40 CFR Part 799

[OPTS-42033B; FRL-2983-8]

Cresols; Testing Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The EPA is issuing a final rule establishing testing requirements under section 4(a) of the Toxic Substances Control Act (TSCA) for manufacturers and processors of cresols. Cresols is a chemical category consisting of three cresol isomers: *ortho*-cresol (CAS No. 95-48-7), *meta*-cresol (CAS No. 108-39-4), and *para*-cresol (CAS No. 106-44-5). The testing requirements include (1) mutagenic effects studies (including tests for chromosomal aberrations, gene mutations, and cellular transformations) on specified cresol isomers, (2) a developmental toxicity study (teratogenicity) with each cresol isomer, and (3) a two-generation reproductive effects study with each cresol isomer.

DATES: In accordance with 40 CFR 23.5 (50 FR 7271; February 21, 1985), this rule shall be promulgated for purposes of judicial review at 1 p.m. eastern ["daylight" or "standard" as appropriate] time on May 12, 1986. This rule shall become effective on June 11, 1986.

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SUPPLEMENTARY INFORMATION: In the Federal Register of July 11, 1983 (48 FR 31812), EPA issued a proposed rule for cresols under section 4(a) of TSCA to require testing of cresols for subchronic toxicity, mutagenicity, carcinogenicity, developmental toxicity (teratogenicity), reproductive effects, neurotoxicity, and skin sensitization. Public comments on the proposed rule have been received and reviewed. EPA is now promulgating a final test rule requiring that manufacturers and processors of cresols test these chemicals for mutagenic effects, developmental toxicity, and reproductive effects. In addition, in its Initial Report (42 FR 55026; October 12, 1977), the Interagency Testing Committee recommended that the cresols be tested not only for health effects, but also for environmental effects. However, EPA has decided not to require environmental effects testing because available information allows

EPA to reasonably predict that exposure of aquatic organisms to cresols should not cause chronic effects. Further, EPA is finalizing only a portion of the testing which was initially proposed. Based on the results of studies conducted in accordance with this rule, a second rule requiring chronic testing of the cresols may be issued later.

I. Introduction

This document is part of the overall implementation of section 4 of the Toxic Substances Control Act (TSCA, Pub. L. 94–469, 90 Stat. 2003 *et seq.* (15 U.S.C. 2601 *et seq.*)); which contains authority for EPA to require development of data on assessing the risks to health and the environment posed by exposure to particular chemical substances or mixtures.

Under section 4(a)(1) of TSCA, EPA must require testing of a chemical substance or mixture to develop health or environmental data if the Administrator finds that:

(A)(i) the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment,

(ii) there are insufficient data and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data; or

(B)(i) a chemical substance or mixture is or will be produced in substantial quantities, and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (II) there is or may be significant or substantial human exposure to such substance or mixture,

(ii) there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data.

EPA uses a weight-of-evidence approach in making a section 4(a)(1)(A)(i) finding in which both exposure and toxicity information are considered to make the finding that the chemical may present an unreasonable risk. For the finding under section 4(a)(1)(B)(i), EPA considers only production, exposure, and release information to determine whether there is or may be substantial release. For the second finding under both sections 4(a)(1) (A) and (B), EPA examines toxicity and fate studies to determine whether existing information is adequate to reasonably determine or predict the effects of human exposure to, or environmental release of, the chemical. In making the third finding, that testing is necessary, EPA considers whether any ongoing testing will satisfy the information needs for the chemical and whether testing that the Agency might require would be capable of developing the necessary information.

For a more complete understanding of the statutory section 4 findings, see EPA's proposals on chloromethane and chlorinated benzenes (45 FR 48510; July 18, 1980) and dichloromethane, nitrobenzene, and 1,1,1-trichloroethane (46 FR 30300; June 5, 1981).

II. Background

A. Profile

Cresols ($CH_3C_6H_4OH$) is a chemical category of three isomers: *ortho*-cresol (CAS No. 95–48–7), *meta*-cresol, (CAS No. 108–39–4), and *para*-cresol (CAS No. 106–44–5). The cresols are available commercially as individual isomers and as isomer mixtures. They are also contained in cresylic acid, a mixture of cresols and other phenolic compounds. U.S. production of cresols and cresylic acid, or "cresylics" in 1984 was about 117.5 million pounds. Of this amount, 40.7 million pounds was *ortho*-cresol, and 76.8 million was all other cresols (Ref. 1). Imports of *ortho*-, *meta*-, *para*-, (*meta*, *para*)-cresol mixtures, and cresylic acid were 14.9 million pounds in 1984 (Ref. 2). Therefore, the total production and imports of cresols and cresylic acid in 1984 was about 132.4 millon pounds.

Cresols are used as wire enamel solvents, automotive cleaners, and organic intermediates in manufacturing phenolic resins and phosphate esters. Additional uses of either individual isomers or mixtures are as follows: in the production of several herbicides and disinfectants; as cleaning compounds, degreasers, and antioxidants; and in ore flotation. The level I Economic Impact Analysis, which accompanied the proposed cresols rule, contains a detailed description of uses and manufacturing processes.

B. ITC Recommendations

The Interagency Testing Committee (ITC) designated cresols for priority consideration in its Initial Report, published in the Federal Register on October 12, 1977 (42 FR 55026). The ITC recommended that the Agency require industry to test cresols for the following health effects: carcinogenicity, mutagenicity, teratogenicity, and other chronic effects. The ITC also recommended testing for environmental effects, specifically chronic effects in fish and other aquatic organisms.

The ITC's recommendations were based on the large volume of cresols produced in the United States. It was estimated in the ITC's report that the U.S. production of cresols in 1975 was about 90 million pounds. The ITC reported an estimated annual environmental release of approximately 45 million pounds. In addition, the ITC was concerned that the wide use of cresols as industrial solvents could lead to substantial occupational exposure. The ITC cited the National Institute for Occupational Safety and Health's (NIOSH) estimates that roughly 2 million workers are exposed to cresols. The ITC also was concerned that cresols are used in many consumer products and that these uses could result in a large consumer and general population exposure.

C. Proposed Rule

EPA issued a proposed rule, published in the Federal Register of July 11, 1983 (48 FR 31812), which would require that cresols be tested for subchronic toxicity, mutagenic effects including chromosomal aberrations, gene mutations, and cellular transformations, carcinogenicity, developmental toxicity, reproductive effects, neurotoxicity, and skin sensitization.

EPA based its proposed testing requirements on the authority of section 4(a)(1)(B) of TSCA. The Agency found that each of the three cresol isomers is manufactured, processed, and used in substantial quantities, and that these uses may result in substantial human exposure. Furthermore, EPA found that between 600,000 and 1.2 million people are exposed to cresols each year via manufacturing, processing, and/or use activities. Finally, EPA found that there was a lack of data from which to reasonably determine or predict the various effects for which testing was proposed and that testing was necessary to develop such data.

In addition, EPA found that there is evidence of potential adverse human health risks for mutagenic and carcinogenic effects resulting from the manufacture, processing, and use activities associated with cresols. However, the existing data which support this belief of potential risk for these effects were found to be inadequate to reasonably predict or determine the effects of these exposures to cresols. Therefore, in its proposed rule EPA determined that the testing of

cresols for mutagenicity and carcinogenicity can also be based upon section 4(a)(1)(A) of TSCA. EPA also found that it is necessary to develop such data.

In the proposed rule, EPA also presented its reasons for not proposing testing for environmental effects. While the release of cresols to the environment is high, the Agency has determined that adequate information exists which allows EPA to reasonably predict that exposure to cresols should not cause adverse chronic effects to aquatic species. The Agency made a preliminary judgment that no additional environmental effects testing is needed at this time and requested public comments from interested parties on this decision.

D. Studies Received or Intitiated After Proposed Rule

The proposed cresols test rule specified that *meta-* and *para*-cresol be tested in the sister chromatid exchange (SCE) assay to determine the potential for gene mutations. Testing of the *ortho*-cresol isomer was not required because of the availability of an adequately conducted SCE assay on that isomer. However, following publication of the proposed test rule, the Chemical Industry Institute of Toxicology conducted experiments to determine the genotoxic potential of *ortho-*, *meta-*, and *para*-cresol, both *in vitro* and *in vivo*, using the SCE assay as a measure of genotoxicity (Ref. 3).

The Agency has reviewed this study and has found it adequate to meet the needs of the Agency for this proposed testing requirement (Ref. 4). Therefore, the proposed requirement for *meta-* and *para*-cresol to be tested in an SCE assay is not included in this final test rule for cresols.

In addition, a major development in another EPA program has altered the makeup of the final cresols test rule.

The Resource Conservation and Recovery Act (RCRA), as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA), requires that appropriate treatment standards must be met prior to land disposal of hazardous wastes containing cited chemical substance (Ref. 5).

The effect of the 1984 amendments is to establish a statutory presumption against land disposal of hazardous wastes. The amendments further provide that statutory bans on land disposal will go into effect on specific dates unless EPA determines on a case-by-case basis that land disposal is protective of human health and the environment or, prior to land disposal, wastes have been treated to a level or by a method such that threats to human health or the environment are minimized.

In order to make such a determination, EPA is developing treatment standards for wastes, based on technology levels and screening levels for chemical constituents of wastes. Wastes will be prohibited from land disposal, unless the appropriate treatment standards have been observed. To develop these screening levels, EPA requires information on the toxicological effects and the environmental fate of the chemical substances contained in wastes subject to regulation under RCRA.

The chemicals involved have been placed on a prioritized schedule for consideration and analysis of the available data on each chemical. For the majority of substances subject to the HSWA, EPA found sufficient data on which to base standards. However, for some substances either insufficient information is available to establish these screening levels, or, while there may be sufficient information to establish such standards, confirmatory or supporting information is needed to verify any assumptions the Agency may have made in developing these standards.

Cresols are constituents of wastes for which treatment standards must be set by November 8, 1986. Following a review by the Agency, it was determined that insufficient reliable information was available for cresols. As a result either EPA must obtain usable data in order to set an appropriate toxicity reference dose (RfD), or certain wasts containing cresols would be banned as of November 8, 1986 from all land disposal.

The subchronic toxicity studies included in EPA's proposed test rule for cresols would provide the initial data needed to establish RfDs for the cresols. However, the Agency concluded that this rulemaking to require this testing (which has been proposed under the former two-phase test rule process) could not be completed in time to obtain data within the schedule imposed by the HSWA. Therefore, EPA has initiated subchronic toxicity studies for each of the three cresol isomers and OTS will not include such testing in the final cresols test rule.

The proposed cresols test also included requirements that neurotoxicity tests be performed in conjunction with the subchronic studies. The neurotoxicity testing also will be conducted by EPA because of the efficiency of performing such tests jointly with the subchronic studies. Therefore, EPA will conduct neuropathology studies on the individual cresol isomers and an expanded clinical observation of the test animals during the 90-day subchronic study.

In summary, the following tests in the proposed test rule for cresols have either been adequately peformed or are in the process of being performed, and they meet the needs of the Agency for these testing requirements and are not included in the final test rule for cresols: sister chromatid exchange assays on *meta-* and *para*-cresol; 90-day subchronic toxicity studies on *ortho-*, *meta-*, and *para*-cresol; and neuropathology on *ortho-*, *meta-*, and *para*-cresol.

Finally, the National Toxicology Program (NTP) is considering certain health effects testing of cresols. NTP is planning to conduct range-finding and subchronic studies and may initiate bioassays on one or more cresol isomers.

III. Response to Public Comments

The comments received by the Agency in response to the proposed rule for cresols were from the Cresols Task Force (CTF), Natural Resources Defense Council (NRDC), Chemical Manufacturers Association (CMA), Sherwin-Williams, Merichem, Ciba-Geigy, and the American Industrial Health Council (AIHC). The comments from the organizations mentioned above were received in October 1983. Since that time some of the affiliations of the commenters have changed. In May 1984, the CMA established a Cresols Program Panel to address EPA's Section 4 activities on cresols. The Panel consists of the major U.S. manufacturers and importers of cresols and is a refashioning of the CTF. In addition, Sherwin-Williams sold its *para*-cresol production facility to PMC Specialties Group, a subsidiary of PMC of Sun Valley, California (Ref. 6). For this document the commenters will continue to be referred to as the CMA, CTF, and Sherwin-Williams.

The most extensive comments received were those of the CTF. In general, the CTF's comments encompass most of the other significant comments received from other interested parties. Because the CTF submission includes the same subject areas covered by other commenters, EPA will direct the majority of its responses to the CTF submission.

The Agency did not receive any comments which in the Agency's judgment rebutted the substantial production and substantial human findings for cresols. The major issues

identified during the comment period are discussed below.

A. Comments on Exposure Issues

1. *Substantial production.* Several of the commenters stated that the cresols industry has seen a decline in manufacturing and sales, and that it is a mature chemical industry. However, none of the commenters volunteered any revised production estimates.

In the proposed test rule EPA estimated that the annual U.S. production volume was 169 million pounds, with another 17 million pounds imported into the United States each year. The most current EPA estimate is that in 1984 the production and imports of cresols and cresylic acid totalled approximately 132.4 million pounds (Ref. 6). The Agency believes that regardless of whether the total annual production and importation of cresols is 132.4 or 186 million pounds, these estimates still support a finding under section 4(a)(1)(B) of substantial production.

2. *Substantial human exposure.* The CTF, Sherwin-Williams, and Merichem commented that the Agency does not have a basis for the finding of substantial human exposure. They contend that EPA has overestimated the number of people who are exposed to cresols in the workplace and that EPA did not consider the following: whether or not the exposure to cresols is significant, the long history of cresol manufacture and use without any reports of chronic toxicity, the fact that cresols occur naturally in the human body, and that cresols do not occur in any consumer product.

EPA estimated in the proposed rule that between 687,000 and 1.2 million people are potentially exposed to cresols. Human exposure to cresols may occur in facilities which manufacture and process cresols and from the use of products which contain cresols. These exposure estimates made by EPA are intended to represent the upper (1.2 million people) and lower (687,000 people) bound estimates of the total number of persons exposed to cresols. The lower bound estimate was established using data provided by the CTF and Conoco. The upper bound estimate was based on data from the National Occupational Hazard Survey (NOHS) conducted in 1972–74.

The CTF commented that EPA's exposure estimates are inflated. The CTF presented a revised estimate of 126,000 people exposed. The Task Force conducted an analysis of the NOHS exposure estimate and concluded that the NOHS data support an upper-bound actual exposure of 126,000 people or 10 percent of the NOHS estimate (Ref. 7). The CTF also concluded that the NIOSH survey was inaccurate and based on production and use information which was out of date.

The CTF commented that EPA's estimate that 627,000 people are exposed to cresols from the use of cresols in cleaning compounds is also too high. As a result of this belief, the CTF commissioned an occupational survey on this use which, according to the CTF, shows that exposures from this use are very low. The survey was conducted for the CTF by the Johns Hopkins University School of Hygiene and Public Health. The Johns Hopkins report, on the basis of a survey of the Baltimore, Maryland, area estimates that nationwide there are approximately 148,000 mechanics exposed to cresol-containing cleaning compounds (Ref. 7).

The CTF also conducted an analysis of the NOHS estimates based on printouts of the underlying data obtained from NIOSH. According to the CTF's analysis of the data, the NOHS estimates of 1.2 million people exposed to cresols is overstated by a factor of at least 10. The Task Force analysis concentrated on the 14 percent of the NOHS estimate derived from 33,063 actual and tradename observations. The CTF criticized the accuracy of the NOHS numbers. It stated that a portion of the NOHS figures was based on products that may or may not contain cresols and some in which cresols are not used. As a result of its review of the NOHS survey, CTR concluded that the upper-bound limit of actual exposure is 126,000 people.

In addition, the occupational survey conducted by Johns Hopkins for the CTF only evaluates one user group, i.e., automobile mechanics exposed to cresol-containing cleaning compounds. In this survey, the estimates of workers exposed was 148,000. This estimate for only one user group is higher than the CTF's estimate for the total exposure based on CTF's analysis of the 1972–1974 NOHS survey. It is reasonable to assume that if 148,00 workers are estimated to be exposed during one use practice, then a much larger number of people would be exposed if all of the other uses for cresols were considered collectively.

Furthermore, the industry comments pointed out that cresols are not found in any end-use consumer products, but only in industrial products. EPA is aware of this; however, the uses in the automobile industry and wire enamel market and the use of cresols in strippers, cleaners, and degreases are such that substantial numbers of people are potentially exposed at the workplace.

In 1978, Conoco Chemicals Co. estimated the number of workers potentially exposed to cresols in truck and automobile cleaning compounds (Ref. 8). Based on upperbound estimates of 1978 market penetration of cresols-based cleaners, Conoco estimated that 627,000 mechanics may be exposed to cresols in these products. This use involves using cresol-based cleaning compounds in a tank-dipping process used to clean large items, usually automobile carburetors. While this use is still very substantial and results in high occupational exposure, the cresols industry emphasizes that new techniques have been developed which have minimized the exposure during this particular use practice. A new dipping product called an immersion cleaner, manufactured by Safety Kleen Corp., now used in garages is essentially enclosed and results in limited exposure. This method contracts with the open tank dipping used in the past. The industry contends that this new process has roughly half of the market for cresol-based cleaning compounds.

However, even if Conoco's 1978 estimate were halved, the resulting exposure estimates would still be over 300,000 people potentially exposed during this use practice.

In conclusion, EPA agrees with the industry comments on the cresols proposed rule that the estimate of 600,000 to 1.2 million people exposed is overstated. However, if EPA accepts the industry-generated estimate of 126,000 people exposed during manufacturing and processing and the estimate of 300,000 people, which is half of Conoco's original 1978 estimate, approximately 126,000 to 300,000 individuals exposed to cresols in the workplace results. The Agency believes that this estimate still satisfactorily meets the exposure criteria needed to permit it to make a section 4(a)(1)(B) finding, i.e., the chemical is produced in substantial quantities which may result in substantial human exposure.

3. *Inadvertant exposure.* The CTF commented that cresols are found in the human intestine as a natural product of the metabolism of tyrosine, which is one of the amino acids present in the body's protein. It further contends that cresols are ubiquitous in the natural environment and that industrial releases of cresols are minor when compared to the estimated annual volume released by natural sources. The Task Force suggests that these factors undermine the validity of an exposure-based finding under TSCA section 4(a)(1)(B).

However, it is only *para*-cresol which naturally occurs in the human body. The

CTF also has ignored the relationship between cumulative multimedia exposure and threshold toxicity levels. Total exposure, intake, and subsequent uptake of a chemical must be considered from all sources. Total additive uptake must be analyzed in terms of dose/response relationships and threshold toxic levels for chronic and acute toxic effects. Natural occurrence does not negate the effect of higher anthropogenic or cumulative exposures eliciting toxic responses. Therefore, a risk assessment or an assessment for further testing must consider cumulative multimedia exposure. The Agency believes that any additional exposure to cresols may be cause for concern, presenting an additive effect, i.e., increased burden, on the body. An added loading of *para*-cresol may possibly present a cumulative exposure and therefore an unknown risk. The Agency has determined that this risk should be investigated.

4. *Levels of exposure.* The CTF, Merichem, and Sherwin-Williams all included comments in their submissions which concerned the levels of the cresols to which people are potentially exposed. All of the comments, in one way or another, stated that any exposures that may occur are so low that there is not cause for undue concern. The CTF states that "* * * 8-hour exposures of as high as 1 ppm are sustained only by a very few of the most highly exposed workers in cresols manufacturing facilities" (Ref. 7). However, it is also the workers who are exposed for long periods of time at low exposure levels with whom the Agency is concerned. Little information is known on the health risks associated with this type of exposure profile. Even though the industry commented that no chronic health problems have been noted among persons exposed to cresols in the past, there have been no studies, either clinical health or epidemiological, which prove or disprove this premise. Therefore, in order to reasonably determine or predict the risks to workers who are exposed to cresols for a few hours a day over several years, the Agency believes that chronic and other health effects information are needed.

B. Comments on Persons Subject to Testing

1. *Producers of synthetic cresols.* The Sherwin-Williams Co. commented that since it is reported to be the only domestic producer of *para*-cresol, used only in products where the *para*-cresol is consumed in the manufacturing process, it should not be subject to the final rule for cresols. It contends that the Agency cannot support a finding of substantial human exposure for *para*-cresol.

The Agency's finding of substantial occupational exposure to cresols is based on potential widespread exposures both to the individual isomers and to countless mixtures. Cresols are sold commercially in varying mixtures of the three isomers, two isomers, and single isomer, in combination with many other chemical components. Potential exposures in the workplace are to all three of the isomers as constituents of those mixtures, as well as to the pure isomers. *Para*-cresol is a component of those mixtures and hence, a component of the industrial products in which the cresol mixtures are used. It is on this basis that *para*-cresol manufacturers are subject to this rule.

Furthermore, it is the Agency's opinion that Sherwin-Williams manufactures *para*-cresol in substantial quantities and that the potential for widespread occupational exposure during the manufacturing, distribution, loading, shipping, sampling, processing, and/or disposal of *para*-cresol is high.

Therefore, the Agency does not agree with Sherwin-Williams and has determined that Sherwin-Williams is a manufacturer of cresols as defined under sections 3 and 4 of TSCA. The Agency has made no differentiation between different methods of cresols production.

2. *Processors of cresols.* The Ciba-Geigy Co. comments addressed the role of cresols processors in the conduct of and reimbursement for tests required in the final rule. Ciba-Geigy believes that all processors should be exempt from conducting tests and sharing costs. Further, it stated that if processors are to be included, then the processors should be divided into two groups, those who use cresols as raw material to form totally different chemical products and those "* * * who merely [mix] them and [pass] the resulting formulations on to a wider public" * * * "Ciba-Geigy recommends that processors who use cresols solely as raw materials to form new chemical products be exempt from the burden of testing and/or data reimbursement" (Ref. 9).

EPA does not agree that it should differentiate between types of processors in the section 4 test rule process. The definition of "process" in section 3(10) and the language of section 4(b)(3)(B) do not make a distinction such that the responsibilities of the two types of processors (as described by Ciba-Geigy) should differ in any way. Ciba-Geigy is a processor as defined under section of TSCA because it prepares cresols, after its manufacture, for distribution in commerce. However, under EPA's section 4 procedural rule (50 FR 20652) processors would be required to perform testing or be subject to reimbursement only if manufacturers fail to perform testing (See Units IVD and E).

C. Comments on the Economic Impact of the Cresols Test Rule

Several of the public comments submitted in response to the cresols proposed test rule addressed the adverse economic impact which the test rule would have on the cresols industry. The industry comments generally focused on a belief that EPA had underestimated the costs of testing and on an analysis of the price sensitivity of and competition within the cresol marketplace. They contended that the cresols industry is a mature chemical industry which has seen declining sales in recent years. In addition, they argued that EPA severely underestimated the real economic effects of the proposed test rule and that the testing costs on an annualized unit cost basis are not minor, as the Agency stated, but would impact heavily on the industry.

When the proposed cresols test rule was published (July 1983) the Agency's economic analysis was based on the best available information. The Agency attempted to factor in all of the variables which must be considered in conducting an economic assessment of one market of the vast chemical industry. As a result of both industry comments on the proposed rule and the Agency's independent acknowledgment that the economic variables within the cresols industry had changed, EPA conducted a supplemental economic analysis of the proposed cresol test rule program (Ref. 10).

This supplemental report factored in revised test costs and new economic data including more detailed and current information on the affected industry. The conclusions reached in the Agency's revised economic analysis indicate that the potential for adverse economic effects on the cresols-producing industry due to the estimated testing costs contained in the proposed rule was high. Therefore, the Agency is in general agreement with most of the comments about the economic impact of the proposed cresols test rule.

TSCA only requires that EPA acknowledge the existence of a potential economic impact [(TSCA sections 2 (b)(3) and (c), 4(B)(1)(C), and 24(a)(1))], not necessarily take any action because of it. However, the Agency believes that an alternative testing approach can mitigate the

adverse economic impact and also obtain the health effects data which the Agency has determined are necessary. This alternative approach is adopted in this final cresols test rule.

Cresols testing will be conducted in two tiers. At this time, selected mutagenicity tests, developmental toxicity studies, and reproductive effects studies will be finalized in this rule. At the conclusion of all of the testing required in the first test rule there will be an Agency decision point at which time a review of the collective data on cresols will occur. This collective data will include, but not be limited to, the tests finalized in this rule, as well as any health effects testing conducted by EPA and NTP.

At the same time, the Agency will publish in the Federal Register, notification that the testing required in the first cresol test rule has been completed and that the Agency has received all of the data. The Federal Register notice will announce the opening of a short public comment period during which time interested parties can review the data and submit comments as to what, if any, additional testing should be required for cresols. This review will determine the scope of any additional higher-tier testing and the chemical substance(s) which should be tested.

Following that decision, EPA may promulgate a second final test rule which could include 2-year oncogenicity bioassay(s) and upper-tier mutagenicity assay(s) on *ortho*-cresol, *meta*-cresol, and/or *para*-cresol. In addition, neurotoxicity testing may be included in the second final test rule for cresols.

As explained in unit II.D. of this document, EPA is conducting 90-day subchronic toxicity studies for each of the cresol isomers and has included in this testing expanded clinical observations of neurobehavioral characteristics and neuropathological examinations. Therefore, the remaining two neurotoxicity studies initially proposed for cresols, i.e., the functional observation battery and motor activity test, will not be conducted in the first final test rule.

However, if the results of the subchronic and neurotoxicity studies conducted by EPA indicate that the effect of cresols on neurobehavior and neuromotor function is a potential concern, then these two assays will be finalized as part of the second final rule for cresols. In the second final rule, if one is warranted, the neurotoxicity testing could be added to any oncogenicity bioassay as a satellite dose group.

Therefore, the upper-tier definitive health effects studies (oncogenicity and mutagenicity) and neurotoxicity studies (functional observation and motor activity) which have alredy been set forth in the proposed cresols rule (July 11, 1983; 48 FR 31812), will continue in a proposed status to be finalized at a later date should the Agency determine that a second final test rule is necessary to sufficiently characterize the health effects concerns of cresols.

EPA believes that this phased approach to the testing required in the proposed cresols test rule is warranted because it will reduce the possibility of adverse economic impact on the cresols industry resulting from the proposed cresols test rule. Further, and most importantly, the Agency believes that the health effects testing which was initially proposed in the cresols proposed rule will ultimately be fully addressed in this tiered test rule approach (See Unit V for Economic Impact of Final Rule).

D. Comments on Health Effects Testing

1. *Route of administration of test substance.* The proposed test rule required that inhalation be the route of administration of the test substance in the health effects studies (subchronic toxicity, oncogenicity, two-generation reproductive effects) for cresols. The CTF comments recommended that this be reconsidered by the Agency and that ingestion rather than inhalation be used. The cresols manufacturers contend that existing acute data, using oral, dermal, and inhalation routes, do not indicate that cresols induce any unique toxicity by the inhalation route. Further, CTF contends that existing data on cresols indicate that the target organs are systemic (CNS, liver, kidney) and that these organs are targets regardless of the route of administration of the test substance. It is the commenters' conjecture that EPA is, or should be, interested in systemic effects from long-term, low level exposures, and that these effects will be picked up in the animal testing regardless of the route of exposure.

The Agency has considered the CTF comments. While the Agency does not necessarily agree with all of the scientific rationale given by the CTF for altering the route of administration, EPA will allow the change from inhalation to ingestion. EPA believes that the gavage subchronic study being performed by the Agency will give information which will enable the Agency to make the necessary risk evaluations for cresols. Therefore, the Agency agrees to change the route of administration from inhalation to ingestion for the developmental toxicity and reproduction and fertility effects studies.

2. *Test substance.* The CTF commented that the health effects testing should be performed on an equal mixture of the three cresol isomers, i.e., ⅓ *ortho*-cresol, ⅓ *meta-cresol, and* ⅓ *para*-cresol. The industry believes that exposures to workers are more likely to be from a trimeric mixture than from individual isomers. CTF states that the single isomer use of cresol is generally as feedstock in chemical manufacture. However, while these statements are probably the case during the manufacture of cresols, cresols are sold commercially as mixtures of three isomers in a myriad of varying concentrations, mixtures of two isomers, particularly *meta*- and *para*-cresol, as single isomers, and in the commercial product cresylic acid. The Agency believes that widespread exposures are to both individual isomers and countless mixtures. It is because of the production of such a variety of mixtures that the Agency decided to test each isomer separately. There is no "standard" mixture to which people are more predominantly exposed. In addition, the Agency believes that each of the isomers is produced in such substantial quantities that each warrants individual investigations. Finally, the Agency believes that the most useful data will be obtained by using the purest available form of the chemical being studied. Therefore, the Agency disagrees with the industry comments and has determined that the health effects testing will be conducted with specified individual cresol isomers.

3. *Finding of unreasonable risk.* The CTF comments that there is no basis for a finding of potential unreasonable risk under section 4(a)(1)(A) of TSCA for mutagenicity and carcinogenicity. It states that the Agency's finding is only based on questionable and/or flawed studies. Most of the mutagenicity studies in question were conducted for the cresols industry consortium and submitted as a part of their public comments in response to the ITC's initial testing recommendations for cresols (42 FR 55026; October 12, 1977).

The Agency has reviewed the tests and considers that the positive results seen in several of the short-term mutagenicity tests are valid and significant. In addition, the section 4(a)(1)(A) finding of "may present an unreasonable risk" for oncogenicity was based on evidence which suggests that the three cresol isomers have a capacity for promoting the appearance of skin tumors in mice.

However, as explained in unit III. C. of this preamble, the Agency is not requiring oncogenic testing for cresols at this time. However, a finding of potential unreasonable risk for mutagenic effects remains a valid basis for the mutagenicity testing required in this rule.

4. *Neurotoxicity testing.* The CTF commented on the neurotoxicity tests which were proposed in the cresols rule. While CTF apparently agreed with the need for some neurotoxicity testing, it questioned the choice of tests. In addition, it stated that a general screening procedure should be conducted before considering chronic low-level neurotoxicity testing. The most critical of the specific comments had to do with "weak basis" for requiring testing and the inappropriateness of neurotoxicity testing as standard operating procedure for these types of chemicals.

The Agency agrees with the CTF that neurotoxicity testing should begin with a screen, and that was the approach the Agency proposed in the test rule. The proposed testing is the neurotoxicity screening procedure. It is the Agency's general policy in implementing TSCA section 4 to require these three neurotoxicity tests, i.e., neuropathology, motor activity, and functional observation battery, in test rules based on a finding of substantial production and exposure.

However, because EPA is conducting a portion of the proposed neurotoxicity studies, EPA is not requiring that any neurotoxicity studies be performed in this final rule (see units II.D. and III.C. of this document). However, based on the results of the neurotoxicity evaluations conducted by EPA, the Agency may require that the functional observation battery and motor activity evaluations, which were proposed for cresols, be included in the second final test rule.

5. *Tiered mutagenicity scheme.* The CTF, CMA, AIHC, and NRDC submitted comments on the proposed mutagenicity testing requirements for cresols. Some of the issues covered were related to the choice of tests, the automatic triggers to higher level mutagenicity tests and oncogenicity testing, and mutagenicity as a regulatable endpoint. The Agency's response to a variety of public comments on this approach, the test sequences, and the assays (and triggers for oncogenicity testing) contained within them may be found in the final Phase I test rule for the C_9 aromatic hydrocarbon fraction (C_9) (50 FR 20662; May 17, 1985) and the final Phase I test rule for mesityl oxide (MO) (50 FR 51857; December 20, 1985).

A. *Automatic triggers for chronic oncogenicity bioassay.* As discussed in the final Phase I test rules for C_9 and MO, the Agency believes that the use of sequences of tiered tests for mutagenicity testing and the use of automatic triggers to require chronic oncogenicity bioassays based on the results of certain mutagenicity assays are consistent with both current scientific knowledge and the regulatory approach to chemical testing established under section 4 of TSCA. Existing data show a strong correlation between positive results in certain mutagenicity tests and positive results in animal chronic oncogenicity bioassays for a large number of substances tested in both types of systems. Thus, positive results in one or more of these mutagenicity assays provide a basis for concluding that the substance may be an oncogen and, in conjuction with evidence of both an active chemical structure and the potential for human exposure to the substance, that such exposure may present an unreasonable risk of oncogenicity. If all of these mutagenicity tests yield negative results, the likelihood of the specified chemical being oncogenic is small and the chronic bioassay will not be required. Conversely, if any one of these trigger tests is positive, potential oncogenicity of a chemical is suggested and a chronic bioassay is essential to confirm or deny that potential and provide a basis for judging what oncogenic risk exposure to the specific chemical may present.

However, in view of the potential adverse economic impact of the proposed cresols rule on the cresols-producing industry (see unit III. C. of this preamble), the Agency has altered its approach in the final cresols test rule. Because EPA is now using a two-tiered test rule, there are no longer automatic triggers to the oncogenicity bioassays or upper-tier mutagenicity assays, i.e., mouse specific locus assay and heritable translocation assay. These higher-tier, more definitive tests will not be addressed in this document. A second test rule may require 2-year bioassay(s) and upper-tier mutagenicity assay(s), as well as possible neurotoxicity testing.

b. *Mutagenicity as a regulatable endpoint.* While the industry commenters agreed that appropriate mutagenicity assays can be used for assessing carcinogenic potential, they objected to the use of the more elaborate tests to assess mutagenic risk as a separate endpoint. They objected to EPA's apparent use of rigid inflexible testing schemes in favor of a tiered approach to permit informed scientific judgment.

The sequence of tiered tests employed by EPA in assessing the mutagenic potential of chemical substances, which are required in this final Phase I test rule for specific cresol isomers, were previously described in the proposed test rule issued by the Agency for cresols (48 FR 31812; July 11, 1983), and are more completely described in the final Phase I test rule for C_9 and MO. Although these general test sequences are usually employed, the Agency ultimately specifies the required mutagenicity test for each specific chemical substance on a case-by-case basis. In the case of the cresol isomers, many of the isomers have already been tested in several mutagenicity assays. The cresols mutagenicity scheme has been designed so that only selected isomers will be tested in specific test systems.

The Agency feels that there is a consensus in the scientific community on the need for identifying mammalian mutagens. While it is recognized that there is, as yet, no generally accepted single methodology for estimating human risk from mutagenic agents, it is the Agency's view that appropriate methodologies for testing do exist and are valid. Therefore, the Agency concludes that it is appropriate at this time to obtain mutagenicity data on cresols to determine whether additional upper-tier mutagenicity assays, i.e., mouse specific locus and/or heritable translocations, are necessary for one or more of the three cresol isomers. Any additional mutagenicity testing will be required in a subsequent final rule for cresols.

Even though the upper-tier mutagenicity tests and the 2-year bioassays will not be automatically triggered as a result of first and second tiers of mutagenicity testing, the first and second tiers will remain as proposed, except for the deletion of the SCE assays as discussed in Unit II.D. of this preamble. EPA believes the use of automatic triggers between these first tiers is suitable. It should be noted that this does not exclude the public from requesting modification in the test program. Provisions are available under section 21 of TSCA for the public to petition EPA at any time to amend a rule under section 4.

6. *Other health effects testing issues.* In the cresols proposed rule, the Agency included testing each cresol isomer for skin sensitization. The purpose of this evaluation is to identify the effects, and hence possible hazard, to a population repeatedly exposed to a test substance.

After reflecting upon the inclusion of this test in the proposed rule, EPA has

decided to delete the skin sensitization study from the final cresols rule. The Agency has determined that because of the highly corrosive nature of cresols to the skin, little additional useful information would be derived from conducting a sensitization study with cresols.

E. Comments on Environmental Effects Testing

The ITC recommended that cresols be tested for chronic effects in fish and other aquatic organisms. The Agency believes that there is substantial release and exposure to the environment by cresols. However, the Agency made a preliminary decision in the proposed test rule and concluded that there is sufficient information to reasonably predict that cresols do not pose a chronic aquatic toxicity hazard. This information includes ambient concentrations predicted through computer models, a large quantity of acute toxicity data, monitoring data, and known bioconcentration, biodegradation, and persistence values. The Agency acknowledges that there is no existing chronic toxicity data for cresols, but believes that this combined information allows EPA to reasonably predict whether or not exposure of aquatic organisms to cresols should cause chronic effects.

However, EPA was aware that the information on which the Agency made its preliminary decisions is open to many different interpretations. For this reason, EPA specifically requested in the cresols rule that interested parties submit comments on this issue.

The Agency received comments from both NRDC and CTF. NRDC commented that enough consideration was not given "* * * to possible subtle or chronic ecological consequences of discharges during lapses of treatment or to discharges into other bodies of water." In addition, NRDC was concerned that "* * * cresols are acidic compounds and could affect the chemistry of sensitive locales when discharged in large quantities." Therefore, NRDC states that environmental effects testing should be initiated for cresols.

EPA, in response to NRDC's comments, re-reviewed all of the information from which it made the preliminary decision not to test cresols for environmental effects. The Agency believes that the environmental effects data and analyses which exist for cresols are adequate to permit the Agency to make an evaluation of any potential chronic effects which might result from exposure to cresols. The information on which the Agency bases its decision not to require environmental effects testing is extensive, and when properly analyzed and interpreted, can provide information on the potential of a chemical to cause chronic effects. Further, all of the available acute, monitoring, and modeling data, in conjunction with data on the transport and fate of the chemical in an aquatic habitat, provide an important segment of the scientific basis for assessing the risk resulting from the release of that chemical into the environment.

The CTF comments support the Agency's preliminary decision on the environmental effects testing. CTF contends that cresols degrade rapidly in the environment and that concentrations of cresols in the water, even under worst-case conditions, would not approach the levels that would pose a chronic aquatic toxicity hazard.

The Agency has reviewed both sets of comments and has found no basis to alter its initial environmental testing decision. Therefore, no additional environmental effects testing on cresols will be required at this time. The Agency believes that substantial information is available to the Agency to enable it to make an assessment of risk for cresols on aquatic organisms. In sections 4(a)(1)(A)(ii) and (B)(ii) of TSCA, the Agency must find that,

> there are insufficient data and experience upon which the effects to the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on * * * the environment can reasonably be determined or predicted.

EPA does not believe that it can make that finding for cresols for environmental effects testing at this time.

F. Comments on Protocol Submission and the Phased Test Rule Process

The NRDC submitted comments concerning the need for requiring validated protocols and recommended modification of the Agency's two-phase test rule process. These comments were considered and addressed in both the final Phase I test rule for the C_9 aromatic hydrocarbon fraction (50 FR 20662, 20666–20667; May 17, 1985) and the final rule on Test Rule Development and Exemption Procedures, published in the Federal Register of October 10, 1984 (49 FR 39774).

EPA shares NRDC's desire that test rules should be completed as rapidly as possible, and the Agency has decided to modify the test rule development process for cresols. Elsewhere in this issue of the Federal Register, EPA is proposing certain TSCA guidelines as the required test standards for cresols. The Agency is also proposing that the test data from each required study be submitted within certain time frames. By taking this action, EPA believes that testing will be initiated more expeditiously than would occur if the normal two-phase process were followed (see Unit IV.E., below).

IV. Final Test Rule for Cresols

A. Findings

EPA is basing the final testing requirements for cresols on the authority of section 4(a)(1)(B) of TSCA. EPA finds that each of the three cresol isomers is manufactured, processed, and used in substantial quantities that may result in substantial human exposure. Furthermore, EPA finds that there are insufficient data available to either reasonably determine or predict the result of this exposure in the areas of mutagenic, developmental toxicity, and reproductive effects. These findings are based on the following information:

1. There are substantial amounts of cresols produced in or imported into the United States each year. It is estimated that production and imports of cresols totalled 132.4 million pounds in 1984.

2. Estimates indicate that between 148,000 and 300,000 people are exposed to cresols each year via manufacturing, processing, and/or use activities.

3. EPA finds that there are insufficient data on all of these cited human health effects from which to reasonably determine or predict the result of exposure to cresols and that testing of cresols for these effects is necessary to develop such data.

4. EPA does not believe that the final rule will result in a loss to society of the benefits of cresols because the Agency's economic evaluation has shown that the economic impact of testing these substances will be minimal.

In addition, EPA has found that (a) there is evidence of potential unreasonable human health risks from mutagenic effects resulting from the manufacture, processing, and use activities associated with cresols, and that while there are existing data which support this belief with respect to these effects, (b) these existing data are inadequate to reasonably predict or determine the effects of these exposures to cresols, and (c) testing is necessary for these effects. Therefore, EPA believes that requiring testing of cresols for mutagenicity can also be based upon section 4(a)(1)(A) of TSCA.

B. Required Testing

EPA is requiring that each of the three cresol isomers, *ortho*-cresol, *meta*-cresol, and *para*-cresol, shall be tested

in the following health effects studies: (1) Mutagenic effects studies (including tests for chromosomal aberrations, gene mutations, and cellular transformations of specified cresol isomers), (2) developmental toxicity, and (3) two-generation reproductive effects studies.

C. Test Substance

EPA is requiring that *ortho*-cresol, *meta*-cresol, and *para*-cresol of at least 99 percent purity be used as the test substances because this grade is readily available and will best allow EPA to assess the hazards presented by the various cresol isomers.

D. Persons Required to Test

Section 4(b)(3)(B) specifies that the activities for which the Agency makes section 4(a) findings (manufacture, processing, distribution, use and/or disposal) determine who bears the responsibility for testing. Manufacturers are required to test if the findings are based on manufacturing ("manufacture" is defined in section 3(7) of TSCA to include "import"). Processors are required to test if the findings are based on processing. Both manufacturers and processors are required to test if the exposures occur during use, distribution, or disposal. Because EPA has found that the manufacturing, processing, use, and distribution in commerce of *ortho*-, *meta*-, and/or *para*-cresol give rise to potential substantial exposures, EPA is proposing that persons who manufacture or process, or who intend to manufacture or process, any of the cresol isomers at any time from the effective date of this test rule to the end of the reimbursement period be subject to the rule's requirements for that isomer. The end of the reimbursement period ordinarily will be 5 years after the submission of the last final report required under the test rule. As discussed in the Agency's test rule development and exemption procedures (40 CFR Part 790), EPA expects that manufacturers will conduct testing and that processors will ordinarily be exempted from testing.

Because TSCA contains provisions to 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 rule 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 an exemption from that requirement.

E. Test Rule Development and Exemptions

Elsewhere in this issue of the Federal Register, the Agency is proposing that certain TSCA guidelines be utilized as test standards for the development of data under this rule for *ortho*-, *meta*-, and *para*-cresol. As discussed in that notice and in previous notices (50 FR 20652; May 17, 1985), EPA has reviewed the method for development of test rules and has decided that for most section 4 rulemakings, the Agency will utilize single-phase rulemaking. In light of this decision, EPA has reevaluated the process for developing test standards for section 4 rulemakings initiated under a two-phase process and has determined that for certain of these two-phase rules, TSCA test guidelines are generally available for promulgation as relevant test standards. EPA has decided that where TSCA test guidelines are available, the Agency in most cases will propose the relevant guidelines as the test standards for those rules.

EPA believes that, in line with its commitment to expedite the section 4 rulemaking process, it is appropriate to propose the applicable TSCA test guidelines as test standards at the same time as a Phase I final test rule is issued. With regard to the rulemaking for *ortho*-, *meta*-, and *para*-cresol, TSCA test guidelines are available for the testing requirements included in this Phase I final rule. Thus, in the accompanying notice the Agency is proposing these TSCA guidelines as test standards.

The public, including the manufacturers and processors subject to the Phase I rule, will have an opportunity to comment on the use of the TSCA test guidelines or to propose alternate test methods. The Agency will review the submitted comments and will modify the TSCA test guidelines, where appropriate, when the test standards are promulgated.

During the development of a test rule under the two-phase process, persons subject to the Phase I final rule are normally required to submit proposed study plans within 90 days after the effective date of the Phase I final rule (see 40 CFR 790.30(a)(2), published in the Federal Register of May 17, 1985 (50 FR 20658)). However, because EPA is proposing applicable TSCA test guidelines as the test standards for the studies required by this Phase I final rule, persons subject to the rule, i.e., manufacturers and processors of *ortho*-, *meta*-, and/or *para*-cresol, are not required to submit proposed study plans for the required testing. Persons subject to this rule, however, are still required to submit notices of intent to test or exemption applications in accordance with 40 CFR 790.25, published in the Federal Register of May 17, 1985 (50 FR 20657). For this rule, once the test standards are promulgated, persons who have notified EPA of their intent to test must submit study plans (which adhere to the promulgated test standards) no later than 30 days before the initiation of each required test.

Processors of *ortho*-, *meta*-, and/or *para*-cresol subject to this rule, unless they are also manufacturers, will not be required to submit letters of intent, exemption applications, or study plans (before testing is initiated) unless manufacturers fail to sponsor the required tests. The basis for this decision is that manufacturers are expected to pass an appropriate portion of the test costs on to processors through the pricing of products containing *ortho*-, *meta*-, and/or *para*-cresol.

EPA's final regulations for the issuance of exemptions from testing requirements are in 40 CFR Part 790. In accordance with those regulations, any manufacturer or processor subject to this Phase I test rule may submit an application to EPA for an exemption from conducting any or all of the tests required under this rule. If manufacturers perform all the required testing, processors will be granted exemptions automatically without having to file applications.

Because persons subject to this rule for cresols are not required to submit proposed study plans for approval, EPA will grant conditional exemptions under this rule following EPA's receipt of a letter of intent to conduct the required tests rather than after receipt and approvals of a study plan. Notice of EPA's adoption of the final test standards and deadlines will be announced in a final Phase II test rule.

F. Reporting Requirements

EPA is requiring that all data developed under this rule be reported in accordance with the EPA Good Laboratory Practice (GLP) standards pursuant to 40 CFR Part 792.

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. The Agency is proposing these deadlines elsewhere in this issue of the Federal Register. These proposed data submission deadlines are open for public comment and may be modified, where appropriate, when the final Phase II test rule is promulgated.

TSCA section 12(b) requires that persons who export or intend to export

to a foreign country any *ortho-, meta-,* and/or *para*-cresol, subject to the testing requirements of this rule, notify EPA of such exportation or intent to export. While the results of required testing may not be available for some time, a notice to the foreign government about the export of such substances subject to test rules serves to alert it to the Agency's concern about the substances. It gives the government the opportunity to request such data that the Agency may currently possess plus whatever data may become available as a result of testing activities. Thus, upon the effective date of this rule, persons who export or intend to export *ortho-, meta-,* and/or *para*-cresol must submit notices to the Agency pursuant to TSCA section 12(b)(1) and 40 CFR Part 707. For additional information, see the Federal Register of November 19, 1984 (49 FR 45581).

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 announce the receipt within 15 days in the Federal Register as required by section 4(d). Test data received pursuant to this rule will be made available for public inspection by any person except in those cases where the Agency determines that confidential treatment must be accorded pursuant to section 14(b) of TSCA.

G. 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 or (2) submit reports, notices, or other records required by the Act or any regulations issued under TSCA.

Additionally, TSCA section 15(4) makes it unlawful for any person to fail or refuse to permit entry or inspection as required by 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 audits and/or inspections will be conducted periodically in accordance with procedures outlined in TSCA section 11 by designated representatives of the EPA for the purpose of determining compliance with the final rule for *ortho-, meta-,* and *para-cresol.* These inspections may be conducted for purposes which include verification that testing has begun, that schedules are being met, that reports accurately reflect the underlying raw data and interpretations and evaluations thereof, and that the studies are being conducted according to EPA GLP standards and the test standards established in the second phase of this rulemaking.

EPA's authority to inspect a testing facility also derives from section 4(b)(1) 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 test rules are reliable and adequate, and 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 calculated as if they had never submitted their data. Under the penalty provisions of section 16 of TSCA, and person who violates section 15 could be subject to a civil penalty of up to $25,000 per day for each violation. Intentional violations could lead to the imposition of criminal penalties up to $25,000 for each day of violation and imprisonment for up to 1 year. Other remedies are available to EPA under sections 7 and 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 actions. Sections 15 and 16 of TSCA apply to "any person" who violates various 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.

V. Economic Analysis of Final Test Rule

To assess the economic impact of this rule, EPA has prepared an economic analysis that evaluates the potential for significant economic impacts on the industry as a result of the required testing (Ref. 6). The economic analysis estimates the costs of conducting the required testing and evaluates the potential for significant adverse economic impact as a result of these test costs by examining four market characteristics of cresols: (1) Price sensitivity of demand, (2) industry cost characteristics, (3) industry structure, and (4) market expectations.

Total testing costs for the final rule for cresols are estimated to range from $764,095 to $1,050,230. This estimate includes the costs for both the required minimum series of tests as well as the conditional ones.

The estimated 1983 production volume for each of the three isomers is approximately 28, 28, and 49 million pounds for *para-, meta-,* and *ortho-*cresol, respectively. The costs of testing are first allocated to each isomer on the basis of production volume. The test costs for each isomer are then allocated to the commercial products containing the isomer based on percentage composition and total production of the commercial product. Based on this allocation method and the maximum costs of required and conditional testing, the annualized unit costs of testing range from a low of 0.08 cents per pound for cresylic acid, to a high of 0.34 cents per pound for *meta-* and *para*-cresol mixtures. Compared to the unit sales value for the commercial products, the unit test costs range from a low of 0.10 percent of price to a high of 0.42 percent of price.

Based on these costs and a consideration of the market characteristics of cresol products, the economic analysis indicates that the potential for significant economic impact is low. This conclusion is based on the following observations: (1) The estimated unit test costs are small and represent a relatively small percentage of product unit value (i.e., less than one percent of unit value in the worst case); (2) relatively stable, and in some cases moderate, growth is expected in most markets for cresols; and (3) demand in most of the markets does not appear to be very sensitive to small increases in price. For a complete discussion of the economic implications of this rule, see the economic analysis support document (Ref. 6).

VI. 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 programs negotiated with industry in place of rulemaking.

Copies of the study, "Chemical Testing Industry: Profile of Toxicological Testing," October 1981, can be obtained through the NTIS under publication number PB 82-140773. On the basis of this study, the Agency believes that there will be available test facilities and personnel to perform the testing required in this test rule.

VII. Rulemaking Record

EPA has established a public record for this rulemaking (docket number 42033B). This record includes the basic information the Agency considered in developing this rule and appropriate Federal Register notices.

This record includes the following information:

A. Supporting Documentation

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

(a) Notice containing the ITC designation of cresols to the Priority List (42 FR 55026; October 12, 1977).

(b) Notice of proposed rule on cresols (48 FR 31812; July 11, 1983).

(c) Notice of final rule on EPA's TSCA Good Laboratory Practice Standards (48 FR 53922; November 29, 1983).

(d) Notice of final rule on test rule development and exemption procedures (49 FR 39774; October 10, 1984).

(e) Notice of final rule concerning data reimbursement (48 FR 31786; July 11, 1983).

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

(g) Notice of final rule on the C_9 Aromatic Hydrocarbon Fraction (50 FR 20662; May 17, 1985).

(h) Notice of final rule on mesityl oxide (50 FR 51857; December 20, 1985).

(2) Support documents consisting of:

(a) Cresols technical support document for proposed rule.

(b) Economic impact analysis of NPRM for cresols.

(c) Economic impact analysis of final test rule for cresols.

(3) Communications consisting of:

(a) Written public comments.

(b) Transcription of public meeting.

(c) Summaries of phone conversations.

(d) Meeting summaries.

(e) Reports—published and unpublished contractor's reports.

B. References

(1) U.S. International Trade Commission. "Synthetic organic chemicals. United States production and sales, 1984." Washington, D.C.: Government Printing Office. USITC pub. 1745, 1985.

(2) Bureau of Census, U.S. Department of Commerce. "U.S. Imports for consumption and general imports, TSUSA. Commodity by country of origin." Washington, D.C. Government Printing Office. FT-246. Annual 1984, 1985.

(3) Cheng, M., Kligerman, A.D. "Evaluation of the genotoxicity of cresols using sister-chromatid exchange (SCE)." *Mutation Research* 137:51-55, 1984.

(4) U.S. Environmental Protection Agency. Memorandum from Kerry L. Dearfield to Linda Tuxen. "Review of Genotoxicity of Cresols using Sister Chromatid Exchange (SCE)." July 11, 1985.

(5) U.S. Environmental Protection Agency. "40 CFR Part 260 et al.—Hazardous Waste Management System; Land Disposal Restrictions; Proposed Rule." 51 FR 1602; January 14, 1986.

(6) Mathtech, Inc. Economic Impact Analysis of Final Test Rule for Cresols. Contract No. 68-02-4235. January 29, 1986.

(7) Cresols Task Force. Comments on EPA's Proposed Test Rule for Cresols. Submission from Robert V. Zener, CTF to Public Information Office, EPA. October 11, 1983.

(8) Hall, J.J. Comments of CONOCO on ITC listing of cresols. Letter from J.J. Hall to Joan Urguhart, Public Information Office, EPA. March 14, 1978.

(9) Ciba-Geigy Corp. Comments of Ciba-Geigy on Cresols Proposed Test Rule. Letter from Anthony DiBattista to Public Information Office, EPA. October 10, 1983.

(10) Mathtech, Inc. Draft Supplemental Report on Cresols and Cresylic Acid. Memorandum from John K. Orrell to Hollis Call. November 28, 1984.

Confidential Business Information (CBI), while part of the record, is not available for public review. A public version of the record, from which CBI has been deleted, is available for inspection from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays, in Rm. E-107, 401 M St., SW., Washington, D.C.

VIII. Other Regulatory Requirement

A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a regulation is "major" and therefore subject to the requirement of a Regulatory Impact Analysis. This test rule is not major because it does not meet any of the criteria set forth in section 1(b) of the order. First, the actual annual cost of all the testing proposed for cresols is estimated at $764,095—$1,050,230 over the market life of the chemical. Second, because the cost of the required testing will be distributed over a large production volume, the rule will have only very minor effects on users' prices (less than 1 percent a year) for this chemical even if all test costs were passed on. Finally, taking into account the nature of the market for this substance, the low level of costs involved, and the expected nature of the mechanisms for sharing the costs of the required testing, EPA concludes that there will be no significant adverse economic effects of any type as a result of this rule.

This proposed regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Any written comments received from OMB are included in the Public Record for this rulemaking.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (15 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 for the following reasons:

1. There are not a significant number of small businesses manufacturing or importing this chemical.

2. Small processors are not expected to perform testing themselves, or participate in the organization of the testing effort.

3. Small processors will experience only very minor costs, if any, in securing exemption from testing requirements.

4. Small processors are unlikely to be affected by reimbursement requirements.

C. Paperwork Reduction Act

The information collection requirements contained in this rule have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*, and have been assigned OMB control number (2070-0033).

D. Comprehensive Environmental Response, Compensation and Liability Act ("Superfund")

The Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA (42 U.S.C. 9601 *et seq.*, Pub. L. 96-510, December 10, 1980)) requires that persons in charge of vessels or facilities from which hazardous substances have been released in quantities that are equal to or greater than the reportable quantities (RQs) immediately notify the National Response Center (NRC) of the release. (See CERCLA section 103(a), and 50 FR 13456; April 4, 1985). The National Response Center can be notified at (800) 424-8802, except from the Washington, DC metropolitan area, where the telephone number for notification is (202) 426-2675. All designated hazardous substances will have an RQ of one pound until adjusted by regulation under CERCLA, unless such substances are already on the list of CERCLA

hazardous substances and have been assigned an RQ (see CERCLA section 102). Cresols have been assigned an RQ of 1,000 pounds.

List of Subjects in 40 CFR Part 799

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

Dated: April 21, 1986.

John A. Moore,

Assistant Administrator for Pesticides and Toxic Substances.

PART 799—[AMENDED]

Therefore, Part 799 is amended as follows:

1. The authority citation continues to read as follows:

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

2. New § 799.1250 is added, to read as follows:

§ 799.1250 Cresols.

(a) *Identification of test substances.* (1) *ortho*-Cresol (CAS No. 95-48-7), *meta*-cresol (CAS No. 108-39-4), and *para*-cresol (CAS No. 106-44-5) shall each be tested in accordance with this section.

(2) *ortho-*, *meta-*, and *para*-Cresol 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.* (1) All persons who manufacture or process or intend to manufacture or process cresols from the effective date of this rule (June 11, 1986) to the end of the reimbursement period shall submit letters of intent to conduct testing or exemption applications, study plans, and/or shall conduct tests and submit data as specified in this section, Subpart A of this Part, and Part 790 of this chapter.

(2) Persons subject to this section are not subject to the requirements of §§ 790.30 (a) (2), (5), and (6) and (b), and 790.87(a)(1)(ii) of this chapter.

(3) Persons who notify EPA of their intent to conduct tests in compliance with the requirements of this section must submit study plans for those tests no later than 30 days before the initiation of each of those tests.

(4) In addition to the requirements of § 790.87(a) (2) and (3) of this chapter, EPA will conditionally approve exemption applications for this rule if EPA has received a letter of intent to conduct the testing from which exemption is sought and EPA has adopted test standards and schedules in a final Phase II test rule.

(c) *Health effects testing*—(1) *Mutagenic effects—chromosomal aberrations*—(i) *Required testing.* (A) *In vitro* cytogenetics tests shall be conducted individually with *ortho-*, *meta-*, *and para*-cresol;

(B) An *in vivo* cytogenetics test shall be conducted for each isomer which produces a negative result in the *in vitro* cytogenetics test conducted pursuant to paragraph (c)(1)(i)(A) of this section.

(C) A dominant lethal assay shall be conducted for each isomer which produces a positive result in either the *in vitro* or the *in vivo* cytogenetics test conducted pursuant to paragraphs (c)(1)(i) (A) and (B) of this section.

(ii) *Test standards* [Reserved].

(iii) *Reporting requirements* [Reserved].

(2) *Mutagenic effects—gene mutations*—(i) *Required testing.* (A) A DNA damage assay shall be conducted with *meta*-cresol.

(B) A gene mutation in somatic cells assay shall be conducted individually with *meta-* and *para*-cresol.

(C) A sex-linked recessive lethal test in *Drosophila melanogaster* shall be conducted individually with *ortho-* and *para*-cresol.

(D) A sex-linked recessive lethal test in *Drosophila melanogaster* shall be conducted with *meta-* cresol if it produces a positive result in the DNA damage assay or gene mutation in somatic cells assay conducted pursuant to paragraphs (c)(2)(i) (A) and (B) of this section.

(ii) *Test standards* [Reserved].

(iii) *Reporting requirements* [Reserved].

(3) *Mutagenic effects—cellular transformation*—

(i) *Required testing.* (A) A Balb/c-3T3 cellular transformation test performed without metabolic activation shall be conducted individually with *meta-* and *para*-cresol.

(B) A Balb/c-3T3 cellular transformation test performed with metabolic activation shall be conducted with each isomer which produces a negative result in the cellular transformation test without metabolic activation conducted pursuant to paragraph (c)(3)(i)(A) of this section.

(C) A Balb/c-3T3 cellular transformation test performed with metabolic activation shall be conducted with *ortho*-cresol.

(ii) *Test standards* [Reserved].

(iii) *Reporting requirements* [Reserved].

(4) *Developmental toxicity*—(i) *Required testing.* A developmental toxicity study shall be conducted individually with *ortho-*, *meta-*, and *para*-cresol.

(ii) *Test standards.* [Reserved].

(iii) *Reporting requirements* [Reserved].

(5) *Reproductive effects—(i) Required testing.* A two-generation reproductive effects study shall be conducted individually with *ortho-*, *meta-*, and *para*-cresol.

(ii) *Test standards* [Reserved].

(iii) *Reporting requirements* [Reserved].

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

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