

5.3 Registered definitive securities tendered in payment for the Notes allotted and to be held in TREASURY DIRECT are not required to be assigned if the inscription on the registered definitive security is identical to the registration of the note being purchased. In any such case, the tender form used to place the Notes allotted in TREASURY DIRECT must be completed to show all the information required thereon, or the TREASURY DIRECT account number previously obtained.

6. General Provisions

6.1. As fiscal agents of the United States, Federal Reserve Banks are authorized, as directed by the Secretary of the Treasury, to receive tenders, to make allotments, to issue such notices as may be necessary, to receive payment for, and to issue, maintain,

service, and make payment on the Notes.

6.2. The Secretary of the Treasury may at any time supplement or amend provisions of this circular if such supplements or amendments do not adversely affect existing rights of holders of the Notes. Public announcement of such changes will be promptly provided.

6.3. The Notes issued under this circular shall be obligations of the United States, and, therefore, the faith of the United States Government is pledged to pay, in legal tender, principal and interest on the Notes.

Gerald Murphy,

Fiscal Assistant Secretary.

[FR Doc. 87-29757 Filed 12-24-87; 8:45 am]

BILLING CODE 4810-40-M

VETERANS ADMINISTRATION

Advisory Committee on Women Veterans; Renewal

This gives notice under the Federal Advisory Committee Act (Pub. L. 92-463) of October 6, 1972, that the Advisory Committee on Women Veterans has been renewed for a two year period beginning November 27, 1987 through November 27, 1989.

Dated: December 16, 1987.

By direction of the Administrator.

Rosa Maria Fontanez,

Committee Management Officer.

[FR Doc. 87-29655 Filed 12-24-87; 8:45 am]

BILLING CODE 8320-01-M

Sunshine Act Meetings

Federal Register

Vol. 52, No. 248

Monday, December 28, 1987

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

NATIONAL TRANSPORTATION SAFETY BOARD

TIME AND DATE: 9:30 a.m., Tuesday, January 5, 1988.

PLACE: Board Room (Room 812A), Eighth Floor, 800 Independence Avenue, SW., Washington, DC 20594.

STATUS: The first four items are open to the public. The last two items are closed under Exemption 10 of the Government in the Sunshine Act.

MATTERS TO BE CONSIDERED:

1. Aircraft Accident Report: Rosie O'Grady's of Orlando, Inc., SNJ-4 and Midwest Packaging Materials Company C-340A Midair Collision, Orlando, Florida, May 1, 1987

2. Aircraft Accident Report: Midair Collision Involving a Sachs Electric Company Piper PA-31 and a U.S. Army Beech U-21, Lake City Army Ammunition Plant, Independence, Missouri, January 20, 1987

3. Marine Accident Report: Collision between the Hong Kong Bulk Carrier PETERSFIELD and the U.S. Towboat BAYOU BOEUF, New Orleans, Louisiana, October 28, 1986

4. Withdrawal of Recommendation to FAA re Failure of Main Landing Gear Spring Steel Struts on Cessna Model 182F Airplanes

5. Opinion and Order: Administrator v. Gentile, Docket SE-7550; disposition of the appeals of both parties

6. Opinion and Order: Administrator v. Fallon, Docket SE-8065; disposition of the Administrator's appeal

FOR MORE INFORMATION CONTACT: Bea Hardesty, (202) 382-6525.

Bea Hardesty,

Federal Register Liaison Officer.

December 21, 1987.

[FR Doc. 87-29687 Filed 12-23-87; 10:03 am]

BILLING CODE 7533-01-M

PAROLE COMMISSION

Record of Vote of Meeting Closure

Pursuant to the Government in the Sunshine Act (Pub. L. 94-409) (5 U.S.C. Sec. 552b)

I, Benjamin F. Baer, Chairman of the United States Parole Commission, presided at a meeting of said Commission which started at nine o'clock a.m. on Tuesday, December 15, 1987 at the Commission's Central Office, 5550 Friendship Boulevard, Chevy Chase, Maryland 20815. The meeting

ended at or about 10:30 a.m. The purpose of the meeting was to decide approximately 8 appeals from National Commissioners' decisions pursuant to 28 CFR 2.27. Eight Commissioners were present, constituting a quorum, when the vote to close the meeting was submitted.

Public announcements further describing the subject matter of the meeting and certifications of General Counsel that this meeting may be closed by vote of the Commissioners present were submitted to the Commissioners prior to the conduct of any other business. Upon motion duly made, seconded, and carried, the following Commissioners voted that the meeting be closed: Benjamin F. Baer, Sandra Brown Armstrong, Cameron M. Batjer, Jasper Clay, Jr., Carol Pavilack Getty, Daniel R. Lopez, G. MacKenzie Rast, and Victor M.F. Reyes. The Commissioners and a Parole Analyst attended.

In witness whereof, I make this official record of the vote taken to close this meeting and authorize this record to be made available to the public.

Date: December 16, 1987.

Benjamin F. Baer,

Chairman, U.S. Parole Commission.

[FR Doc. 87-29718 Filed 12-23-87; 11:37 am]

BILLING CODE 4410-01-M

Corrections

Federal Register

Vol. 52, No. 248

Monday, December 28, 1987

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents and volumes of the Code of Federal Regulations. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 352

[Docket No. 87-132]

Avocados From Mexico Transiting the U.S. to Foreign Countries

Correction

In rule document 87-28583 beginning on page 47373 in the issue of Monday, December 14, 1987, make the following corrections:

On page 47374, in the first column, under **Comments**, in the first paragraph, in the first line, "states" should read "stated" and in the third line, after "Mexico" insert "through the United States will unnecessarily impede trade between Mexico".

BILLING CODE 1505-01-D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 184

[Docket No. 84G-0384]

Cocoa Butter Substitute Primarily From Palm Oil

Correction

In rule document 87-28959 beginning on page 47918 in the issue of Thursday, December 17, 1987, make the following corrections:

1. On page 47919, in the first column, six lines from the bottom, "§ 184.129" should read "§ 184.1259".

2. On the same page, in the third column, in the 13th line, "and" should read "at".

§ 184.1259 [Corrected]

3. On page 47920, in the third column, in § 184.1259(a)(2), in the sixth line, "approved" should read "approval".

BILLING CODE 1505-01-D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 86P-0083/CP]

Medical Laser Manufacturers Association; Neodymium:Yttrium:Aluminum:Garnet (Nd:YAG) Laser for Posterior Capsulotomy; Panel Recommendations on Petition for Reclassification

Correction

In notice document 87-28630 beginning on page 47454 in the issue of Monday, December 14, 1987, make the following corrections:

1. On page 47455, in the second column, in the second paragraph, in the eighth line, "sits" should read "site".

2. On page 47456, in the first column, in the third complete paragraph, in the first line, "of" should read "for".

3. On the same page, in the third column, in the first complete paragraph, in the 12th line, "vitreous" was misspelled.

4. On page 47457, in the first column, in reference 8, in the first line, "Johnson, S. R." should read "Johnson, S. H.".

BILLING CODE 1505-01-D

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 2619

Valuation of Plan Benefits in Single-Employer Plans; Expected Retirement Age

Correction

In rule document 87-28767 beginning on page 47562 in the issue of Tuesday, December 15, 1987, make the following correction:

PART 2619--[CORRECTED]

On page 47563, in Appendix D, in Table I-88, the column headings did not appear correctly. The table is corrected to read as follows:

TABLE I-88—SELECTION OF RETIREMENT RATE CATEGORY

[For plans with valuation dates after Dec. 31, 1987, and before Jan. 1, 1989]

Participant reaches NRA in year—	Participant's Retirement Rate Category is—			
	Low ¹ if monthly benefit at NRA is less than—	Medium ² if monthly benefit at NRA is—		High ³ if monthly benefit at NRA is greater than—
		From—	To—	
1989.....	297	297	1,250	1,250
1990.....	307	307	1,295	1,295
1991.....	317	317	1,337	1,337
1992.....	326	326	1,374	1,374
1993.....	333	333	1,404	1,404
1994.....	341	341	1,435	1,435
1995.....	348	348	1,467	1,467
1996.....	356	356	1,499	1,499
1997.....	364	364	1,532	1,532
1998 or later.....	372	372	1,566	1,566

¹ Table II-A.² Table II-B.³ Table II-C.

BILLING CODE 1505-01-D

Registered Federal Reporter

Monday
December 28 1987

Part II

Federal Trade Commission

16 CFR Part 455

Used Motor Vehicle Trade Regulation
Rule; Request for Public Comment on
Petition for Exemption by the State of
Maine; Proposed Rule

FEDERAL TRADE COMMISSION

16 CFR Part 455

Used Motor Vehicle Trade Regulation Rule; Request for Public Comment on Petition for Exemption by the State of Maine

AGENCY: Federal Trade Commission.

ACTION: Request for public comment on petition by State of Maine for statewide exemption from the trade regulation rule.

SUMMARY: The Federal Trade Commission seeks public comment on the request by the State of Maine for exemption from the Used Motor Vehicle Trade Regulation Rule, 16 CFR Part 455 (1987). Maine filed its petition pursuant to § 455.6 of the Used Car Rule. If granted, the exemption would require Maine used vehicle dealers to use the disclosure label prescribed by a Maine administrative regulation in the place of the Buyers Guide required by the FTC Rule. Additionally, the Commission would be precluded from enforcing the FTC Rule in Maine for as long as Maine administers and enforces effectively its law. The Commission invites public comment on the Petition generally and on certain questions specifically.

DATES: Written comments will be accepted until January 27, 1988.

ADDRESS: Written comments should be addressed to the Office of the Secretary, Federal Trade Commission, 6th and Pennsylvania Avenue, NW., Washington, DC 20580. Comments should be captioned: "Maine Petition for Statewide Exemption from the Used Car Rule—FTC File No. 215-54."

Copies of the Petition can be obtained from the Public Reference Room, Room 130, Federal Trade Commission, 6th and Pennsylvania Avenue, NW., Washington, DC 20580. (202) 326-2222.

FOR FURTHER INFORMATION CONTACT: Matthew D. Gold (202/326-3019) or Joyce E. Plyler (202/326-3021), Attorneys, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: To facilitate public consideration and comment, the Commission has summarized the information in the Maine Petition. In addition, the Commission has outlined the exemption process it intends to follow.

Outline

- I. Introduction
 - II. Exemption Standards and Procedures
 - III. The Petition
 - A. Contents
 - B. Does the Maine Rule Apply to the Same Transactions to Which the FTC Rule Applies?
 - 1. Definition of "Dealer"
 - 2. Definition of "Consumer"
 - 3. Definition of "Motor Vehicle"
 - 4. Definition of "Used Vehicle"
 - C. Does the Maine Rule Provide an Overall Level of Protection to Consumers Which is as Great as or Greater than that Provided by the FTC Rule?
 - 1. Section 455.1—General Duties of Used Vehicle Dealers
 - 2. Section 455.2—Buyers Guide
 - (a) Format
 - (b) Text of Window Stickers—Similar Provisions
 - (i) The "As Is" Disclosure; (ii) The "Implied Warranties Only" Disclosure;
 - (iii) Information About Express Warranties; (iv) Service Contract Availability; (v) Vehicle, Dealership and Complaint Information; (vi) Statement Concerning Pre-Purchase Independent Inspection; (vii) Spoken Promises Warning; (viii) List of Major Vehicle Systems
 - (c) Text of Window Stickers—Additional Disclosures Required by Maine (i) Prior Use of Vehicle; (ii) How Vehicle Was Acquired; (iii) Known Mechanical Defects or Prior Substantial Damage; (iv) Availability of Prior Owner's Name and Address; (v) Whether Vehicle Has Been Returned to Manufacturer
 - 3. Section 455.3—Window Stickers Given to Purchaser and Incorporated into Contract
 - 4. Section 455.4—Contrary Statements
 - 5. Section 455.5—Spanish Language Sales
 - D. Does Maine Evidence a Willingness and Ability to Enforce its Sticker Rule?
 - 1. Funding and Staffing of Agencies
 - 2. Enforcement Procedures
 - (a) Department of Attorney General
 - (b) Department of Motor Vehicles
 - 3. History of Enforcement of the MUCIA
 - 4. Private Right of Action
- IV. Requests for Public Comment

1. Introduction

On June 1, 1987, the Maine Secretary of State ("Petitioner") filed a petition for a statewide exemption (the "Petition") pursuant to § 455.6 of the Commission's Used Motor Vehicle Trade Regulation Rule (the "FTC Rule" or the "Used Car Rule"), 16 CFR Part 455 (1987).¹ If

¹ The Maine Petition has been placed on the public record and is identified as Document 100-8 in FTC File No. 215-54. It and other documents referred to in this notice are available for inspection at the Office of the Secretary of the Federal Trade Commission, at the above address.

granted, the exemption would require Maine used vehicle dealers to use the disclosure label prescribed by a Maine administrative regulation in the place of the Buyers Guide required by the FTC Rule.² Additionally, the Commission would be precluded from enforcing the FTC Rule in Maine for as long as Maine administers and enforces effectively its law.³

In this notice, the Commission publishes the procedures it will use in its consideration of the Maine Petition. These procedures are patterned after the procedures used in the Commission's consideration of the exemption petition from the State of Wisconsin.⁴ This notice also contains a provision-by-provision comparison of the Maine regulation and the FTC Rule. This comparison is intended to highlight differences in the two regulations that are relevant to the Commission's standards for granting exemptions. Finally, the notice also contains specific questions that the Commission believes will focus public comment on the important issues involved in the Commission's consideration of the Petition.

II. Exemption Standards and Procedures

The FTC Rule includes a specific provision, § 455.6, setting forth the Commission's standards for exempting a state from the Rule's requirements. Section 455.8 states:

(a) If, upon application to the Commission by an appropriate state agency, the Commission determines, that—

(1) There is a state requirement in effect which applies to any transaction to which this rule applies; and

(2) That state requirement affords an overall level of protection to consumers which is as great as, or greater than, the protection afforded by this Rule; then the Commission's Rule will not be in effect in that state to the extent specified by the Commission in its determination, for as long as the state administers and enforces effectively the state requirement.

(b) Applications for exemption under Subsection (a) should be directed to the Secretary of the Commission. When appropriate, proceedings will be commenced in order to make a determination described in Subsection (a), and will be conducted in accordance with Subpart C of Part 1 of the Commission's Rules of Practice.

² The Buyers Guide is the standard disclosure form which must be affixed to a side window of each used vehicle offered for sale by a dealer to a consumer, under § 455.2 of the FTC Rule. Both the FTC and the Maine disclosure forms are printed at the end of this notice.

³ Statement of Basis and Purpose for the Used Car Rule, 49 FR 45,692, 45,711 (Nov. 19, 1984) (hereinafter referred to as the "SBP").

⁴ 50 FR 21,289 (May 23, 1985).

The Commission determines the appropriate relationship between the FTC Rule and state law on a case-by-case basis in an exemption proceeding conducted pursuant to § 1.16 of the Commission's Rules of Practice.⁵ Section 1.16 of the Commission's Rules of Practice is a general provision allowing any person to whom a trade regulation rule would otherwise apply to petition the Commission for an exemption, but it offers no specific guidance to state agencies seeking statewide exemption.

However, final staff guidelines for state exemption petitions have been developed for the Commission's Trade Regulation Rule Concerning Funeral Industry Practices (the "Funeral Rule"), 16 CFR Part 453 (1987).⁶ Because the Funeral Rule has a state exemption provision that is virtually identical to that included in the FTC Rule,⁷ the Commission followed the Funeral Rule guidelines when considering the Wisconsin petition for exemption from the FTC Rule.⁸ Maine followed these guidelines in submitting its petition.

The state exemption guidelines recommend that a complete application be comprised of the following information: (1) A copy of all relevant state statutes, rules, regulations and court cases; (2) a statement comparing the state law with the Commission's rule, on a provision-by-provision basis, which explains how the state law applies to the same transactions as does the Commission's rule and how the state law affords an overall level of protection to consumers that is equal to or greater than that afforded by the Commission's rule; (3) information sufficient to demonstrate the state's willingness and ability to administer and enforce its law effectively; and (4) a statement from the state's attorney general that the state law provides adequate authority to support the rules, regulations, conclusions, interpretations, policies and procedures described in the statement submitted in the application for the statewide exemption from the Commission's rule. The state exemption guidelines also state that once a complete application for statewide exemption has been received, staff will place the materials on the public record and recommend that the Commission publish a notice in the *Federal Register*

allowing a period of time for interested persons to submit written comments. This notice invites interested parties to submit comments on the Maine Petition. The Commission will place written comments on the public record.

The Commission's staff will also place on the public record any factual information received orally on which it relies in making its recommendation to the Commission concerning whether to grant the exemption. Moreover, under the procedures discussed in the Statement of Basis and Purpose,⁹ this exemption proceeding will be subject to the restrictions on *ex parte* communications applicable to a section 18 rulemaking "adapted in such form as may be appropriate to the circumstances of the particular proceeding."¹⁰ The restrictions on *ex parte* communications applicable to a Section 18 rulemaking proceeding are set forth in 16 CFR 1.18(c) (1987). In brief, they require that a communication on the merits to a Commissioner from a person outside the Commission be placed on the public record of the proceeding, and that a communication on the merits to a Commissioner from the rulemaking staff be disclosed on the record to the extent that it contains any fact not already on the record.¹¹

III. The Petition

A. Contents

As noted earlier, the Maine Secretary of State filed its Petition requesting a statewide exemption from the FTC Rule on June 1, 1987. Included in this Petition are the following materials: (1) A provision-by-provision comparison of the FTC Rule and the Maine Rule (Appendix A); (2) a copy of the Maine Rule, which was adopted on January 22, 1987, with an effective date of twenty-one days after a statewide exemption is granted (Appendix B); (3) a copy of the Maine window label (Buyer's Guide) required by the Maine Rule (Appendix C); (4) copies of the relevant Maine statutes, including the Maine Used Car Information Act ("MUCIA"),¹² the

Maine Unfair Trade Practices Act,¹³ and the Maine Annual Car Inspection Law¹⁴ (Appendix D); (5) a discussion of Maine's willingness and ability to enforce the MUCIA and the Maine Rule (Appendix E); and (6) a letter from Maine Attorney General James E. Tierney stating that Maine law provides adequate authority to support the Maine Rule, as well as the conclusions, interpretations, policies and procedures described in the Petition and in the Appendices (Appendix F).

B. Does the Maine Rule Apply to the Same Transactions to Which the FTC Rule Applies?

This section compares the definitions which determine the scope of the FTC Rule with their counterparts in the Maine Rule. Whether a transaction is covered by the FTC Rule depends upon three factors: (1) the identity of the person or entity offering the vehicle for sale;¹⁵ (2) the identity of the person or entity to whom the vehicle is offered for sale;¹⁶ and (3) the characteristics of the vehicle being offered for sale.¹⁷

1. Definition of "Dealer"

Section I(A)(2) of the Maine Rule defines "dealer" as "any person or legal entity which meets the [definition of that term at] M.R.S.A. 1471, sub-section 2." That definition "includes a natural person, firm, corporation, partnership and any other legal entity that is engaged in the business of selling, offering for sale, or negotiating the sale of used motor vehicles, except auctioneers licensed by the Secretary of State * * *¹⁸ Also excluded from this definition are 'departments and agencies of the State when selling, offering for sale or negotiating the sale of used state-owned motor vehicles.'¹⁹

The FTC Rule definition of "dealer," at § 455.1(d)(3), includes "any person or business which sells or offers for sale a used vehicle after selling or offering for sale five (5) or more used vehicles in the previous twelve months, but does not include a bank or financial institution, a

information were to conflict with information required by the MUCIA.

¹³ Me. Rev. Stat. Ann. tit. 5, secs. 207-14 (1980 & Supp. 1985-1986).

¹⁴ Me. Rev. Stat. Ann. tit. 29, secs. 2501-25 (1980 & Supp. 1986).

¹⁵ The term "dealer" is defined in § 455.1(d)(3) of the FTC Rule.

¹⁶ The term "consumer" is defined in § 455.1(d)(4) of the FTC Rule.

¹⁷ The terms "vehicle" and "used vehicle" are defined in §§ 455.1(d)(1) and (2) of the FTC Rule, respectively.

¹⁸ Me. Rev. Stat. Ann. tit. 10, Sec. 1471(2) (Supp. 1986).

¹⁹ Id.

⁹ 49 FR at 45,711.

¹⁰ 16 CFR 1.26(b) (1987).

¹¹ See also 50 FR at 12,522.

¹² Me. Rev. Stat. Ann. tit. 10, Secs. 1471-1477 (1980 & Supp. 1985-1986). The MUCIA was amended in 1985 to include, *inter alia*, provisions requiring Maine used vehicle dealers to affix a written disclosure statement to each used vehicle offered for sale, and authorizing the Division of Motor Vehicles to promulgate rules implementing this requirement. See Secs. 1475(1); 1475(2)(G). The Maine Rule was promulgated under this authority. Section 1475(2)(G) of the MUCIA specifically authorizes the Division of Motor Vehicles to include on its uniform disclosure sticker any information contained on the FTC Buyers Guide, unless such

⁵ Id. See also 16 CFR 1.16 (1987).

⁶ 50 FR 12521 (March 29, 1985).

⁷ See 16 CFR 453.9 (1987).

⁸ The Staff Compliance Guidelines for the Used Car Rule, 52 FR 18552 (May 18, 1987); 52 FR 19845 (May 28, 1987), recommended that states interested in filing a petition for statewide exemption from the Used Car Rule consult the Funeral Rule state exemption guidelines. 52 FR 18561.

business selling a used vehicle to an employee of that business, or a lessor selling a leased vehicle by or to that vehicle's lessee or to an employee of the lessee."

The Maine Rule's definition of "dealer" differs from that found in the FTC Rule in several respects. First, there is no requirement that a minimum volume of vehicles be offered for sale before the Maine Rule would apply. Instead, one must be "engaged" in the used car business to be considered a dealer in Maine. A recent case, however, indicates that the number of vehicles necessary to meet this threshold may be even lower than the FTC Rule's minimum.²⁰

The Maine Rule also specifically excludes auctioneers from the definition of "dealer." However, while the auction house itself is excluded, dealers selling their vehicles through auctions are required to comply with the Maine Rule.

The Maine Rule also differs in that it covers all sales by banks or financial institutions, leasing companies, or other businesses. The FTC Rule specifically excludes sales by banks or financial institutions and some sales by leasing companies and businesses.

2. Definition of "Consumer"

Section I(A)(1) of the Maine Rule defines "consumer" as "any person who is not a used vehicle dealer." This language tracks exactly the definition of "consumer" in the FTC Rule. The Maine Rule also includes within its definition any person defined as a "purchaser" in the MUCIA. This MUCIA definition includes "any person who has obtained ownership of a used motor vehicle from a dealer by transfer, gift or purchase."²¹ Although the Maine Rule definition explicitly excludes dealers, the "General Duty" clause, section 1(C)(1) of the Maine Rule, requires the posting of the Maine Buyer's Guide prior to offering for sale used vehicles "to a consumer or another dealer."²² The MUCIA also appears to include dealers. In any event, the Maine Rule definition is at least as inclusive as that found in the FTC Rule.

3. Definition of "Motor Vehicle"

Section I(A)(5) of the Maine Rule specifically incorporates the definition of "motor vehicle" found in the MUCIA.²³ That definition includes "any

self-propelled vehicle designed primarily to transport not more than 14 individuals, except motorcycles * * * and any vehicles operated exclusively on a rail or rails. This definition is intended to include motor trucks that have a gross vehicle weight of not more than 10,000 pounds * * *."

The FTC Rule definition of "vehicle," at § 455.1(d)(1), also excludes motorcycles, but includes motorized vehicles with a gross vehicle weight of less than 8500 pounds, a curb weight of less than 6000 pounds, and a frontal area of less than 46 square feet.

These definitions are substantially similar. Any vehicle included in the FTC Rule definition is included in the Maine Rule's definition. The Maine Rule definition is slightly more inclusive in that it also covers vehicles with gross vehicle weights of between 8500 and 10,000 pounds.

4. Definition of "Used Vehicle"

The Maine Rule's definition of this term, found at section I(A)(8), is virtually identical to that contained in § 455.1(d)(2) of the FTC Rule, except that it expressly includes "demonstrators" or "company cars," and any vehicle that meets the definition of "reconstructible motor vehicle" in the MUCIA.²⁴ Although the FTC Rule does not specifically mention these types of vehicles, they are included under the Rule's definition.²⁵

C. Does the Maine Rule Provide an Overall Level of Protection to Consumers Which is as Great as or Greater than that Provided by the FTC Rule?

This portion of the notice compares the Maine Rule with the FTC Rule on a provision-by-provision basis. This discussion will follow the format of the FTC Rule.

1. Section 455.1—General Duties of Used Vehicle Dealers

Section 455.1(a) of the FTC Rule states that the following acts or practices are deceptive when committed by used vehicle dealers offering for sale used vehicles in or affecting commerce: (1) misrepresenting the mechanical condition of a used vehicle; (2)

misrepresenting the terms of any warranty; and (3) representing that a used vehicle is sold with a warranty when that is not true. Section 455.1(b) of the Rule further states that the following acts or practices are unfair when committed by used vehicle dealers offering for sale used vehicles in or affecting commerce: (1) Failing to disclose, prior to sale, that a used vehicle is sold without a warranty; and (2) failing to make available, prior to sale, the terms of any written warranty offered in connection with the sale of a used vehicle. However, a violation of one of these Sections, in and of itself, would not constitute a violation of the FTC Rule. Section 455.1(c)(3) of the FTC Rule states that "[i]f a used vehicle dealer complies with the requirements of §§ 455.2 through 455.5 of this part [proper preparation and display of the Buyers Guide], the dealer does not violate this Rule."

In terms of enforcement, therefore, violations of §§ 455.1(a) and (b) of the FTC Rule would be actionable under Section 5 of the FTC Act,²⁶ rather than under the Rule. The comparable provisions in the Maine Rule, sections I(B)(1) and I(B)(2), differ in that violations would be actionable under the Maine Rule itself. Therefore, unlike the case in the FTC Rule, civil penalties would be available for violations of these sections.

These "general duty" sections of the Maine Rule also differ in that only written misrepresentations are prohibited. The FTC Rule does not distinguish between written and oral misrepresentations. The Maine Rule, however, does note that verbal misrepresentations may be a violation of Maine common law or statutory law, such as the Maine Unfair Trade Practices Act or the Maine Uniform Commercial Code.²⁷

2. Section 455.2—Buyers Guide

(a) *Format.* Both the FTC Rule and the Maine Rule require dealers to complete and display a disclosure form on a side window of each used vehicle offered for sale to consumers.²⁸ Both laws specify the exact format of the disclosure form. The provisions of the Maine Rule regarding format and display of the Maine Buyer's Guide are virtually identical to the comparable provisions in the FTC Rule.²⁹ Additionally, the

²⁰ See *Tanguay v. Seacoast Tractor Sales, Inc.*, 494 A.2d 1364 (Me. 1985). Maine's Supreme Judicial Court held that a seller of at least one dozen vehicles over a twenty-year period qualified as a "dealer" under the MUCIA definition. *Id.*

²¹ See Me. Rev. Stat. Ann. tit. 10, sec. 1471, subsection 6.

²² James McKenna of the Maine Attorney General's Office confirmed that the intent of the

Maine Rule is to include sales to dealers within its scope.

²³ Me. Rev. Stat. Ann. tit. 10, sec. 1471, subsection 4.

²⁴ See Me. Rev. Stat. Ann. tit. 10, sec. 1471, subsection 6-A. This definition includes "a used motor vehicle which does not meet the inspection standards as set forth in Title 29, section 2502, and which is sold, offered for sale or negotiated for sale to a person other than another dealer for the purpose of transportation after repair or rebuilding."

²⁵ The SBP Specifically states that such vehicles are intended to be included within the Rule's coverage. See 49 FR 45707.

²⁶ 15 U.S.C. 45 (1978 & Supp. 1987).

²⁷ See Section I(B)(1), n. 1., of the Maine Rule.

²⁸ Maine's sticker is called a "Buyer's Guide," while the FTC's sticker is called a "Buyers Guide" (no apostrophe).

printing specifications for the Maine Buyer's Guide are designed to create a window form that is very similar in appearance to the FTC Buyers Guide. The Maine Rule, however, calls for a minimum size of 12½ inches high by 8½ inches wide, as opposed to the FTC Rule's minimum of 11 inches by 7¼ inches. The additional disclosures on the Maine Buyer's Guide necessitate its larger size.

(b) *Text of Window Stickers—Similar Provisions.* All of the disclosures required on the FTC Rule Buyers Guide are also required on the Maine Rule Buyer's Guide. However, in some instances, the wording of these disclosures on the Maine window sticker varies from the language used on the FTC sticker. Following is a brief comparison of FTC Rule Buyers Guide disclosures with the equivalent Maine Rule Buyer's Guide disclosure.

(i) *The "As Is" Disclosure.* Section 455.2(b)(1)(i) of the FTC Rule requires dealers to check a large box next to the words "AS IS—NO WARRANTY" when offering a used vehicle for sale on that basis. This disclosure is printed in conspicuously large type. The purpose of this disclosure is to inform consumers that the dealer will not be responsible for post-purchase repairs to the vehicle.³⁰ The FTC Buyers Guide includes an explanation of the meaning of the words "as is" immediately underneath the words "AS IS—NO WARRANTY."³¹

In Maine, the MUCIA states that, except in the case of reconstructible motor vehicles,³² a dealer may not sell or transfer a vehicle unless it meets the state inspection standards and displays a valid inspection sticker issued during the thirty days prior to the date of sale or transfer. Consequently, section 1(C)(2)(f) of the Maine Rule requires Maine dealers to check a box on the Buyer's Guide next to the words "WARRANTY OF INSPECTABILITY," unless the vehicle is a reconstructible motor vehicle. Directly underneath the box is a one-sentence explanation of this state-required warranty.

Under section 1(C)(2)(g) of the Maine Rule, if the dealer chooses to offer the vehicle without an express warranty other than the state-required warranty of inspectability, the dealer must check a box next to the words "NO EXPRESS WARRANTY EXCEPT THAT VEHICLE

MEETS STATE INSPECTION STANDARDS." Underneath this statement is the following explanation:

YOU WILL PAY ALL COSTS FOR ANY REPAIRS NOT RELATED TO MEETING STATE INSPECTION STANDARDS. REGARDLESS OF ANY ORAL STATEMENTS ABOUT THE VEHICLE, THE DEALER ACCEPTS NO RESPONSIBILITY FOR REPAIRS EXCEPT THOSE NECESSARY TO PASS STATE INSPECTION.

When the box next to this disclosure is checked (in addition to the box informing the consumer of the warranty of inspectability), the consumer is put on notice that the dealer's express warranty obligations extend only to the inspectability of the vehicle. A Maine dealer's minimum post-sale responsibility extends to the repair of any defect in systems or components on the state inspection "checklist," if the purchaser can show that the defect existed at the time of sale. Also, Maine dealers may choose not to disclaim state law implied warranties in addition to offering the express warranty of inspectability.

(ii) *The "Implied Warranties Only" Disclosure.* Section 455.2(b)(1)(ii) of the FTC Rule requires that an "IMPLIED WARRANTIES ONLY" disclosure be used in place of the "AS IS—NO WARRANTY" disclosure in states that limit or prohibit "as is" sales and in instances where a dealer choose to sell a used vehicle with neither an express warranty nor on an "as is" basis. This disclosure informs consumers that the dealer may be legally obligated to repair serious problems even though it did not provide an express warranty.

Section 1(C)(2)(j) of the Maine Rule contains a detailed explanation of a Maine dealer's options regarding implied warranties. Under the words "IMPLIED WARRANTIES" on the Maine Buyer's Guide are three boxes, one of which the dealer must check. The dealer must check the box next to the word "YES" if the dealer chooses not to disclaim implied warranties. If the parties enter into a service contract at the time of sale, implied warranties may not be disclaimed and the "YES" box must be checked.³³ The dealer must check the box next to the word "NO" if the dealer chooses to disclaim implied warranties.³⁴ If the dealer offers an

express warranty, implied warranties may not be disclaimed, but they can be limited to the duration of the express warranty.³⁵ In this case, the dealer must mark the box next to the words "LIMITED TO DURATION OF EXPRESS WARRANTY," but only if such limitation is "conscionable."³⁶ There is no space on the FTC Buyers Guide for a dealer to disclose its intention to limit implied warranties to the duration of an express warranty.

Another difference between the Maine Rule and the FTC Rule regarding implied warranties is the explanation of implied warranty rights on the window stickers. The FTC Buyers Guide provides the general statement that state law implied warranties "may give you some rights to have the dealer take care of serious problems that were not apparent when you bought the vehicle."³⁷ The Maine Rule Buyer's Guide, on the other hand, goes into slightly more detail, referring to both the implied warranty of merchantability and the implied warranty of fitness for a particular use.³⁸

(iii) *Information About Express Warranties.* Section 1(C)(2)(h) of the Maine Rule requires dealers offering an express warranty to check a box next to the words "DEALER EXPRESS WARRANTY" on the Maine Buyer's Guide. Subsections (i)—(iv) and (vi) of section 1(C)(2)(h) of the Maine Rule track the language of § 455.2(b)(2)(i)—(b)(2)(v) of the FTC Rule by requiring that the following warranty terms be disclosed:

- Whether the warranty is full or limited;³⁹
- Which systems are covered by the warranty;⁴⁰
- The duration of the warranty;⁴¹ and
- The percentage of repair costs to be paid by the dealer.⁴²

³⁰ Under section 108(b) of the Magnuson-Moss Warranty Act, 15 U.S.C. 2308(b) (1983 & Supp. 1987), a dealer could limit the duration of implied warranties to the duration of express warranties offered, so long as such a limitation is both conscionable and clearly disclosed.

³¹ See Me. Rev. Stat. Ann. tit. 10, sec. 1475(2)(E).

³² See § 455.2(b)(1)(ii) of the FTC Rule.

³³ See section 1(C)(2)(j) of the Maine Rule.

³⁴ Compare section 1(C)(2)(h)(i) of the Maine Rule with 16 CFR 455.2(b)(2)(i) (1987).

³⁵ Compare section 1(C)(2)(h)(ii) of the Maine Rule with 16 CFR 455.2(b)(2)(ii) (1987). See also Me. Rev. Stat. Ann. tit. 10, sec. 1474(3)(B)(2).

³⁶ Compare section 1(C)(2)(h)(iii) of the Maine Rule with 16 CFR 455.2(b)(2)(iii) (1987). See also Me. Rev. Stat. Ann. tit. 10, sec. 1474(3)(B)(1).

³⁷ Compare section 1(C)(2)(h)(iv) of the Maine Rule with 16 CFR 455.2(b)(2)(iv) (1987).

²⁹ Compare sections 1(C)(1)(a) and (b) of the Maine Rule with 16 CFR 455.2(a)(1) and (2) (1987).

³⁰ SBP at 45,705.

³¹ This statement reads: "You will pay all costs for any repairs. The dealer assumes no responsibility for any repairs regardless of any oral statements about the vehicle."

³² See *supra* note 24.

³³ Under section 108(a) of the Magnuson-Moss Warranty Act, 15 U.S.C. 2308(a) (1983 & Supp. 1987), implied warranties may not be limited or disclaimed if the parties enter into a service contract on the vehicle within ninety days of the time of sale.

³⁴ *Id.* See also Me. Rev. Stat. Ann. tit. 10, sec. 1475(2)(E).

The Maine Rule, like the FTC Rule, also gives dealers the option of disclosing whether the manufacturer's original warranty still applies.⁴³

In addition to the above disclosures, the Maine Rule requires that dealers disclose a deductible, if applicable, in a space provided in the warranty section of the Maine Buyer's Guide.⁴⁴ The FTC Rule does not contain an analogous provision.⁴⁵

Subsection (vii) of section 1(C)(2)(h) of the Maine Rule states that if the dealer originally offers the vehicle with an express warranty but, after negotiations with the consumer, sells the vehicle with no express warranty, it should cross out the warranty disclosure on the Maine Buyer's Guide and check the box next to the "NO EXPRESS WARRANTY EXCEPT THAT VEHICLE MEETS STATE INSPECTION STANDARDS" disclosure. This section of the Maine Rule is analogous to the last two paragraphs in § 455.2(b)(2) of the FTC Rule concerning how to note negotiated changes in warranty coverage on the Buyers Guides.

(iv) *Service Contract Availability.* Section 1(C)(2)(i) of the Maine Rule requires dealers to check the box next to the words "SERVICE CONTRACT" if it chooses to offer such a contract. This section tracks § 455.2(b)(3) of the FTC Rule.

(v) *Vehicle, Dealership and Complaint Information.* Section 455.2(d) of the FTC Rule requires dealers to include certain vehicle information on the Buyers Guide, including the make, model, model year and vehicle identification number. Dealers may also include their vehicle stock number. These disclosures are designed to enhance the value of the Buyers Guide as evidence of the agreement between the dealer and the consumer.⁴⁶ The Maine provision, section 1(C)(2)(a), is identical to this FTC Rule provision.

Similar to § 455.2(c) and (e) of the FTC Rule, section 1(C)(2)(m) of the Maine Rule requires dealers to disclose on the back of the Buyer's Guide the name and address of the dealership, and the name, title and phone number of the dealership employee who should be contacted if complaints arise after the sale. Unlike

the FTC Rule, this section of the Maine Rules also requires that if warranty repairs are not to be performed at the dealership providing the warranty, dealers must place the name, address and other identifying information of each facility within a radius of 50 miles of the dealer's place of business to which the vehicle may be brought for warranty service.⁴⁷

(vi) *Statement Concerning Pre-Purchase Independent Inspection.* Near the bottom of the FTC Buyers Guide there is a required disclosure suggesting that consumers inquire about the availability of an independent, pre-purchase inspection.⁴⁸ The Maine Rule requires a similar disclosure, in larger lettering, placed toward the top of the Maine Buyer's Guide.⁴⁹

(vii) *Spoken Promises Warning.* An identical warning against relying on spoken promises is required to be included on the top of both the FTC Buyers Guide and the Maine Rule Buyer's Guide.

(viii) *List of Major Vehicle Systems.* An identical list of the fourteen major mechanical and safety systems of an automobile and some of the major problems that can occur in these systems is required on the back of both the FTC Buyers Guide and the Maine Rule Buyer's Guide.

(c) *Text of Window Stickers—Additional Disclosures Required by Maine.* In addition to the disclosures required by the FTC Rule, the Maine Rule requires several disclosures that are not required by the FTC Rule. These additional disclosures are discussed below.

(i) *Prior Use of Vehicle.* Section 1(C)(2)(b) of the Maine Rule requires that dealers disclose, on the Buyer's Guide, "the principal use to which the vehicle was put by the former owner." This disclosure would be made in one of two ways. If the former owner used the vehicle for personal use, the dealer would check the box next to the word "PERSONAL." If the prior owner used the vehicle for other than personal use (e.g., police car, daily rental car, taxi, etc.), the dealer would check the box next to the word "OTHER," and state that prior use in the space provided.

(ii) *How Vehicle Was Acquired.* Section 1(C)(2)(d) of the Maine Rule requires the dealer to disclose, on the Buyer's Guide, "the type of sale by which [the dealer] acquired the vehicle." This disclosure would be made in one of two ways. If the dealer obtained the vehicle through a trade-in, it would check the box next to the word "TRADE-IN." If the dealer obtained the vehicle through another method, such as a sheriff's sale, repossession, auction, etc., it would check the box next to the word "OTHER," and state that method on the space provided.

(iii) *Known Mechanical Defects or Prior Substantial Damage.* Section 1(C)(2)(c) of the Maine Rule requires that dealers disclose, on the Buyer's Guide all mechanical defects known at the time of sale, even if the dealer has fully repaired the defect.⁵⁰ Further, section 1(C)(2)(e) of the Maine Rule requires dealers to disclose on the Buyer's Guide "any and all substantial damage that the vehicle has sustained that is known to [the dealer], including damage to the body or engine from collision, fire, water or other causes. [The dealer] must make this disclosure even if [the dealer has] fully repaired the damage."⁵¹ In large letters under the spaces for this disclosure and the disclosure of known mechanical defects is the following statement: "IMPORTANT: THESE ARE THE ONLY PROBLEMS KNOWN TO THE DEALER. ASK IF YOU MAY GET AN INDEPENDENT INSPECTION BEFORE PURCHASE."

The FTC Rule Buyers Guide also contains (at the bottom) a statement suggesting that the consumer request an independent inspection of the vehicle prior to purchase. The Maine Rule's disclosure is in larger type than its FTC Rule counterpart. It is placed adjacent to the mechanical defects and prior substantial damage disclosures on the Maine Rule Buyer's Guide.

(iv) *Availability of Prior Owner's Name and Address.* Section 1(C)(2)(k) of the Maine Rule would require dealers to place a disclosure at the bottom of the Buyer's Guide informing the consumer that the previous owner's name and address is available from the dealer upon request.⁵²

(v) *Whether Vehicle Has Been Returned to Manufacturer.* Section 1(C)(2)(l) of the Maine Rule requires dealers to disclose, on the reverse side of the Maine Rule Buyer's Guide,

⁴³ Compare section 1(C)(2)(h)(vi) of the Maine Rule with 16 CFR 455.2(b)(2)(v) (1987).

⁴⁴ See section 1(C)(2)(h)(v) of the Maine Rule.

⁴⁵ The staff compliance guidelines for the Used Car Rule suggest that dealers disclose the existence of a deductible by placing asterisks next to the percentage of parts and labor disclosures and writing an explanation of the terms of the deductible on the top line of the "systems covered/duration" portion of the Buyers Guide. See 52 FR at 18559, 19854.

⁴⁶ See SBP at 45,710.

⁴⁷ See also Me. Rev. Stat. Ann. tit. 10, sec. 1474(3)(A)(1).

⁴⁸ This disclosure states: "PRE PURCHASE INSPECTION: ASK THE DEALER IF YOU MAY HAVE THIS VEHICLE INSPECTED BY YOUR MECHANIC EITHER ON OR OFF THE LOT."

⁴⁹ This disclosure reads, in pertinent part: "ASK IF YOU MAY GET AN INDEPENDENT INSPECTION BEFORE PURCHASE." This provision is addressed further in this notice in the sections discussing disclosure of known mechanical defects and substantial damage.

⁵⁰ See also 10 M.R.S.A. sec. 1475(2)(C).

⁵¹ See also Me. Rev. Stat. Ann. tit. 10, sec. 1475(2)(D).

⁵² See also Me. Rev. Stat. Ann. tit. 10, sec. 1475(2)(B).

whether the vehicle has been returned to the manufacturer because of non-conformity with express warranties. If the dealer knows that the vehicle has been so returned, it must describe the non-conformities in the space provided.

3. Section 455.3—Window Stickers Given to Purchaser and Incorporated into Contract

Section 455.3(a) of the FTC Rule directs dealers to give purchasers of used vehicles a Buyers Guide that includes any agreed-upon warranty coverage. The Maine Rule contains a substantially similar provision at section 1(D)(1). Similar to § 455.3(b) of the FTC Rule, section 1(D)(2) of the Maine Rule provides that the information on the Buyer's Guide is incorporated into the contract of sale and overrides any contrary provisions in the contract of sale. This section also requires that dealers place a two-sentence disclosure in the contract of sale informing consumers of this fact.⁵³ This disclosure is identical to the disclosure required by § 455.3(b) of the FTC Rule. The Maine Rule, however, specifies that the disclosure be placed in 10-point bold caps, while the FTC Rule merely requires that the disclosure be placed "conspicuously" in the contract.

4. Section 455.4—Contrary Statements

Section 455.4 of the FTC Rule prohibits dealers from making any statements, oral or written, or from taking other actions which alter or contradict the disclosures required by the Rule. Further, it recognizes that dealers may negotiate with consumers over warranty coverage, but requires that the final warranty terms be identified in the contract of sale and summarized on the final Buyers Guide that is given to the consumer. Sections 1(D)(3) and (4) of the Maine Rule contain equivalent requirements.

5. Section 455.5—Spanish Language Sales

Unlike the FTC Rule, Maine Rule does not contain a requirement that dealers prepare, display, and provide a Spanish language Buyers Guide if the transaction is conducted in that language. In noting this difference, the Maine petition states that such a requirement is not necessary in the Maine Rule due to Maine's low percentage of Spanish-speaking people. According to information obtained by the Commission from the U.S. Bureau of

the Census,⁵⁴ in 1980 Maine had both the lowest percentage and the lowest raw number of Spanish speaking persons among the fifty states and the District of Columbia.⁵⁵

D. Does Maine Evidence a Willingness and Ability To Enforce its Sticker Rule?

Pursuant to 16 CFR 455.6 (1987), the final requirement for obtaining and retaining a statewide exemption from the FTC Rule is a showing that a state administers and enforces effectively the state requirement that would replace the FTC Rule. Accordingly, the Funeral Rule state exemption guidelines ask states to submit sufficient information to show a willingness and ability to enforce their laws effectively.⁵⁶ Specifically, those guidelines state that staff will consider the following information as relevant to this determination:

(1) The fiscal arrangements and funding of the state agency (or agencies) which is charged with enforcing the state law, or other information indicating that the state agency has adequate funding to properly enforce the law;

(2) The number and qualifications of persons engaged in the enforcement and administration of the state law, or other information indicating that the state has adequate qualified personnel to administer and enforce the law;

(3) The state's current or planned enforcement procedures;

(4) The state's past history of enforcement of statutes which are comparable to the Commission's rule; and

(5) The level of compliance with any state statutes or regulations governing the practices covered by the Commission's rule, insofar as this information is relevant to the state's enforcement history.⁵⁷

⁵⁴ June 12, 1987 Letter from Paul M. Siegel, Chief, Education and Social Stratification Branch, Population Division, Bureau of the Census, United States Department of Commerce, Washington, DC 20233.

⁵⁵ These data are derived from two census questions. First, the subject was asked: "Does this person speak a language other than English at home?" If the answer to that question was yes, the person was asked: "What is that language?" 2,987 Maine citizens, or 0.3% of Maine's population, answered "Yes" and "Spanish," respectively, to these questions in 1980. This data compares to 3,270,267, or 14.5% of California residents. Of course, this information does not specifically reveal the number of Spanish-speaking people who have little or no comprehension of English, and would therefore require a Spanish language Buyer's Guide while shopping for a used vehicle.

⁵⁶ 50 FR at 12525.

⁵⁷ *Id.* The guidelines also recognize that some of this information may not be relevant or available in certain states and that each state application may differ accordingly.

Appendix E of the Maine Petition discusses enforcement of the Maine Rule, and is summarized below.

Both the Maine Department of the Attorney General and the Maine Department of Motor Vehicles enforce the provisions of the Maine Used Car Information Act, the enabling statute for the Maine Rule. A violation of the Maine Rule is a *per se* violation of the Maine Unfair Trade Practices Act, which the Maine Attorney General's office is primarily responsible for enforcing.⁵⁸ The Department of Motor Vehicles has the power to deny, suspend or revoke the license of any dealer who does not comply with the Maine Rule.⁵⁹ To qualify as a "dealer" under the licensing provisions of the Maine Code, one must comply with the disclosure requirements of the MUCIA.⁶⁰

1. Funding and Staffing of Agencies

According to the Maine Department of the Attorney General, there are four assistant attorneys general, five paralegals, one investigator and two clerical workers assigned exclusively to consumer protection matters in the state.⁶¹ The enforcement staff at the Department of Motor Vehicles consists of fifteen investigators and two clerical workers.⁶² Additionally, there are two state police officers who conduct MUCIA inspections on a part-time basis.⁶³

2. Enforcement Procedures

(a) *Department of Attorney General.* According to the Maine Petition, enforcement of the MUCIA can commence in at least two ways. First, investigators within the Consumer and Antitrust Division of the Attorney General's Office have been instructed generally to survey used car lots during their travels around the state and to submit reports of their findings to the Director of Investigations.⁶⁴ Second,

⁵⁸ See section I(E) of the Maine Rule; Appendix E of Petition, at 1; Letter from Maine Attorney General James E. Tierney to Secretary, Federal Trade Commission, Apprxix F of Petition, at 2.

⁵⁹ See Me. Rev. Stat. Ann. tit. 29, sec. 343(1)(F); Me. Rev. Stat. Ann. tit. 29, sec. 350-A(F); Appendix E of Petition, at 2.

⁶⁰ See Me. Rev. Stat. Ann. tit. 29 sec. 343(1)(F).

⁶¹ September 17, 1987 telephone conversation between James McKenna and Matthew Gold. Mr. McKenna stated that the yearly budget for the attorney general's office is not broken down among the various divisions, so he is unable to provide staff with a specific dollar amount representing the budget for his division.

⁶² *Id.*

⁶³ *Id.*

⁶⁴ See attachment to Appendix E.

⁵³ This disclosure reads as follows: "The information you see on the window form for this vehicle is part of this contract. Information on the window form overrides any contrary provisions in the contract of sale."

mediators in that office attempt to resolve complaints involving used motor vehicle transactions. As part of this process, the mediator determines whether the dealer in question has been making the disclosures required by both the Maine Rule and the FTC Rule. According to the Petition, repeated failure to make the required disclosures results in an unfair trade practice investigation, which may lead to an Assistant Attorney General initiating a formal enforcement action.

Each violation of the MUCIA subjects the violator to a civil penalty of between \$100 and \$1,000.⁶⁵ Under the FTC Act, violators of trade regulation rules may be punished by penalties of up to \$10,000 per violations.⁶⁶ The Maine Rule contains a two-year statute of limitations.⁶⁷ This contrasts with the five-year statute of limitations applicable to enforcement of FTC trade regulations rules.⁶⁸ Additionally, the Maine Rule specifically provides dealers with a defense if the alleged violations are shown to be "unintentional" and "bona fide error[s]."⁶⁹ Neither the FTC Rule nor the FTC Act contains a defense based on intent.⁷⁰

(b) *Department of Motor Vehicles.* The Department of Motor Vehicles employs investigators who enforce the disclosure requirements of the MUCIA.⁷¹ According to the Petition, the DMV typically gives a violating dealer ten days to comply. Failure to do so results in the issuance of a civil complaint in state district court.⁷²

3. History of Enforcement of the MUCIA

The mediation program of the Consumer and Antitrust Division of the Attorney General's Office has resolved 197 out of 481 complaints received since

January, 1985.⁷³ During the past two years, that Division has conducted 59 MUCIA civil or criminal investigations, eleven of which were litigated. All eleven resulted in either a consent decree or a court injunction with penalties.⁷⁴

4. Private Right of Action

A dealer who violates the MUCIA may be liable to the purchaser in an amount not less than \$100 and not more than \$1,000 in liquidated damages, in addition to costs and reasonable attorneys fees.⁷⁵ This penalty may be imposed in addition to any civil penalty awarded in a separate action brought by a state agency.⁷⁶

IV. Requests for Public Comment

The Commission has determined that the Maine Petition contains sufficient information to initiate a proceeding on whether to grant an exemption pursuant to § 455.6 of the FTC Rule. Accordingly, the Commission requests public comment on whether to grant a statewide exemption to the State of Maine from the FTC Rule.

The following questions are designed to elicit public comment on whether the Maine Rule provides protection to consumers that is equal to or greater than that provided by the FTC Rule. To that end, commenters are encouraged to support their conclusions with factual information or data.

1. Does the Maine Rule apply to the same transactions as does the FTC Rule, and, if not, how do the differences in coverage affect the level of protection afforded to consumers in the State of Maine?

2. How does the disclosure regarding the mandatory "warranty of inspectability" on the Maine Rule Buyer's Guide affect the overall level of protection afforded to consumers by the state laws?

3. How does the disclosure regarding implied warranties on the Maine Rule Buyer's Guide affect the overall level of protection afforded to consumers by the state laws?

4. What is the impact on the overall level of protection provided to consumers by disclosures included in the Maine Rule (for example, the "prior use" and "how acquired" disclosures)

but which are not included in the FTC Rule?

5. In what way does the private right of action available in Maine affect the overall level of protection provided to consumers by the state law?

6. Compared with the FTC Rule, what is the impact of the Maine Rule on the overall level of protection provided to Spanish-speaking consumers, given that the Maine Rule does not require that a Spanish-language Buyer's Guide be used if the sale is conducted in Spanish?

7. In general, do the Maine Rule and other state laws provide an overall level of protection to consumers which is as great as, or greater than, the protection afforded by the FTC Rule?

The following questions are designed to elicit public comment on whether the Petition demonstrates Maine's willingness and ability to enforce adequately its state law. To that end, commenters are encouraged to support their conclusions with factual information or data.

8. Are the sanctions available under state law sufficient to deter violations of the Maine Rule?

9. In general, has Maine demonstrated its willingness and ability to enforce the Maine Rule?

Under the Funeral Rule state exemption guidelines, additional procedures for public participation may be scheduled if necessary for a full and fair presentation of significant issues.⁷⁷ For example, the guidelines state that oral hearings may be necessary if there are significant factual issues that can be adequately presented only through an oral hearing, such as where cross-examination is necessary to present significant factual issues fully and fairly.⁷⁸ In the Commission's opinion, a determination as to whether such procedures will be necessary can not be made at this time. However, interested parties may request that the Commission schedule an oral hearing or a period for rebuttal comments.

List of Subjects in 16 CFR Part 455 (1987)

Used cars, Trade practices.

By direction of the Commission.

Emily H. Rock,
Secretary.

Editorial Note: This form, which appears in the Code of Federal Regulations in 16 CFR Part 455, is republished for the convenience of the reader.

BILLING CODE 6750-01-M

⁷⁷ 50 FR at 12523, 12525-26.

⁷⁸ *Id.* at 12,525.

⁶⁵ Me. Rev. Stat. Ann. tit. 10, sec. 1477(2).

⁶⁶ 15 U.S.C. 45(m)(1)(A) (1978 & Supp. 1987).

⁶⁷ Me. Rev. Stat. Ann. tit. 10, sec. 1477(2). The statute reads: "No action may be brought for a civil violation under this subsection more than 2 years after the date of the occurrence of the violation."

⁶⁸ 28 U.S.C. 2462 (1978 & Supp. 1987).

⁶⁹ *Id.* The statute reads: No dealer may be held liable for a civil violation under this subsection if he shows by a preponderance of the evidence that the violation was unintentional and a bona fide error, notwithstanding the maintenance of procedures reasonably adopted to avoid any such error."

⁷⁰ But see section 45(m)(1)(A) of the FTC Act, 15 U.S.C. 45(m)(1)(A) (1978 & Supp. 1987), which requires the Commission to prove "actual knowledge [of a trade regulation rule] or knowledge fairly implied on the basis of objective circumstances." The Maine Rule does not contain a specific notice requirement.

⁷¹ Petition, Appendix E, at 2. See also *supra* text accompanying note 61.

⁷² *Id.*

⁷³ Petition, Appendix E, at 1.

⁷⁴ *Id.* See also *supra* note 65 and accompanying text.

⁷⁵ Me. Rev. Stat. Ann. tit. 10, sec. 1477(3).

⁷⁶ *Id.*

BUYERS GUIDE

IMPORTANT: Spoken promises are difficult to enforce. Ask the dealer to put all promises in writing. Keep this form.

VEHICLE MAKE _____

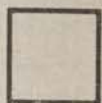
MODEL _____

YEAR _____

VIN NUMBER _____

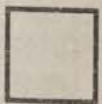
DEALER STOCK NUMBER (Optional) _____

WARRANTIES FOR THIS VEHICLE:



AS IS - NO WARRANTY

YOU WILL PAY ALL COSTS FOR ANY REPAIRS. The dealer assumes no responsibility for any repairs regardless of any oral statements about the vehicle.



WARRANTY

☐ FULL

☐ LIMITED WARRANTY. The dealer will pay _____% of the labor and _____% of the parts for the covered systems that fail during the warranty period. Ask the dealer for a copy of the warranty document for a full explanation of warranty coverage, exclusions, and the dealer's repair obligations. Under state law, "implied warranties" may give you even more rights.

SYSTEMS COVERED:

DURATION:

☐ SERVICE CONTRACT. A service contract is available at an extra charge on this vehicle. Ask for details as to coverage, deductible, price, and exclusions. If you buy a service contract within 90 days of the time of sale, state law "implied warranties" may give you additional rights.

PRE PURCHASE INSPECTION: ASK THE DEALER IF YOU MAY HAVE THIS VEHICLE INSPECTED BY YOUR MECHANIC EITHER ON OR OFF THE LOT.

SEE THE BACK OF THIS FORM for important additional information, including a list of some major defects that may occur in used motor vehicles.

Below is a list of some major defects that may occur in used motor vehicles.

Frame & Body

Frame-cracks, corrective welds, or rusted through
Dogtracks—bent or twisted frame

Engine

Oil leakage, excluding normal seepage
Cracked block or head
Belts missing or inoperable
Knocks or misses related to camshaft lifters and push rods
Abnormal exhaust discharge

Transmission & Drive Shaft

Improper fluid level or leakage, excluding normal seepage
Cracked or damaged case which is visible
Abnormal noise or vibration caused by faulty transmission or drive shaft
Improper shifting or functioning in any gear
Manual clutch slips or chatters

Differential

Improper fluid level or leakage excluding normal seepage
Cracked or damaged housing which is visible
Abnormal noise or vibration caused by faulty differential

Cooling System

Leakage including radiator
Improperly functioning water pump

Electrical System

Battery leakage
Improperly functioning alternator, generator, battery, or starter

Fuel System

Visible leakage

Inoperable Accessories

Gauges or warning devices
Air conditioner
Heater & Defroster

Brake System

Failure warning light broken
Pedal not firm under pressure (DOT spec.)
Not enough pedal reserve (DOT spec.)
Does not stop vehicle in straight line (DOT spec.)
Hoses damaged
Drum or rotor too thin (Mfr. Specs)
Lining or pad thickness less than 1/32 inch
Power unit not operating or leaking
Structural or mechanical parts damaged

Steering System

Too much free play at steering wheel (DOT specs.)
Free play in linkage more than 1/4 inch
Steering gear binds or jams
Front wheels aligned improperly (DOT specs.)
Power unit belts cracked or slipping
Power unit fluid level improper

Suspension System

Ball joint seals damaged
Structural parts bent or damaged
Stabilizer bar disconnected
Spring broken
Shock absorber mounting loose
Rubber bushings damaged or missing
Radius rod damaged or missing
Shock absorber leaking or functioning improperly

Tires

Tread depth less than 2/32 inch
Sizes mismatched
Visible damage

Wheels

Visible cracks, damage or repairs
Mounting bolts loose or missing

Exhaust System

Leakage

DEALER

ADDRESS

SEE FOR COMPLAINTS

IMPORTANT: The information on this form is part of any contract to buy this vehicle. Removal of this label before consumer purchase (except for purpose of test-driving) is a violation of federal law (16 C.F.R. 455).

Editorial Note: This form will not appear in the Code of Federal Regulations.

USED VEHICLE BUYER'S GUIDE

IMPORTANT: Spoken promises are difficult to enforce. Ask the dealer to put all promises in writing. Keep this form.

VEHICLE MAKE

MODEL

YEAR

VIN NUMBER

DEALER STOCK NUMBER (Optional)

PRIOR USE: ☐ PERSONAL: ☐ OTHER

HOW ACQUIRED: ☐ TRADE-IN: ☐ OTHER

MECHANICAL DEFECTS IF ANY KNOWN:

PRIOR SUBSTANTIAL DAMAGE TO BODY OR ENGINE IF ANY KNOWN:

IMPORTANT: THESE ARE THE ONLY PROBLEMS KNOWN TO THE DEALER. ASK IF YOU MAY GET AN INDEPENDENT INSPECTION BEFORE PURCHASE.

☐ WARRANTY OF INSPECTABILITY

STATE LAW REQUIRES THAT THIS VEHICLE MEETS STATE INSPECTION STANDARDS AND HAS A VALID INSPECTION STICKER ISSUED WITHIN 30 DAYS OF THE SALE OF THIS VEHICLE.

☐ NO EXPRESS WARRANTY EXCEPT THAT VEHICLE MEETS STATE INSPECTION STANDARDS

YOU WILL PAY ALL COSTS FOR ANY REPAIRS NOT RELATED TO MEETING STATE INSPECTION STANDARDS. REGARDLESS OF ANY ORAL STATEMENTS ABOUT THE VEHICLE, THE DEALER ACCEPTS NO RESPONSIBILITY FOR REPAIRS EXCEPT THOSE NECESSARY TO PASS STATE INSPECTION.

☐ DEALER EXPRESS WARRANTY

☐ FULL

☐ LIMITED WARRANTY. The dealer will pay _____% of the labor and _____% of the parts for the covered systems that fail during the warranty period. Ask the dealer for a copy of the warranty document for a full explanation of warranty coverage, exclusions, and the dealer's repair obligations. Under Maine law, "implied warranties" may give you even more rights and cannot be limited by the dealer while this express warranty is still in effect. For each repair the buyer will pay a deductible of \$ _____

SYSTEMS COVERED:

DURATION:

☐ SERVICE CONTRACT: A service contract is available at an extra charge on this vehicle. Ask for details as to coverage, deductible, price, and exclusions. If you buy a service contract within 90 days of the time of sale, Maine "implied warranties" cannot be limited by the dealer and may give you additional rights.

IMPLIED WARRANTIES

☐ YES ☐ NO ☐ LIMITED TO DURATION OF EXPRESS WARRANTY

Maine's implied warranty law may give you additional rights. If the vehicle is still within its useful life and has not been abused, you may have the right to have the dealer repair defects in materials or workmanship that were not apparent when you bought the vehicle. Or you may be able to return the car if the dealer promised you it was fit for a particular use and it was not.

IMPORTANT INFORMATION

- PRIOR OWNERS NAME AND ADDRESS IS AVAILABLE FROM THE DEALER UPON REQUEST.
- SEE THE BACK OF THIS FORM FOR ADDITIONAL INFORMATION, INCLUDING A LIST OF SOME MAJOR DEFECTS THAT MAY OCCUR IN USED MOTOR VEHICLES.

IMPORTANT NOTE: THIS FORM HAS BEEN REDUCED FROM THE 8 1/2" x 12 1/2" MINIMUM SIZE PRESCRIBED BY SECTION 1(C) (1)(b) OF THE MAINE USED CAR INFORMATION ACT STICKER RULE

Below is a list of some major defects that may occur in used motor vehicles.

Frame & Body

Frame-cracks, corrective welds, or rusted through
Dogtracks — bent or twisted frame

Engine

Oil leakage, excluding normal seepage
Cracked block or head
Belts missing or inoperable
Knocks or misses related to camshaft lifters and push rods
Abnormal exhaust discharge

Transmission & Drive Shaft

Improper fluid level or leakage, excluding normal seepage
Cracked or damaged case which is visible
Abnormal noise or vibration caused by faulty transmission or drive shaft
Improper shifting or functioning in any gear
Manual clutch slips or chatters

Differential

Improper fluid level or leakage excluding normal seepage
Cracked or damaged housing which is visible
Abnormal noise or vibration caused by faulty differential

Cooling System

Leakage including radiator
Improperly functioning water pump

Electrical System

Battery leakage
Improperly functioning alternator, generator, battery or starter

Fuel System

Visible leakage

Inoperable Accessories

Gauges or warning devices
Air conditioner
Heater & Defroster

Brake System

Failure warning light broken
Pedal not worn under pressure (DOT spec.)
Not enough pedal reserve (DOT spec.)
Does not stop vehicle in straight line (DOT spec.)
Hoses damaged
Drum or rotor too thin (Mfr. Specs.)
Lining or pad thickness less than 1/32 inch
Power unit not operating or leaking
Structural or mechanical parts damaged

Steering System

Too much free play at steering wheel (DOT specs.)
Free play in linkage more than 1/4 inch
Steering gear binds or jams
Front wheels aligned improperly (DOT specs.)
Power unit belts cracked or slipping
Power unit fluid level improper

Suspension System

Ball joint seals damaged
Structural parts bent or damaged
Stabilizer bar disconnected
Spring broken
Shock absorber mounting loose
Rubber bushings damaged or missing
Radius rod damaged or missing
Shock absorber leaking or functioning improperly

Tires

Tread depth less than 2/32 inch
Sizes mismatched
Visible damage

Wheels

Visible cracks, damage or repairs
Mounting bolts loose or missing

Exhaust System

Leakage

Vehicle Returned to Manufacturer.

This vehicle has _____ has not _____ been returned to the manufacturer, its agent or authorized dealer, for its non-conformity with express warranties. These non-conformities were: _____

Notice of Breach of Warranty.

If a dealer fails to perform his obligation under the warranty, the purchaser shall give the dealer written notice of such failure before the purchaser initiates a civil action in accordance with 10 MRSA § 1476. This notice must be sent by registered or certified mail to the dealer's last known business address.

Dealer _____

Address _____

If you have a complaint about this vehicle contact the following representative of the dealer:

Name _____

Title _____

Phone _____

IMPORTANT: The information on this form is part of any contract to buy this vehicle. Removal of this label before consumer purchase (except for purpose of test-driving) is a violation of the Used Car Information Act (10 MRSA §§ 1471-1477) and the Rules promulgated by the Maine Secretary of State.

Environmental Protection Agency Federal Register

**Monday
December 28, 1987**

Part III

Environmental Protection Agency

40 CFR Parts 160 and 792

**Federal Insecticide, Fungicide and
Rodenticide Act (FIFRA) and Toxic
Substances Control Act (TSCA); Good
Laboratory Practice Standards; Proposed
Rules**

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 160

[OPP-300165; FRL 3245-5]

Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); Good Laboratory Practice Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to expand the scope of the FIFRA Good Laboratory Practice (GLP) Standards by requiring GLP compliance for testing conducted in the field and for such disciplines of testing as ecological effects, chemical fate, residue chemistry, and, as required by 40 CFR 158.160, product performance (efficacy testing). EPA is proposing this amendment in order to ensure the quality and integrity of all data submitted to the Agency in conjunction with pesticide product registration, or other marketing and research permits. EPA is also proposing to amend the FIFRA GLPs to incorporate many of the changes made by the Food and Drug Administration (FDA) to its GLP regulations.

DATE: Submit written comments on or before March 28, 1988.

ADDRESS: Submit written comments, identified by the document control number (OPP-300165), by mail to: Information Services Section, Program Management and Support Division (TS-757C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. In person, deliver comments to: Rm. 236, CM - 2, 1921 Jefferson Davis Highway, Arlington, VA.

Information submitted in any comment concerning this proposed rule may be claimed confidential by marking any part 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 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. All written comments will be available for public inspection in Rm. 236 at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Daniel A. Helfgott, Office of Compliance Monitoring (EN-342), Rm. E-707B, 401 M

St. SW., Washington, DC 20460, Telephone: (202) 382-7825.

SUPPLEMENTARY INFORMATION:

Following is an index to the remainder of this preamble:

- I. Introduction
 - A. Legal Authority
 - B. Background
 - C. Consistency With FDA GLP Regulations
 - D. Proposed Changes to the FIFRA GLP Regulation
- II. Economic Analysis
- III. Statutory Requirements
- IV. Other Regulatory Requirements
 - A. Executive Order 12291
 - B. Regulatory Flexibility Act
 - C. Paperwork Reduction Act

I. Introduction

A. Legal Authority

These standards are promulgated under the authority of sections 3, 5, 6, 8, 18, 24(c), and 25(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq., sections 408, 409, and 701 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 et seq., and Reorganization Plan No. 3 of 1970.

B. Background

EPA originally published enforceable FIFRA Good Laboratory Practice Standards in the *Federal Register* of November 29, 1983 (48 FR 53446), which were codified as 40 CFR Part 160. At the same time, EPA published GLP standards applicable to testing required under the Toxic Substances Control Act (TSCA), 48 FR 53922, 40 CFR Part 792. These regulations were promulgated in response to investigations by EPA and FDA during the mid-1970s 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. For instance, some studies had been submitted which did not adhere to specified protocols, were conducted by underqualified personnel and supervisors, or were not adequately monitored by study sponsors. 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 record-keeping techniques. The FIFRA GLP standards specify minimum practices and procedures which must be followed 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.

When EPA published its final FIFRA and TSCA GLP standards in the *Federal Register* of November 29, 1983, the Agency 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 GLP regulations exist only to the extent necessary to reflect the Agencies' different statutory TSCA, FIFRA, and the Federal Food, Drug, and Cosmetic Act (FFDCA) responsibilities. Similar to the FDA GLP regulations, the FIFRA and TSCA GLPs delineate standards for studies designed to determine the health effects of a test substance; however, the TSCA GLPs also contain provisions related to environmental testing (i.e., ecological effects and chemical fate).

Compliance with EPA's GLP regulations has been monitored through a program of laboratory inspections and study audits coordinated between EPA and FDA. Under an Interagency Agreement originating in 1978, FDA carries out inspections at laboratories which conduct health effects testing. EPA primarily performs laboratory inspections and data audits for environmental studies.

After a thorough review of its GLP regulations and compliance program, FDA concluded that some of the provisions of the GLPs needed to be clarified, amended, or deleted in order to reduce the regulatory burden on testing facilities. Accordingly, FDA proposed revisions to its GLPs in the *Federal Register* of October 24, 1984 (49 FR 43530), which were intended to simplify the regulation without compromising study integrity. FDA's proposed revision has recently been published as a final rule in the *Federal Register* of September 4, 1987 (52 FR 33768).

EPA agrees with FDA that many provisions of the GLP regulations can be streamlined without compromising the goals of the GLPs. Therefore, EPA is proposing to amend the FIFRA GLP standards to incorporate many of the changes recently made by FDA to its GLP regulations. In addition, EPA is proposing to expand the scope of the FIFRA GLPs to include the environmental testing provisions currently found in the TSCA GLPs. EPA's proposed revision to the GLPs also extends the scope of the regulation to include product performance data (efficacy testing) as required by 40 CFR 158.160. In sum, the proposed FIFRA GLPs will allow the Agency to ensure the quality and integrity of all data

submitted in support of pesticide product research or marketing permits. In another notice in this **Federal Register**, EPA is proposing similar changes to the TSCA GLP standards.

C. Consistency With FDA GLP Regulations

It is EPA's policy to minimize the regulatory burden on the public which might arise from conflicting requirements which could be promulgated under different regulatory authorities. In keeping with this policy, the final FIFRA 1983 GLP standards, 40 CFR Part 160, followed the format and, with few exceptions, the wording of FDA's final GLP regulations, 21 CFR Part 58. Differences between the EPA and FDA GLP regulations were based upon varying needs and responsibilities under each Agency's regulatory statutes. This proposed revision to the FIFRA GLPs follows this same policy by conforming to many of the changes FDA made to its GLP regulations, published in the **Federal Register** of September 4, 1987 (52 FR 33768). EPA has varied from FDA's revised GLP regulations only when necessary due to EPA's statutory responsibilities. The most significant differences between the EPA proposal and the FDA revised GLP regulations are the scope of the testing and test systems affected.

More specifically, EPA is proposing to require compliance with the FIFRA GLPs for all studies submitted to the Agency which are intended to support pesticide product research or marketing permits. Under the current FIFRA Good Laboratory Practice regulations, and consistent with the FDA GLP regulations, this Agency only requires GLP compliance for health effects testing. However, unlike FDA, testing required by EPA in support of research or marketing permits may include ecological effects, environmental and chemical fate, and efficacy (as stipulated by 40 CFR 158.160 *Product performance data requirements*), as well as health effects testing. Therefore, in an effort to attain consistency in the quality and the integrity of all data submitted to the Agency, EPA has determined that it is necessary to expand the scope of the FIFRA GLPs to require that all types of testing which are used to obtain data in support of research or marketing permits be conducted in accordance with the proposed GLP standards.

EPA's proposed FIFRA GLP standards also vary from FDA's in their coverage of testing conducted in the field. To ensure the quality and integrity of all data submitted in support of research or marketing permits, EPA believes that GLP standards must apply whenever

data collection occurs. Because many of the test data required by EPA are developed in the field, or more accurately in outdoor laboratories (i.e., ground-water studies, air monitoring studies, degradation in soil, etc.), EPA is proposing to include field testing within the scope of these regulations.

This Agency's proposed FIFRA GLPs also differ from FDA's in the scope of the requirements provided for test system care facilities, test system supply facilities, and test system care. Because testing required by FDA is focused on health testing, in which animals are the central test system, it is appropriate for FDA's GLP regulations to focus on requirements for appropriate animal care facilities (21 CFR 58.43), adequate animal supply facilities (21 CFR 58.45), and proper animal care (21 CFR 58.90). However, the broad range of testing required by EPA may involve plants, soils, and microorganisms, as well as animals, for the primary test systems. In order to ensure the quality and integrity of all data submitted to this Agency, it is proposed that § 160.43 *Animal care facilities*, § 160.45 *Animal supply facilities*, and § 160.90 *Animal care* be expanded to cover facilities, handling, and care of all test systems.

Accordingly, EPA is proposing that these sections be retitled as follows: § 160.43 *Test system care facilities*, § 160.45 *Test system supply facilities*, and § 160.90 *Animal and other test system care*. Further, in most instances, EPA is proposing to replace the term "animal," which is currently used in the FIFRA GLP regulations, with the broader term "test system." Specifically, this change is proposed in §§ 160.43, 160.45, 160.81, 160.90 and 160.120. These proposed changes are further discussed in Unit I.D. of this preamble.

The remaining differences between the EPA and FDA GLP regulations are described in the preamble to this proposed rule and the preamble to the FIFRA Good Laboratory Practice Standards, published in the **Federal Register** of November 29, 1983 (48 FR 53946). EPA has coordinated this proposal with FDA and has considered comments received on the proposal to amend the FDA GLP regulations (49 FR 43530; October 29, 1984).

D. Proposed Changes to the GLP FIFRA Regulations

1. *Section 160.3 Definitions.* a. EPA proposes to define the term "carrier" to mean any material, such as feed, water, soil, nutrient material, etc., with which the test substance is combined for administration to test organisms. The term "carrier" is currently used in

§ 160.113 and is not defined. EPA proposes to define this term to clarify it.

b. EPA proposes to conform with the September 4, 1987, FDA GLP regulations by amending the definition of "control substance" to exclude feed and water. EPA agrees with FDA's statement regarding this change (52 FR 33769; September 4, 1987) that "the term control [substance] should be reserved for the discrete substances/articles, and vehicles other than water administered to groups of the test system to provide a basis of comparison with the test [substance]."

FDA contends that, under the current definition of "control substance," because the control group of a test system provides the basis for comparison with a test substance, any substance administered to the control group would be considered a control substance. This would mean that feed and water given to the control group of a study are considered a control substance. For instance, in studies in which the test substance or mixture is administered to the test system orally, through feed or drinking water, gavage, or injection, the feed or water is considered a control substance. As a control substance, the feed or water is subject to § 160.105(a) for substance characterization, § 160.105(b) for testing for stability and solubility, § 160.105(c) for requirements for appropriate storage, § 160.105(d) for retention of reserve samples, and § 160.107 for documentation of receipt and distribution of each batch. EPA agrees with FDA that placing these requirements on the use of feed and water as a control substance in control groups unnecessarily burdens the regulated community and is not essential for ensuring the quality and integrity of the data generated by a study.

However, under 40 CFR Part 160, feed and water used as a carrier for the test and control substances or mixtures are still covered by the applicable sections for the testing and storage of test, control, and reference substances and mixtures. For example, § 160.31(e) requires testing facility management to ensure materials are available as scheduled; § 160.45 requires that test system supply facilities shall be provided to ensure proper feed storage; § 160.81(b)(2) requires Standard Operating Procedures (SOP) for test system care, including nutrition; § 160.90(g) requires periodic analysis of feed and water to ensure that contaminants which would interfere with the study are not present; § 160.120(a)(9) requires the protocol to

describe and/or identify the diet used in the study, including the level of contaminants expected in the dietary materials.

c. EPA also proposes to modify the definition of "control substance" by adding the phrase "for no effect levels." This addition to the definition is being proposed merely to clarify the difference between the term "reference substance" and "control substance." While a control substance is used to determine a baseline comparison to no effect levels, a reference substance is used to determine a baseline comparison to an established effect level.

d. EPA proposes to add and define the terms "experimental start date" and "experimental termination date." "Experimental start date" is proposed to mean the first date the test substance is applied to the test system. Under this definition, as of the experimental start date: (1) Under proposed § 160.105(b), the stability and, if important to the conduct of the experiment, the solubility of the test, control, and reference substances would have been determined; (2) under proposed § 160.113(a)(2), the stability and, if important to the conduct of the experiment, the solubility of the test, control, and reference substance in the mixture would have been determined and; (3) under proposed § 160.120(a)(4), the proposed experimental start date would appear in the protocol.

EPA proposes that "experimental termination date" be defined as the last date on which data are collected directly from the study. Under § 160.120(a)(4) as proposed, EPA would require the proposed experimental termination date to appear in the protocol. EPA considers histopathology after scheduled terminal animal sacrifice to be carried out before the experimental termination date.

Experimental start and termination dates would be expressed as the actual calendar dates, not just time-line increments. Therefore, when determining the proposed experimental start and termination dates, as would be required by proposed § 160.120(a)(4), the submitter should consider any lag time relating to protocol approval and laboratory contracting.

e. EPA proposes to add and define the term "reference substance" to mean any chemical substance or mixture or material other than a test substance that is administered to or used in analyzing the test system in the course of a study for purposes of establishing a basis for comparison with the test substance for known effect levels. EPA proposes the use of the term "reference substance" in the revised FIFRA GLP regulations

because of its common usage in environmental testing and, therefore, its proposed use in these regulations.

In this proposed GLP regulation, all the requirements provided for test and control substances would also apply to "reference substances." Accordingly, the term "reference substance" has been added wherever the term "test and control substance" appears in these standards. Specifically, the term "reference substance" is added to proposed § 160.29 (d) through (f); § 160.43(b); § 160.47(a) (1) through (3) and (b); § 160.81(b)(3); the Subpart F heading; § 160.90(c); § 160.105 (a) through (e); § 160.107; § 160.113 (a) and (b); § 160.120(a) (2), (9), and (11); § 160.185(a) (4) and (5); and § 160.195(c).

f. EPA proposes to broaden the definition of the term "study" to be consistent with EPA's proposal to amend these regulations to require GLP compliance for all testing required to be submitted to the Agency in conjunction with a pesticide product's research or marketing permit.

EPA is proposing to delete the phrase "in vivo or in vitro" from the definition of "study." The Agency still intends the requirements of these regulations to apply to "in vivo and in vitro" experiments. However, since the Agency intends these regulations to apply to all studies required to be submitted under FIFRA, including those conducted in the field, EPA feels that including the phrase "in vivo or in vitro" in the definition of "study" is too limiting.

Further, EPA is proposing to delete the term "prospectively" from the definition of "study." In this way, epidemiological studies, which could be "retrospective," will be required to be presented to the Agency in accordance with the GLP standards. EPA recognizes that data used in an epidemiological study may not have been generated in conformance with the FIFRA GLP standards, however, it is EPA's contention that the epidemiological study itself can be conducted and submitted to the Agency in accordance with the GLPs.

EPA is also proposing to delete from the current definition of "study" the following sentence: "The term does not include studies utilizing human subjects or clinical studies or field trials in animals." Again, this change is consistent with EPA's intention to require compliance with GLPs for all studies submitted to the Agency in support of a research or marketing permit for pesticide products, including biomonitoring or efficacy studies. FIFRA does not prohibit pesticide testing on humans (as long as the informed-consent conditions specified in FIFRA

section 12(a)(2)(P) are met, and provided the records required by 40 CFR 169.2(j) are maintained). EPA feels that testing that is performed on humans must be conducted in accordance with the GLPs, if that data is submitted to the Agency in support of a marketing or research permit.

It is also proposed that studies designed to determine the physical or chemical characteristics of a test substance be included within the scope of these regulations. Therefore, EPA is proposing that the phrase "or to determine physical or chemical characteristics of a test substance" be deleted from the definition of the term "study." This proposed change is consistent with the definition of the term "study" as it now appears, and as it is proposed to appear, in the TSCA Good Laboratory Practice Standards at 40 CFR Part 792. However, as specified in proposed § 160.135, exclusions from certain GLP requirements are provided for studies related to determining the physical or chemical characterization of a test, control, or reference substance (e.g., studies designed to determine color, odor, physical state, melting point, pH measurement, etc.).

g. EPA proposes to incorporate the FDA definitions for "study completion date" and "study initiation date" in § 160.3. "Study completion date" is proposed to mean the date the final report is signed by the study director. EPA advises that the phrase "close of the study" as used in § 160.33(f), and the phrase "study is completed" as used in § 160.195(b)(3) both refer to the "study completion date." Consistent with this definition, as of that date: (1) Under § 160.33(f), the study director must ensure that all raw data, documentation, protocols, specimens, and final reports are transferred to the archives; (2) after this date under § 160.185(c), corrections or additions to the final report must be in the form of an amendment by the study director under the procedures specified in that section; and (3) in the applicable situations described in § 160.195(b)(3), records must be maintained for a period of at least 2 years following the study completion date.

EPA proposes to define "study initiation date" as the date the protocol is signed by the study director. EPA advises that the phrase "study is initiated" as used in § 160.31(a), and the phrase "study was initiated" as used in § 160.35(b)(1) would refer to the "study initiation date." Therefore, as of the study initiation date: (1) Under § 160.31(a), the testing facility management would designate a "study

director; (2) under § 160.35(b)(1), the study would be entered on the master schedule sheet by the quality assurance unit; and (3) under § 160.120(b), after this date all changes or revisions in the protocol would be documented, signed by the study director, and dated. EPA also expects that as of the study initiation date, under § 160.31(e), the testing facility management would have ensured that personnel, resources, facilities, equipment, material, and methodologies are available as scheduled.

h. EPA proposes to replace the term "test substance or mixture" with the term "test substance." This is an editorial change which makes usage consistent in the GLP standards. The term "test substance" is proposed to be defined to include mixtures.

i. EPA proposes to expand the definition of "test system" to include chemical or physical matrices (e.g., soil or water). This proposal is consistent with the Agency's intent to expand these regulations to include environmental effects testing.

j. EPA proposes to define the term "vehicle" to mean any agent which facilitates the mixture, dispersion, or solubilization of a test substance with a carrier.

2. *Section 160.31 Testing facility management.* In conformance with the revised FDA GLP regulations, in § 160.31(b), EPA proposes to delete the requirement that the replacement of a study director must be documented as "raw data." EPA agrees with FDA that this requirement is redundant with other provisions of the GLPs. For instance, § 160.35(b)(1) states that the master schedule sheet must contain the name of the study director. As FDA notes (52 FR 33770), any replacement of the study director would be reflected on the master schedule sheet, which is already considered "raw data." Further, § 160.120(b) states that all changes in an approved protocol must be documented and signed by the study director. Replacement of the study director is considered to be a change in the approved protocol.

3. *Section 160.35 Quality assurance unit (QAU).* a. In § 160.35(a), EPA proposes to conform with the revised FDA GLP regulations by substituting the term "which" for the current phrase "composed of one or more individuals who." This change clarifies that EPA does not require the QAU to be a fixed, permanently staffed unit whose only functions are to monitor the quality of a study. The Agency is only concerned that there be a distinct separation of duties between those personnel involved with the conduct or direction of

a study and those personnel performing quality assurance on the same study. Therefore, EPA does intend proposed § 160.35(a) to prohibit personnel from performing quality assurance activities on their own study.

b. In § 160.35(b)(1), EPA proposes to delete the requirement that the name of the study sponsor appear on the master schedule sheet. Instead, it is proposed that under § 160.35(b)(1) the sponsor's identity appear on the master schedule sheet. This change is being proposed to be consistent with the FDA's recent revision and to provide the regulated community the option of using an identity code on the master schedule in lieu of the sponsor's name.

EPA agrees with FDA's contention that requiring the sponsor to be identified specifically by name on the master schedule is not essential to fulfill the requirements of the GLPs or the goal of ensuring the quality and integrity of the data generated from the studies. However, while the name of the study sponsor would not be required to appear on the master schedule sheet, this information must be made available to the Agency upon request.

c. As in the revised FDA GLP regulations, EPA is also proposing to delete the requirement in § 160.35(b)(1) that the master schedule sheet contain the status of the final report. EPA agrees with FDA that this requirement is redundant in view of the other information required by § 160.35(b)(1) such as the date the experiment began and the current status of each study.

d. In conformance with the revised FDA GLP regulations, EPA proposes to modify the requirements of § 160.35(b)(3) to provide for inspections of a study on a schedule adequate to ensure the integrity of the study. This section currently specifies that the quality assurance unit must inspect each phase of a study periodically. This section also currently specifies that for studies lasting more than 6 months, quality assurance inspections shall be conducted every 3 months, and for studies lasting less than 6 months, quality assurance inspections shall be conducted at intervals adequate to ensure the integrity of the study.

The proposed changes to this section will allow the QAU the necessary latitude to adjust its monitoring activities to meet the individual problems of each study. EPA agrees with FDA's contention that an inspection of each phase of the study is not necessary to ensure that a study is being conducted properly. However, EPA also agrees with FDA that each study, no matter how short, must be inspected at least once while in

progress. EPA expects that by allowing the QAU flexibility in designing a reasonable inspection schedule, the goal of ensuring the quality of the study can be best achieved.

e. Consistent with the revised FDA GLPs, EPA is proposing to delete § 160.35(e) in its entirety. Section 160.35(e) currently requires that all quality assurance records be kept in one location at the testing facility. As FDA pointed out in its October 29, 1984, proposed GLP revision, since § 160.190(b) already requires the use of archives for the orderly storage and expedient retrieval of all reports and records, the requirements of § 160.35(e) are not necessary. However, EPA maintains that all reports and records, including those of the QAU, must be easily accessible and made available to EPA and FDA inspectors when requested.

4. *Section 160.41 General.* FDA has deleted from its GLPs the requirement that the location of each testing facility be suitable to facilitate the proper conduct of studies. However, EPA is proposing that § 160.41 require that testing facilities which are not located within an indoor controlled environment be suitably located to facilitate the proper conduct of studies.

The studies FDA requires are generally conducted within the confines of a traditional indoor laboratory. Because the conditions specified within a protocol can be artificially manipulated within the traditional indoor laboratory, the location of these laboratories is generally not a factor in determining the quality of a study. Therefore, it is not necessary to ensure that a traditional indoor testing facility is suitably located to facilitate the proper conduct of the study.

However, the studies EPA requires are not necessarily conducted within the confines of the traditional indoor scientific laboratory (i.e., field studies, groundwater studies, ecological toxicity studies, etc.). EPA considers any site where testing is undertaken to generate data required by the Agency to be a testing facility. The conditions required by the protocol are not necessarily conducive to artificial manipulation in the field, or other outdoor testing facilities. Therefore, ensuring the suitability of the location of these types of testing facilities is both a valid and necessary part of EPA's GLP Standards.

5. *Section 160.43 Test system care facilities.* a. EPA is proposing to revise the title of § 160.43 from "Animal care facilities" to "Test system care facilities". The proposed heading for § 160.43 more adequately reflects the

Agency's intent to specify facility requirements for the care of chemical or physical matrices (e.g., soil or water), plants, and microorganisms, as well as animals. Accordingly, the Agency is proposing to further modify § 160.43 by incorporating the term "test system" when facility requirements should extend beyond "animal" care.

Consistent with the Agency's intent stated above, paragraphs (a)(1), (a)(2), (d), (e), (f), (g), and (h) in proposed § 160.43 have been added or modified in order to ensure proper care facilities are provided for the additional test systems covered by the expanded section.

b. EPA proposes to modify § 160.43(a) to allow testing facilities to provide for isolation areas rather than quarantine areas. This change is consistent with the proposal to modify § 160.90(b) to allow "isolation" of newly received animals rather than require "quarantine" [See Unit I.D. of this preamble for a discussion of proposed § 160.90(b)].

c. In § 160.43(c), EPA proposes to delete the requirement that separate areas be provided in all cases for the diagnosis, treatment, and control of test system diseases. Instead, it is proposed that such separate areas be provided "as appropriate." This proposal is consistent with the September 4, 1987, revised FDA GLP regulations.

EPA has proposed this modification in order to allow laboratories the option of disposing of diseased animals and other test systems without also bearing the expense of maintaining separate areas in testing facilities for diagnosis, treatment, and control of disease. Additionally, EPA recognizes that the diagnosis and treatment requirements of § 160.43(c) may not be appropriate when dealing with such test systems as soil, plants, or microorganisms. However, if the decision is made not to dispose of the test system, then test system care facilities, as specified in proposed § 160.43(c), must be provided.

d. EPA proposes to conform to the revised FDA GLPs by deleting § 160.43(e) in its entirety. Currently, § 160.43(e) requires test system facilities to be designed, constructed, and located so as to minimize disturbances which may interfere with the study. EPA agrees with FDA that this provision is already adequately covered in § 160.41, which requires that facilities be of suitable size, construction, and, for outdoor testing facilities, location to facilitate the proper conduct of the study.

6. *Section 160.45 Test system supply facilities.* a. EPA proposes to expand the scope of § 160.45 to require that supply facilities necessary for environmental testing be provided when appropriate.

b. Consistent with the proposed expanded scope of this section, EPA is also proposing to retitle § 160.45, from "Animal supply facilities" to "Test system supply facilities."

c. EPA also proposes to modify § 160.45 to state "Perishable supplies shall be preserved by appropriate means." This change is being proposed to conform with the revised FDA GLPs and recognizes that there are a variety of acceptable storage and preservation procedures available besides refrigeration. Depending on the stability characteristics of the perishable material, acceptable storage and preservation methods may include desiccation, room temperature-low humidity, and constant temperature-low humidity.

d. EPA also proposes to delete the phrase "or feed" from the last sentence of § 160.45. Both EPA and FDA consider "feed" to be a "supply." Therefore, the use of the word "feed" in § 160.45 is redundant.

7. *Section 160.49 Laboratory operation areas.* a. EPA proposes to conform with FDA's revised GLP regulations by deleting paragraph (b) from § 160.49, adding the phrase "and specialized" after the word "routine" and before the word "procedures," and deleting the qualifying phrase "including specialized areas for performing activities such as aseptic surgery, intensive care, necropsy, histology, radiography, and handling of biohazardous materials."

Paragraphs (a) and (b), as currently worded, describe activities which require that separate laboratory space be provided. As FDA noted in its proposal to modify its corresponding section (49 FR 43532), the list of activities that currently appears in paragraphs (a) and (b) is not all inclusive and is not essential for the clarity of these sections. Further, by adding the phrase "and specialized," the proposed new paragraph will encompass all activities now listed in paragraphs (a) and (b).

b. In § 160.49, EPA proposes to add the phrase "and other space" after the words "laboratory space" and before the word "shall." As discussed in Unit I.C. of this preamble, this change to § 160.49 is being proposed to reflect that testing does not necessarily take place within the confines of a traditional indoor laboratory. Proposed § 160.49 would require that there be enough space provided to perform the procedures required by the protocol. Wherever testing takes place (i.e., indoor laboratory or field station).

8. *Section 160.53 Administrative and personnel facilities.* As in the revised FDA GLP regulations, EPA proposes to

delete § 160.53 in its entirety. EPA agrees with FDA that the requirements of this section are not necessary for achieving the goals of the FIFRA GLP standards.

9. *Section 160.61 Equipment design.* In § 160.61, EPA proposes to delete the phrase "Automatic, mechanical, or electronic" from the beginning of the first sentence. EPA agrees with FDA that the deletion of these qualifying terms provides for a more general interpretation of the word "equipment."

10. *Section 160.63 Maintenance and calibration of equipment.* a. Consistent with the FDA GLPs, EPA is proposing to amend § 160.63(b) to state that standard operating procedures (SOPs) for remedial action for equipment, in the event of failure or malfunction of equipment, need only be established when "appropriate." This change acknowledges that laboratories may choose to discard rather than repair equipment, and in such cases SOPs which delineate remedial action are not necessary.

b. EPA is also proposing to conform to the revised FDA GLP regulations by deleting from § 160.63(b) the provision that copies of the SOPs shall be made available to laboratory personnel. EPA still believes that laboratory personnel must have access to laboratory SOPs; however, since this requirement is clearly stated in § 160.81(c), EPA considers the inclusion of this requirement in § 160.63(b) to be redundant.

11. *Section 160.81 Standard operating procedures.* a. In § 160.81(b) (1), (2), (6), (7), and (12), EPA is proposing to replace the term "animal" with the term "test system." As discussed previously in this preamble, this modification is consistent with the broad scope of test systems which may be used in testing undertaken in support of a pesticide product research or marketing permit.

b. In § 160.81(b)(5), EPA is proposing to require that SOPs be established for tests wherever the testing is undertaken, including those conducted in the field. Accordingly, it is proposed that § 160.81(b)(5) read "Laboratory or other tests" (see discussion of "field testing" in Unit I.C. of this preamble).

c. In conformance with FDA's revised GLP regulations, EPA is proposing to delete the list of examples for laboratory manuals and SOPs required to be made immediately available under § 160.81(c). EPA still intends that laboratory areas must have immediately available manuals and SOPs for laboratory procedures being performed. This requirement still includes toxicology, histology, clinical chemistry,

hematology, teratology, and necropsy, if applicable. However, this list is not all inclusive and is too broad to serve as a useful guide. For example, this requirement also includes SOPs for the maintenance, repair, and calibration of equipment as described in § 160.63(b).

d. EPA is also proposing to amend the language of § 160.81(c) to clarify that the requirement of this section also applies to field testing facilities. Therefore, it is proposed that § 160.81(c) will read, "Each laboratory or other study area shall have immediately available manuals and standard operating procedures relative to the laboratory or field procedures being performed."

12. *Section 160.90 Animal and other test system care.* a. EPA is proposing to retitle § 160.90 from "Animal care" to "Animal and other test system care". As previously stated, testing required by EPA may involve plants, soils, microorganisms, and other test systems, in addition to animals. The proposed title to § 160.90 reflects the broader scope of this Agency's regulatory responsibilities, these regulations, and this section, to provide for the quality and integrity of all data submitted in support of pesticide product research and marketing permits.

Consistent with the Agency's proposal stated above, paragraphs (b), (d), (e)(1), (f), (g), and (j) in proposed § 160.90 have been added or modified in order to ensure the proper care of all test systems used in a study.

b. EPA proposes to modify § 160.90(b) to provide for the evaluation of a test system's health status, or the appropriateness of the test system for the study, according to acceptable "scientific practice." This section, as proposed, will still require that newly received animals must have their health status evaluated according to acceptable veterinary medical practices. However, EPA recognizes that it may not be appropriate to evaluate the health status of certain test systems (e.g., soil or water) or to require that a plant, microorganism, soil, or water be evaluated according to acceptable veterinary medical practice to determine their appropriateness for a study. EPA is only concerned that test systems used in a study are free of any disease or condition which may interfere with the purpose or conduct of the study, and that the proper precautions, as stated in § 160.90(b), are taken to comply with this requirement.

c. Additionally, EPA is proposing to modify § 160.90(b), to require "isolation" rather than "quarantine" of newly received animals. This proposal is consistent with FDA's revision to its GLPs.

As previously stated, the intent of § 160.90(b) is to prevent the entry of unhealthy or inappropriate test systems into the study, as required by § 160.90(c). Currently, § 160.90(b) provides that this intent be achieved through "quarantine." However, the term "quarantine" suggests a rigid set of procedures, including a mandatory holding period, a specific list of diagnostic procedures, and the use of specialized facilities and test system care practices, which may be an unnecessary burden to industry.

EPA agrees with FDA's conclusion, discussed in the preamble to its revised GLPs (52 FR 33775; September 4, 1987), that isolation and evaluation of health status are sufficient precautions against contamination of test systems and, therefore, fulfill the intent of this section. FDA further states that such a revision would provide laboratories the flexibility to develop isolation and health status evaluation procedures best suited for the age, species, class, and type of the test system, as well as the type of study to be performed.

d. EPA proposes to conform to the FDA GLPs by modifying § 160.90(c) to require isolation of diseased test systems only when necessary.

Currently, § 160.90(c) requires that animals which contract a disease or condition shall be isolated in all cases. This requirement would in turn require that separate facilities be available for the isolation of these animals. However, as discussed in the proposal for § 160.43(c), both EPA and FDA believe that laboratories should be given flexibility in their disposition of diseased test systems. As FDA discussed in the proposed revisions to its GLP regulations (49 FR 43533; October 29, 1984), the proposed modification to § 160.90(c) will allow laboratories the option of: (1) Leaving the diseased test system in the experiment provided that the integrity of the study will not be adversely affected by this action; (2) disposing of the test system; or (3) isolating treating, and returning the test system to the study.

13. *Section 160.105 Test, control, and reference substance characterization.* a. In revised 21 CFR 58.105(a), FDA deleted the requirement that test and control substance characteristics shall be determined and documented for each batch "before the initiation of the study." This change has not been adopted by EPA in its proposed revision to § 160.105(a). However, EPA proposes to modify § 160.105(a) to require that test, control, or reference substance characterization be determined and documented for each batch before its use in the experiment. EPA feels that

this proposed requirement is necessary because it is essential that characteristics of test, control, and reference substances be known prior to their administration or use in an experiment.

EPA's recent experience with antimony trioxide has shown that extensive analytical work was necessary prior to test initiation. Certain assumptions regarding the product's characteristics were used in the protocols for antimony trioxide testing which proved invalid. These invalid assumptions necessitated modifications to the proposed study, resulting in the delay and rescheduling of other subsequent studies. If the analytical work had preceded the toxicology studies, the studies would not have failed and modifications to the studies would not have been necessary. The Agency's conclusion is that it is better to delay study schedules than to initiate improper experimental procedures which will produce invalid results.

b. FDA has modified 21 CFR 58.105(b) to provide for the determination of the stability of the test or control substance either before the initiation of the study or through periodic analysis of each batch according to written standard operating procedures. EPA has chosen not to adopt this approach in proposed § 160.105(b) because the Agency does not agree that stability can adequately be demonstrated by periodic analysis without initial evaluation.

Further, there are many studies required by EPA where solubility of the test, control, or reference substance is of critical importance, such as aquatic toxicity studies. Therefore, EPA is proposing that solubility of the test, control, or reference substance be determined before the experimental start date if knowledge of solubility characteristics is relevant for the proper conduct of the experiment.

It is EPA's contention that both stability and solubility of the test, control, and reference substance need to be determined before the experimental start date in order to ensure proper handling and administration of the test substance to the test system. However, since the determination of the solubility of the test, control, and reference substance is not a requirement in FDA's GLP regulations, EPA is interested in receiving public comment on this issue.

14. *Section 160.113 Mixtures of substances with carriers.* a. FDA has revised 21 CFR 58.113(a)(2) to require determination of the stability of the test and control substance in a mixture, as required by the conditions of the study, either before the initiation of the study

or through periodic analysis of each batch. While EPA does not propose to modify § 160.113(a)(2) to provide the option of determining the stability of the mixture either before study initiation or through periodic analysis (see discussion for § 160.105(b)), EPA will modify this section to require stability testing only to the extent required by the conditions of the experiment. As proposed for § 160.105(b), EPA is also proposing to require that, when appropriate to the conduct of the experiment, solubility of the test, control, or reference substance in the mixture be determined in the same manner (see discussion for § 160.105(b)). Additionally, as proposed for § 160.105(a) and (b), EPA is proposing to replace the phrase "before the initiation of the study" with the phrase "before the experimental start date" (see discussion for § 160.105(a)).

The phrase "as required by the conditions of the experiment" has been added in order to clarify that determination of stability and, if appropriate, solubility of a test, control, or reference substance in a mixture is only necessary to support the actual time of use in the experiment. Therefore, it is not necessary to provide data which illustrate long-term stability of a mixture when the actual time that the mixture is used is short-term. For example, a test, control, or reference substance in a mixture that will be used the same day it is prepared will only require data sufficient to show stability and, if appropriate, solubility for 1 day.

b. EPA proposes to add § 160.113(c) which states, that 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.

15. *Section 160.120 Protocol.* a. In revised 21 CFR 58.120(a), FDA has replaced the qualifying phrase "but shall not necessarily be limited to" with the phrase "as applicable." EPA proposes to adopt FDA's approach with some modifications. It is proposed that the phrase "Where applicable" appear before the information specified in § 160.120(a)(9), and continue to appear before the information required by § 160.120(a)(6). The phrase "but shall not necessarily be limited to" would remain in this section.

In FDA's discussion of this proposal (49 FR 43533; October 29, 1984), concerns were expressed that some of the information required to appear in the protocol is not applicable to all types of testing. Specifically, FDA points to the information required by 21 CFR 58.120(a)(9) and (11). In 21 CFR 58.120, paragraph (a)(9) requires a description of the diet

used in a study as well as solvents, emulsifiers, and/or other materials used to solubilize or suspend the test or control substance before mixing with the carrier. FDA points out that this requirement is not applicable to radiation-emitting products. Section 58.120(a)(11) specifies that the protocol shall specify dosage level, and this requirement is not applicable to implantable medical devices.

Clearly, the basis for FDA's change is to accommodate concerns that are specific to the types of testing required by FDA and do not necessarily apply to testing required by EPA. Further, EPA is concerned that placing the phrase "as applicable" in § 160.120(a) suggests that there may be cases where it is not applicable for any of the other information required by § 160.120(a) to appear in the protocol. Therefore, the phrase "as applicable" should only appear before those items which are not necessarily appropriate to appear in the protocol for certain types of testing.

For example, there may be testing required by EPA where it may not be appropriate to require a protocol to contain the information specified in § 160.120(a)(9), such as describing and/or identifying the diet of a human subject involved in exposure testing. Therefore, EPA proposes to add the phrase "Where applicable" before the information specified in proposed § 160.120(a)(9).

b. In revised 21 CFR 58.120(a)(4), FDA has deleted the requirement that the protocol contain "The proposed starting and completion dates." EPA is proposing to retain this requirement in § 160.120(a)(4), but is proposing to modify this paragraph to require, "The proposed experimental start and termination dates."

EPA believes that this information is necessary for the evaluation of a protocol, and the Agency scheduling of additional related studies and audit reviews. Section 160.120(a)(4) is related to the selected study method, laboratory, and specialist availability, and other Agency and industry priorities. Often a group of experiments are carried out in sequence, so that both start and termination dates affect subsequent study expectations and timetables. Projected experimental start and termination dates identify the normal duration for a given experiment type and reflects any special considerations that may be unique to a laboratory, anticipated analytical or methodology work, and available resources, and it may also affect pending regulatory timetables.

Given that there are hundreds of studies that EPA must track, these

estimated schedules, combined with those from other studies, allow the Agency to more efficiently schedule audits and regulatory action. Further considerations are the following: (1) The availability of composite schedules for many studies may be necessary to set realistic regulatory action goals; (2) composite study schedules are evaluated to schedule audits while several studies are ongoing or recently completed, and which may all be at a given laboratory or geographic location, thus directly reducing EPA resources necessary for audit and regulatory review functions; and (3) standard business management by objectives requires intermediate calendar goals when scheduling multiple outputs, or a long-term single product. The master on-site laboratory schedule will incorporate these dates to carry out the study.

c. In 21 CFR 58.120(a)(5), FDA has deleted the requirement that the protocol contain a justification for the selection of the test system. EPA has chosen to leave this requirement in proposed § 160.120(a)(5).

Environmental studies, including both ecological effects and chemical fate, are more diverse than health effects testing. Further, details relevant to the test system design are more chemically dependent in the case of environmental effects and chemical fate testing than in the case of health effects testing. Many of the test systems in environmental studies must be modified in accordance with specific chemical characteristics. Therefore, EPA must allow a much broader range of flexibility in the nature of tests and selection of test systems. In order to fully understand the test and its results, EPA needs to have a discussion of the reasons for selection of the test system. In addition, EPA recognizes that industry may be engaged in state-of-the-art environmental testing. Under proposed § 160.120(a)(5), EPA can keep abreast of industry advances in such testing and ensure that their use of test systems is appropriate. EPA is interested in receiving public comment on whether to limit the requirement that the protocol contain a justification of the test system to environmental testing.

d. FDA has deleted from 21 CFR 58.120(a)(10) the requirement that the protocol include the route of administration and the reason for its choice. EPA has chosen to retain this requirement in proposed § 160.120(a)(10).

The chemicals regulated by FDA will usually have a predefined route of exposure. Therefore, it makes sense for FDA to eliminate the requirement to stipulate the route of administration and

the reason for its choice within the protocol. Unlike FDA, EPA is concerned with presence in or exposure to various media (i.e., air, water, soil, sediment, chemicals, etc.) and may not know in advance the routes of exposure for the chemicals it regulates. Most chemicals and products regulated by EPA do not have set routes of exposure and may even have multiple routes of exposure. Therefore, EPA must consider a wide range of possible exposure routes in its regulatory decisions. Further, the route of administration is essential to determine the effectiveness of a test system for the purposes of a specific toxicology study. The route of administration affects the real dosage rates and, therefore, affects whether the impact of the exposure of the test substance is acute or chronic.

Therefore, EPA believes that, for its purposes, it is essential that the protocol contain the route of administration and the reason for its choice. This requirement will therefore remain in the FIFRA GLPs in § 160.120(a)(10).

e. EPA proposes to delete current § 160.120(a)(12) in its entirety. Currently, § 160.120(a)(12) requires that the protocol contain the method by which the degree of absorption of the test and control substance by the test system will be determined. EPA agrees with FDA's conclusion that this requirement is not necessary in the protocol.

f. In proposed § 160.120(a)(14), redesignated from current paragraph (a)(15), EPA proposes to conform with FDA's revised GLP regulations and require that the study director's signature be dated on the protocol.

EPA is proposing in § 160.3 that the study initiation date be defined as the date the protocol is signed by the study director. It is through the proposed requirement of § 160.120(a)(14), that the Agency will be able to identify the official study initiation date.

16. *Section 160.130 Conduct of a study.* a. FDA has modified 21 CFR 58.130(d) to provide that records of gross findings for a specimen from postmortem observations "should" be made available to the pathologist when examining that specimen's histopathology. EPA is proposing to retain the requirement that these records "shall," in all cases, be provided to a pathologist during study of the specimen.

EPA agrees with FDA's conclusion that for most studies it is important for the pathologist to have the records of gross findings available when examining a specimen histopathologically.

However, it is FDA's contention that replacing the word "shall" with the word "should" will allow the

histopathological evaluation of specimens in a "blind" fashion. EPA also recognizes that it may be appropriate for some studies to provide for "blinding" in histopathological evaluation. However, EPA maintains that, when specified by the protocol, the pathologist can accomplish "blinding," without violating § 160.130 by not looking at the records which have been provided. Therefore, it will remain EPA's requirement that the pathologist must have access to the records of gross findings when examining a specimen histopathologically.

b. In conformance with the revised FDA GLP regulations, in § 160.130(e), EPA proposes to replace the terms "computer" and "computer driven" with the term "automated data collection." EPA agrees with FDA that the terms "computer" or "computer driven" do not adequately reflect the data collection and storage technologies currently used by testing facilities. The Agency believes that the proposed term "automated data collection" provides a more appropriate description of the data collection and storage systems available for industry use.

17. *Section 160.135 Physical and chemical characterization studies.* EPA proposes to add § 160.135 in order to specify the provisions of the proposed FIFRA GLP standards which will not apply to studies designed to determine the physical and chemical characteristics of a test, control, or reference substance. Most studies designed to determine the physical or chemical characteristics of a test, control, or reference substance rarely involve any modifications to the protocol or experimental design and are usually conducted in an assembly line fashion. Therefore, proposed § 160.135(a) relaxes the requirements of the GLP standards without compromising the quality or integrity of data generated from these studies.

However, in § 160.135(b), EPA is also proposing that the exemptions listed in proposed § 160.135(a) will not apply to studies designed to determine stability, solubility, octanol water partition coefficient, volatility, and persistence of a test, control, or reference substance. These types of physical and chemical characterization studies are more complex in design, execution, and interpretation, and EPA does not believe that it can be assured of the quality and integrity of data generated from these studies without complete GLP compliance.

18. *Section 160.185 Reporting of study results.* a. In § 160.185(a)(5), EPA is proposing to require that the final report include information relating to the

solubility, in addition to stability, of the test, control or reference substance if solubility information was important to the conduct of the experiment. This change is consistent with the proposed modification to §§ 160.105(b) and 160.113(a)(2) (see discussion of proposed §§ 160.105(b) and 160.113(a)(2)).

19. *Section 160.190 Storage and retrieval of records and data.* a. In § 160.190(a), EPA proposes to conform to the revised FDA GLP regulations by modifying this section to state that specimens obtained from mutagenicity tests and specimens of blood, urine, feces, and biological fluids generated as a result of a study need not be retained. EPA is also proposing that § 160.190(a) state that specimens of soil, water, and plants obtained from environmental testing need not be retained. EPA agrees with FDA's conclusion that retention of these specimens beyond initial evaluation is burdensome and does not have a significant impact on the quality of a study.

b. As in the revised FDA GLPs, EPA proposes to revise § 160.190(e) by deleting the requirement that study materials which are retained in archives must be indexed specifically by test substance, date of study, test system, and nature of study. EPA agrees with FDA that the intent of this section is to require indexing of materials in such a way as to permit expedient retrieval from archives. EPA does not believe it is necessary to stipulate the specific indexing terms which must be used.

20. *Section 160.195 Retention of records.* a. In § 160.195, EPA proposes to delete the examples provided in the first sentence of paragraph (c). EPA has proposed this change in conformity with FDA's recent revision because EPA agrees with FDA that these examples do not clarify which materials must be retained from a study, and therefore, are not necessary in this section.

b. EPA is also proposing to modify § 160.195(c) to state that specimens obtained from mutagenicity tests, specimens of soil, water, and plants, and wet specimens of blood, urine, feces, biological fluids, do not need to be retained beyond quality assurance review. This change has been adopted in order to be consistent with the change discussed in proposed § 160.190(a).

c. In new § 160.195(i), EPA proposes to allow records and other "raw data" required by these regulations to be retained either as original records or as true copies, such as photocopies, microfiche, or other accurate reproductions of the original records. This provision would be incorporated in the FIFRA GLPs, in § 160.195(i), in order

to be consistent with the recent changes to FDA's Good Laboratory Practice Regulations.

II. Economic Analysis

In order to satisfy requirements for analysis as specified by Executive Order 12291 and the Regulatory Flexibility Act, the Agency developed a document entitled "Regulatory Impact Analysis of the FIFRA Good Laboratory Practices Regulations". This document, which is available for public inspection, estimates the costs of compliance with the proposed revisions to the FIFRA Good Laboratory Practices Regulations. Compliance costs were estimated using data from a survey of laboratories potentially affected by the revised GLP regulation and from data on pesticides testing demand and costs taken from a 1980 study of the pesticides testing industry.

It was found that the GLP revisions will not increase the costs of health effects testing and that non-health effects testing costs will increase by about 20 percent. It is estimated that the adoption of the proposed GLP revisions would increase annual pesticide testing costs by between \$6.3 and \$9.9 million in 1986 dollars.

III. Statutory Requirements

As required by FIFRA section 25, copies of this proposed rule were provided to the Scientific Advisory Panel, the Secretary of Agriculture, the Senate Committee on Agriculture, Nutrition, and Forestry, and the House Committee on Agriculture. No comments were received from either Congressional Committee and the FIFRA Scientific Advisory Panel waived its review of this proposal. The following are the comments of the Secretary of the Department of Agriculture and the response of EPA:

The Secretary of the Department of Agriculture requested that the definition of "study" be modified to more clearly reflect EPA's intent that GLP compliance for efficacy testing be limited to product performance as required by 40 CFR 158.160. We have modified the definition of "study" accordingly.

The Secretary asked if the regulation requires that only studies conducted in accordance with the GLPs are acceptable for Agency review and, are there any conditions under which a study can be accepted which did not fully comply with the GLPs?

Studies may be submitted to EPA which do not completely conform to the GLPs as long as the Statement of Compliance, required by § 160.12(b) of the GLP regulations, describes in detail all differences between the practices

used in the study and those required by the GLPs. EPA will review these studies. However, EPA will decide on a case-by-case basis whether studies which deviate from the GLPs are acceptable to support the pesticide product registration, or other marketing and research permit.

The Secretary of Agriculture asked if studies which reflect negatively on a chemical use, or studies which report toxic or carcinogenic effects will automatically be ignored by EPA if they have not been conducted under verifiable GLP conditions.

EPA will not ignore scientific data which does not comply with the FIFRA GLP standards, and may choose to rely on such data for purposes of showing adverse effects. However, as stated by § 160.17(a) of the FIFRA GLPs, EPA may determine that data which does not comply with the GLPs is not reliable to support an application for a research or marketing permit. Further, § 160.15(b) of the GLPs states that "The determination that a study will not be considered in support of an application for a research or marketing permit does not, however, relieve the applicant for such a permit of any obligation under any applicable statute or regulation to submit the results of the study to EPA." Adverse effects data, which is required to be submitted to the Agency under FIFRA section 6(a)(2), must be submitted to the Agency regardless of whether it complies with the GLPs or not. The Agency does not now, and will not in the future, require FIFRA section 6(a)(2) data to be generated and submitted to the Agency in accordance with the GLPs. EPA will not ignore any FIFRA section 6(a)(2) data. However, additional testing required by the Agency as a result of the FIFRA section 6(a)(2) finding must be conducted in accordance with the GLPs.

The Department of Agriculture commented that if they are required to conduct the analyses described in §§ 160.105 and 160.113, it would greatly limit their resources and capability to conduct studies under the minor use pesticide program. They state that they are working with labeled pesticides which already have tolerances established in food crops, and that are being utilized under simulated commercial conditions. Therefore, they believe that the information gained from these analyses would not be of any real significance to the results of the studies for efficacy, phytotoxicity, and residue.

EPA continues to believe that adequate test, control, and reference substance characterization, and knowledge of their behavior in the mixture, is essential to assure the

quality and integrity of the test. EPA agrees that the analyses of a test, control, or reference substance mixed with a carrier, as required by § 160.113, may be costly. However, some cost savings can be realized by obtaining the documentation of the identity, strength, purity, and composition for each batch of the test, control, and reference substance, as required by § 160.105, from the manufacturer of these chemicals (this is particularly pertinent when the chemical is specifically synthesized for the test). These analyses do not have to be repeated by the testing facility.

Finally, please note, the analyses required by §§ 160.105 and 160.113 are only required for efficacy testing of the types of products specified by 40 CFR 158.160 (e.g., for pesticide products that claim to control microorganisms that pose a threat to human health and pesticides that claim to control vertebrates that may transmit diseases to humans). Therefore, in most cases efficacy testing that is conducted under the Department of Agriculture's minor use pesticide program is not required to comply with the requirements of the GLPs, including the analyses required by §§ 160.105 and 160.113.

Finally, the Secretary of the Department of Agriculture asked if there is a grandfather provision for studies conducted prior to the implementation of the regulations.

EPA does not intend to require compliance with the revised GLP standards for studies begun significantly before the effective date of the final version of these proposed regulations.

IV. Other Regulatory Requirements

A. Executive Order 12291

Under Executive Order 12291, EPA is required to judge whether a rule is a "major" one and is therefore subject to the requirement of a Regulatory Impact Analysis. The proposed amendments of the FIFRA Good Laboratory Practice Standards would not be a major rule because they do not meet any of the criteria set forth and defined in section 1(b) of the Order.

B. Regulatory Flexibility Act

This rule has been reviewed under the Regulatory Flexibility Act of 1980 (Pub. L. 96-354; 94 Stat. 1165 (5 U.S.C. 60 et. seq.)) and it has been determined that it will not have significant economic impact on a substantial number of small businesses, small governments, or small organizations.

C. Paperwork Reduction Act

The Office of Management and Budget (OMB) has approved the information collection requirements contained in this proposed rule under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*, and has assigned OMB control numbers: 2070-0024, 2070-0032, 2070-0040, 2070-0055, 2070-0057, 2070-0060. Comments on these requirements should be submitted to the Office of Information and Regulatory Affairs of OMB, marked "Attention: Desk Officer for EPA." The final rule will respond to any OMB or public comments on the information collection requirements.

List of Subjects in 40 CFR Part 160

Good laboratory practices, Laboratories, Environmental protection, Hazardous materials, Chemicals, Recordkeeping and reporting requirements.

Dated: December 8, 1987.

Lee M. Thomas,
Administrator.

Therefore, it is proposed that 40 CFR Part 160 be amended as follows:

PART 160—[AMENDED]

1. The authority citation for Part 160 continues to read as follows:

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

2. In § 160.3, by removing the alphabetical paragraph designations in paragraphs (a) through (q); by revising the definitions for "Control substance," "Study," and "Test system"; by replacing the term "Test substance or mixture" with the term "Test substance"; and by alphabetically inserting definitions for "Carrier," "Experimental start date," "Experimental termination date," "Reference substance," "Study completion date," "Study initiation date," and "Vehicle", to read as follows:

§ 160.3 Definitions.

"Carrier" means any material (e.g., feed, water, soil, nutrient media) with which the test substance is combined for administration to test organisms.

"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 study for the purpose of establishing a basis for comparison with the test substance for no-effect levels.

"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.

"Reference substance" means any chemical substance or mixture 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 purposes of establishing a basis for comparison with the test substance for known effect levels.

"Study" means any experiment 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 (efficacy as required by 40 CFR 158.160), environmental and chemical fate, persistence and residue, or other characteristics in humans, other living organisms, or media. The term does not include basic exploratory studies carried out to determine whether a test substance has any potential utility.

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

"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.

"Test system" means any animal, plant, microorganism, chemical or physical matrix (e.g., soil or water), or subparts thereof, to which the test or control 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.

"Vehicle" means any agent which facilitates the mixture, dispersion, or solubilization of a test substance with a carrier.

3. In § 160.29, by revising paragraphs (d), (e), and (f) to read as follows:

§ 160.29 Personnel.

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

(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, and test, control, and reference substances, and any other operation or function that may adversely affect the study until the 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.

4. In § 160.31, by revising paragraph (b) to read as follows:

§ 160.31 Testing facility management.

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

5. In § 160.35, by revising paragraphs (a) and (b) (1) and (3) and removing paragraph (e) to read as follows:

§ 160.35 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.

(b) The quality assurance unit shall:

(1) Maintain a copy of a master schedule sheet of all studies conducted at the testing facility indexed by test substance and containing the test system, nature of study, date study was

initiated, current status of each study, identity of the sponsor, and name of the study director.

(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.

6. By revising § 160.41 to read as follows:

§ 160.41 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.

7. By revising § 160.43 to read as follows:

§ 160.43 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 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.

8. By revising § 160.45 to read as follows:

§ 160.45 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 housing the test systems 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. These include:

(1) Facilities, as specified in the protocol, for holding, culturing, and maintaining algae and aquatic plants.

(2) Facilities, as specified in the protocol, for plant growth (e.g., greenhouses, growth chambers, light banks).

(c) When appropriate, facilities for aquatic animal tests shall be provided. These include aquaria, holding tanks, ponds, and ancillary equipment, as specified in the protocol.

9. By revising § 160.47 to read as follows:

§ 160.47 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.

10. By revising § 160.49 to read as follows:

§ 160.49 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.

§ 160.53 [Removed]

11. By removing § 160.53 *Administrative and personnel facilities.*

12. By revising § 160.61 to read as follows:

§ 160.61 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 protocol and shall be suitably located for operation, inspection, cleaning, and maintenance.

13. In § 160.63, by revising paragraph (b) to read as follows:

§ 160.63 Maintenance and calibration of equipment.

(b) The written standard operating procedures required under

§ 160.81(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 responsible for the performance of each operation.

14. In § 160.81, by revising paragraphs (b) (1), (2), (3), (5), (6), (7), and (12) and (c) to read as follows:

§ 160.81 Standard operating procedures.

- (b) * * *
- (1) Test system room preparation.
 - (2) Test system care.
 - (3) Receipt, identification, storage, handling, mixing, and method of sampling of the test, control, and reference substances.
 - (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.

(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.

15. By revising § 160.90 to read as follows:

§ 160.90 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 evaluated. This evaluation shall be in accordance with acceptable veterinary medical practice or scientific practice.

(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, toe clip, 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 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 organisms shall be acclimatized, prior to their use in an experiment, to the environmental conditions of the test.

Subpart F—Test, Control, and Reference Substances

16. By revising the heading for Subpart F to read as set forth above.

17. By revising § 160.105 to read as follows:

§ 160.105 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 an experiment. Methods of synthesis, fabrication, or derivation of the test, control, or reference substance shall be documented by the sponsor or the testing facility.

(b) The stability and, when relevant to the conduct of the experiment, the solubility of each test, control, or reference substance shall be determined by the testing facility or by the sponsor before the experimental start date. Where periodic analysis of each batch is required by the protocol, there shall be written standard operating procedures that shall be followed.

(c) Each storage container for a test, control, or reference substance shall be labeled by name, chemical abstracts service number (CAS) or code number, batch number, expiration date, if any, and, where appropriate, 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.

(d) For studies of more than 4 weeks duration, reserve samples from each batch of test, control, and reference substances shall be retained for the period of time provided by § 160.195.

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

18. In § 160.107, by revising the section heading and introductory text to read as follows:

§ 160.107 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:

* * *

19. By revising § 160.113 to read as follows:

§ 160.113 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) To determine the stability and, when relevant to the conduct of the experiment, the solubility of the test, control, or reference substance in the mixture, before the experimental start date. Determination of the stability and solubility of the test, control, or reference substance in the mixture shall be done under the environmental conditions specified in the protocol and as required by the conditions of the experiment. Where periodic analysis of the mixture is required by the protocol, there shall be written standard operating procedures that shall be followed.

(b) 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.

(c) 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.

20. In § 160.120, by revising paragraph (a) to read as follows:

§ 160.120 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) number or code number.

(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, 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 of frequency of administration.

(12) The type and frequency of test 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 proposed statistical method.

* * *

21. In § 160.130, by revising paragraphs (d) and (e) to read as follows:

§ 160.130 Conduct of a study.

* * *

(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.

22. By adding § 160.135 to read as follows:

§ 160.135 Physical and chemical characterization studies.

(a) Except as provided in paragraph (b) of this section, the following provisions shall not apply to studies designed to determine physical and chemical characteristics of a test, control, or reference substance:

§ 160.31 (c), (d), and (g)

§ 160.35 (b) and (c)

§ 160.43

§ 160.45

§ 160.47

§ 160.49

§ 160.81(b) (1), (2), (6) through (9), and (12)

§ 160.90

§ 160.105 (a) through (d)

§ 160.113

§ 160.120(a) (5) through (12), and (15)

§ 160.185(a) (5) through (8), (10), (12), and (14)

§ 160.195 (c) and (d)

(b) The exemptions provided in paragraph (a) of this section shall not apply to physical/chemical characterization studies designed to determine stability, solubility, octanol water partition coefficient, volatility, and persistence (such as biodegradation, photodegradation, and chemical degradation studies), and such studies shall be conducted in accordance with this part.

23. In § 160.185, by revising paragraphs (a) (4) and (5) to read as follows:

§ 160.185 Reporting of study results.

(a) * * *

(4) The test, control, and reference substances identified by name, chemical abstracts service (CAS) number or code number, strength, purity, and composition, or other appropriate characteristics.

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

* * *

24. In § 160.190, by revising paragraphs (a) and (e) to read as follows:

§ 160.190 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 beyond quality assurance. Correspondence and other documents relating to interpretation and evaluation of data, other than those documents contained in the final report, also shall be retained.

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

25. In § 160.195, by revising paragraph (c) and adding paragraph (i) to read as follows:

§ 160.195 Retention of records.

(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 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, biological fluids, do not need to be retained beyond quality assurance review. In no case shall retention be required for longer periods than those set forth in paragraph (b) of this section.

(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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40 CFR Part 792

[OPTS-46016; FRL-3245-6]

Toxic Substances Control Act (TSCA); Good Laboratory Practice Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to amend the TSCA Good Laboratory Practice (GLP) Standards to incorporate many of the changes made by the Food and Drug Administration (FDA) to its GLP regulations and to expand the scope of

the TSCA GLP standards to apply to testing conducted in the field under TSCA. EPA is proposing this amendment in order to ensure the quality and integrity of data generated from such studies.

DATE: Submit written comments on or before March 28, 1988.

ADDRESS: Submit written comments, identified by the document control number (OPTS-46016), in triplicate to: TSCA Public Information Office (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. NE-C004, 401 M St., SW., Washington, DC 20460.

The public record supporting this action is available for inspection at the above address from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Rm. E-543, 401 M St., SW., Washington, DC 20460 (202) 554-1404.

SUPPLEMENTARY INFORMATION: Following is an index to the remainder of this preamble:

- I. Introduction
 - A. Legal Authority
 - B. Background
 - C. Consistency With FDA GLP Regulations
 - D. Proposed Changes to the TSCA GLP Regulations
- II. Economic Analysis
- III. Other Regulatory Requirements
 - A. Executive Order 12291
 - B. Regulatory Flexibility Act
 - C. Paperwork Reduction Act

I. Introduction**A. Legal Authority**

On November 29, 1983 (48 FR 53922), EPA promulgated the GLP standards under the authority of TSCA section 4 (90 Stat. 2006, 15 U.S.C. 2603). Section 4(a) of TSCA authorizes the EPA Administrator to require, by rule, that manufacturers (including importers) and processors of identified chemical substances and mixtures test such chemicals if certain findings are made. Section 4(b)(1) of TSCA specifies that each test rule shall include standards for the development of test data. These standards are defined in section 3(12) of TSCA to mean a prescription of—

- (A) the—
 - (i) health and environmental effects, and
 - (ii) information relating to the toxicity, persistence, and other characteristics which affect health and the environment, for which test data for a chemical substance or mixture are to be developed and any analysis that is to be performed on such data, and

(B) to the extent necessary to assure that data respecting such effects and characteristics are reliable and adequate—

- (i) the manner in which such data are to be developed,
- (ii) the specification of any test protocol or methodology to be employed in the development of such data, and
- (iii) such other requirements as are necessary to provide such assurance.

In summary, the specific authority to issue the GLP standards is provided by section 4(b)(1) of TSCA, which is further explained by the definitions in sections 3(12)(B)(i) and 3(12)(B)(iii).

In addition, the Agency also requires sponsors to utilize these GLP standards when conducting testing under TSCA section 4 testing consent agreements and will include provisions to adhere to these GLP standards in those agreements (see 40 CFR 790.60(a)(7)). Also, it is the Agency's policy that all data developed as a result of rules or orders under section 5 of TSCA should be in accordance with the GLP standards. If data developed under section 5 of TSCA are not generated in accordance with the GLP standards, the Agency may elect to consider such data insufficient to evaluate the health effects, environmental effects, and fate of the chemical.

B. Background

EPA originally published enforceable TSCA Good Laboratory Practice Standards in the Federal Register of November 29, 1983 (48 FR 53922), which were codified as 40 CFR Part 792. At the same time, EPA published GLP standards applicable to testing under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA, 48 FR 53963, 40 CFR Part 160). These regulations were promulgated in response to investigations by EPA and FDA during the mid-1970s 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 decisionmaking process. For instance, some studies had been submitted which did not adhere to specified protocols, were conducted by underqualified personnel and supervisors, or were not adequately monitored by study sponsors. 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 TSCA GLP standards specify minimum practices and