

## §79.58 Special provisions.

(a) Relabeled Additives. Sellers of relabeled additives (pursuant to §79.50) are not required to comply with the provisions of §79.52, 79.53 or 79.59, except that such sellers are required to comply with §79.59(b).

(b) Low Vapor Pressure Fuels and Additives. Fuels which are not designated as “evaporative fuels” and fuel additives which are not designated as “evaporative fuel additives” pursuant to the definitions in §79.50 need not undergo the emission characterization or health effects testing specified in §§79.52 and 79.53 for evaporative emissions. At EPA's discretion, the evaporative emissions of such fuels and additives may be required to undergo Tier 3 testing, pursuant to §79.54.

(c) Alternative Tier 2 Provisions. At EPA's discretion, EPA may modify the standard Tier 2 health effects testing requirements for a fuel or fuel additive (or group). Such modification may encompass substitution, addition, or deletion of Tier 2 studies or study specifications, and/or changes in underlying engine or equipment requirements, except that a Tier 2 endpoint will not be deleted in the absence of existing information deemed adequate by EPA or alternative testing requirements for such endpoint. If warranted by the particular requirements, EPA will allow additional time for completion of the alternative Tier 2 testing program.

(1) When EPA intends to require testing in lieu of or in addition to standard Tier 2 health testing, EPA will notify the responsible manufacturer (or group) by certified letter of the specific tests which EPA is proposing to require in lieu of or in addition to Tier 2, and the proposed schedule for completion and submission of such tests. A copy of the letter will be placed in the public record. EPA intends to send the notification prior to November 27, 1995, or in the case of new fuels and additives (as defined in §79.51(c)(3)), within 18 months of EPA's receipt of an intent to register such product. However, EPA's notification to the manufacturer (or group) may occur at any time up to EPA's receipt of Tier 2 data for the product(s) in question. EPA will provide the manufacturer with 60 days from the date of receipt of the notice to comment on the tests which EPA is proposing to require and on the proposed schedule. If the manufacturer believes that undue costs or hardships will occur as a result of EPA's delay in providing notification of alternative Tier 2 requirements, then the manufacturer's comments should describe and include evidence of such hardship. In particular, if the standard Tier 2 toxicology testing for the fuel or additive in question has already begun at the time the manufacturer receives EPA's notification of proposed alternative Tier 2 requirements, then EPA shall refrain from requiring alternative Tier 2 tests provided that EPA receives the standard Tier 2 data and report (pursuant to §79.59(c)) within one year of the date on which the toxicology testing began.

(2) EPA will issue a notice in the Federal Register announcing its intent to require special testing in lieu of or in addition to the standard Tier 2 testing for a particular fuel or additive manufacturer or group, and that a copy of the letter to the manufacturer or group describing the proposed alternative Tier 2 testing for that manufacturer or group is available in the public record for review and comment. The public shall have a minimum of 30 days after the publication of this notice to comment on the proposed alternative Tier 2 testing.

(3) EPA will include in the public record a copy of any timely comments concerning the proposed alternative Tier 2 testing requirements received from the affected manufacturer or group or from the public, and the responses of EPA to such comments. After reviewing all such comments received, EPA may adopt final alternative Tier 2 requirements by sending a certified letter describing such final requirements to the manufacturer or group. In that event, EPA will also issue a notice in the Federal Register announcing that it has adopted final alternative Tier 2 requirements and that a copy of the letter adopting the requirements has been included in the public record.

(4) After EPA's receipt of a manufacturer's (or group's) submittals, EPA will notify the responsible manufacturer (or group) regarding the adequacy of the submittal and potential Tier 3 testing requirements according to the same relative time intervals and by the same procedures as specified in §79.51 (c) and (d) for routine Tier 1 and Tier 2 submittals.

(d) Small Business Provisions. (1) For purposes of these provisions, when subsidiary, divisional, or other complex business arrangements exist, manufacturer is defined as the business entity with ultimate ownership of all related parents, subsidiaries, divisions, branches, or other operating units. Total annual sales means the average of the manufacturer's total sales revenue, excluding

08 March 2019

any revenue which represents the collection of Federal, State, or local excise taxes or sales taxes, in each of the three years prior to such manufacturer's submittal to EPA of the basic registration information pursuant to §79.59(b)(2) through (b)(5).

(2) Provisions Applicable to Baseline and Non-baseline Products. A manufacturer with total annual sales less than \$50 million is not required to meet the requirements of Tier 1 and Tier 2 (specified in §§79.52 and 79.53) with regard to such manufacturer's fuel and/or additive products which meet the criteria for inclusion in a Baseline or Non-baseline group pursuant to §79.56. Upon such manufacturer's satisfactory completion and submittal to EPA of basic registration data specified in §79.59(b), the manufacturer may request and EPA shall issue a registration for such product, subject to §79.51(c) and paragraphs (d)(4) and (d)(5) of this section.

(3) Provisions Applicable to Atypical Products. A manufacturer with total annual sales less than \$10 million is not required to meet the requirements of Tier 2 (specified in §79.53) in regard to such manufacturer's fuel and/or additive products which meet the criteria for inclusion in an Atypical group pursuant to §79.56. Upon such manufacturer's satisfactory completion and submittal to EPA of basic registration data specified in §79.59(b) and Tier 1 information specified in §79.52 for an Atypical fuel or additive, the manufacturer may request and EPA shall issue a registration for such product, subject to §79.51(c) and paragraphs (d)(4) and (d)(5) of this section. Compliance with Tier 1 requirements under this paragraph may be accomplished by the individual manufacturer or as a part of a group pursuant to §79.56.

(4) Any registration granted by EPA under the provisions of this section are conditional upon satisfactory completion of any Tier 3 requirements which EPA may subsequently impose pursuant to §79.54. In such circumstances, the Tier 3 requirements might include (but would not necessarily be limited to) information which would otherwise have been required under the provisions of Tier 1 and/or Tier 2.

(5) The provisions in paragraphs (d)(2) and (d)(3) of this section are voluntary on the part of qualifying small manufacturers. Such manufacturers may choose to fulfill the standard requirements for their fuels and additives, individually or as a part of a group, rather than satisfying only the requirements specified in paragraphs (d)(2) and/or (d)(3) of this section. If a qualifying small manufacturer elects these special provisions rather than the standard requirements for a product, then EPA will generally assume that any additional information submitted by other manufacturers, for fuels and additives meeting the same grouping criteria (under §79.56) as that of the small manufacturer's product, is pertinent to further testing and/or regulatory decisions that may affect the small manufacturer's product.

(6) In the case of an additive for which the manufacturer is not required to meet the requirements of Tier 2 pursuant to paragraph (d)(3) of this section:

(i) A fuel manufacturer which blends such an additive into fuel shall not be required to meet the requirements of Tier 2 with respect to such additive/fuel mixture.

(ii) An additive manufacturer which blends such an additive with one or more other registered additive products and/or with substances containing only carbon and/or hydrogen shall not be required to meet the requirements of Tier 2 with respect to such additive or additive blend.

(e) Aftermarket Aerosol Additives. (1) To obtain registration for an aftermarket aerosol fuel additive, the manufacturer shall provide existing information in the form of a literature search, a discussion of the potential exposure(s) to such product, and the basic registration data specified in §79.59(b).

(2) The literature search shall include existing data on potential health and welfare effects due to exposure to the aerosol product itself and its raw (uncombusted) components. The analysis for potential exposures shall be based on the actual or anticipated production volume and market distribution of the particular aerosol product, and its estimated frequency of use. Other Tier 1 and Tier 2 requirements are not routinely required for aerosol products. EPA will review the submitted information and, at EPA's discretion, may require from the manufacturer further information and/or testing under Tier 3 on a case-by-case basis.

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