PART 270—EPA ADMINISTERED PERMIT PROGRAMS: THE HAZARDOUS WASTE PERMIT PROGRAM

11. The authority citation for part 270 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912, 6924, 6925, 6927, 6939, and 6974.

12. In § 270.42, the list of permit modifications in Appendix I is amended by adding D.1.f. to read as follows:

§ 270.42 Permit modification at the request of the permittee.

* * * * *

Appendix I to § 270.42—Classification of Permit Modifications

Modifications	Class
* * * * *	
D. * * *	
1. * * *	

Modifications	Class
f. Extension of the closure period to allow a landfill, surface impoundment or land treatment unit to receive non-hazardous wastes after final receipt of hazardous wastes under § 264.113 (d) and (e).....	2
* * * * *	

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August 14, 1989

Part IV

Environmental Protection Agency

40 CFR Parts 795 and 799
Tributyl Phosphate; Final Test Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 795 and 799

[OPTS-42100B; FRL-3627-4]

Tributyl Phosphate; 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 tributyl phosphate (TBP, CAS No. 126-73-8) to perform testing for health effects (oncogenicity, neurotoxicity, reproductive and developmental toxicity, mutagenicity, dermal sensitization, and oral/dermal pharmacokinetics), environmental effects (acute effects on algae, fish and aquatic invertebrates, and triggered chronic effects on fish and aquatic invertebrates and sediment bioassay), and chemical fate (vapor pressure, Koc, and hydrolysis rate). This rule is in response to the TSCA Interagency Testing Committee's (ITC) designation of TBP for priority health effects, chemical fate, and environmental effects testing.

DATES: This rule shall become effective on September 27, 1989. For purposes of judicial review, in accordance with 40 CFR 23.5, this rule shall be promulgated at 1 p.m. eastern (standard or daylight as appropriate) time on August 28, 1989. The incorporation by reference in this rule is approved by the Director of the Federal Register as of September 27, 1989.

FOR FURTHER INFORMATION CONTACT: Michael M. Stahl, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Room EB-44, 401 M Street SW., Washington, DC 20460, (202) 554-1404, TDD (202) 554-0551.

SUPPLEMENTARY INFORMATION: EPA is promulgating a final test rule under section 4(a) of TSCA requiring health effects, environmental effects and chemical fate testing of TBP.

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 authorizes EPA to require the development of data relevant to assessing the risk to health and the environment posed by exposure to particular chemical substances or mixtures (chemicals).

Under section 4(a) of TSCA, EPA must require testing of a chemical to develop 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 EPA's first and second proposed test rules published in the **Federal Register's** of July 18, 1980 (45 FR 48510) and June 5, 1981 (46 FR 30300).

B. Regulatory History

The ITC recommended TBP with intent-to-designate in its eighteenth report published in the **Federal Register** of May 19, 1986 (51 FR 18368), and designated TBP for priority testing consideration in its nineteenth report published in the **Federal Register** of November 16, 1986 (51 FR 41417). In response to this designation, EPA issued a proposed test rule in the **Federal Register** of November 12, 1987 (52 FR 43346) which would require that manufacturers and processors of TBP test the chemical for various health and environmental effects, under sections 4(a)(1)(A) and (B) of TSCA.

II. Response to Comments

EPA received written comments on the TBP proposed test rule from the Tributyl Phosphate Task Force (TBPTF) of the Synthetic Organic Chemical Manufacturers Association (SOCMA) on January 12, 1988 (Ref. 1). The TBPTF also requested a public meeting on their comments which was held on April 7, 1988. The comments received by EPA in response to the proposed rule for TBP are given below.

A. Exposure

1. *TBPTF exposure survey.* The TBPTF commented that the exposure information available to EPA was insufficient to support a finding of significant or substantial human exposure since the data were merely suggestive. The TBPTF proposed to do an industry-wide survey of U.S. sites distributing, processing, and using TBP and products containing TBP to determine the uses, use conditions, and potential worker exposure associated with TBP. EPA agreed to consider the study results in its deliberations for a final rule. TBPTF commissioned Temple, Barker, Sloane, Inc., to conduct and validate the survey. On April 7, 1988, the TBPTF presented EPA with the first part of a report, "1987 U.S. Survey of Tributyl Phosphate Users, Potential Exposure and Safety Procedures" (Ref. 2). The report did not contain an estimate of the number of workers potentially exposed to aircraft hydraulic fluid, a product that accounts for a major part of TBP usage (69 percent by volume). After a public meeting with the TBPTF, EPA granted TBPTF a brief period to estimate the numbers and extent of potential worker exposure to aircraft hydraulic fluid containing TBP from survey and additional data. On July 11, 1988, TBPTF submitted a report to EPA on estimated exposure to TBP-containing aircraft hydraulic fluid (Ref. 3).

The TBPTF reported that the greatest number of workers potentially exposed was in the use of aircraft hydraulic fluid. The three primary uses include aircraft manufacturing, hydraulic system component manufacturing, and commercial airline operations (passenger and freight). The TBPTF reported each type of user exposure in terms of estimated numbers of employees potentially exposed on an infrequent basis (less than once per week for less than one hour) and on a more frequent or routine basis. On the basis of confidential discussions with two major aircraft manufacturers, TBPTF estimates that 740 workers in this industry may be infrequently exposed to fluid, and 241 workers may be frequently exposed to hydraulic fluid containing TBP. On the basis of survey responses from aircraft component manufacturers, the TBPTF estimates that 176 employees in this industry may be frequently exposed to aircraft hydraulic fluid containing TBP, and 411 employees may be infrequently exposed. On the basis of confidential estimates by one of the major airlines, TBPTF estimates that 2,200 employees in this industry are routinely exposed to aircraft hydraulic fluid containing TBP and approximately 43,000 aircraft mechanics at some time could be exposed to aircraft hydraulic fluid. The activities potentially causing exposure include: Venting of pressurized systems at service sites, removal and repair of components, and testing and inspection of components. Aircraft manufacturers report that they require mechanics to use protective equipment (gloves, aprons, sleeve shields, goggles/face shields).

In the survey, the other two types of hydraulic fluid users report these and other methods of protection. However, the survey report indicates that in practice, aircraft mechanics only take minimal precautions to prevent contact even though they are aware of the irritating properties of hydraulic fluid. Also, according to the survey, aircraft mechanics do not wear protective gloves.

Survey respondents reported that 100 distributor workers for 298 worker-hours per year and 200 processor workers for

108,358 worker-hours per year have direct exposure to TBP.

An estimated total of 245 distributor workers (estimated from survey respondents and non-respondents) are potentially exposed for 502 worker-hours per year according to the survey. An estimated total of 345 processor workers (estimated from survey respondents and non-respondents) are potentially exposed for 183,382 worker-hours per year.

Other uses of TBP involve partially enclosed or open operations, and the concentration of TBP in these products is under 10 percent. Of these miscellaneous uses, paint spraying operations represent the most likely exposure potential, but spray booths are often used and the paint is used only by original equipment manufacturers, suggesting that exposure is limited to manufacturing use.

2. *EPA's response to TBPTF's exposure survey.* EPA reviewed the exposure survey performed by the TBPTF and finds the conclusions regarding potential occupational exposure to TBP to be reasonable. EPA has concerns about the completeness and accuracy of the survey but these do not interfere with the adequacy of the study for present purposes (Refs. 4 and 5). The survey results simply confirm EPA's earlier conclusion that potential human exposure to TBP is substantial.

B. Testing

1. *Genotoxicity.* The TBPTF commented that studies of gene mutation in mammalian cells in culture and in vivo cytogenetics, specifically the mouse micronucleus test, should be conducted to determine potential clastogenic effects, and that a program review of the entire genotoxicity data base should precede any considerations for further genotoxicity testing.

EPA agrees that a study of gene mutation in somatic cells in culture is necessary as an early tier teset for gene mutation effects of TBP. However, EPA believes that an in vitro mammalian cytogenetics test and in vivo mammalian bone marrow cytogenetics chromosomal analysis test are necessary early tier tests for cytogenetics effects. EPA is reviewing the mouse micronucleus test as a potential alternative test for cytogenetic effects in future test rules.

2. *Pharmacokinetics.* The TBPTF commented that the rat oral and dermal absorption, distribution and excretion pharmacokinetics, and oral metabolism studies should be performed as proposed. However, the TBPTF recommended dermal absorption testing in the pig (mini-pig or weanling swine) rather than the guinea pig, because pig skin is a better model for human skin than guinea pig skin.

EPA has reviewed the evidence the TBPTF has submitted to support testing the pig over the guinea pig and EPA agrees that the pig (mini-pig or weanling pig) is an acceptable substitute testing model for the guinea pig for dermal absoprption testing (Refs. 6 through 9).

3. *Oncogenicity.* The TBPTF commented that, because potential worker exposure is significant only by the dermal route as indicated by the exposure survey, a pilot 28-day dermal study in the rat should be conducted first to evaluate the feasibility of performing chronic efforts and oncogenicity studies by that route. The TBPTF believes that a decision regarding oncogenicity studies should be deferred pending results of the proposed pilot dermal studies and the completion of pharmacokinetics studies.

EPA reported in the proposed rule that the available data suggest TBP may have oncogenic potential. EPA is requiring an oncogenicity study by the oral route because the comparative oral/dermal pharmacokinetics data will allow analysis of effects related to differences in route of administration. Protocol design for dermal bioassays present many problems including: Selection of appropriate species; estimation and demonstration of absorbed versus applied dose; criteria for defining the maximum tolerated dose, e.g., whether based on skin or systemic effects. EPA is assessing the literature on this subject and has sponsored a workshop on dermal carcinogenesis bioassay problems and protocol development. In the near future EPA hopes to publish a generic protocol for dermal bioassays and publish guidelines on when testing should be done by that route.

4. *Dermal sensitization.* TBPTF commented that additional dermal sensitization testing is unnecessary because a mixture containing TBP has been tested in a human study and no sensitization occurred. TBPTF believes that if TBP were a sensitizer, some reaction would have occurred and results of (any) human study should take precedence over those obtained in animal (guinea pig) studies (Ref. 1).

EPA is requiring a dermal sensitization study because photosensitization was not evaluated in the available human study, and the exact TBP concentration in the test mixture was unknown and may have been too low (reported as "less than 25 percent") to have elicited a reaction.

5. *Developmental toxicity.* TBPTF comments that because the exposure survey indicates there is insignificant exposure potential for women of child-bearing age and because of irritant warning properties and low exposure levels, developmental toxicity testing should not be required.

For purposes of requiring testing under section 4 of TSCA, EPA is not required to take into account gender-specific exposure patterns in its deliberations. EPA does not assume that gender-specific exposure patters will persist. Because there is a potential for substantial human exposure to TBP, developmental toxicity testing is required.

6. *Reproductive toxicity.* TBPTF comments that reproductive testing should be triggered by more general indications of reproductive toxicity such as in vivo genotoxicity tests (*Drosophila* and in vivo cytogenetics) because there are very low levels of exposure of both males and females to TBP. In addition, two long-term studies, an 18-week study by Laham et al. and a 13-week study by FMC, showed no effect on gonadal tissues.

While EPA recognizes that there are situations where short-term tests may be appropriate to screen for reproductive effects, EPA does not agree that in the present situation the in vivo genotoxicity tests are adequate to screen for the reproductive toxicity of TBP. And although the two studies mentioned by TBPTF do not show reproductive effects, they are not adequate by themselves to determine whether TBP has reproductive toxicity. It is well documented that there are effects on reproduction that are not detectable by simple histopathological analysis, i.e. effects on reproductive performance, hormones, outcomes of pregnancy, growth and maturation of offspring postnatally. Therefore testing specific for reproductive toxicity is required.

7. *Neurotoxicity.* The TBPTF suggested a tiered approach consisting of an acute functional observational battery and motor activity screen to be followed by a subchronic behavioral evaluation if required after program reveiw. The TBPTF commented that neurotoxicity testing should be by the dermal route if this route proves feasible from the results of the 28-day study. The TBPTF believes that because available studies conclusively show that TBP is not a delayed neurotoxicant (organophosphorus induced delayed neurotoxicity (OPIDN) is the primary mechanism by which organophosphates act directly on the nerves) a further concern for neuropathy is unwarranted

and requirements for in situ perfusion should be removed from the test rule.

EPA does not agree with TBPTF's tiered approach. Both acute and subchronic tests are necessary because EPA is concerned about acute effects as well as the potential effects following repeated exposure. EPA encourages use of the relevant route of administration when possible. Although the dermal route of administration is theoretically acceptable, there are a number of practical problems which must be addressed before a dermal study would be acceptable. First, there must be a demonstration that a sufficient dose of the compound can be absorbed to produce neurobehavioral changes. Without such a high dose level effect, negative results would not be conclusive. Second, dermal application may interefere with satisfactory interpretation of neurobehavioral information. Dermal application can serve as a stress inducer and produce alterations in various neurobehavioral parameters. To account for this possible confounding effect it would be necessary to use a positive control which can also be applied dermally (e.g., acrylamide). Because these problems have not been addressed, neurotoxicity testing by the oral route is required.

EPA believes that, although available studies indicate that under the conditions tested, TBP does not produce organophosphorus-induced delayed neuropathy (OPIDN), other available literature provides evidence of neurobehavioral changes following exposure to TBP, and a standard battery of tests is still indicated (Refs. 10 through 13).

8. *Environmental effects.* The TBPTF commented that EPA's proposed environmental effects testing is generally reasonable and supportable. TBPTF raised the following points. First, TBP argued that the chronicity ratio of 24- to 96-hour LC50 for fish and certain aquatic invertebrates (e.g., *Gammarus*) or the ratio of the 24- to 48-hour LC50 for daphnid of 2 or greater is extremely stringent and should be modified. Second, TBPTF believes there is no clear need for plant translocation tests because there is no or low level exposure for this environment, as TBP is shown to be readily biodegradable in the OECD screening test, by semi-continuous activated sludge, in a river die-away test and in ultimate biodegradation. Third, with respect to specific guidelines, the TBPTF believes that ascertaining whether the test material is in solution does not require analysis of both the total and filtered concentrations of the test material. The concentration in only a filtered sample should be required except in the algal test, where measurements of the amount of test material associated with the algal cells is required. Centrifuging the samples is better because filtration may trap TBP in the filter medium. Requiring analysis of both total and filtered or centrifuged test medium will double analysis costs without any real need. Fourth, the time allotted (9 months) for the completion of the flow-through acute tests may not be adequate. Flow-through tests with analytical measurement of test solutions tend to experience more problems than simple static tests; 12 months from official notification to final report would be a more reasonable estimate.

EPA does not agree with the TBPTF that the chronicity ratio for fish and invertebrates is too stringent because historical data confirm the predictive capability of this decision criterion. EPA agrees with TBPTF that the plant translocation test is unnecessary and EPA is not requiring this test because human exposure from plant dietary uptake does not appear to be of concern. EPA is considering whether it should propose the early seedling growth test to determine the toxicity of TBP to plants. EPA does not agree that only the filtered sample should require analysis and supports the testing guidelines which require analysis of both total and filtered samples. Testing both the total and filtered samples is necessary to know how much dissolved test substance is available during aquatic toxicity tests. EPA is not requiring that both the total and dissolved chemical be measured for every sample. If the dissolved test substance being measured is consistently greater than or equal to 80 percent of total measured test substance, for all test substance concentrations, then it is necessary to measure only the dissolved or total test substance not both. EPA does not agree with TBPTF that 9 months is inadequate to conduct acute flow-though testing because the TBPTF does not provide adequate evidence to the contrary.

C. Economic Issues

1. *Comment:* The TBPTF has estimated the cost of the testing program at about $2.4 million. The information to be developed by the testing program is not a capital asset; and therefore the cost involved must be treated as current expenses. Using the EPA estimated production volume range of 6 to 9 million pounds during an approximate 2-year test program, the cost of the testing proposed per pound would be $0.15 and $0.20 per pound of TBP produced. TBPTF does not believe this is an inconsequential amount.

Response: EPA's estimate of the test cost is between $1.3 million and $1.7 million. TBPTF's estimate of the oncogenicity test is roughly double EPA's estimate, and accounts for the largest portion of the difference. Some of the other estimates submitted by the TBPTF range from 2 to almost 10 times greater than EPA's estimates.

EPA has developed detailed test cost information for each test included in the rule. TBPTF has provided no such information nor any documentation regarding their test cost estimates. In addition, TBPTF has not addressed the method used by EPA to estimate test cost or any of the detailed estimates. Without any such information, EPA cannot address the estimates provided by TBPTF.

Also, TBPTF confuses the procedures used to determine reimbursement for testing costs under section 4 of TSCA with the analysis used to determine economic impacts of the rule. TBPTF looks at the accounting method used to pay for the costs associated with testing, while EPA's economic analysis employs cost recovery analysis to estimate the likelihood of adverse economic impact. In the economic analysis, test costs are annualized over the assumed market life of the product to estimate the amount which firms will have to increase price of the product to recover the costs associated with testing. This estimate of product price increase, as explained in the economic analysis, is used as an indicator of the potential for adverse economic impact. EPA's analysis method is fully explained in the economic analysis document accompanying the proposed rule.

2. *Comment:* Domestic TBP, and TBP-based end-use products, effectively compete in the international market. Aircraft hydraulic fluids containing TBP are used by every major airline in the free world, and more than one-half of the fluid produced domestically is exported. While these fluids are currently only available from domestic sources, excessive testing requirements and associated costs can only encourage the entry of non-domestic suppliers, thus placing an unfair competitive burden on domestic manufacturers and processors of TBP.

Response: As the TBPTF has indicated, fluids containing TBP are used by every major commercial airline in the free world and there are only U.S. sources of these fluids. TBPTF has not demonstrated that a price increase of 1.4 percent to 2.0 percent to cover the costs of testing will be a great enough

incentive for companies outside of the U.S. to begin production of TBP. In addition, any person who begins to import TBP from the effective date of the rule through the reimbursement period would also be subject to the test rule and therefore would be subject to reimbursement of the test costs.

3. *Comment:* TBPTF comments further that conclusions regarding the burden of testing, which are based on fixed assumptions in the inexact field of economic theory, must be seriously and thoroughly evaluated. The ability to pass through costs under conditions of inelastic demand and stable market conditions may be true, but dramatically increased costs at only some producers or processors creates unstable conditions from both supply and consumption dynamics. In a world-wide market, domestic producers and processors of TBP could be placed at an unfair disadvantage. Even if domestic suppliers were able to pass through costs to domestic customers, it is less likely that such pass-through could be successful in foreign markets, putting a double burden on the domestic marketplace. It is economically more prudent and more realistic to assume demand for TBP to be elastic with little probability of increasing price enough to cover costs of testing in a reasonable time. These increased costs, under such assumptions, will directly impact the profitability of TBP production and may ultimately eliminate one or more producers, or even the product, from the market.

Response: TBPTF has not demonstrated that an increase in price of 1.4 percent to 2.0 percent qualifies as "dramatically increased costs". Moreover, as the TBPTF has indicated, there are no foreign sources of TBP-containing fluids. As a result, all producers of TBP would incur these increased costs. EPA has not been able to identify any viable substitutes for TBP in its largest use. Producers of TBP should be able to pass along the cost of testing to all of these customers and not just to domestic customers.

III. Final Test Rule

EPA is basing its final health and environmental effects testing for TBP on the authority of sections 4(a)(1) (A) and (B) of TSCA.

A. Findings

Under section 4(a)(1)(A), EPA finds that the manufacturing, processing, distribution, use, and disposal of TBP in aircraft hydraulic fluid and other uses may present an unreasonable risk of adverse oncogenic effects, neurotoxic effects, and dermal sensitization. These findings are based on the available toxicity data discussed in Unit II of this preamble and in Unit II.F. of the preamble to the proposed rule (52 FR 43346).

Under section 4(a)(1)(B), EPA finds that TBP is produced in substantial quantities and that there is or may be substantial human exposure to TBP in its manufacture, processing, distribution, use, and disposal. The estimated 1985 production capacity of TBP is 6 to 9 million pounds per year (Ref. 14). Potentially 43,000 aircraft mechanics and another roughly 3000 aircraft industry employees at some time could be exposed to aircraft hydraulic fluid containing TBP (Ref. 3). The exposure of mechanics is mainly dermal exposure from removing and repairing components, venting pressurized systems at service sites, and the testing and visual and manual inspection of components. There is also potential of mainly dermal exposure to TBP of approximately 500 TBP manufacturing, processing, and distribution workers from such operations as handling, transfer and packaging of products, equipment repair, cleaning equipment and spill cleanups. There is also potential limited dermal exposure to users of other TBP-containing products (less than 10 percent concentration representing in total 28 percent of TBP volume) including use in original equipment, paints and coatings, inks, leather finishing, liquid fluorescent penetrant, sewage treatment, vinyl floor finish for commercial and industrial applications, and stripping agents.

Under section 4(a)(1)(B), EPA finds that TBP is produced in substantial quantities, and that it enters or may reasonably be anticipated to enter the environment in substantial quantities as a result of its manufacture, processing, distribution, use, and disposal as indicated by its presence in surface water, sediment and groundwater. As stated in the proposed rule, TBP is expected to enter the environment as a result of wastewater release from sites where it is made or used and from leachate releases from landfills (see Unit II.D. of the proposed rule). EPA believes that the low concentrations of TBP detected in or released to the environment at numerous and widely dispersed locations suggest that the total release is substantial under section 4(a)(1)(B) of TSCA.

1. *Health effects.* EPA finds that the available data for insufficient to reasonably determine or predict the oncogenicity, neurotoxicity, dermal sensitization, developmental toxicity, reproductive and fertility effects, mutagenicity, and oral/dermal pharmacokinetics of TBP resulting from exposure during manufacturing, processing, distribution, use, and disposal. EPA finds that testing is necessary to develop these data. EPA believes that the data resulting from this testing will be relevant to a determination as to whether the manufacturing, processing, distribution, use, or disposal of TBP does or does not present an unreasonable risk of injury to human health.

2. *Environmental effects and chemical fate.* EPA believes that, for chemicals that have substantial production and substantial environmental release, reliable data should be developed to assess their toxicity and persistence. Available data are insufficient to reasonably determine or predict TBP's acute toxicity to algae, fish, and aquatic invertebrates, and chronic toxicity to fish and aquatic invertebrates (free swimming and in sediment). Available data are insufficient to reasonably determine or predict TBP's vapor pressure data at 25°C, Koc, and hydrolysis rate. Vapor pressure data at 25°C are needed to estimate a reliable Henry's Law Constant (Hc) for TBP. Data on Koc are needed to estimate the sorption of TBP to soil and sediments. Finally, hydrolysis rate data, which complement the available biodegradation data, are needed to estimate the persistence of TPB in aquatic systems. EPA finds that testing is necessary to develop environmental effects data and chemical fate data, and believes that the data resulting from these test requirements will be relevant to a determination that the manufacturing, processing, use and disposal of TBP does or does not present an unreasonable risk of injury to the environment.

B. Required Testing, Test Standards and Reporting Requirements

On the basis of these findings EPA is requiring that chemical fate, environmental effects and health effects testing be conducted for TBP in accordance with specific test guidelines set forth in 40 CFR parts 796, 797 and 798, or other published test methods as specified in this test rule as listed in the following table.

REQUIRED TESTING, TEST STANDARDS, AND REPORTING REQUIREMENTS FOR TRIBUTYL PHOSPHATE

Test	Test standard 40 CFR citation	Reporting deadline for final rule [1]	Number interim (6-mo) reports required
Chemical fate:			
Vapor pressure	§ 796.1950	6	0
Hydrolysis rate at 25 °C	§ 796.3500	6	0
Sediment and soil adsorption isotherm	§ 796.2750	9	0
Environmental effects:			
Gammarid acute toxity	§ 795.120	9	0
Selenastrum acute toxicity	§ 797.1050	9	0
Rainbow trout acute toxicity	§ 797.1400	9	0
Daphnid acute toxicity	§ 797.1300	9	0
Daphnid chronic toxicity	§ 797.1330	21	1
Fish early life stage	§ 797.1600	21	1
Sediment invertebrate bioassay	Adams et al. (Ref. 15)	21	1
Health effects:			
Oral/dermal pharmacokinetics	§ 798.228	12	1
Oncogenicity	§ 798.3300	53	8
Reproduction and fertility effects (oral)	§ 798.4700	29	4
Developmental toxicity (oral)	§ 798.4900	12	1
Dermal sensitization	§ 798.4100	6	0
Functional observation battery (acute and subchronic)	§ 798.6050	18	2
Motor activity (acute and subchronic)	§ 798.6200	18	2
Neuropathology	§ 798.6400	18	2
Mammalian cells in culture	§ 798.5300	10	1
Drosophila sex-linked recessive lethal	§ 798.5275	22	1
In vitro cytogenetics	§ 798.5375	10	1
In vivo cytogenetics	§ 798.5385	24	1
Dominant lethal assay	§ 796.5450	36	5
Heritable translocation assay	§ 798.5460	[2] 25	3

[1] Number of months after effective date, except as indicated.
[2] Figure indicates the reporting deadline, in months, calculated from the date of notification of the test sponsor by certified letter or FEDERAL REGISTER notice that following public review of all the existing data for TBP, the Agency has determined that required testing must be performed.

Although the major occupational exposure route for TBP is dermal, EPA is requiring that testing for oncogenicity, neurotoxicity, development toxicity, reproductive and fertility effects shall be by the oral route because (1) the skin irritating effects of TBP could confound the results of dermal testing, (2) existing supporting studies have been done by the oral route, and (3) there are technical problems conducting dermal tests. EPA is also requiring oral/dermal pharmacokinetics. EPA is specifying that the Sprague-Dawley rat be used for both oncogenicity and pharmacokinetics testing because existing data presented in the proposed rule show this species to be sensitive to TBP.

EPA requires that all data developed under this rule be reported in accordance with its TSCA Good Laboratory Practice (GLP) Standards, 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. Final testing requirements, test standards and reporting requirements for this TBP test rule are summarized in the preceding table. Interim progress reports for the tests shall be provided to EPA at 6-month intervals after the effective date of this rule until the final report is submitted to EPA.

TSCA section 14(b) governs EPA disclosure of all test data submitted pursuant to section 4 of TSCA. Upon receipt of data required by this rule, EPA 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 TBP must report to EPA the first annual export or intended export of TBP to each country. EPA will notify the foreign country concerning the test rule for TPB.

For the purpose of this test rule, these guidelines are the test standards that must be met by the test sponsors. The route of administration of TBP for all tests shall be oral unless otherwise specified. Data resulting from these tests will assist EPA in conducting health and environmental risk assessments for TBP. The TSCA test guidelines, proposed modifications, and other cited test guidelines discussed in the following paragraphs in III.B. specify generally accepted minimal conditions for determining toxicities and properties of substances such as TBP to which human and aquatic life are expected to be exposed. Conducting the required studies in accordance with these TSCA guidelines will help ensure that the test results are reliable and adequate.

The oral/dermal pharmacokinetics test guideline in the proposed rule has been revised based upon public comments and is promulgated as § 795.228 Oral/dermal pharmacokinetics test.

EPA periodically reviews the TSCA Test Guidelines, according to the process described at 47 FR 41857 (September 22, 1982).

1. *Health effects.* The neurotoxicity testing required will consist of an acute and subchronic functional observation battery specified in § 798.6050, as modified in § 799.4360(c)(1)(i)(A)(*2*), an acute and subchronic motor activity test specified in § 798.6200, as modified in § 799.4360(c)(1)(i)(B)(*2*), and a subchronic neuropathologic evaluation of tissues perfused in situ specified in § 798.6400, as modified in § 799.4360(c)(1)(i)(C)(*2*).

To assess the developmental effects of TBP, EPA is requiring that testing be conducted by gavage according to § 798.4900, as modified in § 799.4360(c)(2)(i)(B).

To assess the reproductive and fertility effects of TBP, EPA is requiring that testing be conducted according to § 798.4700, as modified in § 799.4360(c)(3)(i)(B) (i)(B).

To assess the mutagenic effects of TBP, EPA is requring that testing be conducted in tiers. First-tier testing will consist of the detection of gene mutation in somatic cells in culture using the test guideline § 798.5300, an in vitro mammalian cytogenetics test using the test guideline in § 798.5375, and an in vivo mammalian bone marrow cytogenetics chromosomal analysis test using the test guideline in § 798.5385, as modified in § 799.4360(c)(5)(i)(B)(*2*). Unless the results of the gene mutation in somatic cells in culture are negative, a sex-linked recessive lethal test in *Drosophila melanogaster* will be required. Second-tier testing will consist of a sex-linked recessive lethal assay in *Drosophila melanogaster* using the test guideline in § 798.5275, as modified in § 799.4360(c)(4)(i)(B)(*2*), and a rodent dominant lethal test using the test guideline in § 798.5450; third-tier testing will consist of a rodent heritable translocation test using the test guidelines in § 798.5460, and as modified in § 799.4360(c)(5)(i)(D)(*2*).

In the proposed rule, EPA would have required third-tier testing consisting of a mouse visible specific locus test using the test guideline in § 798.5200 as modified. Positive results in the sex-linked recessive lethal test may have triggered the requirement for conducting a mouse visible specific locus (MVSL) test. EPA believes that the MVSL may be necessary, when these lower-tier tests are positive, to establish definitively whether a substance is capable of eliciting heritable gene mutations. Under the approach proposed, EPA would have considered the positive results in the lower-tier tests in a public program review, together with other relevant information, during which interested persons would be able to give their views to EPA. If, after the review, EPA had determined that the MVSL was still appropriate, EPA would have notified the test sponsors by letter or **Federal Register** notice that they must conduct the test. If EPA had determined that the test was no longer necessary, EPA would have amended the rule to delete the test requirement.

The final test rule for TBP includes requirements to conduct the lower-tier tests for gene mutation. However, EPA is not promulgating the requirement for the MVSL for TBP at this time. EPA has based its proposal to require the MVSL, in part, on information and assumptions about the cost of conducting the test and the availability of laboratories capable of performing the test. The information and assumptions have since proven to be incorrect. Accordingly, EPA is in the process of reexamining the MVSL requirement for all those chemical substances for which the MVSL has been required or proposed to be required. In particular, EPA is reviewing whether any laboratories are available to perform the MVSL for industry in accordance with the TSCA Good Laboratory Practice Standards at 40 CFR part 792 and the cost of such testing, EPA is also reviewing possible alternative tests to the MVSL for which costs may be lower or laboratory availability may be more certain.

EPA has published a notice in the **Federal Register** concerning the MVSL for TBP and other substances subject to proposed and final TSCA section 4 test rules (53 FR 51897). This notice provides up-to-date information on the cost of MVSL testing, availability of laboratories to perform the MVSL, and possible alternative tests to the MVSL together with their costs and laboratory availability. The notice also addresses EPA's intentions about any changes to the MVSL requirements in the various test rules and provides an opportunity for public comment. If, after this proposed rule is finalized and if after lower tier mutagenicity testing of TBP, EPA concludes that the MVSL is appropriate for TBP, EPA will amend this rule to include the MVSL requirements with any appropriate modifications.

Should the gene mutation in somatic cells test prove negative, no further gene-mutation tests will be required. If the sex-linked recessive lethal test is negative, no further gene-mutation test will be required of TBP.

If the results of the in vitro mammalian cytogenetics test are negative, an in vivo mammalian bone marrow cytogenetics, chromosomal analysis test will be required. Unless the results of the in vivo test are negative, a rodent dominant lethal test will be required. A positive result in the rodent dominant lethal test will trigger the requirement that a heritable translocation test be conducted. Should the in vivo mammalian cytogenetics test results prove negative, no further chromosomal effects testing will be required. If the dominant lethal test is negative, no further chromosomal effects testing will be required for TBP.

Under this final rule, if the result of the second-tier rodent dominant lethal test is positive, EPA will hold a public program review before industry will be required to initiate the third-tier heritable translocation test. The public will participate in this program review either by submitting written comments or commenting during a public meeting. A request for public comment or notification of public meeting will be published in the **Federal Register**. Should EPA determine, from the available weight of evidence, that proceeding to the heritable translocation test is no longer warranted, EPA will propose to repeal this testing requirement and, after public comment, issue a final amendment to rescind this requirement. EPA will notify the test sponsors by certified letter or **Federal Register** notice, following the public program review of all the then-existing data for TBP, if the heritable translocation test must be performed. EPA will also conduct internal program reviews of the reports of the gene mutations in somatic cells in culture assay, the in vitro mammalian bone marrow cytogenetics test, and the in vivo mammalian bone marrow cytogenetics test and other available mutagenicity data to evaluate whether the sex-linked recessive lethal and the rodent dominant lethal tests have been triggered.

For a more detailed discussion of mutagenicity tiered testing and public program review procedures, see EPA's final test rule for the C9 aromatic hydrocarbon fraction published in the **Federal Register** of May 17, 1985 (50 FR 20662).

To assess the oncogenic effects of TBP, EPA is requiring that testing be conducted according to § 798.3300 in Sprague-Dawley rats and in mice via the oral route of administration.

To assess the dermal sensitization effects of TBP, EPA is requiring that testing be conducted according to § 798.4100.

To compare the oral route of administration of TBP in § 798.3300 and the dermal route, in § 798.4100 which is thought to be a primary route of human exposure, EPA is requiring an oral/dermal pharmacokinetic test with TBP to examine absorption, distribution, metabolism, and excretion. EPA is requiring that testing be conducted according to § 798.7485. The decision to require most testing of TBP by the oral route is based on the results of dermal irritation tests showing TBP effects to range from irritating to corrosive (Unit II.F.1. of preamble to proposed rule). Moreover, dermal application of the corrosive TBP could stress the test animals, which may distort test results. TBP is well tolerated by the oral route (Unit II.F. of preamble to proposed rule).

EPA is not requiring the renal effects test recommended by the ITC. Acute and subacute oral studies by Mitomo et al. (Ref. 16) showed kidney tubule damage in rats and mice. However, two oral subchronic rats studies of 90 days and 126 days showed no kidney damage even at dosages higher than the Mitomo studies (Refs. 17 and 18). EPA believes that there are adequate data available to assess the effects of TBP on kidney tubules.

2. *Environmental effects.* EPA is requiring the following environmental effects testing to determine the toxicity of TBP to an alga, a fish, and aquatic invertebrates: (1) *Selenastrum capricornutum,* in accordance with § 797.1050 as modified in § 799.4360(d)(1)(i)(B); (2) rainbow trout in accordance with § 797.1400, as modified in § 799.4360(d)(2)(i)(B); (3) daphnids in accordance with § 797.1300, and as modified in § 799.4360(d)(3)i)(B); and (4) gammarids in accordance with § 795.120, as modified in § 799.4360(d)(4)(i)(B). Only one test species, rainbow trout, is required for the fish acute toxicity test because an acute test for the fathead minnow is available and adequate in combination with the testing required for the rainbow trout for purposes of assessing the acute toxicity of TBP of fish (see Unit II.G.). All the acute aquatic toxicity data from these tests will be used to determine whether chronic aquatic testing is necessary according to the testing scheme presented in the following figure:

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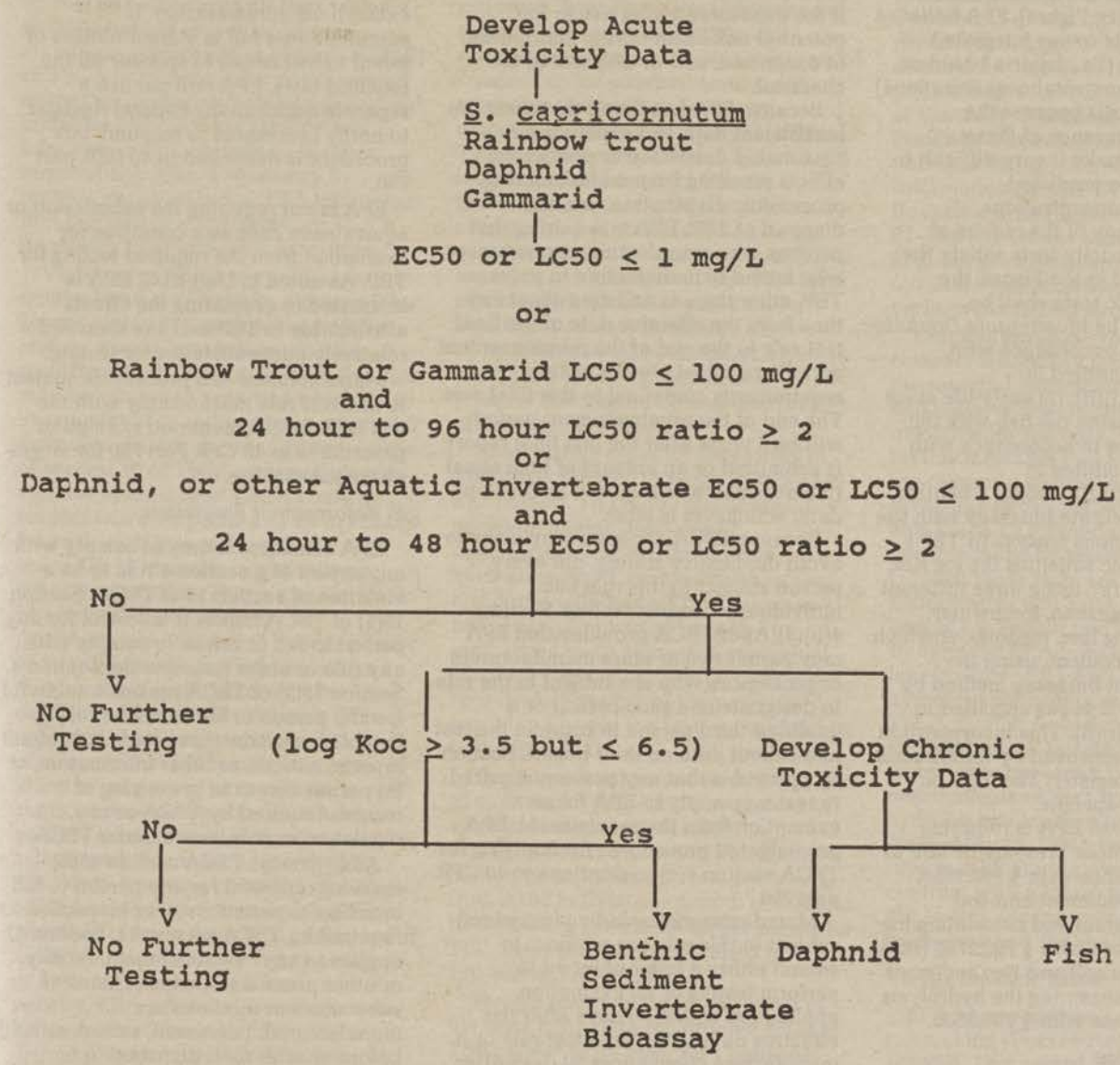
Figure--DECISION LOGIC FOR DEVELOPING ENVIRONMENTAL EFFECTS DATA



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EPA believes that, for chemicals with substantial production and ubiquitous environmental distribution, reliable data should be developed to assess their toxicity and persistence. EPA also believes that, for widely distributed chemicals such as TBP, hazard-based decision criteria should be applied to the data to determine the need to conduct further testing (see Figure). EPA believes it is inappropriate to use integrated decision criteria (i.e., criteria based on predicted environmental concentrations) for these chemicals because the widespread occurrence of these chemicals may make it very difficult to calculate reliable predicted environmental concentrations.

Therefore, if any of the results of acute aquatic toxicity tests satisfy the criteria specified in the Figure, the following chronic tests shall be conducted: (1) The invertebrate *Daphnia* life-cycle test in accordance with § 797.1330, as modified in § 799.4360(d)(5)(i)(B); (2) early-life stage toxicity to fish using the fish with the lower LC50 value in accordance with § 797.1600, as modified in § 799.4360(d)(6)(i)(B); and (3) a benthic sediment invertebrate bioassay with the midge, *Chironomous tentans* (if TBP's measured log Koc satisifies the log Koc criterion in Figure), using three different TBP—containing clean, freshwater sediments having low, medium, and high organic carbon content, using the benthic sediment bioassay method by Adams et al. (Ref. 16) as specified in § 799.4360(d)(7)(i)(B). This incorporation by reference is approved by the Director of the Federal Register. The log Koc criterion is TBP-specific.

3. *Chemical fate.* EPA is requiring measuring the vapor pressure of TBP at 25° C in accordance with § 796.1950, measuring the sediment and soil adsorption isotherm and calculating log Koc in accordance with § 796.2750 (EPA will provide two soil and two sediment samples), and measuring the hydrolysis rate in accordance with § 796.3500.

C. Test Substance

EPA is requiring that TBP of at least 99 percent purity shall be used as the test substance. TBP of such purity is commercially available.

D. Persons Required to Test

Section 4(b)(3)(B) specifies that the activities for which EPA makes section 4(a) findings (manufacture, proceeding, 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 manufacturing, processing, distribution, use and disposal of TBP, EPA is requiring that persons who manufacture or process, or who intend to manufacture to process TBP, other than as an impurity, at any time from the effective date of the final test rule to the end of the reimbursement period are subject to the testing requirements contained in this final rule. The end of the reimbursement period will be 5 years after the last final report is submitted or an amount of time equal to that which was required to develop data, whichever is later.

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 test and submit data on their behalf. Section 4(c) provides that any persons required to test may apply to EPA for an 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 or if manufacture commences 30 days after the effective date of the rule but before the end of the reimbursement period, by the date manufacture begins. The required procedures for submitting such letters and applications are described in 40 CFR part 790. Although EPA has not identified any individuals who manufacture TBP as a byproduct, such persons will be subject to the requirements of this test rule.

Processors rule to this subject, 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. EPA 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 intent to test or fail to sponsor all the required tests, EPA 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 or equivalence data as a condition for exemption from the required testing for TBP. As noted in Unit III.C, EPA is interested in evaluating the effects attributable to TBP 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. Enforcement Provisions

EPA 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 or any regulation or rule 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 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 * * *" EPA 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 designated representatives of EPA for the purpose of determining compliance with the final rule for TBP. 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 this rule.

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 testing rules are reliable and adequate, and to include such other requirements as are necessary to provide such assurance. EPA 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 be applicable primarily to manufacturers that fail to submit a letter of intent or an exemption request and that continue manufacturing after the deadlines for such submissions. This provision would also apply to processors that fail to submit a letter of intent or an exemption application and continue processing after EPA has notified them of their obligation to submit such documents (see 40 CFR 790.28(b)). Knowing or willful violations could lead to the imposition of criminal penalties of up to $25,000 for each day of violation, imprisonment for up to 1 year, or both. 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 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 actions. 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 this final 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. The economic analysis estimates the costs of conducting the required testing and evaluates the potential costs by examining four market characteristics of TBP: (1) Price sensitivity of demand, (2) industry cost characteristics, (3) industry structure, and (4) market expectations. If these indications are negative, no further economic analysis is 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 testing of TBP are estimated to range from $1.3 to $1.7 million. To predict the financial decision-making 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 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 $140,400 to $186,700. Based on 1986 production of 6 million pounds, the unit test costs range from $0.02 to $0.03 per pound. In relation to the selling price of $1.60 per pound for TBP, these costs are equivalent to 1.46 to 1.95 percent of the price.

Though the annualized unit costs of the tests relative to the product price of TBP appear to be high, EPA believes that the potential for adverse economic impact is low. This conclusion is based on the following observations:

1. The demand for TBP appears to be inelastic with respect to price in its largest use, primarily because of the current lack of viable substitutes.

2. The market for TBP appears to be stable.

Refer to the economic analysis which is contained in the public record for this rulemaking for a complete discussion of test costs estimation and 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 this section 4 test rule (Ref. 19). 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). On the basis of this study, EPA 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 required neurotoxicity tests (Ref. 20) and believes that facilities will be available for the tests. The laboratory review indicates that few laboratories are currently conducting these tests according to the TSCA test guidelines and TSCA GLP Standards. However, the barriers faced by testing laboratories to conduct these tests are not formidable. Laboratories will have 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 C9 aromatic hydrocarbon fraction test rule (50 FR 20675; May 17, 1985). Pursuant to that rule, 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 (Docket Number OPTS–42100B). This record contains the basic information considered by EPA in developing this proposal and appropriate **Federal Register** notices.

This record includes:

A. Supporting Documentation

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

(a) Notice containing the ITC's intent to designate TBP to the Priority List (51 FR 18368; May 19, 1986), and the designation of TBP to the Priority List (51 FR 41417; November 14, 1986).

(b) Rules requiring TSCA section 8(a) and 8(d) reporting on TBP (51 FR 18323; May 19, 1986).

(c) TSCA test guidelines cited as test standards for this rule.

(2) Economic Impact Analysis of Proposed Test Rule for Tributyl Phosphate.

(3) Communications consisting of: (a) Written public comments and letters.

(b) Contact reports of telephone conversations.

(c) Meeting summaries.

(4) Reports—published and unpublished factual materials.

B. References

(1) TBPTF. Tributyl Phosphate Task Force of the Synthetic Organic Chemicals Manufacturers Association. Washington, DC. Comments on EPA's proposed test rule for tributyl phosphate. (January 11, 1988).

(2) TBPTF. 1987 U.S. Survey of Tributyl Phosphate Users, Potential Exposure and Safety Procedures, conducted by Temple, Barker, Sloan Inc. (1987).

(3) TBPTF. Letter from J. Kneiss, Managing Director of the Tributyl Phosphate Task Force to M. McCommas, Office of Toxic Substances, U.S. Environmental Protection Agency, July 11, 1988.

(4) USEPA. U.S. Environmental Protection Agency. Exposure Tech Team notes on TBPTF's exposure survey from S. Shapley to M. McCommas, Office of Toxic Substances (1988).

(5) USEPA. Tributyl Phosphate (TBP) task force exposure estimates for populations handling aircraft hydraulic fluids containing TBP. Memo from V. Rodriguez to M. McCommas. Office of Toxic Substances (1988).

(6) Ainsworth, M. "Methods for measuring percutaneous absorption." *Journal of the Society of Cosmetic Chemistry* 11:69–78 (1960).

(7) Marzulli, F.N., Callahan, J.F., and Brown, D.W.C. "Chemical structure and skin penetrating capacity of a short series of organo phosphates and phosphoric acid." *Journal of Investigative Dermatology* 44:339–344 (1965).

(8) Tregar, R. "The permeability of mammalian skin to ions." *Journal of Investigative Dermatology* 46:16–23 (1966).

(9) Marzulli, F.N. et al. "Techniques for studying skin penetration." *Toxicology and Applied Pharmacology* Supplement 2, 3:76–83 (1969).

(10) Robertson, D.G., Mattson, A.M., Bestervelt, L.L., Richardson, and R.J., Anderson, R.J., "Time course of electrophysiological effects induced by di-n-butyl-2,2-dichlorovinyl phosphate (DBCV) in the adult hen." *Journal of Toxicology and Environmental Health* 23:283–294 (1988).

(11) Roberts, D.V. "A longitudinal electromyographic study of six men occupationally exposed to organophosphorus compounds." *International Archives of Occupational and Environmental Health* 38:221–229 (1977).

(12) Brown, D.R. and Murphy, S.D. "Factors influencing dimethoate and trimethyl phosphate-induced narcosis in rats and mice." *Toxicology and Applied Pharmacology* 18:895–906 (1971).

(13) Deichmann, W.B. and Witherup, S. "Observations on the effects of trimethyl phosphate upon experimental animals." *Journal of Pharmacology and Experimental Therapeutics* 88:338–347 (1946).

(14) USEPA. Aggregated production volume for CASRN 126–73–8, 1985. U.S. Environmental Protection Agency, Confidential Data Branch, Office of Toxic Substances, Washington, DC (1987).

(15) Adams, W.J., Kimmerle, R.A., and Mosher, R.G. "Aquatic safety assessment of chemicals sorbed to sediments." Published in Aquatic Toxicology and Hazard Assessment Seventh Symposium, ASTM STP 854, American Society for Testing and Materials, Philadelphia, PA pp. 429–453 (1985).

(16) Mitomo, I., Ito, T., Ueno, Y., and Terao, K. "Toxicological studies on tributyl phosphate. I. Acute and Subacute Toxicities." *Journal of Toxicological Services* 5:270–271 (1969).

(17) Laham, S., Long, G., and Broxup, B. "Induction of urinary bladder hyperplasia in Sprague–Dawley rats orally administered tri-n-butyl phosphate." *Archives of Environmental Health* 40:301–306 (1985).

(18) FMC Corporation. TSCA 8(d) submission 86800000106, Thirteen week feeding study of tributyl phosphate in rats. Office of Toxic Substances, U.S. EPA, Washington, DC (1986).

(19) NTIS. National Technical Information Service. Chemical Testing Industry: Profile of Toxicological Testing (PB 82–140773). Springfield, VA (1986).

(20) USEPA. Evaluation of TSCA test guidelines for neurotoxicity testing. Mathtech, Inc. Contract Number 68–02–4235. Regulatory Impact Branch. Office of Toxic Substances, Washington, DC. (April 4, 1987).

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 in the OPTS Reading Room G–004, NE Mall, 401 M Street, SW., Washington, DC, from 8 a.m. to 4 p.m., Monday through Friday except legal holidays.

VII. Other Regulatory Requirements

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. 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 regulation 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 responses 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

The information collection requirements contained in this rule have been approved by the OMB under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3502 *et seq.* and have been assigned OMB control number 2070–0033.

Public reporting burden for this collection of information is estimated to average 486 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 Chief, Information Policy Branch, PM–223, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked "Attention: Desk Officer for EPA."

List of Subjects in 40 CFR Parts 795 and 799

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

Dated: August 3, 1989.

Victor J. Kimm,

Acting Assistant Administrator for Pesticides and Toxic Substances.

Therefore, 40 CFR Chapter I, Subchapter R is amended as follows:

PART 795—[AMENDED]

1. In part 795:

a. The authority citation continues to read as follows:

Authority: 15 U.S.C. 2603.

b. Section 795.228 is added to subpart D, to read as follows:

§ 795.228 Oral/dermal pharmacokinetics.

(a) *Purpose.* The purpose of these studies are to: (1) Ascertain whether the pharmacokinetics and metabolism of a chemical substance or mixture ("test substance") are similar after oral and dermal administration.

(2) Determine bioavailability of a test substance after oral and dermal administration.

(3) Examine the effects of repeated dosing on the pharmacokinetics and metabolism of the test substance.

(b) *Definitions.* (1)"Bioavailability" refers to the rate and relative amount of administered test substance which reaches the systemic circulation.

(2) "Metabolism" means the study of the sum of the processes by which a particular substance is handled in the body and includes absorption, tissue distribution, biotransformation, and excretion.

(3) "Percent absorption" means 100 times the ratio between total excretion of radioactivity following oral or dermal administration and total excretion following intravenous administration of test substance.

(4) "Pharmacokinetics" means the study of the rates of absorption, tissue distribution, biotransformation, and excretion.

(c) *Test procedures*—(1) *Animal selection*—(i) *Species.* The rat shall be used for pharmacokinetics testing because it has been used extensively for metabolic and toxicological studies. For dermal bioavailability studies, the rat and the mini-pig shall be used.

(ii) *Test animals.* For pharmacokinetics testing and dermal studies, adult male and female Sprague-Dawley rats, 7 to 9 weeks of age, shall be used. For dermal studies, young adult mini-pigs shall also be used. The animals should be purchased from a reputable dealer and shall be identified upon arrival at the testing laboratory. The animals shall be selected at random for the test groups and any animal showing signs of ill health shall not be used. In all studies, unless otherwise specified, each test group shall contain at least 4 animals of each sex for a total of at least 8 animals.

(iii) *Animal care.* (A) The animals shall be housed in environmentally controlled rooms with at least 10 air changes per hour. The rooms shall be maintained at a temperature of 24 ± 2 °C and humidity of 50 ± 20 percent with a 12-hour light/dark cycle per day. The animals shall be kept in a quarantine facility for at least 7 days prior to use and shall be acclimated to the experimental environment for a minimum of 48 hours prior to administration of the test substance.

(B) During the acclimatization period, the animals shall be housed in suitable cages. All animals shall be provided with certified feed and tap water *ad libitum.* The mini-pig diet shall be supplemented with adequate amounts of ascorbic acid in the drinking water.

(2) *Administration of test substance*—(i) *Test substance.* The use of a radioactive test substance is required for all studies. Ideally, the purity, radioactive and nonradioactive, is greater than 99 percent. The radioactive and nonradioactive test substances shall be chromatographed separately and together to establish purity and identity. If the purity is less than 99 percent or if the chromatograms differ significantly, EPA should be consulted.

(ii) *Dosage and treatment*—(A) *Intravenous.* The low dose of test substance, in an appropriate vehicle, shall be administered intravenously to groups of rats and mini-pigs of each sex. If feasible, the same low dose should be used for intravenous, oral, and dermal studies.

(B) *Oral.* Two doses of text substance shall be used in the oral study, a low dose and a high dose. The high dose should ideally induce some overt toxicity, such as weight loss. The low dose should correspond to a no-observed effect level. The oral dosing shall be accomplished by gavage or by administering the encapsulated test substance. If feasible, the same high and low doses should be used for oral and dermal studies.

(C) *Dermal.* (*1*) Dermal treatment. For dermal treatment, two doses, comparable to the low and high oral doses, shall be dissolved in a suitable vehicle and applied in volumes adequate to deliver comparable doses. The backs of the animals should be lightly shaved with an electric clipper 24 hours before treatment. The test substance shall be applied to the intact shaven skin (approximately 2 cm^2 for rats, 5 cm^2 for mini-pigs). The dosed areas shall be protected with a suitable porous covering which is secured in place, and the animals shall be housed separately.

(*2*) Washing efficacy study. Before initiation of the dermal absorption studies, an initial washing efficacy experiment shall be conducted to assess the removal of the applied low dose of the test substance by washing the exposed skin area with soap and water and an appropriate organic solvent. The low dose shall be applied to 4 rats and 4 mini-pigs in accordance with paragraph (c)(2)(ii)(C)(*1*) of this section. After application (5 to 10 minutes), the treated areas of 2 rats and 2 mini-pigs shall be washed with soap and water and the treated areas of the remaining rats and pigs shall be washed with an appropriate solvent. The amounts of test substance recovered in the washings shall be determined to assess efficacy of its removal by washing.

(iii) *Dosing and sampling schedule*—(A) *Rat studies.* After administration of the test substance, each rat shall be placed in a metabolic unit to facilitate collection of excreta. For the dermal studies, excreta from the rats shall also be collected during the 6 hour exposure periods. At the end of each collection period, the metabolic units shall be cleaned to recover any excreta that might adhere to them. All studies, except the repeated dosing study, shall be terminated at 7 days or after at least 90 percent of the radioactivity has been recovered in the excreta, whichever occurs first.

(*1*) *Intravenous study.* Group A shall be dosed once intravenously at the low dose of test substance.

(*2*) *Oral study.* (*i*) Group B shall be dosed once per os with the low dose of test substance.

(*ii*) Group C shall be dosed once per os with the high dose of test substance.

(*3*) *Dermal studies.* Unless precluded by corrosivity, the test substance shall be applied and kept on the skin for a minimum of 6 hours. At the time of removal of the porous covering, the treated area shall be washed with an appropriate solvent to remove any test substance that may be on the skin surface. Both the covering and the washing shall be assayed to recover residual radioactivity. At the termination of the studies, each animal shall be sacrificed and the exposed skin area removed. An appropriate section of the skin shall be solubilized and assayed for radio-activity to ascertain if the skin acts as a reservoir for the test substance. Studies on the dermal absorption of corrosive test substances should be discussed with EPA prior to initiation.

(*i*) Group D shall be dosed once dermally with the low dose of test compound.

(*ii*) Group E shall be dosed once dermally with the high dose of the test substance.

(*4*) *Repeated dosing study.* Group F shall receive a series of single daily oral low doses of nonradioactive test substance over a period of at least 7 days. Twenty-four hours after the last nonradioactive dose, a single oral low dose of radioactive test substance shall be administered. Following dosing with

the radioactive substance, the rats shall be placed in individual metabolic units as described in paragraph (c)(2)(iii) of this section. The study shall be terminated at 7 days after the last dose, or after at least 90 percent of the radioactivity has been recovered in the excreta, whichever occurs first.

(B) *Mini-Pig studies.* For all mini-pig studies, the test groups shall consist of four young adult animals. After administration of the test substance, each mini-pig shall be kept in a metabolic unit to facilitate collection of excreta. At the end of each collection period, the metabolic units are to be cleaned to recover any excreta that might adhere to them. All studies shall be terminated at 7 days, or after at least 90 percent of the radio-activity has been recovered in the excreta, whichever occurs first.

(1) *Intravenous study.* Group G is to be dosed once intravenously at the low dose of the test substance.

(2) *Dermal studies.* Following the experimental guidance described in (c)(2)(iii)(A)(*3*) of this section:

(*i*) Group H shall be dosed once dermally with the low dose of test substance.

(*ii*) Group I shall be dosed once dermally with the high dose of the test substance.

(3) *Types of studies*—(i) *Pharmacokinetics studies*—(A) *Rat studies.* Groups A through F shall be used to determine the kinetics of absorption of the test substance. In the group administered the test substance by intravenous routes, (i.e., Group A), the concentration of radioactivity in blood and excreta shall be measured following administration. In groups administered the test substance by the oral and dermal route (i.e., Groups B, C, D, E and F), the concentration of radioactivity in blood and excreta shall be measured at selected time intervals during and following the exposure period.

(B) *Mini-Pig studies.* Groups G, H, and I shall be used to determine the extent of dermal absorption of the test substance. The amount of radioactivity in excreta shall be determined at selected time intervals.

(ii) *Metabolism studies—Rat studies.* Groups A through F shall be used to determine the metabolism of the test substance. Urine, feces, and expired air shall be collected for identification and quantification of the test substance and metabolites.

(4) *Measurements*—(i) *Pharmacokinetics.* Four animals from each group shall be used for these purposes.

(A) *Rat studies*—(*1*) *Bioavailability.* The levels of radioactivity shall be determined in whole blood, blood plasma or blood serum at 15 and 30 minutes and at 1, 2, 8, 24, 48, and 96 hours after initiation of dosing.

(*2*) *Extent of absorption.* The total quantities of radioactivity shall be determined for excerta collected daily for 7 days or until at least 90 percent of the radioactivity has been recovered in the excreta.

(*3*) *Excretion.* The quantities of radioactivity eliminated in the urine, feces, and expired air shall be determined separately at appropriate time intervals. The collection of carbon dioxide may be discontinued when less than one percent of the dose is found to be exhaled as radioactive carbon dioxide in 24 hours.

(*4*) *Tissue distribution.* At the termination of each study, the quantities of radioactivity in blood and in various tissues, including bone, brain, fat, gastrointestinal tract, gonads, heart, kidney, liver, lungs, muscle, skin, and residual carcass of each animal shall be determined.

(*5*) *Changes in pharmacokinetics.* Results of pharmacokinetics measurements (i.e., bioavailability and extent of absorption, tissue distribution, and excretion) obtained in rats receiving the single low oral dose of the test substance (Groups B and C) shall be compared to the corresponding results obtained in rats receiving repeated oral doses of the test substance (Group F).

(B) *Mini-Pig studies—Extent of absorption.* The total quantities of radioactivity shall be determined for excreta daily for 7 days or until at least 90 percent of the test substance has been excreted.

(ii) *Metabolism.* Four animals from each group shall be used for these purposes.

(A) *Rat studies*—(*1*) *Biotransformation.* Appropriate qualitative and quantitative methods shall be used to assay urine, feces, and expired air collected from rats. Efforts shall be made to identify any metabolite which comprises 5 percent or more of the administered dose and the major radioactive components of blood.

(*2*) *Changes in biotransformation.* Appropriate qualitative and quantitative assay methodology shall be used to compare the composition of radioactive compounds in excreta from rats receiving a single oral dose (Groups B and C) with those in the excreta from rats receiving repeated oral doses (Group H).

(d) *Data and reporting.* The final test report shall include the following:

(1) *Presentation of results.* Numerical data shall be summarized in tabular form. Pharmacokinetic data shall also be presented in graphical form. Qualitative observations shall also be reported.

(2) *Evaluation of results.* All quantitative results shall be evaluated by an appropriate statistical method.

(3) *Reporting results.* In addition to the reporting requirements as specified in 40 CFR part 792, the following specific information shall be reported:

(i) Species and strains of laboratory animals.

(ii) Chemical characterization of the test substance, including:

(A) For the radioactive test substances, information on the site(s) and degree of radiolabeling, including type of label, specific activity, chemical purity, and radiochemical purity.

(B) For the nonradioactive compound, information on chemical purity.

(C) Results of chromatography.

(iii) A full description of the sensitivity, precision, and accuracy of all procedures used to generate the data.

(iv) Percent of absorption of test substance after oral and dermal exposures to rats and dermal exposure to mini-pigs.

(v) Quantity and percent recovery of radioactivity in feces, urine, expired air, and blood. In dermal studies on rats and mini-pigs, include recovery data for skin, skin washings, and residual radioactivity in the covering as well as results of the washing efficacy study.

(vi) Tissue distribution reported as quantity of radioactivity in blood and in various tissues, including bone, brain, fat, gastrointestinal tract, gonads, heart, kidney, liver, lung, muscle, skin and in residual carcass of rats.

(vii) Materials balance developed from each study involving the assay of body tissues and excreta.

(viii) Biotransformation pathways and quantities of test substance and metabolites in excreta collected after administering single high and low doses to rats.

(ix) Biotransformation pathways and quantities of the test substance and metabolites in excreta collected after administering repeated low doses to rats.

(x) Pharmacokinetics model(s) developed from the experimental data.

PART 799—[AMENDED]

2. In part 799:

a. The authority citation continues to read as follows:

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

b. Section 799.4360 is added to subpart B to read as follows:

§ 799.4360 Tributyl phosphate.

(a) *Identification of test substance.* (1) Tributyl phosphate (TBP, CAS No. 126–73–8) shall be tested in accordance with this section.

(2) TBP 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 and byproduct manufacture) or process or intend to manufacture or process TBP, other than as an impurity, from the effective date of the final rule 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 part 790 of this chapter for single-phase rulemaking.

(c) *Health effects testing*—(1) *Neurotoxicity*—(i) *Required testing.* (A)(*1*) An acute and subchronic functional observational battery shall be conducted with TBP in accordance with § 798.6050 of this chapter except for the provisions of paragraphs (d) (5) and (6) of § 798.6050.

(*2*) For the purpose of this section, the following provisions also apply:

(*i*) *Animal selection.* Testing shall be performed in laboratory rats.

(*ii*) *Duration of testing.* For the acute testing, the substance shall be administered over a period not to exceed 24 hours; for the subchronic testing, test species shall be exposed daily for at least 90 days.

(*iii*) *Route of exposure.* Animals shall be exposed to TBP orally.

(B)(*1*) An acute and subchronic motor activity test shall be conducted with TBP in accordance with § 798.6200 of this chapter except for the provisions of paragraphs (d) (5) and (6) of § 798.6200.

(*2*) For the purpose of this section, the following provisions also apply:

(*i*) *Animal selection.* Testing shall be performed in laboratory rats.

(*ii*) *Duration of testing.* For the acute testing, the substance shall be administered over a period not to exceed 24 hours; for the subchronic testing, test species shall be exposed daily for at least 90 days.

(*iii*) *Route of administration.* Animals shall be exposed to TBP orally.

(C)(*1*) A neuropathology test shall be conducted with TBP in accordance with § 798.6400 of this chapter except for the provision of paragraphs (d)(1)(i) (5) and (6) of § 798.6400.

(*2*) For the purpose of this section, the following provisions also apply:

(*i*) *Animal selection.* Testing shall be performed in laboratory rats.

(*ii*) *Duration of testing.* Animals shall be exposed for at least a 90-day period.

(*iii*) *Route of administration.* Animals shall be exposed to TBP orally.

(*ii*) *Reporting requirements*—(A) The neurotoxicity tests required under paragraph (c)(1)(i) (A), (B), and (C) of this section shall be completed and final reports submitted to EPA within 18 months of the effective date of the final rule.

(B) An interim progress report for these neurotoxicity tests shall be submitted to EPA 6 months after the effective date of the final rule.

(2) *Developmental toxicity*—(i) *Required testing.* (A) A developmental toxicity study shall be conducted with TBP in accordance with § 798.4900 of this chapter, except for the provisions of paragraph (e)(5) of § 798.4900.

(B) for the purpose of this section, the following provision also applies:

(*1*) *Route of administration.* The animals shall be exposed to TBP by gavage.

(*2*) [*Reserved*]

(ii) *Reporting requirements.* (A) The developmental toxicity study required under paragraph (c)(2) of this section shall be completed and a final report submitted to EPA within 12 months of the effective date of the final rule.

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

(3) *Reproductive and fertility*—(i) *Required testing.* (A) A reproduction and fertility study shall be conducted with TBP in accordance with § 798.4700 of this chapter, except for the provisions of paragraph (c)(5)(i)(A) of § 798.4700.

(B) for the purpose of this section, the following provisions also apply:

(*1*) *Route of administration.* Animals should be exposed to TBP by gavage.

(*2*) [*Reserved*]

(ii) *Reporting requirements.* (A) The reproduction and fertility effects study required under paragraph (c)(3) of this section shall be completed and a final report submitted to EPA within 29 months of the effective date of the final rule.

(B) Interim program 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.

(4) *Mutagenic effects—Gene mutation*—(i) *Required testing.* (A) A detection of gene mutation in somatic cells in culture test shall be conducted with TBP in accordance with § 798.5300 of this chapter.

(B)(*1*) If TBP produces a positive result in the assay conducted pursuant to paragraph (c)(4)(i)(A) of this section, a sex-linked recessive lethal test in *Drosophila melanogaster* shall be conducted with TBP in accordance with § 798.5275 of this chapter, except for the provisions of paragraph (d)(5)(iii) of § 798.5275.

(*2*) For the purpose of this section, the following provisions also apply:

(*i*) *Route of administration.* Animals shall be exposed to TBP orally.

(*ii*) [Reserved]

(*iii*) *Reporting requirements.* (*A*) The somatic cells in culture assay shall be completed and the final report submitted to EPA, within 10 months after the effective date of the final rule. If required, the *Drosophila* sex-linked recessive lethal assay shall be completed and the final report submitted to EPA within 22 months after the effective date of the final rule.

(*B*) Interim progress reports shall be submitted to EPA at 6 month intervals beginning 6 months after initiation of the sex-linked recessive lethal test in *Drosophila* until the applicable final reports are submitted to EPA.

(5) *Mutagenic effects—Chromosomal aberration*—(i) *Required testing.* (A) An in vitro mammalian cytogenetics test shall be conducted with TBP in accordance with § 798.5375 of this chapter.

(B)(*1*) If TBP produces a negative result in the in vitro cytogenetics test conducted pursuant to paragraph (c)(5)(i)(A) of this section, an in vivo mammalian bone marrow cytogenetics test shall be conducted with TBP in accordance with § 798.5385 of this chapter, except for the provisions of paragraph (d)(5)(iii) of § 798.5385.

(*2*) For the purpose of this section, the following provisions also apply:

(*i*) *Route of administration.* Animals shall be exposed to TBP orally.

(*ii*) [*Reserved*]

(C)(*1*) If TBP produces a positive result in either the in vitro or the in vivo cytogenetics test conducted pursuant to paragraphs (c)(5)(i) (A) and (B) of this section, a rodent dominant-lethal assay shall be conducted with TBP in accordance with § 798.5450 of this chapter, except for the provisions of paragraph (d)(5)(iii) of § 798.5450.

(*2*) For the purpose of this section, the following provisions also apply:

(*i*) *Route of administration.* Animals shall be exposed orally to TBP.

(*ii*) [*Reserved*]

(D)(*1*) A rodent heritable translocation assay shall be conducted with TBP if the dominant-lethal assay conducted for TBP pursuant to paragraph (c)(5)(i)(C) of this section produces a positive result, and if, after a public program review, EPA issues a **Federal Register** notice or sends a certified letter to the test

sponsor specifying that the testing shall be initiated. This test shall be conducted in accordance with § 798.5460 of this chapter except for the provisions of paragraph (d)(5)(iii) of § 798.5460.

(2) For the purpose of this section, the following provisions also apply:

(*i*) *Route of administration.* Animals shall be exposed to TBP orally.

(*ii*) [*Reserved*]

(ii) *Reporting requirements.* (A)(*1*) The in vitro mammalian cytogenetics test shall be completed and the final report submitted to EPA within 10 months after the effective date of the final rule.

(*2*) If required, the in vivo mammalian bone-marrow cytogenetics test shall be completed and the final report submitted to EPA within 24 months after the effective date of the final rule.

(*3*) If required, the dominant lethal assay shall be completed and the final report submitted to EPA within 36 months after the effective date of the final rule.

(*4*) If required, the heritable translocation assay shall be completed and the final report submitted to EPA within 25 months after the date of EPA's notification of the test sponsor under paragraph (c)(5)(i)(D) of this section that testing shall be initiated.

(B) Interim progress reports shall be submitted to EPA at 6 month intervals beginning 6 months after initiation of the rodent dominant lethal assay and the rodent heritable translocation assay respectively, if required, until the applicable final reports are submitted to EPA.

(6) *Oncogenicity*—(i) *Required testing.* (A) An oncogenicity test shall be conducted with TBP in accordance with § 798.3300 of this chapter except for the provisions of paragraphs (b) (1)(i) and (6)(i) of § 798.3300.

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

(*1*) *Animal selection.* TBP shall be tested in Sprague-Dawley rats and in mice.

(*2*) *Route of administration.* Animals shall be exposed to TBP orally.

(ii) *Reporting requirements.* (A) The oncogenicity test required under paragraph (c)(6) of this section shall be completed and a final report submitted to EPA within 53 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.

(7) *Dermal sensitization*—(i) *Required testing.* A dermal sensitization test shall be conducted with TBP in accordance with § 798.4100 for this chapter.

(ii) *Reporting requirements.* The dermal sensitization test shall be completed and the final report submitted to EPA within 6 months of the effective date of the final rule.

(8) *Oral/Dermal Pharmacokinetics*—(i) *Required testing.* A pharmacokinetics test shall be conducted with TBP in accordance with § 795.228 of this chapter.

(ii) *Reporting requirements.* (A) The pharmacokinetics test required in paragraph (c)(8)(i) of this section shall be completed and the final report submitted to EPA within 12 months of the effective date of the final rule.

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

(d) *Environmental effects testing*—(1) *Algal acute toxicity*—(i) *Required testing.* (A) Algal acute toxicity testing shall be conducted with TBP using *Selenastrum capricornutum* in accordance with § 797.1050 of this chapter except for the provisions of paragraphs (c)(6)(i)(A),(B), and (ii) of § 797.1050.

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

(*1*) *Summary of the test.* The algal cells at the end of 24, 48, and 72 hours shall be enumerated.

(*2*) *Chemical measurement.* The final separation of the algal cells from the test solution shall be done using an ultrafiltration (e.g., 0.45 micrometer pore size) technique. 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 and 96 hours.

(ii) *Reporting requirements.* The algal acute toxicity test required in paragraph (d)(1) of this section shall be completed and the final report submitted to EPA within 9 months of effective date of the final rule.

(2) *Fish acute toxicity*—(i) *Required testing.* (A) Fish acute toxicity testing shall be conducted with TBP using *Salmo gairdneri* (rainbow trout) in accordance with § 797.1400 of this chapter.

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

(*1*) *Chemical measurement.* The total and dissolved (e.g., filtered) concentrations of the test substance shall be measured in each test chamber delivery chamber before the test. If the dissolved test substance concentration is greater than 80 percent of total test substance concentration, then only total or dissolved test concentration shall be measured in each chamber at 0, 48, and 96 hours. If the dissolved test substance concentration is less than or equal to 80 percent of total test substance, then total and dissolved test substance concentration shall be measured at 0, 48 and 96 hours.

(*2*) *Test procedures.* The test shall be performed under flow-through conditions.

(ii) *Reporting requirements.* The fish acute toxicity test shall be completed and the final report submitted to EPA within 9 months of the effective date of the final rule.

(3) *Daphnid acute toxicity*—(i) *Required testing.* (A) Daphnid acute toxicity testing shall be conducted with TBP using *Daphnia magna* or *D. pulex* in accordance with § 797.1300 of this chapter.

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

(*1*) *Chemical measurement.* 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. If the dissolved test substance concentration is greater than 80 percent of total test substance concentration, then only total or dissolved test concentration shall be measured in each chamber at 0, 24, and 48 hours. If the dissolved test substance concentration is less than or equal to 80 percent of total test substance, then total and dissolved test substance concentration shall be measured at 0, 29, and 48 hours.

(*2*) *Test procedures.* The test shall be performed under flow-through conditions.

(ii) *Reporting requirements.* The daphnid acute toxicity test shall be completed and the final report submitted to EPA within 9 months of the effective date of the final rule.

(4) *Gammarid acute toxicity*—(i) *Required testing.* (A) *Gammarid* acute toxicity testing shall be conducted with TBP using *Gammarus lacustris, G. fasciatus,* or *G. pseudolimnaeus* in accordance with § 795.120 of this chapter.

(B) For the purpose of this section, the following provisons also apply:

(*1*) *Chemical measurement.* 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. If the dissolved test substance concentration is greater than 80 percent of total test substance concentration, then only total or dissolved test concentration shall be measured in each chamber at 0, 48, and 96 hours. If the dissolved test substance concentration is less than or equal to 80 percent of total test substance, then total and

dissolved test substance concentration shall be measured at 0, 48, and 96 hours.

(2) *Test procedures.* The test shall be performed under flow-through conditions.

(ii) *Reporting requirements.* The *Gammarid* acute toxicity test shall be completed and the final report submitted to EPA within 9 months of the effective date of the final rule.

(5) *Daphnid chronic toxicity*—(i) *Required testing.* (A) Daphnid chronic toxicity testing shall be conducted with TBP using *Daphnia magna* or *D. pulex* in accordance with § 797.1330 of this chapter, if the algal EC50, the rainbow trout LC50, the daphnid EC50, or the gammarid LC50 determined in accordance with paragraphs (d)(1), (2), (3) and (4) of this section satisfy the following criteria: Any such value is < 1 mg/L; or any fish or aquatic invertebrate EC50 or LC50 is < 100 mg/L and either the rainbow trout or gammarid 24-hour to 96-hour LC50 ratio > 2, or the daphnid 24-hour to 48-hour EC50 or LC50 ratio is > 2.

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

(1) *Chemical measurement.* 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. If the dissolved test substance concentration is greater than 80 percent of total test substance concentration, then only total or dissolved test substance concentration shall be measured in each test chamber at 0, 7, 14, and 21 days. If the dissolved test substance concentration is less than or equal to 80 percent of total test substance concentration, then total and dissovled test substance concentration shall be measured at 0, 7, 14, and 21 days.

(2) *Test procedures.* The test shall be performed under flow-through conditions.

(ii) *Reporting requirements.* (A) The daphnid chronic toxicity test, if required, shall be completed and the final report submitted to EPA within 21 months of the effective date of the final rule.

(B) An interim progress report shall be submitted to EPA 6 months after the initiation of the test.

(6) *Fish early-life stage toxicity*—(i) *Required testing.* A fish early-life stage toxicity test shall be conducted with TBP in accordance with § 797.1600 of this chapter, using the fish with the lower LC50 value (either the rainbow trout (*Salmo gairdneri*) or the fathead minnow (*Pimephales promelas*)), if the algal EC50, the rainbow trout LC50, the gammarid LC50 or the daphnid EC50 determined in accordance with paragraphs (d)(1), (2), (3), and (4) of this section satisfy the following criteria: Any such value is < 1 mg/L; or any fish or aquatic invertebrate EC50 or LC50 is < 100 mg/L and either the rainbow trout or gammarid 24 hour to 96 hour LC50 ratio > 2, or the daphnid 24-hour to 48-hour EC50 ratio is > 2.

(ii) *Reporting requirements.* (A) The fish early-life stage flow-through toxicity test shall be completed and the final report submitted to EPA within 21 months of the effective date of the final rule.

(B) An interim progress report shall be submitted to EPA 6 months after the initiation of the test.

(7) *Benthic sediment invertebrate bioassay*—(i) *Required testing.* (A) A benthic sediment invertebrate bioassay shall be conducted on TBP with the midge (*Chironomus tentans*) if chronic toxicity testing is required pursuant to paragraph (d)(5) of this section and if the log Koc calculated according to paragraph (e)(2)(B)(1) of this section is greater than or equal to 3.5 but less than or equal to 6.5. The total aqueous sediment concentrations and interstitial water concentrations of the test substance shall be measured in each test chamber at 0, 4, 7, 10, and 14 days. The aqueous concentrations of the test substance in the delivery chamber shall be measured at 0, 4, 7, 10, and 14 days. TBP-spiked clean freshwater sediments containing low, medium, and high organic carbon content shall be used.

(B) The benthic sediment invertebrate bioassay shall be conducted according to the test procedure specified in the American Society for Testing and Materials, Special Technical Publication 854 (ASTM STP 854) entitled, "Aquatic Safety Assessment of Chemicals Sorbed to Sediments," by W.J. Adams, R.A. Kimerle, and R.G. Mosher, published in *Aquatic Toxicity and Hazard Assessment: Seventh Symposium,* ASTM STP 854, pp. 429–453, R.D. Caldwell, R. Purdy, and R.C. Bahner, Eds., 1985 which is incorporated by reference. This published procedure is available for public inspection at the Office of Federal Register, Room 8301, 1100 L St., NW., Washington, DC 20408, and copies may be obtained from the EPA TSCA Public Docket Office in Rm. G–004, NE Mall, 401 M St., SW., Washington, DC 20460. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 522(a) and 1 CFR part 51. The method is incorporated as it exists on the effective date of this rule and a notice of any change to the method will be published in the **Federal Register.**

(ii) *Reporting requirements.* (A) The benthic sediment invertebrate bioassay, if required, shall be completed and the final report submitted to EPA within 21 months of the effective date of the final rule.

(B) An interim progress report shall be submitted to EPA for the benthic sediment invertebrate bioassy 6 months after the initiation of the test.

(e) *Chemical fate testing*—(1) *Vapor pressure*—(i) *Required testing.* Vapor pressure testing shall be conducted with TBP in accordance with § 796.1950 of this chapter.

(ii) *Reporting requirements.* The vapor pressure test required in paragraph (d)(1) of this section shall be completed and the final report submitted to EPA within 6 months of the effective date of the final rule.

(2) *Sediment and soil adsorption isotherm*—(i) *Required testing.* Sediment and soil absorption isotherm testing shall be conducted with TBP in accordance with § 796.2750 of this chapter and EPA will provide two soil and two sediment samples.

(ii) *Reporting requirements.* (A) The sediment and soil absorption isotherm test required under paragraph (d)(2) of this section shall be completed and the final report submitted to EPA within 6 months of the effective date of the final rule.

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

(1) A Koc value shall be calculated for each test sediment using the equation Koc=K/ (percent of organic carbon in test sediment).

(2) [*Reserved*]

(3) *Hydrolysis as a function of pH at 25°C*—(i) *Required testing.* Hydrolysis testing shall be completed with TBP in accordance with § 796.3500 of this chapter.

(ii) *Reporting requirements.* The hydrolysis test required under paragraph (e)(3) of this section shall be completed and the final report submitted to EPA within 6 months of the effective date of the final rule.

(f) *Effective date.* (1) The effective date of the final rule is September 27, 1989.

(2) The guidelines and other test methods cited in this section are referenced here as they exist on September 27, 1989.

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

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Monday
August 14, 1989

Part V

Environmental Protection Agency

40 CFR Parts 116, 117, and 302
Reportable Quantity Adjustments; Delisting of Ammonium Thiosulfate; Final Rules

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 302

[SW H-FRL 3281-8]

Reportable Quantity Adjustments

AGENCY: U.S. Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Sections 103(a) and (b) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended, require that persons in charge of vessels or facilities from which hazardous substances have been released in quantities that are equal to or greater than their reportable quantities (RQs) immediately notify the National Response Center of the release. Section 102(b) sets an RQ of one pound for hazardous substances, except those substances for which different RQs have been established pursuant to section 311(b)(4) of the Clean Water Act (CWA). In addition to these reporting requirements section 304 of the Superfund Amendments and Reauthorization Act of 1986 (SARA) Title III requires that releases of hazardous substances in quantities equal to or greater than their RQs (or one pound if a reporting trigger is not established by regulation) be reported to State and local authorities.

Section 102(a) of CERCLA authorizes the U.S. Environmental Protection Agency (EPA or "the Agency") to adjust RQs for hazardous substances and to designate as hazardous substances those substances that, when released into the environment, may present substantial danger to the public health or welfare or the environment. Currently there are 725 CERCLA hazardous substances.[1] In this rulemaking, EPA is promulgating the RQ adjustments for six of the 273 hazardous substances whose RQs were proposed to be adjusted in a March 16, 1987 Notice of Proposed Rulemaking (NPRM). These six substances are: 1,4-dioxane, 2-ethoxyethanol, ethylene oxide, 2-nitropropane, perchloroethylene, and saccharin. By making the adjustments contained in this rulemaking, the Agency will be able to focus its resources on those releases which are most likely to pose potential threats to public health or welfare or the environment. In addition, by making these adjustments, EPA will relieve the regulated community of the burden of reporting releases which are unlikely to pose such threats.

EFFECTIVE DATE: August 14, 1989.

ADDRESSES: The toll-free telephone number of the National Response Center is 1–800/424–8802; in the Washington, DC metropolitan area the number is 1–202/267–2675.

Docket: Copies of materials relevant to this rulemaking are contained in Room M2427 at the U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460 (Docket Number 102 RQ–273C). The docket is available for inspection between the hours of 9:00 a.m. and 4:00 p.m. Monday through Friday, excluding Federal holidays. To review docket materials, you may make an appointment by calling 1–202/382–3046. The public may copy a maximum of 50 pages from any regulatory docket at no cost. Additional copies cost $.20 per page.

FOR FURTHER INFORMATION CONTACT: Ivette O. Vega, Response Standards and Criteria Branch, Emergency Response Division, U.S. Environmental Protection Agency (OS–210), 401 M Street, SW, Washington, DC 20460, or the RCRA/Superfund Hotline at 1–800/424–9346; in the Washington, DC metropolitan area at 1–202/382–3000.

SUPPLEMENTARY INFORMATION: The contents of today's preamble are listed in the following outline:

I. Introduction

A. Statutory Authority

Section 102(b) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) (Pub. L. 96–510), 42 U.S.C. 9601 *et seq.*, as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA) (Pub. L. 99–499), establishes reportable quantities (RQs) of one pound for releases of hazardous substances, except for hazardous substances whose RQs were established at a different level pursuant to section 311 of the CWA. Section 102(a) of CERCLA authorizes EPA to adjust all of these RQs by regulation.

Sections 103(a) and (b) of CERCLA require that the person in charge of a vessel or facility notify the National Response Center immediately when there is a release of a hazardous substance in an amount equal to or greater than the RQ for that substance. This notification requirement serves as a trigger for informing the government of a release so that Federal personnel can evaluate the need for a Federal removal or remedial action and undertake any necessary action in a timely fashion. Under section 104 of CERCLA, the Federal government may respond whenever there is a release or substantial threat of a release of a hazardous substance into the environment. Responses are to be taken, to the extent practicable, in accordance with the National Oil and Hazardous Substances Pollution Contingency Plan (40 CFR Part 300), which was originally developed under the CWA and which has been revised to reflect the responsibilities and authority created by CERCLA.

[1] EPA proposed RQ adjustments for the hazardous substances whose RQs are promulgated in this final rule on March 16, 1987. As of that date, there were 717 CERCLA hazardous substances. Changes to the list of CERCLA hazardous substances since March 16, 1987 are described below. Four hazardous waste streams (K123, K124, K125, and K126) were added in a final rule (51 FR 37725) that became effective on April 24, 1987, bringing the total number of CERCLA hazardous substances to 721. EPA removed iron dextran and strontium sulfide from the list in two final rules (53 FR 43878 and 53 FR 43881) effective October 31, 1988, thus reducing the number of CERCLA hazardous substances to 719. Six hazardous substances (waste streams K064, K065, K066, K088, K090, and K091) were added to the CERCLA list in a final rule (53 FR 35412) that became effective on March 13, 1989, increasing the number of CERCLA hazardous substances to 725, which is the current total. Lastly, based on a final rule published elsewhere in today's **Federal Register**, ammonium thiosulfate will be removed from the CERCLA list 60 days from today's date, thus reducing the number of CERCLA hazardous substances to 724.

If a release meets certain statutory criteria set out in CERCLA section 103(f)(2), the release may be subject to more limited reporting requirements. Specifically, a release is subject to these limited requirements if the release: (1) Is continuous and stable in quantity and rate, and is from a facility for which notification has been given under CERCLA section 103(c), or (2) is a release for which notification has been given under CERCLA sections 103(a) and (b) for a period sufficient to establish continuity, quantity, and regularity of the release. Notification must still be given annually and when there is a statistically significant increase in the release. In addition, CERCLA section 103 provides a reporting exemption for federally permitted releases. The definition of federally permitted release in CERCLA section 101(10) specifically identifies releases permitted under certain other Federal or State programs. Several commenters claimed that their particular releases are subject to continuous and/or federally permitted release treatment. EPA published proposed regulations to clarify the reduced reporting requirement for continuous releases on April 19, 1988 (53 FR 12868). EPA also clarified the reporting exemption for federally permitted releases in proposed regulations published on July 19, 1988 (53 FR 27268). Comments on continuous and federally permitted release issues submitted in response to the March 16, 1987 NPRM will be addressed in the upcoming final rules for continuous and federally permitted releases.

In addition to the reporting requirements established by CERCLA, section 304 of SARA Title III requires the owners and operators of certain facilities to report releases of CERCLA hazardous substances to State and local authorities. SARA Title III section 304 notification must be given immediately after the release of an RQ or more (one pound or more if a reporting trigger is not established by regulation) to the community emergency coordinator for each local emergency planning committee for any area likely to be affected by the release, and to the State emergency response commission of any State likely to be affected by the release. These notification requirements apply only to releases that have potential for off-site exposure and that are from facilities at which a "hazardous chemical" (defined by regulations under the Occupational Safety and Health Act of 1970 (29 CFR 1910.1200(c)) and section 311 of SARA Title III) is produced, used, or stored.

Section 109 of CERCLA and section 325 of SARA Title III authorize EPA to assess civil penalties for failure to report releases of hazardous substances that equal or exceed their RQs. Section 103 of CERCLA, as amended, authorizes EPA to seek criminal penalties for submitting false or misleading information in a notification made pursuant to CERCLA section 103, and increases the maximum penalties and years of imprisonment for violation of the CERCLA section 103 reporting requirement.

B. Background of This Rulemaking

On May 25, 1983, EPA proposed a rule (48 FR 23552) to clarify procedures for reporting releases of CERCLA hazardous substances and to adjust RQs for 387 of the then 696 hazardous substances.[2] In the May 25, 1983 Notice of Proposed Rulemaking (NPRM) EPA also compiled for the first time the list of "hazardous substances" defined under section 101(14) of CERCLA. In the preamble to that NPRM, EPA discussed in detail the CERCLA notification provisions, the methodology and criteria used to adjust the RQ levels, and the RQ adjustments proposed under section 102 of CERCLA and under section 311 of the CWA. EPA promulgated final RQ adjustments for 340 hazardous substances in an April 4, 1985 final rule (50 FR 13456) and for an additional 102 substances in a September 29, 1986 final rule (51 FR 34534). In an NPRM published on March 16, 1987 (52 FR 8140), EPA proposed RQ adjustments for 273 hazardous substances. The March 16, 1987 **Federal Register** also contained an NPRM in which EPA proposed RQ adjustments for radionuclides.[3] In addition, in an NPRM published on March 2, 1988 (53 FR 6762), EPA reproposed RQ adjustments for lead metal and four lead compounds, and proposed to delist ammonium thiosulfate as a CERCLA hazardous substance.

This rulemaking finalizes the RQ adjustments for six of the 273 hazardous substances whose RQs were proposed for adjustment in the March 16, 1987 NPRM. This rule contains EPA's responses to all issues raised by the commenters relating to the RQ adjustment methodology for potential carcinogenicity, except those methodology issues not relevant to the six RQ adjustments promulgated in this final rule (for further discussion, see Section II.B.2 of this preamble). This rule also contains responses to public comments received on the specific RQ adjustments for the hazardous substances in this rulemaking. Comments were received on the proposed RQ adjustments for only three hazardous substances (1,4-dioxane, perchloroethylene, and saccharin) of the six hazardous substances for which RQ adjustments are promulgated in this rule.

RQ adjustments for 258 hazardous substances, including 254 of the 273 hazardous substances whose RQs were proposed for adjustment in the March 16, 1987 NPRM, are contained in a final rule published elsewhere in today's **Federal Register**. As explained in Section II.C.2.i of the preamble to the other final RQ adjustment rule published in today's **Federal Register**, EPA will address the RQs for the remaining 13 substances of the 273 substances that were the subject of the March 16, 1987 NPRM in a future action.

Section 306(a) of CERCLA, as amended by SARA section 202, requires the U.S. Department of Transportation (DOT) to list and regulate CERCLA hazardous substances as hazardous materials under the Hazardous Materials Transportation Act. Pursuant to this requirement, DOT promulgated on November 21, 1986, a final rule (51 FR 42174) providing that, when a hazardous substance is shipped in a quantity equal to or greater than its RQ, it must be identified as such in shipping papers and by package markings. This rule became effective on July 1, 1987 (51 FR 46672). The rule requires shippers of hazardous substances in quantities at or above their RQs to place the notation "RQ" and the name of the substance on shipping papers and package markings.

RQs for many of the hazardous substances proposed for adjustment in the March 16, 1987 NPRM (including the six substances whose adjusted RQs are being promulgated today) were proposed to be adjusted upward from their statutory RQs. The estimated production volume for the six hazardous substances whose adjusted RQs are being promulgated today is 4.6 billion

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[2] Since the May 25, 1983 NPRM, 31 substances have been added and two substances have been deleted from the CERCLA list, bringing the total number of CERCLA hazardous substances to 725. The 31 substances added to the list are: waste stream F024 (49 FR 5308); coke oven emissions (49 FR 36560); waste streams F020, F021, F022, F023, F026, F027, and F028 (50 FR 1978); waste streams K111, K112, K113, K114, K115, and K116, o-toluidine and p-toluidine (50 FR 42936); waste streams K117, K118, and K136 (51 FR 5327); 2-ethoxyethanol (51 FR 6537); waste streams K123, K124, K125, and K126 (51 FR 37725); and waste streams K064, K065, K066, K088, K090, and K091 (53 FR 35412). The two substances deleted from the list are: iron dextran (53 FR 43878) and strontium sulfide (53 FR 43881).

[3] RQ adjustments for radionuclides were promulgated in a final rule published on May 24, 1989 (54 FR 22524).

pounds annually. Because this amount represents a relatively large proportion of the total production volume of all 273 hazardous substances proposed for RQ adjustment in the March 16, 1987 NPRM, many shippers would be subject to a regulatory burden that is not justified by the hazards that these substances pose to human health and the environment. Once final RQ adjustments are promulgated for these six hazardous substances, shippers of less than the adjusted RQ of a substance will not be subject to DOT regulations relating to shipping papers and package markings. Accordingly, EPA is expediting the promulgation of a final rule adjusting RQs for these substances by making this rule effective immediately upon promulgation. Because this rule "grants or recognizes an exemption or relieves a restriction" under section 553(d)(1) of the Administrative Procedure Act (APA), the APA requirement that final rules become effective no less than 30 days after publication does not apply.

In finalizing these RQ adjustments, this rule amends Table 302.4 of 40 CFR Part 302. Section II of this preamble discusses the RQ adjustments promulgated in this rulemaking and the methodology used in making these adjustments. Section II also includes EPA's responses to public comments on the March 16, 1987 NPRM that are relevant to the six RQ adjustments made in this rule and to the RQ adjustment methodology on which these six adjustments are based. Section III provides a summary of the analyses supporting this rulemaking.

II. Reportable Quantity Adjustments

A. Introduction

In this rulemaking, the Agency adjusts RQs based upon specific scientific and technical criteria that relate to the possibility of harm from the release of a hazardous substance at certain levels. The quantity released is but one factor considered by the government when assessing the need to respond to such a release. Other factors, assessed on a case-by-case basis, include but are not limited to: (1) The location of the release; (2) its proximity to drinking water supplies or other valuable resources; and (3) the likelihood of exposure or injury to nearby populations. The RQ adjustments made today will enable the Agency to focus its resources on those releases that are most likely to pose potential threats to public health or welfare or the environment. These adjustments will also relieve the regulated community and emergency response personnel from the burden of making and responding to reports of releases that are unlikely to pose such threats.

In this final rule, the Agency is adjusting RQs for 1,4-dioxane, 2-ethoxyethanol, ethylene oxide, 2-nitropropane, perchloroethylene, and saccharin. With the exception of 2-ethoxyethanol (which was not identified as a potential carcinogen under the identification methodology discussed in Section II.B. below), all of these hazardous substances have been evaluated for potential carcinogenicity as well as other primary criteria. The final RQ adjustments promulgated today are based on the results of this evaluation. In the case of 2-ethoxyethanol, its final RQ adjustment is based on the primary criterion of chronic toxicity (see the discussion below).

B. Reportable Quantity Adjustment Methodology

1. Summary of the Methodology

The Agency has wide discretion in adjusting the statutory RQs for hazardous substances under CERCLA. Administrative feasibility and practicality are important considerations. The Agency's methodology for adjusting RQs begins with an evaluation of the intrinsic physical, chemical, and toxicological properties of each hazardous substance. The intrinsic properties examined—called "primary criteria"—are aquatic toxicity, mammalian toxicity (oral, dermal, and inhalation), ignitability, reactivity, chronic toxicity,[4] and potential carcinogenicity.

The Agency ranks hazardous substances for each intrinsic property (except potential carcinogenicity) on a five-tier scale, associating a specific range of values on each scale with a particular RQ value.[5] This five-tier scale uses the five RQ levels of one, 10, 100, 1000, and 5000 pounds, originally established pursuant to CWA section 311 (see 40 CFR 117 and 44 FR 50776). For hazardous substances evaluated for potential carcinogenicity, each substance is assigned a hazard ranking of "high," "medium," or "low." These hazard rankings correspond to RQ levels of one, 10, and 100 pounds, respectively (see below). Each hazardous substance evaluated under the various primary criteria is assigned several tentative RQ values based on its particular properties as data allow. The lowest of the tentative RQs becomes the "primary criteria RQ" for that substance. After the primary criteria RQs are assigned, substances are further evaluated for their susceptibility to certain degradative processes, which are used as secondary adjustment criteria. These natural degradative processes are biodegradation, hydrolysis, and photolysis (BHP). For further discussion of BHP, see Section II.B.2.a of the preamble to the final rule in which EPA promulgates RQ adjustments for 258 hazardous substances, published elsewhere in today's Federal Register.

If a hazardous substance, when released into the environment, degrades relatively rapidly to a less hazardous form by one or more of the BHP processes,[6] its RQ (as determined by the primary RQ adjustment criteria) is raised one level. This adjustment is made because the relative potential for harm to public health or welfare or the environment posed by the release of such a substance is reduced by these degradative processes. Conversely, if a hazardous substance degrades to a more hazardous product after its release, the original substance is assigned an RQ equal to the RQ for the more hazardous substance, which may be one or more levels lower than the RQ for the original substance. The downward adjustment is appropriate because the hazard posed by the release of the original substance is increased as a result of BHP.

To identify those CERCLA hazardous substances that may be potential carcinogens, EPA reviewed four sources of human epidemiologic and/or animal bioassay data on hazardous substances that suggest possible carcinogenic effect. These sources are: (1) The Annual Reports on Carcinogens of the National Toxicology Program (NTP), U.S. Department of Health and Human Services; (2) the Monographs of the International Agency for Research on Cancer (IARC); (3) final Agency determinations published in the **Federal Register** identifying substances as potential carcinogens; and (4) ongoing determinations by the Agency's Office of Health and Environmental

[4] EPA is aware that some chronic effects result from acute (short-term) exposures and considers such data in the chronic toxicity evaluations. The Agency is further evaluating data on chronic effects resulting from acute exposures to ensure that such data receive adequate consideration in the RQ adjustment process.

[5] All of the RQs promulgated in this rulemaking are subject to the Agency's review of the most recent systemic (i.e., relating to a particular organ system) toxicity data. These RQs will be revised, if necessary, in a future rulemaking based on the results of this review.

[6] The specific thresholds for the application of BHP to hazardous substances are discussed in the Technical Background Document to Support Rulemaking Pursuant to CERCLA Section 102, Volume 1, March 1985, available for inspection at Room M2427, U.S. EPA, 401 M Street, SW., Washington, DC 20460.

Assessment that substances may be potential carcinogens, based on either published or unpublished data.[7] The Agency compared the list of substances derived from these four sources with the list of the CERCLA hazardous substances to determine which hazardous substances should be evaluated for potential carcinogenicity.

Not all of the substances so identified are subsequently ranked for potential carcinogenicity. Only those substances that fall within the Agency's weight-of-evidence Groups A, B, or C discussed below (i.e., known, probable, or possible human carcinogens) are ranked and assigned tentative RQs based on potential carcinogenicity.

The evaluation of hazardous substances for potential carcinogenicity initially involves a qualitative assessment of the available scientific literature on the substance. The data are reviewed to determine the degree of certainty or weight of evidence that a particular hazardous substance is a human carcinogen. The substance is then classified in an overall weight-of-evidence category (A, B, C, D, or E).

A hazardous substance is placed in Group A (known human carcinogen) only if "sufficient" evidence from human epidemiologic studies supports a causal connection between exposure to the hazardous substance and cancer. Group B (probable human carcinogen) is divided into two subgroups, B1 and B2. Group B1 includes hazardous substances for which the weight of evidence of human carcinogenicity based on epidemiologic studies is "limited." Group B2 includes hazardous substances for which there is "no data," "inadequate evidence," or "no evidence" of human carcinogenicity from epidemiologic studies, but for which the weight of evidence of carcinogenicity based on animal studies is "sufficient." Group C (possible human carcinogen) includes hazardous substances with "limited" evidence of carcinogenicity in animals and "inadequate evidence," "no data," or "no evidence" from human epidemiologic studies. As mentioned in the March 16, 1987 NPRM (52 FR 8144), Group D substances (not classifiable for human carcinogenicity) and Group E substances (evidence of noncarcinogenicity for humans) are not considered potential carcinogens for purposes of this rulemaking.

The evaluation of hazardous substances for potential carcinogenicity also involves a quantitative assessment of the available data to calculate the relative strength of a hazardous substance to elicit a carcinogenic response (i.e., the "potency factor").[8] This quantitative assessment allows the Agency to rank potential carcinogens on a numerical scale by identifying the most potent substances as the most hazardous. Group 1 includes those hazardous substances with the highest potencies. Other potential carcinogens with medium and low potencies are placed in Groups 2 and 3, respectively.

The final step in the hazard ranking procedure is to combine the qualitative weight-of-evidence groups and the quantitative potency factor groups using a matrix to yield a relative hazard ranking for each substance. Thus, hazard rankings are based on two factors—weight of evidence and potency—that the Agency believes are important in describing carcinogenic hazards. The following is the matrix used to assign hazard rankings to potential carcinogens in today's two final rules:

HAZARD RANKING

Weight-of-evidence group	Potency group		
	1 (highest)	2	3 (lowest)
A	High	High	Medium.
B	High	Medium	Low.
C	Medium	Low	Low.
D	No hazard ranking is made. The other primary criteria are used to assign the RQ.		
E	No hazard ranking is made. The other primary criteria are used to assign the RQ.		

The matrix is used to group the potential carcinogens into "high," "medium," and "low" hazard categories, and is arranged so that as the weight of evidence and the potency decrease, the hazard ranking also decreases. RQ levels are then assigned to the hazard rankings as follows: high—one-pound RQ; medium—10-pound RQ; and low—100-pound RQ.

For a more detailed discussion of the RQ adjustment methodology based on the primary criterion of potential carcinogenicity, see the preamble to the March 16, 1987 NPRM (52 FR 8140) and the Technical Background Document to Support Rulemaking Pursuant to CERCLA Section 102, Volume 3, available for inspection at Room M2427, U.S. EPA, 401 M Street, SW., Washington, DC 20460.

EPA stated in the March 16, 1987 NPRM (see 52 FR 8146) that it was reviewing its position on consideration of benign tumors and pooling of tumor sites and types, as set forth in the Agency's Guidelines for Carcinogen Risk Assessment.[9] The effect of this review on RQs for potential carcinogens is discussed in the preamble to the final rule published elsewhere in today's **Federal Register** in which EPA promulgates RQ adjustments for 258 hazardous substances.

2. Responses to Comments Received on the Methodology

The Agency received 35 comment letters on the March 16, 1987 NPRM (52 FR 8140). Ten of these letters contain comments that address the RQ adjustment methodology proposed in that NPRM for evaluating CERCLA hazardous substances for potential carcinogenicity. The comments on the RQ adjustment methodology are grouped into five categories: (1) Carcinogen hazard ranking methodology and the 100-pound maximum RQ; (2) the use of NTP and IARC publications in the Agency's identification methodology; (3) the Agency's use of its Guidelines for Carcinogen Risk Assessment to derive RQs; (4) the application of the secondary RQ adjustment criteria of BHP to potential carcinogens; and (5) the application of the CWA mixture rule to hazardous waste streams. Because none of the six hazardous substances that are the subject of this final rule meets the criteria for applying BHP and none are hazardous waste streams, the following discussion focuses on the first three comment categories. Comments that fall within the last two categories are addressed in a final rule published elsewhere in today's **Federal Register** that promulgates RQ adjustments for 254 of the 273 hazardous substances proposed for adjustment in the March 16, 1987 NPRM.

[7] In addition to this application of unpublished data to identify potential carcinogens, EPA intends to use such data for the purpose of ranking potential carcinogens under the CERCLA RQ methodology. Currently, the Agency is evaluating unpublished data received on the weight of evidence and potency of certain potential carcinogens and will present the results of this evaluation, along with any RQ adjustments, in a future rulemaking.

[8] For an explanation of how potency factors are calculated, see the Technical Background Document to Support Rulemaking Pursuant to CERCLA Section 102, Volume 3, available for inspection at Room M2427, U.S. EPA, 401 M Street, SW., Washington, DC 20460.

[9] As discussed in Section II.B.2.c below, the Guidelines provide that benign tumors should be considered along with malignant tumors unless there is evidence that the benign tumors do not have the potential to progress to malignancies of the same histogenic origin. The Agency pools tumor sites and types when each site or type, viewed separately, shows a tumor incidence that is elevated significantly above the incidence in control animals (51 FR 33992, September 24, 1986).

a. Carcinogen Hazard Ranking Methodology and the 100-Pound Maximum RQ. In the March 16, 1987 NPRM (52 FR 8140), EPA proposed RQ adjustments for potential carcinogens of one, 10, and 100 pounds. Several commenters objected to the proposed 100-pound maximum RQ for potential carcinogens. The commenters recommended that hazardous substances with no greater than "inadequate" evidence of cancer in humans and "limited" evidence of cancer in animals receive 1000- or 5000-pound RQs.

EPA disagrees with the commenters for the reasons discussed below. First, as stated in the March 16, 1987 NPRM, although cancer is a unique health effect with its own special properties, it is also a type of chronic effect. EPA, therefore, has determined that reference to the Agency's chronic toxicity methodology is appropriate in assigning RQs to potential carcinogens. Under the chronic toxicity methodology, each substance is assigned two rating values, one based on the dose that causes a particular effect, and one based on the severity of the effect. The dose ratings range from one to 10, with 10 representing the most toxic substances. The effect ratings also range from one to 10, with 10 representing the most severe effect. The product of the dose and effect ratings for each substance yields a composite ranking score between one and 100. Because cancer is a life-threatening effect, the effect rating for cancer would be 10 if cancer were ranked on the chronic toxicity scale. Therefore, the composite score for any potential carcinogen would be at least 10. A composite score of 10 corresponds to an RQ of 1000 pounds. Thus, a 5000-pound RQ for a potential carcinogen would be inappropriate based on the Agency's chronic toxicity scale (see 52 FR 8145).

Two commenters stated that this analogy between chronic toxicity and potential carcinogenicity is not valid because chronic toxicants have *known* human health effects, whereas the human health effects of potential carcinogens are often determined by speculation based on animal data. EPA believes that these commenters have exaggerated the distinction between the data for chronic toxicity and the data for potential carcinogenicity. The human health effects of both chronic toxicants and potential carcinogens are based to a large degree on observation of health effects in experimental animals. Therefore, the Agency believes that reference to its chronic toxicity methodology in determining the RQ levels for potential carcinogens is appropriate.

Second, EPA believes that the special properties of potential carcinogens are important in assigning RQ levels to these substances. These special properties are: (1) The lack of a demonstrated threshold level below which a potential carcinogen presents no risk of cancer; (2) the cumulative nature of cancer risks; and (3) the fact that cancer has a latent period that does not allow direct observation of carcinogenic risks from substances newly released into the environment (52 FR 8145, March 16, 1987).

These three special properties of potential carcinogens suggest a conservative approach by the Agency in assigning RQ levels to these substances. Where a potential carcinogen does not have a threshold level of exposure below which it presents no risk of cancer, each individual exposure, regardless of amount, may cause irreversible health effects. The lack of demonstrated threshold levels for potential carcinogens also means that an individual may develop cancer (an irreversible health effect) at doses that cause no other physical effects. The cumulative nature of cancer risks means that each additional exposure, at any dose, further increases the likelihood of a carcinogenic response. Additionally, for substances that have a latent period that does not allow direct observation of carcinogenic risks, the Agency has greater reason to be conservative in assessing the health risks accompanying exposure at any dose. In particular, the latent period of cancer, when taken together with the fact that cancer may develop from doses too small to cause other physical effects, means that individuals may not be aware that they need to leave release sites at which they may be exposed to dangerous levels of potential carcinogens. The Agency, therefore, has determined that the special properties of potential carcinogens justify assigning lower RQs (i.e., one, 10, and 100 pounds) to potential carcinogens than the RQs that are assigned to other hazardous substances (i.e., one, 10, 100, 1000, and 5000 pounds).

In summary, a 100-pound maximum RQ for potential carcinogens is retained because (1) reference to the Agency's chronic toxicity scale shows that a 5000-pound RQ would be inappropriate for any potential carcinogen; and (2) the Agency believes that the special properties of potential carcinogens justify a more conservative approach in setting RQ levels for these substances than for other hazardous substances.

Several commenters objected to the fact that the Agency assigns the same "low" hazard ranking (and resultant 100-pound RQ) to weight-of-evidence Group C, potency Group 3 potential carcinogens that it assigns to weight-of-evidence Group B2, potency Group 3 potential carcinogens. Thus, the commenters disagreed with the proposed 100-pound maximum RQ for potential carcinogens. The commenters recommended that hazardous substances with no greater than "inadequate" evidence of cancer in humans and "limited" evidence of cancer in animals (i.e., weight-of-evidence Group C) receive 1000- or 5000-pound RQs.

At this time, EPA has decided to retain the 100-pound maximum RQ for potential carcinogens. However, EPA plans to evaluate the RQ adjustment methodology for potential carcinogens, particularly the weight-of-evidence Group C, potency Group 3 substances.[10] The results of this evaluation will be addressed in a future Agency action. Note that this continuing investigation does not alter today's determination that these substances be assigned RQs of no more than 100 pounds.

b. Use of NTP and IARC Determinations. Several commenters suggested that the Agency not rely on NTP and IARC determinations as a basis for RQ rulemakings and recommended that EPA independently evaluate the qualitative evidence of carcinogenicity for each hazardous substance. In the March 16, 1987 NPRM (52 FR 8143), the Agency proposed a procedure for screening the list of CERCLA hazardous substances to identify hazardous substances that might require assessment for potential carcinogenicity. The NTP annual reports and IARC monographs are used only as an initial screen for substances to be evaluated for potential carcinogenicity by the Agency. The conclusions reached by IARC or NTP on specific chemicals do not determine directly whether a hazardous substance is considered a potential carcinogen for purposes of establishing RQs. Rather, EPA follows

[10] Five individual hazardous substances are in this category: 5-nitro-o-toluidine; saccharin; p-toluidine; 1,1,1,2-tetrachloroethane; and 1,1,2-trichloroethane. EPA is promulgating an RQ adjustment of 100 pounds for saccharin in this final rule. RQ adjustments of 100 pounds for the other four weight-of-evidence Group C, potency Group 3 substances are promulgated in a final rule published elsewhere in today's Federal Register. In that same final rule, EPA also promulgates RQ adjustments for seven waste streams (F002, K073, K095, K096, K112, K113, and K114) that contain one or more of the five weight-of-evidence Group C, potency Group 3 substances.

the procedures set out in its Guidelines for Carcinogen Risk Assessment to make this determination.

c. Application of EPA's Carcinogen Assessment Guidelines. EPA's methodology for adjusting RQs for potential carcinogens is derived from the Agency's Guidelines on Carcinogen Risk Assessment. The comments addressed in this section are directed toward the Guidelines' classification of potential carcinogens. Although the discussion of these issues below is not an independent defense of the Guidelines, the Agency's responses to public comments in this rulemaking are fully consistent with EPA's response to comments received during preparation of the final Guidelines.

Two commenters objected to the Agency's lack of distinction between the B1 and B2 weight-of-evidence Groups for hazard ranking purposes. These commenters suggested that weight-of-evidence Groups B1 and B2 be distinguished by assigning B2 potential carcinogens hazard rankings one level higher than the hazard rankings for B1 potential carcinogens.

As discussed in Section II.B.1 above, the Agency has divided weight-of-evidence Group B into two subgroups, B1 and B2. Where there is limited evidence of carcinogenicity from epidemiologic studies, a hazardous substance usually is placed in Group B1. Hazardous substances for which there is "sufficient" evidence from animal studies and "inadequate" evidence or "no data" from human epidemiologic studies are usually placed in Group B2. The decision to divide Group B into two subgroups reflects only the type of evidence of carcinogenicity, not a judgment that B2 substances are of lesser concern than B1 substances. Furthermore, because it is reasonable to treat hazardous substances for which there is sufficient evidence of carcinogenicity in animals (Group B2) as if they present a carcinogenic risk to humans, such substances, along with other substances for which there is limited evidence from human epidemiologic studies (Group B1), are classified as probable human carcinogens (Group B). Thus, the Agency believes that, for RQ adjustment purposes, no distinction in levels of concern is warranted between Group B1 and Group B2 substances.

Two commenters suggested that the Agency not count benign tumors equally with malignant tumors when there is no evidence that the benign tumors are precursors of malignant tumors or are life threatening. EPA agrees with the commenters that benign tumors should not be treated equally with malignant tumors if there is no evidence that the benign tumors will progress to malignancies of the same histogenic origin. It is recognized, however, that benign tumors frequently induce malignant tumors and that benign tumors often progress to malignant tumors (see 51 FR 33992, 33994, citing Interdisciplinary Panel on Carcinogenicity, 1984, Science 225:686, note 4). In such cases, the Agency's consideration of benign tumor data in assessing potential carcinogenicity is appropriate.

Several commenters disagreed with the Agency's use of body surface area ratios for deriving human potency values from animal potency calculations and recommended the use of body-weight ratios instead. The commenters argued that the use of body surface area as an interspecies scaling factor is based on data relating to the noncarcinogenic effects of drugs. The Agency's use of body surface area to extrapolate from animals to humans was discussed in the response to comments on the Proposed Guidelines for Carcinogen Risk Assessment. In that response, the Agency concluded that the choice of the body surface area scaling factor could be justified by the data on effects of drugs in various species, and that EPA would continue to use this scaling factor unless data on a specific agent suggests that a different scaling factor is justified. Furthermore, because RQs are based on a relative ranking of substances, the consistent application of scaling factors to all substances should not have a material effect on the relative rankings.

Two commenters objected to the Agency's policy of pooling tumors at different sites. The Agency pools tumor sites, however, only when each site, viewed separately, shows a significant elevated tumor incidence. EPA believes that pooling of tumor sites is justified in these limited circumstances because an agent that induces cancer in two locations is of greater concern than an agent that induces cancer in only one location.

The same two commenters objected to the Agency's use of effective dose (which takes into account absorption, distribution, metabolism, and excretion of potential carcinogens) to calculate potency. The commenters argued that administered dose (the actual experimental dose) should be used to estimate relative carcinogenic potency for purposes of assigning RQs. The commenters acknowledged that effective dose is appropriate for estimating absolute measures of risk. The commenters failed to demonstrate, however, that effective dose is inappropriate for measuring relative risk. As a practical matter, for most hazardous substances (approximately 90 percent), EPA uses administered dose because the Agency lacks information necessary to distinguish between administered dose and effective dose. Nevertheless, where such information is available, the Agency prefers to use effective dose rather than administered dose, because the former is more appropriate for measuring relative levels of risk (e.g., RQ levels). Effective dose is used to determine carcinogenic potency only when a substance has undergone extensive studies that have been subject to peer review.

One commenter stated that the Agency proposed to regulate animal carcinogens in the same manner as known human carcinogens and that regulation should focus on exposures to substances with known human health effects. This commenter is mistaken in believing that the RQ adjustment methodology treats animal and human carcinogens equally. The hazard ranking methodology used to establish RQs for potential carcinogens assigns lower RQs to known human carcinogens of the same potency as known animal carcinogens for which the human evidence is limited or inadequate. Moreover, EPA does not believe that its regulation of potential carcinogens should be limited to those which have *known* human health effects, because the Agency strongly believes that animal data are relevant to predict the potential for a carcinogenic response at some dose in humans.

One commenter argued that extrapolation from continuous low-dose exposure studies to effects of one-time releases cannot be made. The Agency acknowledges that estimating the absolute effect of one-time releases from experimental data is difficult. However, the establishment of RQs is not based on an assessment of absolute effects, and the Agency believes that the Guidelines for Carcinogen Risk Assessment (which were followed in this rulemaking) provide a reasonable basis for determining a relative ranking of potential carcinogens. These guidelines have been peer reviewed and revised based on public comments and therefore provide a reasonable basis for carcinogenic assessment. Furthermore, the commenter failed to note certain implications of the relationship between one-time releases and one-time exposures. One-time releases can contaminate water or soil, resulting in continuous low-dose exposures over a period of years. Thus, the Agency's extrapolation from continuous low-dose

exposure studies to effects of one-time releases is reasonable.

This commenter also noted that there are significant uncertainties involved in low-dose extrapolation. EPA agrees and, therefore, has developed an RQ methodology that does not use low-dose extrapolation. The methodology relies instead on the ED10, that is, the dose that causes an increased cancer incidence of 10 percent. Use of the ED10 is advantageous because it eliminates the issue of low-dose extrapolation for RQ adjustment purposes.

The same commenter argued that low doses of certain heavy metals are essential to human health, and that low exposures to suspected carcinogens may not pose significant incremental risks. Thus, according to the commenter, extrapolation over a wide range of doses may not be appropriate.

EPA agrees with the commenter that certain substances can have both beneficial effects at low doses and toxic effects at high doses. In addition, low doses can have both beneficial and toxic effects simultaneously. The question of whether a particular release will cause exposed individuals to experience toxic effects, however, is a question of risk assessment to be made by the Federal On-Scene Coordinator (OSC) based on all available information pertinent to the particular release. As stated earlier, the establishment and adjustment of RQs is intended to be a reporting trigger rather than a risk assessment.

For the reasons discussed above, EPA has decided at this time that no changes to the Agency's Guidelines for Carcinogen Risk Assessment are necessary. Nevertheless, the Agency continually reviews the Guidelines; if new information or procedures become available, the Agency will consider whether revisions are warranted.

C. Substances for Which RQs Are Adjusted

1. Summary

Today's final rule adjusts the RQs for six of the 273 hazardous substances whose RQs were proposed to be adjusted in the March 16, 1987 NPRM. These six RQ adjustments are shown in the following table:

Hazardous substance	Statutory RQ	Proposed and final RQ adjustment
1,4-Dioxane	1	100
2-Ethoxyethanol	1	1000
Ethylene oxide	1	10
2-Nitropropane	1	10
Perchloroethylene	1	100
Saccharin and salts	1	100

EPA has promulgated the proposed RQ adjustments without change for each of these six substances. For the reasons discussed in Section I.B. of this preamble, the Agency has decided to expedite the promulgation of RQ adjustments for these six substances.

2. Response to Comments

Public comments on the March 16, 1987 NPRM addressed proposed RQ adjustments for three of the six hazardous substances in this rulemaking: 1,4-dioxane, saccharin, and perchloroethylene. No comments were received on the proposed RQ adjustments for 2-ethoxyethanol, ethylene oxide, and 2-nitropropane.

Two commenters supported adjusting the RQ for 1,4-dioxane from the one-pound statutory level to 100 pounds. One commenter supported the proposed RQ adjustment of 100 pounds for saccharin because, the commenter suggested, the new reporting level would be consistent with public health concerns in general, and with the lack of hazard posed by a potential release of between one and 100 pounds of saccharin during transportation. The Agency agrees that the one-pound statutory RQ for saccharin does not appropriately reflect its carcinogenic potential. Saccharin is a weight-of-evidence Group C, potency Group 3 substance which therefore receives a low hazard ranking and a 100-pound RQ.

Three commenters recommended that perchloroethylene should be classified as a weight-of-evidence Group C substance, rather than as a Group B2 substance as proposed in the March 16, 1987 NPRM. The available rat tumor data and mouse tumor data, when considered together, support the Agency's current position that perchloroethylene should fall into the B2 category based on sufficient animal evidence of carcinogenicity (see Addendum to Health Assessment Document for Tetrachloroethylene (Perchloroethylene), External Review Draft, April 2, 1986; NTIS #PB86-174489). EPA's position on this issue is consistent with the IARC classification of perchloroethylene. However, it is important to note that EPA's B2 classification for perchloroethylene is based on a draft carcinogenicity assessment that has not yet been finalized. If this classification changes based on the final assessment, and the change warrants an adjustment of the RQ for perchloroethylene, the RQ will be adjusted in a future rulemaking. Pending the results of the Agency's final carcinogenicity assessment, the B2 classification and 100-pound RQ adjustment for perchloroethylene will be maintained in this final rule.

In a final rule published elsewhere in today's **Federal Register**, the Agency responds to public comments on 254 of the 273 RQ adjustments proposed in the March 16, 1987 NPRM. As explained in Section II.C.2.i of the preamble to that final rule, EPA will address the RQs for the remaining 13 substances that were the subject of the March 16, 1987 NPRM in a future action.

III. SUMMARY OF SUPPORTING ANALYSES

A. Executive Order No. 12291

Executive Order (E.O.) 12291 requires that regulations be classified as major or nonmajor for purposes of review by the Office of Management and Budget (OMB). According to E.O. 12291, major rules are regulations that are likely to result in:

(1) An annual effect on the economy of $100 million or more; or

(2) A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or

(3) Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

An economic analysis performed by the Agency, available for inspection at Room M2427, U.S. EPA, 401 M Street, SW., Washington, DC 20460, shows that today's final rule is nonmajor, because the rule will result in estimated net cost savings of $1.5 million annually. The annual net cost savings of all RQ adjustments promulgated or proposed to date (including those contained in this final rule) is estimated to be $34.7 million. It should be noted that these net cost savings reflect only those effects of the RQ adjustments that are: (1) Readily quantifiable in dollars; and (2) associated with the notification requirements under CERCLA section 103 and SARA section 304 (including the associated activities of recordkeeping, notification processing, monitoring, and response).

This final rule has been submitted to OMB for review, as required by E.O. No. 12291.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 requires that a Regulatory Flexibility Analysis be performed for all rules that are likely to have a "significant impact on a substantial number of small entities." To determine whether a Regulatory Flexibility Analysis was necessary for today's final rule, a preliminary analysis was conducted using a computer model that simulated the typical operation of a small U.S. chemical company.

The results of the simulation indicate that the upper-bound total cost of compliance to small firms is negligible. See the Regulatory Impact Analysis of Reportable Quantity Adjustments Under Sections 102 and 103 of the Comprehensive Environmental Response, Compensation, and Liability Act, Volume I, March 1985, available for inspection at Room M2427, U.S. EPA, 401 M Street, SW., Washington, DC 20460. Therefore, because today's final rule is not expected to have a significant impact on small entities, EPA certifies that no Regulatory Flexibility Analysis is necessary.

C. Paperwork Reduction Act

EPA requires an Information Impact Analysis for all rules that impose a paperwork burden on the public. This analysis estimates the burden imposed on parties outside EPA for activities such as notification or recordkeeping. Today's final rule will provide a decrease in the paperwork burden imposed on the regulated community for information collection associated with fewer releases being reportable. Because the effect of this final rule on the paperwork burden is a reduction, EPA has determined that no further Information Impact Analysis need be performed.

The information collection requirements contained in this rule have been approved by the OMB under the provisions of the Paperwork Reduction Act, 44 U.S.C. Section 3501 *et seq.*, and have been assigned OMB control number 2050–0046.

The public reporting burden for this collection of information is estimated to vary from 8 to 11 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 Chief, Information Policy Branch, PM–223, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked "Attention: Desk Officer for EPA."

List of Subjects in 40 CFR Part 302

Air pollution control, Chemicals, Hazardous materials, Hazardous materials transportation, Hazardous substances, Hazardous wastes, Intergovernmental relations, Natural resources, Oil pollution, Pesticides and pests, Reporting and recordkeeping requirements, Superfund, Waste treatment and disposal, Water pollution control, Water supply.

Dated: June 26, 1989.

William K. Reilly,

Administrator.

For the reasons set forth in the preamble, 40 CFR Part 302 is amended as follows:

PART 302—DESIGNATION, REPORTABLE QUANTITIES, AND NOTIFICATION

1. The authority citation for Part 302 is revised to read as follows:

Authority: 42 U.S.C. 9602; 33 U.S.C. 1321 and 1361.

§ 302.4 [Amended]

2. Section 302.4 is amended by revising the following entries in Table 302.4 and Appendix A to read as set forth below. The note preceding Table 302.4 is republished without change.

* * * * *

Note: The numbers under the column headed "CASRN" are the Chemical Abstracts Service Registry Numbers for each hazardous substance. Other names by which each hazardous substance is identified in other statutes and their implementing regulations are provided in the "Regulatory Synonyms" column. The "Statutory RQ" column lists the RQs for hazardous substances established by section 102 of CERCLA. The "Statutory Code" column indicates the statutory source for designating each substance as a CERCLA hazardous substance: "1" indicates that the statutory source is section 311(b)(4) of the Clean Water Act, "2" indicates that the source is section 307(a) of the Clean Water Act, "3" indicates that the source is section 112 of the Clean Air Act, and "4" indicates that the source is RCRA section 3001. The "RCRA Waste Number" column provides the waste identification numbers assigned to various substances by RCRA regulations. The column headed "Category" lists the code letters "X," "A," "B," "C," and "D," which are associated with reportable quantities of 1, 10, 100, 1000, and 5000 pounds, respectively. The "Pounds (kg)" column provides the reportable quantity adjustment for each hazardous substance in pounds and kilograms.

TABLE 302.4—LIST OF HAZARDOUS SUBSTANCES AND REPORTABLE QUANTITIES

Hazardous substance	CASRN	Regulatory synonyms	Statutory			Final RQ	
			RQ	Code†	RCRA waste No.	Category	Pounds (Kg)
*	*	*	*	*	*	*	*
1,2-Benzisothiazolin-3-one, 1,1-dioxide, and salts	81072	Saccharin and salts	1*	4	U202	B	100 (45.4)
*	*	*	*	*	*	*	*
1,4-Diethylene dioxide	123911	1,4-Dioxane	1*	4	U108	B	100 (45.4)
*	*	*	*	*	*	*	*
1,4-Dioxane	123911	1,4-Diethylene dioxide	1*	4	U108	B	100 (45.4)
*	*	*	*	*	*	*	*
Ethene, 1,1,2,2-tetrachloro-	127184	Perchloroethylene Tetrachloroethene Tetrachloroethylene	1*	2,4	U210	B	100 (45.4)
*	*	*	*	*	*	*	*
2-Ethoxyethanol	110805	Ethylene glycol monoethyl ether	1*	4	U359	C	1000 (454)
*	*	*	*	*	*	*	*
Ethylene glycol monoethyl ether	110805	2-Ethoxyethanol	1*	4	U359	C	1000 (454)

TABLE 302.4—LIST OF HAZARDOUS SUBSTANCES AND REPORTABLE QUANTITIES—Continued

Hazardous substance	CASRN	Regulatory synonyms	Statutory			Final RQ	
			RQ	Code†	RCRA waste No.	Category	Pounds (Kg)
* * *	*	* * *			*		
Ethylene oxide	75218	Oxirane	1*	4	U115	A	10 (4.54)
* * *	*	* * *			*		
2-Nitropropane	79469	Propane, 2-nitro-	1*	4	U171	A	10 (4.54)
* * *	*	* * *			*		
Oxirane	75218	Ethylene oxide	1*	4	U115	A	10 (4.54)
* * *	*	* * *			*		
Perchloroethylene	127184	Ethene, 1,1,2,2-tetrachloro- Tetrachloroethene Tetrachloroethylene	1*	2,4	U210	B	100 (45.4)
* * *	*	* * *			*		
Propane, 2-nitro-	79469	2-Nitropropane	1*	4	U171	A	10 (4.54)
* * *	*	* * *			*		
Saccharin and salts	81072	1,2-Benzisothiazolin-3-one,1,1-dioxide, and salts	1*	4	U202	B	100 (45.4)
* * *	*	* * *			*		
Tetrachloroethene	127184	Ethene, 1,1,2,2-tetrachloro- Perchloroethylene Tetrachloroethylene	1*	2,4	U210	B	100 (45.4)
Tetrachloroethylene	127184	Ethene, 1,1,2,2-tetrachloro- Perchloroethylene Tetrachloroethene	1*	2,4	U210	B	100 (45.4)
* * *	*	* * *			*		

†—indicates the statutory source as defined by 1, 2, 3, or 4 below:
1—indicates that the statutory source for designation of this hazardous substance under CERCLA is CWA Section 311(b)(4)
2—indicates that the statutory source for designation of this hazardous substance under CERCLA is CWA Section 307(a)
3—indicates that the statutory source for designation of this hazardous substance under CERCLA is CAA Section 112
4—indicates that the statutory source for designation of this hazardous substance under CERCLA is RCRA Section 3001
1*—indicates that the 1-pound RQ is a CERCLA statutory RQ

Appendix A

SEQUENTIAL CAS REGISTRY NUMBER LIST OF CERCLA HAZARDOUS SUBSTANCES

CASRN	Hazardous substance
* * * * *	
75218	Ethylene oxide Oxirane
* * * * *	
79469	Propane, 2-nitro- 2-Nitropropane
* * * * *	
81072	1,2-Benzisothiazolin-3-one,1,1-dioxide, and salts Saccharin and salts
* * * * *	
110805	Ethylene glycol monoethyl ether 2-Ethoxyethanol
* * * * *	
123911	1,4-Diethylene dioxide 1,4-Dioxane
* * * * *	
127184	Ethene, 1,1,2,2-tetrachloro- Perchloroethylene Tetrachloroethene Tetrachloroethylene
* * * * *	

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 116, 117, and 302

[SW H-FRL 3372-8]

Reportable Quantity Adjustments; Delisting of Ammonium Thiosulfate

AGENCY: U.S. Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Sections 103(a) and (b) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended, require that persons in charge of vessels or facilities from which hazardous substances have been released in quantities that are equal to or greater than their reportable quantities (RQs) immediately notify the National Response Center of the release. Section 102(b) sets an RQ of one pound for hazardous substances, except those substances for which different RQs have been established pursuant to section 311(b)(4) of the Clean Water Act (CWA). In addition to these reporting requirements, section 304 of the Superfund Amendments and Reauthorization Act of 1986 (SARA) Title III requires that releases of hazardous substances in quantities equal to or greater than their RQs (or one pound if a reporting trigger is not established by regulation) be reported to State and local authorities.

Section 102(a) of CERCLA authorizes the U.S. Environmental Protection Agency (EPA or "the Agency") to adjust RQs for hazardous substances and to designate as hazardous substances those substances that, when released into the environment, may present substantial danger to the public health or welfare or the environment. Currently, there are 725 CERCLA hazardous substances.[1] In this rulemaking, EPA is promulgating final RQ adjustments for 258 hazardous substances. Of these 258 hazardous substances, 254 had RQs proposed for adjustment by EPA in a Notice of Proposed Rulemaking (NPRM) published on March 16, 1987 (52 FR 8140).[2] RQs for four additional hazardous substances that were not proposed for adjustment in the March 16, 1987 NPRM are also included in this final rule. These four hazardous substances are waste streams that were listed as hazardous under section 3001 of the Resource Conservation and Recovery Act (RCRA)

[1] See Note 1 at the end of the text of this preamble.

[2] See Note 2 at the end of the text of this preamble.