

(202) 260-1826, or by e-mail at siddiqui.ahmar@epa.gov.

SUPPLEMENTARY INFORMATION:

Title: Minimum Monitoring Requirements for Direct and Indirect Discharging Mills in the Bleached Papergrade Kraft and Soda Subcategory and the Papergrade Sulfite Subcategory of the Pulp, Paper, and Paperboard Point Source Category (EPA ICR No. 1878.01). This is a new collection.

Abstract: The Environmental Protection Agency (EPA) imposed minimum monitoring requirements on bleached papergrade kraft and soda (subpart B) and papergrade sulfite (subpart E) mills under 40 CFR part 430 as part of the effluent limitations guidelines and standards promulgated on April 15, 1998 (63 FR 18504). With approval of this ICR, the permitting and pretreatment control authority must require applicable facilities subject to subparts B or E to monitor their effluent for adsorbable organic halides (AOX), 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD), 2,3,7,8-tetrachlorodibenzofuran (TCDF), chloroform, and 12 chlorinated phenolics at specified frequencies. See 40 CFR 430.02. Under 40 CFR 122.41(e)(4), the discharger must then report these monitoring results to the permitting or pretreatment control authority using either Discharge Monitoring Reports (DMRs) or Periodic Compliance Reports (PCRs). These additional minimum monitoring requirements and corresponding additional reporting requirements are necessary to demonstrate compliance with the effluent limitations guidelines and standards promulgated at 40 CFR part 430, subparts B and E. 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. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15. The **Federal Register** document required under 5 CFR 1320.8(d), soliciting comments on this collection of information was published on March 19, 2001 (66 FR 15424-15427). EPA received no comments.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 392 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes

of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: Entities potentially affected by this action are those operations that chemically pulp wood fiber using kraft or soda methods to produce bleached papergrade pulp, paperboard, coarse paper, tissue paper, fine paper, and/or paperboard; and those operations that chemically pulp wood fiber using papergrade sulfite methods to produce pulp and/or paper.

Estimated Number of Respondents: 94.

Frequency of Response: Not less than annually for direct dischargers and not less than twice annually for indirect dischargers.

Estimated Total Annual Hour Burden: 36,858 hours.

Estimated Total Annualized Cost Burden (non-labor costs): \$ 19,002,000.

Send comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques to the following addresses. Please refer to EPA ICR No. 1878.01 in any correspondence.

Dated: November 11, 2001.

Oscar Morales,

Director, Collection Strategies Division.

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ENVIRONMENTAL PROTECTION AGENCY

[FRL-7110-6]

Notice of Opportunity To Provide Additional Information and Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of opportunity to provide additional information and comment on draft revised Guidelines for Carcinogen Risk Assessment (July 1999), availability of draft revised Guidelines, and adoption of draft revised Guidelines as interim guidance.

SUMMARY: EPA is today announcing its intent to proceed to issue final revised

Guidelines for Carcinogen Risk Assessment in 2002. The Agency is soliciting additional scientific information and comments that could assist us in completing the final Guidelines. In 1996, EPA published for public comment proposed revisions to EPA's 1986 Guidelines for Carcinogen Risk Assessment. Since the 1996 proposal, we have benefitted from extensive public comment and scientific peer review, including three reviews by EPA's Science Advisory Board (SAB). EPA scientists are currently addressing these comments under the auspices of the Agency's Science Policy Council. The draft revised Guidelines from which the Agency will proceed to make its final revisions is that provided to the SAB in July 1999 (with minor formatting changes). Even though EPA has received considerable input from the public during the 1996 public comment period and thereafter, we are providing an additional opportunity for the public to provide (1) information or comment on experience gained in applying the 1996 proposed Guidelines or the 1999 draft revised Guidelines and (2) other new information or comment that addresses issues raised during the public comment period and the SAB reviews. The major issues currently being considered by EPA as it proceeds to issue final Guidelines are identified in the Supplementary Information section of this notice. Information and comments already submitted to EPA need not be resubmitted. Until final Guidelines are issued, the July 1999 draft revised Guidelines will serve as EPA's interim guidance to EPA risk assessors preparing cancer risk assessments.

DATES: Information and comments should be received by January 28, 2002.

ADDRESSES: The draft revised Guidelines for Carcinogen Risk Assessment are available via the Internet from www.epa.gov/ncea/raf/cancer.htm. Also available here are supplementary materials described within the Supplementary Information section of this notice. A limited number of paper copies of the draft revised Guidelines are available from the Technical Information Staff (8623D), NCEA-W, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; telephone: 202-564-3261; facsimile: 202-565-0050.

You may submit information and comments in paper form or by e-mail. Your comments will be most useful if you include appropriate and detailed supporting rationale, data, and analysis. Send paper copies of information and

comments (in duplicate if possible) to the Air Docket at the address listed below. You may also submit information and comments via e-mail to "a-and-r-Docket@epa.gov." In your correspondence, refer to Docket ORD-CAN-2001-01. EPA's Air Docket makes materials related to this notice available for review in Public Docket No. ORD-CAN-2001-01 at the following address: U.S. Environmental Protection Agency (EPA), Air Docket (6102), Room M-1500 (on the ground floor in Waterside Mall), 401 M Street, SW., Washington, DC 20460 between 8 a.m. and 5:30 p.m., Monday through Friday, except on government holidays. You can reach the Air Docket by telephone at (202) 260-7548, and by facsimile (202) 260-4400. We may charge a reasonable fee for copying docket materials, as provided in 40 CFR part 2.

Persons providing information or comments should not submit personal information (such as medical data). If you submit proprietary information for our consideration, you should clearly separate it from non-proprietary information and comments by labeling it Confidential Business Information and send it directly to the contact person listed below under For Further Information instead of the public docket. This will help ensure that no one inadvertently places proprietary information in the public docket. Acknowledgments will not be sent.

FOR FURTHER INFORMATION CONTACT: Dr. William P. Wood, Risk Assessment Forum (mail code 8601D), U.S. Environmental Protection Agency, Washington, DC 20460, telephone (202) 564-3361, or send electronic mail inquiries to risk_forum@epa.gov.

SUPPLEMENTARY INFORMATION:

Background

In 1983, the National Academy of Sciences (NAS)/National Research Council (NRC) published its report entitled *Risk Assessment in the Federal Government: Managing the Process*. In that report, the NRC recommended that Federal regulatory agencies establish "inference guidelines" to promote consistency and technical quality in risk assessments and to ensure that the risk assessment process was maintained as a scientific effort separate from risk management. EPA responded to this recommendation by publishing a set of risk assessment guidelines in 1986, including Guidelines for Carcinogen Risk Assessment (51 FR 33992, Sept. 24, 1986). These Guidelines set forth principles and procedures to guide EPA scientists in assessing the cancer risks from chemicals or other agents in the

environment and inform the public about these procedures. EPA continues to revise its risk assessment guidelines and to develop new guidelines as experience and scientific understanding evolve. Revisions to the Guidelines for Carcinogen Risk Assessment are intended to make greater use of the increasing scientific understanding of the mechanisms that underlie the carcinogenic process. As part of that process, the Agency published Proposed Guidelines for Carcinogen Risk Assessment in 1996 (61 FR 17960, Apr. 23, 1996).

The draft revisions to the Guidelines have been subject to extensive public comment and scientific peer review, including three reviews by EPA's Science Advisory Board (SAB). The SAB provided its initial comments to the Agency in September 1997. In July 1999, the SAB provided additional comments on major sections of the 1996 proposed Guidelines that had been revised to address prior SAB and public comments. In September 2000, the SAB provided further comments on new discussions focusing on assessing risks to children that are contained in the draft revised Guidelines (July 1999). This review, while supportive of EPA's efforts, did not reach a consensus on several important issues. Such lack of consensus is not uncommon in peer reviews. Since 1996, EPA has also hosted scientific workshops on children's cancer risks and received input from EPA's Children's Health Protection Advisory Committee.

Issues in Completing the Revised Guidelines

EPA has commenced the process to issue final Cancer Guidelines in light of these reviews and activities, as well as public comments received. The July 1999 draft revised Guidelines will be the basis from which the Agency moves forward to issue final Guidelines and are being made available today. EPA is in the process of evaluating peer review and public comments received in order to determine what revisions to the draft revised Guidelines may be appropriate. Additionally, EPA is providing an opportunity for the public to provide (1) information or comment on experience gained in applying the 1996 proposed Guidelines or the July 1999 draft revised Guidelines and (2) other new information or comment that addresses issues raised during the public comment period and in the SAB reviews, particularly the 1999 and 2000 SAB reports. The issues currently being considered by EPA as it proceeds to issue final Guidelines are described in the January 2001 response to the SAB

(see Supplementary Materials). Issues include, but are not limited to, the nature and use of default assumptions; definition and application of hazard descriptors; identification of carcinogenic mode(s) of action and, in particular, consideration of relevancy for children (e.g., the potential for differential life stage susceptibility); and guidance on the use of the margin of exposure analysis.

Supplementary Materials

In addition to the July 1999 draft revised Guidelines, supplementary materials are available at the website www.epa.gov/ncea/raf/cancer.htm relevant to the development of the current draft revised Guidelines. These materials include the SAB's review letter (September 1997) and EPA's (March 1998) response covering the 1996 proposed Guidelines; the SAB's review letter (July 1999) summarizing the January 1999 review of selected revised sections of the 1996 Guidelines; the SAB's review letter (September 2000) covering EPA's July 1999 revisions to address the protection of children; EPA's January 2001 response to the latter two SAB reviews; a letter (May 1999) from EPA's Children's Health Protection Advisory Committee which presented issues for consideration by the Agency; and a summary of a workshop co-sponsored by EPA on information needs to address children's cancer risk.

Interim Use of 1999 Draft Revised Guidelines

Effective immediately, the July 1999 draft revised Guidelines will serve as EPA's interim guidance to EPA risk assessors preparing cancer risk assessments. As with all previous versions of the cancer risk assessment Guidelines, the predominant guidance provided in the July 1999 draft revised Guidelines is for risk assessors to use the best science and risk assessment techniques available to them at the time a risk assessment is conducted. Thus, while the July 1999 draft revised Guidelines will be available to EPA risk assessors as guidance, any final cancer risk assessment may take a different approach depending on evolving science, the facts of a particular case, or comments from peer reviewers, the public or others.

Dated: November 20, 2001.

Henry L. Longest II,

Acting Assistant Administrator for Research and Development.

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