

1INFORMATION COLLECTION REQUEST (ICR)
Part A of the Supporting Statement

Title: Registration of Fuels and Fuel Additives: Health-Effects
Research Requirements for Manufacturers (40 CFR 79, Subpart F)
(Renewal)
EPA ICR Number 1696.10, OMB Control Number 2060-0297
Docket ID Number EPA-HQ-OAR-2006-0525

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 an emissions characterization (combustion, and in certain instances, evaporative) and 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 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.

There are approximately 625 fuel manufacturers, 1,290 additive manufacturers, 940 registered fuels, and 9,200 registered additives. These numbers change daily.

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

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 and 2014. Due to their broad public emissions exposure, motor vehicle gasoline and diesel fuel, and their additives, were designated.

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:

(1) Gasoline

Baseline Group - gasoline/additive elements are limited to carbon, hydrogen, oxygen, nitrogen and sulfur (for convenience, hereby referred to as CHONS), gasoline oxygen content is less than 1.5 weight percent, and the gasoline meets ASTM International specifications.

Non-baseline Group - gasoline/additive elements are limited to CHONS, gasoline oxygen content is 1.5 weight percent or greater, and the gasoline meets ASTM International specifications. A group is established for each oxygenate (e.g., ethanol).

Atypical Group - a group is established for each non-CHONS element (e.g., manganese), combination of non-CHONS elements, property that does not meet ASTM International specification, or combination of properties that do not meet ASTM International specifications.

(2) Diesel

Baseline Group - diesel/additive elements are limited to CHONS, the fuel oxygen content is less than 1.0 weight percent, and the fuel meets ASTM International specifications.

Non-baseline Group - diesel/additive elements are limited to CHONS, the fuel oxygen content is 1.0 weight percent or greater, and the fuel meets ASTM International specifications. A group is established for each oxygenate or specified oxygenate combinations.

Atypical Group - a group is established for each non-CHONS element (e.g., iron), combination of non-CHONS elements, property that does not meet ASTM International specification, or combination of properties that do not meet ASTM International specifications.

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 shale, used oil, and waste plastics. 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. For products registered as of May 27, 1994, the Tier 1 data were due by May 27, 1997. For products currently seeking registration, 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 registered as of May 27, 1994, the Tier 2 data were due by May 27, 1997, or evidence of a contract that would provide the Tier 2 data by May 27, 2000. For products currently seeking registration, the Tier 2 data are due before registration can occur. (There are several exceptions to the above. For biodiesel products, the Tier 1 deadline was March 17, 1998, and the Tier 2 deadline was May 27, 2000. For atypical products, the Tier 2 deadline for evidence of a contract was November 27, 1998, with the Tier 2 data due by November 27, 2001.) 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.

In 1994 the API formed a consortium of the major fuel and additive manufacturers. In 1997 it submitted Tier 1 data for baseline gasoline, baseline diesel, and six non-baseline gasoline groups (di-isopropyl ether (DIPE), ethanol, ethyl tertiary butyl ether (ETBE), methyl tertiary butyl ether (MTBE), tertiary amyl methyl ether (TAME), and tertiary butyl alcohol (TBA)). Tier 2 data were submitted for baseline diesel. In 1997 a consortium submitted information for aerosol additive manufacturers. In 1997 Tier 1 data were submitted for two atypical gasoline groups and five atypical diesel groups. In 1998 and 2000, Tier 1 and Tier 2 data were submitted for biodiesel, respectively. In 2000 and 2002, Tier 1 and Tier 2 data were submitted for summer PuriNOx, an emulsion of water and diesel. In 2003 Tier 1 data were submitted for Clean Fuels Technology Emulsified Diesel Fuel. In 2005 Tier 1 data were submitted for an iron-based diesel additive known as CleanBoost. In 2006 Tier 1 data were submitted for the cerium-based diesel additive Envirox, a mixture of ethanol and diesel fuel known as O2Diesel, and the diesel additive Green Plus 850. In 2007 Tier 1 data were submitted for Renewable Diesel Mixtures, Green Plus 851, and a mixture of ethanol, diesel and biodiesel. In 2008 Tier 1 data were submitted for NExBTL Renewable Diesel and Nextfuels, Inc. biodiesel. In 2009 Tier 1 data were submitted for two renewable diesels. In 2011-2015 Tier 1 data were submitted for 15% ethanol in gasoline, 16% isobutanol in gasoline, seven diesel fuels with renewable content, and eight gasolines with renewable content.

On August 20, 1997 the API was informed of proposed Alternative Tier 2 requirements for baseline gasoline and the six non-baseline gasoline groups for which Tier 1 data were submitted. After public notice and comment, and discussions with API, the alternative requirements were finalized, and API was notified on November 2, 1998. Notice was published in the Federal Register. The research has been completed, except for some of the TBA testing, which API decided not to complete, and some protocols for DIPE and ETBE that have yet to be established.

In 1994 the Ethyl Corporation (Ethyl) was informed that Alternative Tier 2 testing would be required for its manganese additive MMT and alternative requirements were proposed in a January 25, 1999 letter to Ethyl and announced in the Federal Register. These requirements were finalized in a May 11, 2000 letter to Ethyl and announced in the Federal Register. The research has been completed.

Alternative Tier 2 requirements were also established for winter PuriNOx. The procedure as described above was followed and the data were submitted in 2003.

2. 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.

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.

EPA does not publish the results, but provides the reports upon request. There have not been many requests.

3. 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.

These are typical test reports in the submitter's choice of format, and have been submitted electronically and/or in hard copy.

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

Certain small businesses are exempt from some or all of these requirements. Manufacturers of baseline and/or non-baseline products, who have an annual sales revenue of less than \$50 million, are exempt from Tier 1 and Tier 2. Manufacturers of atypical products, who have an annual sales revenue 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. 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 product. If this information was not collected, EPA would not be able to compare the emissions of new categories of gasoline and diesel fuels to fuels in commerce. EPA is not aware of a less burdensome approach to developing basic emissions data.

7. Explain any special circumstances that would cause an information collection to be conducted in a manner:

- requiring respondents to report information to the agency more often than quarterly;
- requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- requiring respondents to submit more than an original and two copies of any document;
- requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records, for more than three years;
- in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;
- requiring the use of a statistical data classification that has not been reviewed and approved by OMB;
- that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- requiring respondents to submit proprietary trade secrets, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

None. All Office of Management and Budget (OMB) guidelines are met.

8. 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.

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.

A Federal Register notice requesting public comment on this ICR was published on May 21, 2019 (84 FR 23047). No comments were received.

Information was requested from the following three fuel industry companies:

- Chevron Corporation
- Butamax Advanced Biofuels, LLC
- Weaver LLP

Butamax was the only industry representative to reply to the request for an evaluation of the costs and manpower estimates as the company recently completed an Alternative Tier 2 test. The respondent stated his company's labor costs for the Tier 1 literature review were double the EPA estimate. Also, their Tier 2 labor costs were double the overall EPA estimate. Based on his input, the burden and cost in Section 6 of this document were increased accordingly.

9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

EPA does provide any payment or gift to respondents.

10. 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 Tier 2 health-effects testing 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.

11. 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.

There are no sensitive questions.

12. 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. Unless directed to do so, agencies should not conduct special surveys to obtain information on which to base hour burden estimates. Consultation with a sample (fewer than 10) of potential respondents is desirable. If the hour burden on respondents is expected to vary widely because of differences in activity, size, or complexity, show the range of estimated hour burden, and explain the reasons for the variance. 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 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 under ‘Annual Cost to Federal Government’.

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

4(b) Information Requested

(i) Data Items

Respondent are required to read or hear the regulations at 40 CFR 79, Subpart F, obtain the required data, review the data, and prepare the required reports and send the report(s) to EPA

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. There are no recordkeeping requirements.

Tier 1 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.

It is likely that only limited additional Tier 1 research will be done. Future fuels and additives subject to Tier 1 will almost exclusively be those that can group with existing Tier 1 data, and likely will come from manufacturers who have already paid for the Tier 1 data. 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 revenue are exempt from Tier 1, so there may be continuing registration activity in that area.

In the previous ICR it was concluded that the few new products for which a new Tier 1 would be required are likely to be in the atypical or non-baseline category, with an estimated Tier 1 cost of about \$393,000 per product, with about \$68,000 for the literature search and about \$325,000 for the emissions characterization. Actual data provided by an industry representative showed the literature review cost should be double the EPA estimate. After the capital/start-up costs are included, the estimated literature search cost increased to \$124,980 while the estimated emissions characterization cost increased to \$339,380. We believe the estimated labor rates and hours for those who conduct these literature searches and emission studies account for the increased costs.

The new estimate of \$476,360 was 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 2017 National Occupational Employment and Wage Estimates, mean wages were:

Managerial	\$70.33 per hour
Legal	\$68.22 per hour
Prof/Tech	\$54.05 per hour
Clerical	\$18.24 per hour

Doubling for company overhead and employing a 2% annual inflation factor to bring the rates to 2019, and, for convenience, rounding up to the even dollar, gives the following rates that will be used in this ICR:

Total Employer Cost

Managerial	\$145 per hour
Legal	\$140 per hour
Prof/Tech	\$110 per hour
Clerical	\$ 37 per hour

Our estimates are:

Worksheet 1: Tier 1 Literature Search

The estimated burden hours and costs are:

<u>Activity</u>	<u>mgmt</u>	<u>legal</u>	<u>prof/tech</u>	<u>clerical</u>
read regs	40/\$5800	40/\$5600	40/\$4400	40/\$1480
obtain data	40/\$5800	40/\$5600	200/\$22000	200/\$7400
review data	40/\$5800	40/\$5600	200/\$22000	200/\$7400
prepare report and send to EPA	40/\$5800	40/\$5600	100/\$11000	100/\$3700
totals	160/23,200	160/\$22,400	540/\$59,400	540/\$19,980
grand total	1400/\$124,980			

The 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. 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:

<u>Activity</u>	<u>mgmt</u>	<u>legal</u>	<u>prof/tech</u>	<u>clerical</u>
read regs	40/\$5800	40/\$5600	40/\$4400	40/\$1480
obtain data	40/\$5800	40/\$5600	500/\$55000	500/\$18500
review data	40/\$5800	40/\$5600	100/\$11,000	100/\$3700
prepare report and send to EPA	40/\$5800	40/\$5600	100/\$11,000	100/\$3700
totals	160/\$23,200	160/\$22,400	740/\$81,400	740/\$27,380
Grand Total	1,800 hours/\$279,360			

Tier 2

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, 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 information obtained during the literature search of Tier 1. The full report(s) summarized in Tier 1 would be required.

EPA estimates that the Standard Tier 2/Alternative Tier 2 activity will be limited. The EPA has concluded that existing data cover Tier 2 for baseline diesel. Alternative Tier 2 covers baseline gasoline, six 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, in addition to DIPE and ETBE, for manufacturers with \$50 million or greater in annual revenue would be subject to the standard Tier 2 or Alternative Tier 2 requirements. EPA estimates that there will be two Tier 2 submittals over the next three years with an estimate burden of 64,000 hours plus a Tier 3 for 32,000 hours.

Tier 3

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.

EPA has yet to require a Tier 3, but has estimated the burden to be similar to that for Tier 2/Alternative Tier 2. However, it is extremely unlikely that EPA will require a Tier 3 during the next three years. As a placeholder, EPA estimates that there will be one three Tier 3 submittal over the next three years in lieu of a Tier 2 with an estimate burden of 32,000 hours.

Standard Tier 2/Alternative Tier 2/Tier 3 activity also will be very limited. The EPA has concluded that existing data cover Tier 2 for baseline diesel. Alternative Tier 2 covers baseline gasoline, six 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, in addition to DIPE and ETBE, for manufacturers with \$50 million or greater in annual revenue would be subject to the standard 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. EPA estimates that there will be three standard Tier 2/Alternative Tier 2/Tier 3 submittals over the next three years, at an estimated annualized cost of about \$3.2 million each.

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

The estimated hours and costs are:

<u>Activity</u>	<u>mgmt</u>	<u>legal</u>	<u>prof/tech</u>	<u>clerical</u>
read regs	320/\$46400	320/\$44800	320/\$35200	320/\$11840
obtain data	320/\$46400	320/\$44800	16000/\$1760000	8000/\$296000
review data	320/\$46400	320/\$44800	1600/\$176000	1600/\$59200
prepare report and send to EPA	320/\$46400	320/\$44800	800/\$88000	800/\$29600
totals	1280/\$185,600	1280/\$179,200	18720/\$2,059,200	10720/\$396,640

grand total 32000/\$2,820,640

As discussed, 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 three Tier 2/Alternative Tier 2/Tier 3 submissions over the next three years, at an estimated cost of \$0.4 million for each Tier 1 and \$3.6 million for each Tier 2/Alternative Tier 2/Tier 3, for an annual burden of about \$4 million. The estimated annual EPA burden is \$93,600.

Worksheet 4: Annual Industry Burden

<u>Activity</u>	<u>Capital/Start-up</u>	<u>O&M costs</u>	<u>Total Hours</u>	<u>Total Cost</u>
Tier 1	1	\$45,000	\$152,000	3,200 \$476,360
Tier 2/ Alt. 2/T3	1	\$150,000	\$250,000	32,000 \$3,220,640
Totals	2	\$195,000	\$402,000	35,200 \$3,697,000

<u>Activity</u>	<u>Respondents Reports</u>	<u>Capital Start-up</u>	<u>O&M</u>	<u>Hours/Cost</u>	<u>Total Cost</u>
Tier 1	1/1	\$45K	\$152K	3,200/\$279,360	\$476,360
Tier 2/3	1/1	\$150K	\$250K	32K/\$2,828,640	\$3,220,640
Totals	2/2	\$195K	\$402K	3.52K/\$3,100,000	\$3,697,000

13. 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). 476,360

- 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 take into account 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 time 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. In developing cost burden estimates, agencies may consult with a sample of respondents (fewer than 10), utilize the 60-day pre-OMB submission public comment process and use existing economic or regulatory impact analysis associated with the rulemaking containing the information collection, as appropriate.
- 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.

Tier 1

Operating and maintenance costs are estimated at \$2000 for computer maintenance, document storage, and shipping of the report and documents to EPA.

Capital/start-up costs are estimated at \$35,000 for the purchase of test engines 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 $\$124,980 + \$10,000 + \$2,000 + \$154,380 + \$35,000 + \$150,000 = \$476,360$.

Tier 1

O&M - \$2,000 (computers)

\$150,000 (lab costs)

Capital/Start-up

\$10,000 (literature search and supplies)

\$35,000 (test engine, lab equipment)

Tier 2

Capital/start-up costs are estimated at \$150,000 for the purchase of animals, cages/related equipment, and computer hardware/software. Operating and maintenance costs are estimated at \$250,000 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 submission is $\$2,820,640 + \$150,000 + \$250,000 = \$3,220,640$.

14. 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. Agencies may also aggregate cost estimates from Items 12, 13, and 14 in a single table.

It is estimated that the EPA will expend about one-half of a Full Time Equivalent (FTE) annually, allocated among several professionals, for the activities listed in section 5(a). Assuming \$90 per hour, for government salary and overhead at the professional level, gives an annual cost of \$93,600 to the EPA. Costs for storage and public availability will be nominal.

15. Explain the reasons for any program changes or adjustments to the number of respondents or burden hours.

The one industry representative who responded, and whose company has recently undertaken an Alternative Tier 2 test, reported that the EPA labor estimates needed to be doubled. this recommendation was applied to the Tier 1 Literature review and Tier 2/Alternative Tier 2 labor hours.

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

	Respondents	Annual Burden Hours
Previous	2	17,600
Requested	2	35,200
Change	0	17,600

16. 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.

There is no schedule. The requirements apply when a manufacturer applies for registration. The reports are not published.

The reports will be reviewed by the Office of Transportation and Air Quality and the Office of Research and Development. The quality of the data will be determined by professionals knowledgeable with emissions and health-effects testing. The review will be manual. 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.

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

There are no forms.

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

None.