

2 FAM 1180 RULEMAKING

(CT:GEN-346; 09-29-2008)
(Office of Origin: A/ISS/DIR)

2 FAM 1181 POLICY, SCOPE, AND AUTHORITY

2 FAM 1181.1 Policy

(CT:GEN-346; 09-29-2008)

It is Department of State policy that all Department rulemakings will be processed and issued in a uniform and consistent manner.

2 FAM 1181.2 Scope and Applicability

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These policies and procedures apply to all Department units and employees worldwide.

2 FAM 1181.3 Definitions

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Advance Notice of Proposed Rulemaking (ANPRM): A notice published in the Federal Register that provides public notice of a proposed rule making, and solicits comments from the public for a period of usually 60 days. An ANPRM generally does not go into the specific subject matter of the planned rule in detail but asserts what the rule is intended to do and why. The ANPRM starts the rulemaking process. Its purpose is to solicit public input on various issues relating to the intent of and reason for the rulemaking.

Final rule: A final rule is the formal, permanent issuance of a rule. Usually preceded by an interim or proposed rule, a final rule does not solicit comments from the public, but contains the appropriate regulatory analyses. A direct final rule is one that has not been preceded by an interim or proposed rule, but does solicit comments from the public, usually for a period of 60 days. A direct final rule is withdrawn if the Department receives negative comments.

Interim rule: An interim rule goes into effect, but is temporary in nature, pending the issuance of a final rule or its withdrawal. An interim rule solicits comments from the public for a period of, usually, 60 days.

Proposed rule: A proposed rule solicits comments from the public for a period of usually 60 days.

Regulatory findings (also regulatory analysis and notices): The part of a rule notice that addresses the issuing agency's required responses to the following (but not limited to them):

- Administrative Procedure Act (APA)
- Regulatory Flexibility Act (RFA)
- Unfunded Mandates Reform Act of 1995 (UMRA)
- Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA)
- Executive Order 12866
- Executive Order 13132
- Paperwork Reduction Act (PRA)

Regulation Identification Number (RIN): Obtained by the Office of the Legal Adviser, Legislation and General Management (L/LM) for program offices, this is a tracking number for planned regulatory Code of Federal Regulations (CFR) changes.

Regulations.gov: The National Archives and Records Administration (NARA) Web site for participating agencies. Rule notices submitted to the Office of the Federal Register (OFR) are posted here for public review and comment.

ROCIS (Regulatory Information Service Center (RISC) and Office of Information and Regulatory Affairs (OIRA) Combined Information System): Managed by the Office of Management and Budget (OMB) and NARA, this is the basic database for OMB rule reviews. All Executive Order (EO) review submissions are done through this system by uploading the rule notice and any relevant documents.

Unified Regulatory Agenda (Unified Agenda): The Agenda provides information, in a uniform format, about regulations that the U.S. Government is considering or reviewing. The Agenda includes regulatory agendas from 60 Federal departments and agencies, excluding agencies of the U.S. Congress. The OMB's Office of Information and Regulatory Affairs (OIRA) is the chief governmental office responsible for compiling the Agenda. The Agenda appears in the Federal Register semiannually.

2 FAM 1181.4 Authorities

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Department rulemaking is executed under the applicable laws of the United States, principally those contained in:

- a. See also 2 FAM 1120 and 2 FAM 1240.
- b. Federal Register Act (44 U.S.C. Chapter 15).
- c. Administrative Procedure Act (5 U.S.C. Subchapter II).
- d. Federal Advisory Committee Act (5 U.S.C. Appendix 2).
- e. Freedom of Information Act (5 U.S.C. 552).
- f. Privacy Act (5 U.S.C. 552a).
- g. Government in the Sunshine Act (5 U.S.C. 552b(e)(3)).
- h. Negotiated Rulemaking Act (5 U.S.C. 561 *et seq.*).
- i. Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*)
- j. Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 801 *et seq.*)
- k. Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*)
- l. Executive Order 12866
- m. Executive Order 13132

2 FAM 1182 RESPONSIBILITIES

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- a. **Program offices:** Develop rules, ensure proper formatting, obtain relevant clearances, ensure that copies of rules are sent to GAO, the House and Senate, and other U.S. Government agencies as appropriate, and review the ECA-IIP/EX Web site for confirmation of publication.
- b. **Office of the Legal Adviser (L):** Reviews rules as appropriate for content and structure; provides guidance and direction to program offices as needed, and ensures accuracy of legal citations. The Office of Legal Affairs, Legislation and General Management (L/LM) compiles and submits the Unified Regulatory Agenda; obtains Regulation Identification Numbers (RINs) for Department of State rules.
- c. **Office of Directives Management (A/ISS/DIR):**
 - (1) Provides overall coordination of issuance of rules to OMB and the Federal Register;
 - (2) Provides single point of contact (POC) for OMB for other agency rules for which OMB requests Department comment;

- (3) Provides single POC for Department rules that OMB will review; and
 - (4) Provides regulatory review of rules prior to issuance in the Federal Register; this includes all regulatory analyses, such as small business paperwork relief issues, information collection, etc. DIR verifies clearances as needed; ensures that the Office of the Legal Adviser (L) reviews all rules; and verifies copies sent to other U.S. Government offices, as appropriate.
- d. The **Regulatory Coordinator** (located in DIR):
- (1) Exercises DIR rulemaking responsibilities;
 - (2) In cooperation with L, also tasks reviews or responses, or makes comment, as appropriate, on other rules or legislation and also serves as the backup to Office of Legal Affairs, Legislation and General Management (L/LM) for obtaining RINs and updating the Department's Regulatory Agenda;
 - (3) Serves as primary Department liaison with the Office of Management and Budget for rulemaking issues, arrangement for Department participation in briefings and meetings with OMB, etc.;
 - (3) Serves as the Department's single POC for the public on small business assistance, compliance, and enforcement issues (in coordination with the Bureau of Administration, Office of Small and Disadvantaged Business Utilization (A/SDBU)); and
 - (4) Serves as lead on e-rulemaking issues for the Department.
- e. **Federal Register Liaison (FRL)** located in the Office of Directives (DIR): Serves as the sole conduit for sending material to the Federal Register for publication. The Federal Register liaison must review all documents before submission to the FR to make sure that they meet FR document publication requirements and that rules have the correct signature and proper billing code. The FR liaison provides the Federal Register with correctly signed and certified copies for publication, a submission letter with instructions regarding publication, and a submission letter and certified electronic disk. Requests to change or remove submitted documents must come from the FRL by signed letter. Corrections and revisions to regulatory documents may be made by the legal staff but must be coordinated by the FRL. The Federal Register liaison must provide the General Accountability Office (GAO) general counsel letters when publishing certain regulatory material.
- f. **Office of Management and Budget's Office of Regulatory and Information Administration (OMB/OIRA)**: Has oversight responsibility for all U.S. Government agency rulemakings and has clearance authority. See also 2 FAM 1184.
- g. **Bureau of Resource Management (RM)**: Sends draft copies of rules to

the General Accounting Office, and provides input to budgetary needs for rulemaking.

- h. **Office of Congressional Relations (H)**: Sends draft copies of rules to the President of the Senate and the Speaker of the House.

2 FAM 1183 DOS PROCESSING

2 FAM 1183.1 Procedures for Publishing Rules

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- a. The substantive office, in consultation with L and other Department offices, as needed, develops rule drafts. The regulatory coordinator can provide review, advice, and templates for rule notices.
- b. The substantive office obtains clearance from appropriate offices, with L as the final clearance. Required clearance points are:
 - (1) Office of the Legal Adviser (L) (**always** a clearance point);
 - (2) RM (Bureau of Resource Management) for financial issues. RM drafts the pertinent regulatory letters that are sent to the GAO General Counsel]
 - (3) Bureau of Human Resources (HR) for personnel issues.DIR may determine and require additional specific clearances.
- c. After obtaining L approval, the program office forwards the rule package to A/ISS/DIR for review and processing.
- d. The regulatory coordinator reviews the rule package and ensures that appropriate clearances have been obtained. The DIR regulatory coordinator may seek review and comment from the A/ISS Deputy Assistant Secretary or from the Assistant Secretary for Administration (A).
- e. As appropriate, the coordinator submits material to OMB for review through OMB's Regulatory Information Service Center (RISC) and Office of Information and Regulatory Affairs (OIRA) Combined Information System) (ROCIS) system (see 2 FAM 1184). The coordinator acts as conduit for review questions and comments from OMB, including uploading into ROCIS revised versions of the rule package as needed. Once OMB clearance is obtained, the regulatory coordinator notifies the originating office, which obtains the appropriate signature on the rule notice.
- f. The coordinator forwards the public notice portion of the package to the Federal Register (FR) liaison for processing.

- g. The FR liaison reviews the notice and accompanying diskette for accuracy and Federal Register requirements and forwards the material to the Federal Register for publication. See also 2 FAM 1120.
- h. Program offices may review the Federal Register Web site for confirmation of publication. The Office of the Federal Register also has a listserv that provides daily notification of publication to the FR liaison.

2 FAM 1183.2 Regulatory Analyses

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All rules, unless corrections or adoptions without change of proposed or interim rules, must carry a regulatory analysis section, usually titled “Regulatory Findings” or “Regulatory Analysis and Notices.” This section must contain but is not limited to the following analyses under the:

- (1) Administrative Procedure Act (2 FAM 1183.2-1);
- (2) Regulatory Flexibility Act (2 FAM 1183.2-2);
- (3) Unfunded Mandates Reform Act of 1995 (2 FAM 1183.2-3); and
- (4) Small Business Regulatory Enforcement Fairness Act of 1996 (2 FAM 1183.2-4).

2 FAM 1183.2-1 Administrative Procedure Act

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- a. The Administrative Procedure Act (APA) is the law under which U.S. Government regulatory agencies create the rules and regulations necessary to implement and enforce major legislative acts. The APA describes two kinds of rulemaking—formal and informal. “Formal rulemaking” calls for a trial-like, on-the-record proceeding. The Department generally develops its rules through “informal rulemaking.” The main requirements for the latter are:
 - (1) Publication of a Notice of Proposed Rulemaking (NPRM) in the Federal Register;
 - (2) Opportunity for public participation by submission of written comments;
 - (3) Consideration by the agency of the public comments and other relevant material; and
 - (4) Publication of a final rule not less than 30 days before its effective date, with a statement explaining the purpose of the rule.
- b. Rules that are exempt from the “notice-and-comment” requirements of the APA are those dealing with military or foreign affairs functions and

those “relating to agency management or personnel or to public property, loans, grants, benefits or contracts.”

2 FAM 1183.2-2 Regulatory Flexibility Act

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- a. You must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rule on small entities (i.e., small businesses, small organizations, and small governmental jurisdictions).
- b. However, no regulatory flexibility analysis is required if the head of an agency certifies and provides a statement of the factual basis for certifying that a rule will not have a significant economic impact on a substantial number of small entities.

2 FAM 1183.2-3 Unfunded Mandates Reform Act of 1995

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This comes into play when a rule would cost State, local, or tribal governments \$50 million or more, or the private sector \$100 million or more. Federal agencies are required to consult with State, local, and tribal governments about a rule-making that contains an unfunded mandate before the general public knows about the rule. The act also requires agencies to assess the effects of final and proposed regulations issued when the bill takes effect.

2 FAM 1183.2-4 Small Business Regulatory Enforcement Fairness Act of 1996

(CT:GEN-346; 09-29-2008)

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 is intended to minimize the burden on small businesses in complying with statutes and rules enforced by a Federal agency. It calls on regulatory agencies to detail policies for providing compliance assistance to small businesses and for mitigating civil penalties for small businesses that may violate statutes and rules. SBREFA also directs agencies regulating small businesses to establish mechanisms to allow for a reduction or waiver of civil penalties for violations of statutes or laws in appropriate circumstances.

2 FAM 1183.2-5 Executive Order 12866

(CT:GEN-346; 09-29-2008)

Under Executive Order 12866 (58 FR 51735 (October 4, 1993)), an agency must determine whether a regulatory action is “significant” and therefore subject to Office of Management and Budget (OMB) review and the requirements of the Executive Order. The order defines “significant regulatory action” as one that is likely to result in a rule that may:

- (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;
- (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
- (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
- (4) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

2 FAM 1183.2-6 Executive Order 13132—Federalism

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You may not issue a regulation that has federalism implications; that imposes substantial direct compliance costs; and that is not required by statute, unless the Federal Government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or the Department consults with State and local officials early in the process of developing the proposed regulation. You also may not issue a regulation that has federalism implications and that preempts State law, unless the Department consults with State and local officials early in the process of developing the proposed regulation.

2 FAM 1183.2-7 Paperwork Reduction Act (PRA)

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If your rule will result in a new or existing information collection, you must include the appropriate information. Consult with the Office of Legal Affairs, Legislation and General Management (L/LM) and the Department’s Information Collection Coordinator located in DIR. According to the

Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., an agency may not conduct or sponsor, and a person is not required to respond, to a collection of information that requires OMB approval under the PRA, unless it has been approved by OMB and displays a currently valid OMB control number.

2 FAM 1183.3 Types of Rules

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The program office determines the type of rule, depending on its purposes. Some types are:

- Advance notice of proposed rulemaking
- Proposed rule
- Proposed rule with request for comments
- Final rule
- Final rule; delay of effective date
- Final rule; suspension of effectiveness
- Final rule; confirmation of effective date
- Final rule; correction
- Final rule; interpretation
- Final rule; petition for reconsideration
- Interim rule
- Interim rule with request for comments
- Direct final rule
- Temporary rule
- Policy statement
- Interpretation
- Clarification

The majority of Department rule types are proposed, interim, final, and direct final. DIR can provide advice on which to use. The regulatory section reviews the final draft of a rule for adherence to Federal Register publication requirements and returns the redlined document to the program office. The final version of the rule is processed by the regulatory section. The Federal Register in DIR sends the final version of the rule to the Federal Register.

2 FAM 1183.4 Rule Formatting

(CT:GEN-346; 09-29-2008)

A/ISS/DIR ensures that all DOS rules comply with the formatting requirements found in the Federal Register's (FR's) Document Drafting Handbook(DDH). The DDH contains information on content of the various parts of a rule notice. A/ISS/DIR has created different rule type templates and made them available from the DIR Web site or from the Regulatory Coordinator.

2 FAM 1184 OMB REVIEW

2 FAM 1184.1 Authority

(CT:GEN-346; 09-29-2008)

- a. All rule documents are subject to review by the Office of Management and Budget (OMB) under Executive Order 12866 on Federal Regulations and Approval of Collection of Information Under the Paperwork Reduction Act of 1980 and 5 CFR 1320. Certain subjects may be exempt from OMB review. Contact the Regulatory Coordinator in A/ISS/DIR on any questions regarding the OMB review process. See also 2 FAM 1160.
- b. The OMB review is undertaken prior to, and separate from, the submission of the rule to the Federal Register for publication. The OMB review is to be completed within 90 days, unless OMB requests a withdrawal and resubmission. Upon clearance from OMB, and if there are no changes needed, DIR submits the rule to the Federal Register for publication.

2 FAM 1184.2 OMB Submission Requirements

(CT:GEN-346; 09-29-2008)

The rule must be contained in the ROCIS system for OMB review. DIR will upload the rule notice after its review and approval. The Office of Legislation and General Management (L/LM) is the backup for uploading material for the review.

2 FAM 1184.2-1 Submission Under Paperwork Reduction Act of 1980 and 5 CFR 1320

(CT:GEN-346; 09-29-2008)

In addition to the OMB review under E.O. 12866, rules that involve

information collection, affect agency reporting requirements, or create additional paperwork burdens on agency activities require review and approval by OMB under the Paperwork Reduction Act. See also 2 FAM 1160.

2 FAM 1184.3 OMB Review and Processing

(CT:GEN-346; 09-29-2008)

OMB notifies the regulatory coordinator of approval or requests clarification or provides questions. The regulatory coordinator in turn tasks to bureaus the OMB questions for response and coordinates briefings and meetings, as appropriate.

2 FAM 1185 Unified Regulatory Agenda and Regulation Identification Number (RIN)

(CT:GEN-346; 09-29-2008)

- a. The Office of the Legal Adviser, Legislation and General Management (L/LM) maintains the Department's Unified Regulatory Agenda and sends it to OMB semiannually.
- b. The activities included in the agenda are, in general, those that will have a regulatory action within the next 12 months. Participating agencies have the option of including activities that will impose a regulatory action beyond 12 months. The Agenda shows actions or reviews completed or withdrawn since the last Agenda and may issue or propose other regulations not included in their agency's agenda. L/LM routinely contacts bureaus that deal with regulations, such as Consular Affairs (CA), Political-Military Affairs (T/PM), and Educational and Cultural Affairs (ECA), to see if they have new or continuing submissions for the agenda.
- c. The Unified Agenda helps agencies comply with their obligations under the regulatory flexibility act and various Executive Orders and other statutes. The Regulatory Flexibility Act (RFA) requires agencies to identify those rules that may have a significant economic impact on a substantial number of small entities. Agencies meet that requirement by including the information in their submissions for the unified agenda. Agencies may also indicate those regulations that they are reviewing as part of their periodic review of existing rules under the RFA.
- d. Program offices are responsible for ensuring that their planned regulations are given Regulation Identification Numbers (RINs) and that those planned regulations are included in the Unified Agenda. Contact L/LM, who will obtain and assign a RIN.
- e. Not all rules will take RINs. Consult L/LM when in doubt.

2 FAM 1186 OTHER AGENCY RULES

(CT:GEN-346; 09-29-2008)

OMB sends rules drafted by other Federal agencies to the regulatory coordinator in DIR, who tasks bureaus and offices with reviewing and providing comments and/or clearance on the drafts. As needed, the coordinator compiles the Department response on behalf of the commenting offices and does such follow-up liaison and discussion as needed.

2 FAM 1187 INFORMING CONGRESS AND OTHER AGENCIES

(CT:GEN-346; 09-29-2008)

Program offices are responsible for ensuring that the Congress, the General Accountability Office (GAO), and other U.S. Government agencies are notified of rulemakings as required by law. L provides advice and guidance on submitting material through H or through another permitted process.

2 FAM 1188 FOREIGN AFFAIRS MANUAL

(CT:GEN-346; 09-29-2008)

Rules should not be developed or implemented in a vacuum. Program offices are to ensure that CFR rules are appropriately and timely reflected in the Department's directives program: the Foreign Affairs Manual and its supplementary series, the Foreign Affairs Handbooks. See 2 FAM 1110.

2 FAM 1189 UNASSIGNED