U.S. Environmental Protection Agency
Information Collection Request

Title: Registration of Fuels and Fuel Additives: Health-Effects Research Requirements for Manufacturers (40 CFR 79 - Subpart F) (Renewal)

OMB Control Number: OMB Control Number 2060-0297

EPA ICR Number: EPA ICR Number 1696.11

Abstract: In accordance with the regulations at 40 CFR 79, Subparts A, B, C, D and F (there is no Subpart E), Registration of Fuels and Fuel Additives, manufacturers (includes importers) of (1) motor vehicle gasoline, (2) motor vehicle diesel fuel, and (3) additives for those fuels are required to have their products registered by the Environmental Protection Agency (EPA) prior to their introduction into commerce. Registration involves providing (1) a chemical description of the fuel or additive, (2) certain technical and marketing information, and (3) certain health-effects information. Periodic reports on production and related information are required. Subpart F requires the conduct of health-effects research. This ICR addresses the information collection requirements of that research. The information collection requirements of Subparts A through D, and the supplemental notification requirement of Subpart F (indicating how the manufacturer plans to satisfy the research requirements or qualifies for an exemption) are covered by a separate ICR (EPA ICR Number 309.15, OMB Control Number 2060-0150).

The program is operated by the Compliance Division, Office of Transportation and Air Quality, Office of Air and Radiation. The information developed by the health-effects research will be used to identify products with evaporative or exhaust emissions that may pose a particular threat to public health, thus meriting further investigation and/or regulation. Manufacturers of similar products are allowed to group in order to share the research costs. Several groups, also known as consortiums, have been formed. The largest consortium, organized by the American Petroleum Institute (API), represents most of the manufacturers of conventional gasolines, diesel fuels, and additives. The regulations define the fuel/additive categories for which the research is required. There are three tiers of requirements. Tier 1 requires (1) operation of an engine on the candidate fuel, (2) identification of the emissions (emissions characterization), and (3) a literature search over the past 30 years for health-effects information on those emissions. Tier 2 (also known as standard Tier 2) requires short-term inhalation exposures of laboratory animals to candidate-fuel emissions (combustion, and if required under Tier 1, evaporative) to screen for adverse health effects. The EPA has the authority to require “Alternative Tier 2" testing if there is a reasonable basis to conclude that such testing is more appropriate. The EPA reached that conclusion with respect to gasoline and gasoline-oxygenate blends. The API consortium was notified of the proposed alternative requirements in 1997. After public review and comment, and discussions with API, the alternative requirements were finalized and API notified in 1998. Similar situations existed for a manganese gasoline additive known as MMT, manufactured by the Ethyl Corporation (now Afton Chemical Corporation), and a blend of diesel fuel and water, known as PuriNOx, manufactured by the Lubrizol Corporation. Tier 3 provides for follow-up research. Tier 3 can be required when 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 the emissions from such products. Tier 3 requirements are established via a public process comparable to that for Alternative Tier 2. No Tier 3 requirements have been established.

Supporting Statement A

1. NEED AND AUTHORITY FOR THE COLLECTION

Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection.

Motor vehicles comprise a major source of air pollution in urban areas and account for about half the toxic air emissions in the United States. Congress demonstrated its strong concern for the protection of public health by providing broad legislative authority to monitor and regulate fuels, fuel additives, and their emissions. This registration program was established by the Air Quality Act of 1967, carried forward into the Clean Air Act (Act) of 1970, and strengthened in the Act's 1977 and 1990 reauthorizations.

Section 211(a) of the Act provides EPA with the authority to designate, by regulation, any mobile source fuel or additive for registration. Any fuel or additive used to such an extent that there is, or would be, significant public emissions exposure, is an appropriate candidate. Once designated, it may not be introduced into commerce until it has been registered by EPA. Section 211(b) requires that the manufacturer provide certain compositional and related information. It provides EPA with the authority to require health-effects testing and the submittal of health-effects data and related data. Section 211(e), a 1977 amendment, made the health-effects research requirements mandatory. The original regulations were promulgated by the Department of Health, Education, and Welfare in 1970 and transferred to the EPA shortly thereafter. They ultimately resided at 40 CFR 79 and were revised in 1975, 1976, 1978, 1994, 1996, 1997, 1998, 2014 and 2020. Due to their broad public emissions exposure, motor vehicle gasoline and diesel fuel, and their additives, were designated.

2. PRACTICAL UTILITY/USERS OF THE DATA

Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

The regulations at 40 CFR 79 - Subpart F, promulgated on May 27, 1994, require research for each of the following fuel/additive groups whose components are derived from conventional petroleum, heavy oil deposits, coal, tar sands and/or oil sands: gasoline (baseline, non-baseline, and atypical) and diesel (baseline, non-baseline, and atypical). The regulations also establish non-baseline groups for each gasoline, diesel fuel, and additive group that is derived in whole or in part from sources other than those mentioned above, such as animal fats and plant oils. The fuel/additive group is defined by the source.

The research is structured into three tiers of requirements for each group. Tier 1 requires an emissions characterization and a literature search for the health effects of those emissions. The Tier 1 data must be submitted before the product can be registered. Tier 2 requires short-term inhalation exposures of laboratory animals to emissions (exhaust/evaporative for gasoline, exhaust only for diesel) to screen for adverse health effects. For products currently seeking registration, the Tier 1 or Tier 2 data are due

before registration can occur. The regulations also allow EPA to establish Alternative Tier 2 requirements in lieu of standard Tier 2, if warranted. Follow-up studies, if required, would occur under Tier 3.

The objective of the program is to determine if there are any fuels and/or additives whose evaporative emissions or products of combustion pose a particular danger to public health or welfare. Section 211(c) of the Act provides EPA with the authority to regulate such fuels and additives. For example, the use of lead additives in gasoline, gasoline volatility, and the sulfur content of gasoline and diesel fuel, have been regulated under this section. These health-effects data will allow decision makers to assess the relative risks of the fuel/additive groups described above. Should areas of concern be identified for certain products, further investigation or regulatory action could be taken.

The data may also be used by non-EPA organizations, such as fuel/additive producers and trade organizations, to review a product's potential toxicity, exposure, or registration status, to determine whether the submittal of further information would be duplicative, or to contact producers to use the registration already granted and share in the cost of previous compliance. Public interest and environmental organizations may review the data and perform their own evaluations. Laboratories may review the test reports for guidance on sound laboratory practices and data generation. Academic and medical experts may use the information in research or to compare with independent findings. State and local agencies responsible for protecting the public health may find these data to be of interest. The California Environmental Protection Agency assessed the use of oxygenates in gasoline, not only from an emissions standpoint, but also from a groundwater contamination standpoint, due to leaking storage tanks.

3. USE OF TECHNOLOGY

Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.

The nature of the reports makes them unsuitable for automatic data processing. The reports will be available to the public in hard copy, and, if so submitted, electronically. They will be stored in the format submitted.

4. EFFORTS TO IDENTIFY DUPLICATION

Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item 2 above.

To our knowledge, this is the only program which requires the manufacturers of motor vehicle fuels and fuel additives to develop emissions health-effects data. The regulations allow manufacturers of similar products to group and test one representative of the group, thus minimizing duplicative testing.

5. MINIMIZING BURDEN ON SMALL BUSINESSES AND SMALL ENTITIES

If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.

To lessen the burden for small businesses, manufacturers of baseline and/or non-baseline products, who have a total annual sales of less than $50 million, are exempt from Tier 1 and Tier 2. Manufacturers of atypical products, who have a total annual sales of less than $10 million, are exempt from Tier 2. There are less burdensome provisions for the manufacturers of aerosol additives. Manufacturers who merely re-label a registered product are not subject to Tier 1, Tier 2 and Tier 3.

6. CONSEQUENCES OF LESS FREQUENT COLLECTION

Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

These are one-time requirements for each fuel or additive unless follow-up research is warranted.

7. GENERAL GUIDELINES

Explain any special circumstances that require the collection to be conducted in a manner inconsistent with OMB guidelines.

Some records may contain confidential information on the composition of a fuel or additive. Such information is stored in a secure area with access only to those authorized. Paper files are in locked cabinets. Electronic records are in secure databases. There are no other special circumstances. All Office of Management and Budget (OMB) guidelines are met.

8. PUBLIC COMMENT AND CONSULTATIONS

8a. Public Comment

If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the Agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the Agency in response to these comments. Specifically address comments received on cost and hour burden.

A Federal Register notice requesting public comment on this ICR was published on July 5, 2023. No comments were received.

8b. Consultations

Describe efforts to consult with persons outside the Agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported. Consultation with representatives of those from whom information is to be obtained or those who must compile records should occur at least once every 3 years - even if the collection of information activity is the same as in prior periods. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.

Information was requested from the following three fuel industry companies:

- A fuel manufacturer
- An industry consultant
- A consulting company to the fuel/additive industry

Vance Koop, Energy Compliance Services, Weaver - 720.279.3011
Brittany Tucker, Associate Fuels Regulatory Analyst, Valero - 210.345.4289
Dr. Bob Hall, Managing Director, Top & Jeffries Limited - +44 7903 129548

Discussion of responses: Two of the three consultants responded that the estimates were reasonable.

9. PAYMENTS OR GIFTS TO RESPONDENTS

Explain any decisions to provide payments or gifts to respondents, other than remuneration of contractors or grantees.

No payments or gifts are provided to respondents.

10. ASSURANCE OF CONFIDENTIALITY

Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or Agency policy. If the collection requires a systems of records notice (SORN) or privacy impact assessment (PIA), those should be cited and described here.

Section 211(b)(2)(B) of the Act requires that the results of the health-effects research shall not be considered confidential. Some Tier 1 data, particularly those related to composition, could be claimed as confidential and would be subject to EPA's freedom of information provisions at 40 CFR 2. A SORN and a PIA are not required.

11. JUSTIFICATION FOR SENSITIVE QUESTIONS

Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the Agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

This information collection does not contain sensitive questions.

12. RESPONDENT BURDEN HOURS & LABOR COSTS

Provide estimates of the hour burden of the collection of information. The statement should:

- *Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. Generally, estimates should not include burden hours for customary and usual business practices.*
- *If this request for approval covers more than one form, provide separate hour burden estimates for each form and the aggregate the hour burdens.*
- *Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories. The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included as O&M costs under non-labor costs covered under question 13.*

12a. Respondents/NAICS Codes

The fuel and fuel additive manufacturers are related to the following major group North American Industry Classification System (NAICS) six-digit codes and Standard Industrialization Classification (SIC) four-digit codes:

324110 - Petroleum Refineries

2911 - Diesel Fuels Manufacturing

2911 - Gasoline Made in Petroleum Refineries

324119 - All Other Petroleum and Coal Products Manufacturing

2999 - Oil-based Additives Made from Refined Petroleum

325110 - Petrochemical Manufacturing

2865 - Benzene, Olefins, Toluene, and Xylene

2869 -Butane

325193 - Ethyl Alcohol Manufacturing

2869 - Ethanol

12b. Information Requested

Data items, including recordkeeping requirements.

The following is required to be submitted for each fuel and additive subject to the Tier 1 requirements (40 CFR 79.52):

1. Name of the manufacturer and name of the fuel or additive;
2. Group/consortium identification;
3. Literature search over the past 30 years for existing information pertaining to health effects, environmental effects, and emissions of the fuel or additive; includes description of data bases searched, search period, and summary of relevant information found, including abstracts and references;
4. Chemical characterization of combustion and evaporative emission products; report on emissions generation procedures, analytic methods, and results. This requirement can be mitigated by adequate existing information obtained during the literature search in item 3. The full report(s) summarized in item 3 would be required.

The following is required to be submitted for each fuel and additive subject to the Tier 2 or Alternative Tier 2 requirements (40 CFR 79.53):

1. Name of the manufacturer and name of the fuel or additive;
2. Group/consortium identification;
3. Results of subchronic, 90-day, inhalation exposure of lab animals to combustion emissions (if Tier 2), and in separate testing, if applicable, to evaporative emissions, for screening of general toxicity, carcinogenicity, mutagenicity, adult reproduction/teratogenicity, pulmonary toxicity, and neurotoxicity for Tier 2, or related negotiated testing for Alternative Tier 2. This requirement can be mitigated by adequate existing “reasonably comparable” information obtained during the literature search of Tier 1. The full report(s) summarized in Tier 1 would be required.

The following is required to be submitted for each fuel and additive subject to the Tier 3 requirements (40 CFR 79.54):

1. Name of the manufacturer and name of the fuel or additive;
2. Group/consortium identification;
3. Results of follow-up testing to resolve uncertainties identified upon analysis of Tier 1 and/or Tier 2/Alternative Tier 2 data. The test requirements will be established through notice and comment and negotiation with the manufacturer(s). The burden will likely be comparable to that for Tier 2 testing.

See 40 CFR 79.59(c) for the detailed documentation requirements of the Tier 1, Tier 2, and Alternative Tier 2 reports. See 40 CFR 79.59(d) for the detailed documentation requirements for a Tier 3 report. No Tier 3 requirements have been established.

There are no recordkeeping requirements.

12c. Respondent Activities

The following activities are required:

1. Read or hear the regulations at 40 CFR 79, Subpart F;
2. Obtain the required data;
3. Review the data;
4. Prepare the required report(s);
5. Send the report(s) to EPA.

12d. Respondent Burden Hours and Labor Costs

The pace of Tier 1 submissions has been about one per year for the past four years. Thus, it is estimated that there will only be one Tier 1 submission per year over the next three years. However, manufacturers of baseline and non-baseline products with less than $50 million in annual sales are exempt from Tier 1, so there may be continuing registration activity in that area.

In the previous ICR, with capital/start-up costs included, the estimated Tier 1 literature search cost was $136,980, the estimated Tier 1 emissions characterization cost was $339,380, and the estimated Tier 2/Alternative Tier 2/Tier 3 cost was $3,220,640.

The new estimates were determined as follows:

In discussions with fewer than ten fuel and fuel additive manufacturers, four labor categories were identified as having involvement: managerial, legal, professional/technical (prof/tech), and clerical. According to the Bureau of Labor Statistics, May 2021 National Occupational Employment and Wage Estimates, mean wages were:

Managerial	$59.31 per hour
Legal	$54.38 per hour
Prof/Tech	$44.10 per hour
Clerical	$20.88 per hour

Doubling for company overhead and employing a 5% annual inflation factor to bring the rates to 2023, and, for convenience, rounding up, gives the following rates that will be used in this ICR:

Managerial	$135 per hour
Legal	$120 per hour
Prof/Tech	$100 per hour
Clerical	$50 per hour

Our burden hour, labor costs and O&M/capital estimates are as follows. Per OMB's existing Terms of Clearance, the labor costs and capital/O&M costs were calculated and described below separately.

Worksheet 1: Tier 1 Literature Search

Activity	Mgmt	Legal	Prof/Tech	Clerical
read regs	40/$5400	40/$4800	40/$4000	40/$2000
obtain data	40/$5400	40/$4800	200/$20000	200/$10000
review data	40/$5400	40/$4800	200/$20000	200/$10000
prepare report and send to EPA	40/$5400	40/$4800	100/$10000	100/$5000
totals	160/21,600	160/$19,200	540/$54,000	540/$27,000
grand total	1400/$121,800			

Capital/start-up costs for the literature search are estimated at $10,000 for the purchase of computer hardware/software for recording the search and the purchase of filing cabinets for storage. Operating and maintenance costs are estimated at $2000 for computer maintenance, document storage, and shipping of the report to EPA. This research takes less than a year and thus these are annualized costs.

Worksheet 2: Tier 1 Emissions Characterization

The estimated hours and costs are:

Activity	Mgmt	Legal	Prof/Tech	Clerical
read regs	40/$5400	40/$4800	40/$4000	40/$2000
obtain data	40/$5400	40/$4800	500/$50000	500/$20000
review data	40/$5400	40/$4800	100/$10000	100/$5000
prepare report and send to EPA	40/$5400	40/$4800	100/$10000	100/$5000
totals	160/$21,600	160/$19,200	740/$74,000	740/$32,000
grand total	1800/$146,800			

Capital/start-up costs are estimated at $35,000 for the purchase of a test engine and computer hardware/software. Operating and maintenance costs are estimated at $150,000 for lease of laboratory space and test equipment. This research takes less than a year and thus these are annualized costs.

Thus, the total estimated cost for a Tier 1 submission is $121,800 + $10,000 + $2,000 + $146,800+ $35,000 + $150,000 = $465,600.

Tier 2/Alternative Tier 2/Tier 3 activity is projected to be very limited. The EPA has concluded that existing data cover Tier 2 for baseline diesel. Alternative Tier 2 covers baseline gasoline, five non-baseline gasoline oxygenates, and the atypical gasoline additive MMT. Thus, only atypical products for manufacturers with $10 million or greater in annual revenue and new non-baseline products, such as gasoline and diesel from renewable sources that haven't already been tested, would be subject to the Tier 2 or Alternative Tier 2 requirements. While EPA has yet to require a Tier 3, it is likely to have a burden similar to that for Tier 2/Alternative Tier 2. The most recent Tier 2 report was submitted 20 years ago. The most recent Alternative Tier 2 report was submitted six years ago. Since, manufacturers have been able to rely on existing Tier 2 and Alternative Tier 2 reports. We believe that it is very unlikely that additional Tier 2/Alternative 2 testing, which involves animal exposure to vehicle emissions, will be necessary. However, as a placeholder, below is our estimate for one Tier 2/Alternative Tier 2/Tier 3 report over the next three years, at an estimated annualized cost of about $3.3 million.

Worksheet 3: Tier 2/alternative Tier 2/Tier 3 Inhalation Research

The estimated hours and costs are:

Activity	Mgmt	Legal	Prof/tech	Clerical
read regs	320/$43200	320/$38400	320/$32000	320/$16000
obtain data	320/$43200	320/$38400	16000/$1600000	8000/$400000
review data	320/$43200	320/$38400	1600/$160000	1600/$80000
prepare report and send to EPA	320/$43200	320/$38400	800/$80000	800/$40000
totals	1280/$172,800	1280/$153,600	18720/$1,872,000	10720/$536,000
grand total	32000/$2,734,400			

Capital/start-up costs are estimated at $300,000 for the purchase of a test engine, animals, cages/related equipment, and computer hardware/software. Operating and maintenance costs are estimated at $300,000 for the lease of laboratory space and test equipment, and animal supplies. The research takes about a year and thus these are annualized costs. The total estimated cost for a Tier 2/Alternative Tier 2/Tier 3 report is $2,734,400 + $300,000 + $300,000 = $3,334,400. Since we estimate one report for the next three years, a third of the above will be used in the annual burden discussed below.

Worksheet 4: Summary Total Annual Industry Burden

Activity	Number	Capital/Start-up	O&M costs	Total Hours	Total Cost
Tier 1	1	$45,000	$152,000	3,200	$465,600
Tier 2/ Alt. 2/T3	0.33	$100,000	$100,000	10,667	$1,111,467

Totals	1.33	$145,000	$252,000	13,867	$1,557,067

13. RESPONDENT CAPITAL AND O&M COSTS

Provide an estimate for the total annual cost burden to respondents or record keepers resulting from the collection of information. (Do not include the cost of any hour burden already reflected on the burden worksheet).

The cost estimate should be split into two components: (a) a total capital and start-up cost component (annualized over its expected useful life) and (b) a total operation and maintenance and purchase of services component. The estimates should consider costs associated with generating, maintaining, and disclosing or providing the information. Include descriptions of methods used to estimate major cost factors including system and technology acquisition, expected useful life of capital equipment, the discount rate(s), and the period over which costs will be incurred. Capital and start-up costs include, among other items, preparations for collecting information such as purchasing computers and software; monitoring, sampling, drilling, and testing equipment; and record storage facilities. If cost estimates are expected to vary widely, agencies should present ranges of cost burdens and explain the reasons for the variance. The cost of purchasing or contracting out information collections services should be a part of this cost burden estimate.

Generally, estimates should not include purchases of equipment or services, or portions thereof, made: (1) prior to October 1, 1995, (2) to achieve regulatory compliance with requirements not associated with the information collection, (3) for reasons other than to provide information or keep records for the government, or (4) as part of customary and usual business or private practices.

A discussion of and accounting for all capital and O&M costs is included in Section 12 above.

14. AGENCY COSTS

Provide estimates of annualized costs to the Federal government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information.

14a. Agency Activities

The following activities are required:

1. Respond to inquiries on the Tier 1, Tier 2, Alternative Tier 2, and Tier 3 requirements;
2. Provide links to, or copies of, the regulations;
3. Review the Tier 1, Tier 2, Alternative Tier 2, and Tier 3 reports;
4. Upon completion of a review, notify the submitter that the report is adequate, or, if it is inadequate, notify the submitter of the deficiencies;
5. Establish public access to the test results, as required by the Act, while maintaining the confidentiality of data so entitled;
6. Store the reports.

14b. Agency Labor Cost

It is estimated that the EPA will expend about one-quarter of a Full Time Equivalent (FTE) annually, allocated among several professionals, for the activities listed in section 5(a). Assuming $100 per hour, for government salary and overhead at the professional level, gives an annual cost of $52,000 to the

EPA. Costs for storage and public availability will be nominal. It is anticipated that Tier 1 and standard Tier 2/Alternative Tier 2/Tier 3 activities will be very limited. There may be three Tier 1 submissions and one Tier 2/Alternative Tier 2/Tier 3 submissions over the next three years, at an estimated cost of $0.6 million for each Tier 1 and $3.3 million for each Tier 2/Alternative Tier 2/Tier 3, for an annual burden of about $2 million. The estimated annual EPA burden is $93,600.

15) REASONS FOR CHANGE IN BURDEN

Explain the reasons for any program changes or adjustments reported in the burden or capital/O&M cost estimates.

Worksheet 5: Change in Burden - Annual Responses/Annual Hours

Previous	Requested	Change Reason	
2/35,200	1.33/13,867	-.67/-21,333	Significantly reduced need for animal testing.

16) PUBLICATION OF DATA

For collections of information whose results will be published, outline plans for tabulation and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.

The results of this collection of information will not be published.

17) DISPLAY OF EXPIRATION DATE

If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

EPA will display the expiration date for OMB approval of the information collection as needed.

18) CERTIFICATION STATEMENT

Explain each exception to the topics of the certification statement identified in "Certification for Paperwork Reduction Act Submissions."

There are no exceptions to the topics of the certification statement.