

(3) A person may assert a claim of confidentiality for any information submitted to EPA in connection with this rule. Any claim of confidentiality must accompany the information when submitted to EPA. Persons claiming information as confidential should do so by circling, bracketing, or underlining it and marking it with "CONFIDENTIAL." EPA will disclose information subject to a claim of confidentiality only to the extent permitted by section 14 of TSCA and 40 CFR part 2, subpart B. If a person does not assert a claim of confidentiality for information at the time it is submitted to EPA, EPA may make the information public without further notice to that person.

(j) *Enforcement.* (1) Failure to comply with any provision of this section is a violation of section 15 of the Act (15 U.S.C. 2614).

(2) Failure or refusal to establish and maintain records or to permit access to or copying of records, as required by the Act, is a violation of section 15 of the Act (15 U.S.C. 2614).

(3) Failure or refusal to permit entry or inspection as required by section 11 of the Act (15 U.S.C. 2610) is a violation of section 15 of the Act (15 U.S.C. 2614).

(4) Violators may be subject to the civil and criminal penalties in section 16 of the Act (15 U.S.C. 2615) for each violation.

(k) *Inspections.* EPA will conduct inspections under section 11 of the Act (15 U.S.C. 2610) to ensure compliance with this section.

[55 FR 240, Jan. 3, 1990, as amended at 59 FR 42773, Aug. 19, 1994]

PART 750—PROCEDURES FOR RULE- MAKING UNDER SECTION 6 OF THE TOXIC SUBSTANCES CON- TROL ACT

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AUTHORITY: 15 U.S.C. 2605.

Subpart A—Procedures for Rule- making Under Section 6 of the Toxic Substances Control Act

SOURCE: 42 FR 61259, Dec. 2, 1977, unless otherwise noted.

§ 750.1 Applicability.

This part applies to all rulemakings under authority of section 6 of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2605.

§ 750.2 Notice of proposed rulemaking.

(a) Each rulemaking becomes subject to this part with the publication of a Notice of Proposed Rulemaking in the FEDERAL REGISTER. A proceeding under section 6 of the Toxic Substances Control Act may begin, as appropriate, with the publication in the FEDERAL REGISTER of a Notice of Proposed Rulemaking, an Advance Notice of Proposed Rulemaking, or notice of other

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action, such as a formal regulatory investigation designed to lead to issuance of rules within a reasonable time.

(b) Each such notice shall contain:

(1) A draft finding that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use or disposal of the chemical substance(s) or mixture(s) at issue, or any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment.

(2) A Notice of Proposed Rulemaking stating with particularity the reasons for the proposed rule together with a statement why the proposed rule protects adequately against the risk(s) involved using the least burdensome requirements authorized by TSCA.

(3) Either the draft text of the proposed rule (which may include alternative approaches among which a final choice has not yet been made) or a description of the approaches and provisions being considered for inclusion in the rule, or some combination of the above.

(4) Except for rules published under authority of section 6(e), a draft statement with respect to:

(i) The effects of the substance(s) or mixture(s) at issue on health and the magnitude of the exposure of human beings to such substance(s) or mixture(s);

(ii) The effects of the substance(s) or mixture(s) at issue on the environment and the magnitude of the exposure of the environment to such substance(s) or mixture(s).

(iii) The benefits of the substance(s) or mixture(s) at issue for various uses and the availability of substitutes for such uses; and

(iv) The reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health.

(v) Major impacts of alternatives to the proposed rule shall also be analyzed.

(5) In cases where the administrator, in his or her discretion, determines that a risk of injury to health or the environment could be eliminated or re-

duced to a sufficient extent by actions taken under a Federal law (or laws) other than TSCA administered in whole or in part by the Administrator, a finding that it is in the public interest to proceed against such risk under TSCA. Any such finding shall be accompanied by a brief statement discussing:

(i) All relevant aspects of the risk;

(ii) A comparison of the estimated costs of complying with actions taken under TSCA and under such other law (or laws); and

(iii) The relative efficiency of actions under TSCA and under such other law (or laws) to protect against risk of injury.

Two or more or all of the statements required above may be combined in the same narrative for efficiency of exposition as long as each of the required points is discussed. Any statement required by this paragraph may reference other documents which are not published in the FEDERAL REGISTER. All such referenced documents shall be included in the rulemaking record. Either the statements required by this paragraph or the documents they reference shall contain a discussion of the factual, analytical, policy and legal considerations behind the agency decision to issue the proposed rule in the form chosen. A brief summary of these considerations shall be included in the preamble in any case. All factual materials and each analytical methodology seriously considered shall be fully disclosed. Significant areas of uncertainty known to the Agency under each heading shall be identified, and the manner in which the Agency intends to deal with them shall be specified.

(c) In addition to the material required under paragraph (b) of this section, each notice of proposed rulemaking shall contain:

(1) A statement of the time and place at which the informal hearing required by section 6(c)(2)(C) of TSCA shall begin, or, to the extent these are not specified, a statement that they will be specified later in a separate FEDERAL REGISTER notice *Provided*, That FEDERAL REGISTER notice of the date and city at which any informal hearing shall begin shall be given at least 30 days in advance;

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(2) A statement identifying the place at which the official record of the rulemaking is located, the hours during which it will be open for public inspection, the documents contained in it as of the date the notice of proposed rulemaking was issued, and a statement of the approximate times at which additional materials such as public comments, hearing transcripts, and agency studies in progress will be added to the record. If any material other than public comments or material generated by a hearing is added to the record after publication of the notice required by this section, and notice of its future addition was not given at the time of that initial publication, a separate FEDERAL REGISTER notice announcing its addition to the record and inviting comment shall be published;

(3) The due date for public comments, which shall be at least two weeks prior to the informal hearing for main comments and no more than two weeks after the informal hearing for reply comments;

(4) The name, address and office telephone number of the Record and Hearing Clerk for the rulemaking in question; and

(5) A nonbinding target date for issuing the final rule.

[42 FR 61259, Dec. 1977, as amended at 54 FR 21623, May 19, 1989]

§ 750.3 Record.

(a) No later than the date of proposal of a rule subject to this part, a rulemaking record for that rule shall be established. It shall consist of a separate identified filing space containing:

(1) All documents required by § 750.2(b);

(2) All documents cited in the documents required by § 750.2(b);

(3) All public comments timely received;

(4) All public hearing transcripts;

(5) All material received during an informal hearing and accepted for the record of that hearing; and

(6) Any other information which the Administrator considers to be relevant to such rule and which the Administrator identified, on or before the date of the promulgation of the rule, in a notice published in the FEDERAL REGISTER.

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All material in the record shall be appropriately indexed. Each record shall be available for public inspection during normal Agency business hours. Appropriate arrangements allowing members of the public to copy record materials that do not risk the permanent loss of such materials shall be made. All material required to be included in the record shall be added to the record as soon as feasible after its receipt by the Agency.

(b) The Record and Hearing Clerk for each rulemaking shall be responsible for Agency compliance with the requirements of paragraph (a) of this section.

§ 750.4 Public comments.

(a) Main comments shall be post-marked or received no later than the time specified in the Notice of Proposed Rulemaking and shall contain all comments on and criticisms of that Notice by the commenting person, based on information which is or reasonably could have been available to that person at the time.

(b) Reply comments shall be post-marked or received no later than two weeks after the close of all informal hearings on the proposed rule and shall be restricted to comments on:

(1) Other comments;

(2) Material in the hearing record; and

(3) Material which was not and could not reasonably have been available to the commenting party a sufficient time before main comments were due.

(c) Extensions of the time for filing comments may be granted in writing by the Record and Hearing Clerk. Application for an extension shall be made in writing. Comments submitted after the comment period and all extensions of it have expired need not be added to the rulemaking record and need not be considered in decisions concerning the rule. Unless the Notice of Proposed Rulemaking states otherwise, four copies of all comments shall be submitted.

§ 750.5 Subpoenas.

(a) Where necessary, subpoenas requiring the production of documentary material, the attendance of persons at the hearing, or responses to written