Committee on Regulation Draft Recommendation

International Regulatory Cooperation (Updating ACUS Recommendation 91-1)

In June 1991, the Administrative Conference issued Recommendation 91-1, "Federal Agency Cooperation with Foreign Government Regulators," finding that "[i]f American administrative agencies could ever afford to engage in regulatory activities without regard to the policies and practices of administrative agencies abroad, the character and pace of world developments suggest that that era has come to a close," and recommending practices such as information exchanges and establishment of common regulatory agendas to facilitate regulatory cooperation. While many of the issues identified in that recommendation remain relevant today, the pace of globalization in the past two decades has created new challenges and dynamics since then. Not only have institutions promoting international cooperation become more robust, with relevant developments including the founding of the World Trade Organization and increasing integration amongst the member states of the European Union, but the volume of trade in goods, services, and information across borders has increased dramatically.

Given these developments, the Administrative Conference commissioned a research project to review international regulatory cooperation at United States government agencies today, assess how the 1991 recommendation has been implemented (or not), identify new challenges that have emerged in the past 20 years, and advise how the 1991 recommendation might be updated to guide agencies in improving international coordination today, to benefit regulatory goals and competitiveness. This research shows that, since the 1991 recommendation was adopted, the international coordination efforts of agencies have greatly expanded. Yet the need for international coordination has also greatly expanded due to increased trade in goods, services, and information. Incompatible regulatory requirements in different countries persist. Sometimes these regulations are different for non-substantive reasons – regulators share common goals and methods of regulation, but for historical or other reasons, regulations remain inconsistent. Sometimes regulations differ because regulators in different countries do not agree on important substantive issues, such as how to weigh scientific evidence or balance competing priorities. When differences are substantive, they can sometimes be ascribed to countries' asserting legitimate national goals such as protecting health, safety, or the environment at the levels that they consider appropriate. Other substantive differences, however, disrupt trade and serve no legitimate objective, or otherwise

operate as de facto protectionist measures. Moreover, even when standards are aligned, different national requirements for conformity assessment, such as testing, certification, inspection, or accreditation, frequently impose their own costs and delays.

The Administrative Conference finds that improved international regulatory cooperation is desirable for two major reasons. First, it helps United States agencies accomplish their statutory regulatory missions domestically. Indeed, in some areas like regulating the safety of food and drugs, a large proportion of which are imported to the United States, awareness and participation in foreign regulatory processes may be essential to ensure the safety of products reaching United States markets. Second, international regulatory cooperation can remove non-tariff barriers to trade and exports, promoting global commerce and United States competitiveness. Moreover, these benefits of international regulatory cooperation are not incompatible and can be pursued in unison.

Because of the global nature of the economy, the domestic regulatory mission of agencies is affected by what happens overseas. For example, imports of food and pharmaceutical products to the United States have greatly increased over the past 20 years, so that the Food and Drug Administration's (FDA) mission of ensuring food, drug, and device safety in the United States is necessarily intertwined with how these products are regulated in their countries of origin. The Consumer Product Safety Commission faces a similar challenge. Pollutants do not respect political boundaries, so the Environmental Protection Agency's missions of ensuring clean air and clean water in the United States are reliant on environmental regulations in other countries. Financial institutions in the United States participate in the global banking system and are exposed to risks in economies all over the world, which requires financial regulators to coordinate globally in their missions of ensuring safety and soundness of United States institutions. And trade in data crosses national boundaries, requiring the Federal Trade Commission to cooperate with other global regulators in policing Internet fraud.

In addition to the impact on regulatory goals such as health, safety, environmental and consumer protection in the United States, inconsistent regulatory regimes can act as barriers to trade. For example, different food labeling requirements between the United States and Europe require producers who distribute food in both markets to produce the same goods in different packaging, depending on the market, which hinders economies of scale and adds cost and delay. Another example is that the United States and Europe have different approaches to regulating the length of tractor-trailers. Though the American design has better fuel economy, American manufacturers cannot export their trucks which comply with United States

requirements into European markets without significant redesign, thereby creating an unnecessary barrier to trade.

Although desirable, global regulatory cooperation can be difficult to accomplish. Some agencies claim that they lack statutory authority to account for international effects when making regulatory decisions. Several agency officials, as well as high-level leaders, indicated that international regulatory cooperation was a low priority for agency leaders, as it is an issue with little visibility when accomplished successfully. Agencies indicated that legal restrictions on information sharing can hinder international cooperation. Finally, coordination among agencies within the United States government is a challenge, particularly for independent regulatory agencies, and agencies focused on trade and competitiveness are not always aware of the activities of other federal regulators.

Despite these challenges, many agencies are effectively engaging in international cooperation. Notably, there is evidence that better international cooperation can help agencies more proficiently accomplish their regulatory missions with fewer resources by dividing work, where appropriate, with foreign counterparts and mutually recognizing each others' inspection regimes and laboratory or test results. The FDA believes there is great potential for cost savings and improved health and safety in mutual reliance on the data from clinical trials and manufacturing quality inspection regimes in other countries. For example, the FDA recently concluded a pilot project with European and Australian regulators to inspect manufacturing plants in China and other countries that manufacture active pharmaceutical ingredients. The agencies compared their lists of plants subject to inspection and the resources that each country had available, and where two or more agencies were scheduled to visit the same plant, the agencies agreed on one agency to inspect that plant or to do a joint inspection, and reallocated resources so that they could cover more plants. Building on the success of that pilot, the FDA is now pursuing a similar project with European regulators for site inspections of clinical trials. These cooperative approaches, which show potential for cost savings without diminishing regulatory effectiveness, might be expanded to other agency settings for further cost-saving effects.

Twenty years after the adoption of ACUS Recommendation 91-1, agencies increasingly recognize that international regulatory cooperation is a necessary component of their regulatory missions in today's globally integrated economy. While progress has been made, the scope of the problem leaves more work to be done to eliminate systemic barriers to coordination. The following recommendation restates the parts of the 1991 recommendation that remain valid and relevant and also addresses new considerations, to include promotion of

best practices in transparency, mutual reliance, information sharing, and coordination within the United States.

RECOMMENDATION

1. Agencies should inform themselves of the existence of foreign (including regional and international) authorities whose activities may relate to their missions. Agencies should consider strategies for regulatory cooperation with relevant foreign authorities when appropriate to further the agencies' regulatory missions and/or remove unjustified barriers to international trade.

2. Agencies should review their legal authorities to cooperate with foreign authorities and international organizations under their authorizing statutes, the World Trade Organization Agreement on Technical Barriers to Trade and other relevant treaties adopted by the U.S., and Office of Management and Budget (OMB) guidance. Where legal authorities do not sufficiently permit international cooperation that would benefit regulatory missions and United States competitiveness, agencies should recommend corrective legislation to OMB and Congress. As a general matter, absent clear conflict with their legal authority, agencies should evaluate the international implications of regulatory activities.

3. When agencies conclude that they have legal authority and the interest in cooperation from foreign authorities, they should consider various modes of cooperation with those authorities, including but not limited to:

a. establishment of common regulatory agendas;

b. exchange of information about present and proposed foreign regulation;

c. concerted efforts to reduce differences between the agency's rules and those adopted by foreign government regulators where those differences are not justified;

d. holding periodic bilateral or multilateral meetings to assess the effectiveness of past cooperative efforts and to chart future ones; and

e. mutual recognition of tests, inspections, clinical trials, and certifications of foreign agencies.

4. To deploy limited resources more effectively, agencies should identify foreign regulatory agencies that maintain high quality and appropriate standards and practices and identify areas in which the tests, inspections, or certifications by agencies and such foreign agencies overlap. Where appropriate, agencies should divide responsibility for necessary tests, inspections, and certifications and mutually recognize their results. When practicable, agencies should also create joint technical or working groups to conduct joint research and development and to identify common solutions to regulatory problems (for example, through parallel notices of proposed rulemaking) and establish joint administrative teams to draft common procedures and enforcement policies. Agencies should document cost savings and regulatory benefits from such mutual arrangements.

5. To assess accurately whether foreign authorities maintain high quality and appropriate standards and practices, agencies should develop and maintain relationships with foreign counterparts by providing training and technical assistance to foreign agencies and developing employee exchange programs, as resources permit. Agencies should also review whether foreign or international practices would be appropriate for adoption in the United States.

6. Agencies should engage in exchanges of information with their foreign counterparts to promote better data-driven decisionmaking. Types of information exchanges can range from formal agreements to share data to informal dialogues among agency staff. To the extent practicable, information exchange should be mutually beneficial and reciprocal. Prior to exchanging information, agencies must reach arrangements with foreign counterparts that will protect confidential information, trade secrets, or other sensitive information.

7. Agency interactions with their foreign counterparts should generally be transparent, subject to appropriate exceptions to protect law enforcement, trade secret, or similar sensitive information. When engaging in regulatory dialogues with foreign counterparts, agencies should seek input and participation from interested parties as appropriate, through either formal means such as Federal Register notices and requests for comments or informal means such as outreach to regulated industries, consumers, and other stakeholders. Agencies should, consistent with their statutory mandate and the public interest, consider petitions by private and public interest groups for proposed rulemakings that contemplate the reduction of differences between agency rules and the rules adopted by foreign government regulators, where those differences are not justified. While international consultations of the sort described in this recommendation do not usually depart from an agency's standard practices in compliance with applicable procedural statutes, an agency engaged in such consultations

should describe those consultations in its notices of proposed rulemaking, rulemaking records, and statements of basis and purpose under the Administrative Procedure Act. Where the objective of aligning American and foreign agency rules has had a significant influence on the shape of the rule, that fact also should be clearly acknowledged.

8. Agencies should promote to their foreign counterparts and to other standards-setting bodies the principles of transparency, openness and participation, evidence-based and risk-based regulation, cost-benefit analysis, consensus-based decisionmaking, and impartiality that undergird the United States administrative and regulatory process. An agency engaging in international regulatory cooperation should also be alert to the possibility that foreign regulatory bodies may have different regulatory objectives, particularly where a government-owned or controlled enterprise is involved.

9. When engaging with foreign authorities, agencies should consult with other government agencies with interests that may be affected by the engagement, including but not limited to OMB's Office of Information and Regulatory Affairs (OIRA); the Office of the United States Trade Representative (USTR); and the Departments of Commerce, State, and Defense. In particular, agencies should adhere to the requirements of 22 C.F.R. § 181.4, requiring agencies to consult with OIRA before entering into international agreements that require significant regulatory action, and 19 U.S.C. § 2541, giving USTR responsibility for establishing mutual arrangements for standards-related activities.

10. To provide high-level, government-wide leadership on international regulatory issues, the Executive Office of the President should consider creating a high-level interagency working group of agency heads and other senior officials. The Chairman of the Administrative Conference should convene a meeting of the heads of interested agencies to consider the best form of organization for such a working group, including funding and staffing of such a mechanism; the incorporation of existing efforts at interagency coordination; and differences among agencies with respect to existing international cooperation agreements. One goal of this meeting would be to recommend whether an Office of International Affairs should be established within OIRA or some other executive branch agency to coordinate international regulatory cooperation.