

Signature/approval of "Record of Compliance" document

a. This may be done before the proposed rule (preferably) or when the proposed rule goes forward for appropriate signature. The surname route should be as follows:

1. PDM
2. External review (Executive Secretariat, Office of Program Analysis, Small and Disadvantaged Business Utilization, and Small Business Administration) - 15 days to complete review
3. Concurrence by Assistant Director
4. Concurrence by Director
5. Approval by Assistant Secretary

Preparation of proposed rule by originating office

- Using the Record of Compliance (ROC), which stays with the rulemaking package, develop and type the proposed rule.
- In developing your rule, use the 12 principles of regulation (E. O. 12866), which determine that each agency shall:
 - a. Identify the problem it intends to address as well as assess the significance of that problem.
 - b. Examine whether existing regulations (or other law) have, created/contributed to the problem that a new regulation is intended to correct and whether those regulations/other law should be modified to achieve the intended goal of regulation more effectively.
 - c. Identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public.
 - d. In setting priorities, consider (to a reasonable extent) the degree/nature of the risks posed by various substances/activities within its jurisdiction.
 - e. When determining that a regulation is the best available method of achieving the regulatory objective, design regulation in the most cost-effective manner to achieve the regulatory objective. Consider incentives for innovation, consistency, predictability, costs of enforcement and compliance (to the government, regulated entities, and the public)

flexibility, distributive impacts, and equity.

f. Assess costs/benefits of the intended regulation and recognizing that it may be difficult to quantify, propose/adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its cost.

g. Base its decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation.

h. Identify and assess alternative forms of regulation and shall, to the extent feasible, specify performance objectives, rather than specifying the behavior/ manner of compliance that regulated entities must adopt.

i. Wherever feasible, seek views of appropriate State, local and tribal officials before imposing regulatory requirements that might significantly/uniquely affect those governmental entities. Each agency shall assess the effects of Federal regulations on State, local and tribal governments, including specifically the availability of resources to carry out those mandates, and seek to minimize those burdens that uniquely or significantly affect such governmental entities, consistent with achieving regulatory objectives. In addition, as appropriate, seek to harmonize Federal regulatory actions with related State, local and tribal regulatory and other governmental functions.

j. Avoid regulations that are inconsistent, incompatible, or duplicative with its other regulations or those of other Federal agencies.

k. Tailor its regulations to impose the least burden on society, including individuals, businesses of differing sizes, and other entities (including small communities and governmental entities), consistent with obtaining the regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations.

l. Draft its regulations to be simple/easy to understand, with the goal of minimizing the potential for uncertainty and litigation arising from such uncertainty.

Surnames and Signature of your proposed rule (in the following order):

- Originating division
- Other affected divisions (for technical program matters)
- PDM (for compliance with statutory, regulatory or other external requirements, plain English, and tracking)
- Executive Secretariat (ES) for advance review of rule
- A/D for tracking

- Solicitor (for legal review)
- A/D
- Director (for signature on ES listings/delistings/reclassifications, or non-policy notices only)
- Assistant Secretary (for signature)

Disposition of rule after Assistant Secretary signature

- PDM holds 3 original signed copies and returns surname copy to originating office.
- Originating office forwards copy of signed rule (plus copy of surname page) to the Director, Office of Executive Secretariat [formerly Office of Regulatory Affairs] for their review.

Role of Director, Office of Executive Secretariat (ES) [formerly Office of Regulatory Affairs] -

- Pre-signature, ES reviews rule for Departmental policy and plain English within 15 days
- Post-signature, ES receives a copy of the signed rule, including a copy of both the signature and surname pages and completes final administrative review within 48 hours.
- Consults with OMB for rule's significance under E.O. 12866 (see page 5/major status under the Small Business Regulatory Enforcement Act of 1996 [5 U.S.C. 801, et seq.]).
- Informal guidance from ES is that OMB is considering any rule that is "significant" to be "major." If a rule is "significant" economically under E.O. 12866, it also will be a "major" rule under SBREFA. On the other hand, if a rule is "significant" because it creates a serious inconsistency problem or because it raises novel legal or policy issues, it may not be "major."
- If rule is determined to be significant under E.O. 12866, program office completes OMB submission form which is signed by the originating office, PDM, and ES. Copy of rule and signed form is forwarded to OMB for their review (review may take up to 90 days per E.O. 12866).
- OMEB clears rule and contacts ES who, in turn, notifies PDM.

Publication of proposed rule

- PDM contacts originating office after clearances by ES and OMB, if required, are obtained.
- Originating office delivers three original signature copies of rule to Federal Register (800 N. Capitol Street, NW, 7th Floor, Suite 700, Washington, DC 20001 or handcarry between 8:45 and 5:15 Monday through Friday).
- Unless questions/problems from the Register (PDM contacted directly), the rule generally will be published three working days after receipt, unless otherwise provided for.

Review of final rules by Congress and GAO

After clearance by ES/OMB, copies of final rules must be submitted to GAO and Congress prior to the rule becoming effective. The copies may be hand-delivered by FWS personnel or sent by courier. Instructions for couriers are on the next page. Congress has the opportunity to pass a joint resolution of disapproval (5 U.S.C. 802) for any rule, even after that rule has been made effective for consideration by the President.

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

1. The National Environmental Policy Act of 1969, as amended, (NEPA) is our basic national charter for the protection of the environment. NEPA procedures must ensure that environmental information is available to public officials and citizens before decisions are made or actions are taken. The NEPA process is intended to help public officials make decisions based on an understanding of environmental consequences and take actions that protect, restore, and enhance the environment. NEPA requires public participation in the planning process with the Federal action agencies. All regulations must comply with NEPA. For further guidance, consult 40 CFR 1500 or 516 DM, implemented by 505 FW 1.

Section 7 consultation (16 U.S.C. 1531 et seq., 50 CFR 402)

1. Necessary for any regulations that may have an effect on listed species. Entails a determination of what impact the regulations will have on the continued existence of the species.