement toward international harmonization of domestic regulations creates a set of procedural challenges for administrative rulemaking. This report indicates the background and nature of these issues and proposes a statement of good practice regarding public participation in harmonization decisionmaking that may require new regulations or the amendment of existing regulations. As the report will explain, the recommendation reflects an effort to increase citizen input without unduly hampering the government’s ability to negotiate international agreements relating to harmonization.

Harmonization Issues

The United States can gain substantial benefits from harmonization.² Regulations in a foreign country can constitute a barrier to entry for United States companies. In addition, because the United States is a country with high levels of consumer and environmental protection, domestic companies can be disadvantaged in open competition with firms operating in jurisdictions with less rigorous (and costly) regulation. Finally, substantial differences among countries concerning production processes and methods can distort competition and create incentives for industrial relocation from the United States to foreign countries.

The public is interested in harmonization because of its economic potential, but also because of the potential impact of harmonization on the nature of regulatory protection available in the United States after regulations are harmonized. Theoretically, international harmonization can occur at the lowest or highest level of public health, worker safety or environmental protection, or somewhere

¹ The FDA Modernization Act of 1997, P.L. 105-115 (1997), encourages FDA to participate in international harmonization efforts, and the National Technology Transfer and Advancement Act of 1995, P.L. 104-113 (1996), promotes the use of voluntary standards. OMB Circular A-119 calls on all agencies to "use existing voluntary consensus standards, both domestic and international, in their regulatory and procurement activities as a means of carrying out policy objectives." Circular No. A-119, Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities (Revised Feb. 10, 1998).

² See Daniel C. Esty and Damien Geradin, *Market Access, Competitiveness and Harmonization: Environmental Protection in Regional Trade Agreements*, 21 Harv. Env. L. Rev. 265, 268-73 (1997) (describing market access and competitiveness problems addressed by harmonization).

in between. Public interest groups and others therefore have an interest in determining whether a particular harmonization initiative raises, lowers, or does not change the regulatory protection that is currently available, and in seeking to favor or oppose a change in regulatory protection that they do not favor.

The Development of Harmonized Standards

The United States uses several processes for harmonization. It can engage in bilateral or multilateral negotiations to produce common regulatory standards³ or agree to abide by standards set by international standard setting organizations.⁴ In addition, this country (or another) can agree to treat a foreign country's regulatory standards as equivalent to its own. This report and the accompanying recommendation address negotiated harmonized standards. The recommendation does not apply to the process by which agencies determine whether a foreign country has regulatory standards that are equivalent to those in the United States. It is limited to harmonization decisionmaking that may lead to the promulgation of new regulations or the amendment of existing ones.

The effort to develop a harmonized system of chemical classification and labeling, known as the "globally harmonized system" (GHS), helps illustrate the process of negotiating a harmonized standard.⁵ Interest in the GHS dates back to 1984, when the United States established an interagency policy on chemical labeling issues. In 1992, the United States entered into a series of agreements concerning a GHS with other countries in conjunction with the United Nations

³ These can be uniform standards (which establish the same regulatory standard), maximum standards (which establish a ceiling on stringency of regulations), minimum standards (which establish a regulatory floor below which no country may go), common standards (which require countries to meet standards established by multilateral agreements), goal standards (which establish uniform goals, but permit states to choose the regulatory method(s) to meet the goals), essential requirements standards (which establish common core minimum requirements, but permit nations to add additional regulations), pre-standards (which use common data collection processes, testing protocols, scientific methodologies, and risk assessment procedures), public information harmonization (which adopts common requirements concerning consumer and environmental labeling), and systems conformity standards (which requires countries to use certain established systems or procedures, but allows them to adopt different substantive standards).

⁴ Such organizations include, for example, the ISO or International Organization for Standardization (which is developing standards for environmental management systems, environmental auditing, product life-cycle analysis, and environmental labeling, as well as occupational safety and health rules) and the Codex Alimentarius (which is a voluntary-standard setting body of the World Health Organization and the U.N. Food and Agricultural Organization).

⁵ See 62 Fed. Reg. 15951, 15952-56 (1997)(describing the GHS process). It should be noted, however, that efforts such as the GHS to promote voluntary guidance on harmonization of regulatory measures, while useful as a model because of their relative lack of complexity, present a somewhat special case. Additional considerations may be raised by various other types of international efforts to promote international standards and harmonization of national measures.

For example, in the case of multilateral negotiations to address environmental issues through binding instruments, impact assessments may be somewhat more difficult to perform, as negotiating governments may maintain substantially different positions on major features of the accord until quite late in the negotiations. Also, public notice and comment may have to be more carefully managed in the context of such negotiations for a binding instrument that could mandate changes to United States law. To negotiate effectively, it may be particularly important, for instance, for the United States to maintain the confidentiality of its precise negotiating positions. Nevertheless, federal agencies should make efforts to seek public input sufficiently early in the process to inform the development of negotiating positions, including through the use of the advisory process.

Conference on Environment and Development (UNCED) in 1992. The UNCED objective is: "A globally harmonized hazard classification and compatible labeling system, including material safety data sheets and easily understandable symbols, should be available, if feasible, by the year 2000." In 1997, the government established an inter-agency working group,⁶ and its representatives have participated in numerous international meetings, which are still on-going in four major international institutions (International Labor Organization, Organization for Economic Cooperation and Development, Inter-Organization Program for the Sound Management of Chemicals, and United Nation Committee of Experts on the Transport of Dangerous Goods).⁷

Several agencies participate in the interagency working group, and when the negotiations are complete, they are likely to impact a number of important domestic safety and environmental laws and regulations. Agencies in the interagency working group include the Department of State, Environmental Protection Agency (EPA), Department of Transportation (DOT), Occupational Safety and Health Administration (OSHA), Consumer Product Safety Commission (CPSC), Food and Drug Administration (FDA), Department of Commerce, Department of Agriculture (USDA), and U.S. Trade Representative (USTR). The GHS will be a non-binding instrument, including provisions for classifying chemicals regarding their degree of danger they pose to the public, the preparation and dissemination of information about hazardous chemicals, the appropriate safe handling procedures for hazardous chemicals, and rules for labels, placards, material safety data sheets, and other written materials.

To the extent that agencies decide, in light of international efforts such as the GHS negotiations, to amend existing regulations or adopt new ones, agencies must comply with the rulemaking requirements in section 553 of the Administrative Procedure Act (APA).⁸ In the harmonization context, however, literal compliance with the APA procedures may be ineffective in achieving meaningful citizen participation in the development of regulations because an international commitment to harmonize standards will have already been made without the benefits of such input. Therefore, special efforts may be necessary to obtain meaningful public participation in harmonization.

Harmonization and Citizen Participation

The benefits of public participation in agency decisionmaking are widely recognized.⁹ Members of the public are often in a position to furnish valuable information or insights to an agency at a low cost to an agency. As Michael Asimow has noted:

Rules adopted with public participation are likely to be more effective and less costly to administer than rules written without such participation. They contain fewer mistakes. They are more likely to deal with unexpected and unique applications of

⁶ *Id.* at 15952.

⁷ See 65 Fed. Reg. 19036 (2000) (announcing a public meeting concerning future international meetings on GHS.).

⁸ 5 U.S.C. §553.

⁹ See, e.g., Michael Asimow, *Interim Final Rules: Making Haste Slowly*, 51 AD. L. REV. 703, 707-08 (1999).

exceptional situations, and are more politically acceptable to the persons who must live with them.¹⁰

Public participation also provides legitimacy to the rulemaking process. Agencies occupy an awkward position in our democratic system because unelected officials have the power to adopt legally binding rules. In many cases it is the "agency, not Congress, [that] will make the policy decisions significant to a regulatory program."¹¹ Public participation reduces the undemocratic character of such rulemaking by creating a surrogate for the political process.¹² For example, it provides "a channel that allows interested persons to exercise political power by indicating mass opposition to a rule."¹³ Public participation also enhances the legitimacy of rulemaking by enhancing the capacity of Congress and the President to oversee the rulemaking process. By indicating constructive proposals for change, or even their total opposition, members of the public alert political overseers concerning the wisdom of proposed policies.¹⁴

The APA's notice and comment rulemaking procedure¹⁵ promotes these ends, but the process of harmonization can make these goals more difficult to achieve. The APA does not apply to harmonization activities, because the agency is not proposing to amend or promulgate a rule, and voluntary compliance with the APA's rulemaking procedures may be inappropriate at the point at which a harmonization activity is launched. However, if the agency waits until the harmonization activity ends to solicit citizen input, the benefits of citizen input may be diminished or lost.

At the point at which an agency launches an harmonization effort, it may be inappropriate to engage in the type of notice that is used to comply with the APA. Under the APA, an agency is required to include "either the terms or substance of the proposed rule or a description of the subjects and issues involved."¹⁶ Most agencies, however, publish the text of the proposed rule when commencing rulemaking, and some enabling statutes expressly require that an agency do so.¹⁷ When an agency commences an harmonization activity, however, there is no text of a proposed rule to propose. Moreover, it may harm the agency's ability to negotiate effectively if it published what it expected to be the outcome of the negotiations. Nonetheless, special efforts may be necessary to obtain meaningful participation, such as through cleared advisors or other appropriate means.

By the time a rule is proposed to harmonize a domestic regulation, there is an international commitment to make the change. An agency, having spent many months negotiating and finally

¹⁰ *Id.* at 707-08.

¹¹ RICHARD J. PIERCE, JR., SIDNEY A. SHAPIRO AND PAUL R. VERKUIL, *ADMINISTRATIVE LAW AND PRACTICE* 36 (3rd ed. 1999).

¹² See Sidney A. Shapiro, *Administrative Law After the Counter-Reformation: Restoring Faith In Pragmatic Government*, 48 U. KANS. L. REV. 689, 694-96 (2000).

¹³ Asimow, *supra* note 9, at 708.

¹⁴ See Mathew D. McCubbins et. al., *Administrative Procedure As Instruments of Political Control*, 3 J.L. ECON. & ORG. 243 (1987) (arguing that administrative procedures facilitate legislative oversight).

¹⁵ 5 U.S.C. §553.

¹⁶ 5 U.S.C. § 553(b)(2).

¹⁷ JEFFREY S. LUBBERS, *A GUIDE TO FEDERAL AGENCY RULEMAKING* 183 (3d ed. 1998).

agreeing to a harmonized standard, is likely to be predisposed to adopt that standard. An agency, of course, may be stubborn about changing a proposed rule when it does not concern a harmonization activity. Harmonization activity, however, is different because there may be additional costs to the agency (and the United States) of changing a significant harmonization-related rule. Because an important change in the harmonized standard could violate the harmonization deal, the United States might have to renegotiate the deal with its foreign partners. This disincentive does not exist when an agency decides, on the basis of comments received during rulemaking, to make changes in a rule that does not concern harmonization. A citizen or group would no doubt have a difficult time proving that a proposed rule is a *fait accomplis* because of an international agreement to implement a harmonization regulation, particularly in the case of a non-binding regime such as for the GHS, and no such proof exists at the present time. Nevertheless, the potential that the harmonization process may limit the effectiveness of public input is of concern because of the value of public input to agency decisionmaking. The harmonization process is different in other respects which make it more difficult to promote meaningful citizen participation. Agencies currently do not publish notices of their intention to enter into negotiations concerning a harmonized regulation, or their continued participation in such a process, as part of their regulatory agenda. As discussed below, some agencies issue periodic notices of such participation,¹⁸ but these may not present a full picture of an agency's harmonization activity. Moreover, unlike the regulatory agenda, such notices do not conveniently provide the public with one source document to find out about an agency's harmonization activity.

The harmonization process also differs because many harmonization activities occur out of the United States, or at a site other than Washington, D.C. in the United States. For example, the GHS effort, described above, is being undertaken by numerous working groups that meet in Europe and elsewhere. With a domestic regulation, citizen groups usually have the opportunity to monitor the rulemaking process, both before and after a rule is proposed, to the extent that there is public information available through formal or informal channels. This capacity may be lessened in the harmonization process to the extent that some public meetings are held at distant locations from Washington and to the extent that public documents may be available in other countries, but not in the United States. The distant location raises another issue. Regulated entities, or their trade associations, may have the wherewithal to participate in harmonization activities, even if they are located abroad or in other locations distant from Washington, D.C., whereas other citizen groups often lack this capacity. Of course, such differences in resources are common in the domestic regulatory process. However, the foreign location of harmonization activity may make any such imbalance greater, though these factors would not prevent (and have not prevented) agencies from seeking and receiving input from the public through written comment, public meetings and other means in the United States, as well as at negotiating locations outside the country.

¹⁸ See notes 19-23 *infra* & accompanying text.

Harmonization Procedures

Agencies have begun to recognize that special efforts may be useful to obtain meaningful citizen input concerning harmonization activity. These initiatives have taken various forms. Agencies, such as the National Highway Traffic Safety Administration,¹⁹ have sought public comment on pending harmonization activities. The Office of the Trade Representative and the Department of Commerce have also experimented with various means of securing public input and guidance.²⁰ Some agencies have had public meetings to receive input on their harmonization activity. Earlier this year, for example, EPA held a public meeting concerning the effort to develop a GHS,²¹ described earlier. Some agencies, such as the Federal Aviation Administration (FAA),²² have involved their advisory committees in developing harmonization proposals and positions, which invites public participation through the provisions of the Federal Advisory Committee Act (FACA).²³

Recommendations

Harmonization processes may require the promulgation of new or amended domestic rules under the rulemaking process of the APA. In traditional rulemaking, agencies typically will make changes in a proposed rule in response to public comments, but agencies may have less flexibility to do so in the context of harmonization, where proposed rules are the result of international negotiation and agreement, and where significant changes in a proposed rule may require new negotiations and agreement. Agencies can address this possibility by seeking ways to obtain meaningful public comment before and during the harmonization process, and some agencies have done so, as detailed in the last paragraph. This recommendation seeks to endorse these efforts and recommend them to other agencies, and to propose additional ways to involve the public in the development of harmonized regulations.

¹⁹ See, e.g., Department of Transportation, National Highway Traffic Safety Administration, Agency Priorities and Public Participation in the Implementation of the 1998 Agreement on Global Technical Regulations: Statement on Policy, Request for Comments; Notice of Public Workshop, 64 Fed. Reg. 563 (1999); Department of Transportation, National Highway Traffic Safety Administration, Revision of the 1958 United Nations Economic Commission for Europe Agreement Regarding the Regulation of Motor Vehicle Equipment and Parts, 59 Fed. Reg. 10856 (1994) (notice of participation of NHTSA and EPA in harmonization activity).

²⁰ See, e.g., 64 Fed. Reg. 1853 (Jan. 12, 1999) (notice by USTR concerning a telecommunications MRA in OAS); 63 Fed. Reg. 60122 (Nov. 6, 1998) (notice by USTR of intention to extend an existing MRA to include road safety equipment, marine safety equipment, and calibration services); 62 Fed. Reg. 62095 (Nov. 20, 1997) (notice by USTR concerning a telecommunications MRA in APEC).

²¹ 65 Fed. Reg. 19036 (Apr. 10, 2000).

²² 65 Fed. Reg. 17936 (Apr. 5, 2000) (notice that the Aviation Rulemaking Advisory Committee will provide advice and recommendations on various aspects of its commitment to harmonize U.S. aviation regulations and practices with its European and Canadian trading partners).

²³ 5 U.S.C. Appendix 2; see note 25 *infra* & accompanying text (describing how FACA promotes public participation).

Paragraph (1)

The first recommendation asks the President to take two steps to seek to ensure effective public participation in significant agency efforts to harmonize domestic and foreign regulations through international negotiations that may require new regulations or the amendment of existing regulations.

Regulatory Agenda: The first is to require agencies to list significant proposed and ongoing harmonization activities in their annual regulatory agendas or some equally available medium, such as the agency's web site. As noted earlier in the report, agencies are already required to prepare an agenda of regulations under review and development in order to maximize consultation with the public and with state, local and tribal officials concerning regulatory planning. The addition of harmonization activities would alert the public to such activities and thereby promote public participation. As compared to this benefit, this recommendation should impose little additional cost on agencies. Moreover, agencies are beginning to put harmonization activities in their regulatory agendas, suggesting that this is a feasible and useful step.

Impact Statements: While recognizing that it may be difficult to prepare meaningful impact assessments early in the negotiation process when many major issues likely still remain unresolved, the President should require federal agencies to prepare impact statements already required by statute or executive order as near as is practical to the time of the agency's consideration of a decision to engage in negotiation of significant harmonization. This step would put the agency in compliance with impact analysis requirements at a time when the information compiled could inform both the agency and the public concerning the pending harmonization activity. By comparison, if the study were undertaken at the time of a proposed rulemaking, the harmonization activity would be completed and the study would be of much less value in promoting these objectives. Since an agency is obligated to perform the analysis, this recommendation should not increase the agency's costs.

Paragraph (2)

The second recommendation asks agencies to take into consideration public input concerning significant efforts to harmonize domestic and foreign regulations through international negotiations by taking three actions.

Public Comment and Meetings: First, agencies should invite the public periodically to comment on new and ongoing significant harmonization activities and to attend public meetings concerning such activities. In some cases, the agency could, for instance, employ an Advanced Notice of Proposed Rulemaking (ANPR) to obtain public comments. The request for public comments and the notice of public meetings should be placed on the agency's web site, and if feasible be published in the *Federal Register*.

As discussed earlier, there are substantial benefits to public participation in the development of harmonized standards and new rules. By facilitating public participation in the development of harmonization proposals and activities throughout the negotiating process, the recommendation

reduces the potential that public input will come at a time when a harmonization approach, and any associated rulemaking proposal, is close to complete.

Some agencies are already engage in such activities, and this proposal would signal approval of these actions and a recommendation that other agencies do likewise. Yet, because it suggests that agencies voluntarily engage in these activities, agencies are free to experiment with the best way to obtain meaningful citizen input, including the timing of such input.

Advisory Committees: Agencies can also involve the public by referring significant harmonization issues to advisory committees where appropriate. This referral can create a forum for discussion of harmonization issues under the auspices of FACA. FACA requires advisory committees to be open to the public, subject to certain exceptions, and requires that "[i]nterested persons shall be permitted to attend, appear before, or file statements with any advisory committee," subject to agency regulations governing this process.²⁴

Harmonization Docket: The final method by which agencies can foster effective public participation is to establish a public docket of documents and studies available under the Freedom of Information Act (FOIA) pertaining to each significant harmonization activity.²⁵ This step should promote public participation by making it easier for the public to obtain relevant non-confidential information concerning a harmonization activity. Without this step, the public would have to resort to FOIA requests for the same information, which is more time-consuming and inconvenient for both the public and the agency. The agency could enhance the usefulness of its docket to the public by making available documents that would otherwise be available only in foreign countries.

Respectfully submitted,

Ronald M. Levin, Chair, Section of Administrative Law
and Regulatory Practice

Daniel Magraw, Chair, Section of International Law
and Practice

August, 2001

²⁴ FACA, *supra* note 25, §10(a)(3).

²⁵ This recommendation does not require the agency to disclose any information that would not be required to be disclosed under the FOIA. Thus, for example, it would not require the disclosure of confidential inter-agency or intra-agency documents that describe an agency's negotiation strategy. Such documents would be exempt under the FOIA. *See* 5 U.S.C. § 552(b)(5) (exemption apply to inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency). Similarly, trade secrets and confidential commercial information obtained from a person is exempt from disclosure. *Id.* § 552(b)(4).

GENERAL INFORMATION FORM

Submitting Entity: Section of Administrative Law and Regulatory Practice

Submitted by: Ronald M. Levin, Chair

1. Summary of Recommendation.

The resolution recommends that the President and agencies take a series of procedural steps that seek to ensure effective public participation in significant agency efforts to harmonize domestic and foreign regulations through international negotiations that may require new regulations or the amendment of existing regulations.

2. Approval by Submitting Entity.

Approved at a regularly scheduled meeting of the Section Council on April 29, 2001.

3. Previous submission to the House or relevant Association position.

None

4. Existing Relevant Association Policies

None

5. Urgency

The resolution offers guidance concerning current agency activities and those likely to start in the near future.

6. Status of Legislation.

Not applicable.

7. Cost to the Association.

None

8. Disclosure of Interest.

None

9. Referrals

A copy of the Report with Recommendation will be circulated to all Section and Division Chairs.

10. Contact Person Prior to the Meeting

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11. Contact Persons at the Meeting. (Who will present the report to the House.)

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EXECUTIVE SUMMARY

1. Summary of the recommendation

The resolution recommends that the President take two steps to seek to ensure effective public participation in significant agency efforts to harmonize domestic and foreign regulations through international negotiations that may require new regulations or the amendment of existing regulations. Federal agencies can list at an appropriate time significant proposed and ongoing harmonization activities in their annual regulatory agendas or equally widely available medium, and they can prepare impact statements already required by statute or executive order as near as is practical to the time of the agency's consideration of a decision to engage in negotiation of significant harmonization. The resolution also recommends that federal agencies take into consideration public input concerning significant agency efforts to harmonize domestic and foreign regulations through international negotiations by taking three steps. Agencies can invite the public periodically to comment on new and ongoing significant harmonization activities and to attend public meetings concerning such activities. They can also refer significant harmonization issues to advisory committees where appropriate and possible. Finally, they can establish a public docket of documents and studies available under the Freedom of Information Act (FOIA) pertaining to each significant harmonization activity.

2. Summary of the issue which the recommendation addresses.

Global efforts to "harmonize" government regulation have increased in recent years. "Harmonization" is the name given to efforts to conform domestic regulations with uniform international standards. In response to federal law and policies that encourage, if not mandate, harmonization efforts, harmonization activities are underway at most federal agencies.

The value of citizen input regarding regulatory policy decision is widely recognized, but the process of harmonization can make it more difficult to obtain effective citizen input. One reason is that by the time a rule is proposed to harmonize a domestic regulation, there may be an international commitment to make the change. Another reason is that there is no established process by which citizens are entitled to make such input at a time before agencies make such commitments. Moreover, because many harmonization activities take place outside of the United States, it is more difficult for citizens to monitor such activities, as compared to domestic regulatory activities.

30 Explanation of how the proposed policy position will address the issue.

Some federal agencies have recognized the difficulties as outlined above and have sought ways to obtain meaningful public comment before and during the harmonization process. This recommendation seeks to endorse these efforts and recommend them to other agencies, and proposes additional ways to involve the public in the development of harmonized regulations.