

designated representative of the fuel/additive group to which each separate atypical additive product belongs.

(2) When the disparate additive products are not for the same purpose-in-use, the fuel manufacturer shall nevertheless be responsible for testing a separate formulation for each such additive product, as described in paragraph (g)(1) of this section, if these additives are not ordinarily blended together in the same commercial formulation of the fuel.

(3) When the disparate additive products are ordinarily blended together in the same commercial formulation of the fuel, then the fuel manufacturer shall be responsible for the testing of a single test formulation containing all such simultaneously used atypical additive products. Alternatively, this responsibility can be satisfied by enrolling such fuel product in a group which includes other fuel or additive products with the same total combination of atypical elements as that occurring in the fuel product in question. If the basic registration data for the subject fuel includes any alternative additives which contain atypical elements not represented in the test formulation, then the fuel manufacturer is also responsible for testing a separate formulation for each such additional disparate additive product.

(k) *Emission Control System Testing.* If any information submitted in accordance with this subpart or any other information available to EPA shows that a fuel or fuel additive may have a deleterious effect on the performance of any emission control system or device currently in use or which has been developed to a point where in a reasonable time it would be in general use were such effect avoided, EPA may, in its judgment, require testing to determine whether such effects in fact exist. Such testing will be required in accordance with such protocols and schedules as the Administrator shall reasonably require and shall be paid for by the fuel or fuel additive manufacturer.

[59 FR 33093, June 27, 1994, as amended at 61 FR 36511, July 11, 1996; 62 FR 12575, Mar. 17, 1997]

#### § 79.52 Tier 1.

(a) *General Specifications.* Tier 1 requires manufacturers of designated fuels or fuel additives (or groups of manufacturers pursuant to § 79.56) to supply to the Administrator the identity and concentration of certain emission products of such fuels or additives and any available information regarding the health and welfare effects of the whole and speciated emissions of such fuels or additives. In addition to any information required under § 79.59 and in conformance with the reporting requirements thereof, manufacturers shall provide, pursuant to the timing provisions of § 79.51(c), the following information.

(b) *Emissions Characterization.* Manufacturers must provide a characterization of the emission products which are generated by evaporation (if required pursuant to § 79.58(b)) and by combustion of the fuel or additive/base fuel mixture in a motor vehicle. For this purpose, manufacturers may perform the characterization procedures described in this section or may rely on existing emission characterization data. To be considered adequate in lieu of performing new emission characterization procedures, the data must be the result of tests using the product in question or using a fuel or additive/base fuel mixture meeting the same grouping criteria as the product in question. In addition, the emissions must be generated in a manner reasonably similar to those described in § 79.57, and the characterization procedures must be adequately performed and documented and must give results reasonably comparable to those which would be obtained by performing the procedures described herein. Reports of previous tests must be sufficiently detailed to allow EPA to judge the adequacy of protocols, techniques, and conclusions. After the manufacturer's submittal of such data, if EPA finds that the manufacturer has relied upon inadequate test data, then the manufacturer will not be considered to be in compliance until the corresponding tests have been conducted and the results submitted to EPA.

(1) *General Provisions.* (i) The emissions to be characterized shall be generated, collected, and stored according

to the processes described in § 79.57. Characterization of combustion and evaporative emissions shall be performed separately on each emission sample collected during the applicable emission generation procedure.

(ii) As provided in § 79.57(d), if the emission generation vehicle/engine is ordinarily equipped with an emission aftertreatment device, then all requirements in this section for the characterization of combustion emissions must be completed both with and without the aftertreatment device in a functional state. The emissions shall be generated three times (on three different days) without a functional aftertreatment device and, if applicable, three times (on three different days) with a functional aftertreatment device, and each such time shall be analyzed according to the remaining provisions in this paragraph (b) of this section.

(iii) Measurement of background emissions: It is required that ambient/dilution air be analyzed for levels of background chemical species present at the time of emissions sampling (for both combustion and evaporative emissions) and that sample values be corrected by subtracting the concentrations contributed by the ambient/dilution air. Background chemical species measurement/analysis during the FTP is specified in §§ 86.109-94(c)(5) and 86.135-94 of this chapter.

(iv) Concentrations of emission products shall be reported either in units of grams per mile (g/mi) or grams per brake-horsepower/hour (g/bhp-hr) (for chassis dynamometer and engine dynamometer test configurations, respectively), as well as in units of weight percent of measured total hydrocarbons.

(v) Laboratory practice must be of high quality and must be consistent with state-of-the-art methods as presented in current environmental and analytical chemistry literature. Examples of analytical procedures which may be used in conducting the emission characterization/speciation requirements of this section can be found among the references in paragraph (b)(5) of this section.

(2) Characterization of the combustion emissions shall include, for prod-

ucts in all fuel families (except when expressly noted in this section):

(i) Determination of the concentration of the basic emissions as follows: total hydrocarbons, carbon monoxide, oxides of nitrogen, and particulates. Manufacturers are referred to the vehicle certification procedures in 40 CFR part 86, subparts B and D (§§ 86.101 through 86.145 and §§ 86.301 through 86.348) for guidance on the measurement of the basic emissions of interest to this subpart.

(ii) Characterization of the vapor phase of combustion emissions, as follows:

(A) Determination of the identity and concentration of individual species of hydrocarbon compounds containing 12 or fewer carbon atoms. Such characterization shall begin within 30 minutes after emission collection is completed.

(B) Determination of the identity and concentration of individual species of aldehyde and ketone compounds containing eight or fewer carbon atoms. Characterization of these emissions captured in cartridges shall be performed within two weeks if the cartridge is stored at room temperature, and one month if the cartridge is stored at 0 °C or less. If the emissions are sampled using the impinger method, the sample must be stored in a capped sample vial at 0 °C or less and characterized within one week.

(C) Determination of the identity and concentration of individual species of alcohol and ether compounds containing six or fewer carbon atoms, for those fuels and additive/base fuel mixtures which contain alcohol and/or ether compounds containing from one to six carbon atoms in the uncombusted state. For fuel and additive formulations containing alcohols or ethers with more than six carbon atoms in the uncombusted state, alcohol and ether species with that higher number of carbon atoms or less must be identified and measured in the emissions. Such characterization shall begin within four hours after emission collection is completed.

(iii) Characterization of the semi-volatile and particulate phases of combustion emissions to identify and

measure polycyclic aromatic compounds, as follows:

(A) Analysis for polycyclic aromatic compounds shall not be conducted at or soon after the start of a recommended engine lubricant change interval.

(B) Analysis for polycyclic aromatic hydrocarbons (PAHs) and nitrated polycyclic aromatic hydrocarbons (NPAHs), specified in paragraph (b)(2)(iii)(D) of this section, need not be done for any fuels and additives in the methane or propane fuel families, nor for fuels and additives in the atypical categories of any other fuel families, pursuant to the definitions of such families and categories in § 79.56.

(C) Analysis for poly-chlorinated dibenzodioxins and dibenzofurans (PCDD/PCDFs), specified in paragraph (b)(2)(iii)(E) of this section, is required only for fuels and additives which contain chlorine as an atypical element, pursuant to paragraph (b)(2)(iv) of this section, which requires all individual emission products containing atypical elements to be determined for atypical fuels and additives. However, manufacturers of baseline and nonbaseline fuels and fuel additives in all fuel families, except those in the methane and propane fuel families, are strongly encouraged to conduct these analyses on a voluntary basis.

(D) The analytical method used to measure species of PAHs and NPAHs should be capable of detecting at least 1 ppm (equivalent to 0.001 microgram ( $\mu\text{g}$ ) of compound per milligram of organic extract) of these compounds in the extractable organic matter. The concentration of each individual PAH or NPAH compound identified shall be reported in units of microgram per mile or nanograms per brake-horsepower/hour (for chassis dynamometer and engine dynamometer test configurations, respectively). Each compound which is present at 0.001  $\mu\text{g}$  per mile (0.5 nanograms per brake-horsepower/hour) or more must be identified, measured, and reported. The following individual species shall be measured:

- (1) PAHs:
  - (i) Benzo(a)anthracene;
  - (ii) Benzo(b)fluoranthene;
  - (iii) Benzo(k)fluoranthene;
  - (iv) Benzo(a)pyrene;
  - (v) Chrysene;

- (vi) Dibenzo[a,h]anthracene; and
- (vii) Indeno[1,2,3-c,d]pyrene.

- (2) NPAHs:
  - (i) 7-Nitrobenzo[a]anthracene;
  - (ii) 6-Nitrobenzo[a]pyrene;
  - (iii) 6-Nitrochrysene;
  - (iv) 2-Nitrofluorene; and
  - (v) 1-Nitropyrene.

(E) The analytical method used to measure species and classes of PCDD/PCDFs should be capable of detecting at least 1 part per trillion (ppt) (equivalent to 0.001 picogram ( $\text{pg}$ ) of compound per milligram of organic extract) of these compounds in the extractable organic matter. The concentration of each individual PCDD/PCDF compound identified shall be reported in units of picograms ( $\text{pg}$ ) per mile or picograms per brake-horsepower/hour (for chassis dynamometer and engine dynamometer test configurations, respectively). Each compound which is present at 0.5  $\text{pg}/\text{mile}$  (0.3  $\text{pg}/\text{bhp-hr}$ ) or more must be identified, measured, and reported.

(1) With respect to measurement of PCDD/PCDFs only, the liquid extracts from the particulate and semi-volatile emissions fractions may be combined into one sample for analysis.

(2) The manufacturer is referred to 40 CFR part 60, appendix A, Method 23 for a protocol which may be used to identify and measure any potential PCDD/PCDFs which might be present in exhaust emissions from a fuel or additive/base fuel mixture.

(3) The following individual compounds and classes of compounds of PCDD/PCDFs shall be identified and measured:

- (i) Individual tetra-chloro-substituted dibenzodioxins (tetra-CDDs);
- (ii) Individual tetra-chloro-substituted dibenzofurans (tetra-CDFs);
- (iii) Penta-CDDs and penta-CDFs, as one class;
- (iv) Hexa-CDDs and hexa-CDFs, as one class;
- (v) Hepta-CDDs and hepta-CDFs as one class; and
- (vi) Octo-CDDs and octo-CDFs as one class.

(iv) With respect to all phases (vapor, semi-volatile, and particulate) of combustion emissions generated from those fuels and additive/base fuel mixtures classified in the atypical categories

(pursuant to § 79.56), the identity and concentration of individual emission products containing such atypical elements shall also be determined.

(3) For evaporative fuels and evaporative fuel additives, characterization of the evaporative emissions shall include:

(i) Determination of the concentration of total hydrocarbons for the applicable vehicle type and class in 40 CFR part 86, subpart B (§§ 86.101 through 86.145).

(ii) Determination of the identity and concentration of individual species of hydrocarbon compounds containing 12 or fewer carbon atoms. Such characterization shall begin within 30 minutes after emission collection is completed.

(iii) In the case of those fuels and additive/base fuel mixtures which contain alcohol and/or ether compounds in the uncombusted state, determination of the identity and concentration of individual species of alcohol and ether compounds containing six or fewer carbon atoms. For fuel and additive formulations containing alcohols or ethers with more than six carbon atoms in the uncombusted state, alcohol and ether species with that higher number of carbon atoms or less must be identified and measured in the emissions. Such characterization shall begin within four hours after emission collection is completed.

(iv) In the case of those fuels and additive/base fuel mixtures which contain atypical elements, determination of the identity and concentration of individual emission products containing such atypical elements.

(4) *Laboratory quality control.* (i) At a minimum, laboratories performing the procedures specified in this section shall conduct calibration testing of their emissions characterization equipment before each new fuel/additive product test start-up. Known samples representative of the compounds potentially to be found in emissions from the product to be characterized shall be used to calibrate such equipment.

(ii) Laboratories performing the procedures specified in this section shall agree to permit quality control inspections by EPA, and for this purpose shall admit any EPA Enforcement Officer, upon proper presentation of cre-

dentials, to any facility where vehicles are conditioned or where emissions are generated, collected, stored, sampled, or characterized in meeting the requirements of this section. Such laboratory audits may include EPA distribution of "blind" samples for analysis by participating laboratories.

(5) *References.* For additional background information on the emission characterization procedures outlined in this paragraph, the following references may be consulted:

(i) "Advanced Emission Speciation Methodologies for the Auto/Oil Air Quality Improvement Program—I. Hydrocarbons and Ethers," Auto Oil Air Quality Improvement Research Program, SP-920, 920320, SAE, February 1992.

(ii) "Advanced Speciation Methodologies for the Auto/Oil Air Quality Improvement Research Program—II. Aldehydes, Ketones, and Alcohols," Auto Oil Air Quality Improvement Research Program, SP-920, 920321, SAE, February 1992.

(iii) ASTM D 5197-91, "Standard Test Method for Determination of Formaldehyde and Other Carbonyl Compounds in Air (Active Sampler Methodology)."

(iv) Johnson J. H., Bagley, S. T., Gratz, L. D., and Leddy, D. G., "A Review of Diesel Particulate Control Technology and Emissions Effects—1992 Horning Memorial Award Lecture," SAE Technical Paper Series, SAE 940233, 1994.

(v) Keith *et al.*, ACS Committee on Environmental Improvement, "Principles of Environmental Analysis," The Journal of Analytical Chemistry, Volume 55, pp. 2210-2218, 1983.

(vi) Perez, J.M., Jabs, R.E., Leddy, D.G., eds. "Chemical Methods for the Measurement of Unregulated Diesel Emissions (CRC-APRAC Project No. CAPI-1-64), Coordinating Research Council, CRC Report No. 551, August, 1987.

(vii) Schuetzle, D., "Analysis of Nitrated Polycyclic Aromatic Hydrocarbons in Diesel Particulates," Analytical Chemistry, Volume 54, pp. 265-271, 1982.

(viii) Siegl, W.O., *et al.*, "Improved Emissions Speciation Methodology for Phase II of the Auto/Oil Air Quality

Improvement Research Program—Hydrocarbons and Oxygenates”, SAE Technical Paper Series, SAE 930142, 1993.

(ix) Tejada, S. B. *et al.*, “Analysis of Nitroaromatics in Diesel and Gasoline Car Emissions,” SAE Paper No. 820775, 1982.

(x) Tejada, S. B. *et al.*, “Fluorescence Detection and Identification of Nitro Derivatives of Polynuclear Aromatic Hydrocarbons by On-Column Catalytic Reduction to Aromatic Amines,” *Analytical Chemistry*, Volume 58, pp. 1827-1834, July 1986.

(xi) “Test Method for Determination of C1-C4 Alcohols and MTBE in Gasoline by Gas Chromatography,” 40 CFR part 80, appendix F.

(c) [Reserved]

(d) *Literature Search.* (1) Manufacturers of fuels and fuel additives shall conduct a literature search and compilation of information on the potential toxicologic, environmental, and other public welfare effects of the emissions of such fuels and additives. The literature search shall include all available relevant information from in-house, industry, government, and public sources pertaining to the emissions of the subject fuel or fuel additive or the emissions of similar fuels or additives, with such similarity determined according to the provisions of § 79.56.

(2) The literature search shall address the potential adverse effects of whole combustion emissions, evaporative emissions, relevant emission fractions, and individual emission products of the subject fuel or fuel additive except as specified in the following paragraph. The individual emission products to be included are those identified pursuant to the emission characterization procedures specified in paragraph (b) of this section, other than carbon monoxide, carbon dioxide, nitrogen oxides, benzene, 1,3-butadiene, acetaldehyde, and formaldehyde.

(3) In the case of the individual emission products of non-baseline or atypical fuels and additives (pursuant to § 79.56(e)(2)), the literature data need not be submitted for those emission products which are the same as the combustion emission products of the respective base fuel for the product’s fuel family (pursuant to § 79.55). For

this purpose, data on the base fuel emission products for the product’s fuel family:

(i) May be found in the literature of previously-conducted, adequate emission speciation studies for the base fuel, or for a fuel or additive/fuel mixture capable of grouping with the base fuel (see, for example, the references in paragraph (b)(5) of this section).

(ii) May be compiled while gathering internal control data during emissions characterization studies on the manufacturer’s non-baseline or atypical product; or

(iii) May be obtained from various manufacturers in the course of their testing different additive(s) belonging to the same fuel family, or in the testing of a base fuel serving as representative of the baseline group for the respective fuel family.

(e) *Data bases.* The literature search must include the results of searching appropriate commercially available chemical, toxicologic, and environmental databases. The databases shall be searched using, at a minimum, CAS numbers (when applicable), chemical names, and common synonyms.

(f) *Search period.* The literature search shall cover a time period beginning at least thirty years prior to the date of submission of the reports specified in §§ 79.59(b) through (c) and ending no earlier than six months prior to the date on which testing is commenced or reports are submitted in compliance with this subpart.

(g) *References.* Information on base fuel emission inventories may be found in references in paragraphs (b)(5)(i) through (xi) of this section, as well as in the following:

(1) Auto/Oil Air Quality Improvement Research Program, Technical Bulletin #1, December 1990.

(2) Keith *et al.*, ACS Committee on Environmental Improvement, “Principles of Environmental Analysis,” *The Journal of Analytical Chemistry*, Volume 55, pp. 2210-2218, 1983.

(3) “The Composition of Gasoline Engine Hydrocarbon Emissions—An Evaluation of Catalyst and Fuel Effects”—SAE 902074 and “Speciated Hydrocarbon Emissions from Aromatic,

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Olefin, and Paraffinic Model Fuels''—SAE 930373.

[59 FR 33093, June 27, 1994, as amended at 61 FR 36511, July 11, 1996; 62 FR 12571, Mar. 17, 1997]

### § 79.53 Tier 2.

(a) *Generally.* Subject to the provisions of § 79.53(b) through (d), the combustion emissions of each fuel or fuel additive subject to testing under this subpart must be tested in accordance with each of the testing guidelines in §§ 79.60 through 79.68, except that fuels and additives in the methane and propane fuel families (pursuant to § 79.56(e)(1)(v) and (vi)) need not undergo the *Salmonella* mutagenicity assay in § 79.68). Similarly, subject to the provisions of § 79.53(b) through (d), the evaporative emissions of each designated evaporative fuel and each designated evaporative fuel additive subject to testing under this subpart must be tested according to each of the testing guidelines in §§ 79.60 through 79.67 (excluding § 79.68, *Salmonella typhimurium* Reverse Mutation Assay).

(b) *Manufacturer Determination.* Manufacturers shall determine whether the information gathered pursuant to the literature search in § 79.52(d) contains the results of adequately performed and adequately documented previous testing which provides information reasonably comparable to that supplied by the health tests described in §§ 79.62 through 79.68 regarding the carcinogenicity, mutagenicity, neurotoxicity, teratogenicity, reproductive/fertility measures, and general toxicity effects of the emissions of the fuel or additive. When manufacturers make an affirmative determination, they need submit only the information gathered pursuant to § 79.52(d) for such tests. EPA maintains final authority in judging whether the information is an adequate substitution in lieu of conducting the associated tests. EPA's determination of the adequacy of existing information shall be guided by the considerations described in paragraph (d) of this section. If EPA finds that the manufacturer has relied upon inadequate test data, then the manufacturer will not be considered to be in compliance until the corresponding tests have been con-

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ducted and the results submitted to EPA.

(c) *Testing.* (1) All testing required pursuant to this section must be done in accordance with the procedures, equipment, and facility requirements described in §§ 79.57, 79.60, and 79.61 regarding emissions generation, good laboratory practices, and inhalation exposure testing, respectively, as well as any other requirements described in this subpart. The laboratory conducting the animal studies shall be registered and in good standing with the United States Department of Agriculture and regularly inspected by United States Department of Agriculture veterinarians. In addition, the facility must be accredited by a generally recognized independent organization which sets laboratory animal care standards. Use of inadequate test protocols or substandard laboratory techniques in performing any testing required by this subpart may result in cancellation of all affected registrations.

(2) Carcinogenic or mutagenic effects in animals from emissions exposures shall be determined pursuant to § 79.64 *In vivo* Micronucleus Assay, § 79.65 *In vivo* Sister Chromatid Exchange Assay, and § 79.68 *Salmonella typhimurium* Reverse Mutation Assay. Teratogenic effects and reproductive toxicity shall be examined pursuant to § 79.63 Fertility Assessment/Teratology. General toxicity and pulmonary effects shall be determined pursuant to § 79.62 Subchronic Toxicity Study with Specific Health Effect Assessments. Neurotoxic effects shall be determined pursuant to § 79.66 Neuropathology Assessment and § 79.67 Glial Fibrillary Acidic Protein Assay.

(d) *EPA Determination.* (1) After submission of all information and testing, EPA in its judgment shall determine whether previously conducted tests relied upon in the registration submission are adequately performed and documented and provide information reasonably comparable to that which would be provided by the tests described herein. Manufacturers' submissions shall be sufficiently detailed to allow EPA to judge the adequacy of protocols, techniques, experimental design, statistical analyses, and conclusions. Studies shall be performed using