ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 79 and 80

[FRL–5651–3]

Regulation of Fuels and Fuel Additives: Minor Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The purpose of this action is to make minor revisions and corrections affecting recently-promulgated rules. First, a regulatory provision included in the health effects testing requirements for fuel and fuel additive registration (at 40 CFR part 79) is revised to ensure sufficient scheduling flexibility when test laboratories encounter technical problems. Second, a provision inadvertently omitted from both the Interim Detergent Program and the Detergent Certification Program is added to the regulations (at 40 CFR part 80). The new provision will allow a detergent additive manufacturer to apply one set of performance demonstration tests to multiple detergent additive products containing the same active ingredients. Finally, a regulatory numbering error and a syntactical error affecting the Detergent Certification rule are corrected.

These changes are being implemented without prior notice because EPA believes that they are not controversial. Both of the affected programs serve the public health and environmental protection goals of the Clean Air Act (CAA). The detergent certification program is intended to ensure the emission reduction and fuel efficiency benefits of gasoline detergent additives. The fuel and fuel additive (F/FA) health effects testing program is designed to determine if the emissions of certain gasoline or diesel F/FAs present an unacceptable risk to the public health. The corrections implemented by today's action will facilitate attainment of these program objectives by simplifying the regulatory requirements which might otherwise pertain to some regulated parties.

DATES: This action will be effective on January 17, 1997 unless EPA receives an adverse comment or a request for a public hearing by December 18, 1996. If EPA receives an adverse comment or hearing request by that date, EPA will publish timely notice in the Federal Register withdrawing this rule.

ADDRESSES: Materials relevant to this rulemaking have been placed in Dockets A–90–07 and A–91–77. The dockets are located at the U.S. Environmental Protection Agency, Air Docket Section (LE–131), 401 M Street, S.W., Washington, DC 20460 in Room M–1500 of Waterside Mall. Documents may be inspected between the hours of 8:00 a.m. and 5:30 p.m., Monday through Friday. A reasonable fee may be charged for copying. Those wishing to notify EPA of their intent to submit an adverse comment or request a public hearing should contact Jeff Herzog (313) 668–4227, U.S. EPA, Office of Mobile Sources, Fuels and Energy Division, 2565 Plymouth Rd., Ann Arbor, MI 48105 or Jim Caldwell (202) 233–9303, EPA, Office of Mobile Sources, Fuels and Energy Division, Mail Code 6401J, 401 M St. SW., Washington DC 20460.

FOR FURTHER INFORMATION CONTACT: For information related to the registration of fuels and fuel additives under 40 CFR part 79, contact: Joseph Fernandes (202) 233–9756 or James W. Caldwell (202) 233–9303, U.S. EPA, Office of Mobile Sources, Fuels and Energy Division, Mail Code 6406J, 401 M Street, SW., Washington, DC 20460. For information related to detergent additive certification under 40 CFR part 80, contact: Jeffrey A. Herzog, U.S. EPA (FED), Office of Mobile Sources, Fuels and Energy Division, 2565 Plymouth Road, Ann Arbor, MI 48105.

SUPPLEMENTARY INFORMATION:

I. Regulated Entities

Regulated categories and entities potentially affected by this action include:

Category	Examples of regulated entities
Industry	Manufacturers of gasoline and diesel fuel. Manufacturers of additives for gasoline and diesel fuel.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your entity would be affected by this action, you should carefully examine this preamble and the proposed changes to the regulatory text. You should also carefully examine the existing provisions of the Fuels and Fuel Additives Registration Program at 40 CFR part 79 and the Detergent Certification Program at 40 CFR part 80.

II. F/FA Health Effects Testing Program Correction

A. Background

In accordance with CAA sections 211 (a) and (b)(1), EPA issued, in 1975, basic registration requirements applicable to gasoline and diesel fuels and their additives. These regulations require manufacturers to submit information on their F/FA products (e.g., commercial identity, chemical composition, purpose-in-use, and recommended range of concentration) in order to have such products registered by EPA and to be permitted to market them in the U.S.

Additional registration requirements, implementing sections 211 (b)(2) and (e), were finalized on May 27, 1994 (59 FR 33042, June 27, 1994). These regulations require manufacturers, as part of their F/FA registration responsibilities, to conduct tests and submit information on the health effects of their F/FA products. Organized within a three-tier structure, the requirements include detailed emissions analysis, literature search, and toxicologic studies involving the exposure of laboratory animals to F/FA emissions.

On July 11, 1996, EPA published two additional Federal Register notices concerning the F/FA registration and health effects testing requirements. One was a Notice of Proposed Rulemaking (61 FR 36535) requesting public comment on proposed changes designed to clarify and streamline a variety of organizational, technical, and record keeping provisions of the program. The second notice (61 FR 36506) was a direct final rule which, in the absence of adverse public comment prior to August 12, 1996, implemented several other, relatively minor technical changes.

One of the regulatory sections affected by the direct final rule was § 79.61(d)(5), which contains general rules governing exposure interruptions during toxicologic studies. In changing this section, the intent was to clarify the rule's language and to make the exposure interruption rules more consistent with customary laboratory practices. EPA wished to allow reasonable flexibility in the scheduling and conduct of these complex studies. On the other hand, EPA's interest in the relative toxicity of different F/FAs dictated that controllable sources of variability between tests and test labs should be minimized. Thus, as discussed in the preamble to the rule, EPA expressly intended not to include allowances for Federal holidays in the exposure rules. It was for this reason that the revised language included the

constraint that ''No more than two non-exposure days may occur consecutively during the exposure period, including days on which the minimum exposure time has not been met.'' Toxicologic studies which did not comply with this rule would be considered void.

B. Today's Action

EPA now realizes that, as revised, the exposure rules are considerably more stringent than intended. While the prohibition against three consecutive non-exposure days does effectively disallow holiday downtime, it may also unreasonably penalize testers who unintentionally miss a third consecutive exposure day due to technical difficulties. This might occur, for example, if unexpected equipment problems are encountered on a Monday after an ordinary two-day weekend off. As currently written, the rule does not provide a way to remedy such occurrences. Thus, studies which are otherwise acceptable could become void unnecessarily, and large financial expenditures for repeat testing might be incurred.

The revisions finalized today will prevent these unintended results. The new version still specifies that three consecutive non-exposure days are normally not permitted. However, if a third consecutive day is missed due to circumstances beyond the tester's control, the rule provides that it may be cured by adding a supplementary exposure day at the next available opportunity or, if necessary, at the end of the standard test period. These mechanisms should furnish the scheduling flexibility needed to address equipment and other technical problems which arise during the conduct of laboratory studies. Nevertheless, sufficient regulatory controls are retained to encourage good-faith efforts to adhere to regular test schedules, technical procedures, and effective preventive maintenance practices.

It should be noted that, in instances where the exposure requirements of a specific test protocol differ from the general exposure guidelines finalized today, then the requirements of the specific test protocol take precedence. For example, the general exposure guidelines do not affect the exposure timing requirement specified in § 79.63(e)(4)(iii) of the fertility assessment-teratology guideline, which states that pregnant animal subjects ''shall be exposed to the test atmosphere on each and every day between (and including) the first and fifteenth day of gestation.''

III. Detergent Additive Program Correction

A. Background

The final rule establishing the Detergent Certification Program was published July 5, 1996 (61 FR 35309). The certification rule modified, and will later supersede,[1] the existing Interim Detergent Program, which was published October 14, 1994 (59 FR 54678) and became effective January 1, 1995. These rules were promulgated in compliance with CAA section 211(l), which requires all gasoline sold or transferred to the consumer beginning January 1, 1995 to contain additives preventing the accumulation of deposits in engines or fuel supply systems. The CAA charged EPA with the task of establishing specifications for such detergent additives.

The interim detergent program requires virtually all gasoline used by the consumer to contain effective detergent additives for the control of port fuel injector deposits (PFID) and intake valve deposits (IVD). However, the interim program does not include specific performance tests and standards for the additives. In contrast, the detergent certification program requires manufacturers to conduct specific vehicle-based performance tests, using industry-standard test procedures and specified test fuels, to demonstrate the effective control of IVD and PFID. These certification tests are the basis for determining the minimum concentration at which a detergent additive can be used in gasoline (i.e., the lowest additive concentration or LAC).

B. Today's Actions

1. Multiple Versions of Detergent Packages

Detergent additive manufacturers commonly produce and market (and thus must register under 40 CFR part 79) a number of commercial additive products containing the same detergent-active ingredient(s) at different concentrations. EPA understands that this is a normal business practice, and does not believe it is necessary or desirable to require the effectiveness of each such product variant to be demonstrated in separate certification tests. As EPA stated in the preamble to the interim detergent rule:

> EPA agrees that separate performance tests should not be needed for multiple detergent additive packages which contain the same active detergent ingredients in different concentrations, provided that the minimum recommended treat rate specified in the registration information for each additive package properly accounts for the variations in concentration. Specifically, for each registered detergent package which the manufacturer intends to support with a single set of test data, the final concentration of active detergent ingredients (resulting when the detergent package is added to gasoline at its respective minimum recommended treat rate) must be no less than the minimum concentrations shown to be effective by the testing * * * [S]eparate supporting data are needed only if the actual chemical identity of an active detergent ingredient is changed. (59 FR 54688–89)

Thus, it has not been EPA's intent to require duplicative certification testing for different versions of a particular detergent additive package. Through an oversight, however, a regulatory provision to codify this principle was not included in the interim detergent program regulations, nor did such a provision appear in the final certification program regulations. Today's action corrects these unintentional oversights by adding new regulatory text at § 80.141(c)(3)(v) and § 80.161(b)(1)(ii)(D). The new regulatory provisions permit a detergent additive manufacturer to apply one set of performance data to multiple detergent additive products containing the same active ingredients, provided that the minimum recommended concentration or LAC recorded for each product is adjusted accordingly.

2. Typographical Corrections

The Federal Register document which published the detergent certification final rule (61 FR 35309) contained a numbering error affecting a regulatory provision. Specifically, the provision on ''Procedures for curing use restrictions,'' which should have been labeled as paragraph (9) (nine) in § 80.169(c), was mistakenly labeled as paragraph (g) in § 80.169. In the same paragraph, a reference to ''this paragraph (g)'' should have referred to ''this paragraph (c)(9)''. In addition, the title of the paragraph should have appeared in italic rather than regular type font. These errors are corrected in this direct final rule.

Finally, a syntactical error was made in § 80.172(e), which concerns penalties related to non-conformity with the product transfer document requirements of the detergent certification program. In paragraph (2) of this section, there is an erroneous reference to ''gasoline not additized in conformity with interim detergent program requirements,'' rather than a proper reference to ''gasoline not additized in conformity with detergent

[1] In general, the requirements of the certification program become mandatory for detergent additive manufacturers and blenders on July 1, 1997 and for gasoline retailers on August 1, 1997.

certification program requirements.'' This error is corrected in this direct final rule.

IV. Administrative Requirements

A. Administrative Designation and Regulatory Analysis

Under Executive Order 12866 (58 FR 51735, Oct. 4, 1993), the Agency must determine whether this regulatory action is ''significant'' and therefore subject to OMB review and the requirements of the Executive Order. The order defines ''significant regulatory action'' as any regulatory action that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or,

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, EPA has determined that this direct final rule is not a ''significant regulatory action''. The regulatory corrections included in this notice will result in reduction of potential testing costs and related compliance burdens.

B. Regulatory Flexibility Analysis

EPA has determined that it is not necessary to prepare a regulatory flexibility analysis in connection with this direct final rule. EPA has determined that this rule will not have a significant adverse economic impact on a substantial number of small businesses. On the contrary, the corrections implemented by this rule will simplify compliance and reduce potential testing requirements for all affected parties.

C. Paperwork Reduction Act

The Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq., and implementing regulations, 5 CFR Part 1320, do not apply to this action as it does not involve the collection of information as defined therein.

D. Unfunded Mandates Reform Act

Under section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in expenditure by State, local, and tribal governments, in the aggregate; or by the private sector, of $100 million or more. Under Section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule. The Agency has determined that the direct final rule promulgated today does not include a federal mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This action does not establish regulatory requirements that may significantly or uniquely affect small governments. In fact, this action has the effect of reducing potential regulatory burdens. Therefore, the requirements of the Unfunded Mandates Reform Act do not apply.

E. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A) as added by the Small Business Regulatory Enforcement Fairness Act of 1996, EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of the rule in today's Federal Register. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

V. Electronic Copies of Rulemaking Documents

Electronic copies of this rule, and earlier rulemaking documents related to the F/FA Registration Program, the Interim Detergent Program, and the Detergent Certification Program, are available free of charge on EPA's Technology Transfer Network Bulletin Board System (TTNBBS) and on the Internet. For specific instructions, contact Joseph Fernandes at the phone number or address above. These documents are also available in the public dockets referenced above.

List of Subjects

40 CFR Part 79

Environmental protection, Fuels, Fuel additives, Gasoline, Motor vehicle pollution, Penalties, Reporting and recordkeeping requirements.

40 CFR Part 80

Environmental protection, Fuel additives, Gasoline detergent additives, Gasoline, Motor vehicle pollution, Penalties, Reporting and recordkeeping requirements.

Dated: November 7, 1996.

Carol M. Browner,

Administrator.

For the reasons set forth in the preamble, parts 79 and 80 of title 40 of the Code of Federal Regulations are amended as follows:

PART 79—[AMENDED]

1. The authority citation for part 79 continues to read as follows:

Authority: 42 U.S.C. 7414, 7524, 7545 and 7601.

2. Section 79.61 is amended by revising paragraph (d)(5) to read as follows:

§ 79.61 Vehicle emissions inhalation exposure guideline.

* * * * *

(d) * * *

(5) *Exposure conditions.* Unless precluded by the requirements of a particular test protocol, animal subjects shall be exposed to the test atmosphere based on a nominal 5-day-per-week regimen, subject to the following rules:

(i) Each daily exposure must be at least 6 hours plus the time necessary to build the chamber atmosphere to 90 percent of the target exposure atmosphere. Interruptions of daily exposures caused by technical difficulties, if infrequent in occurrence and limited in duration, may be made up the same day by adding equivalent exposure time after the technical problem has been corrected and the exposure atmosphere restored to the required level.

(ii) Normally, no more than two non-exposure days may occur consecutively during the test period. However, if a third consecutive non-exposure day should occur due to circumstances beyond the tester's control, it may be remedied by adding a supplementary exposure day. Federal and other holidays do not constitute such circumstances. Whenever possible, a make-up day should be taken at the first opportunity, i.e., on the next day which would otherwise have been an intentional non-exposure day. If a compensatory day must be scheduled at the end of the standard test period, then it may occur either:

(A) Immediately following the last standard exposure day, with no intervening non-exposure days; or

(B) With up to two intervening non-exposure days, provided that no fewer than two consecutive compensatory exposure days are completed before the test is terminated and the animals sacrificed.

(iii) Except as allowed in paragraph (d)(5)(ii)(B) of this section, in no case shall there be fewer than four exposure days per week at any time during the test period.

(iv) A nominal 90-day (13-week) subchronic test period shall include no fewer than 63 total exposure days.

* * * * *

PART 80—[AMENDED]

1. The authority citation for part 80 continues to read as follows:

Authority: 42 U.S.C. 7414, 7545 and 7601(a).

2. § 80.141 is amended by adding paragraph (c)(3)(v) to read as follows:

§ 80.141 Interim detergent gasoline program.

* * * * *

(c) * * *

(3) * * *

(v) A manufacturer may use a single set of test data to demonstrate the deposit control effectiveness of more than one registered detergent additive product, provided that:

(A) the additive products contain all of the same detergent-active components and no detergent-active components other than those contained in common; and

(B) the minimum concentration recommended for the use of each such additive product is specified such that, when each additive product is mixed in gasoline at the recommended concentration, each of its detergent-active components will be present at a final concentration no less than the lowest concentration for that component shown to be effective by the data available for the tested additive product.

* * * * *

3. § 80.161 is amended by adding paragraph (b)(1)(ii)(D) to read as follows:

§ 80.161 Detergent additive certification program.

* * * * *

(b) * * *

(1) * * *

(ii) * * *

(D) A manufacturer may use a single set of certification test data to demonstrate the deposit control effectiveness of more than one registered detergent additive product, provided that:

(*1*) the additive products contain all of the same detergent-active components and no detergent-active components other than those contained in common; and

(*2*) the minimum concentration recommended for the use of each such additive product is specified such that, when each additive product is mixed in gasoline at the recommended concentration, each of its detergent-active components will be present at a final concentration no less than the lowest concentration of that component which was present when the tested additive product met the PFID and IVD performance standards specified in § 80.165.

* * * * *

§ 80.169 [Amended]

4. § 80.169 is amended by redesignating paragraph (g) as paragraph (c)(9); in newly designated paragraph (c)(9) introductory text, by revising the reference ''this paragraph (g)'' to read ''this paragraph (c)(9)''; and by italicizing the heading of paragraph (c)(9).

5. § 80.172 is amended by revising paragraph (e)(2) to read as follows:

§ 80.172 Penalties.

* * * * *

(e) * * *

(2) The day that gasoline not additized in conformity with detergent certification program requirements, as a result of the PTD non-conformity, is offered for sale or is dispensed to the ultimate consumer.

* * * * *

[FR Doc. 96–29180 Filed 11–15–96; 8:45 am]

BILLING CODE 6560–50–P