



SASAKAWA USA
Sasakawa Peace Foundation USA

Administrative Law and the Biden Administration

Implications for the U.S.-Japan Economic and Trade Relationship

Mr. John S. Gardner

The United States and Japan are each strong democracies but with very different constitutions. The United States, with a system of three co-equal branches of government, thus has a different system of administrative law than Japan's Cabinet-based system. As so much of the technical nature of the U.S.-Japan economic relationship across many important industries and sectors – autos, energy, the environment, pharmaceuticals, telecommunications, and many others – is governed by regulations issued under principles of U.S. administrative law, a better understanding of U.S. administrative law can deepen the U.S.-Japan economic relationship. Further, closer regulatory cooperation between agencies in the U.S. and Japan, even leading to regulatory harmonization where possible, can help smooth regulatory differences and make future trade deals easier – an important consideration as the U.S. considers whether to rejoin the Trans-Pacific Partnership (TPP) process now represented by the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP).¹

The Biden Administration, like those before it, will make many regulatory changes that will affect all companies operating in the United States. Japanese companies can participate in this process and help agencies develop strong regulatory policies that will further the U.S.-Japan economic relationship.

¹ Text available at <https://www.dfat.gov.au/trade/agreements/in-force/cptpp/official-documents>

Americans, too, can benefit from a deeper understanding of administrative law and how it has already changed under President Biden.

Basic Principles of Administrative Law

Administrative law in the United States is governed by the Administrative Procedure Act (APA),² signed in 1946 by President Truman. It applies to all Federal agencies; 60 agencies participate in the regulatory agenda of the Office of Management and Budget (OMB).³ It is a somewhat different statute than the 行政手続法 (*Gyōsei tetsuzuki-hō*)⁴ enacted in 1993 in Japan under the Hosokawa Cabinet. Under the APA, Congress enacts laws (for instance, the Clean Air Act⁵ or the Occupational Safety and Health Act⁶) that give agencies power to implement regulations, and agencies then adopt regulations in conformity with the APA. In U.S. administrative law, a “rule” is the formal term for a regulation. Rules, once adopted, are law; violations are subject to civil and even criminal penalties. An understanding of U.S. administrative law is thus very important for companies operating in regulated industries.

Agencies must publish proposed and final rules in the *Federal Register*,⁷ essentially the equivalent of Japan’s *Official Gazette*. The *Federal Register* also includes some Presidential documents (tariff determinations and other proclamations); other Presidential documents are included in the *Weekly Compilation of Presidential Documents*. The text of a proposed rule will indicate the deadline for comments, which is very strict, and a contact person. A final rule will indicate the date on which it goes into effect. Happily, in recent years the *Federal Register* website has become much more user-friendly, organized by topic as well as by agency. Further, agencies often describe proposed rules publicly before their official publication.

A short history of administrative law in the last eight years is that the Trump Administration repealed many rules adopted under President Obama, and

²Administrative Procedure Act (hereinafter APA); Pub. L. 79-404, 60 Stat. 237., codified at 5 U.S.C. § 551 *et seq.*

³Office of Information and Regulatory Affairs, Office of Management and Budget, Unified Agenda of Regulatory and Deregulatory Actions; <https://www.reginfo.gov/public/do/eAgendaMain>

⁴*Gyōsei tetsuzuki-hō* [Administrative Procedure Act], Law No. 88 of 1993 [Heisei 5], text and translation available at http://www.cas.go.jp/jp/seisaku/hourei/data/APA_2.pdf. For background on the situation before 1993, see Kawai Yoshikazu, “A Gulf Between Constitutional and Administrative Law in Japan,” (1991); <https://www.jstor.org/stable/40709669?seq=1>

⁵42 U.S.C. §7401 *et seq.* (1970), as amended.

⁶29 U.S.C. ch. 15 § 651 *et seq.*

⁷Available at <https://www.federalregister.gov>

President Biden will now try to repeal many of those rules, to adopt policies closer to Obama-era policies. These changes apply both to the *process* of regulation and the *substance* of the regulations themselves.

As both U.S. policymakers and regulated industries know, adopting a new rule can be a complex and long process, although ironically it is termed “informal rulemaking” in the law (in contrast to “formal rulemaking,” which requires hearings⁸). Under “informal” or “notice-and comment” rulemaking under Section 553 of the APA,⁹ agencies must generally propose rules, receive comments on them, and then revise the rules based on the substance of “significant” comments received as well as its own views before issuing a final rule. (Some agencies also permit “reply comments,” a second round of comments.)

Public input is vital to the process. Comments come in all types – from a few paragraphs to hundreds of pages. Comments may be submitted (and other commenters’ comments viewed) at <https://www.regulations.gov>. Agencies sometimes state the format in which comments should be presented. Better comments often use strong economic and legal arguments or examples from their own business of how a proposed rule would affect it. Any member of the public, including corporations, has a First Amendment right to submit comments; there is no restriction to attorneys.

Some commenters supplement their formal comments with activities such as lobbying Congress, opinion articles, advertising campaigns, and similar efforts. This can be particularly important for major rules such as on climate change, labor rights, and others. These campaigns sometimes help encourage Congress and the public to become involved in the public debate. However, only the formal comments help the agency determine the legal outcome.

Companies, both in Japan and subsidiaries in the United States, may – and are strongly encouraged to – participate in this process. Several Japanese companies and their U.S. subsidiaries already do so. Nothing in the APA or in general agency practice prohibits foreign persons or foreign corporations, organizations, or federations from making comments in virtually all agency rulemakings or proceedings.

⁸ 5 U.S.C. §§ 556-567

⁹ 5 U.S.C. § 553

Agencies welcome a wide variety of types of comments from foreign parties:

- *Substantive comments, both economic and scientific*, on a proposed rule, which indicate how the rule would impact the commenter and why the commenter agrees or disagrees with the economic or scientific assumptions in the rule. Both positive and negative comments are very important to an agency. Positive comments help support an agency's position and may be reflected in the preamble to the final rule.
- Comments about the rule's *impact on trade with or employment in the U.S.* The impact on jobs is particularly important for the Biden Administration.
- *Informational comments* that do not take a position for or against a rule but simply explain formally to the agency how similar policies are imposed (or not) in foreign countries like Japan. This type of comment is frequently overlooked but significant. It helps smooth U.S.-Japan economic relations and may help encourage efforts at regulatory harmonization.

Comments from persons or corporations in countries such as Japan, including Japanese companies in the U.S., and other important trade partners are thus very important to the agency decision-making process. The only problem has come in recent years when fake comments have been generated by bots both here and in foreign countries (not in Japan); for instance, there were possibly 17 million fake comments in the "net neutrality" proceeding in 2018.¹⁰

The general principle is that comments from companies, organizations, and federations are both very welcome and very important to our rulemaking process. Agencies need the perspective of those who would be affected by proposed rules. It is important to the U.S.-Japan economic and political relationship and ensures that Japanese voices are included in regulatory decision-making.

Other Types of Rulemaking: The Role of the Courts

Two other types of rulemaking have achieved prominence in recent years.

First are "interim final" rules. As the name implies, an "interim final" rule is effective when issued, unless a court blocks it. By law, an agency should adopt an "interim final" rule only when it does not anticipate any negative comments. However, the Trump Administration used this technique widely, essentially to avoid public comment process on many contentious rules. Many courts rebuked it for these attempts; it lost nearly 80% of the cases brought against it on

¹⁰ Elizabeth Montalbano; "80% of Net Neutrality Comments to FCC Were Fudged," Threatpost; May 7, 2021; <https://threatpost.com/net-neutrality-comments-fcc-fudged/165943/>

regulation,¹¹ an astounding figure. The Biden Administration will try to repeal many of these rules – but they will almost certainly have to use the longer, public comment process to do so.

The second type is informal guidance documents. Done well, they can be useful in providing guidance to industry on what an agency might do in the future – for instance, explaining what guidelines FDA would use to approve a new drug for Alzheimer’s disease without committing in advance to approve any individual drug. This is a good use of guidance, very helpful to industry.

However, under the Obama Administration in particular, some agencies used informal guidance to address difficult and controversial issues without a public comment process, for instance on some aspects of the Obamacare law, driverless cars, and guidance on the determination of an employee and an independent contractor for purposes of overtime and benefits. In these instances, the guidance was not a rule enforceable by law, yet industry believed it had to comply with the government guidance.

Agency rules are subject to review by Federal courts, which play an increasingly important role in administrative law. Many complex and important rules are litigated, often on the grounds that agencies have not addressed “significant” comments in the final rule. Commenters can sue an agency if they believe the rule exceeds Congress’ grant of power to the agency, has not addressed significant comments, is “arbitrary and capricious,” not supported by “substantial evidence,” or did not follow proper procedures.

This can delay implementation significantly, particularly for important rules, as judicial review can take up to several years. Agencies must make clear to industry what rules apply when a court decision blocks a new rule. Broadly, one may expect that parties opposed to many of the Administration’s proposed new rules will sue in court to try to block them but that many will nevertheless be approved and come into effect eventually.

¹¹ Institute for Policy Integrity, “Roundup: Trump-Era Agency Policy in The Courts,” April 1, 2001; <https://policyintegrity.org/trump-court-roundup>

The Administration's Regulatory Agenda: Process and Substantive Changes

President Biden's regulatory agenda is ambitious and not limited simply to the repeal of regulations enacted in the previous four years. The new Administration's regulatory policies include both major procedural and substantive reforms.

The process reforms began on Inauguration Day when the President, acting through his Chief of Staff, "froze" regulations that had been proposed by the previous Administration but not yet adopted.¹² Most of those regulations, in particular from EPA, have now been stopped, leaving older regulations in place. President Biden also revoked several Trump Executive Orders on the process of adopting regulations¹³ and issued a Presidential Memorandum on "Modernizing Regulatory Review," which will eventually revise the methods agencies use to determine economic cost-benefit analysis – itself a significant change impacting many regulations.¹⁴

Business in regulated industries is on notice that the Biden Administration will have a very robust regulatory agenda:

It is the policy of my Administration to use available tools to confront the urgent challenges facing the Nation, including the coronavirus disease 2019 (COVID-19) pandemic, economic recovery, racial justice, and climate change. To tackle these challenges effectively, executive departments and agencies must be equipped with the flexibility to use robust regulatory action to address national priorities. This order revokes harmful policies and directives that threaten to frustrate the Federal Government's ability to confront these problems, and empowers agencies to use appropriate regulatory tools to achieve these goals.¹⁵

¹² Ronald A. Klain, Chief of Staff; "Regulatory Freeze Pending Review," Jan. 20, 2021; <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/regulatory-freeze-pending-review/>; See generally Mark Fabrizio; "Biden is Using Multiple Mechanisms to Reverse Trump's Regulatory Agenda," April 21, 2021; <https://regulatorystudies.columbian.gwu.edu/biden-using-multiple-mechanisms-reverse-trumps-regulatory-agenda>

¹³The White House; "Executive Order on Revocation of Certain Executive Orders Concerning Federal Regulation," Jan. 20, 2021; <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-revocation-of-certain-executive-orders-concerning-federal-regulation/>

¹⁴ The White House, "Modernizing Regulatory Review"; Jan. 21, 2021; <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/modernizing-regulatory-review/>

¹⁵ Ibid.

On substantive changes to regulations, OMB's Office of Information and Regulatory Affairs, which has the right to review both proposed and final regulations before they are published, issues a regulatory agenda document under the Regulatory Flexibility Act¹⁶ which generally details the upcoming regulatory agenda.

It is already clear, however, what much of that agenda will be. *Environmental and energy policy* top the list, repealing Trump-era rules in this area and adopting regulations that will help fight climate change, as outlined in a very broad Executive Order¹⁷ that requires all agencies to review anything done in the previous four years that is inconsistent with achieving climate change goals. Notably, the Order promises new regulations in methane reduction, fuel economy standards for vehicles, energy efficiency standards for consumer products, and emission regulations for utilities.

The issue of climate change was very prominent in the President's April meeting with Prime Minister Suga Yoshihide,¹⁸ President Biden's first meeting at the White House with a foreign leader. Climate change will be equally prominent in the regulatory agenda. The President's climate Order outlines the direction of forthcoming action, aligning U.S. regulatory policy with climate change goals.

Second, actions related to *pandemic response and economic recovery*. There has already been some activity to cancel student debt.¹⁹ One may expect more in the healthcare area, possibly next year.

Third, issues concerning *labor and workplaces*. President Biden has said he wants to be a good President for labor and unions. It reflects his personal background and his passions over 40 years in government; politically, he wishes to recapture the working-class vote for the Democrats. One may expect regulations

¹⁶ 5 U.S.C. 601 et seq.; see, e.g., Office of Information and Regulatory Affairs, Office of Management and Budget, Unified Agenda of Regulatory and Deregulatory Actions;

<https://www.reginfo.gov/public/do/eAgendaMain>

¹⁷ The White House, "Executive Order on Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis," Jan. 20, 2021; <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-protecting-public-health-and-environment-and-restoring-science-to-tackle-climate-crisis/>

¹⁸ The White House, U.S.- Japan Joint Leaders' Statement: "U.S. – JAPAN GLOBAL PARTNERSHIP FOR A NEW ERA," April 16, 2021; <https://www.whitehouse.gov/briefing-room/statements-releases/2021/04/16/u-s-japan-joint-leaders-statement-u-s-japan-global-partnership-for-a-new-era/>

¹⁹ See, e.g., Adam Minsky, "Biden Administration Will Review Income Based Repayment, Student Loan Forgiveness Programs," *Forbes*, May 24, 2021;

<https://www.forbes.com/sites/adamminsky/2021/05/24/biden-administration-announces-major-revamp-of-income-based-repayment-student-loan-forgiveness-programs/?sh=522095f26d81>

on family and medical leave, overtime, and perhaps the classification of employees.

Next, *science*. The President's climate Executive Order required agencies to "listen to the science" in proposing regulations – a rebuke to the Trump Administration. He also issued a Presidential Memorandum on "restoring scientific integrity" and outlining how the government will use science in policymaking.²⁰ Science, and competing scientific theories, will be the arena in which many substantive regulations will be decided in agencies and the courts. Comments on the scientific basis for a rule are thus essential to the ultimate outcome of regulation.

Finally, the President has asked agencies to examine *systemic racial equality* in developing regulations. This will be significant not only in environmental regulation but in many other areas, including the Departments of Housing and Urban Development, Agriculture, Health and Human Services (including FDA), Transportation, Treasury, and other financial regulators such as the Securities and Exchange Commission. Presidents often seek to examine these types of cross-cutting issues in their regulatory policies; notably, President Reagan asked agencies to examine how regulations impact state governments. Now, President Biden and Domestic Policy Adviser Susan Rice are focusing on the impacts of regulation on racial equality.

Already, the Biden Administration has produced the largest early shifts in policy since President Reagan in 1981. Looking forward over the next year one may predict forthcoming regulations in areas such as use of Federal lands, transportation (highway safety, trucks, fuel standards, aviation), perhaps another net neutrality proceeding at the FCC, and many others.

Regulatory Policy: Towards Regulatory Harmonization?

What implications does all this have for deepening the U.S.-Japan economic relationship? Discussions of regulation naturally raise the related question of competing regulatory standards among advanced economies and whether those standards may be harmonized to ease and promote trade. Here, rulemaking may play a crucial role – if regulated industries are attentive to the opportunity.

²⁰ The White House, "Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking," Jan. 27, 2021; <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/27/memorandum-on-restoring-trust-in-government-through-scientific-integrity-and-evidence-based-policymaking/>. A Presidential Memorandum does not have the force of law as an Executive Order does; however, it is binding on agencies in the Executive Branch.

For instance, the EU-Japan trade agreement²¹ included provisions on regulatory harmonization, notably regarding autos.²² Those who favor a closer U.S.-Japan economic relationship must ensure that the U.S.-Japan trade relationship will not be left behind, even as the Administration has not yet made decisions on rejoining the TPP process or other trade efforts.

Some areas covered in the TPP process, such as copyright and dispute resolution, are governed by statute rather than regulation. But other areas – agriculture (including food), energy and the environment, pharmaceuticals and medical devices, telecommunications products (such as 5G and 6G equipment), and information technology products – are often addressed through administrative law in both countries.

Regulatory harmonization in some form will be important in future trade agreements, bilateral or multilateral, involving the U.S. and Japan.²³ The U.S. meets the TPP's standard of "transparent, nondiscriminatory rules for developing regulations, standards, and conformity assessment procedures" specifically through the APA – yet another reason why Japanese participation in regulatory rulemaking is so important. Areas of possible policy convergence between the U.S. and Japan, such as climate change, energy, or 5G policy are influenced and to some degree directed by administrative law.

Recommendations

Policymakers in the U.S. and Japan can take several steps to reinforce the importance of administrative law in the economic relationship, make future trade agreements easier, deepen U.S.-Japan economic cooperation, and assist Japanese companies investing in the United States:

First, *pay attention to current rulemakings*. This applies both to the private sector that is most affected by the proposed rules and to policymakers in both countries. No one wants regulatory surprises, either in their business or in bilateral economic relations. Companies, for their part, should not be afraid to participate in rulemakings and even to give forthright views on scientific or economic issues

²¹ "EU-Japan Economic Partnership Agreement," Dec. 8, 2017; text at <http://trade.ec.europa.eu/doclib/press/index.cfm?id=1684>

²² Congressional Research Service; "EU-Japan FTA: Implications for U.S. Trade Policy," June 26, 2020; <https://fas.org/sgp/crs/row/IF11099.pdf> See also Trans-Pacific Partnership, Appendix D-1: "Between Japan and the United States on Motor Vehicle Trade," <https://ustr.gov/sites/default/files/TPP-Final-Text-Japan-Appendix-D-1-Appendix-between-Japan-and-the-United-States-on-Motor-Vehicle-Trade.pdf>

²³ See generally World Bank, "[Potential Macroeconomic Implications of the Trans-Pacific Partnership](#)" (PDF), *January 2016*, pp. 230ff.

where they differ from those of the agency. Robust, honest policy debate, on the basis of sound science and economics, is welcome and vital to the regulatory process.

Second, *deepen cooperation between regulatory agencies and find areas of common interest*. This already works well in some areas but can always be improved. In areas where each country anticipates forthcoming rulemakings (for instance, on 5G technology or climate change), an informal exchange of views between U.S. and Japanese regulators may smooth future progress, while respecting each side's sovereignty and independent procedures. Beyond this, perhaps a fellowship program to bring young regulators from each country to the other for six months or a year could give greater insights into the workings of regulatory policymaking and build personal ties among future regulators.

Third, *focus on the process of rulemaking*. The Administrative Conference of the United States (ACUS) is an agency whose "initiatives promote efficiency, participation, and fairness in the promulgation of federal regulations and in the administration of federal programs."²⁴ ACUS could seek input from foreign commentators on barriers to participation in U.S. rulemakings and propose solutions to make the process easier and fairer to interested foreign parties while guarding strictly against fake or mass-generated comments. An exchange of views between ACUS representatives and their Japanese counterparts could generate useful ideas.

Fourth, *deepen ties between law schools* in each country, so that comparative law courses (and advanced administrative law courses) include analysis of both country's systems, to promote greater understanding and prepare future lawyers for careers in regulatory policy and trade.

Fifth, each country's *development initiatives on the rule of law*²⁵ can be expanded to include helping countries in the developing world, including the Indo-Pacific, to reform administrative law where necessary. While each country in the CPTPP will meet the standard of transparent and non-discriminatory rulemaking through its own national procedures, reforms in those procedures will aid in deepening ties among the Indo-Pacific nations committed to CPTPP.

²⁴ <https://www.acus.gov/administrative-conference-united-states-acus>

²⁵ See generally, "Rule of Law for Sustainable Development and Access to Justice for All," JICA's World, January 2017, <https://www.jica.go.jp/english/publications/j-world/c8h0vm0000anz0xu-att/1701.pdf>; "Rule of Law Practitioner's Guide," July 2020, <https://www.usaid.gov/democracy/documents/rule-law-practioners-guide>.



Mr. John S. Gardner served President George H.W. Bush as Special Assistant to the President and Deputy Staff Secretary at the White House, the deputy in the office responsible for managing the flow of paper in the White House and the execution and implementation of Presidential decisions. At the beginning of the Administration of President George W. Bush, he served as Deputy Assistant to the President in a similar role. From 2001-2005, he served as General Counsel for the U.S. Agency for International Development, where he was responsible for all aspects of legal work at USAID, especially statutory analysis, administrative law, and government contracts law. In this capacity, he worked extensively on international health issues and served as U.S. member of the Governance and Partnership Committee of the Global Fund to Fight AIDS, TB, and Malaria and as a founding member of its Ethics Committee. President Bush also appointed Mr. Gardner to the Board of Governors of the U.S. Postal Service, where he served on the Strategic Planning and Capital Projects Committees.

Currently he is an attorney, consultant, and writer working in the fields of strategic communications, policy communications, regulatory and policy analysis, research, opinion writing, speechwriting, and editing. He works in telecommunications and related fields, economic and international development, foreign policy, transportation and travel, healthcare, litigation communications consulting, extractive industries, and financial services. He has a special emphasis on U.S. and EU economic regulation, Japan, and Southeast Asia.

In the private sector, Mr. Gardner was Vice President – Government Affairs & Policy at AT&T and Vice President of the Schwab Washington Research Group, where he was a research analyst providing analysis to institutional investors on transportation industries and on antitrust mergers and cases and U.S. and EU competition policy issues. He covered U.S. v. Microsoft on behalf of institutional investors and was one of the first analysts to report intensively on European competition law, including the Microsoft investigation and the proposed mergers of MCI/Bell Atlantic, Boeing/McDonnell Douglas, and GE/Honeywell. After law school, he was associated with the law firm of Davis Polk & Wardwell in New York.

He was graduated from Harvard Law School cum laude in 1995, where he was the Articles Editor of the Harvard Journal of Law and Public Policy and a pre-law and public service tutor at Lowell House, Harvard College. He studied advanced European law, was a Food and Drug Law Institute scholar, and his paper “The Still More Difficult Task” was the first published academic paper on the European Medicines Evaluation Agency. He earned an M. Litt. in Modern History from Oxford University in 1989 and received an AB in history cum laude from Harvard in 1984, with a concentration on American and East

Asian history. He is married; a member of the bar of New York State; and resides in Alexandria, Virginia.