



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OAR-2006-0525; FRL-11844-01-OMS]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Fuels and Fuel Additives: Health-Effects Research Requirements for Manufacturers (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Fuels and Fuel Additives: Health-Effects Research Requirements for Manufacturers (EPA ICR Number. 1696.11, OMB Control Number 2060-0297) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through March 31, 2024. Public comments were previously requested via the *Federal Register* on July 5, 2023, during a 60-day comment period. This notice allows for 30 days for public comments.

DATES: Comments may be submitted on or before [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Submit your comments, referencing Docket ID Number EPA-HQ-OAR-2006-0525, to EPA online using www.regulations.gov (our preferred method), by email to a-and-r-docket@epa.gov, or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave., NW, Washington, DC 20460. EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Submit written comments and recommendations to OMB for the proposed information collection within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain.

Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: James W. Caldwell, Compliance Division, Office of Transportation and Air Quality, Mail Code: 6406J, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: (202) 343-9303; fax number: (202) 343-2800; email address: caldwell.jim@epa.gov.

SUPPLEMENTARY INFORMATION: This is a proposed extension of the ICR, which is currently approved through March 31, 2024. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Public comments were previously requested via the Federal Register on July 5, 2023 during a 60-day comment period (88 FR 42939). This notice allows for an additional 30 days for public comments. Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at www.regulations.gov or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave., NW, Washington, DC. The telephone number for the Docket Center is 202-566-1744. For additional information about EPA's public docket, visit <http://www.epa.gov/dockets>.

Abstract: In accordance with the regulations at 40 CFR 79, Subparts A, B, C, and D, Registration of Fuels and Fuel Additives, manufacturers (including importers) of motor-vehicle gasoline, motor-vehicle diesel fuel, and additives for those fuels, are required to have these products registered by the EPA prior to their introduction into commerce. Registration involves providing a chemical description of the fuel or additive, and certain technical, marketing, and health-effects information. The development of health-effects data, as required by 40 CFR 79, Subpart F, is the subject of this ICR. The information collection requirements for Subparts A through D, and the supplemental notification requirements of Subpart F (indicating how the manufacturer will

satisfy the health-effects data requirements) are covered by a separate ICR (OMB Control Number 2060-0150). The health-effects data will be used to determine if there are any products which have evaporative or combustion emissions that may pose an unreasonable risk to public health, thus meriting further investigation and potential regulation. This information is required for specific groups of fuels and additives as defined in the regulations. For example, gasoline and gasoline additives which consist of only carbon, hydrogen, oxygen, nitrogen, and/or sulfur, and which involve a gasoline oxygen content of less than 1.5 weight percent, fall into a “baseline” group. Oxygenated additives, such as ethanol, when used in gasoline at an oxygen level of at least 1.5 weight percent, define separate “non-baseline” groups for each oxygenate. Additives which contain elements other than carbon, hydrogen, oxygen, nitrogen, and sulfur fall into separate “atypical” groups. There are similar grouping requirements for diesel fuel and diesel fuel additives.

Manufacturers may perform the research independently or may join with other manufacturers to share in the costs for each applicable group. Several research consortiums (groups of manufacturers) have been formed. The research is structured into three tiers of requirements for each group. Tier 1 requires an emissions characterization and a literature search for information on the health effects of those emissions. Tier 1 data have been submitted for biodiesel, water/diesel emulsions, several atypical additives, and renewable gasoline and diesel fuels. Tier 2 requires short-term inhalation exposures of laboratory animals to emissions to screen for adverse health effects. Tier 2 data have been submitted for baseline diesel, biodiesel, and water/diesel emulsions. Alternative Tier 2 requirements were established for the API consortium for baseline gasoline and six gasoline-oxygenate blends. Tier 3 provides for follow-up research, at EPA’s discretion, when remaining uncertainties as to the significance of observed health effects, welfare effects, and/or emissions exposures from a fuel or fuel/additive mixture interfere with EPA’s ability to make reasonable estimates of the potential risks posed by emissions from a fuel or additive. Under regulations promulgated pursuant to Section 211 of the

Clean Air Act, submission of the health-effects information is necessary for a manufacturer to obtain registration of a motor-vehicle gasoline, diesel fuel, or fuel additive, and be allowed to introduce that product into commerce and the information shall not be considered confidential.

Form Numbers: None.

Respondents/affected entities: Manufacturers of motor-vehicle gasoline, motor-vehicle diesel fuel, and additives for those fuels.

Respondent's obligation to respond: Mandatory per 40 CFR 79.

Estimated number of respondents: 2

Frequency of response: On occasion

Total estimated burden: 13,867 hours per year. Burden is defined at 5 CFR 1320.03(b)

Total estimated cost: \$1.7 million per year, includes \$0.6 million annualized capital or operation & maintenance costs.

Changes in the Estimates: There is a \$2 million decrease in cost. This is due to an estimated decrease in the number of fuels and additives for which testing will be required.

Courtney Kerwin,

Director, Regulatory Support Division

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