(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 Availablity 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.

Subpart B—Organization and Personnel

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. If data are not developed in accordance with the provisions of this part, EPA will consider such data insufficient to evaluate the health and environmental effects of the chemical substances unless the submitter provides additional information demonstrating that the data are reliable and adequate.

§ 792.3 Definitions.

As used in this part the following terms shall have the meanings specified:

Batch means a specific quantity or lot of a test, control, or reference substance that has been characterized according to § 792.105(a).

Carrier means any material, including but not limited to, feed, water, soil, and nutrient media, with which the test substance is combined for administration to a test system.

Control substance means any chemical substance or mixture, or any other material other than a test substance, feed, or water, that is administered to the test system in the course of a study for the purpose of establishing a basis for comparison with the test substance for chemical or biologicaI measurements.

EPA means the U.S. Environmental Protection Agency.

Experimental start date means the first date the test substance is applied to the test system.

Experimental termination date means the last date on which data are collected directly from the study.

FDA means the U.S. Food and Drug Administration.

Person includes an individual, partnership, corporation, association, scientific or academic establishment, government agency, or organizational unit thereof, and any other legal entity.

Quality assurance unit means any person or organizational element, except