ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 799

[OPTS-42074A; FRL-3420-2]

Cumene; Final Test Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is issuing a final test rule, under section 4 of the Toxic Substances Control Act (TSCA), requiring manufacturers and processors of cumene (isopropyl benzene, CAS No. 98-82-8) to perform testing in the areas of health effects, environmental effects, and chemical fate. The health effects testing requirements include: Oral and inhalation comparative pharmacokinetics, subchronic inhalation toxicity, developmental toxicity, neurotoxicity, and, if triggered, two generation reproductive effects. The environmental effects and chemical fate testing requirements include: Acute toxicity to fish and invertebrates, biodegradation in an aquatic system, volatilization from an aquatic system, and, if triggered, chronic toxicity to fish and invertebrates.

DATES: In accordance with 40 CFR 23.5, this rule shall be promulgated for purposes of judicial review at 1 p.m. eastern [daylight or standard as appropriate] time on August 10, 1988. This rule shall become effective on September 9, 1988. The incorporation by reference in the rule is approved by the Director of the Federal Register as of September 9, 1988.

FOR FURTHER INFORMATION CONTACT: Michael M. Stahl, Acting Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Rm. E-543, 401 M St., SW., Washington, DC 20460, (202) 554-1404, TDD: (202) 554-0551.

SUPPLEMENTARY INFORMATION: EPA is issuing a final test rule under section 4(a) of TSCA to require health effects, environmental effects, and chemical fate testing for cumene.

Public reporting burden for this collection of information is estimated to average 535 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

1. Chief, Information Policy Branch (PM-223), EPA, 401 M St., SW., Washington, DC 20460.
2. Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Washington, DC 20503.

I. Introduction

A. Test Rule Development Under TSCA

This final rule is part of the overall implementation of section 4 of TSCA (Pub. L. 94-469, 90 Stat. 2003 *et seq.*, 15 U.S.C. 2601 *et seq.*), which contains authority for EPA to require the development of data relevant to assessing the risk to health and environment posed by exposure to particular chemical substances or mixtures (chemicals).

T3

Under section 4(a) of TSCA, EPA must require testing of a chemical to develop health effects, environmental effects, or chemical fate data if the Administrator makes certain findings as described in TSCA under section 4(a)(1) (A) or (B). Detailed discussions of the statutory section 4 findings are provided in the Agency's first and second proposed test rules which were published in the Federal Register of July 18, 1980 (45 FR 48510) and June 5, 1981 (46 FR 30300).

B. Regulatory History

The Interagency Testing Committee (ITC) designated cumene for priority testing consideration in its 15th Report, published in the Federal Register of November 29, 1984 (49 FR 46939). The ITC recommended that cumene be considered for health effects testing, including short-term genotoxicity, chronic toxicity including oncogenicity, teratogenicity, and reproductive effects; and environmental effects testing, including acute and chronic toxicity to saltwater and freshwater fish and invertebrates. The bases for these recommendations were: Annual production capacity of 4 to 5 billion pounds, potential for occupational and environmental exposure, and insufficient data to assess the risk of cumene exposure to human health and the environment.

EPA responded to the ITC's recommendations for cumene by issuing a proposed rule, published in the Federal Register of November 6, 1985 (50 FR 46104), which would require that cumene be tested for oral and inhalation comparative pharmacokinetics, oral and inhalation subchronic toxicity, mutagenicity, developmental toxicity, neurotoxicity, oncogenicity, acute and chronic toxicity to saltwater and freshwater fish and invertebrates, biodegradation in an aquatic system, volatilization from an aquatic system, and, if triggered, a two-generation reproductive effects study.

The proposed rule contained a chemical profile of cumene, a discussion of EPA's TSCA section 4(a) findings, and the proposed test standards.

II. Response to Public Comments

The Agency received written comments on the cumene proposed rule from the Chemical Manufacturers Association's (CMA) Cumene Program Panel (the Panel) on February 28, 1986 (Ref. 1). The Panel includes manufacturers and processors of cumene. Panel members are Texaco Chemical Company, Chevron Chemical Company, Dow Chemical Company, Champlin Petroleum Company, Koch Refining, Inc., Ashland Oil Company, US Steel Corporation, and Georgia Gulf Corporation.

Dow Chemical Company (Dow) also submitted written comments separately on an earlier date (February 13, 1986) that dealt specifically with the Agency's proposed guidelines for oral and inhalation pharmacokinetic studies (Ref. 2). The pharmacokinetic guidelines proposed by the Agency for cumene were subsequently referred to in the final Phase I test rule for 1,2-Dichloropropane published in the Federal Register of September 9, 1986 (51 FR 32107). Dow's comments on the proposed pharmacokinetic guidelines and the Agency's responses are summarized in the final test rule for 1,2-dichloropropane published in the Federal Register of October 5, 1987 (52 FR 37138). A detailed explanation of the Agency's position on Dow's comments on the proposed pharmacokinetic guidelines may be found in the support document (Ref. 3) prepared for EPA by Syracuse Research Corporation (SRC) and a memorandum written by EPA's Health and Environmental Review Division within the Office of Toxic Substances (Ref. 4). Dow's comments have resulted in modifications to the proposed pharmacokinetic guidelines and these modifications are described in the final test rule for 1,2-dichloropropane. A summary of the Panel's comments will be briefly stated in the following sections along with the Agency's responses to the comments.

A. Comments on Oncogenicity and Mutagenicity Testing Requirements

The Panel believes that the reported positive results of two short-term mutagenicity tests with cumene (cell transformation and unscheduled DNA synthesis (UDS) assays) conducted by the Gulf Life Sciences Center (Gulf, Ref. 5) do not justify the requirement for higher-tier mutagenicity and oncogenicity testing. The Panel's conclusion is based upon apparent technical difficulties with the assays, rendering the results equivocal at best. The Panel reported that it would repeat three of the four tests conducted by Gulf and also perform an Ames *Salmonella* assay and an *in vitro* cytogenetics assay on a voluntary basis.

EPA agrees that some doubt existed as to whether the Gulf results are positive or equivocal. Nevertheless, these data were suggestive of the possible genotoxicity of cumene and could not have been dismissed without additional evidence to the contrary. The results of five voluntary mutagenicity tests submitted to EPA by the Panel have provided the evidence needed to clarify the Gulf results (Ref. 6). Cumene was clearly negative in the cell transformation and UDS assays that were repeated by the Panel. The results were also negative for three other mutagenicity assays submitted by the Panel (*Salmonella* (Ames)), Chinese Hamster Ovary (CHO)/Hypoxanthine-Guanine Phosphoribosyl Transferase (HGPRT) mutation, and chromosome aberrations in CHO cells). Since all tier I tests proposed by the Agency or equivalent to those proposed by the Agency are already available and negative, including a micronucleus test of cumene from Gulf (Ref. 7) which the Panel did not repeat and which the Agency considers adequate, the Agency has reconsidered its proposed requirements for higher-tier mutagenicity and oncogenicity under both sections 4(a)(1) (A) and (B). The Agency has decided that no further testing in these areas is necessary at this time.

B. Comments on the Exposure Finding

The Panel commented that EPA has not properly justified its finding of significant or substantial exposure under section 4(a)(1)(B) of TSCA. The Panel believes that EPA has overstated cumene levels in the environment; that the contribution of manufacturing, processing, use, and distribution activities to cumene levels in the environment is negligible compared to cumene emissions from motor vehicle fuel exhaust, the quantities of cumene naturally present in the environment, and other cumene sources such as cigarette smoke and volatilization during the cooking of foods; and that exposure levels cited by EPA are, in any event, far too low to merit concern about cumene's potential risks to the general population.

1. *Estimation of air emissions from manufacturing and processing operations.* In the proposed rule for cumene, EPA estimated that approximately 3 million pounds of cumene is released annually to the environment from cumene manufacturing and processing facilities. This estimate was derived from emission rate data for devices such as vents, flanges, drains, valves, and pumps suspected of leaking cumene in the average cumene manufacturing and/or processing unit. Approximately 15 to 16 million people live in areas near cumene manufacturing and processing facilities. EPA is concerned about the increased levels of cumene to which this surrounding population is exposed. The Panel commented that EPA overstated the amount of cumene released from manufacturing and processing facilities.

T4

The Panel presented a revised estimate of 843,750 pounds of cumene that is released annually as fugitive emissions from cumene manufacturing and processing. The Panel's figure is extrapolated from emissions data from 11 of 16 active cumene manufacturing and processing plants. These 11 plants account for just under 80 percent of the cumene produced, imported, and processed in 1984. Some 675,000 pounds of cumene was reported released from these 11 plants by the manufacturers and processors. The Panel assumed that the other 5 plants, which account for the remaining 20 percent of the cumene, released a proportional amount. This figure is 168,750 pounds, which yields a total fugitive emissions of 843,750 pounds of cumene annually.

EPA believes that the Panel's estimate does not include fugitive emissions of cumene from cumene processing facilities, especially from those which are located on the same site as the manufacturing facility. Since many of the cumene manufacturers also process cumene at the same site using a separate physical system, the fugitive emissions of cumene from processing, which are generally estimated to be twice those from manufacturing, should be included in the total emissions from a site. In addition, EPA believes that, in extrapolating a value for cumene emissions from plants for which emissions data are available to plants for which no data are available, the Panel has incorrectly assumed that cumene emissions are strictly proportional to the amount of cumene manipulated, regardless of whether the cumene was manufactured or processed. Furthermore, there was no consideration given to the age or size of the plant.

2. *Contribution of manufacturing and processing activities to overall cumene levels in the ambient air.* The Panel has stated that cumene emissions into the environment are primarily from gasoline and diesel fuel use and that industrial emission sources contribute a far smaller amount of this chemical to the environment on a national scale. In addition, the Panel pointed out there are many other sources of cumene, unrelated to cumene manufacturing and processing activities, such as cigarette smoke and volatization from cooking certain foods. The Panel believes that this confirms that emissions from cumene manufacturing and processing represent only an insignificant source of cumene in the environment.

EPA is aware of the many sources of cumene in the environment, and it also recognizes that distinguishing the contribution of one source from another is very difficult. EPA is also aware that, when the country is taken as a whole, land vehicle emissions are believed to contribute about five times as much cumene to the environment as cumene manufacturing and processing facilities. However, in communities close to cumene manufacturing and processing facilities, it appears that these facilities emit approximately 3.6 times the amount of cumene emitted by land vehicles exhaust and, hence, are the dominant source of atmospheric cumene (Ref. 8).

3. *The significance of air emission levels near cumene facilities.* The Panel has suggested that cumene concentrations in the atmosphere, resulting from cumene manufacturing and processing, even near manufacturing and processing facilities, are not significant. The Panel quotes the Test Rule Support Document worst case cumene concentrations calculated for a 1 and 5 km radius from the plant, which were 3.5 to 59.9 parts per billion (ppb) and from 0.6 to 3.1 ppb, respectively. The Panel points out that these levels may be seen during occasional excursions, but do not represent common air concentrations (Ref. 9). It goes on to say that the 1.4 ppb annual average 1 km from a plant and the 6 and 11 ppb cumene concentrations seen near a production facility in Deer Park, TX, both presented in the Test Rule Support Document, are more reasonable. In addition, these values are more in line with a modeling study done for Georgia Gulf's Bound Brook, NJ phenol facility, which also predicts a 1.4 ppb annual average at 1 km from the plant (Ref. 10). The worst case at this facility was calculated to be 34.8 ppb. The Panel also states that, considering the short half-life of cumene in the atmosphere, there is no reason to believe that, except for populations very close to the plant, there is any general population exposure. The Panel contends, finally, that the 15 to 16 million persons that EPA suggests are living in metropolitan areas near cumene manufacturing and use facilities is misleading. It suggests that, because of cumene's rapid atmospheric degradation kinetics, this value is too high, and only a small fraction of these people would be exposed to cumene concentrations above the ambient level.

The majority of monitoring data that are available for places without cumene manufacturing or processing facilities indicate cumene concentrations at or below 2 ppb in the air (Ref. 9). However, modeling and monitoring data developed for places that have cumene manufacturing and processing facilities indicate much higher concentrations of cumene in the air. Some of the highest monitored cumene concentrations (6 an 11 ppb) were near the Shell Oil Company manufacturing complex in Deer Park, TX, despite the fact that insufficient data are available to determine whether or not the facility was in operation at the time the sampling took place (Ref. 9). In addition, worst case cumene concentrations predicted via models, which are discussed above, for areas closest to cumene manufacturing and processing sites are significantly above the cumene levels detected in places without cumene manufacturing and processing facilities.

The more recent data on the half-life of cumene in the atmosphere, which the Agency referred to in the proposed test rule for cumene, appears to be on the order of one or two days. At this rate of removal, the cumene emissions from ongoing manufacturing and processing activities would be expected to be distributed over a large portion of the communities near the manufacturing and processing facilities depending on the prevailing atmospheric conditions.

The figure of 15 to 16 million persons estimated by EPA to be the total population living within a 50 km radius of all cumene manufacturing and processing facilities was derived using 1980 Census information (Ref. 11). The 1985 Census shows that approximately 13.5 million people live in areas near cumene manufacturing and processing facilities (Ref. 8). It should be noted that 97 percent of the cumene capacity and 66 percent of phenol capacity are concentrated in areas with a population of about 7 million people. Thus it appears that most exposure to cumene from cumene manufacturing and processing facilities occurs in a population of about 7 million people. Cumene manufacturing and processing facilities are predicted to emit some 2.58 million pounds of cumene per year into the atmosphere in these areas, based on the total cumene emissions predicted from all facilities. By comparison, automobiles in these areas are predicted to emit only 0.47 million pounds per year (Ref. 8). Also, since the half-life of cumene in the atmosphere is long enough to allow for some transport, the vast majority of atmospheric cumene in these areas must come from cumene manufacturing and processing facilities.

4. *Cumene levels in water.* The Panel has suggested that EPA, in presenting the data for wastewater, groundwater, and drinking water in the proposed test rule, has not given sufficient weight to the monitoring data which show that cumene is rarely detected in water and, even where found, is present in trace

15

amounts. The Panel concludes that: (1) When present, cumene concentrations are low; (2) for the most part, where present, cumene concentrations in water can be linked to a source of contamination that does not involve cumene manufacturing, processing, or transportation; and (3) cumene is not detected the majority of the time.

EPA finds the Panel's conclusions to be less than convincing, because monitoring data from waters near cumene manufacturing and processing facilities are not available for evaluation. Without this information, no conclusions can be made concerning the presence or absence of cumene or the levels of cumene that might be present in the waters near these facilities. EPA does know that a number of cumene-bearing waste streams are generated from industrial processes and that cumene is discharged to the aquatic environment (Ref. 12). Therefore, testing for the effects to aquatic populations near outfalls of cumene manufacturing and processing facilities is warranted.

5. *Potential for adverse effects at actual or expected cumene concentration levels in the environment.* The Panel believes that, even if EPA's estimates of environmental exposure resulting from cumene manufacturing and processing activities are correct, the existing data base for cumene allays any concern about cumene's potential risks to the general population.

EPA does not believe, as previously explained in the proposed rule, that the current health effects data base for cumene is adequate to allay the concern that cumene may present a threat of chronic adverse health effects at levels presently in the environment. The available acute and subchronic data are not sufficient to reasonably predict the dose-response curve for chronic human exposure.

6. *Significance of occupational exposure to cumene.* The Panel commented that worker exposure to cumene at manufacturing and processing facilities is neither "substantial" nor "significant" under section 4(a)(1)(B) of TSCA. To support this contention, the Panel presented a summary of its industrial hygiene survey which was submitted to EPA in April, 1985 (Ref. 13).

The Panel's survey presented information about a total of 739 employees who were reported as "having potential exposure" to cumene. Of these, 393 were routinely exposed and 346 were intermittently exposed. The personal exposure data, provided by manufacturers and processors of cumene, were from sampling done over the period 1973 to 1984. A total of 1,487 samples were reported. There were 6 samples in the range of 4.01 to 30 parts per million (ppm), 4 samples in the range of 3.01 to 4 ppm, 25 samples in the range of 1.01 to 2 ppm, and the remaining samples were below 1 ppm.

The Agency's review of the survey data identified several potential problems with the personal monitoring data submitted. It was reported in the Panel's survey that toluene, ethylbenzene, and water vapor were interferences for the National Institute of Occupational Safety and Health (NIOSH) charcoal tube method used for some of the personal sampling, and water vapor was an interference for the 3M 3500 OVM badge method used for the remainder of the sampling. Without some knowledge of the magnitude of these interferences, no assessment of the validity of these measurements can be made. If water vapor exerts substantial interference, then the entire set of data in the survey may be suspect. In addition, not all companies provided personal monitoring data for cumene. Nevertheless, the information provided by the survey is of concern to the Agency because of the potential for chronic adverse health effects to workers from exposure levels reported.

In conclusion, the Agency believes that occupational exposure to cumene, when considered along with the potential for general population exposure to cumene, meets the exposure criteria needed to make a section 4(a)(1)(B) finding under TSCA (i.e., the chemical is produced in substantial quantities and there is potential for substantial human exposure).

C. Comments on Scope of Health Effects Testing Requirements

The Panel recommends that the testing program for cumene, if required, should be designed to address only the concerns relevant to occupational exposure conditions. Specifically, the Panel sees no need for testing by the oral or dermal routes of exposure and, therefore, no need for pharmacokinetic data to aid in route-to-route extrapolation for risk assessment. In addition, the Panel proposes modifications to the proposed developmental toxicity and reproductive effects testing and sees no need for a separate neurotoxicity test.

EPA has concluded that the general populations of areas in the vicinity of cumene manufacturing the processing facilities are potentially being exposed to elevated levels of cumene as a result of the releases of this chemical to the environment from these facilities. Therefore, the Panel's position that the testing program should be designed to focus only on workplace exposure to cumene appears unwarranted.

1. *Route of exposure.* The Panel believes that all testing should be conducted by inhalation, which it believes is the only relevant route of exposure.

EPA believes that inhalation is the most relevant route of human exposure, and, for this reason, it has required testing only with this route whenever that was adequate. Nevertheless, the potential for human exposure to cumene via the oral route is also of some concern to the Agency because monitoring data for ground and surface water near cumene manufacturing and processing facilities are not available. The water in these areas may have elevated concentrations of cumene due to releases of cumene-bearing effluents from the manufacturing and processing facilities. In addition, the use of the oral route is preferred by the Agency for reproductive toxicity testing, because the use of inhalation exposure for this testing presents numerous difficulties. For example, it has become routine to separate the postpartum dam from her neonates for 6 to 8 hours/day while she is exposed in an inhalation chamber. The separation of neonates from their mothers can have adverse effects on their growth and development. Therefore, it is difficult to interpret results of such studies when one does not know how much the study has been compromised by introducing a critical confounding factor. Furthermore, once the dams are returned to their cages, the offspring are eager to nurse since they have been deprived for 6 to 8 hours. This leads to the offspring licking the fur of the mothers and thereby being exposed directly to the test agent. The dose levels obtained this way may be too toxic for the neonates and could further complicate the findings of the study.

Pharmacokinetics testing with cumene is being required by both routes, oral and inhalation. EPA will use the pharmacokinetics data for extrapolating from one route to the other. Thus, the Agency's concern regarding the potential of exposure to cumene via the oral route will also be addressed without having to require the proposed 90-day oral subchronic study.

2. *Pharmacokinetics/metabolism testing.* The Panel recommends that only a very limited amount of pharmacokinetics testing with cumene (non-radiolabeled) be performed initially and further testing in this area be considered only if a significant toxic end-point is defined in the subchronic or chronic studies. In addition, the Panel believes that the availability of an

T6

estimate for human absorption of inhaled cumene and metabolism data from earlier animal studies justifies dropping the bioavailability and metabolite identification testing requirements.

The Agency does not agree with the Panel's assumption that pharmacokinetic data are only useful for evaluating toxicity. Pharmacokinetics testing is being required to generate comparative, dose-dependent, oral and inhalation absorption, tissue distribution, bioaccumulation, metabolism, and excretion data. These data are needed for high to low dose, route-to-route, and species to species extrapolation. Furthermore, the Agency does not believe that the single report on human absorption and several animal studies conducted primarily in the 1950's satisfy the need for pharmacokinetics/metabolism data (Refs. 14, 15, and 16). An estimate of human absorption will not assist in the evaluation of toxicity studies conducted in the rat. Likewise, metabolism studies conducted without the benefit of a radiolabeled test compound or by state-of-the-art methods are of little value for risk assessment purposes. The elucidation of metabolic pathways and identification of metabolites would be more difficult using the Panel's recommendation that studies be performed with non-radiolabeled cumene.

3. *Developmental toxicity testing.* The Panel believes that EPA should require only a single species (rat), instead of a two-species, inhalation developmental toxicity study, because the purpose of this testing would be to confirm or refute an inadequate report in the eastern European literature (Ref. 17) which claims that cumene is teratogenic at relatively low doses in the rat.

EPA disagrees with the Panel. Experience has indicated that there may be considerable species variation in degree and sensitivity of response in evaluating the potential teratogenic effects to a chemical substance. Therefore, two species are generally required even if data indicate that one is positive. Concern remains that the second species may be more sensitive in terms of dose level needed to see adverse effects. This requirement is consistent with those of the EPA Office of Pesticide Programs and the Organization for Economic Cooperation and Development (OECD).

4. *Reproductive effects testing.* The Panel commented that EPA's proposed triggering criteria for the two-generation reproductive effects study are too inflexible and unscientific.

In response to the Panel's comments, EPA has revised the triggering criteria to increase their scientific reliability. In addition, if the results from the subchronic inhalation toxicity test indicate that the triggering criteria used for predicting reproductive effects are positive, EPA will hold a public program review before requiring the two-generation reproductive effects test. Public participation in this program review will be in the form of written public comments or a public hearing. Request for public comments or notification of a public meeting will be published in the **Federal Register**. Should the Agency determine, from the weight of evidence then available, that proceeding with the two-generation test is not warranted, the Agency would propose to repeal that test requirement and, after public comment, issue a final amendment to rescind the requirement.

5. *Neurotoxicity testing.* The Panel recommends that the separate neurotoxicity testing proposed for cumene not be required. Instead, the Panel contends that the requirement for neurotoxicity testing can be satisfied by modifying the protocol for the 90-day subchronic study.

It is the Agency's policy in implementing the TSCA section 4 to require the three proposed neurotoxicity tests, i.e., functional observation battery, motor activity, and neuropathology, in test rules based on a finding of substantial production and exposure. These tests are deemed necessary to adequately screen for neurotoxicity. The neurotoxicity tests may be combined with the subchronic toxicity test as long as the results of the various tests are not compromised.

D. Comments on Environmental Effects Testing

The Panel believes that environmental concentration levels for cumene are not sufficient to justify a finding of "significant" environmental release. The Panel contends that, in light of cumene's limited solubility in fresh and saltwater, rapid biodegradability in freshwater, and propensity for volatilization from saltwater, the duration of exposure of aquatic organisms to cumene would be insignificant. In addition, the Panel contends that the data on cumene's acute toxicity to birds, fish, invertebrates, and microorganisms indicate an adequate margin of safety. Finally, the Panel has a number of testing recommendations which it wants EPA to consider if additional testing is to be required.

The Panel recommends that: (1) EPA should select test species which are readily available and for which there exists a good toxicology data base and; (2) EPA should tier chronic aquatic testing requirements.

EPA believes, as previously stated in response to comments on cumene levels in water, that cumene manufacturing and processing facilities discharge cumene-bearing wastewater to the environment. The detection of cumene in surface water also suggests that cumene has a long enough half-life to build up detectable concentrations in surface water systems (Refs. 8 and 9). The existing data on the acute toxicity of cumene to aquatic species show mu variability, and the deficiencies and omission of adequate description in methodology prohibit the use of the available data in a comprehensive appraisal of the toxic potential of cumene in the aquatic environment (Re 9). Furthermore, the available aquatic toxicity data obtained using nominal concentrations and under static conditions are of limited value in the accurate estimation of the potential toxicity of volatile organic chemicals (i.e. cumene), because the toxicant in th solution has probably evaporated durin the exposure. Therefore, in the absence of definitive acute toxicity data for aquatic organisms indicating the toxic potential of cumene, EPA finds it necessary to require environmental effects testing for cumene. EPA, however, agrees with the Panel's recommendations for test species, and the need for tiering chronic toxicity testing requirements. Therefore, EPA has modified the testing requirements accordingly (see Unit III. B.).

E. Comments on Chemical Fate Testing

The Panel contends that EPA's proposed method of studying biodegradation of cumene in water, the Core-Chamber Method developed by Bourquin et al., is not a standard method for degradation as outlined in TSCA guidance and was not validated for application to TSCA, and that finding qualified laboratories for testing under Good Laboratory Practice (GLP) standards may be difficult. In addition, the Panel has suggested that the biodegradation and volatilization tests be run in the same test chambers, allowing for a more cost-effective experiment, since the Bourquin test apparatus can be modified to develop both types of data concurrently.

EPA believes that the Core-Chamber Method developed by Bourquin et al. (Ref. 18) is the best available method for evaluating the persistence of cumene in a combined sediment/water environment because: (1) It can be modified to minimize volatilization: (2) it provides reliable data on ultimate biodegradation; and (3) it is a cost-effective approach to simulating *in situ* biodegradation. In addition, since the test requires only readily available materials for the construction of the necessary aquaria, there should be no

difficulty in finding qualified laboratories to conduct the test, and GLP standards should be readily adaptable to the test. The final rule for tetrabromobisphenol A (TBBPA), published in the Federal Register of July 6, 1987 (52 FR 25219), also requires biodegradation testing using the Core-Chamber Method, and the test sponsor for TBBPA has found a qualified laboratory to conduct this test.

EPA does not believe combining the biodegradation and volatilization tests will allow for the development of the volatilization rate constant as discussed in Smith et al. (Ref. 19). This value is very important for aquatic environmental modeling efforts that the Agency may use for helping to elucidate the fate of cumene in different aquatic systems. However, these tests may be combined as long as the results of the two separate tests are not compromised.

III. Final Test Rule for Cumene

A. Findings

EPA is basing the final health effects, environmental effects, and chemical fate testing requirements for cumene on the authority of section 4(a)(1)(B) of TSCA.

EPA finds that cumene is produced in substantial quantities and that it enters the environment in substantial quantities, with the potential for resulting substantial human exposure to cumene, from its manufacture, processing, use, and disposal. The available data on cumene, discussed in Unit II. of this preamble and in Unit II. of the preamble to the proposed rule (50 FR 46104), shows that U.S. production of cumene in 1984 was reported to be 3.35 billion pounds, and an additional 339 million pounds was imported. Approximately 95 percent of the cumene manufactured and imported is used in the production of phenol and acetone. The remaining 5 percent is primarily exported and a small amount is also used in the production of alpha-methylstyrene and as a high-octane component in aviation fuel. The number of workers that are known to be exposed to cumene during its manufacturing and processing is between 700 and 800. The fugitive emissions of cumene to the atmosphere from manufacturing, processing, and use activities are estimated to be 3 million pounds per year. Although this amount is only approximately one-fifth the estimated atmospheric release of cumene from land transportation vehicles in the U.S., the industrial releases of cumene are concentrated in a few large metropolitan areas where the majority of cumene manufacturing and processing facilities are located and are predicted to be the more significant source of exposures to the general population living in the vicinity of these facilities. Approximately 13.5 million people live in the vicinity of cumene manufacturing and processing facilities. The releases of cumene to the aquatic environment are expected as a result of cumene-bearing wastewater discharged from cumene manufacturing and processing facilities.

EPA finds that there are insuffici data to reasonably determine or p the pharmacokinetic, subchronic, developmental, neurotoxic and reproductive effects of human exposure to cumene resulting from the manufacture, processing, use, and disposal of the chemical. Furthermore, there are insufficient data to reasonably determine or predict the biodegradation and volatilization of cumene in aquatic systems and the acute and chronic toxicity of cumene to saltwater and freshwater fish and invertebrates resulting from the manufacture, processing, use, and disposal of the chemical substance. EPA finds that testing of cumene is necessary to develop such data. EPA believes that the data generated from this testing will be relevant to a determination as to whether the manufacture, processing, use, and disposal of cumene does or does not present an unreasonable risk of injury to human health or to the environment.

B. Required Testing and Test Standards

On the basis of these findings, the Agency is requiring that health effects, environmental effects, and chemical fate testing be conducted for cumene in accordance with specific test guidelines set forth in 40 CFR Parts 795, 797, and 798, or other published test methods specified in this test rule as enumerated in the following Table.

TABLE—REQUIRED TESTING, TEST STANDARDS, AND REPORTING REQUIREMENTS FOR CUMENE

Test	Test standard (40 CFR citation)	Reporting deadline for final report [1]	Number of interim (6-month) reports required
HEALTH EFFECTS TESTS			
1. Oral and inhalation pharmacokinetics	795.230	15	2
2. Subchronic inhalation toxicity	798.2450	15	2
3. Inhalation developmental toxicity	798.4350	15	2
4. Subchronic neurotoxicity:			
Functional observation battery	798.6050	15	2
Motor activity	798.6200	15	2
Neuropathology	798.6400	15	2
5. Two-generation reproductive effects	798.4700	[2] 29	4
ENVIRONMENTAL EFFECTS TESTS			
1. Acute toxicity to *Daphnia magna*	797.1300	12	1
2. Acute toxicity to *Mysidopsis bahia*	797.1930	12	1
3. Acute toxicity to *Salmo gairdneri*	797.1400	12	1
4. Acute toxicity to *Cyprinodon variegatus*	797.1400	12	1
5. Chronic toxicity to *Daphnia magna*	797.1330	[2] 24	1
6. Chronic toxicity to *Mysidopsis bahia*	797.1950	[2] 24	1
7. Early life stage toxicity to *Salmo gairdneri*	797.1600	[2] 24	1
8. Early life stage toxicity to *Cyprinodon variegatus*	797.1600	[2] 24	1
CHEMICAL FATE TESTS			
1. Biodegradation in aquatic system	([3])	12	1
2. Volatilization from aquatic system	([4])	12	1

[1] Number of months after the effective date of the final rule except that the reporting deadline for the reproductive effects test is calculated from the date the test sponsor is notified.
[2] Triggered tests (Required only if the specified triggers are met).
[3] Bourquin, et al.
[4] Smith, et al.

Applicable revisions to these guidelines were proposed in the Federal Register of January 14, 1986 (51 FR 1522), and were promulgated in the Federal Register of May 20, 1987 (50 FR 19056).

1. The health effects tests to be conducted for cumene are: Oral and inhalation comparative pharmacokinetics, using the test guideline at 40 CFR 795.230 as specified in the final rule for 1,2-dichloropropane (52 FR 37138); subchronic inhalation toxicity using the test guideline at 40 CFR 798.2450, and as modified in 40 CFR 799.1285(c)(2)(i)(B); developmental toxicity, using the test guideline at 40 CFR 798.4350 and; neurotoxicity, using the test guidelines specified at 40 CFR 798.6050, 798.6200, and 798.6400. In addition, the Agency is requiring that a reproductive effects study be conducted if the results of the gross or histopathological evaluation of the reproductive tissues in male or female exposed animals from the subchronic exposure test show adverse effects or if significant alteration in reproductive organ weights occur. If the results from the subchronic study indicate adverse reproductive effects or altered organ weights, EPA will hold a public program review prior to requiring the initiation of the two-generation reproductive effects study.

2. Environmental effects tests to be conducted for cumene, in flow-through systems, are: Acute toxicity to the freshwater invertebrate, *Daphnia magna*, using the test guideline at 40 CFR 797.1300; acute toxicity to the saltwater invertebrate, *Mysidopsis bahia*, using the test guideline at 40 CFR 797.1930; acute toxicity to freshwater fish, *Salmo gairdneri*, using the test guideline at 40 CFR 797.1400; acute toxicity to saltwater fish, *Cyprinodon variegatus*, using the test guideline at 40 CFR 797.1400; chronic toxicity to *Daphnia magna* and *Mysidopsis bahia*, using the guidelines specified at 40 CFR 797.1330 and 797.1950, if the results of the acute toxicity tests required for these species show EC_{50} or LC_{50} of less than or equal to 1 mg/L; and early life stage toxicity to *Salmo gairdneri* and *Cyprinodon variegatus*, using the test guidelines at 40 CFR 797.1600, if the results of the acute toxicity tests required for these species show LC_{50} of less than or equal to 1 mg/L.

3. Chemical fate tests to be conducted for cumene are: Biodegradation in an aquatic system, using the Core-Chamber Method described by Bourquin et al. (Ref. 18) and volatilization from an aquatic system, using the method described by Smith et al. (Ref. 19).

The Agency is requiring that the above-referenced TSCA Health Effects and Environmental Effects Test Guidelines and revisions and other cited methods be test standards for the purposes of the required tests for cumene. The TSCA test guidelines for health effects and aquatic toxicity testing specify generally accepted minimum conditions for determining health effects and aquatic organism toxicities for substances like cumene.

The required methods of Bourquin et al. (1977) for investigating the biodegradation rate of cumene in an aquatic system and Smith et al. for investigating the volatilization of cumene from an aquatic system specify generally accepted minimum conditions (Refs. 18 and 19). The Agency believes that these tests methods reflect the current state-of-the-science for testing the fate of chemicals such as cumene in the aquatic system.

C. Test Substance

EPA is requiring that cumene of at least 99 percent purity be used as the test substance. Commercial cumene is generally greater than 99 percent pure. In addition, radiolabeled ^{14}C cumene is required for the pharmacokinetics testing.

D. Persons Required to Test

Section 4(b)(3)(B) specifies that the activities for which EPA makes section 4(a) findings (manufacture, processing, distribution in commerce, use, and/or disposal) determine who bears the responsibility for testing a chemical. Manufacturers and persons who intend to manufacture the chemical are required to test if the findings are based on manufacturing ("manufacture" is defined in section 3(7) of TSCA to include "import"). Processors and persons who intend to process the chemical are required to test if the findings are based on processing. Manufacturers and processors and persons who intend to manufacture and process the chemical are required to test if the exposures giving rise to the potential risk occur during distribution in commerce, use, or disposal of the chemical.

Because EPA has found that there are insufficient data and experience to reasonably determine or predict the effects resulting from manufacture, processing, use, and disposal of cume EPA is requiring that persons who manufacture or process, or who inten to manufacture or process, cumene, other than as an impurity, at any time from the effective date of the final tes rule to the end of the reimbursement period are subject to the testing requirements contained in this final r While EPA has not identified any byproduct manufacturers of cumene, such persons are covered by the requirements of this test rule. The end the reimbursement period will be 5 years after the last final report is submitted or an amount of time equal that which was required to develop data, if more than 5 years after the submission of the last final report required under the test rule.

Because TSCA contains provisions t avoid duplicative testing, not every person subject to this rule must individually conduct testing. Section 4(b)(3)(A) of TSCA provides that EPA may permit two or more manufacturers or processors who are subject to the ru to designate one such person or a qualified third person to conduct the tests and submit data on their behalf. Section 4(c) provides that any person required to test may apply to EPA for a exemption from the requirement. EPA promulgated procedures for applying for TSCA section 4(c) exemptions in 40 CFR Part 790.

Manufacturers (including importers) subject to this rule are required to submit either a letter of intent to perform testing or an exemption application within 30 days after the effective date of the final test rule. The required procedures for submitting such letters and applications are described in 40 CFR Part 790.

Processors subject to this rule, unless they are also manufacturers, will not be required to submit letters of intent or exemption applications, or to conduct testing, unless manufacturers fail to submit notices of intent to test or later fail to sponsor the required tests. The Agency expects that the manufacturers will pass an appropriate portion of the costs of testing on to processors through the pricing of their products or other reimbursement mechanisms. If manufacturers perform all the required tests, processors will be granted exemptions automatically. If manufacturers fail to submit notices of

T9

intent to test or fail to sponsor all the required tests, the Agency will publish a separate notice in the **Federal Register** to notify processors to respond; this procedure is described in 40 CFR Part 790.

EPA is not requiring the submission of equivalence data as a condition for exemption from the required testing for cumene. As noted in Unit III.C., EPA is interested in evaluating the effects attributable to cumene and has specified a relatively pure substance for testing.

Manufacturers and processors subject to this test rule must comply with the test rule development and exemption procedures in 40 CFR Part 790 for single-phase rulemaking.

E. Reporting Requirements

EPA requires that all data developed under this rule be reported in accordance with its TSCA Good Laboratory Practice (GLP) standards, which appear in 40 CFR Part 792.

In accordance with 40 CFR Part 790 under single-phase rulemaking procedures, test sponsors are required to submit individual study plans at least 45 days before initiation of each test.

EPA is required by TSCA section 4(b)(1)(C) to specify the time period during which persons subject to a test rule must submit test data. Specific reporting requirements for each of the required tests are given in Table 1 and are as follows:

1. The oral and inhalation pharmacokinetics study, the subchronic inhalation study, the inhalation developmental toxicity study, and the neurotoxicity studies shall be completed and the final results submitted to EPA within 15 months of the effective date of the final test rule.

2. The two-generation reproductive effects study, if triggered, shall be completed and the final results submitted to EPA within 29 months following notification by EPA that testing has been triggered and is to be initiated.

3. The acute toxicity studies in saltwater and freshwater invertebrates and fish shall be completed and the final results submitted to EPA within 12 months of the effective date of the final test rule.

4. The chronic toxicity studies in saltwater and freshwater invertebrates and early life stage toxicity studies in saltwater and freshwater fish, if triggered, shall be completed and the final results submitted to EPA within 24 months of the effective date of the final test rule.

5. The biodegradation and volatilization studies in aquatic systems shall be completed and the final results submitted to EPA within 12 months of the effective date of the final test rule.

Interim progress reports for each of these studies shall be provided to the Agency at 6 month intervals after the effective date of this rule, or after a test is triggered, until the final report is submitted to EPA.

TSCA section 14(b) governs Agency disclosure of all test data submitted pursuant to section 4 of TSCA. Upon receipt of data required by this rule, the Agency will publish a notice of receipt in the **Federal Register** as required by section 4(d).

Persons who export a chemical which is subject to a section 4 test rule are subject to the export reporting requirements of section 12(b) of TSCA. Final regulations interpreting the requirements of section 12(b) are in 40 CFR Part 707. In brief, as of the effective date of this test rule, an exporter of cumene must report to EPA the first annual export or intended export of cumene to each country. EPA will notify the foreign country concerning the test rule for the chemical.

F. Enforcement Provisions

The Agency considers failure to comply with any aspect of a section 4 rule to be a violation of section 15 of TSCA. Section 15(1) of TSCA makes it unlawful for any person to fail or refuse to comply with any rule or order issued under section 4. Section 15(3) of TSCA makes it unlawful for any person to fail or refuse to: (1) Establish or maintain records, (2) submit reports, notices, or other information, or (3) permit access to or copying of records required by TSCA. Section 15(4) makes it unlawful for any person to fail or refuse to permit entry or inspection as required by TSCA section 11. Section 11 applies to any "* * * establishment, facility, or other premises in which chemical substances or mixtures are manufactured, processed, stored, or held before or after their distribution in commerce * * *." The Agency considers a testing facility to be a place where the chemical is held or stored and, therefore, subject to inspection. Laboratory inspections and data audits will be conducted periodically in accordance with the authority and procedures outlined in TSCA section 11 by duly designated representatives of the EPA for the purpose of determining compliance with the final rule for cumene. These inspections may be conducted for purposes which include verification that testing has begun, schedules are being met, and reports accurately reflect the underlying raw data, interpretations, and evaluations, and to determine compliance with TSCA GLP standards and the test standards established in the rule.

EPA's authority to inspect a testing facility also derives from section 4 of TSCA, which directs EPA to promulgate standards for the development of test data. These standards are defined in section 3(12)(B) of TSCA to include those requirements necessary to assure that data developed under testing rules are reliable and adequate, and to include such other requirements as are necessary to provide such assurance. The Agency maintains that laboratory inspections are necessary to provide this assurance

Violators of TSCA are subject to criminal and civil liability. Persons who submit materially misleading or false information in connection with the requirement of any provision of this rule may be subject to penalties which may be calculated as if they never submitted their data. Under the penalty provisions of section 16 of TSCA, any person who violates section 15 of TSCA could be subject to a civil penalty of up to $25,000 for each violation with each day of operation in violation constituting a separate violation. This provision would apply primarily to manufacturers who fail to submit a letter of intent or an exemption request and continue manufacturing after the deadlines for such submissions. This provision would also apply to processors who fail to submit a letter of intent or an exemption application and continue processing after the Agency has notified them of their obligation to submit such documents (see 40 CFR 790.48(b)). Knowing or willful violations could lead to the imposition of criminal penalties of up to $25,000 for each day of violation and imprisonment for up to 1 year. In determining the amount of penalty, EPA will take into account the seriousness of the violation and the degree of culpability of the violator, as well as all the other factors listed in TSCA section 16. Other remedies are available to EPA under section 17 of TSCA, such as seeking an injunction to restrain violations of TSCA section 4.

Individuals as well as corporations could be subject to enforcement action. Sections 15 and 16 of TSCA apply to "any person" who violates provisions of TSCA. EPA may, at its discretion, proceed against individuals as well as companies themselves. In particular, this includes individuals who report false information or who cause it to be reported. In addition, the submission of false, fictitious, or fraudulent statements is a violation under 18 U.S.C. 1001.

IV. Economic Analysis of Final Rule

To assess the potential economic impact of the rule, EPA has prepared an economic analysis (Ref. 20) that evaluates the potential for significant economic impact on the industry as a result of the required testing. The economic analysis estimates that costs of conducting the required testing and evaluates the potential four significant adverse economic impact as a result of these test costs by examining for market characteristics of cumene: (1) Price sensitivity of demand, (2) industry cost characteristics, (3) industry structure, and (4) market expectations. If there is no indication of adverse effect, no further economic analysis is to be performed; however, if the first level of analysis indicates a potential for significant economic impact, a more comprehensive and detailed analysis is conducted which more precisely predicts the magnitude and distribution of the expected impact.

Total testing costs for the final rule for cumene are estimated to range from $822,148 to $1,157,214. In order to predict the financial decisionmaking practices of manufacturing firms, these costs have been annualized. Annualized costs are compared with annual revenue as an indication of potential impact. The annualized costs represent equivalent constant costs which would have to be recouped each year of the payback period in order to finance the testing expenditure in the first year.

The annualized test costs (using a cost of capital of 7 percent over a period of 15 years) range from $90,264 to $127,051. Based on the 1986 estimated production and import volume for cumene of 4.0 billion pounds, the unit test costs will range from about $0.002 to $0.003 cents per pound. In relation to the selling price of $0.16 per pound for cumene, these costs are equivalent to 0.01 to 0.02 percent of price.

Based on these costs and the uses of cumene, the economic analysis indicates that the potential for significant adverse economic impact as a result of this testing rule is low. This conclusion is based on the following observations:

1. The estimated unit test costs are very low, 0.02 percent of current price in the upper-bound case.
2. The overall demand for cumene appears relatively inelastic.
3. Five of ten manufacturers produce cumene at highly integrated plants where minor cost increases can be dispersed over cumene-derived chemicals.
4. The market expectations for cumene end use products appear favorable.

Refer to the economic analysis support document for a complete discussion of test cost estimation and the potential for economic impact resulting from these costs.

V. Availability of Test Facilities and Personnel

Section 4(b)(1) of TSCA requires EPA to consider "the reasonably foreseeable availability of the facilities and personnel needed to perform the testing required under the rule." Therefore, EPA conducted a study to assess the availability of test facilities and personnel to handle the additional demand for testing services created by section 4 test rules. Copies of the study, Chemical Testing Industry: Profile of Toxicological Testing, can be obtained through the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161 (PB 82-140773) or the docket for this rule. On the basis of this study, the Agency believes that there will be available test facilities and personnel to perform the testing specified in this rule.

EPA has reviewed the availability of contract laboratory facilities to conduct the neurotoxicity testing requirements (Ref. 21) and believes that facilities will be made available for conducting these tests. The laboratory review indicates that few laboratories are currently conducting these tests according to TSCA test guidelines and TSCA GLP standards. However, the barriers faced by testing laboratories to gear up for these tests are not formidable. Laboratories will need to invest in testing equipment and personnel training, but EPA believes that these investments will be recovered as the neurotoxicity testing program under TSCA section 4 continues. EPA's expectations of laboratory availability were borne out under the testing requirements of the C_9 aromatic hydrocarbon fraction test rule at 40 CFR 799.2175. Pursuant to that rule, the manufacturers were able to contract with a laboratory to conduct the testing according to TSCA test guidelines and TSCA GLP standards.

VI. Rulemaking Record

EPA has established a record for this rulemaking proceeding [docket number OPTS-42074A]. This includes:

A. Supporting Documentation

(1) **Federal Register** notices pertaining to this rule consisting of:

(a) Notice containing the ITC designation of cumene to the priority list (49 FR 46931; November 29, 1984).

(b) Rules requiring TSCA section 8(a) and 8(d) reporting on cumene (49 FR 46739; November 28, 1984).

(c) Notice of EPA's proposed test rule on cumene (50 FR 46104; November 6, 1985).

(d) Notice of final rulemaking on data reimbursement (48 FR 31786; July 11, 1983).

(e) Notice of interim final rule on single-phase test rule development and exemption procedures (50 FR 20652; May 17, 1985).

(f) Notice of final rule on TSCA test guidelines (40 CFR Parts 796, 797, and 798; September 27, 1985).

(g) TSCA GLP standards (48 FR 53092; November 29, 1983).

(h) Notice of proposed rule on TSCA test guidelines revisions (51 FR 1522; January 14, 1986).

(i) Notice of final rule revising TSCA test guidelines (52 FR 19056; May 20, 1987).

(2) Communications consisting of:

(a) Written public comments.

(b) Transcript of public meeting.

(c) Summaries of phone conversations.

(3) Reports—published and unpublished factual materials including: Chemical Testing Industry: Profile of Toxicological Testing (October, 1981).

B. References

(1) CMA's Cumene Program Panel. Comments on EPA's Proposed Test Rule for Cumene submitted to Public Information Office, USEPA (February 28, 1986).

(2) Dow Chemical Company. Comments on EPA's proposed pharmacokinetics test submitted to Public Information Office, USEPA (February 13, 1986).

(3) Syracuse Research Corporation. "Response to General Comments on the Oral and Inhalation Pharmacokinetics Tests." Contract No. 68-02-4209 (January 22, 1987).

(4) U.S. Enviornmental Protection Agency. Response to Test Rules Development Branch (TRDB) request on review of SRC response to comments on pharmacokinetics tests. Interagency memorandum to Gary E. Timm, TRDB, from Health and Environmental Review Division (April 10, 1987).

(5) Gulf Oil Products Company. TSCA section 8(e) submission 8EHQ-1184-0536. Cell Transformation (Project No. 84-2131) and Unscheduled DNA Synthesis (Project No. 84-2130) tests of Cumene (November 21, 1984).

(6) CMA's Cumene Program Panel. Results from voluntary mutagenicity testing program submitted to TRDB (1987).

(7) Gulf Oil Products Company. "Micronucleus Test of Cumene," Project No. 84-2129 (May 14, 1985).

(8) Syracuse Research Corporation. "Technical Response to Public Comments: Cumene." Contract No. 68-02-4209 (September 18, 1986).

(9) Syracuse Research Corporation. "Test Rule Support Document: Cumene." Contract No. 68-02-4209 (June 13, 1985).

(10) CMA's Cumene Program Panel. Appendices to the comments on EPA's Proposed Test Rule for Cumene submitted to Public Information Office, USEPA (February 28, 1986).

(11) U.S. Environmental Protection Agency. Exposure to fugitive emissions of cumene. Interagency memorandum to Jennifer Orme, TRDB, from Design and Development Branch (March 29, 1985).

(12) Science Applications International Corporation. Letter from Martin Huppert to Beth Hesse of Dynamac Corporation concerning discharges of cumene to the environment (February 8, 1988).

(13) CMA's Cumene Program Panel. Industrial Hygiene Survey (April 1985).

(14) Senczuk, W. and Litewka, B. "Absorption of cumene through the respiratory tract and excretion of dimethylphenylcarbinol in urine." *British Journal of Industrial Medicine* 33: 100-105 (1976).

(15) Valette, G., and Cavier, R. "Absorption Percutanee et Constitution Chimique: Cas des hydrocarbures des alcools et des estes." *Archives of International Pharmacodynamics* 97: 232-240 (1954).

(16) Robinson, D., Smith, J.N., and Williams, R.T. "Studies in detoxication: the metabolism of alkylbenzenes, isopropylbenzene (cumene) and derivatives of hydrotropic acid." *Biochemical Journal.* 59: 153-159 (1955).

(17) Serebrennikov. O.A., and Ogleznev G.A. "Developmental anomalies in the mother-fetus system following exposure to petrochemical products." *Deposited Document.* 2667-78: 151-152 (1978).

(18) Bourquin, A.W., Hood, M.A., and Garnas, R.L. "An artificial microbial ecosystem for determining effects and fate of toxicants in a salt-marsh environment." *Developments in Industrial Microbiology* 18: 185-191 (1977).

(19) Smith, J.H., Bomberger, D.C., Haynes, D.L. "Prediction of the volatilization of high volatility chemicals from natural water bodies. *Environmental Science & Technology.* 14(11): 1332-1337 (1980).

(20) U.S. Environmental Protection Agency. Economic Impact Analysis of Final Test Rule for Cumene. Washington, DC. Office of Toxic Substances, USEPA (February 29, 1988).

(21) Mathtech, Inc. "Evaluation of TSCA guidelines for neurotoxicity testing: Impact of increased testing requirements." Prepared for Regulatory Impacts Branch, US EPA (April 14, 1987).

The record is available for inspection from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays, in Rm. NE-G004, 401 M St., SW., Washington, DC 20460.

VII. Other Regulatory Requirements

A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a rule is "major" and therefore subject to the requirement of a Regulatory Impact Analysis. EPA has determined that this test rule is not major because it does not meet any of the criteria set forth in section 1(b) of the Order; i.e., it will not have an annual effect on the economy of at least $100 million, will not cause a major increase in costs or prices, and will not have a significant adverse effect on competition or the ability of U.S. enterprise to compete with foreign enterprises.

This rule was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Any written comments from OMB to EPA, and any EPA response to those comments, are included in the rulemaking record.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*, Pub. L. 96-354, September 19, 1980), EPA is certifying that this test rule will not have a significant impact on a substantial number of small businesses because: (1) They are not likely to perform testing themselves, or to participate in the organization of the testing effort; (2) they will experience only very minor costs, if any, in securing exemption from testing requirements; and (3) they are unlikely to be affected by reimbursement requirements.

C. Paperwork Reduction Act

OMB has approved the information collection requirements contained in this final rule under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*, Pub. L. 96-511, December 11, 1980), and has assigned OMB control number 2070-0033.

Public reporting burden for this collection of information is estimated to average 535 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

1. Chief, Information Policy Branch (PM-223), EPA, 401 M St., SW., Washington, DC 20460.

2. Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Washington, DC 20503, (Attn: Desk Officer for EPA).

List of Subjects in 40 CFR Part 799

Testing, Environmental protection, Hazardous substances, Chemicals, Recordkeeping and reporting requirements, Incorporation by reference.

Dated: July 5, 1988.

Victor J. Kimm,

Acting Assistant Administrator for Pesticides and Toxic Substances.

Therefore, 40 CFR Part 799 is amended as follows:

PART 799—[AMENDED]

1. The authority citation for Part 799 continues to read as follows:

Authority: 15 U.S.C. 2603, 2611, 2625.

2. By adding § 799.1285 to read as follows:

§ 799.1285 Cumene.

(a) *Identification of test substance.* (1) Cumene (isopropylbenzene, CAS No. 98-82-8) shall be tested in accordance with this section.

(2) Cumene of at least 99 percent purity shall be used as the test substance.

(b) *Persons required to submit study plans, conduct tests, and submit data.* All persons who manufacture (including import or byproduct manufacture) or process or intend to manufacture or process cumene, other than as an impurity, after September 9, 1988, to the end of the reimbursement period shall submit letters of intent to conduct testing, submit study plans, conduct tests, and submit data, or submit exemption applications, as specified in this section, Subpart A of this part, and Parts 790 and 792 of this chapter for single-phase rulemaking.

(c) *Health effects*—(1) *Oral and inhalation pharmacokinetic test*—(i) *Required testing.* Pharmacokinetic testing using the oral and inhalation routes shall be conducted with cumene in accordance with § 795.230 of this chapter.

(ii) *Reporting requirements.* (A) The pharmacokinetic testing shall be completed and the final report submitted to EPA within 15 months of the effective date of the final rule.

(B) Interim progress reports shall be submitted to EPA at 6-month intervals beginning 6 months after the effective date of the final rule, until the final report is submitted to EPA.

(2) *Subchronic inhalation toxicity*—(i) *Required testing.* (A) A subchronic inhalation toxicity test shall be conducted with cumene in accordance with § 798.2450 of this chapter except for the provisions of paragraphs (d)(1)(iv), (5), (6), (9), (12)(iii), (13)(i), and (e)(3)(iv)(D) of § 798.2450.

(B) For the purpose of this section, the following provisions also apply.

(*1*) *Animal selection—Numbers.* At least 30 animals (15 males and 15

females) shall be used for each test group.

(2) *Exposure conditions.* The animals shall be exposed to the test substance 6 hours per day, 5 days per week for 13 weeks (65 days of exposure).

(3) *Observation of animals.* Animals shall be weighed weekly, and their food and water consumption shall also be measured weekly.

(4) *Gross pathology.* The following additional organs shall be preserved in a suitable medium for future histopathological examination: The vas deferens, the oviducts, and the vagina.

(5) *Histopathology.* The accessory genital organs (epididymis), prostate, seminal vesicles) and the vagina shall be examined histopathologically. In addition, preparations of testicular and associated reproductive organ samples for histology shall follow the recommendations of Lamb and Chapin (1985) under paragraph (f)(1) of this section, or an equivalent procedure, with particular attention directed toward achieving optimal quality in the fixation and embedding, and including an evaluation of the spermatogenic pattern. Spermatid counts shall be performed as described by Johnson et al. (1980) and Blazak et al. (1985) under paragraphs (d) (2) and (3) of this section or an equivalent procedure. Epididymal sperm count and sperm morphology shall also be done.

(6) *Test report—Individual animal data.* The specific test report information shall include "Food and water consumption data."

(ii) *Reporting requirements.* (A) The subchronic toxicity test shall be completed and the final report submitted to EPA within 15 months of the effective date of the final rule.

(B) Interim progress reports shall be submitted to EPA at 6-month intervals beginning 6 months after the effective date of the final rule, until the final report is submitted to EPA.

(3) *Inhalation developmental toxicity*—(i) *Required testing.* An inhalation developmental toxicity test shall be conducted with cumene in accordance with § 798.4350 of this chapter.

(ii) *Reporting requirements.* (A) The inhalation developmental toxicity test shall be completed and the final report submitted to EPA within 15 months of the effective date of the final rule.

(B) Interim progress reports shall be submitted to EPA at 6-month intervals beginning 6 months after the effective date of the final rule, until the final report is submitted to EPA.

(3) *Neurotoxicity*—(i) *Required testing.* (A) Neurotoxicity tests shall be conducted with cumene by inhalation in accordance with §§ 798.6050, 798.6200, and 798.6400 of this chapter. Each test shall be performed for a period of 90 days.

(ii) *Reporting requirements.* (A) The neurotoxicity tests shall be completed and the final reports submitted to EPA within 15 months of the effective date of the final rule.

(B) Interim progress reports for each test shall be submitted to EPA at 6-month intervals beginning 6 months after the effective date of the final rule, until the applicable final report is submitted to EPA.

(5) *Two-generation reproductive effects*—(i) *Required testing.* A two-generation reproductive effects test shall be conducted with cumene in accordance with § 798.4700 of this chapter if either the gross or histopathological evaluation of the reproductive tissues in male or female exposed animals from the subchronic exposure test specified in paragraph (c)(2) of this section shows adverse effects or if significant alteration in reproductive organ weights occurs in the subchronic exposure test which can be related to exposure to cumene. EPA will hold a public program review, following submission of the subchronic toxicity test, to decide whether the two-generation reproductive effects test is to be required. If required, the test should be conducted using the oral route of exposure.

(ii) *Reporting requirements.* (A) The two-generation reproductive effects test shall be completed and the final report submitted to EPA within 29 months following EPA's notification to the test sponsor, through certified letter or **Federal Register** notice, that testing shall be initiated.

(B) Interim progress reports shall be submitted to EPA at 6-month intervals beginning 6 months after the date of EPA's notification to the test sponsor that testing shall be initiated, until the final report is submitted to EPA.

(d) *Environmental effects*—(1) *Aquatic acute toxicity*—(i) *Required testing.* Saltwater and freshwater invertebrate and vertebrate tests, in a flow-through system, shall be conducted with cumene on the following organisms: *Daphnia magna,* to be conducted in accordance with § 797.1300 of this chapter; *Mysidopsis bahia* to be conducted in accordance with § 797.1930 of this chapter; and *Salmo gairdneri* and *Cyprinodon variegatus* to be conducted in accordance with § 797.1400 of this chapter. The total and dissolved (e.g. filtered) concentrations of the test substance shall be measured in each test chamber and the delivery chamber before the test and in each test chamber at 0, 24, and 48 hours (*Daphnia magna*) and 0, 48, and 96 hours (*Mysidopsis bahia, Salmo gairdneri,* and *Cyprinodon variegatus*) to ascertain whether it is in solution.

(ii) *Reporting requirements.* (A) The acute toxicity tests shall be completed and the final reports submitted to EPA within 12 months of the effective date of the final rule.

(B) An interim progress report for each acute test shall be submitted to EPA 6 months after the effective date of the final rule.

(2) *Aquatic chronic toxicity*—(i) *Required testing.* Aquatic chronic toxicity tests, in a flow-through system, shall be conducted with cumene on *Daphnia magna,* in accordance with § 797.1330 of this chapter, and *Mysidopsis bahia,* in accordance with § 797.1950 of this chapter, if the results of the acute toxicity tests conducted for those species under paragraph (d)(1) of this section show EC_{50} or LC_{50} of less than or equal to 1 mg/L. The total and dissolved (e.g. filtered) concentrations of the test substance shall be measured in each test chamber and the delivery chamber before the test and in each test chamber and the delivery chamber at 0, 7, 14, and 21 days to ascertain whether it is in solution.

(ii) *Reporting requirements.* (A) The chronic toxicity tests, if required under paragraph (d)(2)(i) of this section, shall be completed and the final reports submitted to EPA within 24 months of the effective date of the final rule.

(B) An interim progress report for each chronic test shall be submitted to EPA 18 months after the effective date of the final rule.

(3) *Aquatic early life stage toxicity*—(i) *Required testing.* Aquatic early life stage toxicity tests, in a flow-through system, shall be conducted with cumene on *Salmo gairdneri* and *Cyprinodon variegatus,* in accordance with § 797.1600 of this chapter, if the results of the acute toxicity tests conducted for those species under paragraph (d)(1) of this section show LC_{50} of less than or equal to 1 mg/L.

(ii) *Reporting requirements.* (A) The early life stage toxicity tests, if required under paragraph (d)(3) of this section, shall be completed and the final reports submitted to EPA within 24 months of the effective date of the final rule.

(B) An interim progress report for each test shall be submitted to EPA 18 months after the effective date of the final rule.

(e) *Chemical fate*—(1) *Biodegradation*—(i) *Required testing.* Biodegradation testing in an aquatic system shall be conducted with cumene

ccordance with the method cribed in an article by Bourquin et al. itled "An Artificial Microbial system for Determining Effects and f Toxicants in a Salt-Marsh onment," reprinted from Vol. 18 of Society of Industrial Microbiology's *elopments in Industrial robiology*, Chapter 11, 1977, which is orporated by reference. The method vailable for public inspection at the ice of the Federal Register, Rm. 8301, h and L St., NW., Washington, DC 08, and copies may be obtained from EPA TSCA Public Docket Office -793), Rm. G-004 Northeast Mall, 401 St., SW., Washington, DC 20460. This orporation by reference was roved by the Director of the Federal gister in accordance with 5 U.S.C. (a) and 1 CFR Part 51. The method is orporated as it exists on the effective e of this rule and a notice of any nge to the method will be published he **Federal Register.**

ii) *Reporting requirements.* (A) The degradation test in an aquatic system ll be completed and the final report mitted to EPA within 12 months of effective date of the final rule.

B) An interim progress report shall be mitted to EPA 6 months after the ective date of the final rule.

2) *Volatilization*—(i) *Required ting.* A test for volatilization from atic system shall be conducted with ne in accordance with the method cribed in an article by Smith et al. itled "Prediction of the Volatilization tes of High-Volatility Chemicals from tural Water Bodies," published in l. 14, Number 11, of the American emical Society's *Environmental ence & Technology*, 1980, which is orporated by reference. The method available for public inspection at the fice of the Federal Register, Rm. 8301, h and L St., NW., Washington, DC 08, and copies may be obtained from EPA TSCA Public Docket Office -793), Rm. G-004 Northeast Mall, 401 St., SW., Washington, DC 20460. This orporation by reference was proved by the Director of the Federal gister in accordance with 5 U.S.C. 2(a) and 1 CFR Part 51. The method is orported as it exists on the effective te of this rule and a notice of any nge to the method will be published the **Federal Register.**

(ii) *Reporting requirements.* (A) The latilization test in an aquatic system all be completed and the final report bmitted to EPA within 12 months of effective date of the final rule.

(B) An interim progress report shall be bmitted to EPA 6 months after the ective date of the final rule.

(f) *References.* For additional background information, the following references should be consulted:

(1) Lamb, J.C. and Chapin, R.E. "Experimental models of male reproductive toxicology," *Endocrine Toxicology*. Eds. J.A. Thomas, K.S. Korach, J.A. McLachlan. New York, NY: Raven Press, pp. 85–115 (1985).

(2) Johnson, L., Petty, C.S., and Neaves, W.B. "A comparative study of daily sperm production and testicular composition in humans and rats," *Biology of Reproduction*, 22:1233–1243. (1980).

(3) Blazak, W.F., Ernest, T.L., and Stewart, B.E. "Potential indicators of reproductive toxicity: Testicular sperm production and epididymal sperm number, transit time and motility in Fischer 344 rats," *Fundamental and Applied Toxicology*, 5:1097–1103 (1985).

(g) *Effective date.* (1) The effective date of this final rule for cumene is September 9, 1988.

(2) The guidelines and other test methods cited in this section are referenced here as they exist on September 9, 1988.

(Information collection requirements have been approved by the Office of Management and Budget under control number 2070–0033.)

[FR Doc. 88–16752 Filed 7–26–88; 8:45 am]

BILLING CODE 6560–50–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Public Land Order 6685

[AK–932–08–4220–10; A–067673]

Partial Revocation of Public Land Order No. 245 for Selection of Lands by the State of Alaska; Alaska

AGENCY: Bureau of Land Management, Interior.

ACTION: Public Land Order.

SUMMARY: This order revokes a public land order (PLO) insofar as it affects 34.84 of public lands reserved for townsite purposes. The lands are no longer needed for the purpose for which they were withdrawn. This action will also classify the lands as suitable for selection by the State of Alaska, if such lands are otherwise available. If not selected by the State, the lands will become subject to the terms and conditions of PLO No. 5180, as amended, and will remain closed to location for metalliferous minerals until a further opening order is published.

EFFECTIVE DATE: July 27, 1988.

FOR FURTHER INFORMATION CONTACT: Sandra C. Thomas, BLM State Office, 701 C Street, Box 13, Anchorage, Alaska 99513, 907–271–5477.

By virtue of the authority vested in the Secretary of the Interior by section 204 of the Federal Land Policy and Management Act of 1976, 90 Stat. 2751; 43 U.S.C. 1714, and by section 17(d)(1) of the Alaska Native Claims Settlement Act of December 18, 1971, 85 Stat. 708 and 709; 43 U.S.C. 1616(d)(1), it is ordered as follows:

1. Public Land Order No. 245 is hereby revoked insofar as it affects the following described lands:

Moose Pass Townsite

U.S. Survey 2676, lot 9, Block 2; lot 1, Block 3 and Blocks 7 and 8.

The areas described aggregate 34.84 acres.

2. Subject to valid existing rights, the lands described above are hereby classified as suitable for and opened to selection by the State of Alaska under either the Alaska Statehood Act of July 7, 1958, 72 Stat. 339, et seq.; 48 U.S.C. prec. 21, or section 906(b) of the Alaska National Interest Lands Conservation Act of December 2, 1980, 94 Stat. 2437–2438; 43 U.S.C. 1635.

3. As provided by section 6(g) of the Alaska Statehood Act, the State of Alaska is provided a preference right of selection for the lands described above, for a period of ninety-one (91) days from the date of publication of this order, if the lands are otherwise available. Any of the lands described herein that are not selected by the State of Alaska will be subject to the terms and conditions of PLO No. 5180, as amended, and any other individuals of record, and shall remain closed to location for metalliferous mining until a further opening order is published.

July 12, 1988.

J. Steven Griles,

Assistant Secretary of the Interior.

[FR Doc. 88–16910 Filed 7–26–88; 8:45 am]

BILLING CODE 4310–JA–M

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR PART 64

[Docket No. FEMA 6802]

Suspension of Community Eligibility; California, et al.

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Final rule.