Administrative Conference Recommendation 2011-6

International Regulatory Cooperation

Adopted December 8, 2011

In June 1991, the Administrative Conference issued Recommendation 91-1, Agency Cooperation wit [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

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.

However, 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 certain agency leaders, as it is an issue with little visibility when accomplished successfully. Some agencies indicated that legal restrictions on information sharing can hinder international cooperation. Finally, coordination among some agencies within the United States government is a challenge, and agencies focused on trade and competitiveness, such as the Office of the United States Trade Representative (USTR), are not always aware of the activities of federal regulators.

Twenty years after the adoption of ACUS Recommendation 91-1, agencies increasingly recognize that international regulatory cooperation is an important component of their

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. Accordingly, the recommendation supersedes Recommendation 91-1.

RECOMMENDATION

1. Agencies should inform themselves of the existence of foreign authorities[1]

3. When agencies conclude that they have legal authority and the

(a) consider dividing responsibility for necessary tests, inspections, and certifications and mutually recognizing their results;

(b) 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);

(c) establish joint administrative teams to draft common procedures and enforcement and dispute resolution policies; and/or

(d) document and publish cost savings and regulatory benefits from such mutual arrangements.

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

6. Agencies should engage in exchanges of information with foreign authorities to promote better, evidence-based decision-making. 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. When engaging in regulatory dialogues with foreign authorities, 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, where consistent with their statutory authority, missions, 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 authorities, 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 foreign authorities the principles that undergird the United States administrative and regulatory process, including, as appropriate:

(a) transparency, openness and public participation,
(b) evidence-based and risk-informed regulation,
(c) cost-benefit analysis,
(d) consensus-based standard setting,
(e) accountability under the law,
(f) clearly defined roles and lines of authority,
(g) fair and responsive dispute resolution procedures, and
(h) impartiality.

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, as appropriate, share information and consult with other government agencies having interests that may be affected by the engagement, including but not limited to Office of Information and Regulatory Affairs (OIRA); the Office of the United States Trade Representative (USTR); and the Departments of Commerce, State, and Defense.[2]

10. The Executive Office of the President should consider creating a high-level interagency working group of agency heads and other senior officials to provide government-wide leadership on, and to evaluate and promote, international regulatory cooperation.

[2] Agencies should fully comply with 22 C.F.R. § 181.4, requiring, among other things, 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.