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(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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Under Section 6 of the Toxic Sub-
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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 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

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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 reduced 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;

(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

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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.

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 re-

quirements 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 questions may be issued. Subpoenas may be issued either upon request as provided in paragraph (b) of this section or by EPA on its own motion.

(b) All subpoena requests shall be in writing. Hearing participants may request the issuance of subpoenas as follows:

(1) Subpoenas for the attendance of persons, and for the production of documents or responses to questions at the legislative hearing may be requested at any time up to the deadline for filing main comments.

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(2) Subpoenas for production of documents or answers to questions after the legislative hearing may be requested at any time between the beginning of the legislative hearing and the deadline for submitting reply comments.

(c) EPA will rule on all subpoena requests filed under paragraph (b)(1) of this section no later than the beginning of the legislative hearing. Such requests may be granted, denied, or deferred. EPA will rule on all subpoena requests filed under paragraph (b)(2) of this section and all deferred subpoena requests filed under paragraph (b)(1) of this section no later than the promulgation of the final rule. Such requests shall be either granted or denied.

§ 750.6 Participation in informal hearing.

(a) Each person or organization desiring to participate in the informal hearing required by section 6(c)(2)(C) of TSCA shall file a written request to so participate with the Record and Hearing Clerk which shall be postmarked or received no later than three weeks prior to the scheduled start of such hearing. The request shall include:

(1) A brief statement of the interest of the person or organization in the proceeding;

(2) A brief outline of the points to be addressed;

(3) An estimate of the time required; and

(4) If the request comes from an organization, a nonbinding list of the persons to take part in the presentation. Organizations are requested to bring with them, to the extent possible, employees with individual expertise in and responsibility for each of the areas to be addressed. No organization not filing main comments in the rulemaking will be allowed to participate at the hearing, unless a waiver of this requirement is granted in writing by the Record and Hearing Clerk or the organization is appearing at the request of EPA or under subpoena.

(b) No later than one week prior to the start of the hearing, the Record and Hearing Clerk shall make a hearing schedule publicly available and mail or deliver it to each of the persons who requested to appear at the hearing. This schedule shall be subject to

change during the course of the hearing at the discretion of those presiding over it.

(c) Opening statements should be brief, and restricted either to points that could not have been made in main comments, or to emphasizing points which are made in main comments, but which the participant believes can be more forcefully urged in the hearing context.

§ 750.7 Conduct of legislative hearing.

(a) A panel of EPA employees shall preside at each hearing conducted under section 6(c)(2)(C) of TSCA. In appropriate cases other Executive Branch employees may also sit with and assist the panel. The membership of the panel may change as different topics arise during the hearing. In general, the panel membership will consist of agency employees with special responsibility for the final rule or special expertise in the topics under discussion. One member of the panel shall be named to chair the proceedings and shall attend throughout the hearing, unless unavoidably prevented by sickness or similar personal circumstances.

(b) The panel may question any individual or group participating in the hearing on any subject relating to the rulemaking. Cross-examination by others will normally not be permitted at this stage. It may be granted in compelling circumstances at the sole discretion of the hearing panel. However, persons in the hearing audience may submit questions in writing for the hearing panel to ask the participants, and the hearing panel may, at their discretion, ask these questions.

(c) Participants in the hearing may submit additional material for the hearing record and shall submit such additional material as the hearing panel may request. All such submissions shall become part of the record of the hearing. A verbatim transcript of the hearing shall be made.

§ 750.8 Cross-examination.

(a) After the close of the legislative hearing conducted under § 750.7, any participant in that hearing may submit a written request for cross-examination. The request shall be received by

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EPA within one week after a full transcript of the legislative hearing becomes available and shall specify:

(1) The disputed issue(s) of material fact as to which cross-examination is requested. This shall include an explanation of why the questions at issue are “factual”, rather than of an analytical or policy nature, the extent to which they are in “dispute” in the light of the record made thus far, and the extent to which and why they can reasonably be considered “material” to the decision on the final rule; and

(2) The person(s) the participant desires to cross-examine, and an estimate of the time necessary. This shall include a statement by the cross-examination requested can be expected to result in “full and true disclosure” resolving the issue of material fact involved.

(b) Within one week after receipt of all requests for cross-examination under paragraph (a) of this section the hearing panel shall rule on them. The ruling shall be served by the Record and Hearing Clerk on all participants who have requested cross-examination and shall be inserted in the record. Written notice of the ruling shall be given to all persons requesting cross-examination and all persons to be cross-examined. The ruling shall specify:

(1) The issues as to which cross-examination is granted,

(2) The persons to be cross-examined on each issue,

(3) The persons to be allowed to conduct cross-examination, and

(4) Time limits for the examination of each witness by each cross-examiner.

In issuing this ruling, the panel may determine that one or more participants who have requested cross-examination have the same or similar interests and should be required to choose a single representative for purposes of cross-examination. In such a case the order shall simply assign time for cross-examination by that single representative without identifying the representative further. Subpoenas for witnesses may be issued where necessary.

(c) Within one week after the insertion into the record of the ruling under

paragraph (b) of this section, the hearing at which the cross-examination will be conducted shall commence. One or more members of the original panel shall preside for the Agency. The panel shall have authority to conduct cross-examination on behalf of any participant, although as a general rule this right will not be exercised. The panel shall also have authority to modify the governing ruling in any respect and to make new rulings on group representation under section 6(c)(3)(C) of TSCA. A verbatim transcript of the hearing shall be made.

(d)(1) No later than the time set for requesting cross-examination, a hearing participant may request that other alternative methods of clarifying the record (such as informal conferences or the submittal of additional information) be used. Such requests may be submitted either in lieu of cross-examination requests, or in conjunction with them.

(2) The panel in passing on a cross-examination request may as a precondition to ruling on its merits require that alternative means of clarifying the record be used whether or not that has been requested under paragraph (d)(1) of this section. In such a case the results of the use of such alternative means shall be made available to the person requesting cross-examination of a one-week comment period, and the panel shall make a final ruling on cross-examination within one week thereafter.

(e) Waivers or extensions of any deadline in this section applicable to persons other than EPA may be granted on the record of the hearing by the person chairing it or in writing by the Record and Hearing Clerk.

§ 750.9 Final rule.

(a) As soon as feasible after the deadline for submittal of reply comments, the Agency shall issue a final rule. Final versions of the statements required by paragraph (b) of § 750.2 shall be published in the FEDERAL REGISTER together with the final rule. The Agency shall also publish at that time:

(1) A list of all material added to the record (other than public comments and material from the hearing record)

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which has not previously been listed in a FEDERAL REGISTER document, and

- (2) The effective date of the rule.
- (b) [Reserved]

APPENDIX A TO SUBPART A OF PART 750

To assist in reading the regulations set forth above, this appendix sets forth the principal stages through which rules promulgated under section 6 of TSCA will pass.

The second column gives the relationship that one date bears to another whenever that relationship is specified in the regulations, and cites the governing provision. The third column contains estimates of the time that a typical rulemaking is likely to require to reach and complete each stage of these proceedings. In drawing up this third column, we have assumed that 60 days will be allowed for the submission of main comments; that the legislative phase of the informal hearing will take two weeks, and that cross-examination will take four days. Since these are only estimates, in any given rulemaking shorter or longer times may actually be required for each of these stages.

Stage	Timing in relation to other stages	Estimated total time elapsed (days)
Proposed regulation	Sec. 750.2.	
Requests to participate in informal hearing due.	3 weeks prior to beginning of hearing (§ 750.2(a)).	53
Main comments due	2 weeks prior to beginning of hearing (§ 750.2(c)(3)).	60
Begin informal hearing.	74
End legislative hearing.	88
Requests for cross-examination due.	1 week after end of legislative hearing (§ 750.8(a)).	95
Ruling on cross-examination requests.	1 week after requests are due (§ 750.8(b)).	102
Cross-examination begins.	1 week after ruling on cross-examination requests (§ 750.8(c)).	109
Cross-examination ends; informal hearing ends.	113
Reply comments due	2 weeks after end of informal hearing (§ 750.4(b)).	127

Subpart B—Interim Procedural Rules for Manufacturing Exemptions

SOURCE: 43 FR 50905, Nov. 1, 1978, unless otherwise noted.

§ 750.10 Applicability.

Sections 750.10–750.21 apply to all rulemakings under authority of section

6(e)(3)(B) of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2605(e)(3)(B) with respect to petitions filed pursuant to § 750.11(a) of this part.

§ 750.11 Filing of petitions for exemption.

(a) *Who may file.* Any person seeking an exemption from the PCB manufacturing ban imposed by section 6(e)(3)(A) of TSCA may file a petition for exemption. Petitions must be submitted on an individual basis for each manufacturer or individual affected by the 1979 manufacturing ban.

(b) *Where to file.* All petitions pertaining to:

(1) PCB use, which includes storage for use or reuse, manufacture, processing related to manufacture and use, and distribution in commerce related to use or processing for use, must be submitted to: OPPT Document Control Officer (7407T), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

(2) PCB disposal, which includes cleanup, storage for disposal, processing related to disposal, distribution in commerce related to disposal or processing for disposal, and decontamination, must be submitted to: Document Control Officer, Office of Resource Conservation and Recovery (5305P), Environmental Protection Agency, 1200 Pennsylvania, NW., Washington, DC 20460–0001.

(c) *Content of petition.* Each petition shall contain the following:

(1) Name, address and telephone number of petitioner.

(2) Description of PCB ban exemption requested, including items to be manufactured and nature of manufacturing process—such as smelting.

(3) Location(s) of manufacturing sites requiring exemption.

(4) Length of time requested for exemption (maximum length of exemption is 1 year).

(5) Amount of PCB chemical substance or PCB mixture (by pounds and/or volume) to be manufactured or used during requested exemption period and the manner of release of PCB's into the environment associated with such manufacture or use.

(6) The basis for the petitioner's contention that under section 6(e)(3)(B)(i)