

IMPLEMENTATION SUMMIT:

NEXT STEPS & IMPLEMENTATION OF ACUS RECOMMENDATIONS ON
INCORPORATION BY REFERENCE &
INTERNATIONAL REGULATORY COOPERATION



100 Years Standing Up for American Enterprise
U.S. CHAMBER OF COMMERCE

Tuesday, May 1, 2012
U.S. Chamber of Commerce
1615 H St NW; Washington DC 20062

The U.S. Chamber of Commerce Center for Global Regulatory Cooperation and the Administrative Conference of the United States are pleased to partner to bring you:

IMPLEMENTATION SUMMIT

Next Steps & Implementation of ACUS Recommendations on:

Incorporation by Reference & International Regulatory Cooperation

2:30: Opening Remarks

- Sean Heather; Vice President, U.S. Chamber Center for Global Regulatory Cooperation
- Paul Verkuil; Chairman, Administrative Conference of the United States

2:40: INCORPORATION BY REFERENCE

Keynote: Cameron Kerry; General Counsel, Department of Commerce

Panelists:

- Neil R. Eisner; Assistant General Counsel for Regulation and Enforcement, Department of Transportation
- Scott Cooper; Vice President, Government Relations and Public Policy, American National Standards Institute (ANSI)
- Emily S. Bremer; Attorney Advisor, Administrative Conference of the United States
- Cheryl Falvey; General Counsel, Consumer Product Safety Commission
- **Moderator:** Reeve Bull; Attorney Advisor, Administrative Conference of the United States

3:40: Networking & Coffee Break

3:50: INTERNATIONAL REGULATORY COOPERATION

Keynote: Cass Sunstein; Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget

Panelists:

- C. Boyden Gray; former U.S. Ambassador to the European Union
- Hugh Stevenson; Deputy Director, Office of International Affairs, U.S. Federal Trade Commission
- Murray “Mac” Lumpkin; Commissioner's Senior Advisor and Representative for Global Issues, U.S. Food and Drug Administration
- Jeff Weiss; Associate Administrator, Office of Information and Regulatory Affairs
- **Moderator:** Adam Schlosser; Senior Manager, U.S. Chamber of Commerce Center for Global Regulatory Cooperation

Attendees are invited to join us for a networking reception to immediately follow the panels

Speaker Biographies

EMILY SCHLEICHER BREMER is an Attorney Advisor of the Administrative Conference of the United States. Ms. Bremer was an associate in Wiley Rein LLP's telecommunications and appellate litigation practice, where she litigated cases at the trial and appellate levels involving complex federal preemption, jurisdiction, administrative law, and constitutional issues. She also represented clients in proceedings before the FCC, counseled telecommunications companies on the scope of their federal rights, and drafted amicus curiae briefs filed with federal appellate courts and the U.S. Supreme Court.

Previously, Ms. Bremer served as law clerk to Hon. Andrew J. Kleinfeld of the U.S. Court of Appeals for the Ninth Circuit. Ms. Bremer graduated from New York University School of Law, where she was a student editor for the International Journal of Constitutional Law and the Executive Notes Editor of the Journal of Law & Liberty.

Ms. Bremer received her undergraduate degree in Politics with honors from New York University, where she was an accomplished debater in the American Parliamentary Debate Association. She lives in Arlington with her husband, Dan, and their two adorable kitties.

REEVE T. BULL is an Attorney Advisor with the Administrative Conference of the United States. Mr. Bull previously worked in the private sector as an associate with the law firm Gibson, Dunn & Crutcher LLP and in government service as a law clerk to the Honorable Alvin A. Schall of the Federal Circuit Court of Appeals.

During his time as an associate with Gibson Dunn, Mr. Bull worked on a variety of litigation and regulatory matters. He participated in cases appearing before the United States Supreme Court, several federal Courts of Appeals, and numerous federal district courts and state trial courts. His experience spanned a variety of practice areas, including administrative, constitutional, intellectual property, antitrust, environmental, securities, and white collar criminal law. During his clerkship for Judge Schall, Mr. Bull assisted with appeals in cases spanning a variety of areas, with particular emphasis on administrative and patent law.

Mr. Bull attended law school at Duke University, where he graduated with highest honors and was inducted into the Order of the Coif. He was one of two recipients of the Willis Smith Award for compiling the most outstanding academic record in the graduating class and the recipient of the James S. Bidlake Memorial Award for achieving the highest grade in his first year legal writing section. Mr. Bull also served as a Note Editor on the Duke Law Journal. Prior to law school, Mr. Bull attended the University of Oklahoma, where he graduated summa cum laude with a Bachelors in Chemistry and was inducted into Phi Beta Kappa.

SCOTT COOPER is VP for Policy and Government Relations at the American National Standards Institute (ANSI). He has responsibility for managing the development of ANSI policy positions and acts as liaison to Congress, as well as Federal and State legislative and executive agencies. He has been active in initiating programs on global supply chain governance for issues such as lead-free toys, food safety and drug counterfeiting, and in the development of robust, cheap and efficient home cookstoves for use in Asia, Africa and Latin America.

Previous to this, he was federal government affairs manager in the Washington D.C., office of Hewlett-Packard and was responsible for global electronic commerce, Internet and advanced network services issues for HP. Scott has worked closely on U.S. legislation dealing with nanotechnology electronic signatures and authentication, telephone competition, Internet taxes and consumer protection issues, such as privacy. Before joining HP, Scott was director of Electronic Commerce at the American Electronics Association (AEA), and manager of Telecommunications Policy at Intel. He also worked for many years for the U.S. Congress. As professional staff for the Commerce Committee of the House of Representatives he had responsibility for the Federal Trade Commission (FTC), the Federal Communications Commission (FCC), and the Interstate Commerce Commission (ICC).

Scott has also taught and consulted at the University of Massachusetts in Amherst, and subsequently taught online for their MBA program. From 1973-75 Scott built schools in the Andes Mountains of Ecuador for the Peace Corps.

NEIL R. EISNER is currently the Assistant General Counsel for Regulation and Enforcement at the U.S. Department of Transportation. Prior to this, he was Assistant Chief Counsel for Regulation and Enforcement and Deputy Assistant Chief Counsel for Litigation in the Federal Aviation Administration. Mr. Eisner received his J.D. from Columbia University School of Law and an A.B. from Syracuse University. He is a member of the District of Columbia Bar and the D.C. Bar Association. He is also an active member of the American Bar Association (ABA) and a past Chair of the ABA's Section of Administrative Law and Regulatory Practice. In addition, he is an adjunct professor at American University's Washington College of Law. Mr. Eisner was a member of the Administrative Conference of the United States (1982-1995) and Chairman of its Committee on Governmental Processes; he is currently a Senior Fellow in the Conference. He was also a member of the President's National Performance Review Team on Improving Regulatory Systems (1993). He has testified before Congressional committees, published eight articles, spoken at many different forums, been a guest lecturer at a number of law schools, and made presentations to many foreign government officials in the U.S. and elsewhere.

CHERYL A. FALVEY currently serves as the General Counsel of the United States Consumer Product Safety Commission. Ms. Falvey is the CPSC's appointed government member of the Administrative Conference of the United States, and she participates on the Committee on Regulation. In that capacity, she has provided the CPSC's perspective on recommendations related to preemption of state law, e-rulemaking, international regulatory cooperation on standards development, and incorporation by reference in federal regulations.

As the Commission's chief legal officer and adviser, Ms. Falvey advises the Commission and its operating divisions on all legal issues arising under the statutes it administers and has been particularly involved in the interpretation and implementation of the new Consumer Product Safety Improvement Act. Ms. Falvey also handles all federal court litigation and helps assure that the Commission complies with the applicable federal laws, including the Administrative Procedure Act, the Government in the Sunshine Act, the Freedom of Information Act, the Civil Service Reform Act, the Ethics in Government Act, and the Commission's own internal rules and directives.

Prior to joining the Commission, Ms. Falvey was a partner in the law firm of Akin, Gump, Strauss, Hauer & Feld, LLP where she was the head of the litigation practice group in Washington, D.C. Ms. Falvey received her B.A. from Wellesley College in 1984 and her J.D. in 1987 from the Georgetown University Law Center. She is a member of the Virginia, New York and District of Columbia Bars.

C. BOYDEN GRAY, of the District of Columbia, is the former Ambassador to the European Union (2006-2007) and former Special Envoy for Eurasian Energy Diplomacy (2008-2009). He also served as former Special Envoy for European Union Affairs (2008-2009) and as White House Counsel in the administration of President George H.W. Bush (1989-1993).

Prior to his appointment as Special Envoy, Mr. Gray served as U.S. Ambassador to the European Union in Brussels from 2006 to 2007. From 1969 to 1981 and 1993 to 2005, Mr. Gray was a partner in the Wilmer, Cutler, Pickering, Hale and Dorr law firm in Washington. He served as White House Counsel in the administration of President George H.W. Bush (1989-1993) and served as Legal Counsel to Vice President Bush (1981-1989). Mr. Gray also served as counsel to the Presidential Task Force on Regulatory Relief during the Reagan Administration.

While working for Vice President Bush, Mr. Gray began to focus on clean air issues, including the Clean Air Act (CAA). In his role as Counsel to President Bush, Mr. Gray became one of the principal architects of the 1990 Clean Air Act Amendments, and is widely credited with having triggered the CAA acid rain emissions trading system. He was also involved in the creation of the Energy Policy Act of 1992, which aimed to decrease American dependence on foreign oil, protect our environment, and promote economic growth. He has a long history of involvement with clean fuels and reformulated gasoline, extensive experience with the use of market incentives to achieve environmental goals, and is widely credited with having triggered the use of market incentives in connection with the phaseout of CFCs under the Montreal Protocol.

At the law firm of Wilmer, Cutler, Pickering, Hale and Dorr, his practice focused on a range of regulatory matters, with an emphasis on environment, energy, antitrust, public health, and information technology.

Mr. Gray was born in Winston-Salem, North Carolina. He earned his Bachelor's degree magna cum laude from Harvard University and his Juris Doctor with high honors from the Law School of the University of North Carolina at Chapel Hill, where he was editor-in-chief of the Law Review. Following his graduation from university, he served in the U.S. Marine Corps. After law school, he clerked for Earl Warren, Chief Justice of the United States Supreme Court (1968-69).

Mr. Gray has served on the boards of numerous charitable, educational, and professional organizations. He has been a member of Harvard University's Committee to Visit the College and of the Committee on University Development. He is the recipient of the Presidential Citizens Medal and the Distinguished Alumnus Award of the University of North Carolina Law School.

SEAN S. HEATHER is the Vice President of the Center for Global Regulatory Cooperation (GRC). In that capacity he leads the Chamber's work in aligning trade, regulatory, and competition policy in support of open and competitive markets. He also serves as the Executive Director for International Policy and as Executive Director for Antitrust Policy leading the Chamber's competition policy advocacy both domestically and international.

Sean has held a number of positions during his thirteen years at the Chamber, including time as the chief of staff to the Congressional and Public Affairs division as well as part of the Chamber's regional team heading its Chicago office. In these capacities he worked on issues as diverse as: international trade, tax, labor, healthcare, environment, energy, transportation, homeland security, immigration, technology, and corporate governance.

Before joining the Chamber he worked for the Illinois Comptroller as well as with several political campaigns across the state. He holds an undergraduate degree and an MBA from the University of Illinois.

CAMERON F. KERRY: As the General Counsel of the Department of Commerce, Cameron Kerry is the principal legal advisor to the Secretary of Commerce and third ranking secretarial officer. President Obama nominated him on April 20, 2009 and he was confirmed unanimously by the United States Senate on May 21, 2009.

He serves as chief legal officer of the Department and oversees the work of over 325 lawyers in 14 offices who provide legal advice to all components of the Department. Kerry is the Department's chief ethics officer, serves as Chair of the Department of Commerce internal Privacy Council, and co-chairs the Secretary's Internet Policy Task Force, which brings together Commerce agencies with expertise on the internet in the 21st century global economy.

During his tenure as General Counsel, Kerry has been engaged in the wide range of issues facing the Department of Commerce as it seeks to lay a new foundation for economic growth. He has been a leader on work across the US government on patent reform and intellectual property issues, privacy and security, and efforts against transnational bribery, including co-chairing the National Science and Technology Council Subcommittee on Commercial Data Privacy. Kerry has travelled to the People's Republic of China several times and serves as the co-lead in the Transparency Dialogue with China and the US chair of the US-China Legal Exchange.

Previously, Kerry was a partner in the Boston office of Mintz Levin, a national law firm. In over 30 years of practice, he has been a communications lawyer and litigator in a range of complex, developing areas such as telecommunications, environmental law, toxic torts, privacy, and insurance regulation. Prior to joining Mintz Levin, Cameron was an associate at Wilmer, Cutler & Pickering and a law clerk for Judge Elbert Tuttle of the United States Court of Appeals for the Fifth Circuit.

Kerry has taught telecommunications law as an adjunct professor at Suffolk University Law School and written and presented on communications, evidence, and environmental issues in a variety of industry and academic settings. Cameron was a senior advisor and national surrogate for the 2004 Democratic presidential campaign, and has served on boards of nonprofits involved in civic and political engagement and sports.

Kerry received his B.A. cum laude from Harvard College and his J.D. magna cum laude from Boston College Law School where he was Executive Editor of the Law Review and winner of the school's moot court competition.

He and his wife, Kathy Weinman, have two daughters. Their home is in Massachusetts.

MURRAY M. LUMPKIN, M.D., M.Sc. serves as the Commissioner's Senior Advisor and Representative for Global Issues for the U.S. Food and Drug Administration. Dr. Lumpkin is a 23-year FDA career official and was most recently asked in July 2011 by Commissioner Hamburg to be her Senior Advisor and Representative for Global Issues. As such, he is part of the Commissioner's inner circle of senior advisors and is tasked with helping the Commissioner develop and steer FDA's engagement in international regulatory public health arenas. Working with senior agency leaders, he has a primary focus on all of FDA's international programs and how they support both FDA's overall domestic public health mission and a positive FDA role in the international regulatory arena. Much of this work is accomplished through his leadership of FDA's interactions with its counterpart foreign regulatory agencies, embassies, multinational organizations, its harmonization and technical cooperation activities, and its 13 foreign posts which he led the establishment of in 2008.

2001-2011: responsible for the policy development and operational aspects of the FDA's international activities, most recently as Deputy Commissioner for International and Special Programs (2005-2011) during which, under his leadership, FDA's foreign posts were established and FDA's confidentiality arrangements and in-depth working relationships with its foreign counterpart agencies were designed and implemented.

1993-2000: Deputy Center Director of FDA's Center for Drug Evaluation and Research (CDER), responsible for the senior management and policy development for the pre-market development, marketing application assessment and decision-making, advisory committees, and post-marketing oversight of authorized drugs.

1989-1993: Director - Division of CDER's Anti-infective Drug Products.

He is an M.D. with post-graduate training in pediatrics and pediatric infectious diseases at the Mayo Clinic. As a Fulbright Scholar, he completed an M.Sc. in medical parasitology at the London School of Hygiene and Tropical Medicine. He is certified in both pediatrics (U.S.) and tropical medicine and hygiene (U.K.)

ADAM C. SCHLOSSER is senior manager of the U.S. Chamber of Commerce Center for Global Regulatory Cooperation. He leads the Chamber's International Regulatory and Standards Working Group, which coordinates the business community's role in: reshaping the international role, responsibility, and coordination of U.S. regulatory and technical agencies; advancing core principles of better regulations abroad and driving greater sector specific regulatory cooperation efforts; and promoting the dynamic development and deployment of voluntary, consensus standards to meet regulatory challenges and facilitate trade. He leverages a strong background with good regulatory practices and administrative law to lead the Chamber's efforts to advance the international dimension of regulation, its impact on trade, regulatory cooperation, and the role voluntary, consensus standards play in trade.

Prior to coming to the Chamber, Adam served as a Presidential Management Fellow. He spent time with the USDA Foreign Agricultural Service, serving as lead U.S. delegate for food and agriculture issues at the WTO Committee on Technical Barriers to Trade (TBT) as well as participating in bilateral and multilateral negotiations with foreign officials. He also worked at the General Services Administration Office of Governmentwide Policy, where he drafted domestic regulations. He received both an undergraduate and a law degree from the University of Miami.

HUGH STEVENSON is Deputy Director for International Consumer Protection at the U.S. Federal Trade Commission. His team coordinates the FTC's international consumer protection and privacy work. He coordinated FTC work on the 2006 U.S. SAFE WEB Act on international enforcement cooperation, and serves as the US vice chair of the OECD's consumer policy committee and its working party on information security and privacy. Previously he led the creation of the FTC's Consumer Response Center, Identity Theft Clearinghouse program, and Consumer Sentinel complaint system. A Harvard Law School graduate, he has also litigated for the FTC, for state government, and in private practice. As an adjunct professor, he has taught comparative privacy law at Georgetown University Law Center and administrative law for Arizona State University's law school program in Washington, DC.

CASS R. SUNSTEIN is the Administrator of the Office of Information and Regulatory Affairs, located within the Office of Management and Budget. Before becoming Administrator, Cass R. Sunstein was the Felix Frankfurter Professor of Law at Harvard Law School. Mr. Sunstein graduated in 1975 from Harvard College and in 1978 from Harvard Law School magna cum laude. After graduation, he clerked for Justice Benjamin Kaplan of the Massachusetts Supreme Judicial Court and Justice Thurgood Marshall of the U.S. Supreme Court, and then he worked as an attorney-advisor in the Office of the Legal Counsel of the U.S. Department of Justice. He was a faculty member at the University of Chicago Law School from 1981 to 2008.

Mr. Sunstein has testified before congressional committees on many subjects, and he has been involved as an advisor in constitution-making and law reform activities in a number of nations. A specialist in administrative law, regulatory policy, and behavioral economics, Mr. Sunstein is author of many articles and a number of books, including *After the Rights Revolution* (1990), *Risk and Reason* (2002), *Laws of Fear: Beyond the Precautionary Principle* (2005), *Worst-Case Scenarios* (2007), and *Nudge: Improving Decisions about Health, Wealth, and Happiness* (with Richard H. Thaler, 2008).

PAUL R. VERKUIL the tenth Chairman of the Administrative Conference of the United States, was sworn in by Vice President Biden on April 6, 2010. The Conference, consisting of 101 members, was revived by Congress last year after a 15-year hiatus. President Obama named the 10 member Council on July 8, 2010, saying at the time that "ACUS is a public-private partnership designed to make government work better."

Mr. Verkuil is a well-known administrative law teacher and scholar who has coauthored a leading treatise, *Administrative Law and Process*, now in its fifth edition, several other books (most recently, *Outsourcing Sovereignty* Cambridge Press 2007), and over 60 articles on the general topic of public law and regulation.

He is President Emeritus of the College of William & Mary, has been Dean of the Tulane and Cardozo Law Schools, and a faculty member at the University of North Carolina Law School. He is a graduate of William & Mary and the University of Virginia Law School. Among his career highlights is serving as Special Master in *New Jersey v. New York*, an original jurisdiction case in the Supreme Court, which determined sovereignty to Ellis Island.

JEFF WEISS serves as the Associate Administrator of the Office of Management and Budget's Office of Information and Regulatory Affairs (OIRA), where he helps to lead the Obama Administration's development of regulatory policy, White House review of significant Executive Branch regulatory actions, and the Administration's regulatory cooperation initiatives with Canada, the European Union (EU), and Mexico.

Previously, Mr. Weiss served as a senior negotiator on regulatory, standards and conformance matters in the Office of the United States Trade Representative (USTR). As Senior Director for Technical Barriers to Trade, Mr. Weiss represented the United States in bilateral, regional and multilateral fora, including the WTO Committee on Technical Barriers to Trade, the Doha Round's Non-Agricultural Market Access negotiations, and the Trans-Pacific Partnership talks. Working closely with a formal interagency committee and private sector stakeholders, Mr. Weiss negotiated with U.S. trading partners -- including Brazil, China, the EU, India, Korea, and Mexico -- to address problematic regulations that impeded market access for U.S. producers of numerous industrial and agricultural goods. Mr. Weiss has also worked in various international fora to enhance regulatory transparency, incentivize the development of standards through open, transparent, consensus-based processes, encourage the use of good regulatory practices (including cost-benefit analysis), and facilitate greater regulatory alignment with major U.S. trading partners. In all cases, U.S. positions were formulated with a view to ensuring the continued ability of U.S. regulators to protect the health and safety of American citizens and safeguard the environment, at the levels they consider appropriate.

Mr. Weiss' previous experience includes serving as Assistant General Counsel at USTR, Assistant Legal Advisor at the Mission of the United States of America to the World Trade Organization in Geneva, Switzerland, and an Associate at Collier Shannon Scott. He received a J.D. from Harvard Law School, an M.P.P. from Harvard's John F. Kennedy School of Government, and an A.B. from Duke University.

Administrative Conference Recommendation 2011-5

Incorporation by Reference

Adopted December 8, 2011

Incorporation by reference allows agencies to comply with the requirement of publishing rules in the Federal Register to be codified in the Code of Federal Regulations (CFR) by referring to material published elsewhere.¹ The practice is first and foremost intended to—and in fact does—substantially reduce the size of the CFR. But it also furthers important, substantive regulatory policies, enabling agencies to draw on the expertise and resources of private sector standard developers to serve the public interest. Incorporation by reference allows agencies to give effect to a strong federal policy, embodied in the National Technology Transfer and Advancement Act of 1995 and OMB Circular A-119, in favor of agency use of voluntary consensus standards.² This federal policy benefits the public, private industry, and standard developers.

The Conference has conducted a study of agency experience with the practice of incorporation by reference, including the use of voluntary consensus standards. The study focused on three issues agencies frequently confront when incorporating by reference: (1) ensuring materials incorporated by reference are reasonably available to regulated and other interested parties; (2) updating regulations that incorporate by reference; and (3) navigating

¹ See 5 U.S.C. § 552(a)(1); 1 C.F.R. §§ 51.1-51.11.

² See National Technology Transfer and Advancement Act of 1995, Pub. L. No. 104-113 (1996); OFFICE OF MGMT. & BUDGET, EXEC. OFFICE OF THE PRESIDENT, OMB CIRCULAR A-119, FEDERAL PARTICIPATION IN THE DEVELOPMENT AND USE OF VOLUNTARY CONSENSUS STANDARDS AND IN CONFORMITY ASSESSMENT ACTIVITIES (1998); see also Administrative Conference of the United States, Recommendation 78-4, *Federal Agency Interaction with Private Standard-Setting Organizations in Health and Safety Regulation*, 44 Fed. Reg. 1,357 (Jan. 5, 1979) (recommending agencies use voluntary consensus standards in health and safety regulation). Circular A-119 defines voluntary consensus standards as those created by private or international organizations whose processes provide attributes of openness, balance, due process, an appeal, and decision making by general agreement (but not necessarily unanimity). See also American National Standards Institute, “ANSI Essential Requirements: Due process requirements for American National Standards” (2010).

procedural requirements and resolving drafting difficulties when incorporating by reference. Agencies have used a variety of approaches to address these issues within the constraints of federal law and regulatory policy. This recommendation identifies and encourages those approaches that have proven most successful.

Availability of Incorporated Materials. Ensuring that regulated and other interested parties have reasonable access to incorporated materials is perhaps the greatest challenge agencies face when incorporating by reference. When the relevant material is copyrighted—as is often the case with voluntary consensus standards—access issues are particularly problematic. There is some ambiguity in current law regarding the continuing scope of copyright protection for materials incorporated into regulations,³ as well as the question of what uses of such materials might constitute “fair use” under section 107 of the Copyright Act.⁴ Efforts to increase transparency of incorporated materials may conflict with copyright law and with federal policies recognizing the significant value of the public-private partnership in standards.

This recommendation does not attempt to resolve the questions of copyright law applicable to materials incorporated by reference into federal regulations. Rather, the recommendation encourages agencies to take steps to promote the availability of incorporated materials within the framework of existing law. This effort is consistent with the National

³ See, e.g., *Veeck v. S. Bldg. Code Cong. Int’l, Inc.*, 293 F.3d 791 (5th Cir. 2002) (en banc). This case held that where local law had incorporated a privately developed building code, a private party’s posting of the resulting local law did not violate copyright, because the law was in the public domain. *Id.* at 793, 802. However, the court distinguished cases concerning the incorporation by reference of materials “created by private groups for reasons other than incorporation into law,” *id.* at 805, leaving some uncertainty as to the rule applicable to many voluntary consensus standards.

⁴ See, e.g., OFFICE OF LEGAL COUNSEL, DEP’T OF JUSTICE, *Whether and under what Circumstances Government Reproduction of Copyrighted Materials Is a Noninfringing “Fair Use” under Section 107 of the Copyright Act of 1976* (1999). This opinion noted that there is no per se rule under which government reproduction of copyrighted materials for governmental use invariably qualifies as fair use, but also noted that such reproduction would in many contexts constitute a noninfringing fair use. The opinion focused on government reproduction for internal government use and did not consider government republication of copyrighted materials.

Science and Technology Council’s acknowledgment that “the text of standards and associated documents should be available to all interested parties on a reasonable basis, which may include monetary compensation where appropriate.”⁵ The Conference’s research reveals that some agencies have successfully worked with copyright owners to further the goals of both transparency and public-private collaboration. Some agencies have, for example, secured permission to make a read-only copy of incorporated material available in the agency’s public, electronic docket during the pendency of the rulemaking proceeding relating to the material. In other cases, the copyright owner has made the material publicly available in read-only form on its own website. This recommendation encourages agencies to take these or other steps to promote availability of incorporated materials, such as encouraging copyright owners to make incorporated materials available in libraries.

Updating Regulations. Updating regulations that incorporate by reference is another challenge. Agencies are legally required to identify the specific version of material incorporated by reference and are prohibited from incorporating material dynamically.⁶ When an updated version of the incorporated material becomes available, the regulation must be updated if the agency wants the regulation to incorporate the new version. This can require the agency to engage in notice-and-comment rulemaking, which entails a significant investment of agency resources. For agencies that are statutorily required to provide rulemaking procedures beyond those required by Section 553 of the Administrative Procedure Act (APA), updating may prove to be an immense challenge. Nonetheless, agencies have successfully used a variety of techniques to reduce the time and cost constraints of updating rules. Some agencies have used enforcement discretion or “equivalency determinations” to avoid penalizing parties that comply with an updated version of an incorporated standard that the agency finds to be equivalent to or superior to the version still incorporated in the agency’s regulations. Other agencies have

⁵ See SUBCOMMITTEE ON STANDARDS, NAT’L SCI. & TECH. COUNCIL, EXEC. OFFICE OF THE PRESIDENT, *Federal Engagement in Standards Activities to Address National Priorities: Background and Proposed Recommendations* 11 (Oct. 10, 2011).

⁶ See 1 C.F.R. § 51.1(f); see also OFFICE OF MGMT. & BUDGET, EXEC. OFFICE OF THE PRESIDENT, OMB CIRCULAR A-119, FEDERAL PARTICIPATION IN THE DEVELOPMENT AND USE OF VOLUNTARY CONSENSUS STANDARDS AND IN CONFORMITY ASSESSMENT ACTIVITIES ¶ 6(j) (1998).

reduced the burden of updating by tracking forthcoming revisions through participation in standard-development activities.⁷ Still others have used direct final rulemaking to reduce the costs of updating an incorporating regulation. The recommendation encourages these time- and cost-saving techniques. This recommendation also proposes a statutory solution that would streamline the administrative process by which agencies can revise their regulations to account for updates to the incorporated material.

Complying with Procedural Requirements. Finally, successfully incorporating by reference requires agencies to comply with detailed procedures and to draft regulations carefully. The Office of the Federal Register (OFR) is statutorily charged with approving all incorporations by reference, and has issued regulations and guidance establishing policies and procedures for doing so. Procedural errors can delay the publication of rules that incorporate by reference. Poor drafting may create confusion among regulated parties or produce a rule that does not fulfill the agency's regulatory purpose. The Conference's research revealed that agencies reporting few or no problems in complying with OFR's incorporation by reference procedures followed identifiable best practices that other agencies should consider adopting.

RECOMMENDATION

Ensuring Incorporated Materials are Reasonably Available

1. Agencies considering incorporating material by reference should ensure that the material will be reasonably available both to regulated and other interested parties.
2. If an agency incorporates by reference material that is not copyrighted or subject to other legal protection, the agency should make that material available electronically in a location where regulated and other interested parties will be able to find it easily.

⁷ See SUBCOMMITTEE ON STANDARDS, NAT'L SCI. & TECH. COUNCIL, EXEC. OFFICE OF THE PRESIDENT, *Federal Engagement in Standards Activities to Address National Priorities: Background and Proposed Recommendations* (Oct. 10, 2011).

3. When an agency is considering incorporating copyrighted material by reference, the agency should work with the copyright owner to ensure the material will be reasonably available to regulated and other interested parties both during rulemaking and following promulgation.

(a) Agencies should request owners of copyright in incorporated material to consent to its free publication, and, if such consent is given, make the material available as in paragraph (2), above.

(b) If copyright owners do not consent to free publication of incorporated materials, agencies should work with them and, through the use of technological solutions, low-cost publication, or other appropriate means, promote the availability of the materials while respecting the copyright owner's interest in protecting its intellectual property.

(c) If more than one standard is available to meet the agency's need, it should consider the availability of the standards as one factor in determining which standard to use.

4. In deciding whether to incorporate a particular copyrighted material by reference, and in working with a copyright owner to ensure the material is reasonably available, an agency should consider:

(a) The stage of the regulatory proceedings, because access may be necessary during rulemaking to make public participation in the rulemaking process effective;

(b) The need for access to achieve agency policy or to subject the effectiveness of agency programs to public scrutiny;

(c) The cost to regulated and other interested parties to obtain a copy of the material, including the cumulative cost to obtain incorporated material that itself incorporates further materials; and

(d) The types of parties that need access to the incorporated material, and their ability to bear the costs of accessing such materials.

5. When considering incorporating by reference highly technical material, agencies should include in the notice of proposed rulemaking an explanation of the material and how its incorporation by reference will further the agency's regulatory purpose.

Updating Incorporations by Reference

6. Agencies should periodically review regulations and make technical amendments (i.e., nonsubstantive amendments that do not require notice and comment) as necessary to ensure that complete and accurate access information⁸ is included in all regulations that incorporate by reference. Agencies should ensure that they are notified of all changes to access information.

7. Agencies that regularly incorporate private standards should adopt internal procedures to ensure good communication of emerging revisions to those within the agency charged with making policy decisions and writing rules. Agencies should consider participating in standard-setting activities in order to maintain awareness of emerging revisions.⁹

⁸ "Access information" informs the public of where it can inspect or obtain a copy of the incorporated material. See 1 C.F.R. § 51.9(b)(4); Nat'l Archives & Records Admin., Federal Register Document Drafting Handbook § 6.4 (Jan. 2011).

⁹ See Administrative Conference of the United States, Recommendation 78-4, *Federal Agency Interaction with Private Standard-Setting Organizations in Health and Safety Regulation*, 44 Fed. Reg. 1,357 (Jan. 5, 1979).

8. Agencies should not address difficulties with updating by confining incorporations by reference to non-binding guidance documents. If an agency intends to make compliance with extrinsic material mandatory, it should incorporate that material by reference in a legislative rule.

9. In the interests of fairness and transparency, agencies should publish regulations or guidance establishing the policies and principles governing equivalency determinations or guiding this use of enforcement discretion in situations where they have been unable to update incorporations by reference in regulations.

10. For rulemakings subject to Section 553 of the APA, agencies should use direct final rulemaking for noncontroversial updates to incorporations by reference.¹⁰

11. Congress should consider authorizing agencies to use streamlined procedures to update incorporations by reference. An appropriate statutory solution would:

(a) Provide for interested parties to file a petition for rulemaking that would notify the agency of a revised standard, identify the changes from the incorporated version of the standard, explain why updating would be consistent with the agency's regulatory purpose, and provide information on the costs and benefits of incorporating the revised standard;

(b) Vest the agency with authority to determine whether to act on the petition; and

(c) Authorize agencies to grant the petition by issuing a final rule, without regard to otherwise applicable rulemaking requirements, provided that the agency first:

¹⁰ See Administrative Conference of the United States, Recommendation 95-4, *Procedures for Noncontroversial and Expedited Rulemaking*, 60 Fed. Reg. 43,108, 43,112 (June 15, 1995).

- (1) Publishes a notice of the petition in the Federal Register, indicates in that notice what regulations the requested update would affect, and provides for public comment on the petition; and
- (2) Finds that updating regulations as requested in the petition is beneficial and consistent with the regulatory purpose of the relevant regulation.

Navigating Procedural Requirements

12. Each agency that incorporates by reference should task its Office of the Federal Register (OFR) liaison or another employee with being a point of contact with OFR and maintaining a close working relationship between the two agencies. Such agencies should take advantage of OFR's training opportunities and follow the procedures of its Document Drafting Handbook (DDH).

13. When considering a regulation that would incorporate by reference, agencies should ensure legal counsel or other experts in OFR regulations, DDH, and policy are involved early in the rulemaking process to reduce the potential for delays in publishing rules. Agencies considering incorporating by reference should reach out to OFR staff early in the rulemaking process.

14. OFR should continue and expand upon its efforts to make the process easier through an electronic submission and review process for incorporation by reference requests.

Improving Drafting Techniques

15. Agencies should ensure that incorporations by reference support, rather than detract from, the usefulness and readability of the Code of Federal Regulations. Incorporated material may provide detail, but a regulation should, by itself, make the basic concept of the rule understandable without the need for the reader to refer to the incorporated material.

16. Agencies should review the language used in material they are considering incorporating by reference to determine whether it is mandatory or merely advisory or voluntary. Agencies promulgating mandatory regulations should take care to specify in the regulation which portions of the material will be considered mandatory after incorporation.

17. When an agency incorporates a document that references a second (or greater) tier document, the agency should acknowledge and explain the substantive legal effect of the secondarily referenced document(s). OFR should consider amending the DDH to call attention to the potential issue of secondary references. If an agency wants to make a second tier document mandatory, it should ensure that such material is reasonably available both to the regulated community and other interested parties.

18. Agencies should be alert to the possibility that some part of their regulations may inadvertently conflict with a requirement incorporated by reference. When drafting regulations, agencies should avoid or resolve any such conflicts.

Administrative Conference Recommendation 2011-6

International Regulatory Cooperation

Adopted December 8, 2011

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 national goals such as protecting health, safety, or the environment at the levels that they consider appropriate. Other substantive differences, however, may disrupt trade 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 because it can help 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, an agency's awareness of and participation in foreign regulatory processes can help to ensure the safety of products reaching United States markets. International regulatory cooperation can also 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 many 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 success in achieving its mission in the United States can be affected by 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. 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 trucks that comply with United States requirements into European markets without significant redesign, thereby creating an unnecessary barrier to trade.

Many agencies successfully engage in international cooperation through a variety of different methods, such as coordination in regulatory promulgation, mutual recognition of inspection and certification regimes, and coordination and information sharing in enforcement. Some agencies have long coordinated effectively, both with respect to domestic and international issues, even when not mandated to do so. 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.

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 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. Accordingly, the recommendation supersedes Recommendation 91-1.

RECOMMENDATION

1. Agencies should inform themselves of the existence of foreign authorities¹¹ whose activities may relate to their missions. Agencies should consider strategies for regulatory cooperation with relevant foreign authorities when appropriate to further the agencies' missions or to promote trade and competitiveness when doing so does not detract from their missions.

2. Agencies should review their legal authorization to cooperate with foreign authorities under their authorizing statutes, bearing in mind obligations under the World Trade Organization Agreement on Technical Barriers to Trade and other relevant treaties adopted by the United States as well as Office of Management and Budget (OMB) guidance. Where legal authorities do not sufficiently permit appropriate international cooperation in regulation and enforcement that would benefit agencies' missions or promote trade and competitiveness without detracting from their missions, agencies should recommend corrective legislation to OMB and Congress. Absent conflict with their legal authority or missions, agencies should give appropriate consideration to the international implications of regulatory activities.

3. When agencies conclude that they have legal authority and the interest in cooperation from foreign authorities, and that cooperation would further agencies' missions or promote trade and competitiveness without detracting from their missions, 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;

¹¹ Throughout this recommendation, the term "foreign authorities" includes a range of foreign and international counterparts, including but not limited to foreign government agencies, regional and international bodies, and, where appropriate, standard-setting organizations.

- (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 (either in person or by teleconference or video conference) 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, where appropriate and practicable, identify foreign authorities that maintain high quality and effective standards and practices and identify areas in which the tests, inspections, or certifications by agencies and such foreign agencies overlap. Where appropriate and practicable, agencies should:

- (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 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.¹²

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.

¹² 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.



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