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(1) The test which provided the basis for approval of the exemption application has not been started by the deadlines for initiation of testing adopted in the test rule or modified in accordance with § 790.55; or

(2) Data required by the test rule have not been generated in accordance with the test standards or submitted in accordance with the deadlines for submission of test data that were adopted in the test rule or modified in accordance with § 790.55; or

(3) The testing has not been conducted or the data have not been generated in accordance with the Good Laboratory Practice requirements in part 792 of this chapter.

(b) If EPA determines that one or more of the criteria listed in paragraph (a) of this section has been met, EPA will notify each holder of an affected conditional exemption by certified mail or FEDERAL REGISTER notice of EPA's intent to terminate that conditional exemption.

(c) Within 30 days after receipt of a letter of notification or publication of a notice in the FEDERAL REGISTER that EPA intends to terminate a conditional exemption, the exemption holder may submit information to rebut EPA's preliminary decision or notify EPA by letter of its intent to conduct the required test pursuant to the test standard established in the final test rule. Such a letter of intent shall contain all of the information required by § 790.45(c).

(d)(1) The exemption holder may also include a request for a hearing. Hearings will be held in accordance with the procedures set forth in § 790.97.

(2) Hearing requests must be in writing and must be received by EPA within 30 days after receipt of the letter or publication in the FEDERAL REGISTER notice described in paragraph (b) of this section.

(e) EPA will notify the exemption holder by certified letter or by FEDERAL REGISTER notice of EPA's final decision concerning termination of conditional exemptions and will give instructions as to what actions the former exemption holder must take to avoid being found in violation of the test rule.

§ 790.97 Hearing procedures.

(a) Hearing requests must be in writing to EPA and must include the applicant's basis for appealing EPA's decision.

(b) If more than one applicant has requested a hearing on similar grounds, all of those appeals will be considered at the same hearing unless confidentiality claims preclude a joint hearing.

(c) EPA will notify each applicant of EPA's decision within 60 days after the hearing.

§ 790.99 Statement of financial responsibility.

Each applicant for an exemption shall submit the following sworn statement with his or her application:

> I understand that if this application is granted before the reimbursement period described in section 4(c)(3)(B) of TSCA expires, I must pay fair and equitable reimbursement to the person or persons who incurred or shared in the costs of complying with the requirement to submit data and upon whose data the granting of my application was based.

PART 791—DATA REIMBURSEMENT

Subpart A—General Provisions

Sec.
791.1 Scope and authority.
791.2 Applicability.
791.3 Definitions.

Subpart B—Hearing Procedures

791.20 Initiation of reimbursement proceeding.
791.22 Consolidation of hearings.
791.27 Pre-hearing preparation.
791.29 Appointment of hearing officer.
791.30 Hearing procedures.
791.31 Expedited procedures.
791.34 Serving of notice.
791.37 The award.
791.39 Fees and expenses.

Subpart C—Basis for Proposed Order

791.40 Basis for the proposed order.
791.45 Processors.
791.48 Production volume.
791.50 Costs.
791.52 Multiple tests.

Subpart D—Review

791.60 Review.

Subpart E—Final Order

791.85 Availability of final Agency order.

Subpart F—Prohibited Acts

791.105 Prohibited acts.

AUTHORITY: 15 U.S.C. 2603 and 2607.

SOURCE: 48 FR 31791, July 11, 1983, unless otherwise noted.

Subpart A—General Provisions

§ 791.1 Scope and authority.

(a) This part establishes procedures and criteria to be used in determining fair amounts of reimbursement for testing costs incurred under section 4(a) of the Toxic Substances Control Act (TSCA) (15 U.S.C. 2603(a)).

(b) Section 4(c) of TSCA requires EPA to develop rules for the determination of fair and equitable reimbursement (15 U.S.C. 2603 (c)).

§ 791.2 Applicability.

(a) This rule is potentially applicable to all manufacturers, importers and processors who may be required by a specific test rule promulgated under section 4(a) of TSCA to conduct tests and submit data, and who seek the assistance of the Administrator in determining the amount or method of reimbursement. Persons subject to a test rule have an obligation from the date the test rule becomes effective until the end of the reimbursement period, either to test or to obtain an exemption and pay reimbursement.

(b) The provisions of this rule will take effect only when private efforts to resolve a dispute have failed and a manufacturer or processor requests EPA's assistance.

§ 791.3 Definitions.

Terms defined in the Act, and not explicitly defined herein, are used with the meanings given in the Act.

(a) *The Act* refers to the Toxic Substances Control Act (TSCA) (15 U.S.C. 2601 *et seq.*).

(b) *The Agency* or *EPA* refers to the Environmental Protection Agency.

(c) *Byproduct* refers to a chemical substance produced without a separate commercial intent during the manufacture, processing, use or disposal of another chemical substance or mixture.

(d) *Dispute* refers to a present controversy between parties subject to a test rule over the amount or method of reimbursement for the cost of developing health and environmental data on the test chemical.

(e) *Exemption holder* refers to a manufacturer or processor, subject to a test rule, that has received an exemption under sections 4(c)(1) or 4(c)(2) of TSCA from the requirement to conduct a test and submit data.

(f) *Impurity* refers to a chemical substance unintentionally present with another chemical substance or mixture.

(g) A *party* refers to a person subject to a section 4 test rule, who:

(1) Seeks reimbursement from another person under these rules, or

(2) From whom reimbursement is sought under these rules.

(h) *Reimbursement period* refers to a period that begins when the data from the last non-duplicative test to be completed under a test rule is submitted to EPA and ends after an amount of time equal to that which had been required to develop that data or after 5 years, whichever is later.

(i) *Small business* refers to a manufacturer or importer whose annual sales, when combined with those of its parent company (if any) are less than $30 million.

(j) *Test rule* refers to a regulation ordering the development of data on health or environmental effects or chemical fate for a chemical substance or mixture pursuant to TSCA section 4(a).

Subpart B—Hearing Procedures

§ 791.20 Initiation of reimbursement proceeding.

(a) When persons subject to a test rule are unable to reach an agreement on the amount or method of reimbursement for test data development as described in TSCA section 4(c)(3)(A), any of them may initiate a proceeding by filing two signed copies of a request for a hearing with a regional office of the American Arbitration Association and mailing a copy of the request to EPA, and to each person from whom they

seek reimbursement, or who seeks reimbursement from them.

(b) The request for hearing must contain the following:

(1) The names and addresses of the filing party and its counsel, if any.

(2) Identification of the test rule under which the dispute arose.

(3) A list of the parties from whom reimbursement is sought or who are seeking reimbursement, a brief description of the attempts to reach agreement and a concise explanation of the issues on which the parties are unable to agree.

(c) The request for a hearing shall be accompanied by the appropriate administrative fee, as provided in a current Fee Schedule of the American Arbitration Association.

§ 791.22 Consolidation of hearings.

(a) Promptly upon receipt of the request for a hearing, the Administrator will publish a notice in the FEDERAL REGISTER, advising those subject to the test rule that a request for a hearing has been made.

(b) Any other person wishing to participate in the hearing shall so notify EPA within 45 days of the FEDERAL REGISTER notice. EPA will promptly inform the regional office of the American Arbitration Association where the request has been filed of the additional parties.

§ 791.27 Pre-hearing preparation.

(a) *Responses to requests for hearings.* After filing of the request for hearing, if any other party desires to file an answer it shall be made in writing and filed with the American Arbitration Association, and a copy thereof shall be mailed to the other parties within a period of fourteen days from the date of receiving the complete list of parties. After the hearing officer is appointed, however, no new or different claim may be submitted except with the hearing officer's consent.

(b) *Pre-hearing conference.* At the request of the parties or at the discretion of the American Arbitration Association, a pre-hearing conference with a representative of the American Arbitration Association and the parties or their counsel will be scheduled in appropriate cases to arrange for an exchange of information and the stipulation of uncontested facts so as to expedite the proceedings.

(c) *Fixing of locale.* The parties may mutually agree on the locale where the hearing is to be held. If the locale is not designated within 45 days from the time the complete list of parties is received, the American Arbitration Association shall have power to determine the locale. Its decision shall be final and binding. If any party requests, and informs the other parties of its request, that the hearing be held in a specific locale and the other parties file no objection thereto within 14 days of the request, the locale shall be the one requested.

(d) *Time and place.* The hearing officer shall fix the time and place for each hearing. The American Arbitration Association will mail notice to each party at least 14 days in advance.

§ 791.29 Appointment of hearing officer.

(a) *Qualifications of hearing officer.* All hearing officers shall be neutral, subject to disqualification for the reasons specified in paragraph (f) of this section.

(b) *Appointment from panel.* Promptly after receiving the complete list of parties at the close of the notice period described in § 791.22, the American Arbitration Association shall submit simultaneously to each party to the dispute an identical list of names. Each party to the dispute shall have thirty days from the mailing date in which to cross off any names objected to, number the remaining names to indicate the order of preference, and return the list to the American Arbitration Association. If a party does not return the list within the time specified, all persons named therein shall be deemed acceptable to that party. From among the persons who have been approved on all lists, and in accordance with the designated order of mutual preference, the American Arbitration Association shall invite the acceptance of a hearing officer to serve. If the parties fail to agree upon any of the persons named, or if acceptable hearing officers are unable to act, or if for any other reason the appointment cannot be made from the

submitted lists, the American Arbitration Association shall have the power to make the appointment without the submission of any additional list.

(c) *Nationality of hearing officer in international dispute.* If one of the parties is a national or resident of a country other than the United States, the hearing officer shall upon the request of any party, be appointed from among the nationals of a country other than that of the parties.

(d) *Number of hearing officers.* The dispute shall be heard and determined by one hearing officer unless the American Arbitration Association, in its discretion, directs that a greater number of hearing officers be appointed.

(e) *Notice of appointment.* Notice of the appointment of the hearing officer, together with a copy of these rules, and the signed acceptance of the hearing officer shall be filed prior to the opening of the first hearing.

(f) *Disclosure and challenge procedure.* A person appointed as hearing officer shall disclose to the American Arbitration Association any circumstances likely to affect impartiality, including any bias or any financial or personal interest in the result of the hearing or any past or present relationship with the parties or their counsel. Upon receipt of such information from such hearing officer or other source, the American Arbitration Association shall communicate such information to the parties, and, if it deems it appropriate to do so, to the hearing officer and others. Thereafter, the American Arbitration Association shall determine whether the hearing officer should be disqualified and shall inform the parties of its decision, which shall be conclusive.

(g) *Vacancies.* If any hearing officer should resign, die, withdraw, refuse, be disqualified or be unable to perform the duties of the office, the American Arbitration Association may, on proof satisfactory to it, declare the office vacant. Vacancies shall be filled in accordance with the applicable provisions of these rules and the matter shall be reheard unless the parties shall agree otherwise.

§ 791.30 Hearing procedures.

(a) *Representation by counsel.* Any party may be represented by counsel. A party intending to be so represented shall notify the other parties and the American Arbitration Association of the name and address of counsel at least 5 days prior to the date set for the hearing at which counsel is first to appear. When a hearing is initiated by counsel, or where an attorney replies for the other party, such notice is deemed to have been given.

(b) *Stenographic record.* The American Arbitration Association shall make the necessary arrangements for the taking of a stenographic record. The parties shall share the cost of such record.

(c) *Attendance at hearings.* The hearing officer shall have the power to require the exclusion of anyone, including a party or other essential person, during the testimony of any witness to protect confidential business information. It shall be discretionary with the hearing officer to determine the propriety of the attendance of any other person.

(d) *Oaths.* Hearing officers shall swear or affirm their neutrality and their dedication to a fair and equitable resolution. Witnesses shall swear or affirm that they are telling the truth.

(e) *Order of proceedings.* (1) A hearing shall be opened by the filing of the oath of the hearing officer and by the recording of the place, time and date of the hearing, the presence of the hearing officer and parties, and counsel, if any, and by the receipt by the hearing officer of the request for hearing and answer, if any.

(2) The hearing officer may, at the beginning of the hearing, ask for statements clarifying the issues involved.

(3) The party or parties seeking reimbursement shall then present a claim and proofs and witnesses, who shall submit to questions or other examination. The party or parties from whom reimbursement is sought shall then present a defense and proofs and witnesses, who shall submit to questions or other examination. The hearing officer has discretion to vary this procedure but shall afford full and equal opportunity to all parties for the presentation of any material or relevant proofs.

(4) Exhibits, when offered by any party, shall be received in evidence by the hearing officer. The names and addresses of all witnesses and exhibits in order received shall be made a part of the record.

(f) *Hearing in the absence of a party.* A hearing may proceed in the absence of any party which, after due notice, fails to be present or fails to obtain an adjournment. An award shall not be made solely on the default of a party. The hearing officer shall require the parties who are present to submit such evidence as the hearing officer may require for the making of an award.

(g) *Evidence.* (1) The parties may offer such evidence as they desire and shall produce such additional evidence as the hearing officer may deem necessary to an understanding and determination of the dispute. The hearing officer shall be the judge of the relevancy and materiality of the evidence offered and conformity to legal rules of evidence shall not be necessary. All evidence shall be taken in the presence of all the hearing officers and of all the parties, except where any of the parties is absent in default, has waived the right to be present, or has been excluded by the hearing officer to protect confidential business information.

(2) All documents not filed with the hearing officer at the hearing, but arranged for by agreement of the parties, shall be filed with the American Arbitration Association for transmission to the hearing officer, according to the agreed-upon schedule. All parties shall be afforded opportunity to examine such documents.

(h) *Evidence by affidavit and filing of documents.* The hearing officer shall receive and consider the evidence of witnesses by affidavit, but shall give it only such weight as the hearing officer deems it entitled to after consideration of any objections made to its admission.

(i) *Closing of hearings.* The hearing officer shall specifically inquire of all parties whether they have any further proofs to offer or witnesses to be heard. Upon receiving negative replies, the hearing officer shall declare the hearings closed and record the time of closing of the hearing. If briefs are to be filed, the hearings shall be declared closed as of the final date set by the hearing officer for the receipt of briefs. If documents are to be filed as provided for in paragraph (g)(2) of this section and the date set for their receipt is later than that set for the receipt of briefs, the later date shall be the date of closing the hearings.

(j) *Reopening of hearings.* The hearings may be reopened on the hearing officer's own motion, or upon application of a party at any time before the award is made. If the reopening of the hearings would prevent the making of the award within the specified time the matter may not be reopened, unless the parties agree upon the extension of the time limit.

(k) *Waiver of oral hearings.* The parties may provide, by written agreement, for the waiver of oral hearings. If the parties are unable to agree as to the procedure, the American Arbitration Association shall specify a fair and equitable procedure.

(l) *Waiver of rules.* Any party who proceeds with the hearing after knowledge that any provision or requirement of these rules has not been complied with and who fails to state objection thereto in writing, shall be deemed to have waived the right to object.

(m) *Extensions of time.* The parties may modify any period of time by mutual agreement. The American Arbitration Association for good cause may extend any period of time established by these rules, except the time for making the award. (§ 791.37(a)) The American Arbitration Association shall notify the parties of any such extension of time and its reason therefor.

(n) *Communication with hearing officer.* There shall be no direct communication between the parties and a hearing officer other than at oral hearings. Any other oral or written communications from the parties to the hearing officer shall be directed to the American Arbitration Association for transmittal to the hearing officer.

§ 791.31 Expedited procedures.

Unless the American Arbitration Association in its discretion determines otherwise, the Expedited Procedures described in this section shall be applied in any case where the total claim

of any party does not exceed $5,000, exclusive of interest and hearing costs, and may be applied in other cases if the parties agree.

(a) *Application of rules.* The expedited hearings will be conducted according to the same procedures as the regular ones, except for those specifically changed by the expedited rules in this section, § 791.31.

(b) *Notice by telephone.* The parties shall accept all notices from the American Arbitration Association by telephone. Such notices by the American Arbitration Association shall subsequently be confirmed in writing to the parties. Notwithstanding the failure to confirm in writing any notice or objection hereunder, the proceeding shall nonetheless be valid if notice or obligation has, in fact, been given by telephone.

(c) *Appointment and qualifications of hearing officers.* The American Arbitration Association shall submit simultaneously to each party to the dispute an identical list of five persons from which one hearing officer shall be appointed. Each party shall have the right to strike two names from the list on a peremptory basis. The list is returnable to the American Arbitration Association within 10 days from the date of mailing. If for any reasons the appointment cannot be made from the list, the American Arbitration Association shall have the authority to make the appointment without the submission of additional lists. Such appointment shall be subject to disqualification for the reasons specified in § 791.29(f). The parties shall be given notice by telephone by the American Arbitration Association of the appointment of the hearing officer. The parties shall notify the American Arbitration Association, by telephone, within 7 days of any objections to the hearing officer(s) appointed. Any objection by a party to such hearing officer shall be confirmed in writing to the American Arbitration Association with a copy to the other parties.

(d) *Time and place of hearing.* The hearing officer shall fix the date, time and place of the hearing. The American Arbitration Association will notify the parties by telephone, 7 days in advance of the hearing date. Formal notice of hearing will be sent by the American Arbitration Association to the parties.

(e) *The hearing.* Generally, the hearing shall be completed within 1 day. The hearing officer, for good cause shown, may schedule an additional hearing to be held within 5 days.

(f) *Time of award.* Unless otherwise agreed to by the parties, the Award shall be rendered not later than 15 business days from the date of the closing of the hearing.

§ 791.34 Serving of notice.

(a) Each party shall be deemed to have consented that any papers, notices or process necessary or proper for the initiation or continuation of a hearing under these rules and for any appeal to EPA or any court action in connection therewith may be served upon such party by mail addressed to such party or its attorney at its last known address or by personal service, within or without the state wherein the arbitration is to be held (whether such party be within or without the United States of America), provided that reasonable opportunity to be heard with regard thereto has been granted such party.

(b) The American Arbitration Association shall, upon the written request of a party, furnish to such party, at its expense, certified facsimiles of any papers in the American Arbitration Association's possession that may be required in appeal to EPA or judicial proceedings relating to the hearing.

§ 791.37 The award.

(a) *Time of award.* The award shall be made promptly by the hearing officer and, unless otherwise agreed by the parties, no later than 30 days from the date of closing the hearings, or if oral hearings have been waived, from the date of transmitting the final statements and proofs to the hearing officer.

(b) *Form of award.* The award shall be in writing and shall be signed either by the sole hearing officer or by at least a majority if there is more than one. It shall contain a concise statement of its basis and rationale, and a timetable for payment of any ordered reimbursement.

(c) *Delivery of award to parties.* Parties shall accept as legal delivery of

the award the delivery of the award or a true copy thereof by certified mail to the party at its last known address or to its attorney, or by personal service.

§ 791.39 Fees and expenses.

(a) *Administrative fees.* (1) As a not-for-profit organization, the American Arbitration Association shall prescribe an Administrative Fee Schedule and a Refund Schedule to compensate it for the cost of providing administrative services. The schedule in effect at the time of filing or the time of refund shall be applicable.

(2) The administrative fees shall be advanced by the initiating party or parties, subject to final apportionment by the hearing officer in the award. The administrative fee is increased by 10 percent of the original for each additional party.

(3) Fees and expenses in excess of the limit contained in section 26(b) of TSCA ($2,500 per person, or $100 per small business) will be paid by EPA.

(b) *Expenses.* Subject to paragraph (a)(3) of this section, all expenses of the hearing, including the cost of recording (though not transcribing) the hearing and required traveling and other expenses of the hearing officer and of American Arbitration Association representatives, and the expenses of any witness or the cost of any proofs produced at the direct request of the hearing officer, shall be borne equally by the parties, unless they agree otherwise, or unless the hearing officer, in the award, assesses such expenses or any part thereof against any specified party or parties.

(c) *Hearing officer's fee.* Hearing officers will normally serve without a fee. In prolonged or special cases the American Arbitration Association in consultation with the Administrator may determine that payment of a fee by the parties is appropriate and may establish a reasonable amount, taking into account the extent of service by the hearing officer and other relevant circumstances of the case. Any arrangements for compensation shall be made through the American Arbitration Association and not directly between the parties and the hearing officer.

Subpart C—Basis for Proposed Order

§ 791.40 Basis for the proposed order.

(a) The hearing officer shall propose a fair and equitable amount of reimbursement. The formula in paragraph (b) of this section shall be presumed to be fair and equitable as applied to all persons subject to a test rule. However, the hearing officer has the discretion to modify the formula, or to use some other basis for allocation if necessary. Additional factors that may be taken into account include, but are not limited to, relative amounts of exposure attributable to each person and the effect of the reimbursement share on competitive position.

(b) In general, each person's share of the test cost shall be in proportion to its share of the total production volume of the test chemical:

$$R_x = C\frac{V_x}{V_t}$$

Where:

R=the reimbursement share owed by company X.

C=the total cost of the testing required by the test rule.

V_x=the volume of the test chemical produced or imported by company X over the period defined by § 791.48.

V_t=the total volume of the test chemical produced or imported over the period defined by § 791.48.

(c) The burden of proposing modifications to the formula shall lie with the party requesting the modification.

§ 791.45 Processors.

(a) Generally, processors will be deemed to have fulfilled their testing and reimbursement responsibilities indirectly, through higher prices passed on by those directly responsible, the manufacturers. There are three circumstances in which processors will have a responsibility to provide reimbursement directly to those paying for the testing:

(1) When a test rule or subsequent FEDERAL REGISTER notice pertaining to a test rule expressly obligates processors as well as manufacturers to assume direct testing and data reimbursement responsibilities.

(2) When one or more manufacturers demonstrate to the hearing officer that it is necessary to include processors in order to provide fair and equitable reimbursement in a specific case.

(3) When one or more processors voluntarily agree to reimburse manufacturers for a portion of test costs. Only those processors who volunteer will incur the obligation.

(b) A hearing including processors shall be initiated in the same way as those including only manufacturers. Voluntary negotiations must be attempted in good faith first, and the request for a hearing must contain the names of the parties and a description of the unsuccessful negotiations.

(c) When processors as well as manufacturers are required to provide reimbursement, the hearing officer will decide for each case how the reimbursement should be allocated among the participating parties. When a test rule is applicable solely to processors, the hearing officer will apply the formula to the amount of the test chemical purchased or processed.

§ 791.48 Production volume.

(a) Production volume will be measured over a period that begins one calendar year before publication of the final test rule in the FEDERAL REGISTER and continues up to the latest data available upon resolution of a dispute.

(b) For the purpose of determining fair reimbursement shares, production volume shall include amounts of the test chemical imported in bulk form and mixtures, and the total domestic production of the chemical including that produced as a byproduct. Impurities will not be included unless the test rule specifically includes them.

(c) Amounts of the test chemical manufactured for export will not be included unless covered by a finding under TSCA section 12(a)(2).

(d) Chemicals excluded from the jurisdiction of TSCA by section 3(2)(B) need not be included in the computation of production volume. (Chemicals used as intermediates to produce pesticides are covered by TSCA.)

(e) The burden of establishing the fact that particular amounts of the test chemical are produced for exempt purposes lies with the party seeking to exclude those amounts from the calculation of his production volume.

§ 791.50 Costs.

(a) All costs reasonable and necessary to comply with the test rule, taking into account the practices of other laboratories in conducting similar tests, are eligible for reimbursement. Necessary costs include:

(1) Direct and indirect costs of planning, conducting, analyzing and submitting the test results to EPA.

(2) A reasonable profit, and a reasonable rate of interest and depreciation on the tester's initial capital investment.

(3) The cost of repeating or repairing tests where failure was demonstrably due to some cause other than negligence of the tester.

(b) Costs attributable to tests beyond those specified by EPA shall not be eligible for reimbursement under this rule.

§ 791.52 Multiple tests.

When more than one of a particular kind of test required by the test rule is performed, the additional costs will be shared among all those holding exemptions. The costs of all the tests will be added together and each exemption holder shall be responsible for a share of the total which is equal to its share of the total production of the test chemical. The exemption holders shall divide their shares between test sponsors in proportion to the costs of their respective tests. Those sponsoring a particular test do not have to obtain exemptions for that test and therefore do not have reimbursement responsibilities for the same tests done by others.

Subpart D—Review

§ 791.60 Review.

(a) The hearing officer's proposed order shall become the final Agency order 30 days after issuance unless within the 30-day period one of the parties requests Agency review or the Administrator of his own initiative decides to review the proposed order.

(b) The proposed order may be reviewed upon the record of the hearing and the petitions for review. If

necesary, the Administrator may order the transcription of the stenographic record of the hearing, written briefs, oral arguments or any other reasonable aids to making an equitable decision.

(c) The final Agency order may be reviewed in federal court as provided by 26 U.S.C. 2603(c).

Subpart E—Final Order

§ 791.85 Availability of final Agency order.

The final Agency order shall be available to the public for inspection and copying pursuant to 5 U.S.C. 552(a)(2), subject to necessary confidentiality restrictions.

Subpart F—Prohibited Acts

§ 791.105 Prohibited acts.

Failure to provide information required by the Agency or to pay the amounts awarded under this rule within time alloted in the final order shall constitute a violation of 15 U.S.C. 2614(1) or 2614(3).

PART 792—GOOD LABORATORY PRACTICE STANDARDS

Subpart A—General Provisions

Sec.
792.1 Scope.
792.3 Definitions.
792.10 Applicability to studies performed under grants and contracts.
792.12 Statement of compliance or non-compliance.
792.15 Inspection of a testing facility.
792.17 Effects of non-compliance.

Subpart B—Organization and Personnel

792.29 Personnel.
792.31 Testing facility management.
792.33 Study director.
792.35 Quality assurance unit.

Subpart C—Facilities

792.41 General.
792.43 Test system care facilities.
792.45 Test system supply facilities.
792.47 Facilities for handling test, control, and reference substances.
792.49 Laboratory operation areas.
792.51 Specimen and data storage facilities.

Subpart D—Equipment

792.61 Equipment design.
792.63 Maintenance and calibration of equipment.

Subpart E—Testing Facilities Operation

792.81 Standard operating procedures.
792.83 Reagents and solutions.
792.90 Animal and other test system care.

Subpart F—Test, Control, and Reference Substances

792.105 Test, control, and reference substance characterization.
792.107 Test, control, and reference substance handling.
792.113 Mixtures of substances with carriers.

Subpart G—Protocol for and Conduct of A Study

792.120 Protocol.
792.130 Conduct of a study.
792.135 Physical and chemical characterization studies.

Subparts H–I [Reserved]

Subpart J—Records and Reports

792.185 Reporting of study results.
792.190 Storage and retrieval of records and data.
792.195 Retention of records.

AUTHORITY: 15 U.S.C. 2603.

SOURCE: 54 FR 34043, Aug. 17, 1989, unless otherwise noted.

Subpart A—General Provisions

§ 792.1 Scope.

(a) This part prescribes good laboratory practices for conducting studies relating to health effects, environmental effects, and chemical fate testing. This part is intended to ensure the quality and integrity of data submitted pursuant to testing consent agreements and test rules issued under section 4 of the Toxic Substances Control Act (TSCA) (Pub. L. 94–469, 90 Stat. 2006, 15 U.S.C. 2603 *et seq.*).

(b) This part applies to any study described by paragraph (a) of this section which any person conducts, initiates, or supports on or after September 18, 1989.

(c) It is EPA's policy that all data developed under section 5 of TSCA be in accordance with provisions of this part.