40 CFR Parts 795, 796, and 799

[OPTS-42086D; FRL-3396-8]

Office of Solid Waste Chemicals; 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 and/or recommending that manufacturers and processors of 33 chemicals perform testing for human health effects and/or chemical fate in support of EPA's hazardous waste regulatory program under the Resource Conservation and Recovery Act (RCRA) of 1976, as amended. The required health effects testing is a subchronic toxicity study via oral gavage. The required chemical fate testing includes tests to determine one or both of the following: Adsorption characteristics, and hydrolysis rates. EPA is also recommending, but not requiring, anaerobic biodegradation rate testing for 32 chemicals.

DATES: In accordance with 40 CFR 23.5, this rule shall be promulgated for purposes of judicial review at 1 p.m. eastern (daylight or standard as appropriate) time on June 29, 1988. This

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rule shall become effective on July 29, 1988.

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

SUPPLEMENTARY INFORMATION: EPA is issuing a final test rule under section 4(a) of TSCA which requires and/or recommends testing to obtain needed human health effects and chemical fate data for 33 chemicals that have been identified as hazardous constituents under Appendix VIII of 40 CFR Part 261.

I. Introduction

A. Test Rule Development Under TSCA

This final rule is part of the overall implementation of section 4 of TSCA (Pub. L. 94-469, 90 Stat. 2003 et seq., 15 U.S.C. 2601 et seq.), which contains authority for EPA to require the development of data relevant to assessing the risk to health and 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 health or environmental data if the Administrator makes certain findings as described in TSCA under section 4(a)(1) (A) or (B). Detailed discussions of the statutory section 4 findings are provided in the Agency's first and second proposed test rules which were published in the **Federal Register** of July 18, 1980 (45 FR 48510) and June 5, 1981 (46 FR 30300).

B. Regulatory History

Section 4 of TSCA authorizes EPA to require testing of chemicals whose manufacture, processing, distribution in commerce, use, or disposal may present an unreasonable risk of injury to human health or the environment but for which existing data are inadequate to reasonably determine or predict such effects.

EPA's Office of Solid Waste (OSW) identified a need for health effects and/or chemical fate data on 73 chemicals in support of its effort under section 3001 of the Resource Conservation and Recovery Act (RCRA) to identify those wastes which may pose a substantial hazard to human health and the environment if improperly managed. Those chemicals were the subject of a proposed TSCA section 4 test rule (May 29, 1987; 52 FR 20336) that included testing for chemical fate and/or human health effects.

The proposed rule containing an overview of the Solid Waste Disposal Act (SWDA), as amended by RCRA, background on EPA's concentration-based listing program under RCRA, a discussion of EPA's TSCA section 4(a) findings, and proposed test standards to be used, including a provisional anaerobic biodegradation test guideline designed by EPA and proposed for comment.

Testing is not being required or recommended at this time for the 40 chemicals listed in the following Table 1, for one or more of the following reasons: (1) There is insufficient economic information available to perform an adequate economic analysis for the chemical (e.g., the chemical may not currently be in production); (2) the proposed testing was scientifically inappropriate because of the chemical's physical properties and/or chemical fate; and/or (3) there is no available information in the three data bases searched by OSW to suggest a potential for exposure to the chemical.

TABLE 1.—CHEMICALS FOR WHICH TESTING WAS PROPOSED, BUT IS NOT BEING REQUIRED OR RECOMMENDED AT THIS TIME

Chemical name	CAS No.
Acetamide,N-(aminothioxomethyl) [1,3]	591-08-2
Ammonium vanadate [3]	7803-55-6
Benzal chloride [3]	98-87-3
p-Benzoquinone [3]	106-51-4
2,2'-Bioxirane [1,3]	1464-53-5
Bromoacetone [1,3]	598-31-2
1-Bromo-4-phenoxy benzene [1,3]	101-55-3
Carbonyl fluoride [2,3]	353-50-4
Chloral [2,3]	75-87-6
2-Chlorobenzotrichloride [1,2,3]	2136-89-2
2-Chloroethyl vinyl ether [1]	110-75-8
Chlornaphazine [1,3]	494-03-1
1-(*o*-Chlorophenyl)thiourea [1,3]	5344-82-1
Cyanogen bromide [3]	506-68-3
Daunomycin [1,3]	20830-81-3
o,o-Diethyl-*S*-methyldithiophosphate [1,3]	3288-58-2
a,a-Dimethylphenethylamine [3]	122-09-8
4,6-Dinitro-*o*-cyclohexylphenol [1,3]	131-89-5
Ethylene-bis-dithiocarbamic acid [1,3]	111-54-4
Glycidylaldehyde [1,3]	765-34-4
Hexachlorophene [3]	70-30-4
Hexaethyl-tetra-phosphate [1]	757-58-4
Isosafrole [3]	120-58-1
Maleic anhydride [3]	108-31-6
Methacrylonitrile [3]	126-98-7
Methyl chlorocarbonate [3]	79-22-1
1-Naphthylamine [3]	134-32-7
Nicotine [3]	54-11-5
Paraldehyde [3]	123-63-7
Phenacetin [3]	62-44-2
n-Phenylthiourea [3]	103-85-5
Phosgene [3]	75-44-5
1-Propanamine [3]	107-10-8
Propanenitrile [3]	107-12-0
Propanenitrile, 3-chloro [1,3]	542-76-7
Saccharin [3]	81-07-2
Tetraethyldithiopyrophosphate [1,3]	3689-24-5
Thiosemicarbazide [1,3]	79-19-6
o-Toluidine hydrochloride [1,3]	636-21-5
Trypan blue [3]	72-57-1

[1] [2] [3] Refers to reasons 1, 2, and 3, stated in the previous paragraph, why testing is not being required or recommended at this time.

II. Response to Public Comments

Thirty-three sets of written comm pertaining to chemicals subject to th final rule were submitted to EPA (Refs. 1 through 33) by the close of the extended comment period (August 27, 1987). A public meeting was also requested by the Chemical Manufacturers Association (CMA) and was held on September 9, 1987. The comment period was reopened for an additional 30 days on January 14, 1988 to allow time to review additional support data inserted into the public docket. Additional written comments (Refs. 38 through 44, and 49) were received during this time.

The commenters who responded to this proposed rulemaking fall into the following categories: Chemical and/or petroleum producers, trade associations, universities and research centers, Federal and State government organizations, and a public interest group. Comments relevant to chemicals subject to this final rule are discussed below, and divided into four categories: General issues, chemical-specific issues, response to technical comments on the proposed anaerobic biodegradation test guideline, and economic issues.

A. General Issues

1. *Use of TSCA section 4 to obtain data for a RCRA program.* The Procter and Gamble Company in its commen (Refs. 23 and 50) stated its support fo EPA's goal of determining appropriate levels at which the land disposal of the listed chemicals should be regulated, but believes that the Agency's use of section 4 of TSCA to accomplish the goal is inappropriate. Its belief is based primarily on the fact that the subject chemicals are listed on Appendix VIII of 40 CFR Part 261, a Part that governs the disposal of hazardous waste under RCRA and has no direct relationship to TSCA.

EPA, CMA (Ref. 2), and the Natural Resources Defense Council (NRDC; Ref. 20), however, disagree with Procter & Gamble Company on this use of TSCA section 4. CMA believes that EPA should consider the toxicities of the constituent chemicals in making specific relisting decisions, and recognizes that "the Agency might issue TSCA section 4 testing requirements as one of the means to obtain such toxicity data." NRDC believes that EPA clearly has the authority to issue a test rule covering groups of chemicals under TSCA section 4, and considers this test rule "a long overdue and welcome application of this authority."

EPA agrees with CMA and NRDC on this issue and notes, as NRDC did in

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their comments, that TSCA was enacted in 1976 to fill in some of the regulatory gaps that then existed regarding the assessment and prevention of adverse health and environmental effects from potentially toxic substances. This test rule therefore fulfills the intent of Congress, because RCRA contains such a "regulatory gap": it does not itself contain any analogous authority to TSCA that would permit the Administrator to require testing of chemicals.

Nowhere in TSCA is the gathering of data for regulatory purposes under other statutory programs such as RCRA prohibited or discouraged. Instead, the testing policy of Congress as explicitly mandated by TSCA is as follows:

> It is the policy of the U.S. that (1) adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment, and (2) that the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures. (TSCA section 2(b)).

Therefore, EPA believes that: (1) A clear and justifiable need exists for the development of adequate health and environmental data for the chemicals subject to this rule; and (2) TSCA section 4 is an appropriate vehicle through which to obtain such data.

2. *The "may present an unreasonable risk" (section 4(a)(1)(A)(i)) finding.* Many comments were received concerning the basis for the section 4(a)(1)(A) findings of "may present an unreasonable risk of injury to health or the environment" for the chemicals listed in the proposed rule (Refs. 2, 16 through 20, 27, 33, 38 through 44, and 49). Since CMA submitted the most extensive comments on this topic, and many commenters incorporated CMA's comments by reference, those comments will be the primary focus of EPA's response.

a. *Regulation of chemicals as a category.* CMA has stated that "* * * EPA correctly has not proposed that these test rules will apply to a category of chemicals, as that term is defined in TSCA section 26(c)(2), because no such category exists with respect to the 73 chemicals involved," and that "EPA must make each of the section 4(a)(1)(A) findings for each of the 73 chemicals * * *." Monsanto Company also does "not believe that the Agency has the authority to regulate these 73 chemicals as a category, as is being attempted here."

TSCA section 26(c)(2) defines "category of chemical substances" to mean a group of chemical substances which are similar in structure, etc., or "which are in some other way suitable for classification as such for purposes of this Act, except that such term does not mean a group of chemical substances which are grouped together solely on the basis of their being new chemical substances." Therefore, the grouping of chemicals which share a common classification basis, such as hazardous waste constituents, is clearly permitted under TSCA. Thus, while EPA believes that a category approach could legally have been used for the proposed rule, instead EPA chose an individual chemical approach and gathered and made available for comment information to support a section 4(a)(1)(A) finding of "may present an unreasonable risk" for each of the chemicals included in this final rule.

b. *Role of exposure data in section 4(a)(1)(A)(i) findings.* With regard to the rulemaking record, CMA commented that EPA concluded that the 73 chemicals meet the requirements for testing under section 4(a)(1)(A)(i) solely "by virtue of these chemicals being identified as 'hazardous constituents' [under the RCRA program]."

The Agency disagrees with this comment. While all chemicals subject to this final rule are listed on Appendix VIII, this was not the sole criterion used by EPA to meet the requirements for testing under TSCA section 4(a)(1)(A)(i). Other factors listed in the proposed rule include: The nature of potential toxicity, the presence of these chemicals in treatment, storage, or disposal facilities, evidence that existing land fills leak, and the potential for human exposure to these chemicals during treatment, storage, and disposal activities and through possible leaching or volatilization. Also, toxicity data for each of the chemicals are contained in the background document for section 3001, Subtitle C of RCRA, and/or a Health and Environmental Effects Profile (HEEP), contained in the RCRA docket and incorporated by reference into the record for this rulemaking. The one exception is methanethiol; toxicity data for this chemical were inserted into the docket prior to reopening the comment period in December, 1987. Therefore, the section 4(a)(1)(A)(i) finding was not made for these chemical substances solely by virtue of their being identified as hazardous constituents under the RCRA program.

Vulcan Chemicals submitted the comment, "Although it is true that the subject chemicals appear in Appendix VIII, they were not included in Appendix VIII because they presented an unreasonable risk to health or the environment but rather because they presented some degree of toxicity . . . Appendix VIII was established by EPA during the promulgation of the RCRA regulations and the hazardous constituents contained therein are not necessarily of significant toxicity." In response, EPA refers to 40 CFR 261.11(a), which states:

> Substances will be listed on App. VIII only if they have been shown in scientific studies to have toxic, carcinogenic, mutagenic or teratogenic effects on humans or other life forms.

EPA acknowledges that the "unreasonable risk" standard was not used in listing substances on Appendix VIII, but the Agency believes that the toxicity and exposure data made available for public comment do support a finding that the chemicals subject to this final rule "may present an unreasonable risk." In support of EPA's section 4(a)(1)(A)(i) finding for the subject chemicals in the proposed rule, the Natural Resources Defense Council (NRDC; Ref. 20) believes that the threshold requirement for being listed in Appendix VIII is more than adequate to satisfy the "may present an unreasonable risk to health or the environment" finding required by TSCA, noting that:

> Substances will be listed on Appendix VIII only if they have been shown in scientific studies to have toxic, carcinogenic, mutagenic or teratogenic effects on humans or other life forms. (40 CFR 261.11(a)).

NRDC also believes that since EPA is basing its decision for a test rule using the "unreasonable risk" finding rather than the "substantial exposure" (section 4(a)(1)(B)) finding, there is no requirement for a showing of substantial human exposure. Their comments included a discussion of Congressional intent in designing the TSCA testing program, noting that the "unreasonable risk" standard for testing was to be used to identify "those chemical substances and mixtures about which there is a basis for concern, but about which there is inadequate information to reasonably predict or determine their effect on health or the environment." H.R. Rep. No. 94–1679, 94th Cong., 2nd Sess. 61 (1976) (Conference Report). NRDC also cited Rep. Murphy, Chairman of the House Subcommittee that drafted TSCA, when explaining when testing would be required using the "may present an unreasonable risk" prong: "If there is reliable preliminary data indicating that a substance may be dangerous, again it would be reasonable to conclude that the chemical may present an unreasonable risk and that additional testing be done." 122 Cong. Rec. H11347 (daily ed., Sept. 28, 1976).

NRDC pointed out in their comments that TSCA section 4(a)(1)(A) "is completely silent on the issue of exposure", and noted that "The conscious choice by Congress to omit any such reference to exposure under the 'unreasonable risk' prong has been consistently interpreted by EPA to require only the potential for exposure." NRDC also cited a previous EPA position concerning exposure and the TSCA section 4(a)(1)(A) findings: "Monitoring or other specific exposure information will be unavailable in many cases, and therefore, the Agency will be compelled to rely upon reasonable conclusions about exposure potential" (50 FR 859; January 7, 1985). NRDC therefore believes the EPA's conclusion in the proposed rule regarding the potential for human exposure to the subject chemicals during treatment, storage, and disposal activities and through possible leaching or volatilization is sufficient to satisfy the first requirement of section 4(a)(1)(A) of TSCA.

CMA, however, in its first set of comments (Ref. 2) stated its belief that the general assertions made by EPA in the proposed rule with regard to the subject chemicals' potential for exposure to humans, i.e., the subject chemicals are constituents of wastes to which humans might be exposed, "falls far short of the legal standards mandated by TSCA section 4(a)." Other industry commenters agreed.

EPA agrees with NRDC that TSCA section 4(a)(1)(A) does not require a showing or proof of substantial human exposure, and acknowledges that EPA has consistently interpreted this finding to require only potential for exposure. However, since relevent data were easily available and obtained within the time allowed for this rulemaking, the Agency made the decision to further support the findings by documenting the potential for exposure to the subject chemicals.

EPA inserted into the docket for this rule, and opened for comment, data that document the presence of the subject chemicals in waste streams and/or ground water, demonstrating potential for significant human exposure. The data have been obtained by searching three data bases used by the Office of Solid Waste: The Industry Studies Data Base (ISDB), the Damage Incident Data Base (DIDB), and the Hazardous Waste Disposal Site (HWDS) Data Base. Many of the chemicals are listed in more than one data base. Much of the data contained in the ISDB is confidential business information (CBI), and is contained in a separate CBI docket. All non-CBI information was made available for review in the OPTS docket (No. 42088C). A brief description of each data base is contained in the notice to reopen the comment period on the proposed rule, 53 FR 911, January 14, 1988.

The data show that tens of thousands of pounds of the subject chemicals are being released annually via disposal. Also, the type of disposal described in the data bases for the subject chemicals, such as deep-well injection, discharge to landfill, or discharge to a POTW (publicly-owned treatment works), indicate potential for leaching and exposure to these chemicals. Indeed, data exist for many of the chemicals which document incidents in which the chemicals have migrated from their place of treatment, storage, or ultimate diposal. It is likely that these data represent only a portion of actual contamination occurrences throughout the country.

SOCMA (Ref. 40) believes that there is no evidence that each of the chemicals subject to the rule is being released into the environment "in quantities sufficient to pose an unreasonable risk, nor has EPA supplied such proof with the latest additions to the docket containing 'exposure data' from three sources * * *" CMA, in response to the exposure data inserted into the rulemaking record, still maintains that EPA must demonstrate that there are identified, relevant exposures of each chemical to humans, and that such exposures result from the pertinent activities involved—in this case, from the disposal either of such substances or of products containing them." Also, CMA maintains that the "risk must be reasonably well characterized, with respect to both its nature (e.g., effects and populations involved) and its likelihood."

The Agency disagrees, because EPA believes that TSCA does not require that EPA "show" or "prove" the existence of unreasonable (or substantial) risk, but rather that EPA find that a given chemical "may present an unreasonable risk." Accordingly, the exposure data inserted into the rulemaking record were intended to demonstrate potential for exposure, rather than prove both the nature of the risk (effects and populations involved), and its likelihood, as suggested by CMA.

A recent court decision (Ausimont U.S.A. Inc. v. EPA; Ref. 45) supports EPA's position on the role of exposure data and risk determination in section 4(a)(1)(A) findings. The decision notes that "the agency must be reasonably discriminate in selecting subjects for testing. But section 4 focuses on investigating areas of uncertainty as a prelude to regulating harmful substances." It continues,

> Although mere scientific curiosity does not form an adequate basis for a rule, as the seriousness of risk becomes known and the extent of exposure increases, the need for testing fades into the necessity for regulatory safeguards. The issue presented here is where in the spectrum this rule falls. In most administrative proceedings, we examine the record to see if there is a foundation for an agency determination of fact; however, here we look to see if the Administrator produced substantial evidence to demonstrate not fact, but doubt and uncertainty.

With regard to risk, the decision notes that the congressional conference committee report on TSCA stated that the purpose of the testing provision is to

> * * * focus the Administrator's attention on those chemical substances and mixtures about which there is a basis for concern, but about which there is inadequate information to reasonably predict or determine their effects on health or the environment. The Administrator need not show that the substance or mixture does or will present a risk * * * Although cautioning that the agency must act reasonably and prudently, and take into consideration the economic impact of any action, of necessity Congress granted EPA fairly broad discretion in exercising its expertise to determine when data must be produced.

CMA, in their last comment set (Ref. 43) expressed concern that "it appears to be virtually impossible for public commenters to search out chemical-specific information from the three data bases cited by EPA in support of these rules * * *", and that "it is simply not possible for members of the public to review any of the data upon which the Agency currently relies."

The Agency acknowledges that the public does not have full access to the three EPA (and EPA contractor) data bases from which the exposure data were obtained. This is because these data bases contain confidential business information, as claimed by the companies that supplied the data to EPA. CMA itself notes that "at least with respect to one of these data bases, most of its data are proprietary and thus are not legally available to the public." Confidential data, although not available for public review, is not precluded from consideration when making a section 4 finding for testing requirements. Section 14 of TSCA, governing disclosure of data, provides that any confidential data obtained by the Administrator must not be disclosed to the public except under certain circumstances, e.g., in order to protect health or the environment against an

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unreasonable risk of injury to health or the environment.

SOCMA and CMA expressed concern about the lack of detail presented in the information obtained from the data bases. Again, much of the information is confidential, such as the type of disposal indicating potential for leaching and exposure to the subject chemicals (deep well injection, discharge to landfill, or discharge to a publicly-owned treatment works), location of sampling, etc. All non-confidential information available from the three EPA data bases was inserted into the rulemaking record for public review.

3. *The "data are insufficient" (section 4(a)(1)(A)(iii)) finding.* CMA asserted in its original set of comments (Ref. 2) that EPA had not demonstrated that there are insufficient data and experience upon which the health or environmental effects of each chemical can reasonably be determined or predicted, as required by TSCA. EPA disagrees with CMA's comments on this issue for all chemicals subject to this final rule with the exception of three chemicals, for which supporting documentation for one endpoint each was missing from the Literature Search and Critique document contained in the public docket for the proposed rule. That information was inserted into the public record and opened for public comment, 53 FR 911.

With regard to the subchronic toxicity endpoint, the July 24, 1987 memorandum from the Office of Research and Development (ORD) to OSW contained in the Literature Search Results and Critique document (OPTS docket 42088A) describes the search strategy used by EPA's ORD. The strategy involved the review of published literature, computerized data bases, and also applicable non-CBI information in the EPA's Office of Toxic Substances and the Office of Pesticide Programs files. No subchronic toxicity data were found for any of the subject chemicals, with the exception of phosgene. A February 9, 1987 memorandum from EPA's Environmental Criteria and Assessment Office to OSW (contained in the Literature Search document) explains why the existing data for phosgene are insufficient to support OSW's concentration-based listing program. Due to other factors, however, EPA is not requiring testing for phosgene (see Unit II.B.15. of this preamble).

CMA incorrectly assumed in its supplemental comments (Ref. 3) that EPA relied on the absence of a Health and Environmental Effect Profile (HEEP) to support the "data are insufficient" finding for this rule. Those HEEP documents included in the docket by reference instead were intended to support the section 4(a)(1)(A)(i) "may present an unreasonable risk" finding.

To identify and evaluate existing chemical fate information relevant to the concentration-based listing program, a literature search was conducted and the report was made available for public comment in the docket. The report objective was to evaluate existing test data on soil sorption coefficients, anaerobic biodegradation (subsurface) rates, and hydrolysis rates for their applicability to the OSW ground water model. EPA was looking for studies that: (1) Provided quantitative data concerning the designated key parameters; and (2) were collected under physical conditions that approximate the ground water environment. The TSCA test guidelines published on September 27, 1985 (50 FR 39252) for hydrolysis as a function of pH 25 °C (40 CFR 796.3500) and sediment and soil adsorption isotherm (40 CFR 796.2750) provide general guidelines for evaluation of the test methods for hydrolysis rate and sorption coefficient, and data developed in general accordance with these guidelines fulfill both criteria (1) and (2). The available EPA test guidelines for biodegradation of chemical compounds do not simulate the ground water environment, and do not yield data representative of the various subsurface environmental conditions prevalent in the United States.

All chemicals were searched for each endpoint for which data were not already "in hand." Excluding one study on sorption coefficients, the results reported either did not provide quantitative test data for the designated parameters or were conducted under conditions not related to ground water environment. In addition, a large number of chemicals were found to have no published information pertinent to the parameters of interest.

SOCMA stated in its comments (Ref. 27) that "much data are indeed available" on many of the proposed chemicals, but that "because these data do not fit in EPA's quantitative modeling procedure developed to accomplish the concentration-based listing program under RCRA, EPA has determined the existing data to be unacceptable." SOCMA believes that the existing data on several of these chemicals should be considered and that EPA should redesign the model to accommodate these available data. SOCMA did not submit any additional (existing) data with its comments.

As pointed out in the preceding paragraph, EPA has reviewed all existing data found through a thorough search of the literature, and concluded that the existing data either do not provide quantitative test data for the key parameters consistent with the nation-wide implementation of the model, or were obtained under conditions not relevant to ground water media—the medium of potential exposure. Therefore, EPA finds that for these identified data gaps, there are insufficient data and experience upon which the health or environmental effects of the subject OSW chemicals can reasonably be determined or predicted on a nation-wide basis.

4. *Use of TSCA sections 8(a) and 8(d).* CMA stated in its original comments (Ref. 2) that the "pursuing a 'fast track' to the rulemakings," EPA "both has failed to meet its statutory obligations under section 4(a), and has contravened the Agency's own policies for issuing section 4 test rules." CMA refers specifically to the fact that EPA did not "call in existing data under TSCA section 8(a) and 8(d), a process cited as "established EPA policy" in CMA's comments.

EPA believes that these sections of TSCA have served as useful tools in the gathering of production, release, health effects, and safety information for many previous test rule candidates, particularly those recommended for testing to EPA by the Interagency Testing Committee (ITC). Sections 8 (a) and (d) are automatically "triggered" at the time a chemical is formally recommended by the ITC for testing consideration and thus data are obtained expeditiously for ITC chemicals. However, the use of the rulemaking authorities under TSCA section 8 for information gathering purposes is not required prior to conducting rulemaking pursuant to TSCA section 4. No such expeditious automatic mechanism exists for non-ITC chemicals, and conventional rulemaking would not have produced section 8 (a) and (d) data on a timely basis. Furthermore, any available studies could have been submitted to EPA in response to the proposed section 4 rule. Finally, EPA's Office of Research and Development conducted a search of existing TSCA section 8(d) files as part of their literature search for subchronic toxicity data.

5. *The "testing is necessary" (section 4(a)(1)(A)(iii)) finding.* CMA noted in their original comments (Ref. 2) that "under section 4(a), EPA may require testing only if the data to be developed" are relevant to a determination that the manufacture, distribution in commerce, processing, use, or disposal [of the chemical], or that any combination of such activities, does or does not present

an unreasonable risk of injury to health or the environment." CMA believes that EPA did not establish this relationship between the proposed testing and future Agency regulatory determinations concerning unreasonable risks, and that RCRA relisting decisions involve no such determinations.

EPA believes that testing is necessary for each of the chemicals subject to this final rule, as follows from section 4(a)(1)(A) (i) and (ii) findings, to develop data which are relevant to determining whether the disposal of the subject chemicals by various means or various concentrations present an unreasonable risk. The Agency has established that each of these chemicals may present an unreasonable risk, and that for the health effects and chemical fate endpoints of concern, data are either not available or are inadequate for use in the OSW concentration-based listing program. Unit II.A.3. of this preamble contains a discussion of why available data are inadequate and why the particular testing endpoints were determined to be critical to the determination of unreasonable risk of injury to health or the environment through disposal to landfills of certain concentrations of the subject chemicals in waste streams.

6. *Who is subject to testing requirements*—a. *Byproduct and "inadvertent" manufacture.* EPA originally proposed that manufacturers of the subject chemicals as byproducts or impurities be subject to the rule. Procter & Gamble (Refs. 23 and 50), Vulcan Chemicals (Ref. 33), and SOCMA (Ref. 27) believe that the proposed test rule should be revised to exempt companies who manufacture or process the subject chemicals only as byproducts without a separate commercial intent. SOCMA suggested that "in certain limited circumstances it may be appropriate for EPA to propose not to grant a standard section 4 testing exemption to impurity and waste byproduct manufacturers," such as when "no one manufactures or imports the subject chemical and current data show that the subject chemical is being discharged to the environment," or "when the volume of impurities or waste byproducts manufactured is a substantial percentage of the amount of the substance intentionally produced."

Procter & Gamble wrote, "The historical roots of section 4 in the Eckhart Subcommittee work on TSCA were the sharing of the costs of test generation in direct proportion to the economic benefits which producers derived from the chemicals."

EPA does not agree that the intention of Congress to have producers share the cost of testing should be interpreted to exclude producers of byproducts from TSCA section 4 testing requirements. While economic benefit is not derived directly from the production of the subject chemical, the production and disposal of the byproduct are a result of a production process by which the company does derive economic benefit (an indirect benefit). In addition, the potential for significant exposure to a chemical exists through its disposal as a byproduct, such as for the chemicals acetophenone and bis(2-chloroisopropyl)ether subject to this rule, for which environmental release has been documented.

CMA originally recommended (Ref. 2) that EPA adopt a "tiering" approach to the coverage of byproducts and impurities, so that such chemicals would be subject only if the Agency first determines, as part of its test rule implementation, that no persons manufacture (or import) the subject chemicals as primary commercial products.

In their supplemental comments (Ref. 3), however, CMA wrote, "Although we continue to believe that such an approach is viable for these rules, our further consideration of the rules' impacts and analytical requirements leads us to conclude that the Agency should adopt the approach spelled out in these supplemental comments, of limiting testing requirements by the 'known to or reasonably ascertainable by' standard described herein."

CMA acknowledged that "because EPA intends to use the data from these rules as part of the Agency's RCRA relisting activities, and because of the possible involvement of impurities and byproducts in waste-related activities, EPA might be justified in applying the rules to impurities and byproducts in the manner described in these comments."

CMA's major concern with the applicability of the test rule to impurities and byproducts is the "tremendous analytical burdens" which these requirements would impose. CMA believes that the rule would, in effect, require companies to analyze all of their products for each of the chemicals listed in this final rule.

EPA concurs with CMA on this issue, and did not intend under the proposed rule that companies be required to perform analytical work in order to determine whether their manufacturing (and import) operations trigger the final testing requirements. EPA believes a company should be subject to this final rule (with respect to manufacture of the subject chemical solely as byproducts) only if it is known to or reasonably ascertainable by that company that such manufacture takes place.

b. *Impurity manufacture.* EPA proposed that manufacturers of the subject chemicals as impurities be subject to the testing requirements of this rule. While EPA believes that this is logical and appropriate, for the same reasons as stated above for byproduct manufacturers, none of the subject chemicals are produced solely as an impurity, and those produced as impurities are produced by the same companies as byproducts. Therefore, so as not to unduly burden industry and the Agency with applications for exemption from testing, this requirement has been deleted from 40 CFR 799.5055(b).

c. *Nonisolated intermediate manufacture.* Several industry commenters objected to required testing of chemicals produced "solely as nonisolated intermediates." The particular chemicals and companies are identified in Unit II.B. of this preamble, which responds to chemical-specific comments.

While EPA acknowledges that the amount of chemical substance released as a result of this type of production may be less than other types, such as byproducts, manufacturing or processing a chemical as an intermediate does not preclude exposure to that chemical. It is common experience that process waste streams and reactor vessel residues will contain "intermediates." In many instances, these chemicals are released to the environment as fugitive emissions, liquid or solid wastes, and as unreacted feedstock (impurities) in finished products. Furthermore, many intermediates are stored on-site in large quantities until batch reacted on demand for a given product (the same intermediate may be used as feedstock for different products or may be stockpiled until needed). As such, "intermediates" typically exist as chemicals to which there is potential for human exposure. Also, EPA has found data documenting the presence in ground or surface water of the subject chemicals cited by commenters as being produced as nonisolated intermediates, 53 FR 911.

d. *Pesticides.* Two chemicals subject to this final rule, endrin and maleic hydrazide, are not listed in the TSCA Inventory, because their primary use has been (endrin) and is (maleic hydrazide) as pesticides. However, this does not preclude their being subject to this section 4 rule. TSCA section 3(2)(B)(ii) exempts from coverage "any pesticide * * * when manufactured, processed, or distributed in commerce for use as a pesticide." This test rule is based on

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section 4(a)(1)(A) findings for the subject chemicals, due to potential for unreasonable risk associated with their disposal. The disposal of endrin and maleic hydrazide does not constitute "use as a pesticide," and so is subject to regulation under TSCA. Manufacturers and processors of endrin and maleic hydrazide are thus subject to the testing requirements because the chemicals are disposed of, as discussed above.

e. *Research and development, and/or low volume manufacture.* In the proposed rule, EPA discussed several approaches to dealing with chemicals subject to the rule which may be produced only for research and development (R&D) or in small quantities. The Agency has received several comments on this issue, most concurring with an R&D waiver, and an aggregate production threshold for low volume chemicals. It is now apparent, however, that none of the chemicals subject to the final rule fall into either of these categories. Therefore, EPA has not included any R&D waiver provision in the rule.

7. *Export notification.* Section 12(b) of TSCA requires exporters of chemicals for which final test rules have been issued under section 4 to "notify the Administrator of such exportation or intent to export * * *." SOCMA (Ref. 27) commented that if the Agency fails to grant exemptions from testing to those who manufacture the subject chemicals only as byproducts, EPA will be "inundated by useless section 12(b) notifications," and would present an unacceptable burden to the regulated community and to EPA. CMA (Ref. 2) also believes that the section 12(b) requirements should not apply to the chemicals subject to this final rule, and noted that the intention of this rule is "to provide for the environmentally secure disposal of hazardous wastes." CMA suggests that this is not an export issue, and it "should not trigger the unnecessary and burdensome impacts of reporting under section 12(b)."

While EPA acknowledges that this requirement may be burdensome to industry and the Agency for this rule, it is required under TSCA that section 12(b) apply to all chemicals subject to testing under section 4. EPA is continuing to examine the implementation of section 12(b) and ways to reduce burden in relation to TSCA section 4 rules and the Paperwork Reduction Act.

8. *Testing schedule.* CMA suggested (Ref. 2) that "if EPA is unable to complete the modeling necessary for RCRA relisting until all intended data have been generated, then a consistent testing schedule should be established for all of these parameters. If the proposed anaerobic biodegradation protocol is adopted, a 20-month schedule would be appropriate because that protocol requires up to 64 weeks."

EPA disagrees with this comment. The testing schedule as proposed and now finalized is consistent with the time allotted for the various tests in previous section 4 rules. Also, "staggering" the submission of test results rather than requiring the same schedule for all test parameters will allow the Agency time to review the data.

9. *Confidential business information* (CBI). While CMA acknowledged (Ref. 2) that EPA intends to protect CBI submitted under these rules in the same manner that the Agency protects data submitted under other section 4 rules, CMA expressed concern that the final rule would impose testing requirements upon certain chemicals that were reported for the TSCA section 8(b) Inventory, but whose identities were claimed confidential. This comment is no longer applicable, since no such chemicals are subject to this final rule. All CBI (economic and exposure) associated with this final rule has been protected from disclosure.

10. *Proposed toxicity testing requirement.* Three commenters, NRDC (Ref. 20), SOCMA (Ref. 27), and the U.S. Department of Interior (USDOI) (Ref. 28), addressed issues concerning the proposed toxicity testing. NRDC and USDOI concurred that the health effects testing is warranted; however, NRDC believes that the proposed 90-day subchronic toxicity study is grossly inadequate to determine the adverse health effects of the chemicals in question.

NRDC recommended that a series of additional tests be performed to fully ascertain carcinogenic, mutagenic, and neurotoxic effects of these chemicals. First, NRDC advised EPA to replace the 90-day subchronic test in favor of a two-year chronic toxicity test. NRDC maintained that the 90-day test is not adequate to determine long-term effects from prolonged exposure. Second, NRDC urged the adoption of a tiered testing plan that would incorporate:

a. Initial analysis of each chemical to determine whether there exist structural analogues which are carcinogens, mutagens, neurotoxins, or are associated with reproductive effects, and whether the chemical is an alkylating agent.

b. A battery of mutagenicity tests for all chemicals.

c. Satellite tests for carcinogenicity, adverse reproductive effects, and neurotoxicity. NRDC maintained that the plan contained in its comment would fully characterize a chemical's chronic toxicity.

On the other hand, SOCMA recommended that the Agency reevaluate the requirement to perform the 90-day subchronic test in view of chemicals on the list that are not amenable to testing by this method and the impact of testing on the regulated community.

EPA acknowledges NRDC's comment regarding the scope of tests required to fully characterize a given chemical's toxic potential. However, the purpose of this test rule is to obtain data in support of OSW's concentration-based (relisting) program. OSW has determined that relistings can be accomplished using toxicity data from a 90-day study. The Agency maintains that a well-designed and conducted subchronic animal study is minimally sufficient for developing a human reference dose (RfD) for chronic (systemic) toxicity.

With regard to SOCMA's comments, chemicals which are not suited to this method are no longer designated for testing, as discussed in Unit II.B. of this preamble. The impact on the testing community is discussed in the final Economic Analysis for this rule and in Units II.D. and IV. of this preamble.

USDOI wrote that the subchronic toxicity study as proposed is appropriate only for mammalian systems; this test would fail to provide toxicity information for aquatic organisms. USDOI asked that the proposed rule be amended to include testing of invertebrates and fish species and suggested that EPA adopt: (1) A *Daphnia magna* life cycle (21-day renewal) chronic toxicity test; and (2) a fish life cycle toxicity test.

EPA agrees with USDOI's comment that acquiring and using toxicity data for aquatic organisms is necessary. In fact, the Agency is developing a method for assessing the ecological impacts of hazardous waste constituents. However, the Agency believes that it is premature to require the aquatic toxicity tests recommended by USDOI at this time since EPA does not have a well-defined, quantitative process for using aquatic toxicity information in establishing concentration-based listings.

11. *Biodegradation testing should be made optional.* Several commenters addressed EPA's solicitation of comments on whether the proposed anaerobic biodegradation testing should be optional rather than required. Some of these commenters said that manufacturers should be given the opportunity to forego biodegradation testing, thereby tacitly accepting

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establishment of lower relisting concentrations by assuming "zero biodegradation." Only one commenter (NRDC; Ref. 20) stated that biodegradation testing should not be made optional.

EPA has decided not to require the biodegradation test, because it is an expensive test and EPA can fully protect the environment by assuming zero biodegradation (a worst case condition) in the absence of data. In the future, if data becomes available that can be used to more accurately predict a chemical's biodegradation rate, then a non-zero value may be used. Thus, individual manufacturers will be able to decide whether the benefits of developing a more realistic estimate, i.e., for each chemical, performing the test and having the data used in the chemical fate and transport model, is worth the cost of conducting the test, or whether it is more cost-effective to not perform the test and have EPA utilize a model which assumes no biodegradation of that chemical. Persons who must make the decision whether or not to test are reminded that, although the protocol contains only a single assay, it can in many respects be considered at tiered test. Because of the way time points were selected, compounds that degrade rapidly will require a minimum amount of effort, whereas compounds that do not degrade over the 64-week period will require samples at all time periods to be analyzed. This approach has been clarified in the revised (final) protocol. The Agency believes that any alternative (non-tiered) approach would be less cost-effective and more time consuming than the tiered approach described in the protocol.

12. *Chemical fate testing should be "tiered."* Several commenters said that EPA should not require the entire battery of chemical fate testing described in the proposed rule. According to one commenter, it would be more cost-effective to replace the requirements to test for biodegradation, hydrolysis, and soil absorption with a tiered approach to testing. Such an approach would allow affected manufacturers to utilize screening tests to determine whether a more definitive test is indicated.

The objective of the biodegradation protocol is to provide anaerobic degradation rate constants for chemicals listed in the test rule. These rates are to be used in EPA's quantitative modeling procedures to evaluate potential exposure due to groundwater contamination. The key to this protocol is the development of rate constants appropriate for the evaluation of groundwater contamination. Although not of the usual tiered design, the protocol does use a tiered approach. The test has been designed so that, when the test chemical concentration has been reduced by 95 percent the test is terminated. Therefore the test is tiered on the specific time intervals after which samples would have to be taken. In the protocol, samples are to be analyzed at 0, 4, 8, 16, 32 and 64 weeks. If the chemical is completely degraded by week 4, the remaining four samples do not have to be completed. This would reduce the analytical portion of the protocol by 66.6 percent and the microbiological analyses by 33.3 percent. This would effectively reduce the cost of the protocol by more than 25 percent for rapidly degraded chemicals. In light of these considerations, EPA believes that in many cases for chemicals subject to this final rule, it would be advantageous for manufacturers and processors to perform this test for their chemicals. A screening test was considered; however, due to the duration of the adaptation period, the amount of time necessary to complete a screening test could be extensive. Performance of the screening test could result in a significant delay in providing results of the full test, if it were determined that one was needed. Also, the cost savings of such a screening test would not be significant. Therefore, incentive for conducting such a test is reduced.

B. Chemical-Specific Comments

1. *Bis(2-chloroethoxy) methane.* Morton Thiokol, Inc. (MTI) (Ref. 19) commented that the studies specified for bis(2-chloroethoxy) methane in the proposed rule, i.e., subchronic toxicity, hydrolysis, and biodegradation tests, are unwarranted. MTI believes that it is the only manufacturer and processor of this compound. MTI stated that bis(2-chloroethoxy) methane is a site-limited intermediate confined in a completely enclosed system, and it is consumed entirely in the production of polysulfide rubber polymers. According to MTI, all wastes associated with the production of polysulfide rubber are deep-well injected, and thus MTI asserted that there is virtually no human exposure to bis(2-chloroethoxy) methane.

EPA does not believe that the practice of deep-well injection necessarily precludes human exposure. Also, MTI did acknowledge in its comment that past disposal practices (other than deep-well injection) at the company's Moss Point, Mississippi, plant have contaminated the groundwater with bis(2-chloroethoxy) methane at levels as high as 5 mg/L. In addition, wastes from other sources which contain bis(2-chloroethoxy) methane as an impurity may currently be land disposed, and thus could pose a risk to human health and the environment. Finally, as MTI pointed out, bis(2-chloroethoxy) methane has been measured in groundwater at a superfund site in Plumsted Township, New Jersey, thus providing additional evidence that the land disposal of bis(2-chloroethoxy) methane-containing waste can lead to its entry into the human-accessible environment. Therefore, the Agency has retained the specific test requirements for bis(2-chloroethoxy) methane.

2. *Benzal chloride.* Monsanto Co. (Ref. 18) objected to requiring testing on benzal chloride because it is a chemical that rapidly hydrolyzes, and thus the biodegradation testing would not provide meaningful results.

The Agency agrees that the compound hydrolyzes very quickly and thus biodegradation testing is unnecessary. This chemical has not been included among the chemicals recommended for biodegradation testing.

3. *4-Chlorobenzotrichloride.* Occidental Chemical (Ref. 21) submitted information to EPA on 4-chlorobenzotrichloride to support its objections to the proposed health effects testing. Occidental's hydrolysis data indicate that the chemical has an aqueous half-life of 2 minutes at 25 °C. According to Occidental, oral exposure is not a relevant route of exposure for this chemical since it is unlikely that waste leachate, surface, or groundwater would contain 4-chlorobenzotrichloride, because of its short half-life. Occidental also believes that 4-chlorobenzotrichloride is not amenable to the oral gavage toxicity study because hydrolysis would occur in the gastrointestinal tract and thus reduce the effective exposure to 4-chlorobenzotrichloride.

EPA recognizes that the reported rapid hydrolysis of 4-chlorobenzotrichloride would result in water not being a significant medium of exposure to the chemical. However, the Agency disagrees with Occidental's assertion that oral exposure is not a relevant route for 4-chlorobenzotrichloride. The ingestion of 4-chlorobenzotrichloride-contaminated soil (particularly by children) is a potential route of oral exposure. The Agency requires oral toxicity data to assess the associated health hazard.

As for Occidental's concern regarding the technical feasibility of the gavage study, the finding that 4-chlorobenzotrichloride is rapidly hydrolyzed in water does not preclud

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the use of another medium, such as corn oil, as the gavage vehicle.

Occidental also objected to chemical fate testing for this chemical because it will hydrolyze before soil addition/equilibration, and that biodegradation is not expected to be an important fate process. Aqueous hydrolysis testing for this chemical conducted by this commenter has been submitted to EPA.

The Agency agrees that, owing to this chemical's relatively rapid hydrolysis, it is an inappropriate candidate for biodegradation testing and has removed this chemical from the list of chemicals subject to hydrolysis, biodegradation, and soil sorption testing.

4. *Dibutyl phthalate*. [CMA (Ref. 5 and 33) objected to TSCA section 4 biodegradation testing for this chemical, saying that there was no evidence of direct exposure to this chemical as a result of waste disposal activities, and that there was no evidence to conclude that exposure to this chemical at waste sites presents a serious risk of adverse health or environmental effects. The Phthalate Esters Program Panel of CMA "does not dispute that DBP may be found at detectable levels at some waste disposal sites. However, without evidence of concentration levels or of migration away from the sites at detectable levels, there can be no basis for finding that waste disposal activities involving DBP may present an unreasonable risk of injury."

The Agency disagrees with these comments. As explained in Unit II.A.2.b. of this preamble, EPA believes that TSCA section 4(a)(1)(A) does not require a showing or proof of substantial human exposure, and has consistently interpreted this finding to require only potential for exposure. EPA believes that the data contained in the record for dibutyl phthalate documents potential for exposure to this chemical.

CMA (Ref. 38) also commented that "EPA had not identified any adverse health or environmental effects that are reasonably likely to occur as a result of environmental exposure to DBP."

Although a specific health or environmental effect of concern has not been identified for this chemical, the listing of this chemical as a hazardous constituent in Appendix VIII of RCRA, the toxicity data supporting that listing, and the toxicity data supporting this rule summarized in a Health and Environmental Effects Profile (HEEP), all indicate a concern for the general toxicity of this chemical. This concern creates uncertainties with regard to the degree of risk associated with the disposal of wastes that contain dibutyl phthalate as a constituent. EPA requests data on the biodegradation of this chemical to use in modeling, as explained in Units II.A.3. and II.C.2. of this preamble.

CMA (Ref. 38) stated that "the development of anaerobic biodegradation data will not assist EPA in improving its ability to assess the risk these chemicals present to human health or the environment," referring to the chemicals dibutyl phthalate and dimethyl phthalate (DMP). CMA continues, "Moreover, biodegradation data in fact are already available for both DMP and DBP, and the Agency has not explained why additional data are needed or how such data might be used."

EPA disagrees with these comments. As is explained in Units II.A.3. and II.C.2. of this preamble, and was stated in the proposed test rule for these chemicals, the objective of the anaerobic biodegradation protocol finalized in this rule is to provide anaerobic biodegradation rate constants for chemicals. These rates will be used in EPA's subsurface fate and transport model to evaluate the potential risk to human health and the environment from migration of these chemicals in subsurface conditions prevalent in the United States. Units II.A.3. and II.C.2. explain why existing data developed under alternative protocols are not adequate for EPA's determination of whether the disposal of these chemicals by various means or various concentrations presents an unreasonable risk. Biodegradation testing for DBP is recommended, but not required.

5. *Dichlorobenzenes*. Monsanto Co. (Ref. 18) objected to TSCA section 4 testing for these chemcials because EPA had not demonstrated the necessary findings to develop a test rule under TSCA section 4(a).

The Agency disagrees. In addition to available toxicity data, the Agency has data on the occurrence of the chemicals in regulated and unregulated waste streams and in contaminated soil, groundwater, and surface water and has provided that data for public comment, 53 FR 911. Thus, the Agency finds that disposal of the dichlorobenzenes may present an unreasonable risk of injury to human health and/or the environment. Testing is required and recommended for 1,2-dichlorobenzene; for 1,3- and 1,4-dichlorobenzene, no testing is required, but the optional anaerobic biodegradation test is recommended. A detailed discussion of the findings is presented in Units II.A.2.3., and 5. of this preamble.

6. *1,1-Dichloroethane*. Vulcan Chemicals (Ref. 33) objected to testing for this chemical, saying that it is produced as a nonisolated intermediate.

The Agency disagrees. Simply stating that a chemical is produced as a "nonisolated intermediate" does not preclude release of the chemical to the environment as a component of a waste stream or as an impurity in a finished product (see Unit II.A.6.C. of this preamble).

The Agency believes that 1,1-dichloroethane will have a hydrolysis half-life of greater than 10 years in the environment. The Agency needs data on the hydrolysis and anaerobic biodegradation of this chemical to use in modeling, as explained in Units II.A.3. and II.C.2. of this preamble.

7. *2,3-Dichloropropanol*. Eastman Kodak Co. (Ref. 9) objected to testing for this chemical, saying that it is produced in very small quantities (average of 20 kg/yr since 1980) and that a significant adverse economic impact would result if a test rule was imposed.

The Agency disagrees. Although Eastman Kodak Co. produces only a small amount of 2,3-dichloropropanol annually, this compound and 1,3-dichloro-2-propanol, collectively known as dichlorohydrins, are produced as intermediates during the conversion of allyl chloride to epichlorohydrin (Ref. 34). Dow Chemical at Freeport, TX and Shell Chemical at Deer Park, TX are the sole producers of epichlorohydrin using this process. Domestic production of epichlorohydrin using this process was estimated at 440 million pounds in 1984 (Ref. 35). Additional market information obtained subsequent to publication of the proposed rule and incorporated into the revised economic analysis (available for comment January 14, 1988) indicate that the potential for adverse economic impact is low for 2,3-dichloropropanol.

The Agency has data indicating the presence of this chemical in regulated and unregulated waste streams, and requests data on the biodegradation of this chemical to use in modeling, as explained in Units II.A.3. and II.C.2. of this preamble.

8. *Dimethyl phthalate*. CMA (Ref. 5 and 38) objected to TSCA section 4 biodegradation testing for this chemical, saying that there was no evidence of direct exposure to this chemical as a result of waste disposal activities, and that there was no evidence to conclude that exposure to this chemical at waste sites presents a serious risk of adverse health or environmental effects.

The Agency disagrees with these comments. As discussed in Unit II.A.2.b. of this preamble, the data indicating the presence of this chemical in regulated and unregulated waste streams, in groundwater contaminated by releases from RCRA and CERCLA sites, and contaminated soil, groundwater, or surface water resulting from hazardous waste mismanagement incidents documents potential for exposure.

Other comments made by CMA for this chemical (Ref. 38) are the same as the comments submitted for dibutyl phthalate and are addressed in Unit II.B.4. of this preamble. The Agency requests data on the biodegradation of this chemical to use in modeling, as explained in Units II.A.3. and II.C.2. of this preamble.

9. *Endrin.* Velsicol Chemical Corp. (Ref. 32) said that the chemical is no longer manufactured and did not have TSCA-regulated uses when previously manufactured. As a result of its uses which did not fall under TSCA, this commenter believed that it could not have been subject to a TSCA section 4 rulemaking.

This issue has been addressed in Unit II.A.6.d. of this preamble. Confidential data exist which support section 4 rulemaking for this chemical by showing that these chemicals are disposed of, and that potential for exposure exists.

10. *Maleic anhydride.* Maleic Anhydride Consortium (Ref. 16) and Dow Chemical Co. (Ref. 8) noted that there is substantial documentation indicating that this chemical hydrolyzes very rapidly. These commenters felt that maleic anhydride is therefore an inappropriate candidate for soil sorption and biodegradation testing.

The Agency agrees and has removed this chemical from the list of chemicals to be tested for hydrolysis, biodegradation, and soil sorption testing.

11. *Malononitrile.* Lonza, Inc. (Ref. 15) commented that malononitrile, a chemical intermediate imported by the commenter in small amounts (161,800 lbs in 1986) and sold exclusively to the pharmaceutical industry for use in manufacturing several products, should not be tested because it is not land disposed. According to Lonza, malononitrile is consumed during the production of these pharmaceutical products, and, because of its toxicity, is treated to ensure that none remains in the products. The commenter also said that Lonza (as importer) and the pharmaceutical purchasers (as processors) would reclaim any off-specification malononitrile because it is very expensive. Finally, Lonza stated that it would withdraw malononitrile from the market should the rule become final because it cannot justify the expense of the required tests, especially in view of the company's position that malononitrile should be banned from land disposal.

The Agency maintains that malononitrile should undergo the specified tests. In its comment, Lonza said that its material safety data sheet for this chemical states that malononitrile, because of its toxicity, should be disposed of by incineration. However, this recommendation does not necessarily ensure that the users or processors of the chemical are actually incinerating their off-specification material. In fact, malononitrile's presence in unregulated wastes, as documented by the Agency in its January, 1988 notice, published in the Federal Register of January 14, 1988 (53 FR 911), suggests that it may currently be land disposed, and thus, could potentially enter the environment.

Without data on the biodegradation and soil sorption potential of malononitrile, the Agency cannot assess its persistence. Furthermore, without additional data on the toxic potential of this chemical, EPA cannot adequately characterize its effects on health.

12. *Methyl chloride.* The Methyl Chloride Industry Association (Ref. 17 and 42) and Vulcan Chemicals (Ref. 49) objected to testing for this chemical, saying that EPA has not justified its section 4 "may present an unreasonable risk" finding, and had not given full consideration to an earlier proposed test rule (1980) for this chemical that was withdrawn.

The Agency disagrees with these comments. Although a previous (1980) section 4 proposed rule was withdrawn for this chemical, the Agency now has data indicating the presence of this chemical in regulated and unregulated waste streams, in groundwater contaminated by release from RCRA and CERCLA sites, and in contamination resulting from hazardous waste mismanagement incidents.

In addition, as explained in Unit II.A.2.b. of this preamble, EPA believes that TSCA section 4(a)(1)(A) does not require a showing or proof of substantial human exposure, and has consistently interpreted this finding to require only potential for exposure. EPA believes that the data contained in the record for methyl chloride documents potential for exposure to this chemical.

Vulcan Chemicals (Ref. 33) noted that this chemical is produced as a nonisolated intermediate and is normally a gas under ambient conditions. Although methyl chloride has a very low boiling point, the Henry's Law constant for the chemical is .04 atm-m^3/mole (Ref. 46). Henry's Law constant is a ratio of the chemical's vapor pressure to its solubility in water, and provides an indication of whether or not the chemical will be present in groundwater. Due to the value of Henry's Law constant for methyl chloride, and the fact that it has been found in waste streams, the Agency requests data on this chemical to use in modeling, as explained in Units II.A.3. and II.C.2. of this preamble.

13. *p-Nitroaniline.* Monsanto Co. (Ref. 18) opposed the testing of this chemical because it is a small volume chemical intermediate, and there is very little economic justification to support the testing as it has been proposed.

The Agency disagrees. The Agency has data indicating the presence of this chemical in regulated and unregulated waste streams, in groundwater contaminated release from RCRA and CERCLA sites, and in contamination resulting from hazardous waste mismanagement incidents. Thus, despite the fact that *p*-nitroaniline may be a small volume intermediate, it appears that its manufacture and disposal result in the potential for human exposure. The Agency requests biodegradation data on this chemical to use in modeling, as explained in Units II.A.3. and II.C.2. of this preamble.

14. *p-Nitrophenol.* Monsanto Co. (Ref. 18) commented that EPA should exempt *p*-nitrophenol from the required subchronic toxicity test. Given the very small amount of *p*-nitrophenol manufactured for TSCA-regulated purposes, Monsanto said it would cease the TSCA-related production of this chemical if the rule is finalized as proposed. The commenter said that the majority of its *p*-nitrophenol is manufactured as an intermediate in the production of an FDA-regulated product. Monsanto urged the Agency to use existing health effects data to make decisions regarding relisting, and directed EPA to the health effects summary of its *p*-nitrophenol material safety data sheet.

EPA reviewed the above-mentioned summary and concluded that the information discussed is inadequate for quantitative use. Monsanto's information consists of: (1) Very limited, qualitative statements regarding the adverse effects of occupational exposure to the chemical; (2) the results of two acute rodent studies (inhalation and gavage); and (3) several negative mutagenicity or genotoxic activity tests. The Agency requires, at the very minimum, a well-designed and conducted subchronic study for use in deriving an RfD. Such a study does not currently exist for *p*-nitrophenol. Therefore, EPA is requiring that one be performed.

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With regard to the amount of *p*-nitrophenol manufactured for TSCA-regulated purposes, the Agency disagrees with Monsanto's comment. EPA's finding is based on the section 4(a)(1)(A) "may present an unreasonable risk" finding, and not the section 4(a)(1)(B) "substantial production and release" finding; therefore, the TSCA production need not be substantial. Also, the Agency has data indicating the presence of this chemical in regulated and unregulated waste streams, in groundwater contamination from RCRA and CERCLA sites, and in contamination resulting from hazardous waste management incidents. The Agency needs data on this chemical in order to accurately model environmental conditions that are protective of human health and the environment.

15. *Phosgene.* CMA (Ref. 6), Dow (Ref. 8), Olin (Ref. 22), and Vulcan (Ref. 33), objected to including phosgene in the list of chemicals subject to health effects and chemical fate testing. Olin and CMA commented that phosgene is a gas which is manufactured and used in closed-system production units. Vulcan also stated that phosgene is a trace byproduct formed during the production of chlorinated hydrocarbons, and is normally contained within the process unit. The commenters pointed out that a solid phosgene waste is not produced. CMA argued that the entire concept of a subchronic toxicity study for phosgene is inappropriate: Phosgene would react with water in the lung tissue to form carbon dioxide and hydrochloric acid if a toxicity study were conducted via inhalation. If phosgene were administered via oral gavage using water as the vehicle, the chemicals studied would be mostly carbon dioxide and hydrochloric acid, not phosgene.

The Agency concurs that phosgene is an inappropriate candidate for an oral subchronic toxicity study. At ambient temperature, phosgene is normally a gas, and thus it is not in a physical state suited for the oral gavage test protocol. Even if conditions existed whereby phosgene could be introduced into a gavage vehicle, the high reactivity of this chemical would make it nearly impossible to maintain the integrity of the dosing solution. Therefore, EPA is eliminating phosgene from the toxicity testing requirements.

The commenters noted that this chemical is highly reactive and that the proposed chemical fate testing is scientifically inappropriate.

The Agency agrees that this chemical is an inappropriate candidate for the proposed environmental fate testing based on its reactivity and has removed it from the list of compounds to be tested for hydrolysis, biodegradation, and soil sorption.

16. *Phthalic anhydride.* CMA (Ref. 4) objected to TSCA section 4 testing for this chemical because it believed that EPA had not demonstrated that there is evidence of measurable exposure as a result of waste disposal activities, and EPA had not linked health or environmental effects to this chemical from environmental exposure.

The Agency disagrees. The Agency has data indicating the presence of this chemical in regulated and unregulated waste streams and in contaminated soil, groundwater, or surface water resulting from hazardous waste mismanagement incidents. The Agency needs data on this chemical to accurately model environmental conditions so that regulations can be developed that are protective of human health and the environment.

17. *2-Picoline.* Lonza Inc. (Ref. 15) objected to testing of this chemical because it is potentially used up in the production of agricultural chemicals and pharmaceuticals and would be unlikely to be discarded.

The Agency disagrees. There is currently no regulation which places a prohibition on disposal of this chemical on land, and the Agency has data indicating the presence of this chemical in regulated and unregulated waste streams. The Agency requests data on this chemical to accurately model environmental conditions so that regulations can be developed that are protective of human health and the environment.

C. Biodegradation Protocol

Comments on the EPA-developed anaerobic biodegradation testing protocol were received from 15 sources including trade associations, chemical producers, universities, and State and Federal government organizations. Due to the number of commenters, and the similarity of many of their comments, individual commenters will not be identified by name for each issue.

1. *Protocol not peer-reviewed or validated.* Several commenters stated that the proposed protocol is unacceptable because it was neither peer-reviewed nor validated. One commenter stated that the anaerobic biodegradation protocol has not been subjected to the rigorous internal and external peer review that is usually required of TSCA test guidelines. Another commenter stated that manufacturers would be unwilling to undertake validation of this protocol at this stage of development.

In response, EPA notes that this protocol for obtaining microbiological transformation rate data for chemicals in the subsurface environment represents input from government, industry, and academic scientists who attended a workshop on methods to evaluate microbiological process rates, held in 1986. The protocol was developed based on ideas presented by attendees of this workshop. Also, the purpose of proposing the test protocol in the Federal Register was to solicit a peer review. This process has given the public the opportunity to review the documents that support this protocol; in addition, procedures used in the protocol are in current practice as parts of other peer-reviewed protocols, and have appeared in journals and are referenced in the text of this rulemaking.

2. *Use of established protocols.* Several commenters suggested that the proposed biodegradation protocol be abandoned in favor of other established protocols.

The Agency disagrees. The objective of the proposed protocol is to provide anaerobic biodegradation rate constants for chemicals in wastes. These rates will be used in EPA's subsurface fate and transport model to evaluate the potential risk to human health and the environment from migration of these chemicals in subsurface conditions prevalent in the United States. The alternative protocols (40 CFR 796.3150; FIFRA Pesticide Guideline Subdivision N, October 1982, Guideline 1672-2; OECD Guideline 304a, anaerobic) that have been suggested do not meet these conditions. Each of the alternative protocols either: (1) Does not use subsurface materials representing subsurface in-situ conditions as their microbial source; (2) was not developed to produce rate data but was qualitative in nature (except for OECD Guideline 304a); (3) does not provide biodegradation rate constants representative of varying subsurface environmental conditions in the United States; and/or (4) adds nutrients to enhance activity, which may lead to a significant overestimation of biodegradation potential.

3. *Cost of conducting test is "prohibitive", and was underestimated.* According to several commenters, the cost of implementing the proposed anaerobic biodegradation guidelines is prohibitive. They also believe that the economic impact analysis performed for the tests substantially underestimates the real costs to conduct the studies. In addition, according to several commenters, costs of biomass measurements, test concentration

determinations, travel, equipment associated with soil and groundwater sampling, and the cost of locating sampling sites were not factored into the economic impact analysis performed by the Agency.

EPA has estimated the costs of the proposed protocol and assessed the impact of the testing costs on each chemical. The cost of the testing was not found to be prohibitive. The economic analysis accompanying this rulemaking contains a more complete discussion of this conclusion.

Biomass measurements were not included in the cost estimate for the proposed rule; however, the cost of conducting the test has been reestimated for the final rule, and this new cost reflects the cost of the requisite biomass measurements. In addition, costs for analytical chemistry determinations have been added to the test cost estimate for the final rule. The revised analysis was made available for public comment on January 14, 1988 (53 FR 911).

EPA believes that the costs of test concentration determinations will be relatively small. According to § 795.54(b)(2)(iii) of the proposed rule, the test concentration determinations are based upon two factors, the health-based level and the chemical's solubility. In many cases, these data will be readily available and there will be no cost involved in their determination. In some cases, the health-based level will be determined and/or the chemical's solubility will be estimated. The costs for these determinations will be small.

The costs associated with sample collection (specifically, travel, equipment associated with sampling, and the cost of locating sampling sites) are now also included in the cost estimate for the test protocol in the final rule.

4. *Rate of anaerobic vs. aerobic degradation.* The assumption that anaerobic biodegradation is slower than aerobic metabolism and that anaerobic rates can be used as a conservative estimate for biodegradation was challenged by several commenters.

The Agency agrees that anaerobic activity is not always the slowest activity, but it is less likely that data collected under anaerobic conditions would lead to an overestimation of the degradation rate. In the subsurface, aerobic degradation is probably controlled by the influx of oxygen. Thus, the mass transport of oxygen would be the rate limiting step. In the laboratory, oxygen would probably not be the rate limiting step, so degradation rates obtained in the laboratory are likely to be overestimated. Anaerobic processes are not as easily mass transport-limited, and the degradation rate determined in the laboratory could be equal to, or an underestimation of, the actual degradation rate. The Agency maintains that the use of degradation data from anaerobic processes are more appropriate for obtaining modeling information that can be used to protect human health and the environment.

5. *Results would be site-specific.* One commenter said that the results of the testing are likely to be site-specific and only indicative of the particular site tested. This would prevent the results of the testing from being useful to the manufacturers; they would be useful only to the Agency's implementation of the subsurface fate and transport model.

The study would be site-specific if only one site were selected for the study. Six sites (having a range of characteristics) are required by the protocol to provide a spectrum of data that provide a range of biodegradation rates expected to be encountered in the subsurface environments of the United States. The subsurface in-situ biodegradation rate for a chemical constituent depends on, among other factors, Eh, pH, temperature, concentration of the chemical in ground water, and soil microorganisms.

6. *Justification of site/sample collection.* Several commenters did not find that EPA had sufficiently justified the requirement for six samples from six sites, saying that the testing routine is impractical, unnecessary, and will not yield the best information.

Six sites (which have a range of characteristics) were selected to provide a spectrum of data that could provide a range of biodegradation rates to be encountered in subsurface environments in the United States. This matrix of biodegradation rates will be used in a subsurface fate and transport model. A nation-wide simulation of the subsurface environmental conditions is needed because the waste containing a chemical constituent can potentially be managed anywhere in the country. The subsurface fate and transport model is implemented to simulate the nation-wide subsurface conditions using the Monte Carlo procedure. The Monte Carlo procedure utilizes these biodegradation rates to represent the subsurface environmental conditions in the country. Ideally, samples from more than six sites are preferred. However, because of the projected burden on the manufacturers of chemicals, the consensus of the biodegradation workshop, comprised of industrial, academic, and government representatives, was that six sites should be adequate. The characteristics of these sites were also developed by the attendees of the workshop. Although the Agency recognizes that it is difficult to identify six sites, it was the consensus of the workshop that six sites could be identified by researching available hydrogeological information from the U.S. Geological Survey as well as State and County geological and groundwater survey reports.

7. *Influence of biotransformation on chemical fate.* Biotransformation will influence the fate of some organic contaminants; this process has not been considered sufficiently in the proposed guidelines, according to several commenters.

The Agency agrees that biotransformation can result in the alteration of the original chemical, producing intermediates. The formation of degradation intermediates should be quantified in microcosm assays for test chemicals that can potentially be transformed to other test chemicals subject to this rule. Table 2 is a list of chemicals which should be analyzed for the specified intermediates. Analysis for degradation intermediates is indicated when the level of test chemical has been reduced by more than 25 percent.

TABLE 2.—REQUIRED PRODUCT ANALYSIS

Test chemical	Potential product
Trichloromethanethiol	Methanethiol. Chloromethane (methyl chloride).
Pentachlorobenzene	1,2-Dichlorobenzene. 1,3-Dichlorobenzene. 1,4-Dichlorobenzene. 1,2,4,5-Tetrachlorobenzene.
Bromoform	1,2-Dibromomethane.
1,2,4,5-Tetrachlorobenzene.	1,2-Dichlorobenzene. 1,3-Dichlorobenzene. 1,4-Dichlorobenzene.

8. *Interpretation of data under conditions of rapid decay or nutrient-limitation.* The manner in which data will be interpreted in the event that decay is very rapid or in cases where a system becomes nutrient-limited was not addressed in the proposed rule, according to one commenter.

The Agency will interpret biotransformation rate data as described in the proposed rule at 52 FR 20354, May 29, 1987. Where decay is very rapid, the number of samples to be analyzed will be reduced and the cost of testing for that chemical will also be reduced. For those chemicals on Table 2 which degrade rapidly, samples will also be analyzed for the appropriate intermediates.

The subsurface environment is generally nutrient-limited. The addition

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of nutrients would lead to enhanced degradation rates that would not be representative of actual subsurface conditions.

9. *Discrepancy in number of samples collected.* Several commenters noted a discrepancy in the number of samples to be collected for the required analysis.

The Agency agrees with this comment. The discrepancy in the number of samples has been corrected to indicate that two samples will be collected from each site. Data will be reported for each of the two samples from the six different sites (a total of 12 subsurface samples).

10. *More quality assurance.* Several commenters noted that there needs to be more quality assurance on analytical procedures, i.e., methods of analysis for each chemical should be specified.

The Agency agrees that quality assurance must be part of any testing program. A biodegradation laboratory work conducted should follow EPA's TSCA Good Laboratory Practice standards (40 CFR Part 792). The appropriate analytical methods for measuring the degradation of a given chemical will depend on the concentration of the test chemical and the subsurface material being used. Thus, it would be difficult if not impossible for the Agency to identify a method or series of methods for each chemical. To ensure that the selected techniques are appropriate, the reporting of certain quality assurance data, such as reproducibility, precision, and recovery have been added to the protocol.

11. *Number of samples required.* One commenter said that too many samples are required for this protocol, while others indicated that there was confusion as to how many microcosms were needed.

The Agency agrees that the protocol as written in the proposed rule was confusing as to number of microcosms required. The following flow chart (Table 3) clearly illustrates the number of microcosms necessary to test a chemical.

Table 3.—Required Number of Microcosm Assays for Each Chemical

Six Sites
    (x Two samples per site)
12 Samples
    (x Two for sulfate and methanogenic conditions)
24 Microcosms
    (x Two for control and active microcosms)
48 Microcosms
    (x Three for three concentrations)
144 Microcosms
    (x Six for six times periods)
864 = Total Number of Active and Control Microcosms

12. *Determination of minimum concentration.* Several commenters questioned the Agency's selection of 22.5 as the multiplier for the health-based level leading to the minimum concentration. Others stated that it is inappropriate to choose a lower level assay on the basis of a health-based level, and that the selection of a low level assay 22.5 times th health-based level was not justified.

The minimum concentration is the permissible leachate concentration that can be released from a waste disposal site as determined by the EPA modeling approach. Concentrations below this figure would constitute a permissible release and therefore microbiological data would not be needed. The figure of 22.5 was the estimated multiplier to determine the permissible concentration of a contaminant that can leach from a disposal site. The number 22.5 has been revised and the updated multiplier will be 30.

13. *Measure of anaerobicity.* Several commenters noted that the test does not require a measure of anaerobicity and is not designed to ensure that anaerobicity will be maintained in samples.

The Agency agrees with these commenters and has added a measure of anaerobicity to the protocol.

14. *Development of aerobic and microaerophyllic test systems.* Two commenters encouraged EPA to develop aerobic and microaerophyllic test systems in addition to developing an anaerobic biodegradation protocol, saying that these mechanisms are important subsurface attenuation processes and their inclusion would improve anaerobic biodegradation modeling results.

The Agency agrees that aerobic and microaerophyllic processes are important. However, as explained in Unit II.C.4. of this preamble, aerobic degradation rates obtained in the laboratory are often overestimations of actual subsurface aerobic rates. The Agency maintains that modeling subsurface environmental conditions using anaerobic degradation rates is more appropriate and that use of the modeling results based on the anaerobic degradation rates for the development of regulations will be more protective of human health and the environment.

15. *Inclusion of a denitrifying condition.* One commenter suggested that the rule would be improved if a denitrifying condition was included in the testing.

The Agency has not found denitrifying conditions to be representative of the majority of disposal sites in the United States. In addition, denitrifying conditions can lead to more rapid rates of biodegradation for many chemicals. Overestimation of biodegradation rates is inconsistent with the Agency's objective of protecting human health and the environment.

16. *Identification of units for reporting results.* One commenter asked that the units for reporting degradation rate, and characteristics of subsurface and groundwater should be stated clearly.

The Agency agrees, and the protocol has been modified to identify the units for reporting data in the protocol; e.g., residual test chemical (mg/gm dry wt. sediment), redox potential (Eh, standard hydrogen electrode [SHE]), dissolved oxygen (mg/L), etc.

17. *Volatile chemicals.* One commenter said that bottles should be filled to the top for volatile chemicals.

The Agency agrees with this comment. The protocol has been amended to indicate that for all volatile and non-volatile chemicals, the assay bottles should be filled to the top, while maintaining the ratio of dry weight of sediment to volume. Nonvolatile chemicals are included in this amendment, to avoid discrepancy as to what is or is not considered volatile.

18. *Clarification of "dry weight".* One commenter asked that the Agency clarify the term "dry weight."

The term has been modified in the protocol to mean oven dry weight (103 °C).

19. *Biomass measurements.* Several commenters said that there was no justification provided for requiring biomass measurements in the protocol.

The Agency agrees. Biomass measurements were included to ensure comparability of results between subsurface material samples. Rate constants from sediment samples having significantly high or low bacterial populations would be considered suspect. In addition, the ratio of sulfate-reducting and methanogenic organisms are indicative of redox potential of the environment. The protocol has been modified to reflect this.

20. *Adaptation period.* Two commenters questioned how the adaptation period is to be used in this protocol.

The adaptation period is the length of time before biodegradation of the chemical is observed. The adaptation period will be subtracted from the sampling time in which less than 5 percent of the original substrate is detected. This difference will be divided by two to obtain a conservative half-life. This method will be used to determine half-life in the event that insufficient

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data for half-life determination are obtained during testing.

21. *Total organic carbon.* One commenter requested that total organic carbon be analyzed as part of the protocol.

The Agency agrees and has added the analysis of total organic carbon to the protocol.

22. *Choice of 1.0 mL sample size, and dilution series.* One commenter questioned the selection of a 1 milliliter (mL) sample size, and the dilution series included in the protocol for enumeration of heterotrophic bacteria.

Sample sizes are chosen which are large enough to ensure a representative sample, yet small enough to be practical. The Agency has reviewed the sampling procedure in the protocol, and has changed the initial sampling size from 1 mL to 10 mL to ensure that a representative sample is obtained.

Due to the change in initial sampling size, the dilution series described in the revised protocol differs from the series described in the proposed protocol by a power of ten. The dilution series described in the protocol is a recommended guideline; however, it is the responsibility of the laboratory scientist to obtain the correct dilution series for bacterial enumeration.

23. *Use of Wilson method.* Two commenters noted that the use of the method described by Wilson et al., does not preclude oxygen from the subsurface material.

This method has been replaced by an updated method that prevents oxygen contamination of subsurface material, and is reflected in the revised protocol. This updated method is described in Zapico et al. (Ref. 36).

24. *Use of positive control.* Several commenters suggested that the Agency include a positive control in the protocol.

The Agency disagrees with this comment. A positive control is used to indicate if general microbial activity is present in the sediment. An indication of general microbial activity can be obtained by measuring the quantity of microorganisms in the aquifer material. This procedure is already included in the protocol.

25. *Assumption of aerobic metabolism.* One commenter stated that the assumption that "two parts of oxygen are required to completely metabolize one part of an organic compound" may not be conservative.

The Agency disagrees. The assumption of two parts of oxygen is appropriate if one is not attempting to underestimate the approximate ratio. However, the Agency has removed reference to this ratio from the protocol to avoid misinterpretation.

26. *Use of Teflon®-coated silica septa.* Several commenters stated that it was a mistake to specify that Teflon®-coated silica septa be used, because such septa do not maintain anaerobic conditions.

The Agency agrees that Teflon®-coated septa are inappropriate if samples are to be stored outside of an anaerobic chamber, and the protocol has been amended to require the use of 0.5 to 1 cm thick butyl rubber stoppers coated with Teflon®. The requirement to incubate bottles upside down has also been removed from the protocol.

27. *Guidelines for sulfidogenic and methanogenic enumeration techniques.* One commenter noted that the protocol contained elaborate descriptions of more common laboratory techniques, while guidelines for sulfidogenic and methanogenic enumeration techniques are only referenced.

EPA has provided references for two anaerobic enumeration techniques, and does not believe it is necessary to describe them in detail in the protocol. Sulfidogenic enumeration techniques are described in Pankhurst (1971; Ref. 47), and methanogenic enumeration techniques are described in Jones et al. (1982; Ref. 48).

28. *Cutoff levels.* One commenter questioned the 5 percent and 64-week cutoff levels.

If the cut-off level is 5 percent and the reaction gets to 6 percent and the chemical does not degrade further, the protocol would then be completed. The Agency acknowledges that no matter what cut-off point is established, the problem of what should happen if degradation approaches the point but does not surpass it still exists. The 5 percent cut-off level was selected to ensure that degradation of the chemical was essentially complete, and that the reaction did not simply stop when only a portion of the test chemical had been degraded.

29. *Kinetics.* One commenter questioned why kinetics are not obtained, saying that this will result in limited utility of test findings.

The protocol was designed to develop degradation rates that can be used to model environmental conditions so that regulations can be developed which are protective of human health and the environment. A conservative half-life for degradation of a chemical can be estimated by dividing by two the difference between the last sampling time where no detectable degradation had occurred and the sampling time where less than 5 percent of the original substrate is detected. The adaptation period would then be the time over which no detectable degradation of the chemical was observed. This point has been further clarified in the final protocol.

30. *Loss of chemical: Measurement.* One commenter said that the loss of a chemical should not be equated to carbon dioxide and methane production.

The Agency agrees with this comment. The stoichiometry of conversion of the subject chemicals to methane and carbon dioxide is unknown. Therefore, it would not be possible to determine the residual levels of a chemical from carbon dioxide and methane measurements. The amount of residual test chemical will be measured directly.

31. *Adequacy of enumeration techniques.* One commenter said that enumeration techniques may be inadequate.

The Agency recognizes that no enumeration technique is completely accurate. However, if they are consistent from one study to the next, those data can be used in a qualitative manner to indicate the reproducibility of the subsurface samples used in estimating the degradation of the different chemicals to be analyzed. The enumeration of microorganisms in this protocol is primarily for quality assurance and quality control.

32. *Organisms from overlying strata.* One commenter questioned whether organisms from overlying strata would interfere with the protocol.

The purpose of the protocol is to determine the degradation of organic chemicals in subsurface materials. The Agency believes that whether or not the organisms in that material come from the overlying strata is irrelevant.

33. *Modified sampling technique.* A modified sampling technique, developed at the Agency's Environmental Research Laboratory in Ada, Oklahoma, will be presented at the National Water Well Association's Second Outdoor Action and Aquifer Restoration Conference, May 23–26, 1988. Briefly, the modification consists of alterations to hollow-stem auger equipment. A unique sampling tool, referred to as the "Waterloo Cohesionless-Aquifer Core Barrel," for sampling heaving saturated material has been redesigned so the internal vacuum piston can be used in the 4-inch O.D. sample tube. The major alterations consist of a clam-shell cap which is fitted to the bottom of the hollow-stem auger bit replacing the standard center plug. This device serves as a plug for the hollow-stem auger while drilling to a desired depth. Undisturbed samples are collected by lowering the sample tube into the

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hollow auger to the closed clam shell, retracting the auger about one foot—thereby opening the clam shell—and then driving the sample tube to the desired depth with a rig-mounted percussion hammer. The redesigned internal piston inside the sample tube is held stationary by a wire line rigidly fixed to the rig. Holding the piston stationary while lowering the sampler creates a vacuum on the noncohesive sample, holding it in the tube during retrieval from the borehole.

After retrieval, the piston is removed, the sampler is mounted in a hydraulic extruder, and samples are pressed from the tube through an attached paring device inside an aseptic glove-box. The glove-box is designed with a regulated nitrogen flow-through purging system and with a diaphragm port where the sampler can be inserted prior to sample extrusion.

Although EPA did not receive comment on the sampling techniques recommended in the protocol, the Agency is making this information on the modified sampling technique available for the benefit of those who decide to conduct the biodegradation study. For further information on this technique, contact EPA, as directed by this preamble.

D. Economic Issues

Several commenters to this rule (Olin Chemicals, Lonza, Inc., Morton Thiokol, Inc., Velsicol Chemical Corp., Monsanto Co., Dow Chemical Co., Eastman Kodak Co., and Regulatory Network, Inc.; Refs. 22, 15, 19, 32, 18, 8, 9, and 16, respectively) submitted data about specific chemicals, including: phosgene, paraldehyde, malononitrile, 2-picoline, bis(2-chloroethoxy) methane, endrin, hexachlorophene, *p*-nitrophenol, *p*-nitroaniline, benzal chloride, 2,3-dichloro-1-propanol, *p*-benzoquinone, and maleic anhydride. These data have been incorporated in the economic analysis accompanying this final rule. Other non-chemical specific comments are addressed below.

1. The economic analysis accompanying the proposed rule addressed only 49 of 73 chemicals included in the rule (CMA; Ref. 2). In this final rule, testing is required and/or recommended for 33 chemicals. Each of these chemicals has been addressed in the economic analysis for the proposed rule or in the revised economic analysis included in the record upon the reopening of the public comment period on January 14, 1988 (53 FR 911).

2. The Agency cannot justify a test rule for chemicals for which insufficient economic data is available to determine potential economic impact (CMA; Ref. 2). No chemicals for which insufficient economic data are available are included in this final rule.

3. The economic impacts upon manufacturers of byproducts, impurities, and other inadvertent chemicals have not been considered (CMA; Ref. 2). No chemicals identified as chemicals that are manufactured solely as an impurity are included in this final rule. The economic impacts upon manufacturers of byproducts have been included in the economic analysis for each chemical identified as being manufactured solely as a byproduct.

4. The Agency must conduct additional analyses beyond the reliance upon direct cost reviews (CMA, Monsanto; Refs. 2 and 18). The Agency disagrees that a more in-depth analysis is necessary for every chemical included in this rule. The economic analysis for this final rule includes a more in-depth analysis where appropriate. The proposed rule specifically asked for public comment on individual chemicals to assist in the evaluation of significant adverse economic impact. In each case in which such information was submitted, that information has been incorporated into the economic assessment for this final rule. In addition, for each chemical for which the probability of adverse economic impact was determined to be high, or for which insufficient information was available at the time of the proposed rule, additional information has been gathered and incorporated into the economic analysis for this final rule. In sum, the Agency disagrees that such information is required in each and every case. For those specific chemicals for which commenters supplied information, or for which the economic analysis indicated a high probability of adverse impact, a greater level of detail has been incorporated into the final analysis.

5. The economic analysis underestimated the potential economic impact from the rule because the testing costs are annualized over 15 years. Companies required to test will incur these costs over a two-year period, and therefore, the economic analysis underestimates the economic impact of the rule (SOCMA; Ref. 27). This commenter fails to draw a critical distinction between the manner in which firms will pay for testing and the manner in which firms will recover the costs of testing. The method incorporated in the economic analysis of this test rule is aimed at determining the latter—the increase in price necessary to recover the testing cost over the life of each chemical product affected by testing. The commenter instead refers to the former—the accounting method employed to pay for the tests. In the economic analysis, test costs are annualized over the assumed market life of the product, to estimate the amount which a firm would have to increase product price in order to recover the testing cost. As explained in the economic analysis, this estimate of product price increase is used as an indicator of the likelihood of adverse economic impact.

6. EPA has not fulfilled its responsibility to show the availability of testing facilities to conduct the biodegradation test (Olin, Dow; Refs. 22 and 8). In response to this comment, EPA has conducted a survey of testing laboratories (Ref. 37) to determine their capability and likely capacity to conduct the biodegradation test according to the protocol finalized in this rule. The conclusion of this survey is that several laboratories are indeed available to conduct the test at costs comparable to those estimated by EPA.

III. Final Test Rule

A. Findings

The required human health effects and chemical fate testing listed in the following Table 4 is based on the authority of section 4(a)(1)(A) of TSCA. Chemicals recommended for optional (not required) biodegradation testing are also listed in this Table.

TABLE 4.—HAZARDOUS WASTE CONSTITUENTS SUBJECT TO OR RECOMMENDED FOR TESTING[1]

Chemical	CAS No.	Subchronic toxicity testing (required)		Hydrolysis testing (required)		Biodegradation testing (optional)		Soil sorption testing (required)	
		No data	Insufficient data	No data	Insufficient data	No data	Insufficient data	No data	Insufficient data
Acetamide, 2-fluoro	640-19-7	X					X		
Acetophenone	98-86-2					X			

TABLE 4.—HAZARDOUS WASTE CONSTITUENTS SUBJECT TO OR RECOMMENDED FOR TESTING [1]—Continued

Chemical	CAS No.	Subchronic toxicity testing (required)		Hydrolysis testing (required)		Biodegradation testing (optional)		Soil sorption testing (required)	
		No data	Insufficient data	No data	Insufficient data	No data	Insufficient data	No data	Insufficient data
Bis(2-chloroethoxy)methane	111-91-1	X			X	X			
Bis(2-chloroisopropyl)ether	108-60-1			X		X			
4-Bromobenzyl cyanide	16532-79-9	X		X		X		X	
Bromoform	75-25-2				X		X		
4-Chlorobenzotrichloride	5216-25-1	X							
2,4-D	94-75-7			X		X			
Dibromomethane	74-95-3			X		X			
Dibutyl phthalate	84-74-2						X		
1,2-Dichlorobenzene	95-50-1			X			X		
1,3-Dichlorobenzene	541-73-1					X			
1,4-Dichlorobenzene	106-46-7						X		
1,1-Dichloroethane	75-34-3			X			X		
1,3-Dichloropropanol	96-23-1	X					X	X	
2,3-Dichloropropanol	616-23-9					X			
Dihydrosafrole	94-58-6			X		X			
Dimethyl phthalate	131-11-3						X		
2,6-Dinitrotoluene	606-20-2						X		
Endrin	72-20-8			X			X		
Ethyl methacrylate	97-63-2			X		X			
Maleic hydrazide	123-33-1			X			X		X
Malononitrile	109-77-3	X				X		X	
Methanethiol	74-93-1						X		X
Methyl chloride	74-87-3				X	X			
p-Nitroaniline	100-01-6						X		
p-Nitrophenol	100-02-7	X				X			
Pentachlorobenzene	608-93-5			X			X		
Pentachloroethane	76-01-7			X		X			
Phthalic anhydride	85-44-9					X			X
2-Picoline	109-06-8						X		
1,2,4,5-Tetrachlorobenzene	95-94-3			X		X			
Trichloromethanethiol	594-42-3	X		X		X		X	

[1] "X" indicates that the test is needed.

EPA finds that the disposal of these 33 chemicals may present an unreasonable risk of injury to health or the environment; that there are insufficient data and experience to determine or predict the effects of disposal on health or the environment; and that testing is necessary to develop these data.

1. *Subject chemicals may present an unreasonable risk of injury to health or the environment.* All of the chemicals subject to this final test rule have been identified as toxic constituents under Appendix VIII of 40 CFR Part 261, and all have as their primary hazardous property either acute or chronic toxicity. Data document the presence of certain chemicals in waste streams and/or ground water, demonstrating potential for human exposure (53 FR 911; January 14, 1988). The data show that tens of thousands of pounds of these chemicals are being released annually via disposal. Also, the type of disposal described in the data bases for the subject chemicals, such as deepwell injection, discharge to landfill, or discharge to a POTW (publicly-owned treatment works), indicate potential for leaching and exposure to these chemicals. Indeed, data exist for many of the chemicals that document incidents in which the chemicals have migrated from their place of treatment, storage, or ultimate disposal. It is likely that these data represent only a portion of actual contamination occurrences throughout the country.

Therefore, EPA believes that these chemicals meet the requirements for testing under section 4(a)(1)(A)(i) of TSCA. By virtue of these chemicals being identified as "hazardous constituents," the nature of potential toxicity, the presence and evidence of these chemicals in the waste streams of treatment, storage, or disposal facilities, evidence that existing landfills leak, and the potential for human exposure to these chemicals during treatment, storage, and disposal activities and through possible leaching or volatilization, the Agency has determined that the disposal of these chemicals may present an unreasonable risk of injury to human health. A detailed discussion of section 4(a)(1)(A)(i) requirements is contained in Unit II.A.2. of this preamble.

2. *Insufficient data to determine or predict.* All of the chemicals included in this rule have been the subject of a thorough search of the published literature and all standard on-line data bases used by different EPA program offices, including the Toxic Substances Control Act Test Submissions (TSCATS) data base, which identifies data submitted under TSCA section 8(d). The chemicals designated for testing in Table 4 are those for which no acceptable data were found. Specific reasons why data were considered to be inadequate are contained in the health effects and chemical fate Literature Search Results and Critique documents in the public record for this rule.

Therefore, under section 4(a)(1)(A)(ii) of TSCA, the Agency has determined that, for each chemical examined, there are insufficient data upon which the effects of disposal of the subject chemicals on human health can be reasonably determined or predicted.

3. *Testing is necessary.* EPA believes that the testing of the subject chemicals is necessary to determine or predict the effects of disposal of these chemicals on human health so that the Agency can establish concentration levels below which a waste would no longer be considered hazardous under Subtitle C of RCRA.

In the concentration-based listing effort, the Agency will use health effects and chemical fate data on each of the waste constituents to predict the concentration limit that would be the

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basis for defining the waste as hazardous under Subtitle C of RCRA.

Therefore, EPA finds under section 4(a)(1)(A)(iii) of TSCA that the testing of the chemicals included in this final rule is needed, and that the required health effects and chemical fate studies are capable of developing the necessary information to assess the effects of disposal. EPA also finds that the data resulting from the required studies will be relevant to determining whether the disposal of each chemical presents an unreasonable risk of injury to human health.

B. Required and Recommended Testing and Test Standards

On the basis of these findings, EPA is requiring health effects testing and/or specific chemical fate testing for the chemicals subject to this final rule (see Unit III.A. of this preamble). The chemicals and the specific tests are listed in Table 4, along with a test that is recommended (biodegradation), but not required. The required tests are to be conducted in accordance with: (1) EPA's TSCA Good Laboratory Practice Standards in 40 CFR Part 792; and (2) the specific TSCA test guidelines as enumerated in 40 CFR Parts 796 and 798, as amended in this rule. The optional biodegradation test, if conducted, should be conducted in accordance with the EPA-developed guideline, 40 CFR Part 795.54, finalized in this rule.

EPA is requiring that the chemicals listed in Table 4 under Subchronic Testing be tested using the guideline at 40 CFR 798.2650. The subchronic studies will be performed by the oral gavage route. The rat will be the test species.

EPA requires that the chemicals listed in Table 4 under Soil Sorption Testing be tested using the guideline at 40 CFR 796.2750—*Sediment and soil adsorption isotherm.*

EPA further requires that the chemicals listed in Table 4 under Hydrolysis Testing be tested using the guideline at 40 CFR 796.3500—*Hydrolysis as a function of pH at 25 °C,* as modified in this rule. These modifications do not apply to the hydrolysis test requirements of previous rules, such as for anthraquinone. To make this clear, language has been added to the codified portion of this rule stating that the guidelines and other test methods cited in the anthraquinone test rule are referenced as they existed on July 20, 1987.

The Agency is requiring that the above-referenced health effects and chemical fate test guidelines specified in III.B., and any modifications to those guidelines, be the test standards for the purposes of the required and optional testing for these chemicals. The EPA test guidelines for chemical fate and human health effects testing specify generally accepted minimum conditions for determining chemical fate and human health toxicities for substances such as the subject OSW chemicals to which humans may be exposed.

Persons manufacturing or processing the 32 chemicals for which biodegradation testing is recommended, as indicated in Table 4, have the option of performing the test according to the EPA-developed guideline at 40 CFR 795.54, finalized in this rule, or not performing the test and having EPA assume "zero biodegradation" when formulating regulatory requirements for land disposal of hazardous wastes. A discussion of why this test is optional, rather than required, is contained in Unit II.A.11. of this preamble. The guideline was developed by EPA to obtain information on the biodegradation of chemicals in the subsurface environment.

C. Test Substances

EPA is requiring that the test substance in the required studies for each of the chemicals subject to this test rule be of at least 98 percent purity. The Agency has specified relatively pure substances for testing because it is interested in evaluating the effects attributable to the subject chemicals themselves. This requirement lessens the likelihood that any effects seen are due to other chemicals that may be present.

D. Persons Required to Test

Section 4(b)(3)(B) specifies that the activities for which EPA makes section 4(a) findings (manufacture, processing, distribution in commerce, use, and/or disposal) determine who bears the responsibility for testing a chemical. Manufacturers and persons who intend to manufacture a 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 nanufacture and process a chemical, are required to test if the exposure giving rise to the potential risk occurs during distribution in commerce, use, or disposal of a chemical.

Because EPA has found that existing data are inadequate to assess the health risks from the continued disposal of the chemicals subject to this test rule, EPA is requiring that persons who manufacture, import, and/or process, including byproduct manufacture (defined in 40 CFR 791.3), or who intend to manufacture or process these chemicals at any time from the effective date of the final test rule to the end of the reimbursenent period be 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, if more than 5 years after the submission of the last final report required under the test rule.

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 this rule to designate one such person or a qualified third person to conduct the tests and submit data on their behalf. Section 4(c) provides that any person required to test may apply to EPA for an exemption from the requirement. EPA promulgated procedures for applying for TSCA section 4(c) exemptions in 40 CFR Part 790.

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

Processors subject to this rule, unless they are also manufacturers, will not be required to submit letters of intent or exemption applications, or to conduct testing, unless manufacturers fail to submit notices of intent to test or later fail to sponsor the required tests. The Agency expects that the manufacturers will pass an appropriate portion of the costs of testing on to processors through the pricing of their products or 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, the Agency will publish a separate notice in the Federal Register to notify processors to respond; this procedure is described in 40 CFR Part 790.

EPA is not requiring the submission of equivalence data as a condition for exemption from the required testing for the chemicals subject to this final test rule. As noted in Unit III.C. of this

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preamble. EPA is interested in evaluating the effects attributable to each of the chemicals themselves and has specified relatively pure substances 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. This does not include manufacturers and processors of the nine chemicals for which no testing is required, but is recommended (biodegradation).

For those who decide to conduct the optional biodegradation test, EPA requests notification, either in the letter of intent to conduct the required testing or a separate letter, that biodegradation testing will be conducted.

E. Reporting Requirements

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

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

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

The 90-day subchronic toxicity study on each of the designated chemicals shall be completed and the final results submitted to the Agency within 12 months of the effective date of the final test rule.

The soil sorption study on the designated chemicals shall be completed and the final results submitted to the Agency within 9 months of the effective date of the final test rule.

The hydrolysis studies on the designated chemicals shall be completed and the final results submitted to the Agency within 6 months of the effective date of the final test rule.

A progress report on the subchronic toxicity and biodegradation tests will be required every 6 months from the effective date of the final rule until submission of the final report.

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

Persons who export a chemical substance or mixture subject to a section 4 test rule are subject to the export reporting requirement of TSCA section 12(b). Final regulations interpreting the requirement of section 12(b) are in 40 CFR Part 707. In brief, as of the effective date of this test rule, an exporter of any of the chemicals listed at 40 CFR 799.5065(c) must report to EPA the first annual export of the chemical to any one country. EPA will notify the foreign country about the test rule for the chemical.

If a person decides to conduct the optional biodegradation study on a chemical, the person should notify EPA. Testing should begin within 4 months of the effective date of the final rule and the final results of the study should be submitted to the Agency within 6 months of the completion date of the study, but not exceed 25 months from the effective date of the final rule. Persons who decide not to conduct the test should notify EPA of this decision in writing within 4 months of the effective date of the final rule. This letter implies acknowledgement that EPA will assume "zero biodegradation" for purposes of concentration-based listing of the chemical.

F. Enforcement Provisions

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

EPA's authority to inspect a testing facility also derives from section 4(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. The Agency maintains that laboratory inspections are necessary to provide this assurance.

Violators of TSCA are subject to criminal and civil liability. Persons who submit materially misleading or false information in connection with the requirement of any provision of this rule may be subject to penalties which may be calculated as if they never submitted their data. Under the penalty provisions of section 16 of TSCA, any person who violates section 15 of TSCA could be subject to a civil penalty of up to $25,000 for each violation, with each day of operation in violation constituting a separate violation. This provision would 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 the Agency has notified them of their obligation to submit such documents (see 40 CFR 790.48(b)). Knowing or willful violations could lead to the imposition of criminal penalties of up to $25,000 for each day of violation and imprisonment for up to 1 year. In determining the amount of penalty, EPA will take into account the seriousness of the violation and the degree of culpability of the violator as well as 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,

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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 for this rule, EPA has prepared an economic analysis report, contained in the public record for this rule, 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 and recommended testing for each of the 33 chemicals (24 with required and/or recommended testing; 9 recommended for optional testing only) and evaluates the potential for significant adverse economic impact as a result of those costs, incorporating an impact measure based upon unit test cost as a percent of price. For those chemicals for which public comments specifically addressed the potential for economic impact, that information has been incorporated into the economic analysis. For each chemical for which the costs of testing estimated in the economic analysis of the proposed rule indicated a high probability of adverse economic impact, a more detailed assessment has been incorporated into the economic analysis for this final rule to more precisely determine whether that chemical has been classified appropriately.

The total testing costs for testing the 33 chemicals are estimated to range from approximately $6.2 million to $8.2 million if companies consent to conduct the optional biodegradation test for each of the 32 chemicals for which that test is requested. The total testing costs for the required tests alone are estimated to range from $665,000 to $937,000. The estimated testing costs for individual chemicals range from $74,000 to $339,000, again, assuming that the biodegradation test is conducted. If some firms that are subject to required testing opt not to conduct the biodegradation test, for some chemicals, testing costs would be as low as $4,300. See the economic analysis contained in the public record for this rule for the estimated testing costs for each chemical.

The economic impact analysis indicates that for 28 of the 33 chemicals, the probability of significant adverse economic impact as a result of the testing costs is very low. Five chemicals have a potential for significant adverse impact on the basis of the estimated testing costs if the manufacturers and processors of each chemical choose to conduct the optional biodegradation test. If the biodegradation test is not conducted for these five chemicals, only two will have a potential for significant impact. The specific chemicals falling into each of these groups may be found in the economic impact analysis in the public docket.

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

V. Availability of Test Facilities and Personnel

Section 4(b)(1) of TSCA requires EPA to consider "the reasonably foreseeable availability of the facilities and personnel needed to perform the testing required under the rule." Therefore, EPA conducted a study to assess the availability for testing services created by section 4 test rules demands. 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, and a survey of laboratories that can conduct the biodegradation test (Ref. 37), the Agency believes that there will be available test facilities and personnel to perform the testing specified in this rule.

VI. Rulemaking Record

EPA has established a record for this rulemaking proceeding [docket number OPTS-42088D]. This record includes:

A. Supporting Documentation

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

(a) Notice of EPA's proposed test rule for OSW Chemicals (52 FR 20336; May 29, 1987).

(b) Notice to extend comment period on proposed test rule for OSW Chemicals (52 FR 29395; August 7, 1987).

(c) Notice to reopen comment period on proposed test rule for OSW Chemicals (53 FR 911; January 14, 1988).

(d) TSCA test guidelines final rule (40 CFR Parts 796, 797, and 798; September 27, 1985) and modifications (52 FR 19056; May 20, 1987).

(e) TSCA GLP standards (48 FR 53922; November 29, 1983).

(f) Notice of final rulemaking on data reimbursement (48 FR 31768; July 11, 1983).

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

(2) Support documents consisting of:

(a) Literature search results and critique.

(b) Economic impact analysis of NFRM for the chemicals subject to this final rule.

(c) Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976 (40 U.S.C. 10001).

(d) Identification and Listing of Hazardous Waste (40 CFR Part 261).

(3) Communications consisting of:

(a) Written public comments.

(b) Transcript of public meeting.

(4) Report—Chemical Testing Industry: Profile of Toxicological Testing (October, 1981).

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 TSCA Public Docket Office, Rm. NE-G004, 401 M St., SW., Washington, DC from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

B. References

(1) American Petroleum Institute. Robert T. Drew, Ph.D., Director, Health and Environmental Sciences Department. Letter to EPA. (July 28, 1987).

(2) Chemical Manufacturers Association. Geraldine V. Cox, Ph.D., Vice President and Technical Director, et al. Letter to EPA and Attachment: Comments of the Chemical Manufacturers Association on EPA's Proposed Test Rules Concerning 73 Solid Waste Chemicals. (July 28, 1987).

(3) Chemical Manufacturers Association. Geraldine V. Cox, Ph.D., Vice President and Technical Director, et al. Letter to EPA and Attachment: Supplemental Comments of the Chemical Manufacturers Association of EPA's Proposed Test Rules Concerning 73 Solid Waste Chemicals. (August 27, 1987).

(4) Chemical Manufacturers Association. Geraldine V. Cox, Ph.D., Vice President and Technical Director; CMA Phthalate Esters Panel; et al. Letter to EPA and Comments of CMA Phthalate Esters Panel on the Proposed Biodegradation and Adsorption Testing Requirements for Phthalate Anhydride. (August 27, 1987).

(5) Chemical Manufacturers Association. Geraldine V. Cox, Ph.D., Vice President, and Technical Director; CMA Phthalate Esters Panel; et al. Comments of CMA Phthalate Esters Panel on the Proposed Biodegradation Testing Requirements for Dimethyl Phthalate and Dibutyl Phthalate. (August 27, 1987).

(6) Chemical Manufacturers Association. Geraldine V. Cox, Ph.D., Vice President and Technical Director; CMA Phosgene Program Panel; et al. Letter and Attachment: Comments of the CMA Phosgene Program Panel on EPA's Proposed Subchronic Studies Requirements for Phosgene. (August 27, 1987).

(7) Conoco, Inc. Charles E. Downs, Ph.D., Senior Director, Groundwater Programs, Environmental Conservation. Letter to EPA. (July 28, 1987).

(8) The Dow Chemical Company. Robert L. Hagerman, Research Associate. Letter to EPA. (August 26, 1987).

(9) Eastman Kodak Company. Robert F. Brothers, Director, Regulatory Affairs. Letter to EPA. (July 23, 1987).

(10) Florida International University, Drinking Water Center, Tamiami Campus. Frances Parsons, Ph.D., Associate Professor. Letter to EPA. (July 8, 1987).

(11) State of Illinois Department of Energy and Natural Resources, Illinois State Water

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Survey, Aquatic Chemistry Section. Michael J. Barcelona, Head of Aquatic Chemistry Section. Letter to EPA (July 14, 1987).

(12) Interagency Testing Committee. Robert Brink, Executive Secretary. Memorandum to TSCA Public Information Office. (August 19, 1987).

(13) Interchem, Inc. Harold H. Flegenheimer, Director, Environmental Health and Safety Affairs. Letter to EPA. (July 15, 1987).

(14) The Johns Hopkins University, Department of Geography and Environmental Engineering. Edward J. Bouwer, Assistant Professor. Letter to EPA. (July 24, 1987).

(15) Lonza, Inc. Michael J. Reale, Ph.D., Director, Hazard Assessment and Environmental Control. Letter and Attachment: Comments on OPTS-42088A Solid Waste Chemicals: Proposed Test Rule. (July 28, 1987).

(16) Maleic Anhydride Consortium. Prepared by Robert J. Fensterheim, Regulatory Network, Inc. Letter and Attachment: Comments of the Maleic Anhydride Consortium on the U.S. Environmental Protection Agency's Solid Waste Chemicals: Proposed Test Rule Document Control Number (OPTS-42088A) 52 FR 20336 (May 29, 1987). (July 28, 1987).

(17) Methyl Chloride Industry Association (MCIA). Prepared by Robert Sussman and Richard Friedman, Counsel, Covington & Burling. Letter and Attachment: Attachment to the Comments of the Methyl Chloride Industry Association of EPA's Proposed Test Rules for 73 Chemicals, Including Testing for Methyl Chloride. Docket No. OPTS-42088A. Attachment also includes Appendices A through J. (July 24, 1987).

(18) Monsanto Company. D.B. Redington, Director, Regulatory Affairs (RCRA) and J.R. Condray, Director, Regulatory Affairs (TSCA). Letter to EPA and attached Material Safety Data Sheets. (July 27, 1987).

(19) Morton Thiokol, Inc. Arthur E. Slesinger, Director, Environmental Affairs. Letter to EPA. (July 24, 1987).

(20) Natural Resources Defense Council. Helen Greer, Robin Whyatt, and Jacqueline Warren. Comments of the Natural Resources Defense Council on Proposed Test Rule for 73 Solid Waste Chemicals. 52 FR 20336 (May 29, 1987). (August 28, 1987).

(21) Occidental Chemical Corporation. Paul E. Gurba, Ph.D., Corporate Toxicologist. Letter to EPA and Attachments: (1) *para*-Chlorobenzene Vapor Thirty Day Inhalation Toxicity Study in Rats (Huntingdon Research Center); (2) *para*-Chlorobenzene Vapor Thirty Day Inhalation Study in Rats—Microscopic Pathology Addendum (Huntingdon Research Center); (3) Hydrolysis Kinetics for *p*-Chlorobenzotrichloride (p-CBTC). (Oxy Chem Technology Center); (4) Hydrolytic Stabilities for alpha, alpha, alpha-trichlorotoluene, *p*-Chloro, alpha, alpha, alphatrichlorotoluene, benzoyl chloride, *p*-chlorobenzoyl chloride, and 3,5-dichlorobenzoyl chloride. (Hooker); and (5) Biodegradability Testing of Organchlorine Compounds (Vom Wasser v. 67). (July 23, 1987).

(22) Olin Chemicals. Nicholas J. Barone, Manager, Regulatory Services. Letter to EPA. (July 21, 1987).

(23) The Procter and Gamble Company. T.W. Mooney, Technical Government Relations. Letter to EPA. (July 28, 1987).

(24) Reilly Tar & Chemical Corporation. Nicholas Wright, Toxicologist, Corporate Environmental Affairs. Letter to EPA. (July 28, 1987).

(25) Rice University Department of Environmental Science and Engineering. J. Michele Thomas, Research Associate. Letter and Attachment: Critique of EPA Method for Microbial Transformation of Subsurface Materials. (June 26, 1987).

(26) Rice University Department of Environmental Science and Engineering. P.B. Bedient. Letter and attachment: Critique of Protocol for Obtaining Microbiological Transformation Rate Data for Chemicals in Subsurface Aquifers. (June 5, 1987).

(27) Synthetic Organic Chemical Manufacturers Association, Inc. Catherine A. Marshall, Director, Legislative and Regulatory Affairs. Letter and Attachment: Synthetic Organic Chemical Manufacturers Association Comments on Section 4 Test Rule for Solid Waste Chemicals. 52 Fed. Reg. 20336 (May 29, 1987). Document Control No. OPTS-42088A. (August 27, 1987).

(28) United States Department of the Interior, Office of Environmental Project Review. Bruce Blanchard, Director, Environmental Project Review. Letter to EPA. (August 12, 1987).

(29) University of California—Riverside, College of Natural and Agricultural Sciences Citrus Research Center and Agricultural Experiment Station, Department of Nematology. C.E. Castro, Chemist and Professor. Letter to EPA. (July 22, 1987).

(30) The University of Oklahoma, Department of Botany and Microbiology. Joseph M. Suflita, Assistant Professor of Microbiology. Letter to EPA and Attachments: (i) "Biodegradation of cresol isomers in anoxic aquifers." In: *Applied and Environmental Microbiology*, vol. 53, No. 4; and (ii) "Extrapolation of biodegradation results to groundwater aquifers reductive dehalogenation of aromatic compounds." in: *Applied and Environmental Microbiology*, vol. 52, No. 4 (July 8, 1987).

(31) Utah Water Research Laboratory. Ronald C. Sims, Ph.D., Head, Division of Environmental Engineering and Associate Professor, and R. Ryan Dupont. Comments on Provisional Chemical Fate Testing Guidelines. (August 25, 1987).

(32) Velsicol Chemical Corporation. Alfred A. Levin, Manager, Toxic Substances Control. Letter to EPA. (July 8, 1987).

(33) Vulcan Chemicals. Thomas A. Robinson, Ph.D., Director, Environmental Affairs. Letter to EPA. (July 17, 1987).

(34) Kirk-Othmer. "Chlorohydrins." In: *Kirk-Othmer Encyclopedia of Chemical Technology*, 3rd. ed., vol. 5, New York, NY. Wiley Interscience. pp. 848–864. (1979).

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(37) U.S. Environmental Protection Agency. "Survey of laboratories able to conduct anaerobic biodegradation tests." (1988).

(38) Chemical Manufacturers Association. Geraldine V. Cox, Ph.D., Vice President and Technical Director, et al. Letter to EPA and Supplemental Comments of the CMA Phthalate Esters Program Panel on the Proposed Biodegradation Testing Requirements for Dimethyl Phthalate and Dibutyl Phathalate. (February 16, 1988).

(39) Monsanto Company. D.B. Redington, Director, Regulatory Affairs (RCRA) and J.R. Condray, Director, Regulatory Affairs (TSCA). Letter to EPA. (February 12, 1988).

(40) Synthetic Organic Chemical Manufacturers Association, Inc. Catherine A. Marshall, Director, Legislative and Regulatory Affairs. Letter and Attachment: Synthetic Organic Chemical Manufacturers Association Comments on Section 4 Test Rule for Solid Waste Chemicals; Reopening of Comment Period. 53 FR 911 (January 14, 1988) Document Control No. OPTS 42088C. (February 16, 1988).

(41) Eastman Kodak Company. Robert F. Brothers, Director, Regulatory Affairs. Letter to EPA. (February 11, 1988).

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(43) Chemical Manufacturers Association. Geraldine V. Cox, Ph.D. Vice President and Technical Director, et al. Letter to EPA and attachment: Second Supplemental Comments of the Chemical Manufacturers Association of EPA's Proposed Test Rules Concerning 73 Solid Waste Chemicals. (February 16, 1988).

(44) Maleic Anhydride Consortium. Prepared by Robert J. Fensterheim, Regulatory Network, Inc. Letter to EPA re: Solid Waste Chemicals; Reopening of Comment Period on Proposed Test Rule (OPTS-42088C). (February 16, 1988).

(45) Ausimont U.S.A. Inc. v. EPA. No. 87–3502 slip opinion (3rd Cir. 1988) February 1, 1988.

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VII. Other Regulatory Requirements

A. Executive Order 12291

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

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

B. Regulatory Flexibility Act

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

C. Paperwork Reduction Act

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

List of Subjects in 40 CFR Parts 795, 796 and 799

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

Dated: June 3, 1988.

J.A. Moore,

Assistant Administrator for Pesticides and Toxic Substances.

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

PART 795—[AMENDED]

1. In Part 795:

a. The authority citation for Part 795 continues to read as follows:

Authority: 15 U.S.C. 2603.

b. Section 795.54 is added, to read as follows:

§ 795.54 Anaerobic microbiological transformation rate data for chemicals in the subsurface environment.

(a) *Introduction.* (1) This guideline describes laboratory methods for developing anaerobic microbiological transformation rate data for organic chemicals in subsurface materials. The method is based on a time-tiered approach. For chemicals that are degraded rapidly, only a portion (the 0, 4, and 8 week sampling periods, for example) of the test will have to be completed; however, for slowly degrading chemicals, the entire test may have to be performed (64 weeks). The data will be used to calculate degradation rate constants for each tested chemical over a range of environmental conditions. The rate constants obtained from testing will be integrated into algorithms to assess the fate of organic chemicals leaching into ground water from waste management facilities.

(2) Anaerobic transformations are evaluated under methanogenic and sulfur-reducing conditions. Aerobic biodegradation was not included in the modeling analysis for two reasons:

(i) Aerobic biodegradation would be limited by the concentration of oxygen in ground water. In the laboratory, oxygen would probably not be limiting, and the resulting degradation rates obtained would possibly be overestimations of actual subsurface degradation rates.

(ii) Aerobic degradation would only occur at the leading edge of a contaminant plume where dispersion and other processes dilute the plume with oxygenated water, as stated in Wilson et al. (1985), in paragraph (d)(24) of this section.

(3) The anaerobic transformation of chemicals in selected subsurface samples shall be estimated from subsurface microcosm studies using methods adapted from procedures recently reported by Wilson et al. (1986), in paragraph (d)(25) of this section. These procedures shall be used to determine the length of the adaptation period (time interval before detectable degradation of the chemical can be observed) and the half-life of the chemical following the adaptation period. Supporting laboratory methods shall be used to measure the levels of residual test chemical, intermediate degradation products, biomass, and other physical-chemical parameters.

(b) *Laboratory procedures*—(1) *Identification of subsurface sampling sites, collection of subsurface materials, and transportation and storage of subsurface materials.*—(i) A minimum of six subsurface sampling sites shall be identified on the basis of two temperatures and three pH values. Three of the sites shall have annual average temperatures near 10 °C, and three of the sites shall have temperatures near 20 °C. These values are chosen to represent the high and low temperatures commonly observed in aquifers and are one standard deviation on either side of the mean temperature of 15 °C. Generally, low temperature sites are located in northern latitude areas of the United States, and high temperatures correspond to southern latitude areas.

(ii) Acidic (pH 4.5 to 6.0), neutral (pH 6.5 to 7.5), and alkaline (pH 8.0 to 9.5) sites shall be selected for each temperature range. These ranges of pH values for ground waters are selected to estimate the effect of pH on microbial degradation capacity and to examine the effect of chemical form on the degradation of chemicals having dissociable hydrogen (i.e., degradation of the protonated and unprotonated forms of the chemical). Ground waters at all sites shall have dissolved-oxygen levels below 0.1 mg/L and sulfate concentrations below 10 mg/L.

(iii) Samples of subsurface materials shall be collected in a manner that protects them from contamination from surface materials and maintains anaerobic conditions. An appropriate procedure has been reported by Wilson et al. (1983), in paragraph (d)(26) of this section. First, a bore hole is drilled to the desired depth with an auger. Then the auger is removed and the sample taken with a wireline piston core barrel, as reported by Zapico et al., 1987, in paragraph (d)(14) of this section. The core barrel is immediately transferred to an anerobic chamber, filled and continually purged with nitrogen gas, and all further manipulations are performed in the chamber. Using aseptic procedures, up to 5 centimeters (cm) of the core is extruded, then broken off to produce an uncontaminated face. A sterile paring device is then installed, and the middle 30 to 35 cm of the core is extruded, paring away the outer 1.0 cm of core material. As a result, the material that had been in contact with the core barrel, and thus might be contaminated with surface microorganisms, is discarded.

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Modifications of this technique can be used for samples obtained from deep coring devices when auger equipment is insufficient because of the depth of the aquifer. Subsurface material shall be stored under nitrogen gas and on ice and shall be used in microcosm studies within 7 days of collection.

(iv) Ground waters will be collected from the bore hole used to collect subsurface materials. Ground waters will be pumped to the surface. The bore hole should be purged with argon before pumping begins. The pumping mechanism should be flushed with enough ground water to insure that a representative ground water sample is obtained. This flushing process generally requires a volume equal to 3 to 10 times the volume of water in the bore hole. Once flushing is complete, ground water samples should be collected, and stored under nitrogen and on ice for transport back to the laboratory. Ground waters shall be sterilized by filtration through 0.22 micrometer (μm) membranes on-site in a portable anaerobic chamber filled and continually purged with nitrogen gas. The sterile water shall be stored under nitrogen and on ice, and shall be used in microcosm studies within 7 days of collection.

(v) Two samples shall be collected from each of the 6 sites. Each core sample shall be assayed for test chemical degradation and analyzed for biomass (heterotrophic, sulfate-reducing, and methanogenic) and physical-chemical parameters (pH, cation exchange capacity, total organic carbon, percent base saturation, percent silt, percent sand, percent clay, redox potential, percent ash-free dry weight). Each corresponding ground water sample will be analyzed for pH, dissolved oxygen, dissolved organic carbon, nutrients (sulfate, phosphate, nitrate), conductivity, and temperature.

(2) *Anaerobic Microcosm assay.* (i) Microcosms shall consist of 160-milliliter (mL) serum bottles which have been filled completely with a slurry of subsurface material and ground water (20 grams equivalent dry wt (oven dry wt. 103 °C) solid to 80 mL ground water). One series of serum bottles shall be amended to a level of 200 mg/L sulfate (weight/volume added as sodium sulfate) to stimulate sulfate-reducing conditions. If the level of soluble sulfate falls below 50 mg/L at any sampling time, additional sulfate (200 mg/L, weight/volume) should be added to all remaining sulfate-amended microcosms. Soluble sulfate levels should be measured by the method of Watwood et al. (1986), in paragraph (d)(23) of this section. A second series shall be left unamended to simulate methanogenic conditions. All manipulations in preparing the microcosms shall be performed aseptically under strict anaerobic conditions, as described in Kaspar and Tiedje (1982) in paragraph (d)(10) of this section, or other equivalent methods, and all equipment in contact with the subsurface samples shall be sterilized. Sterile controls shall be prepared by autoclaving the samples for a minimum of 1 hour on each of 3 consecutive days. Test chemical amendments shall be prepared in sterile nitrogen-purged ground water. Sparingly soluble and volatile chemicals shall be added to sterile, nitrogen-purged ground water and then stirred overnight without a head space.

(ii) The active and control microcosms shall be dosed with the test chemical and 0.0002 percent (w/v) Resazurin as a redox indicator, and then each unit shall be immediately sealed with a Teflon®-coated gray butyl rubber septum and crimp seal. As stated previously, all manipulations shall be performed under strict anaerobic conditions, as described in Kaspar and Tiedje (1982) in paragraph (d)(10) of this section, or other equivalent methods. The microcosms shall be stored in the dark at the original in-situ temperature. Active microcosms and control microcosms, randomly selected from the sulfate-amended series and the unamended series, shall be sacrificed and analyzed at 0, 4, 8, 16, 32, and 64 weeks for residual test chemical and the formation of degradation intermediates. Once the residual level of the chemical drops below 5 percent of the initial concentration, analysis of microcosms at subsequent time periods is not required. The active microcosms and control microcosms from both series, at weeks 0, 16, and 64 (or randomly selected from the remaining samples the week following 95 percent degradation of the chemical, if less than week 64) shall also be analyzed for heterotrophic, sulfate-reducing, and methanogenic bacteria.

(iii) Three concentrations of each chemical tested shall be used. The test chemical concentrations should range between a low level of 30 times the health-based level and a level that equates to the chemical's solubility (or to a level that causes inhibition of the test chemical's degradation).

(iv) Biomass measurements shall be made for heterotrophic, sulfate-reducing, and methanogenic bacteria. Biomass measurements have been included to insure comparability of results between samples of subsurface materials. Degradation rates derived from sediment samples having significant high or low (student "t" test, 90 percent level) bacterial populations would not be considered in subsequent modeling efforts. Also, the ratio of sulfate-reducing organisms to methanogenic organisms would be used to determine if the dominant redox conditions were sulfate-reducing or methanogenic. Anaerobic techniques described by Kaspar and Tiedje (1982), cited in paragraph (d)(10) of this section, or other equivalent methods, shall be used.

(v) Heterotrophic bacterial concentrations shall be measured by a modification of the procedure developed by Molongoski and Klug (1976) and Clark (1965), cited in paragraphs (d)(13) and (d)(6) of this section, respectively. A ten-mL sample taken from the center of the appropriate microcosm, which has been well mixed, shall be aseptically transferred to 100 mL of sterile dilution medium and agitated to suspend the organisms. Ten-mL samples shall then be transferred immediately from the center of the suspension to a 90-mL sterile dilution medium blank to give a 10^{-2} dilution; 10 mL shall be similarly transferred to another 90-mL of sterile dilution medium to obtain a dilution of 10^{-3}. This process shall be repeated to give a dilution series through at least 10^{-7}. Only the 10^{-1} dilution need be prepared from control samples. The dilution series can be modified to include dilutions of greater than 10^{-7}, if necessary, and if sufficient sample is available. From the highest dilution, 0.1-mL portions shall be transferred to the surface of each of three dilute tryptone glucose extract agar plates. The sample shall be spread immediately over the surface of the plates; the process shall be repeated for lower dilutions. Dilute tryptone glucose agar plates shall be prepared by combining 24.0 g tryptone glucose extract agar in 1 liter of distilled water. The mixture shall be autoclaved, and 25 mL of the molten agar shall be transferred to petri plates. Agar plates should be stored in an anaerobic chamber for a minimum of 24 hours before use. The inoculated plates shall be incubated in plastic bags in the glove box, or, if necessary, removed and kept in anaerobic jars. After 14 days of incubation, the plates shall be examined and the total count per gram of dry sediment material shall be determined. If the plates from the most dilute sample show more than 300 colonies, the dilution series was inadequate. In this case, all of the plates shall be discarded, and the process shall be repeated with greater dilutions, as appropriate.

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(vi) Sulfate-reducing species shall be enumerated by the MPN (most probable number) technique as descibed in Pankhurst (1971) in paragraph (d)(15) of this section, or other equivalent method. The dilution series shall be prepared as described for heterotrophic bacteria.

(vii) Methanogenic bacteria shall be enumerated by the MPN technique as described by Jones et al. (1982) in paragraph (d)(9) of this section, or by another equivalent method. The dilution series shall be prepared as described for heterotrophic bacteria.

(3) *Analytical measures of the loss of test chemical and intermediate degradation products.* (i) The loss of test chemical shall be quantified by measuring the residual test chemical. The formation of degradation intermediates shall be quantified in microcosm assays for test chemicals that can potentially be transformed. Analysis for degradation intermediates shall be required when the level of test chemical has been reduced by more than 25 percent. Concentrations of the potential degradation products 1,2-, 1,3-, and 1,4-dichlorobenzene, and 1,2,4,5-tetrachlorobenzene shall be measured in the appropriate microcosms used to analyze the degradation of pentachlorobenzene. The concentration of the potential degradation product dibromomethane shall be measured in the appropriate microcosms used to analyze the degradation of bromoform. The potential degradation products methanethiol and chloromethane (methyl chloride) shall be measured in the appropriate microcosm used to analyze the degradation of trichloromethanethiol. The potential intermediate products 1,2-, 1,3-, and 1,4-dichlorobenzene shall be measured in the appropriate microcosm used to analyze the degradation of 1,2,4,5-tetrachlorobenzene.

(ii) Measurements of test chemical and intermediate degradation products will require organic analytical techniques tailored to the specific test chemical and subsurface material being investigated. Several extraction and purge-trap techniques are available for the recovery of residual test chemicals and degradative intermediates from subsurface materials. Unique analytical procedures would have to be developed or modified for each test chemical and sediment. The following represent examples of such techniques:

(A) Soxlet extraction as described in Anderson et al. (1985), Bossart et al. (1984), Eiceman et al. (1986), Grimalt et al. (1984), and Kjolholt (1985) in paragraphs (d) (2), (3), (7), (8), and (11) of this section, respectively.

(B) Shake flask method as described in Brunner et al. (1985), and Russel and McDuffie (1983) in paragraphs (d) (4) and (16) of this section, respectively.

(C) Sonification as described in Schellenberg et al. (1984) in paragraph (d)(17) of this section.

(D) Homogenization as described in Fowlie and Sulman (1986), Lopez-Avila et al. (1983), Sims et al. (1982), Stott and Tabatabai (1985), and U.S. EPA (1982) in paragraphs (d) (5), (12), (18), (19), and (22) of this section, respectively.

(E) Purge-trap techniques have been described by Wilson et al. (1986) in paragraph (d)(24) of this section.

(iii) These procedures can be readily coupled to gas chromatography (GC) and high-pressure liquid chromatography (HPLC) procedures to quantify the chemicals of interest. Whatever analytical procedure is selected shall follow Good Laboratory Practice Standards of 40 CFR Part 792.

(4) *Characterization of subsurface materials and ground waters.* (i) Subsurface materials shall be classified, described, and characterized as to soil type and physical and chemical properties using standard procedures as described by the Soil Conservation Service (U.S. Department of Agriculture, 1972 and 1975) in paragraphs (d) (20) and (21) of this section, or other equivalent methods. Ten parameters will be measured as follows:

(A) Total organic carbon (TOC).
(B) pH.
(C) Cation exchange capacity.
(D) Percent base saturation.
(E) Percent silt.
(F) Percent sand.
(G) Percent clay.
(H) Redox potential.
(I) Percent ash-free dry weight.
(J) Texture.

(ii) Ground water shall be characterized for the following, by standard water and wastewater methods described by the American Public Health Association (1985) in paragraph (d)(1) of this section, or other equivalent methods:

(A) pH.
(B) Dissolved oxygen.
(C) Dissolved organic carbon.
(D) Nutrients including sulfate, phosphate, and nitrate.
(E) Conductivity.
(F) Temperature.

(iii) The properties of pH, dissolved oxygen, and temperature shall be measured at the site of collection. All other properties shall be measured in the laboratory.

(c) *Data to be reported to the Agency.* Data shall be reported for the two subsurface samples and corresponding ground waters taken from the six different sampling sites.

(1) The following shall be reported for subsurface sediment samples:

(i) Levels of residual test chemicals (mg/gm/dry wt) quantified in each of the randomly selected replicate microcosm and sterile controls at the specific time periods identified under the anaerobic microcosm assay.

(ii) Numbers of heterotrophic, sulfate-reducing, and methanogenic bacteria (colony forming units (CFU) or most probable number units (MPNU) per gm dry wt) enumerated in each replicate microcosm and sterile controls at the specific time periods identified under the anaerobic microcosm assay.

(iii) Levels of persistent degradation intermediates identified in microcosm and sterile controls at the specific time periods identified under the anaerobic microcosm assay.

(iv) Measured values for pH, cation exchange capacity (meg/100 gm dry wt), percent base saturation, percent silt (percent dry wt), percent sand (percent dry wt), percent clay (percent dry wt), redox potential (Eh, Standard Hydrogen Electrode), percent ash free dry weight (percent dry wt), and a description of texture.

(2) For ground water samples, the analysis report shall provide measured values for:

(i) pH.
(ii) Dissolved oxygen (mg/L).
(iii) Dissolved organic carbon (mg/L).
(iv) Nutrients including sulfate (mg/L), phosphate (mg/L), and nitrate (mg/L).
(v) Conductivity (umho, 25 °C).
(vi) Temperature (°C).

(d) *References.* For additional background information cited in this protocol, the following references should be consulted:

(1) American Public Health Association, American Water Works Association, and Water Pollution Control Federation. "Standard methods for the examination of water and wastewater," 16th ed., A.E. Greenberg, R.R. Trussel, and L.C. Clesceri (eds.). American Public Health Association, Washington, DC (1985).

(2) Anderson, J.W., G.H. Herman, D.R. Theilen, and A.F. Weston. "Method verification for determination of tetrachlorodibenzodioxine in soil." *Chemosphere* 14:1115–1126 (1985).

(3) Bossart, I., W.M. Kachal, and R. Bartha. "Fate of hydrocarbons during oil sludge disposal in soil." *Applied and Environmental Microbiology* 47:763–767 (1984).

(4) Brunner, W., F.H. Sutherland, and D.D. Focht. "Enhanced biodegradation of polychlorinated biphenyls in soil by

analog enrichment and bacterial inoculation." *Journal of Environmental Quality* 14:324–328 (1985).

(5) Fowlie, P.J.A., and T.L. Bulman. "Extraction of anthracene and benzo(a)-pyrene from soil." *Analytical Chemistry* 58:721–723 (1986).

(6) Clark, F.E. "Agar-plate method for total microbial count," p. 1460–1466. In: C.A. Black (ed.), "Methods of soil analysis. Part 2. Chemical and Microbiological Properties." American Society of Agronomy, Inc., Madison WI (1965).

(7) Eiceman, G.A., B. Davani, and J. Ingram. "Depth profiles for hydrocarbons and polycyclic aromatic hydrocarbons in soil beneath waste disposal pits from natural gas production." *Environmental Science and Technology*. 20:508–514 (1986).

(8) Grimalt, J., C. Marfil, and J. Albaiges. "Analysis of hydrocarbons in aquatic sediments." *International Journal of Environmental Analytical Chemistry* 18:183–194 (1984).

(9) Jones, J.G., B.M. Simon, and S. Gardener. "Factors affecting methanogenesis and associated anaerobic processes in the sediments of a stratified eutrophic lake." *Journal of General Microbiology* 128:1–11 (1982).

(10) Kaspar, H.F., and J.M. Tiedje. "Anaerobic bacteria and processes," p. 989–1009. In: A.L. Page (ed.), "Methods of Soil Analysis. Part 2. Chemical and Microbiological Properties." American Society of Agronomy, Madison, WI (1982).

(11) Kjolholt, J. "Determination of trace amounts of organophosphorous pesticides and related compounds in soils and sediments using capillary gas chromatography and a nitrogen-phosphorous detector." *Journal of Chromatography* 325:231–238 (1985).

(12) Lopez-Avila, V., R. Northcutt, J. Onstot, M. Wickham, and S. Billets. "Determination of 51 priority organic compounds after extraction from standard reference materials." *Analytical Chemistry* 55:881–889 (1983).

(13) Molongoski, J.J., and M.J. Klug. "Characterization of anaerobic heterotrophic bacteria isolated from freshwater lake sediments." *Applied Environmental Microbiology* 31:83–90 (1976).

(14) Zapico, M.M., S. Vales, and J.S. Cherry. "A wireline piston core barrel for sampling cohesionless sand and gravel below the water table." *Ground Water Monitoring Review*. Summer, Vol. 7, No. 3:74–82 (1987).

(15) Pankhurst, E.S. "The isolation and enumeration of sulphate-reducing bacteria," p. 223–240. In: D.A. Shapton and R.G. Board (eds.), "Isolation of Anaerobes." Academic Press, Inc., New York (1971).

(16) Russell, D.J., and B. McDuffie. "Analysis for phthalate esters in environmental samples: Separation from PCBs and pesticides using dural column chromatography." *International Journal of Environmental Analytical Chemistry* 15:165–183 (1983).

(17) Schellenberg, K., C.L. Leuenberger, and R.P. Schwarzenback. "Sorption of chlorinated phenols by natural sediments and aquifer materials." *Environmental Science and Technology*. 18:652–657 (1984).

(18) Sims, R.C. "Land treatment of polynuclear wastes." Ph.D. dissertation. North Carolina State University, Raleigh, NC (1982).

(19) Stott, D.E., and M.A. Tabatabai. "Identification of phospholipids in soils and sewage sludges by high-performance liquid chromatography." *Journal of Environmental Quality*. 14:107–110 (1985).

(20) United States Department of Agriculture. "Soil survey laboratory methods and procedures for collecting soil samples." *Soil Survey Investigations Report No. 1*. Soil Conservation Service. Soil Survey Investigation (1972).

(21) United States Department of Agriculture. "Soil taxonomy: a basic system of soil classification for making and interpreting soil surveys." *Agricultural Handbook 436*. Soil Conservation Service (1975).

(22) U.S. Environmental Protection Agency. "Test Methods for Evaluating Solid Wastes: Physical/Chemical Methods." Second Edition. SW–846. U.S. Environmental Protection Agency, Washington, D.C. (1982).

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(25) Wilson, B.H., G.B. Smith, and J.F. Rees. "Biotransformation of selected alkylbenzenes and halogenated aliphatic hydrocarbons in methanogenic aquifer material: A microcosm study." *Environmental Science and Technology*. 20:997–1002 (1986).

(26) Wilson, J.T., J.F. McNabb, D.L. Balwill, and W.C. Ghiorse. "Enumeration and characterization of bacteria indigenous to a shallow water-table aquifer." *Groundwater* 21:134–142 (1983).

PART 796—[AMENDED]

2. In Part 796:

a. The authority citation for Part 796 continues to read as follows:

Authority: 15 U.S.C. 2603.

b. Section 796.3500 is amended by revising the first sentence of paragraph (b)(1)(ii) and revising paragraphs (b)(1)(iii), (iv), (v), (vii), (ix), and (x) and (b)(2)(i) (C)(*1*) and (D) (*1*) and (*2*), to read as follows:

§ 796.3500 Hydrolysis as a function of pH at 25 °C.

* * * * *

(b) * * *

(1) * * *

(ii) *Purity of water*. Reagent-grade water (e.g., water meeting ASTM Type IIA standards or an equivalent grade) shall be used to minimize biodegradation. * * *

(iii) *Sterilization*. All glassware shall be sterilized. Aseptic conditions shall be used in the preparation of all solutions and in carrying out all hydrolysis experiments to eliminate or minimize biodegradation. Glassware can be sterilized in an autoclave or by any other suitable method.

(iv) *Precautions for volatility*. If the chemical is volatile the reaction vessels shall be almost completely filled and sealed.

(v) *Temperature controls*. All hydrolysis reactions shall be carried out at 25 °C (±1 °C) and with the temperature controlled to ±0.1 °C.

* * * * *

(vii) *Concentration of solutions of chemical substances*. The concentration of the test chesical shall be less than one-half the chemical's solubility in water but not greater than 10^{-3}M.

* * * * *

(ix) *Buffer catalysis*. For certain chemicals, buffers may catalyze the hydrolysis reaction. If this is suspected, hydrolysis rate determination shall be carried out with the appropriate buffers and the same experiments repeated at buffer concentrations lowered by at least a factor of five. If the hydrolysis reaction produces a change of greater than 0.05 pH units in the lower concentration buffers at the end of the measurement time, the test chemical concentrations also shall be lowered by at least a factor of five. Alternatively, test chemical concentrations and buffer concentrations may both be lowered simultaneously by a factor of five. A sufficient criterion for minimization of buffer catalysis is an observed equality in the hydrolysis rate constant for two different solutions differing in buffer c

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test chemical concentration by a factor of five.

(x) *Photosensitive chemicals.* The solution absorption spectrum can be employed to determine whether a particular chemical is potentially subject to photolytic transformation upon exposure to light. For chemicals that absorb light of wavelengths greater than 290 nm, the hydrolysis experiment shall be carried out in the dark, under amber or red safelights, in amber or red glassware, or employing other suitable methods for preventing photolysis. The absorption spectrum of the chemical in aqueous solution can be measured under § 796.1050.

* * * * *

(2) * * *

(i) * * *

(C) * * *

(*1*) The concentrations of all the above buffer solutions are the maximum concentration to be employed in carrying out hydrolysis measurements. If the initial concentration of the test chemical is less than 10^{-3}M, the buffer concentration shall be lowered by a corresponding amount; e.g., if the initial test chemical concentration is 10^{-4}M, the concentration of the above buffers shall be reduced by a factor of 10. In addition, for those reactions in which an acid or base is not a reaction product, the minimum buffer concentration necessary for maintaining the pH within +0.05 units shall be employed.

* * * * *

(D) * * *

(*1*) If the test chemical is readily soluble in water, prepare an aqueous solution of the chemical in the appropriate buffer and determine the concentration of the chemical. Alternatively, a solution of the chemical in water may be prepared and added to an appropriate buffer solution and the concentration of the chemical then determined. In the latter case, the aliquot shall be small enough so that the concentration of the buffer in the final solution and the pH of the solution remain essentially unchanged. Do not employ heat in dissolving the chemical. The final concentration shall not be greater than one-half the chemical's solubility in water and not greater than 10^{-3}M.

(*2*) If the test chemical is too insoluble in pure water to permit reasonable handling and analytical procedures, it is recommended that the chemical be dissolved in reagent-grade acetonitrile and buffer solution and then added to an aliquot of the acetonitrile solution. Do not employ heat to dissolve the chemical in acetonitrile. The final concentration of the test chemical shall not be greater than one-half the chemical's solubility in water and not greater than 10^{-3}M. In addition, the final concentration of the acetonitrile shall be one volume percent or less.

PART 799—[AMENDED]

3. In Part 799:

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

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

b. In § 799.500, by revising paragraph (d) to read as follows:

§ 799.500 Anthraquinone.

* * * * *

(d) *Effective date.* (1) The effective date of this final rule for anthraquinone is July 20, 1987.

(2) The guidelines and other test methods cited in this section are referenced as they exist on July 20, 1987.

* * * * *

c. Subpart D is added, consisting at this time of § 799.5055, to read as follows:

Subpart D—Multichemical Test Rules

§ 799.5055 Hazardous waste constituents subject to testing.

(a) *Identification of test substances.* (1) The table in paragraph (c) of this section identifies those chemical substances that shall be tested in accordance with this section.

(2) Substances of at least 98-percent purity shall be used as the test substances.

(b) *Persons required to submit study plans, conduct tests, and submit data.* All persons who manufacuture (including import or manufacture as a byproduct) or process or intend to manufacture or process one or more of the substances in paragraph (c), other than as an impurity, after July 29, 1988, to the end of the reimbursement period shall submit letters of intent to conduct testing, submit study plans, conduct tests, and submit data, or submit exemption applications for those substances they manufacture or process, or intend to manufacture or process, as specified in this section, Subpart A of this part, and Parts 790 and 792 of this chapter for single-phase rulemaking.

(c) *Designation of testing.* The substances identified in the following table by name and CAS number shall be tested in accordance with the designated requirements under paragraphs (d) and (e) of this section. The paragraph numbers listed for a substance refer to the specific testing and reporting requirements specified in paragraphs (d) and (e) of this section.

Chemical name	CAS No.	Required testing under paragraphs (d) and (e) of this section
Acetamide, 2-fluoro	640–19–7	(e)(1)
Bis(2-chloroethoxy)-methane.	111–91–1	(d)(2), (e)(1)
Bis(2-chloroisopropyl)-ether	108–60–1	(d)(2)
4-Bromobenzyl cyanide.	16532–79–9	(d)(1), (2), (e)(1)
Bromoform	75–25–2	(d)(2)
4-Chlorobenzo-trichloride.	5216–25–1	(e)(1)
2,4-D	94–75–7	(d)(2)
Dibromomethane 74–95–3 (d)(2).		
1,2-Dichlorobenzene.	95–50–1	(d)(2)
1,1-Dichloroethane	75–34–3	(d)(2)
1,3-Dichloropropanol.	96–23–1	(d)(1), (e)(1)
Dihydrosafrole	94–58–6	(d)(2)
Endrin	72–20–8	(d)(2)
Ethyl methacrylate	97–63–2	(d)(2)
Maleic hydrazide	123–33–1	(d)(1), (2)
Malononitrile	109–77–3	(d)(1), (e)(1)
Methanethiol	74–93–1	(d)(1)
Methyl chloride	74–87–3	(d)(2)
p-Nitrophenol	100–02–7	(e)(1)
Pentachloroben-zene.	608–93–5	(d)(2)
Pentachloroethane	76–01–7	(d)(2)
Phthalic anhydride	85–44–9	(d)(1)
1,2,4,5-Tetrachloroben-zene.	95–94–3	(d)(2)
Trichloromethan-ethiol.	594–42–3	(d)(1), (2), (e)(1)

(d) *Chemical fate testing*—(1) *Soil adsorption*—(i) *Required testing.* A soil adsorption isotherm test shall be conducted with the substances designated in paragraph (c) of this section in accordance with § 796.2750 of this chapter.

(ii) *Reporting requirements.* The sediment and soil adsorption isotherm tests shall be completed and the final results submitted to the Agency within 9 months of the effective date of the final rule.

(2) *Hydrolysis*—(i) *Required testing.* A test of hydrolysis as a function of pH at 25 °C shall be conducted with the substances designated in paragraph (c) of this section in accordance with § 796.3500 of this chapter.

(ii) *Reporting requirement.* The hydrolysis tests shall be completed and the final results submitted to the Agency within 6 months of the effective date of the final rule.

(e) *Health effects testing*—(1) *Subchronic toxicity*—(i) *Required testing.* An oral gavage subchronic toxicity test shall be conducted in the rat with the substances designated in paragraph (c) of this section in

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accordance with § 798.2650 of this chapter.

(ii) *Reporting requirements.* (A) The oral gavage subchronic tests shall be completed and the final results submitted to the Agency within 1 year of the effective date of the final rule.

(B) Progress reports for each test shall be submitted to the Agency 6 months after the effective date of the final rule.

(2) [Reserved].

(f) *Effective date.* (1) The effective date of the final rule July 29, 1988.

(2) The guidelines and other test methods cited in this section are referenced here as they exist on June 15, 1988.

[Information collection requirements have been approved by the Office of Management and Budget under control number 2070-0033.]

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