



6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OAR-2006-0525; FRL - 9998-35-OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Registration of 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), Registration of Fuels and Fuel Additives: Health-Effects Research Requirements for Manufacturers (EPA ICR Number 1696.10, 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 November 30, 2019. Public comments were previously requested via the *Federal Register* on May 21, 2019 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. 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.

DATES: Additional 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 (1) 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, and (2) OMB via email to oir_submission@omb.eop.gov. Address comments to OMB Desk Officer for EPA.

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.

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: 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 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.

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 largest consortium, organized by the American Petroleum Institute (API), represents most of the manufacturers of baseline gasoline, baseline diesel fuel, baseline fuel additives, and the prominent non-baseline oxygenated additives for gasoline. 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. Voluminous Tier 1 data for gasoline and diesel fuel were submitted by API and others in 1997. 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 testing can be required in lieu of standard Tier 2 testing if EPA concludes that such testing would be more appropriate. EPA reached that conclusion with respect to gasoline and gasoline-oxygenate blends, and alternative requirements were established for the API consortium for baseline gasoline and six gasoline-oxygenate blends. Alternative Tier 2 requirements have also been established for the manganese additive MMT manufactured by the Afton Chemical Corporation (formerly the Ethyl Corporation). 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. To date, EPA has not imposed any Tier 3 requirements.

Under regulations promulgated pursuant to Section 211 of the Clean Air Act, (1) 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 thus be allowed to introduce that product into commerce, and (2) 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, subpart F.

Estimated number of respondents: 2

Frequency of response: On occasion

Total estimated burden: 35,200 hours per year. Burden is defined at 5 CFR 1320.03(b)

Total estimated cost: \$3,697,000 per year, includes \$597,000 annualized capital or operation & maintenance costs.

Changes in the Estimates: There is an increase of 17,600 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This increase is based on input from an industry representative who stated that their actual literature review and Tier 2/Alternative Tier 2 costs were double the EPA estimate.

Courtney Kerwin

Director, Regulatory Support Division

[FR Doc. 2019-20947 Filed: 9/25/2019 8:45 am; Publication Date: 9/26/2019]