allow direct consultation among agencies at the local levels. The proposed approval is limited to Transportation Conformity. The EPA approved the SIP revision for conformity of general Federal actions on September 13, 1996 (61 FR 48409).

The EPA is proposing to approve this SIP revision under sections 110(k) and 176 of the Clean Air Act. The EPA has given its rationale for the proposed approval and other information in the Final Rules section of this **Federal Register**.

In the ''Rules and Regulations'' section of **Federal Register**, EPA is approving the State's SIP revision as a direct final rule without prior proposal because EPA views this as a noncontroversial revision and anticipates no adverse comment. The EPA has explained its reasons for this approval in the preamble to the direct final rule. If EPA receives no adverse comment, no further action will be taken on this proposed rule. If EPA receives adverse comment, the direct final rule will be withdrawn and it will not take effect. The EPA will address all public comments in a subsequent final rule based on this proposed rule. The EPA will not institute a second comment period on this action. Any parties interested in commenting must do so at this time.

DATES: We must receive your comments in writing, postmarked by January 28, 2000.

ADDRESSES: You should send your written comments to Mr. Thomas H. Diggs, Chief, Air Planning Section (6PDL) at the address given below. You may inspect copies of the State's SIP revision and other relevant information during normal business hours at the following locations. If you wish to examine these documents, you should make an appointment with the appropriate office at least 24 hours before the visiting day.

Air Planning Section (6PDL), Multimedia Planning and Permitting Division, Environmental Protection Agency, Region 6, 1445 Ross Avenue, Dallas, TX 75202; Telephone: (214) 665–7214.

Louisiana Department of Environmental Quality, Air Quality, 7290 Bluebonnet Boulevard, Baton Rouge, LA 70810; Telephone: (225) 765–0178.

FOR FURTHER INFORMATION CONTACT: Mr. J. Behnam, P.E., Air Planning Section (6PDL), Multimedia Planning and Permitting Division, Environmental Protection Agency, Region 6, 1445 Ross Avenue, Dallas, TX 75202; Telephone (214) 665–7247.

SUPPLEMENTARY INFORMATION: If you wish to obtain additional information, you should read the Direct Final rule which is located in the Rules section of this **Federal Register**.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: November 22, 1999.

Gregg A. Cooke,

Regional Administrator, Region 6.

[FR Doc. 99–33449 Filed 12–28–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[AK–21–1709–b; FRL–6515–4]

Approval and Promulgation of State Implementation Plans: Alaska

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA proposes to approve the State Implementation Plan (SIP) revisions submitted by the State of Alaska which include revisions to Alaska's Air Quality Control Regulations, Transportation Conformity Rule (18 AAC 50); Emissions Inspection and Maintenance (I/M) requirements for Motor Vehicles (18 AAC 52); and Fuel Requirements for Motor Vehicles (18 AAC 53).

These revisions include changing the I/M program schedule for cars subject to I/M from annual to biennial, replacing the CO contingency measures for Anchorage, and streamlining several portions of the Alaska Air Quality Control Plan for more efficient reading and organization. They also include updating and streamlining the Alaska's Transportation Conformity Rule. In the Final Rules section of this **Federal Register**, the EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal amendment and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this action, no further activity is contemplated. If the EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. The EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time.

DATES: Written comments must be received in writing by January 28, 2000.

ADDRESSES: Written comments should be addressed to Montel Livingston, Environmental Protection Specialist (OAQ–107), Office of Air Quality, at the EPA Regional Office listed below. Copies of the state submittal are available at the following addresses for inspection during normal business hours. The interested persons wanting to examine these documents should make an appointment with the appropriate office at least 24 hours before the visiting day.

Environmental Protection Agency, Region 10, Office of Air Quality, 1200 6th Avenue, Seattle, WA 98101

The Alaska Department of Environmental Conservation, 410 Willoughby Avenue, Suite 105, Juneau, AK 99801–1795.

FOR FURTHER INFORMATION CONTACT: Ms. Montel Livingston, Office of Air Quality, (OAQ–107), EPA, 1200 6th Avenue, Seattle, WA 98101, (206) 553–0180.

SUPPLEMENTARY INFORMATION: For additional information, see the Direct Final rule which is located in the Rules section of this **Federal Register**.

Dated: December 10, 1999.

Chuck Clarke,

Regional Administrator,

Region 10.

[FR Doc. 99–33526 Filed 12–28–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR PARTS 160, 792, and 806

RIN 2020–AA26

[ECDIC–1998–02; FRL–5782–7]

Consolidation of Good Laboratory Practice Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to consolidate its Good Laboratory Practice Standards (GLPS), which currently exist in two separate regulations at 40 CFR part 160 and 40 CFR part 792. The proposed consolidated GLPS rule would be applicable to programs under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Toxic Substances Control Act (TSCA) to which the current rules apply. In addition to the proposed consolidation, EPA is also proposing amendments to the GLPS that streamline and ease

compliance while still maintaining the rule's data integrity assurance purpose. The consolidation will reduce the volume of regulations administered by EPA without adversely affecting current data integrity requirements. GLPS are intended to ensure the integrity of data gathered from studies in a wide variety of disciplines such as toxicology, ecological effects, chemical fate, residue chemistry, and product performance testing. Under FIFRA, compliance with regulations on GLPS applies to all studies required to be submitted in support of pesticide registrations, reregistrations, and experimental use permits. Under TSCA, GLPS are required for testing conducted pursuant to consent agreements/orders and test rules issued under sections 4 and 5 of that Act. Failure to comply with applicable GLPS is an actionable violation which may result in civil or criminal penalties, and can render data from non-compliant studies unacceptable for consideration by EPA.

DATES: Comments, identified by the docket control number EC-1998-02, must be received by March 29, 2000.

ADDRESSES: By mail, submit comments to: Enforcement and Compliance Docket and Information Center (2201A), Office of Enforcement and Compliance Assurance, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Enforcement and Compliance Docket and Information Center, Office of Enforcement and Compliance Assurance, Rm. 4033, Ariel Rios Bldg., 1200 Pennsylvania Ave., Washington, DC. The telephone number for the Enforcement and Compliance Docket and Information Center is (202) 564–2614.

Information submitted and any comment(s) concerning this proposed rule may be claimed confidential by marking any or all of that information as ''Confidential Business Information'' (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment(s) that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice to the submitter. Information on the proposed rule and any written comments received will be available for public inspection in Room 4033 at the Ariel Rios Bldg. address given above, from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to Donna Williams@epamail.epa.gov. Comments and data will also be accepted on disks in WordPerfect in 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket control number EC-1998-02. No CBI should be submitted through e-mail. Electronic comments on this proposed rule, but not the record, may be viewed or new comments filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: David Stangel, Agriculture and Ecosystems Division, Office of Compliance (2225A), U. S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Telephone: (202) 564–4162, e-mail: stangel.david@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

EPA proposes to amend the FIFRA GLPS (40 CFR part 160) and the TSCA GLPS (40 CFR part 792) to consolidate these regulations into one rule. In addition, EPA proposes to provide clarifications of certain requirements and amend other requirements of the rule to reflect the experience gained in administering the GLPS.

A. Legal Authority

These GLPS are promulgated under the authority of sections 3, 4, 5, 6, 8, 18, 24(c), and 25(a) of FIFRA, 7 U.S.C. 136 *et seq.*, as amended, sections 408, 409[1], and 701 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq.*, the Reorganization Plan No. 3 of 1970, and sections 4(b)(1) and 5 of TSCA, 15 U.S.C. 2603 *et seq.*

B. Background

EPA published FIFRA and TSCA GLPS in the **Federal Register** on November 29, 1983 (48 FR 53946 and 48 FR 53922), which were codified as 40 CFR parts 160 and 792 respectively, and were amended on August 17, 1989 (54 FR 34052 and 54 FR 34034). These TSCA and FIFRA regulations were initially promulgated to address assuring the validity of data in the wake of investigations by EPA and the Food and Drug Administration (FDA) during the mid-1970's which revealed that some studies submitted to the Agencies had not been conducted in accordance with acceptable laboratory practices. Some studies had been conducted so poorly that the resulting data could not be relied upon in EPA's regulatory decision-making process. In some cases, results were selectively reported, underreported, or fraudulently reported. In addition, it was discovered that some testing facilities displayed poor animal care procedures and inadequate recordkeeping techniques. The GLPS specify minimum practices and procedures in order to ensure the quality and integrity of data submitted to EPA in support of a research or marketing permit for a pesticide product, or the quality and integrity of data submitted in accordance with a TSCA section 4 or 5 requirement.

When EPA published its initial FIFRA and TSCA GLPS in the **Federal Register** of November 29, 1983, EPA sought to harmonize the requirements and language with those regulations promulgated by the FDA in the **Federal Register** of December 22, 1978 (43 FR 60013), and codified as 21 CFR part 58. Differences between the two Agencies' current GLPS regulations existed only to the extent necessary to reflect the Agencies' different statutory responsibilities under TSCA, FIFRA, and FFDCA. Similar to the FDA GLPS regulations, the FIFRA and TSCA GLPS delineate standards for studies required to be submitted to EPA for its regulatory decision-making.

Compliance with EPA's FIFRA and TSCA GLPS has been monitored through a program of laboratory inspections and data audits coordinated between EPA and FDA. Under an Interagency Agreement originated in 1978 between FDA and EPA, FDA carries out GLPS inspections at laboratories which conduct health effects testing. EPA primarily performs GLPS inspections for environmental laboratories and conducts data audits for health effects and environmental studies. Because of the cooperative nature of FDA's and EPA's GLPS programs, it is important that the GLPS remain substantially consistent not only between programs within each Agency but also between Agencies.

FDA revised its GLPS regulations on September 4, 1987 (52 FR 33768), to simplify the regulations and reduce the regulatory burden on testing facilities without compromising study integrity. EPA published amendments to its FIFRA and TSCA GLPS in the **Federal Register** of August 17, 1989 (54 FR 34052 and 54 FR 34043 respectively). During that rulemaking, EPA expanded the applicability of its FIFRA GLPS to cover all data required to be submitted under FIFRA.

On March 4, 1995, the President directed all Federal agencies to conduct

[1]Prior to August 3, 1996 (the effective date of the Food Quality Protection Act of 1996), data were submitted to the Agency pursuant to section 409. References in this rule to section 409 remain with respect to such data.

a comprehensive review of the regulations these agencies administer and reduce or eliminate unnecessary or duplicative regulations. In response, EPA conducted a review of its regulations to determine candidates for such reductions. During this process, EPA identified the FIFRA and TSCA GLPS as providing an opportunity for such reductions. The goal of consistency of GLPS resulted in the same regulatory language being duplicated throughout these two rules. This proposed rulemaking reflects EPA's belief that it is not necessary to duplicate the same language in two separate regulations.

Since the 1989 rulemaking, EPA has received many requests for clarifications with respect to compliance requirements, especially regarding FIFRA studies that came under GLPS coverage in 1989. EPA's responses to those requests facilitated compliance with the FIFRA GLPS rule and have been made available to the regulated community in a Question and Answer document which may be obtained from the address listed above in the ''FOR FURTHER INFORMATION CONTACT'' section.

EPA has been in communication with representatives of the regulated community who indicated that it would improve the quality of and compliance with the GLPS if previous clarifications were incorporated. As a result of these initial consultations, EPA believes that it makes sense to incorporate these clarifications and consider other suggestions for improving these regulations, and is proposing several modifications to the GLPS requirements as part of this rulemaking.

II. Summary of Proposed Changes

A. Consolidation

Currently, EPA has GLPS at 40 CFR part 160 and part 792. These rules are identical in general format, each consisting of the following subparts: A--General Provisions; B--Organization and Personnel; C--Facilities; D--Equipment; E--Testing Facilities Operation; F--Test, Control, and Reference Substances; G--Protocol for and Conduct of a Study; H and I--[Reserved]; and J--Records and Reports.

Most of the sections under these subparts are identical between the two rules. In such cases, EPA proposes to continue the current language except where amended as provided in Unit II.B. of this preamble. Some sections include rule differences for the two regulatory areas--TSCA and FIFRA. In such cases, it is necessary to provide separate, distinct sections, or subsections applicable to those programs.

Therefore, the proposed 40 CFR part 806 will continue the common language currently found in both 40 CFR parts 160 and 792. Current differences between the TSCA and FIFRA rules will be treated in one of two ways: (1) Differences which are programmatic and necessary will be continued in the form of separate regulatory provisions under the consolidated GLPS; and (2) differences that are determined to be inadvertent, e.g., typographic errors, minor grammatical differences, etc., will be eliminated.

1. *Program differences*. The two subparts in which there are significant differences between the two rules are Subpart A (General Provisions) and Subpart J (Records and Reports). All other subparts are virtually identical.

a. *Subpart A--General Provisions*—i. *§ 806.1--Scope*. Section 806.1(a) proposes to include the relevant statutory authorities under FIFRA and FFDCA (currently applicable to pesticides studies), and the authorities under TSCA (currently applicable to substances regulated under TSCA). In § 806.1(a)(2), the Agency states that the GLPS apply to any study which any person conducts, initiates, or supports by a certain date. If a study is initiated prior to that date but conducted after that date, the GLPS would apply to the study. Only if the study is completed prior to the effective date of the rule would it not be subject to the amended GLPS.

ii. *§ 806.3--Definitions*. Section 806.3 includes definitions which are specific to program areas and are currently listed separately in the two rules.

iii. *§ 806.12--Statement of Compliance or Noncompliance*. Section 806.12 proposes specific and separate applicability under the current program areas (toxics and pesticides) which provide for compliance statements.

b. *Subpart J--Records and Reports*. --§ 806.195--Retention of Records. Section 806.195 proposes separate record retention requirements for documentation records, raw data, and specimens pertaining to FIFRA and TSCA studies.

B. Clarifying Amendments

In addition to consolidating the regulations, the Agency is proposing to amend the current regulatory language in 40 CFR parts 160 and 792 to clarify certain requirements and simplify others. These amendments are being proposed in response to feedback received from the regulated community as well as comments received in response to publication of the Agency's intent to consolidate the FIFRA and TSCA GLPS.

1. *Subpart A--General Provisions*. The proposal would amend the current definitions of the terms ''carrier'' and ''test systems'' by adding the word ''air'' to each definition to clarify that air is considered both a carrier and a test system in certain circumstances. This change will alleviate confusion on this point.

EPA proposes to amend the current definition of the term ''quality assurance unit'' by deleting the phrase ''the study director'' and adding the phrase ''individual(s) directly involved in the conduct of the study, including the study director.'' This change is being proposed because it is equally improper for persons other than the study director who are working directly on the study to perform quality assurance of the study.

EPA proposes to amend the current definition of the term ''vehicle'' by adding examples of substances which are considered vehicles.

EPA proposes to amend the current §§ 160.10 and 792.10 by adding the phrase ''prior to initiation of the study,'' to the end of the sentence as well as requiring the notification to be made in writing. This change clarifies a number of questions that have been raised in the past and is in keeping with normal practices. Section 806.10 reflects the change.

EPA proposes to amend the current §§ 160.17(a)(2) and 792.17(a)(2) by changing the reference to FFDCA section 406, which was a typographical error, to section 408, the proper reference. EPA proposes to amend the term ''consent agreement'' to ''consent agreement/order'' and the reference to ''section 4 of TSCA'' to ''section 4 or 5 of TSCA'' throughout the proposed rule to reflect that GLPS are required in both test rules and consent agreements/orders, and that testing can be required under both sections 4 and 5 of TSCA. Section 806.17(a)(2) reflects these changes.

EPA proposes to amend the current §§ 160.33(f) and 792.33(f) to read: ''. . .during or at the close or termination of the study.'', to address those instances where a study is terminated prior to completion of the study. Section 806.33(f) reflects the change.

2. *Subpart B--Organization and Personnel*. EPA proposes to amend the current §§ 160.35(b)(1) and 792.35(b)(1) to include the following language ''. . .indexed to permit expedient retrieval, which identifies the. . .'' to allow the study director to employ an indexing system which may not reference the test substance but would still allow the

facility to quickly extract the information. Section 806.35(b)(1) reflects this change. EPA proposes to amend the current §§ 160.35(b)(2) and 792.35(b)(2) to read: ''. . .all protocols until study completion pertaining. . . .'' Protocols are required to be archived at the completion of a study and requiring the maintenance of another copy of the protocol would be duplicative. Section 806.35(b)(2) reflects this change.

3. *Subpart C--Facilities*. Questions have been raised in the past about the applicability of the language in the current §§ 160.43(a) and 792.43(a); specifically whether co-exposure of test species to the test substance (e.g., inhalation studies) is allowable given the requirement for proper separation of species or test systems. Co-exposure of test species in inhalation studies is allowable unless the study protocol specifically prohibits the practice. Section 806.43(a) reflects this change.

4. *Subpart D--Equipment*. The Agency proposes to amend the current §§ 160.63 and 792.63 by adding paragraph (d) to address the integrity of data stored and manipulated by computers, data processors, and automated laboratory procedures to make it clear that these types of equipment are subject to the same provisions as other laboratory equipment. Section 806.63 reflects this change.

5. *Subpart E--Testing Facilities Operation*. The Agency is proposing to amend the current §§ 160.83 and 792.83 to allow the testing facility to develop a documentation performance standard as an alternative to an expiration date for the contents of transfer bottles and wash bottles. The testing facility has the option of labeling transfer and wash bottles or developing another well documented system to ensure that these solutions have not deteriorated or exceeded their expiration date. Section 806.63 reflects this change. EPA specifically requests comment on a documentation performance standard that would provide the same assurances that the solutions have not deteriorated or exceeded their expiration date. Other alternatives being considered include the development of a list of substances that do not require expiration dates, e.g., distilled water.

6. *Subpart F--Test, Control, and Reference Substances*. The Agency proposes to amend the current §§ 160.105(b) and 792.105(b) to allow concurrent determination of solubility as well as stability of the test, control, or reference substance. The rule presently allows only concurrent determination of the stability of the test, control, or reference substance. Section 806.105(b) reflects this change.

EPA proposes to amend the current §§ 160.105(c) and 792.105(c) to allow the study director the options of discarding containers which contained the test substance, with proper recordkeeping of the disposition of the containers, or retaining the containers until the termination of the study. The proposal to relax the requirement for retention of test substance containers is being made to address the burden of retaining containers in field studies where large amounts of the test substance are used. The approach proposed is prescriptive in nature and gives the testing facility and study director EPA's position on what the Agency considers adequate documentation. EPA is requesting comments on whether such a prescriptive approach is necessary or should be relaxed to state that the study director may authorize container disposal and simply note in the raw data that this has been done.

In addition, the Agency is proposing to amend the current §§ 160.105(c) and 792.105(c) by deleting the term ''where appropriate'' from the first sentence to now read ''. . .expiration date, if any, and storage conditions necessary to maintain the identity, . . .'' because information on storage conditions is always appropriate. Section 806.105(c) reflects these changes.

The Agency proposes to amend the current §§ 160.113(a)(2) and 792.113(a)(2) by the addition of the following language ''. . .reference substance in the mixture; or if the solubility of the substance is difficult to determine, appropriate homogeneity data, by the testing facility. . .'' to address those situations in which the test, control, or reference substance is insoluble and may create emulsions that are very difficult to analyze. Section 806.113(a)(2) reflects this change. EPA proposes to amend the current §§ 160.113(b) and 792.113(b) to exempt tank mixes and solutions prepared for immediate administration (within 12 hours) in mammalian acute toxicology studies, metabolism studies, or mutagenicity studies from requirements for concentration determinations (but not from uniformity determinations) under §§ 160.113(a)(1) and 792.113(a)(1) and solubility determinations under §§ 160.113(a)(2) and 792.113(a)(2). This addition is being proposed in response to comments that these mixes must be made and used quickly, and it is not possible to perform solubility testing before the experimental start date. Section 806.113(b) reflects this change.

7. *Subpart G--Protocol for and Conduct of a Study*. EPA proposes to amend the current §§ 160.120(a)(2) and 792.120(a)(2) to exempt metabolism studies from the requirement to identify the test, control, or reference substance when their identities are to be determined during the study. In metabolism studies, the identity of the metabolite or metabolites may not be known at the time that the protocol is written. EPA proposes that the protocol need not identify reference substances for metabolites when they cannot be identified before the beginning of the study. This proposal does not affect the requirement to identify metabolism study test, reference, or control substances at the beginning of the study, unless the purpose of the study is to identify them. Section 806.120(a)(2) reflects this change.

EPA proposes to amend the current §§ 160.120(c) and 792.120(c) to allow discontinued studies or studies otherwise terminated before completion to be finalized by writing a protocol amendment with the reasons for the termination, in lieu of preparing a final report. All documentation for the terminated study must be retained in accordance with § 806.195. Sponsors are still obligated to meet section 6(a)(2) of FIFRA and section 8(e) of TSCA requirements for submission of adverse effects data including, but not limited to, those generated by terminated studies. Section 806.120(c) reflects this change.

8. *Subpart J--Records and Reports*. EPA proposes to amend the current §§ 160.185(a)(1) and 792.185(a)(1) by deleting the words ''terminated or discontinued,'' because § 806.120(c) was added to address terminated or discontinued studies. Section 806.185(a)(1) reflects this change.

EPA proposes to amend the current §§ 160.185(a)(7) and 792.185(a)(7) by deleting the phrase ''or other test organisms,'' because the required information is relevant chiefly to animal systems. Section 806.185(a)(7) reflects this change.

Finally, EPA proposes to amend the current § 792.195 by replacing the existing record retention requirements for studies submitted under sections 4 and 5 of TSCA with a single requirement to retain records for a period of 5 years following the date on which the final report of the study is submitted to the Agency. The change will simplify record retention requirements for persons required to retain records by providing a single standard for record retention. Section 806.195 reflects this change.

III. Public Docket

A record has been established for this rulemaking under docket number EC-

1998-02. This record is available for public inspection from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Rm. 4033, Office of Enforcement and Compliance Assurance, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., Washington, DC. Written requests should be mailed to: Enforcement and Compliance Docket and Information Center (2201A), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

IV. Statutory Review

In accordance with FIFRA section 25(a), this proposal was submitted to the FIFRA Scientific Advisory Panel, the Secretary of Agriculture, and appropriate Congressional Committees. No comments were received.

V. Regulatory Assessment Requirements

A. Executive Order 12866

Pursuant to Executive Order 12866 (58 FR 51735, October 4, 1993), it has been determined that this proposed action is not a ''significant regulatory action'' and is therefore not subject to the Office of Management and Budget (OMB) review. The Agency believes that the amendments associated with this action constitute regulatory relief, and therefore will not impose any additional costs or burdens. The analysis related to the costs and burdens of the original requirements were discussed in conjunction with their promulgation in 1989. Because this action consolidates the requirements contained in the original GLPS, no new costs or burdens are imposed. Instead, the Agency believes that the consolidation of the GLPS may actually increase efficiencies for those companies that are required to use both TSCA and FIFRA GLPS, because these companies will now only have one version of GLPS to use. Additionally, many of the changes in the rule allow the laboratories to use more efficient means of achieving the requirements of the GLPS. The Agency solicits comments on the impacts of this consolidation on the regulated community.

B. Executive Order 12898

Pursuant to Executive Order 12898 (59 FR 7629, February 16, 1994), entitled *Federal Actions to Address - Environmental Justice in Minority Populations and Low-Income Populations*, the Agency has considered environmental justice related issues with regard to the potential impacts of this action on the environmental and health conditions in low-income and minority communities. The Agency believes that this action will not adversely impact low-income and minority communities. These regulations consolidate existing regulations and have not been the subject of any environmental justice concerns in the past.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected Tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's proposed rule does not significantly or uniquely affect the communities of Indian tribal governments. The proposed rule does not involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this document.

D. Unfunded Mandates Reform Act and Executive Order 12875

This proposed action does not contain any new requirements or impose any additional burden because it proposes to consolidate requirements together which currently exist in two separate rulemakings. As such, this proposed action is expected to result in savings and burden relief rather than in an expenditure by any State, local, or Tribal governments, or by anyone in the private sector, and will not result in any unfunded Federal mandates as defined by Title II of the Unfunded Mandates Reform Act of 1995 (Public Law 104-4).

In addition, since this action does not contain any Federal mandates on States, localities, or Tribes, it is not subject to the requirements of Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993).

E. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that this regulatory action does not have any significant adverse economic impacts on a substantial number of small entities. This proposed rule does not impose any new requirements that would impose any adverse impacts on small entities. In consolidating the existing requirements, EPA is allowing those companies that are currently conducting various testing for use either pursuant to FIFRA or TSCA, to adhere to and follow a single GLP standard. Given the efficiencies provided, the Agency has determined that this proposal will not result in adverse impacts. As such, no impact analysis is required.

Information related to this determination has been included in the docket for this rulemaking, and, in accordance with Small Business Administration (SBA) policy, will be provided to the Chief Counsel for Advocacy of the SBA upon request. Any comments regarding the economic impacts that this regulatory action may impose on small entities should be submitted to the Agency at the address listed under Unit III. of this preamble.

F. Paperwork Reduction Act

This proposed action does not contain any new information collection requirements. The GLPS do not directly impose any information collection requirements, but they describe standards regarding testing conducted for other information collections currently approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*:

Maximum Residue Limit (MRL) Petitions on Food/Feed Crops and New Inert Ingredients (EPA ICR No. 597.06, OMB Control No. 2070–0024)

Notice of Pesticide Registration by States to Meet a Special Local Need (SLN) under FIFRA Section 24(c) (EPA ICR No. 595.06, OMB Control No. 2070–0055)

Application for New or Amended Registration (EPA ICR No. 277.10, OMB Control No. 2070–0060)

Application for Experimental Use Permit (EUP) to Ship a Pesticide for Experimental Purposes Only (EPA ICR

No. 276.08, OMB Control No. 2070–0040)

Data Call-In for Special Review Chemicals (EPA ICR No. 922.05, OMB Control No. 2070–0057)

Application and Summary Report for an Emergency Exemption for Pesticides (EPA ICR No. 596.05, OMB Control No. 2070–0032)

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15.

G. Request for Comment on Potential Voluntary Consensus Standards to Consider for Future Regulatory Actions

This proposal does not involve a regulatory action that would require the Agency to consider voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Section 12(d) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, business practices, etc.) that are developed or adopted by voluntary consensus standards bodies. The NTTAA requires EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards when the NTTAA directs the Agency to do so.

As indicated earlier, these guidelines represent an Agency effort to harmonize the test guidelines between the Office of Pesticide Programs (OPP) and the Office of Pollution Prevention and Toxics (OPPT), as well as harmonizing the OPP and OPPT test guidelines with those of the Organization for Economic Cooperation and Development. The process for developing and amending these test guidelines includes the extensive involvement of the scientific community, including peer review by the FIFRA SAP and other expert scientific panels, and providing extensive public comment.

In the future, these test guidelines could be incorporated into regulatory actions taken by EPA pursuant to TSCA section 4. Although the NTTAA requirements do not specifically apply to the issuance of these particular test guidelines today, EPA invites your comment on whether or not there are any voluntary consensus standards that should be considered during the development of any future action under TSCA. Future actions under TSCA section 4 would go through notice and comment rulemaking or be negotiated as voluntary testing enforcement agreements/consent orders/decrees, allowing for additional public comment on this issue. Nevertheless, the Agency is interested in whether or not there are any voluntary consensus standards that EPA should considered in lieu of these test guidelines when the Agency develops any future regulatory action that incorporates these test guidelines. Any comments provided will assist the Agency in complying with the NTTAA by facilitating the Agency's identification of voluntary consensus standards that should be considered during the development of a proposed regulatory action that incorporates any standards included in these test guidelines. Please submit your comments to the person identified in the FOR FURTHER INFORMATION CONTACT section.

H. Executive Order 13045

Executive Order 13045 entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997) applies to any rule that: (1) is determined to be ''economically significant'' as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

EPA interprets Executive Order 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5-501 of the Order has the potential to influence the regulation. This proposed rule is not subject to Executive Order 13045 because it does not establish an environmental standard intended to mitigate health or safety risks.

I. Executive Order 13132

On August 4, 1999, President Clinton issued a new executive order on federalism, Executive Order 13132 (64 FR 43255, August 10, 1999), which will take effect on November 2, 1999. In the interim, the current Executive Order 12612 (52 FR 41685, October 30, 1987), on federalism still applies. This proposed rule will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 12612.

List of Subjects

40 CFR Part 160

Environmental protection, Laboratories, Pesticides and pests, Reporting and recordkeeping requirements.

40 CFR Part 792

Environmental protection, Hazardous substances, Laboratories, Reporting and recordkeeping requirements.

40 CFR Part 806

Environmental protection, Data requirements, Good laboratory practice, Hazardous materials, Pesticides and pests, Reporting and recordkeeping requirements, Testing.

Dated: October 28, 1999.

Carol M. Browner,

Administrator.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

PART 160 [Removed]

1. By removing part 160.

PART 792 [Removed]

2. By removing part 792.

3. By adding subchapter S consisting of part 806 to read as follows:

SUBCHAPTER S—STANDARDS, TEST METHODS, AND GUIDELINES

PART 806—GOOD LABORATORY PRACTICE STANDARDS

Subpart A—General Provisions

Sec.

Subpart B—Organization and Personnel

Subpart C—Facilities

Subpart D—Equipment

Subpart E—Testing Facilities Operation

Subpart F—Test, Control, and Reference Substances

Subpart G—Protocol for and Conduct of a Study

Subparts H and I—[RESERVED]

Subparts J--Records and Reports

Authority: 7 U.S.C. 136a, 136c, 136d, 136f, 136j, 136t, 136v, 136w; 15 U.S.C. 2603; 21 U.S.C. 346a, 348, 371, Reorganization Plan No. 3 of 1970.

Subpart A—General Provisions

§ 806.1 Scope.

(a)(1) This part prescribes good laboratory practices for conducting studies that support or are intended to support applications for research or marketing permits for pesticide products regulated by the EPA. This part is intended to assure the quality and integrity of data submitted pursuant to sections 3, 4, 5, 8, 18, and 24(c) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136a, 136c, 136f, 136q, and 136v(c)) and sections 408 and 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended (21 U.S.C. 346a, 348).

(2) This part applies to any study described by paragraph (a)(1) of this section which any person conducts, initiates, or supports on or after [Insert date 60 days after date of publication in the **Federal Register** of the final rule].

(b)(1) This part also prescribes good laboratory practices for conducting studies relating to health effects, environmental effects, and chemical fate testing pursuant to the Toxic Substances Control Act (TSCA) (Public Law 94–469, 90 Stat. 2006, 15 U.S.C. 2603 *et seq.*). This part is intended to assure the quality and integrity of data submitted pursuant to test rules and testing consent agreements/orders issued under section 4 and section 5 of TSCA.

(2) This part applies to any study described by paragraph (b)(1) of this section which any person conducts, initiates, or supports on or after [Insert date 60 days after date of publication in the **Federal Register** of the final rule].

(3) It is EPA's policy that all data developed for submission 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.

§ 806.3 Definitions.

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

Application for research or marketing permit includes:

(1) An application for registration, amended registration, or reregistration of a pesticide product under FIFRA sections 3, 4, or 24(c).

(2) An application for an experimental use permit under FIFRA section 5.

(3) An application for an exemption under FIFRA section 18.

(4) A petition or other request for establishment or modification of a tolerance, for an exemption for the need for a tolerance, or for other clearance under FFDCA section 408.

(5) A petition or other request for establishment or modification of a food additive regulation or other clearance by EPA under FFDCA section 409.

(6) A submission of data in response to a notice issued by EPA under FIFRA section 3(c)(2)(B).

(7) Any other application, petition, or submission sent to EPA intended to persuade EPA to grant, modify, or leave unmodified a registration or other approval required as a condition of sale or distribution of a pesticide.

Batch means a specific quantity or lot of a test, control, or reference substance that has been characterized according to § 806.105(a).

Carrier means any material, including but not limited to feed, water, soil, air, or 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 known chemical or biological 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.

FFDCA means the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 321 *et seq*).

FIFRA means the Federal Insecticide, Fungicide, and Rodenticide Act as amended (7 U.S.C. 136 *et seq*).

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 individual(s) directly involved in the conduct of the study, including the study director), designated by testing facility management to perform the duties relating to quality assurance of the studies.

Raw data means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact

copy or exact transcript may be substituted for the original source as raw data. Raw data may include photographs, microfilm or microfiche copies, computer printouts, any original data captured electronically or by some other medium, dictated observations, and recorded data from automated instruments.

Reference substance means any chemical substance or mixture, or analytical standard, or material other than a test substance, feed, or water, that is administered to or used in analyzing the test system in the course of a study for the purposes of establishing a basis for comparison with the test substance for known chemical or biological measurements.

Specimens means any material or sample derived from a test system for examination or analysis.

Sponsor means:

(1) A person who initiates and supports, by provision of financial or other resources, a study;

(2) A person who submits a study to the EPA: in support of an application for a research or marketing permit; or in response to a TSCA section 4 test rule and/or a person who submits a study under a TSCA section 4 testing consent agreement/order or a TSCA section 5 consent order to the extent the agreement, rule or order references this part; or

(3) A testing facility, if it both initiates and actually conducts the study.

Study means any experiment at one or more test sites, in which a test substance is studied in a test system under laboratory conditions or in the environment to determine or help predict its effects, metabolism, product performance (pesticide efficacy studies only as required by 40 CFR 158.640) environmental and chemical fate, persistence, or residue, or other characteristics in humans, other living organisms, or media. The term ''study'' does not include basic exploratory studies carried out to determine whether a test substance or a test method has any potential utility.

Study completion date means the date the final report is signed by the study director.

Study director means the individual responsible for the overall conduct of a study.

Study initiation date means the date the protocol is signed by the study director.

Test substance means a substance or mixture administered or added to a test system in a study, which substance or mixture:

(1) Is the subject of an application for a research or marketing permit supported by the study, or is the contemplated subject of such an application; or

(2) Is an ingredient, impurity, degradation product, metabolite, or radioactive isotope of a substance described by paragraph (1) of this definition, or some other substance related to a substance described by that paragraph, which is used in the study to assist in characterizing the toxicity, metabolism, or other characteristics of a substance described by that paragraph; or

(3) Is used to develop data to meet the requirements of a TSCA section 4 test rule and/or is developed under a TSCA section 4 testing consent agreement/order or TSCA section 5 consent order to the extent the agreement, rule, or order references this part.

Test system means any animal, plant, microorganism, chemical or physical matrix, including but not limited to soil, water or air, or subparts thereof, to which the test, control, or reference substance is administered or added for study. ''Test system'' also includes appropriate groups or components of the system not treated with the test, control, or reference substance.

Testing facility means a person who actually conducts a study, i.e., actually uses the test substance in a test system. Testing facility encompasses only those operational units that are being or have been used to conduct studies.

TSCA means the Toxic Substances Control Act (15 U.S.C., 2601 *et seq.*)

Vehicle means any agent which facilitates the mixture, dispersion, or solubilization of a test substance with a carrier (e.g., water, mineral oil, animal feed).

§ 806.10 Applicability to studies performed under grant and contracts.

When a sponsor or other person utilizes the services of a consulting laboratory, contractor, or grantee to perform all or a part of a study to which this part applies, that sponsor or person shall notify the consulting laboratory, contractor, or grantee, in writing, that the service is, or is part of, a study that must be conducted in compliance with the provisions of this part, prior to initiation of the study.

§ 806.12 Statement of compliance or non-compliance.

Any person who submits to EPA either an application for a research or marketing permit and who, in connection with the application, submits data from a study to which this part applies, or a test required by a test rule or testing consent agreement/order issued under section 4 or 5 of TSCA, shall include in the application or submission a true and correct statement, signed by the applicant, the sponsor, and the study director, of one of the following types:

(a) A statement that the study was conducted in accordance with this part.

(b) A statement describing in detail all differences between the practices used in the study and those required by this part.

(c) A statement that the person was not a sponsor of the study, did not conduct the study, and does not know whether the study was conducted in accordance with this part.

§ 806.15 Inspection of a testing facility.

(a) Testing facility management shall permit an authorized employee or duly designated representative of EPA or FDA, at reasonable times and in a reasonable manner, to inspect the facility and to inspect (and in the case of records also to copy) all records and specimens required to be maintained regarding studies to which this part applies. The records inspection and copying requirements shall not apply to quality assurance unit records of findings and problems, or to actions recommended and taken, except that EPA may seek production of these records in litigation or formal adjudicatory hearings.

(b) EPA will not consider reliable for purposes of supporting an application for a research or marketing permit, or showing that a chemical substance or mixture does not present a risk of injury to health or the environment, any data developed by a testing facility or sponsor that refuses to permit inspection in accordance with this part. The determination that a study will not be considered in support of an application for a research or marketing permit or reliable for other purposes does not, however, relieve the applicant for such a permit or the sponsor of a required test of any obligation under any applicable statute or regulation to submit the results of the study to EPA.

(c) Because a testing facility is a place where chemicals are stored or held, it is subject to inspection under section 11 of TSCA.

§ 806.17 Effects of non-compliance.

(a)(1) EPA may refuse to consider reliable for purposes of supporting an application for a research or marketing permit any data from a study which was not conducted in accordance with this part.

(2) Submission of a statement required by § 806.12 which is false may form the basis for cancellation, suspension, or modification of the

research or marketing permit, or denial or disapproval of an application for such a permit, under FIFRA section 3, 4, 5, 6, 18, or 24 or FFDCA section 408 or 409, or for criminal prosecution under 18 U.S.C. 2 or 1001 or FIFRA section 14, or for imposition of civil penalties under FIFRA section 14.

(b)(1) The sponsor or any other person who is conducting or has conducted a test to fulfill the requirements of a test rule or testing consent agreement/order issued under section 4 or 5 of TSCA will be in violation of section 15 of TSCA if:

(i) The test is not being or was not conducted in accordance with any requirement of this part;

(ii) Data or information submitted to EPA under this part include information or data that are false or misleading, contain significant omissions, or otherwise do not fulfill the requirements of this part; or

(iii) Entry in accordance with § 806.15 for the purpose of auditing test data or inspecting test facilities is denied. Persons who violate the provisions of this part may be subject to civil or criminal penalties under section 16 of TSCA, legal action in United States District Court under section 17 of TSCA, or criminal prosecution under 18 U.S.C. 2 or 1001.

(2) EPA, at its discretion, may not consider reliable for purposes of showing that a chemical substance or mixture does not present a risk of injury to health or the environment any study which was not conducted in accordance with this part. EPA, at its discretion, may rely upon such studies for purposes of showing adverse effects. The determination that a study will not be considered reliable does not, however, relieve the sponsor of a required test of the obligation under any applicable statute or regulation to submit the results of the study to EPA.

(3) If data submitted to fulfill a requirement of a test rule or testing consent agreement/order issued under section 4 or 5 of TSCA are not developed in accordance with this part, EPA may determine that the sponsor has not fulfilled its obligations under section 4 or 5 of TSCA and may require the sponsor to develop data in accordance with the requirements of this part in order to satisfy such obligations.

Subpart B—Organization and Personnel

§ 806.29 Personnel.

(a) Each individual engaged in the conduct of or responsible for the supervision of a study shall have the appropriate education, training, and experience, or a combination thereof, to enable that individual to perform the assigned functions.

(b) Each testing facility shall maintain a current summary of training and experience and job description for each individual engaged in or supervising the conduct of a study.

(c) There shall be a sufficient number of personnel for the timely and proper conduct of the study according to the protocol.

(d) Personnel shall take necessary personal sanitation and health precautions designed to avoid contamination of test systems and test, control, and reference substances.

(e) Personnel engaged in a study shall wear clothing appropriate for the duties they perform. Such clothing shall be changed as often as necessary to prevent microbiological, radiological, or chemical contamination of test systems and test, control, and reference substances.

(f) Any individual found at any time to have an illness that may adversely affect the quality and integrity of the study shall be excluded from direct contact with test systems, test, control, and reference substances, and any other operation or function that may adversely affect the study until the health or medical condition is corrected. All personnel shall be instructed to report to their immediate supervisors any health or medical conditions that may reasonably be considered to have an adverse effect on a study.

§ 806.31 Testing facility management.

For each study, testing facility management shall:

(a) Designate a study director as described in § 806.33 before the study is initiated.

(b) Replace the study director promptly if it becomes necessary to do so during the conduct of a study.

(c) Assure that there is a quality assurance unit as described in § 806.35.

(d) Assure that test, control, and reference substances or mixtures have been appropriately tested for identity, strength, purity, stability, and uniformity, as applicable.

(e) Assure that personnel, resources, facilities, equipment, materials and methodologies are available as scheduled.

(f) Assure that personnel clearly understand the functions they are to perform.

(g) Assure that any deviations from these regulations reported by the quality assurance unit are communicated to the study director and corrective actions are taken and documented.

§ 806.33 Study director.

For each study, a scientist or other professional of appropriate education, training, and experience, or combination thereof, shall be identified as the study director. The study director has overall responsibility for the technical conduct of the study, as well as for the interpretation, analysis, documentation, and reporting of results, and represents the single point of study control. The study director shall assure that:

(a) The protocol, including any change, is approved as provided by § 806.120 and is followed.

(b) All experimental data, including observations of unanticipated responses of the test system are accurately recorded and verified.

(c) Unforeseen circumstances that may affect the quality and integrity of the study are noted when they occur, and corrective action is taken and documented.

(d) Test systems are as specified in the protocol.

(e) All applicable GLPS regulations are followed.

(f) All raw data, documentation, protocols, specimens, and final reports are transferred to the archives during or at the close or termination of the study.

§ 806.35 Quality assurance unit.

(a) A testing facility shall have a quality assurance unit which shall be responsible for monitoring each study to assure management that the facilities, equipment, personnel, methods, practices, records, and controls are in conformance with the regulations in this part. For any given study, the quality assurance unit shall be entirely separate from and independent of the personnel engaged in the direction and conduct of that study. The quality assurance unit shall conduct inspections and maintain records appropriate to the study.

(b) The quality assurance unit shall:

(l) Maintain a copy of a master schedule sheet of all studies conducted at the testing facility indexed to permit expedient retrieval, which identifies the test substance, the test system, nature of study, date study was initiated, current status of each study, date of completion or termination if study is not ongoing, identity of the sponsor, and name of the study director.

(2) Maintain copies of all protocols until study completion pertaining to all studies for which the unit is responsible.

(3) Inspect each study at intervals adequate to ensure the integrity of the study and maintain written and properly signed records of each periodic inspection showing the date of the

inspection, the study inspected, the phase or segment of the study inspected, the person performing the inspection, findings and problems, action recommended and taken to resolve existing problems, and any scheduled date for reinspection. Any problems which are likely to affect study integrity found during the course of an inspection shall be brought to the attention of the study director and management immediately.

(4) Periodically submit to management and the study director written status reports on each study, noting any problems and the corrective actions taken.

(5) Determine that no deviations from approved protocols or standard operating procedures were made without proper authorization and documentation.

(6) Review the final study report to assure that such report accurately describes the methods and standard operating procedures, and that the reported results accurately reflect the raw data of the study.

(7) Prepare and sign a statement to be included with the final study report which shall specify the dates inspections were made and findings reported to management and to the study director.

(c) The responsibilities and procedures applicable to the quality assurance unit, the records maintained by the quality assurance unit, and the method of indexing such records shall be in writing and shall be maintained. These items including inspection dates, the study inspected, the phase or segment of the study inspected, and the name of the individual performing the inspection shall be made available for inspection to authorized employees or duly designated representatives of EPA or FDA.

(d) An authorized employee or a duly designated representative of EPA or FDA shall have access to the written procedures established for the inspection and may request testing facility management to certify that inspections are being implemented, performed, documented, and followed-up in accordance with this paragraph.

Subpart C—Facilities

§ 806.41 General.

Each testing facility shall be of suitable size and construction to facilitate the proper conduct of studies. Testing facilities which are not located within an indoor controlled environment shall be of suitable location to facilitate the proper conduct of studies. Testing facilities shall be designed so that there is a degree of separation that will prevent any function or activity from having an adverse effect on the study.

§ 806.43 Test system care facilities.

(a) A testing facility shall have a sufficient number of animal rooms or other test system areas, as needed, to ensure: proper separation of species or test systems, isolation of individual projects, quarantine or isolation of animals or other test systems, and routine or specialized housing of animals or other test systems.

(1) In tests with plants or aquatic animals, proper separation of species can be accomplished within a room or area by housing them separately in different chambers or aquaria. Separation of species is unnecessary where the protocol specifies the simultaneous exposure of two or more species in the same chamber, aquarium, or housing unit.

(2) Aquatic toxicity tests for individual projects shall be isolated to the extent necessary to prevent cross-contamination of different chemicals used in different tests.

(b) A testing facility shall have a number of animal rooms or other test system areas separate from those described in paragraph (a) of this section to ensure isolation of studies being done with test systems or test, control, and reference substances known to be biohazardous, including volatile substances, aerosols, radioactive materials, and infectious agents.

(c) Separate areas shall be provided, as appropriate, for the diagnosis, treatment, and control of laboratory test system diseases. These areas shall provide effective isolation for the housing of test systems either known or suspected of being diseased, or of being carriers of disease, from other test systems.

(d) Facilities shall have proper provisions for collection and disposal of contaminated water, soil, or other spent materials. When animals are housed, facilities shall exist for the collection and disposal of all animal waste and refuse or for safe sanitary storage of waste before removal from the testing facility. Disposal facilities shall be so provided and operated as to minimize vermin infestation, odors, disease hazards, and environmental contamination.

(e) Facilities shall have provisions to regulate environmental conditions (e.g., temperature, humidity, photoperiod) as specified in the protocol.

(f) For marine test organisms, an adequate supply of clean sea water or artificial sea water (prepared from deionized or distilled water and sea salt mixture) shall be available. The ranges of composition shall be as specified in the protocol.

(g) For freshwater organisms, an adequate supply of clean water of the appropriate hardness, pH, and temperature, and which is free of contaminants capable of interfering with the study, shall be available as specified in the protocol.

(h) For plants, an adequate supply of soil of the appropriate composition, as specified in the protocol, shall be available as needed.

§ 806.45 Test system supply facilities.

(a) There shall be storage areas, as needed, for feed, nutrients, soils, bedding, supplies, and equipment. Storage areas for feed nutrients, soils, and bedding shall be separated from areas where the test systems are located and shall be protected against infestation or contamination. Perishable supplies shall be preserved by appropriate means.

(b) When appropriate, plant supply facilities shall be provided. As specified in the protocol, these include:

(1) Facilities for holding, culturing, and maintaining algae and aquatic plants.

(2) Facilities for plant growth, including, but not limited to, greenhouses, growth chambers, light banks, and fields.

(c) When appropriate, facilities for aquatic animal tests shall be provided. These include, but are not limited to, aquaria, holding tanks, ponds, and ancillary equipment, as specified in the protocol.

§ 806.47 Facilities for handling test, control, and reference substances.

(a) As necessary to prevent contamination or mixups, there shall be separate areas for:

(1) Receipt and storage of the test, control, and reference substances.

(2) Mixing of the test, control, and reference substances with a carrier, e.g., feed.

(3) Storage of the test, control, and reference substance mixtures.

(b) Storage areas for test, control, and/or reference substance and for test, control, and/or reference mixtures shall be separate from areas housing the test systems and shall be adequate to preserve the identity, strength, purity, and stability of the substances and mixtures.

§ 806.49 Laboratory operation areas.

Separate laboratory space and other space shall be provided, as needed, for the performance of the routine and

specialized procedures required by studies.

§ 806.51 Specimen and data storage facilities.

Space shall be provided for archives, limited to access by authorized personnel only, for the storage and retrieval of all raw data and specimens from completed or terminated studies.

Subpart D—Equipment

§ 806.61 Equipment design.

Equipment used in the generation, measurement, or assessment of data and equipment used for facility environmental control shall be of appropriate design and adequate capacity to function according to the protocol and shall be suitably located for operation, inspection, cleaning, and maintenance.

§ 806.63 Maintenance and calibration of equipment.

(a) Equipment shall be adequately inspected, cleaned, and maintained. Equipment used for the generation, measurement, or assessment of data shall be adequately tested, calibrated, and/or standardized.

(b) The written standard operating procedures required under § 806.81(b)(11) shall set forth in sufficient detail the methods, materials, and schedules to be used in the routine inspection, cleaning, maintenance, testing, calibration, and/or standardization of equipment, and shall specify, when appropriate, remedial action to be taken in the event of failure or malfunction of equipment. The written standard operating procedures shall designate the person(s) responsible for the performance of each operation.

(c) Written records shall be maintained of all inspection, maintenance, testing, calibrating, and/or standardizing operations. These records, containing the date of the operations, shall describe whether the maintenance operations were routine and followed the written standard operating procedures. Written records shall be kept of nonroutine repairs performed on equipment as a result of failure and malfunction. Such records shall document the nature of the defect, how and when the defect was discovered, and any remedial action taken in response to the defect.

(d) The integrity of data from computers, data processors, and automated laboratory procedures involved in the collection, generation, or measurement of data shall be ensured through appropriate validation processes, maintenance procedures, disaster recovery, and security measures.

Subpart E—Testing Facilities Operation

§ 806.81 Standard operating procedures.

(a) A testing facility shall have standard operating procedures in writing setting forth study methods that management is satisfied are adequate to ensure the quality and integrity of the data generated in the course of a study. All deviations in a study from standard operating procedures shall be authorized by the study director and shall be documented in the raw data. Significant changes in established standard operating procedures shall be properly authorized in writing by management.

(b) Standard operating procedures shall be established for, but not limited to, the following:

(1) Test system area preparation.

(2) Test system care.

(3) Receipt, identification, storage, handling, mixing, and method of sampling of the test, control, and reference substances.

(4) Test system observations.

(5) Laboratory or other tests.

(6) Handling of test systems found moribund or dead during study.

(7) Necropsy of test systems or postmortem examination of test systems.

(8) Collection and identification of specimens.

(9) Histopathology.

(10) Data handling, storage, and retrieval.

(11) Maintenance and calibration of equipment.

(12) Transfer, proper placement, and identification of test systems.

(c) Each laboratory or other study area shall have immediately available manuals and standard operating procedures relative to the laboratory or field procedures being performed. Published literature may be used as a supplement to standard operating procedures.

(d) A historical file of standard operating procedures, and all revisions thereof, including the dates of such revisions, shall be maintained.

§ 806.83 Reagents and solutions.

All reagents and solutions in the laboratory areas shall be labeled to indicate identity, titer or concentration, storage requirements, and expiration date. Deteriorated or outdated reagents and solutions shall not be used. As an alternative to labeling wash bottles and transfer bottles with the expiration date, the testing facility may develop a well-documented performance standard to ensure that the reagents or solutions have not deteriorated or are outdated.

§ 806.90 Animal and other test system care.

(a) There shall be standard operating procedures for the housing, feeding, handling, and care of animals and other test systems.

(b) All newly received test systems from outside sources shall be isolated and their health status or appropriateness for the study shall be evaluated. This evaluation shall be in accordance with acceptable veterinary medical practice or scientific methods.

(c) At the initiation of a study, test systems shall be free of any disease or condition that might interfere with the purpose or conduct of the study. If during the course of the study, the test systems contract such a disease or condition, the diseased test systems should be isolated, if necessary. These test systems may be treated for disease or signs of disease provided that such treatment does not interfere with the study. The diagnosis, authorization of treatment, description of treatment, and each date of treatment shall be documented and shall be retained.

(d) Warm-blooded animals, adult reptiles, and adult terrestrial amphibians used in laboratory procedures that require manipulations and observations over an extended period of time or in studies that require these test systems to be removed from and returned to their test system-housing units for any reason (e.g., cage cleaning, treatment, etc.), shall receive appropriate identification (e.g., tattoo, color code, ear tag, ear punch, etc.). All information needed to specifically identify each test system within the test system-housing unit shall appear on the outside of that unit. Suckling mammals and juvenile birds are excluded from the requirement of individual identification unless otherwise specified in the protocol.

(e) Except as specified in paragraph (e)(1) of this section, test systems of different species shall be housed in separate rooms when necessary. Test systems of the same species, but used in different studies, should not ordinarily be housed in the same room when inadvertent exposure to test, control, or reference substances or test system mixup could affect the outcome of either study. If such mixed housing is necessary, adequate differentiation by space and identification shall be made.

(1) Plants, invertebrate animals, aquatic vertebrate animals, and organisms that may be used in multispecies tests need not be housed in

separate rooms, provided that they are adequately segregated to avoid mixup and cross contamination.

(2) [Reserved]

(f) Cages, racks, pens, enclosures, aquaria, holding tanks, ponds, growth chambers, and other holding, rearing and breeding areas, and accessory equipment, shall be cleaned and sanitized at appropriate intervals.

(g) Feed, soil, and water used for the test systems shall be analyzed periodically to ensure that contaminants known to be capable of interfering with the study and reasonably expected to be present in such feed, soil, or water are not present at levels above those specified in the protocol. Documentation of such analyses shall be maintained as raw data.

(h) Bedding used in animal cages or pens shall not interfere with the purpose or conduct of the study and shall be changed as often as necessary to keep the animals dry and clean.

(i) If any pest control or cleaning materials are used, the use shall be documented. Cleaning and pest control materials that interfere with the study shall not be used.

(j) All plant and animal test systems shall be acclimatized to the environmental conditions of the test, prior to their use in a study.

Subpart F—Test, Control, and Reference Substances

§ 806.105 Test, control, and reference substance characterization.

(a) The identity, strength, purity, and composition, or other characteristics which will appropriately define the test, control, or reference substance shall be determined for each batch and shall be documented before its use in a study. Methods of synthesis, fabrication, or derivation of the test, control, or reference substance shall be documented by the sponsor or the testing facility, and the location of such documentation shall be specified.

(b) When relevant to the conduct of the study, the solubility of each test, control, or reference substance shall be determined by the testing facility or the sponsor before the experimental start date or concurrently according to written standard operating procedures, which provide for periodic analysis of each batch. The stability of the test, control, or reference substance shall be determined before the experimental start date or concurrently according to written standard operating procedures, which provide for periodic analysis of each batch.

(c) Each storage container for a test, control, or reference substance shall be labeled by name, Chemical Abstracts Service (CAS) registry number or code number, batch number, expiration date, if any, and storage conditions necessary to maintain the identity, strength, purity, and composition of the test, control, or reference substance. Storage containers shall be assigned to a particular test substance for the duration of the study. With the study director's written approval, test substance storage containers need not be retained after use, provided that full documentation of the disposition of the containers is maintained as raw data for the study. This documentation shall include:

(1)(i) Information of shipments pertaining to each container leaving the storage site (examples of such records are shipping request records, bills of lading, carrier bills, and monthly inventories of warehouse activity).

(ii) Test substance receipt records at each testing facility.

(iii) Complete use logs of material taken from containers.

(iv) A record of the final destination of the container, including the place and date of disposal or reclaiming, and any appropriate receipts.

(2) An inventory record of empty containers before disposal, including sufficient information to uniquely identify containers, maintained in an up-to-date manner recording all arrivals of empty containers and their disposal. This record shall be maintained as raw data for this study.

(3) Locations of facilities; where test substance is stored; where empty containers are stored prior to disposal; where records of use, shipment, and disposal of containers are maintained; and where the test substance is used in studies (i.e., testing facility).

(d) For studies of more than 4 weeks from the experimental start to completion dates, reserve samples from each batch of test, control, and reference substances shall be retained for the period of time provided by § 806.195.

(e) The stability of test, control, and reference substances under storage conditions at the test site shall be known for all studies.

§ 806.107 Test, control, and reference substance handling.

Procedures shall be established for a system for the handling of the test, control, and reference substances to ensure that:

(a) There is proper storage.

(b) Distribution is made in a manner designed to preclude the possibility of contamination, deterioration, or damage.

(c) Proper identification is maintained throughout the distribution process.

(d) The receipt and distribution of each batch is documented. Such documentation shall include the date and quantity of each batch distributed or returned.

§ 806.113 Mixtures of substances with carriers.

(a) For each test, control, or reference substance that is mixed with a carrier, tests by appropriate analytical methods shall be conducted:

(1) To determine the uniformity of the mixture and to determine, periodically, the concentration of the test, control, or reference substance in the mixture.

(2) When relevant to the conduct of the study, to determine the solubility of each test, control, or reference substance in the mixture; or if the solubility of the substance is difficult to determine, appropriate homogeneity data, by the testing facility or the sponsor before the experimental start date.

(3) To determine the stability of the test, control, or reference substance in the mixture before the experimental start date or concomitantly according to written standard operating procedures, which provide for periodic analysis of each batch.

(b) Tank mixes prepared for application to soil or plants by typical agricultural practices within a 12-hour period between preparation and application, and solutions prepared for immediate administration in mammalian acute toxicology studies, metabolism studies, or mutagenicity studies, are exempt from requirements for concentration determinations (but not from uniformity determinations) under paragraph (a)(1) of this section and are exempt from requirements for solubility determinations under paragraph (a)(2) of this section.

(c) Where any of the components of the test, control, or reference substance carrier mixture has an expiration date, that date shall be clearly shown on the container. If more than one component has an expiration date, the earliest date shall be shown.

(d) If a vehicle is used to facilitate the mixing of a test substance with a carrier, assurance shall be provided that the vehicle does not interfere with the integrity of the test.

Subpart G—Protocol for and Conduct of a Study

§ 806.120 Protocol.

(a) Each study shall have an approved written protocol that clearly indicates the objectives and all methods for the conduct of the study. The protocol shall contain but shall not necessarily be limited to the following information:

(1) A descriptive title and statement of the purpose of the study.

(2) Identification of the test, control, and reference substance by name, Chemical Abstracts Service (CAS) registry number or code number. When a reference substance for a metabolite cannot be identified prior to the beginning of a study (only in the case of metabolism studies), it is not necessary to identify the substance in the protocol. However, a statement must be included that the identity of the reference substance will be determined during the course of the study and maintained as raw data.

(3) The name and address of the sponsor and the name and address of the testing facility at which the study is being conducted.

(4) The proposed experimental start and termination dates.

(5) Justification for selection of the test system.

(6) Where applicable, the number, body weight range, sex, source of supply, species, strain, substrain, and age of the test system.

(7) The procedure for identification of the test system.

(8) A description of the experimental design, including methods for the control of bias.

(9) Where applicable, a description and/or identification of the diet used in the study as well as solvents, emulsifiers and/or other materials used to solubilize or suspend the test, control, or reference substances before mixing with the carrier. The description shall include specifications for acceptable levels of contaminants that are reasonably expected to be present in the dietary materials and are known to be capable of interfering with the purpose or conduct of the study if present at levels greater than established by the specifications.

(10) The route of administration and the reason for its choice.

(11) Each dosage level, expressed in milligrams per kilogram of body or test system weight or other appropriate units, of the test, control, or reference substance to be administered and the method and frequency of administration.

(12) The type and frequency of tests, analyses, and measurements to be made.

(13) The records to be maintained.

(14) The date of approval of the protocol by the sponsor and the dated signature of the study director.

(15) A statement of the statistical method to be used.

(b) All changes in or revisions of an approved protocol and the reasons therefore shall be documented, signed by the study director, dated, and maintained with the protocol.

(c) Discontinued studies or studies otherwise terminated before completion shall be finalized by writing a protocol amendment providing the reason(s) for termination. All documentation for terminated studies including the protocol, protocol amendment(s), and raw data, if collected, shall be retained as provided at § 806.195.

§ 806.130 Conduct of a study.

(a) The study shall be conducted in accordance with the protocol.

(b) The test systems shall be monitored in conformity with the protocol.

(c) Specimens shall be identified by test system, study, nature, and date of collection. This information shall be located on the specimen container or shall accompany the specimen in a manner that precludes error in the recording and storage of data.

(d) In animal studies where histopathology is required, records of gross findings for a specimen from postmortem observations shall be available to a pathologist when examining that specimen histopathologically.

(e) All data generated during the conduct of a study, except those that are generated by automated data collection systems, shall be recorded directly, promptly, and legibly in ink. All data entries shall be dated on the day of entry and signed or initialed by the person entering the data. Any change in entries shall be made so as not to obscure the original entry, shall indicate the reason for such change, and shall be dated and signed or identified at the time of the change. In automated data collection systems, the individual responsible for direct data input shall be identified at the time of data input. Any change in automated data entries shall be made so as not to obscure the original entry, shall indicate the reason for change, shall be dated, and the responsible individual shall be identified.

§ 806.135 Physical and chemical characterization studies.

(a) All provisions of the GLPS shall apply to physical and chemical characterization studies designed to determine stability, solubility, octanol water partition coefficient, volatility, and persistence (such as biodegradation, photodegradation, and chemical degradation studies) of test, control, or reference substances.

(b) The following GLPS shall not apply to studies, other than those designated in paragraph (a) of this section, designed to determine physical and chemical characteristics of a test, control, or reference substance: §§ 806.31(c), (d), and (g), 806.35(b) and (c), 806.43, 806.45, 806.47, 806.49, 806.81(b)(1), (2), (6) through (9), and (12), 806.90, 806.105(a) through (d), 806.113, 806.120(a)(5) through (12), and (15), 806.185(a)(5) through (8), (10), (12), and (14), and 806.195(c) and (d).

Subparts H and I—[Reserved]

Subpart J—Records and Reports

§ 806.185 Reporting of study results.

(a) With the exception of discontinued or otherwise terminated studies, as provided at § 806.120(c), a final report shall be prepared for each study and shall include, but not necessarily be limited to, the following:

(1) Name and address of the facility performing the study and the dates on which the study was initiated and was completed.

(2) Objectives and procedures stated in the approved protocol, including any changes in the original protocol.

(3) Statistical methods employed for analyzing the data.

(4) The test, control, and reference substances identified by name, Chemical Abstracts Service (CAS) registry number or code number, strength, purity, and composition, or other appropriate characteristics.

(5) Stability and, when relevant to the conduct of the study, solubility of the test, control, and reference substances under the conditions of administration.

(6) A description of the methods used.

(7) A description of the test system used. Where applicable, the final report shall include the number of animals used, sex, body weight range, source of supply, species, strain and substrain, age, and procedure used for identification. For other test organisms (plants, bacteria), similarly detailed descriptions of the test system are required.

(8) A description of the dosage, dosage regimen, route of administration, and duration.

(9) A description of all circumstances that may have affected the quality or integrity of the data.

(10) The name of the study director, the names of other scientists or professionals, and the names of all supervisory personnel, involved in the study.

(11) A description of the transformations, calculations, or operations performed on the data, a summary and analysis of the data, and a statement of the conclusions drawn from the analysis.

(12) The signed and dated reports of each of the individual scientists or other professionals involved in the study, including each person who, at the request or direction of the testing facility or sponsor, conducted an analysis or evaluation of data or specimens from the study after data generation was completed.

(13) The locations where all specimens, raw data, and the final report are to be stored.

(14) The statement prepared and signed by the quality assurance unit as described in § 806.35(b)(7).

(b) The final report shall be signed and dated by the study director.

(c) Corrections or additions to a final report shall be in the form of an amendment by the study director. The amendment shall clearly identify that part of the final report that is being added to or corrected and the reasons for the correction or addition, and shall be signed and dated by the person responsible. Modification of a final report to comply with the submission requirements of EPA does not constitute a correction, addition, or amendment to a final report.

(d) A copy of the final report and of any amendment to it shall be maintained by the sponsor and the test facility.

§ 806.190 Storage and retrieval of records and data.

(a) All raw data, documentation, records, protocols, specimens, and final reports generated as a result of a study shall be retained. Specimens obtained from mutagenicity tests, specimens of soil, water, and plants, and wet specimens of blood, urine, feces, and biological fluids, do not need to be retained after quality assurance verification. Correspondence and other documents relating to interpretation and evaluation of data, other than those documents contained in the final report, also shall be retained.

(b) There shall be archives for orderly storage and expedient retrieval of all raw data, documentation, protocols, specimens, and interim and final reports. Conditions of storage shall minimize deterioration of the documents or specimens in accordance with the requirements for the time period of their retention and the nature of the documents of specimens. A testing facility may contract with commercial archives to provide a repository for all material to be retained. Raw data and specimens may be retained elsewhere provided that the archives have specific reference to those other locations.

(c) An individual shall be identified as responsible for the archives.

(d) Only authorized personnel shall enter the archives.

(e) Material retained or referred to in the archives shall be indexed to permit expedient retrieval.

§ 806.195 Retention of records.

(a) Record retention requirements set forth in this section do not supersede the record retention requirements of any other regulations in this subchapter.

(b) Except as provided in paragraph (c) of this section, documentation records, raw data, and specimens pertaining to a study and required to be retained by this part shall be retained in the archive(s) for:

(1) In the case of applicability under § 806.1(a), whichever of the following periods is longest:

(i) In the case of any study used to support an application for a research or marketing permit approved by EPA, the period during which the sponsor or any successor(s) hold(s) any research or marketing permit to which the study is pertinent.

(ii) A period of at least 5 years following the date on which the results of the study are submitted to EPA in support of an application for a research or marketing permit.

(iii) In other situations (e.g., where the study does not result in the submission of the study in support of an application for a research or marketing permit), a period of at least 2 years following the date on which the study is completed, terminated, or discontinued.

(2) In the case of applicability under § 806.1(b):

(i) In the case of a study required to be conducted under TSCA section 4 or section 5, except for those items listed in paragraph (c) of this section, all documentation, records, raw data, and specimens pertaining to that study and required to be retained by this part shall be retained in the archive(s) for a period of at least 5 years following the date on which the final report of that required study is submitted to EPA.

(ii) [Reserved]

(c) Wet specimens, samples of test, control, or reference substances, and specially prepared material which are relatively fragile and differ markedly in stability and quality during storage, shall be retained only as long as the quality of the preparation affords evaluation. Specimens obtained from mutagenicity tests, specimens of soil, water, and plants, and wet specimens of blood, urine, feces, and biological fluids, do not need to be retained after quality assurance verification. In no case shall retention be required for longer periods than those set forth in paragraph (b) of this section.

(d) The master schedule sheet, copies of protocols, and records of quality assurance inspections, as required by § 806.35(c) shall be maintained by the quality assurance unit as an easily accessible system of records for the period of time specified in paragraph (b) of this section.

(e) Summaries of training and experience and job descriptions required to be maintained by § 806.29(b) may be retained along with all other testing facility employment records for the length of time specified in paragraph (b) of this section.

(f) Records and reports of the maintenance and calibration and inspection of equipment, as required by § 806.63(b) and (c), shall be retained for the length of time specified in paragraph (b) of this section.

(g) If a facility conducting testing or an archive contracting facility goes out of business, all raw data, documentation, and other material specified in this section shall be transferred to the archives of the sponsor of the study. EPA shall be notified in writing of such a transfer.

(h) Specimens, samples, or other non-documentary materials need not be retained after EPA has notified in writing the sponsor or testing facility holding the materials that retention is no longer required by EPA. Such notification normally will be furnished upon request after EPA or FDA has completed an audit of the particular study to which the materials relate and EPA has concluded that the study was conducted in accordance with this part.

(i) Records required by this part may be retained either as original records or as true copies such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records.

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 76

[CS Docket No. 99–363; FCC 99–406]

Implementation of the Satellite Home Viewer Improvement Act of 1999: Retransmission Consent Issues.

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document proposes to implement certain aspects of the