

profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

As discussed in section IV. of this notice, attainment date extensions under section 186(a)(4) of the CAA do not create any new requirements. Therefore, I certify that today's proposed action does not have a significant impact on small entities.

#### VI. Unfunded Mandates

Under sections 202, 203 and 205 of the Unfunded Mandates Reform Act of 1995 (Unfunded Mandates Act), signed into law on March 22, 1995, EPA must assess whether various actions undertaken in association with proposed or final regulations include a Federal mandate that may result in estimated costs of \$100 million or more to the private sector, or to State, local or tribal governments in the aggregate. EPA believes, as discussed above, that the proposed finding that Clark County nonattainment area meets the criteria in section 186(a)(4) and thereby qualifies for an attainment date extension is a factual determination based upon air quality considerations and must occur by operation of law and, hence, does not impose any Federal intergovernmental mandate, as defined in section 101 of the Unfunded Mandates Act.

#### List of Subjects in 40 CFR Part 81

Environmental protection, Air pollution control, Intergovernmental relations, Carbon monoxide.

Authority: 42 U.S.C. 7401-7671q.

Dated: July 22, 1996.

Felicia Marcus,

*Regional Administrator.*

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#### 40 CFR Part 81

[WA 54-7127; FRL-5550-5]

#### Clean Air Act Reclassification; Spokane, Washington Carbon Monoxide Nonattainment Area: Extension of Comment Period

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule; extension of comment period.

**SUMMARY:** EPA is extending the comment period for a proposed rule published July 1, 1996 (61 FR 33879). On July 1, 1996, EPA proposed to find that the Spokane, Washington carbon monoxide (CO) nonattainment area has not attained the CO national ambient air quality standard by the Clean Air Act

mandated attainment date for moderate nonattainment areas, December 31, 1995.

At the request of the Spokane Air Pollution Control Authority, EPA is extending the comment period for 30 days.

**DATES:** Comments will be accepted until August 31, 1996.

**ADDRESSES:** Written comments should be sent to: Montel Livingston, SIP Manager, Office of Air Quality, M/S OAQ-107, EPA Region 10, Docket #WA 54-7127, 1200 Sixth Avenue, Seattle, Washington 98101.

**FOR FURTHER INFORMATION CONTACT:** William M. Hedgebeth of the EPA Region 10 Office of Air Quality, (206) 553-7369.

Dated: July 30, 1996.

Chuck Clarke,

*Regional Administrator.*

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#### 40 CFR Parts 153 and 159

[OPP-60010E; FRL-5388-1]

RIN 2070-AB50

#### Reporting Requirements for Risk/Benefit Information; Reopening of Comment Period to Request Comments on Burden Estimates

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposal; reopening of comment period.

**SUMMARY:** Under section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), pesticide registrants are required to submit to the Agency information that they acquire which may be relevant to the balancing of the risks and benefits of their pesticide product(s). On September 24, 1992 (57 FR 44290), EPA issued a proposed rule which defined the specifics of this reporting requirement. After evaluating the comments received in response to that proposal, as well as several discussions with stakeholders, the Agency is now working to issue a final rule which clearly defines the reporting obligations of registrants under FIFRA section 6(a)(2). Before issuing this final rule, however, the Agency is reopening the rulemaking record to allow interested individuals to comment on the burdens that would be imposed by the rule in its current draft final form. In addition, the Agency is seeking comments on the revised burden estimates presented in the Information Collection Request (ICR)

related to the draft final rule. Although an ICR was prepared and made available as part of the proposed rule, and the comments received on that ICR have been considered in developing the final draft rule and ICR, the Agency has recently received several letters expressing concern about preliminary burden estimates which were prematurely made publicly available. In order to provide another opportunity for the regulated community to provide new comments or information related to the burden and cost estimates, the Agency has decided to reopen the rulemaking record for the narrow purpose of soliciting additional comment on the sole issue of the costs or burdens associated with the proposed rule and the draft final rule. After consideration of any comments received, the Agency will submit the revised ICR package to the Office of Management and Budget (OMB) for review and approval under the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). EPA is soliciting comments on the specific aspects of the collection described below. This ICR, entitled: Submission of Unreasonable Adverse Effects Information Under FIFRA Section 6(a)(2) [EPA ICR No. 1204.04; OMB No. 2070-0039], will replace the existing ICR once EPA issues the final rule.

**DATES:** Comments must be submitted on or before September 11, 1996.

**ADDRESSES:** Submit written comments identified by the docket control number OPP-60010E and EPA ICR No. 1204.04 by mail to: Public Response Section, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments directly to the OPP docket which is located in Rm. 1132 of Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Electronic comments must be submitted as a ASCII file avoiding the use of special characters and any form or encryption. Comments and data will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number "OPP-60010E" and EPA ICR No. 1204.04. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic comments on this document may be filed online at many Federal Depository Libraries.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All comments will be available for public inspection in Rm. 1132 at the Virginia address given above from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

**FOR FURTHER INFORMATION CONTACT:** Jim Roelofs, Policy and Special Projects Staff, Office of Pesticide Programs, Environmental Protection Agency, Mail Code (7501C), 401 M St., SW., Washington, DC 20460, Telephone: (703) 308-2964, e-mail: roelofs.jim@epamail.epa.gov.

To obtain a copy of the material referenced in this notice (i.e., the Supporting Statement and attachments that make up ICR 1204.04), you may visit the OPP Public Response Section at the address provided above, using docket number OPP-60010E to obtain the information you need, or you can request a copy of the material by calling or e-mailing a request to Jim Roelofs.

**SUPPLEMENTARY INFORMATION:** Electronic Availability: Electronic copies of the ICR and any accompanying material are available from the EPA Public Access gopher (gopher.epa.gov) at the Environmental Sub-Set entry for this document under "Rules and Regulations."

#### I. Request for Comments

The Agency is reopening the rulemaking record today in order to solicit additional comment on the sole issue of the costs or burdens associated with the proposed rule and the latest draft of the final rule [a copy of which is attached as an appendix to the ICR]. In this regard, the Agency notes that it is not soliciting comments on the perceived value to the Agency of the information identified in the proposed rule and draft final rule, nor is it soliciting comments on the legality of either rule. The Agency received a number of such comments during the original rulemaking comment period, and does not believe the changes from the proposal to the draft final rule raise any new issues related to the legality of the rule or the utility of the information which would warrant a reopening of the comment period for those issues. If any

person wishes to submit comments on an issue other than the costs of the rule to registrants, that person may file a petition to reopen the rulemaking record and should include in such petition an explanation of why the requested reopening could lead to significant material changes in the rule and why the comments to be submitted during the reopening could not have been submitted earlier.

In terms of comments on costs and burden estimates, the Agency is interested in detailed comments identifying how the proposed and draft final rules would affect the costs (and any other burdens) imposed upon registrants by their reporting obligations under section 6(a)(2). The Agency is particularly interested in comments addressing the issues set forth below, although interested persons are invited to submit any comments related to cost or burden they believe are material to this reporting rulemaking. Comments that provide detail on how registrants are currently complying or would have to comply with reporting requirements together with an accompanying identification and explanation of the costs (and/or other burdens) associated with each facet of compliance would be particularly helpful.

(1) The nature of the training (and the costs associated with it) that registrants would be obligated to undertake under the terms of the proposed or draft final rule; how that training differs from the training (and the costs associated with it) that registrants are currently required to undertake in order to comply with the existing reporting requirements under section 6(a)(2); and whether and how any particular change in the proposed or draft final rule would affect the nature of the training or the costs associated with it.

(2) The costs and burdens associated with reporting incidents under current reporting requirements; any changes in those costs and burdens associated with reporting pursuant to the provisions of the proposed rule; and any changes in those costs and burdens associated with reporting pursuant to the draft final rule. The Agency would be particularly interested in comments on how the threshold for reporting incidents, the summarization of incidents, and/or the proposal to require the reporting of all incidents (rather than series of incidents) affect the costs and burdens that would have to be borne by registrants in complying with these reporting requirements, as compared to current practices.

(3) The costs and burdens associated with reporting efficacy failure studies

and information concerning pesticide resistance.

#### II. The Information Collection Request

EPA is seeking comments on the following Information Collection Request (ICR), which will revise an ICR currently approved by OMB:

ICR numbers: EPA ICR No. 1204.04; OMB No. 2070-0039.

Expiration: OMB approval of the current ICR expires on November 30, 1996.

Title: Submission of Unreasonable Adverse Effects Information Under FIFRA Section 6(a)(2).

Affected entities: This collection applies to all pesticide registrants. The Standard Industrial Codes assigned to the businesses required to submit a response under this collection activity are 286 and 287.

Abstract: This information collection stems from a non-discretionary statutory requirement. Section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires pesticide registrants to submit information to the Agency that they acquire which may be relevant to the balancing of the risks and benefits of a pesticide product. In *CSMA and NACA v. EPA* 484 F. Supp. 513 (1980), the District Court of the District of Columbia agreed with EPA that FIFRA section 6(a)(2) covers all information relevant to EPA's determination of whether a pesticide may cause unreasonable adverse effects. The Court agreed that submissible information includes the same type of information as that provided by a registrant as part of an application for registration. The Court specifically rejected the argument that the responsibility for determining what constitutes an unreasonable adverse effect shifts to industry once EPA has granted a registration.

As such, the statute requires the registrant to submit any factual information that it acquires regarding adverse effects associated with its pesticidal products, and it is up to the Agency to determine whether or not that factual information constitutes an unreasonable adverse effect. In order to limit the amount of less meaningful information that might be submitted to the Agency, EPA has limited the scope of factual information that the registrant must submit. The draft final rule would serve to limit this scope even further by providing a more detailed description of the reporting obligations of registrants under FIFRA section 6(a)(2).

As further defined by the final rule implementing the FIFRA section 6(a)(2) requirements, registrants are required to report on: (1) Studies showing new or

more severe toxicological responses than previously reported of any type in any strain of test organism; (2) epidemiological or exposure studies of human population groups; (3) studies or incidents tending to show lack of efficacy of certain pesticide products with public-health related uses; (4) incidents involving toxic or adverse effects to non-target organisms; (5) information on excess residues on food or feed, or residues in surface water, ground water, or drinking water; (6) information on metabolites, degradates, contaminants or impurities which may be of toxicological concern; (7) information showing that a product fails to perform as claimed or that pests have developed resistance to the product; and (8) other information which may be relevant to risk/benefit determinations of any type.

Respondents must (1) Read the final rule or instructions, (2) plan activities to ensure required information is identified and submitted, (3) process, compile, and review information for accuracy and appropriateness, (4) complete written instruments to effectuate a submission, and (5) submit the information to EPA. In addition, as a part of the initial implementation for the final rule, the registrant must conduct a "screening" or "initial review" of their existing records. The purpose of this initial exercise is to identify specific information that is within the registrant's possession which has not already been submitted to EPA, but which meets the criteria under the final rule for submission under FIFRA section 6(a)(2).

Since section 6(a)(2) requires the submission of certain information when it is acquired by a registrant, any information meeting the criteria for submission under section 6(a)(2) which happens to be in the possession of the registrant upon the effective date of the final rule, and which has not already been submitted to EPA, would need to be submitted to EPA immediately. The Agency recognizes that some of this information may be out dated and has, therefore, limited the type of information that should be apart of this initial "screening."

Under FIFRA section 6(a)(2), as implemented by the final rule, pesticide registrants have absolutely no obligation to create or seek out this information. Such activities may be conducted by the registrant in support of pesticide registration under FIFRA section 3, or

reregistration under section 4 (which are approved by OMB under separate ICR approvals), or in the normal course of business, such as following up on consumer complaints to gather more information. Regardless of how the information comes into the possession of the registrant, once the registrant acquires information subject to submission under section 6(a)(2), as defined by the final rule, the registrant must submit it to EPA.

Burden statement: EPA estimates that the first year burdens associated with becoming familiar with the changes to the requirements total 38,265 burden hours, with an average of 17.39 burden hours per registrant ( $38,265 \div 2,200$ ). Calculated by taking an estimated total annual burden of 660 hours for registrants to determine who needs to know the new requirements (0.3 hour per registrant x 2,200 registrants) and an estimated total of 37,605 hours for registrants to learn the new requirements (2.5 hours x 15,042 people expected to need instructions).

Another initial first year burden is related to the requirements in 40 CFR 159.159, which requires registrants to check their files for certain reportable information that they may already have but have not sent in earlier, either because it was not required or because of an error. The burden associated with this "audit" depends upon whether the Registrant has such reportable information (which is actually a subset of that information which is reportable) and then whether or not he or she prepares an inventory of the information he or she has, or simply submits copies of the information. In any case, the Agency estimates that this initial audit is likely to result in an estimated average burden of 5 hours for each registrant to review its records, 2 hours for submissions to be prepared, and 0.5 hour for the actual submissions, for a total estimated first year burden of 7.5 hours per registrant, with a total first year burden of 16,500 hours ( $7.5 \times 2,200$  registrants).

After the initial implementation of these amended requirements, EPA estimates that the total annual burden for registrants to determine who needs to know the requirements will decrease to 440 hours (0.2 hour per registrant x 2,200 registrants) and the estimated total for reading the instructions will decrease to 22,563 hours (1.5 hour per person x 15,042 people), for a total estimated annual burden of 23,003

hours associated with annual rule familiarization, with an average burden of 10.46 hours per registrant ( $23,003 \div 2,200$  registrants).

EPA has eliminated any recordkeeping requirements associated with the submittal of section 6(a)(2) information and any burdens associated with maintaining registration related data or information covered by another ICR. However, a registrant may be required to keep information related to a partial submission, so that when information completing the submittal is sent to EPA the registrant provides an appropriate cross reference to the original submission. EPA estimates that this need to cross reference a partial submission may occur a total of 10 or 15 times each year, with an estimated annual burden of 0.5 hour per occurrence, for a total annual burden of 7.5 hours overall, or an average burden of 0.0034 hour per registrant ( $7.5 \div 2,200$ ).

In order to determine an estimated per registrant burden, as requested by OMB, EPA has estimated that each registrant is likely to submit an average number of 4.07 submissions each year (annual submissions expected (8,960)  $\div$  total number of registrants (2,200)). At a total annual burden of 6.4 hours per submission, the annual total burden per registrant for submissions could be 26.05 hours. This burden must be added to the other burdens related to this rulemaking to bring the total annual per registrant burden associated with the rule to 36.3534 hours for the first year (26.05 for submissions + 10.3 for initial burdens + .0034 for follow-up), and 27.7534 hours for subsequent years (26.05 for submissions + 1.7 for training + .0034 for follow-up).

As for the total estimated burdens for the ICR, EPA estimates the first year total burden is 74,996.48 hours, which is expected to decrease in subsequent years to an annual estimated burden of 43,234.48 hours.

#### List of Subjects in Part 153 and 159

Environmental protection, Information collection requests, Pesticides and pests, Reporting and recordkeeping requirements.

Date: August 1, 1996.

Lynn R. Goldman,  
Assistant Administrator for Prevention,  
Pesticides and Toxic Substances.  
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