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ocket EN-83-03 at the Central Docket Station (LE-131) of the EPA, Gallery 1-East Tower, 401 M Street SW., Washington, D.C. 20460, (202) 382-7548, between the hours of 8:00 a.m. to 4:00 p.m. Any comments from interested parties should be addressed to this docket with a copy forwarded to Richard G. Kozlowski, Director, Field Operations and Support Division (EN-397), U.S. Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460. As provided in 40 CFR Part 2, a reasonable fee may be charged for copying services.

FOR FURTHER INFORMATION CONTACT: James W. Caldwell, Chief, Fuels Section, Field Operations and Support Division (EN-397), U.S. Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460, (202) 382-2635.

SUPPLEMENTARY INFORMATION: On May 17, 1983 the American Methyl Corporation (American Methyl) submitted an application for a waiver of the section 211(f) prohibition on certain fuels and fuel additives set forth in the Clean Air Act (Act) for a fuel additive known as METHYL-10. See 48 FR 31083 (July 6, 1983). The public comment period established with respect to this application is scheduled to close on August 22, 1983.

The EPA has received a request from the Atlantic Richfield Company (ARCO) for an extension of the comment period in order to allow time to test and comment upon the additive. In order to provide the maximum amount of information upon which to base a decision the comment period has been extended to September 12, 1983.

The Administration's decision on this waiver application is due on or before November 14, 1983.

Dated: August 26, 1983.

Richard D. Wilson,
Acting Assistant Administrator for Air, Noise and Radiation.

[FR Doc. 83-24104 Filed 9-1-83; 8:45 am]

BILLING CODE 6560-50-M

[OPTS-42021A; TSH-FRL 2400-1]

Antimony Metal, Antimony Trioxide, and Antimony Sulfide; Decision To Accept Negotiated Testing Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In a proposed Negotiated Testing Agreement published in the Federal Register of January 6, 1983 (48 FR 717) the Agency announced a preliminary decision not to initiate rulemaking to require chemical fate,

environmental or health effects testing of antimony metal, antimony trioxide, and antimony sulfide based on the Agency's analysis of the existing data and its preliminary acceptance of a program submitted by the Antimony Oxide Industry Association (AOIA). The Agency has concluded that the testing program sponsored by the AOIA will expeditiously provide more information than initiating rulemaking and finds no reason to modify its preliminary decision. Therefore, EPA will not issue a TSCA section 4(a) rule at this time to require health, environmental effects and chemical fate testing of Sb metal, Sb₂O₃ and Sb₂S₃.

FOR FURTHER INFORMATION CONTACT:

Jack P. McCarthy, Director, TSCA Assistance Office (TS-799), Environmental Protection Agency, Room E-543, 401 M Street SW., Washington, D.C. 20460, Toll Free: (800-424-9065), in Washington, D.C. (554-1404), outside the USA (operator-202-554-1404).

SUPPLEMENTARY INFORMATION:

I. Background

In the Fourth Report of the Interagency Testing Committee (ITC), published in the June 1, 1979, Federal Register (44 FR 31866), the ITC designated antimony metal (Sb metal), antimony trioxide (Sb₂O₃) and antimony sulfide (Sb₂S₃) for priority testing consideration and recommended that these antimony substances be considered for chemical fate as well as environmental and health effects testing. The ITC's designation of these antimony substances was based on: (1) Large production volume; (2) Anticipated occupational and consumer exposure; (3) Expected environmental release; (4) Physical and chemical characteristics; (5) Existing human and animal data on health effects; and (6) Existing chemical fate and environmental effects data. The ITC recommended that Sb metal, Sb₂O₃ and Sb₂S₃ be considered for health effects testing (carcinogenicity, mutagenicity, teratogenicity and other chronic effects, including reproductive effects), for environmental effects testing, for chemical fate testing, and for epidemiology studies.

In a Federal Register notice published on January 6, 1983 (48 FR 717), the Agency responded to the ITC, as required under section 4(e) of TSCA, by describing a Negotiated Testing Agreement developed by the EPA and AOIA and announcing EPA's preliminary decision not to initiate rulemaking under section 4(a) of TSCA to require health, environmental effects and chemical fate testing for the antimony substances. This decision was

based on the Agency's analysis of the existing data and its preliminary acceptance of the program submitted by the AOIA which, in the Agency's view, appeared likely to provide adequate test data more expeditiously than a test rule and which would, in addition, provide for interim control of exposure to antimony substances while testing was being performed. The AOIA program was included in the public record (docket number OPTS-42021). The January 6, 1983, notice requested comment on the AOIA program and the Agency's rationale for not proposing to require testing by rule.

II. EPA's Response to Public Comments

The Agency received comments from the Natural Resources Defense Council (NRDC), the AOIA, and Dr. William Watt, author of one of the oncogenicity studies cited in the January 6, 1983, notice. These public comments and EPA's response to them are summarized below.

1. *NRDC's comments.* NRDC criticized EPA's policy of accepting negotiated testing agreements in lieu of rulemaking to require testing under section 4(a) of TSCA, and argued that the "plain language" of TSCA mandated that testing of section 4(e) chemicals must be accomplished by rule. In addition, NRDC contended that negotiated testing had many procedural and legal deficiencies; in its comments NRDC particularly cited the lack of enforceability of negotiated testing agreements and their failure to trigger other statutory provisions which would be triggered by a TSCA section 4(a) rule. NRDC made no chemical-specific comments about the Agency's testing rationale or the proposed AOIA testing and control program.

EPA has previously addressed NRDC's general concern about negotiated testing in a Federal Register notice published on January 5, 1982 (47 FR 335), which described the negotiated testing program for alkyl phthalates. A more detailed analysis of NRDC's arguments was prepared for inclusion in the public record of that action (docket number OPTS-42005). As was indicated in that notice, EPA believes that neither TSCA nor its legislative history support NRDC's contention that Congress established rules as the exclusive means for accomplishing testing. EPA believes that negotiated testing is consistent with the statutory purpose that adequate data on chemicals be developed expeditiously by the involved companies.

EPA agrees that negotiated testing is not legally enforceable, but as the

Agency has previously indicated in its January 5, 1982, Federal Register notice (47 FR 335), there are practical reasons why it expects that the involved companies will abide by their agreements in the vast majority of cases. For the agreement negotiated with the AOIA, these reasons include a commitment to schedule AOIA/EPA consultations regarding the testing programs, and a commitment to inspection of laboratory facilities in accordance with the authority and procedures outlined in section 11 of TSCA by duly designated representatives of the EPA. Furthermore, the Agency disagrees with NRDC's contention that if EPA is forced to develop a rule because of a failure of a negotiated program, the entire program will take substantially longer than if EPA had initially pursued rulemaking. Rather, EPA believes that it could conduct an expedited rulemaking which should not substantially lengthen the rulemaking process.

NRDC is correct in asserting that acceptance of a negotiated testing program will not trigger certain other statutory provisions that would be initiated if the Agency proposed, and upon promulgated, a test rule for these substances. However, EPA believes that NRDC has considerably exaggerated the practical impact of this difference. Although a negotiated testing program does not trigger the obligation of a manufacturer of a new substance subject to a section 4 rule to submit test data under section 5(b)(1) and to delay manufacturing, that particular requirement only relates to EPA actions under section 4 concerning categories of chemical substances which include chemicals for which TSCA section 5 notices would be required. It would not be applicable to Sb metal, Sb₂O₃, or Sb₂S₃, which were designated by the ITC as individual chemical substances.

In addition, contrary to NRDC's claim, EPA has the same authority to disclose health and safety data generated from negotiated testing as it would if the testing were conducted under a rule. Section 14(b)(1)(A)(i) concerns data from any health and safety study on a chemical in "commercial distribution" (which should include virtually all chemicals designated by the ITC) and makes no distinction based upon how the Agency receives the data.

EPA's position that negotiated testing is a legally sufficient alternative to section 4 rulemaking was examined by the General Accounting Office (GAO) during 1982. The GAO concluded that "neither section 4(a) nor 4(e) compels the promulgation of a test rule

proceeding where adequate test data may be developed pursuant to voluntary testing agreements. GAO further concludes that since voluntary agreements are consistent with significant purposes of section 4, implied authority exists for EPA to negotiate such agreements". (GAO, 1982, EPA Implementation of Selected Aspects of the Toxic Substances Control Act, General Accounting Office, December 7, 1982, GAO//RCED-83-62 pp. 15).

Based on the above, EPA continues to believe that, where appropriate testing is proposed, negotiated testing agreements are an appropriate alternative to expensive, time-consuming rulemaking under section 4 of TSCA.

2. *AOIA's comments.* In its comments, the AOIA urged final acceptance of the AOIA program by the EPA and clarified certain important issues addressed in the January 6, 1983, Federal Register notice (48 FR 717). The Agency has reviewed these comments and its response is provided below:

a. *Advantage of the AOIA negotiated program.* The AOIA reiterated the advantages of the negotiated program. The AOIA stated that the negotiated program will provide a "substantial" margin of safety to exposed workers pending the completion of proposed studies. The Agency believes that a determination of whether that safety margin is "substantial", as stated by the AOIA, must await the results of the testing proposed as part of the negotiated program. However, the Agency believes that the AOIA control program will increase worker protection while testing is being performed.

The AOIA suggests that it is "unclear whether EPA could mandate testing of antimony substances under section 4." The Agency believes that the existing health effects and chemical fate data indicate that exposure to antimony substances may present an unreasonable risk which could have supported rulemaking under TSCA section 4(a)(1)(A)(i) to require testing of antimony substances; and that this issue is not as "unclear" as implied by the AOIA. However, the Agency believes that the testing and control program offered by the AOIA is a more reasonable alternative than rulemaking for the antimony substances.

b. *Worker exposure to antimony substances.* The AOIA commented that "there is virtually no significant exposure to antimony metal and antimony sulfide." The Agency believes it would be difficult to quantify worker exposure as either "significant" or "non-

significant" because of the difficulty in chemically distinguishing Sb metal or Sb₂S₃ from other forms of inorganic antimony in environmental and biological media. Based on production and use data, less worker exposure is likely to Sb and Sb₂S₃ than to Sb₂O₃. Furthermore, if the AOIA was using the term "significant exposure" in the context of TSCA section 4(a)(1)(B)(i), EPA finds that question to be irrelevant since EPA believes that health effects testing could be required on the basis that antimony substances "may present an unreasonable risk" as provided by section 4(a)(1)(A). The AOIA was also concerned that language in the January 6, 1983, Federal Register notice (48 FR 717) gave "the impression that substantial number of workers are exposed to antimony substances near the 0.1 mg/m³ level." The Agency believes that the language in that notice provides an accurate estimate of the "maximum" number of users that would be exposed to antimony substances near those levels, because of existing data on number of users and "worst case" exposure levels for those users.

c. *No sound evidence that antimony poses an unreasonable risk.* The AOIA does not believe that the available toxicological evidence provides a basis to conclude that, at the low levels of exposure that exist under present conditions of production and use, antimony substances present an unreasonable risk for the health of workers." The Agency did not find the antimony substances present an unreasonable risk. Rather, the Agency believes that the antimony substances "may" present an unreasonable risk of health effects, and that existing data are inadequate to reasonably determine or predict the extent of this risk. The bases for these beliefs are presented in the January 6, 1983, notice.

The AOIA reported that the ITC's concern for possible adverse health effects of antimony substances was triggered by an inhalation study in rats, the Watt study, which is discussed in the January 6, 1983, notice. However, the Watt study was submitted to the Agency after the designation of the antimony substances to the priority list by the ITC and was therefore not used to trigger the ITC's concern.

The AOIA reported that "experts who have examined the conditions under which the Watt study was conducted have expressed the opinion that the actual exposure levels experienced in the study were far in excess of the reported levels and were therefore substantially above current industrial levels." The AOIA also stated that the

MRI study, which was cited in the January 6, 1983, notice, provided additional evidence of this deficiency." The Agency is unaware of any expert opinions related to actual levels in the Watt study being far in excess of the reported exposure levels. The reported exposure levels which induced non-neoplastic and neoplastic lesions in female rats were 1.6 ± 1.5 mg/m³ and 4.2 ± 3.2 mg/m³, respectively. The Agency recently received a copy of William Watt's doctoral dissertation which describes in detail the experimental methods that were used to quantify the exposure levels (Watt, W. D. April 1983. Chronic inhalation toxicity of antimony trioxide: validation of the threshold limit value. Doctoral Dissertation, Wayne State University, Detroit, Michigan. 136p.) The Agency has reviewed this dissertation, discussed it with the author, and finds no data to support the AOIA opinion that actual exposure levels were far in excess of the reported levels. Further, the Agency believes a determination of whether the reported levels in the Watt study are "substantially" above current industrial levels, must await the results of the workplace exposure monitoring study. Finally, the Agency believes that the major deficiency in the Watt study was the use of only one sex of rat per exposure level, not whether reported exposure levels exceeded actual exposure levels.

Because the Agency does not believe there is a deficiency between reported and actual exposure levels in the Watt study, the Agency does not believe that the MRI study provides "additional evidence of this deficiency." The Agency does believe that there were problems controlling the exposure levels during the first few weeks of the MRI study, but after these problems were resolved the exposure levels were adequately controlled. However, it should be noted that in the MRI study, with a mean Sb₂O₃ exposure level of 50 mg/m³, the "time to tumor" was 10 months compared to 17 months in the Watt study with a mean Sb₂O₃ exposure level, that induced neoplasia, of 4.2 mg/m³, indicating the biological differences between these exposure levels.

3. *Dr. Watt's comments:* Dr. William Watt supported the NTA for antimony substances, but disagreed with the statement in the January 6, 1983, notice that in his study there was a "lack of adequate control of exposure levels." The Agency provided this statement in reference to the overlap of the exposure levels in the Watt study and on the basis of information it had received prior to the receipt of Dr. Watt's

dissertation; if one standard deviation is used to generate the range of exposures, then the range for the low exposure level would be 0.1-3.1 mg/m³, whereas the range for the high exposure level would be 1-7.4 mg/m³. The Agency is unable to reasonably determine the significance between these exposure levels, except that only the high exposure level induced neoplasia, suggesting that there were some toxicological differences between exposure levels.

In his comments, Dr. Watt also discussed a mutagenicity study for antimony acetate. The Agency examined this study, as well as several others, and does not believe that these data were relevant to assessing the mutagenicity of Sb metal, Sb₂O₃, and Sb₂S₃, because of differences in physical and chemical properties (including significant differences in water solubility) of organic antimony compounds and the antimony substances recommended for testing by the ITC.

Finally, Dr. Watt commented that exposure to Sb₂O₃ may arise during battery charging, during the addition of Sb₂O₃ to plastics and other materials, and during the cutting and sewing of upholstery and carpet containing Sb₂O₃. In conjunction with this comment, Dr. Watt implied that the AOIA epidemiology studies would include only male workers and suggested that epidemiology studies should include work forces outside the AOIA, with substantial number of potentially exposed females, such as the "soft trim" industry (carpet and upholstery cutting and sewing), since it appears as though Sb₂O₃ is neoplastic to female, but not male, rats.

The Agency has no data on estimated or measured levels of antimony substances that might be generated in the "soft trim" industry and to which female workers might be exposed. The Agency is concerned with the potential development of neoplasia in any worker population that may be exposed to antimony substances. However, the Agency is also concerned with the potential development of non-neoplastic lesions and other chronic effects in any worker population that may be exposed to antimony substances. These non-neoplastic lesions have been detected at lower mean exposure levels of antimony substances in male and female rats than have neoplastic lesions. Furthermore, the Agency believes that controlling exposure to antimony substances at levels that would decrease the potential for development of non-neoplastic lesions and other chronic effects in both

sexes would decrease the potential for development of neoplastic lesions in workers of either sex exposed to antimony substances. The Agency believes that the program it developed with the AOIA will provide reasonable interim control of worker exposure to antimony substances until additional toxicology data are developed, as a result of the AOIA testing program, to demonstrate a more precise relationship between antimony substances' exposure levels and development of neoplastic and non-neoplastic lesions in male and female rats and any potential adverse health effects in workers exposed to antimony substances. The Agency believes that these data, in conjunction with the AOIA-endorsed ongoing epidemiology studies and the proposed AOIA medical surveillance program, may be used to estimate the probability that antimony substances may produce adverse health effects in human worker populations.

III. AOIA Program

1. *Scheduled tests.* In a notice published in the January 6, 1983, Federal Register (48 FR 717), the Agency described the AOIA's proposed program. The final study plans for this program are in the public record (docket number OPTS-42021A) and include:

- a. A 90-day subchronic inhalation study of Sb₂O₃, to be initiated in late 1983 and for which a final report will be submitted in late 1984 to early 1985.
- b. Chronic/oncogenic inhalation study of Sb₂O₃, to be initiated in mid 1985 and for which a final report will be submitted in late 1987 to early 1988.
- c. Aerobic and anaerobic biodegradation studies of Sb₂O₃, to be initiated in late 1983 and for which a final report will be submitted in late 1984.
- d. Sediment sorption studies of Sb₂O₃, to be initiated in mid to late 1983 and for which a final report will be submitted in late 1984.

In addition to submitting study plans and associated reports, the AOIA will submit to the Agency periodic status reports on: (1) Voluntary programs to monitor and control occupational exposure to antimony substances; (2) Voluntary programs to monitor and control atmospheric release of antimony substances; and (3) A medical surveillance program and a continuation of ongoing epidemiological studies.

2. *Review and conclusions.* EPA has reviewed the study plans and has concluded that:

- a. The subchronic study will provide sufficient data to: (1) Establish pulmonary clearance rates of Sb₂O₃ in

rats. (2) Assess the histopathological changes that occur in the rat respiratory system and as a result of subchronic Sb_2O_3 exposure. (3) Correlate rat urinary levels of Sb_2O_3 with exposure levels. (4) Assess any hematological and clinical chemistry anomalies in the rat associated with Sb_2O_3 exposure. and (5) Establish exposure levels for the chronic/oncogenic study.

b. The chronic/oncogenic study will provide sufficient data to assess the pathogenesis and dose/response characteristics of neoplastic and non-neoplastic lesions in the rat respiratory system resulting from Sb_2O_3 exposure.

c. The biodegradation and sorption studies will provide sufficient data to determine the fate of Sb_2O_3 in sediments.

d. The voluntary programs to monitor and control occupational exposure and atmospheric release of antimony substances will provide significantly increased protection of workers and the general population in the vicinity of facilities which manufacture and process antimony substances, while the testing program is being completed.

e. The medical surveillance program and a continuation of ongoing epidemiological studies will provide relevant information to assess the occupational exposure to antimony substances and the possible adverse health effects caused by such exposures.

IV. Public Records

EPA has established a public record for this decision not to pursue testing under section 4 (docket number OPTS-42021). This record includes:

- (1) Federal Register notice designating Sb metal, Sb_2O_3 , and Sb_2S_3 to the priority list and comments received thereon.
- (2) Communications with industry related to the AOIA program, consisting of letters, contact reports of telephone conversations, and meeting summaries.
- (3) AOIA program.
- (4) Study plans.
- (5) Published and unpublished data.
- (6) Federal Register notice of the NTA proposal requesting comments on the negotiated program and comments received in response thereto.

The record, containing the information considered by the Agency in developing this decision, is available for inspection from 8:00 a.m. to 4:00 p.m. Monday through Friday except legal holidays in the OPTS Reading Room, E-107, 401 M Street, SW., Washington, D.C. 20460.

The Agency will supplement this record periodically with additional relevant information.

(Sec. 4, 90 Stat. 2003; (15 U.S.C. 2601)).

Dated: August 26, 1983.

William D. Ruskelaus,
Administrator.

[FR Doc. 83-2418 Filed 9-1-83; 8:45 am]

BILLING CODE 6560-50-01

[ER-FRL-2428-2]

Availability of Environmental Impact Statements Filed August 22 Through August 26, 1983 Pursuant to 40 CFR Part 1506-9

RESPONSIBLE AGENCY: Office of Federal Activities, General Information (202) 382-5075 or (202) 382-5076.

Department of the Interior:

EIS No. 830467, Draft, BLM, CA, Red Mountain WSA, Preliminary Wilderness Recommendation, Mendocino Co. Due: *Dec. 1, 1983

EIS No. 830466, Final, BLM, CA, Yokayo Grazing Management Program, Due: Oct. 3, 1983

Department of Transportation:

EIS No. 830461, Final, FHW, WI, US 53 Upgrading, Rice Lake to Trego, Barron and Washburn Counties, Due: Oct. 3, 1983

EIS No. 830462, Final, FHW, IL, Springfield Railroad Relocation Demonstration Project, Sangamon Co., Due: Oct. 3, 1983

EIS No. 830463, Final, FHW, NC, Fayetteville CBD Loop, Hay Street to US 301, Cumberland County, Due: Oct. 3, 1983

EIS No. 830464, Final, FHW, MI, US 12/ Michigan Avenue Improvement, Nowlin St. to Elm St., Wayne Co., Due: Oct. 3, 1983

EIS No. 830442, Final, FHW, NH, I-393 and Approach Completion, NH-106 to NH-9/ US 4, Merrimack County, Due: Oct. 3, 1983

Department of Agriculture:

EIS No. 830460, Final, AFS, SEV, SD, WY, Black Hills National Forest Land and Resource Management Plan, Due: Oct. 3, 1983

Interstate Commerce Commission:

EIS No. 830468, Draft, ICC, REG, Nationwide Coal Rate Guidelines, Due: Oct. 17, 1983

U.S. Postal Service:

EIS No. 830465, DSuppl. UPS, CT, Stamford Post Office General Mail/Vehicle Maintenance Facilities, Due: Oct. 17, 1983

Amended Notices:

EIS No. 724206, Final, SCS, NE, Winters Creek Watershed Project, Sioux, Scotts and Bluff Counties Officially withdrawn

Dated: August 30, 1983.

Pasquale A. Alberico,

Acting Director, Office of Federal Activities.

[FR Doc. 83-24182 Filed 9-1-83; 8:45 am]

BILLING CODE 6560-50-01

[W-4-FRL 2422-5]

Draft General NPDES Permit for Coal Mining Activities in the Commonwealth of Kentucky

AGENCY: Environmental Protection Agency.

ACTION: Notice of draft general NPDES permit.

SUMMARY: The U.S. Environmental Protection Agency (EPA) and the Kentucky Natural Resources and Environmental Protection Cabinet (NREPC) are today giving joint notice of a draft general National Pollutant Discharge Elimination System (NPDES) permit for certain coal mining activities in Kentucky. The Governor of Kentucky has requested that NREPC be given approval by EPA to administer the NPDES program in Kentucky. If the Administrator of EPA grants approval before this general permit is issued, NREPC will be the permit issuing authority. The activities proposed for coverage by this general permit include active mining areas, post-mining areas, coal refuse disposal piles, and coal preparation plant associated areas. The proposed permit will not authorize discharge from facilities meeting the definition of coal preparation plant in 40 CFR 434.11(e) and "new sources" (see 40 CFR 434.11(j) and the Effluent Guidelines Settlement Agreement for coal mines; 40 CFR 122.2 for coal preparation plant associated areas). EPA will continue to issue individual NPDES permits to these categories of dischargers.

The draft general permit establishes effluent limitations, prohibitions, and other conditions based on technology and water quality considerations applicable to the types of wastewater generated by the coal mining activities. The activities involve similar types of operations, discharge the same types of wastes, and require the same effluent limitations and monitoring. For these reasons, Region IV believes that discharges from these activities are more appropriately controlled under a general permit than under individual permits.

To obtain approval to discharge under this general permit, Region IV is requiring the following application requirements:

1. For currently expired NPDES permits, the discharger is required to submit a notice of intent to be covered by the general permit to the Permit Issuing Authority.

2. Dischargers having valid NPDES permits that will expire during the five-year term of the general permit are