(5) If the proposed manufacturer, importer, or processor has shown a *bona fide* intent to manufacture, import, or process the substance and has provided sufficient unambiguous chemical identity information so EPA can make a conclusive determination as to the identity of the substance, EPA will inform the proposed manufacturer, importer, or processor whether the chemical substance is subject to this section.

(6) A disclosure to a person with a *bona fide* intent to manufacture, import, or process a particular chemical substance that the substance is subject to this section will not be considered public disclosure of confidential business information under section 14 of the Act.

(7) EPA will answer any inquiry on whether a particular chemical substance is subject to this section within 30 days after receipt of a complete submission under paragraph (c)(2) of this section.

(d) *Persons who must report.* Any person who intends to manufacture, import (other than as part of an article), or process for commercial purposes, any of the substances listed in paragraph (a) of this section for a significant new use defined in that paragraph must submit a notice to the EPA Office of Toxic Substances in Washington, D.C. under the provisions of section 5(a)(1)(B) of the Act, Part 720 of this Chapter, and this section. Any notice of import must be submitted by the principal importer.

(e) *Notice requirements and procedures.* Each person who is required to submit a significant new use notice under this section must submit the notice at least 90 calendar days before commencing the significant new use. The submitter must comply with any applicable requirement of section 5(b) of the Act, and the notice must include the information and test data specified in section 5(d)(1) of the Act. The notice must be submitted on the notice form in Appendix A to Part 720 of this Chapter and must comply with the requirements of Part 720 except to the extent that they are inconsistent with this section. EPA will process the notice in accordance with the procedures in Part 720 of this Chapter, except to the extent that they are inconsistent with this section.

(f) *Exemptions and exclusions.* The chemical substances listed in paragraph (a) of this section are not subject to the notification requirements of this section if:

(1) The substances are manufactured or processed July only in small quantities solely for research and development, and the substances are manufactured or processed in accordance with the provisions of § 720.36 of this Chapter.

(2) The substances are manufactured or processed only as an impurity or byproduct.

(g) *Enforcement.* (1) Failure to comply with any provision of this section is a violation of section 15 of the Act (15 U.S.C. 2614).

(2) Using for commerical purposes a chemical substance or mixture which a person knew or had reason to know was manufactured, processed, or distributed in commerce in violation of this section is a violation of section 15 of the Act (15 U.S.C. 2614).

(3) Failure or refusal to permit access to or copying of records, as required under section 11 of the Act, is a violation of section 15 of the Act (15 U.S.C. 2614).

(4) Failure or refusal to permit entry or inspection, as required under section 11 of the Act, is a violation of section 15 of the Act (15 U.S.C. 2614).

(5) Violators may be subject to the civil and criminal penalties in section 16 of the Act (15 U.S.C. 2615) for each violation. Persons who submit materially misleading or false information in connection with the requirement of any provision of this section may be subject to penalties calculated as if they never filed their notices.

(6) EPA may seek to enjoin the manufacture or processing of a chemical substance in violation of this section or act to seize any chemical substance manufactured or processed in violation of this section or take other actions under the authority of sections 7 or 17 of the Act (15 U.S.C. 2606 or 2616).

(h) *Recordkeeping.* Manufacturers and processors who manufacture or process any of the substances listed in paragraph (a) of this section, must maintain the following records for five years from the date of their creation:

(1) The names of persons required to wear protective clothing and/or equipment.

(2) Records of respirator fit tests for each person required to wear a respirator.

(3) The name and address of each person to whom any of these substances are sold or transferred and the date of such sale or transfer.

(Approved by the Office of Management and Budget under control number 2070-0012)

[FR Doc. 83-34795 Filed 12-30-83; 8:45 am]

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40 CFR Part 799

[OPTS-42054; TSH-FRL 2500-1]

Aniline and Chloro-, Bromo- and/or Nitroanilines; Response to the Interagency Testing Committee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Advance notice of proposed rulemaking.

SUMMARY: In the Fourth Report of the Interagency Testing Committee (ITC), transmitted to the Administrator of EPA in April 1979, the ITC designated the anilines category for testing consideration. The Agency is publishing this Advance Notice of Proposed Rulemaking (ANPR) to initiate rulemaking to require the testing that appears necessary to characterize the health and environmental effects of the anilines. The amount of data available differs among the various category members and effects, so that testing needs are chemical-and effect-specific. This notice constitutes EPA's response to the ITC's designation of the anilines category for testing consideration. EPA seeks comment on its conclusions as to the need for further testing of the anilines and the submission of data, information and views on a number of issues.

DATE: All comments should be submitted on or before March 5, 1984.

ADDRESS: Written comments should bear the document control number [OPTS-42054] and should be submitted in triplicate to: TSCA Public Information Office (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. E-108, 401 M St. SW., Washington, D.C. 20460.

The administrative record supporting this action is available for public inspection in Rm. E-107 at the above address from 8:00 a.m. to 4:00 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: Jack P. McCarthy, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-543, 401 M St. SW., Washington, D.C. 20460, toll free: (800-424-9065), in Washington, D.C.: (554-1404), outside the USA: (Operator-202-554-1404).

SUPPLEMENTARY INFORMATION:

I. Background

Section 4(a) of the Toxic Substances Control Act (TSCA) (Pub. L. 94-469.90 Stat. 2003 *et seq.*, 15 U.S.C. 2601 *et seq.*) authorizes EPA to promulgate

regulations requiring manufacturers and processors to test chemical substances and mixtures in order to develop data relevant to determining the risks that such chemicals may present to health and the environment. Section 4(e) of TSCA established an Interagency Testing Committee (ITC) to recommend to EPA a list of chemicals to be considered for the promulgation of testing rules under section 4(a) of the Act.

In April 1979, the ITC placed on its priority testing list a category of chemicals known as "aniline and chloro-bromo- and/or nitroanilines" (see 44 FR 31866, June 1, 1979). The ITC defined this category as aniline and aniline substituted in one or more positions with a chloro, bromo, or nitro group, or any combination of these substituents. Anilines bearing other substituents are excluded from the category, even if they also carry one or more of the allowed substituents. The ITC recommended that the anilines be considered for testing for the following health effects: carcinogenicity, mutagenicity, teratogenicity and chronic effects (with special emphasis on blood disorders and neurotoxicity). In addition, the ITC recommended that an epidemiology study be considered because of the large-scale production and potential for substantial occupational exposure to certain anilines. The ITC also recommended that the anilines be considered for environmental effects testing and expressed specific concern about the lack of information on the potential for anilines to persist in the environment, to bioaccumulate and to cause adverse effects in cases where exposure can be identified. This Advance Notice of Proposed Rulemaking provides EPA's response as required by TSCA section 4(e) to the ITC's designation of the anilines.

Under section 4(a)(1) of TSCA, the Administrator shall by rule require testing of a chemical substance to develop appropriate test data if the Agency finds that:

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

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

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

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

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

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

EPA uses a weight to evidence approach in making a section 4(a)(1)(A)(i) finding in which both exposure and toxicity information are considered to make the finding that the chemical may present an unreasonable risk. For the section 4(a)(1)(B)(i) finding, EPA considers only production, exposure, and release information to determine if there is substantial production, significant or substantial exposure, and substantial release. Thus, while EPA can require testing for an effect under section 4(a)(1)(A) only if there is a suspicion of a hazard, under section 4(a)(1)(B) EPA can require testing whether or not there are data suggesting adverse effects if the relevant production, exposure, and release criteria are met.

For the findings under both section 4(a)(1)(B)(ii) and 4(a)(1)(B)(ii), EPA examines toxicity and fate studies to determine if existing information is adequate to reasonably determine or predict the effects of human exposure to, or environmental release of, the chemical. In making the third finding, that testing is necessary, EPA considers whether ongoing testing will satisfy the information needs for the chemcial and whether testing that the Agency might require would be capable of developing the necessary information.

EPA's process for determining when these findings can be made is described in detail in EPA's first and second proposed test rules as published in the Federal Register of July 18, 1980 (45 FR 48526) and June 5, 1981 (46 FR 30300). The section 4(a)(1)(A) finding is discussed in 45 FR 48528, and the section 4(a)(1)(B) finding is discussed in 46 FR 30300.

In evaluating the ITC's testing recommendations for the anilines, EPA considered all available relevant information including the following: Information presented in the ITC's report recommending testing consideration; production volume, use, exposure, and release information reported by manufacturers of anilines under the TSCA section 8(a) Preliminary Assessment Information Rule (40 CFR Part 712); and other published and unpublished data available to the Agency, including information submitted under the TSCA section 8(d) Health and Safety Data Reporting Rule (40 CFR Part 716).

The twenty anilines listed below have been specifically identified by industry as being currently in production.

1. Aniline (CAS No. 62-53-3).
2. 2-Chloroaniline (CAS No. 95-51-2).
3. 3-Chloroaniline (CAS No. 108-42-9).
4. 4-Chloroaniline (CAS No. 106-47-8).
5. 2,3,-Dichloroaniline (CAS No. 608-27-5).
6. 2,4-Dichloroaniline (CAS No. 554-00-7).
7. 2,5-Dichloroaniline (CAS No. 95-82-9).
8. 3,4-Dichloroaniline (CAS No. 95-76-1).
9. 2,4,6-Trichloroaniline (CAS No. 634-93-5).
10. 2-Nitroaniline (CAS No. 88-74-4).
11. 3-Nitroaniline (CAS No. 99-09-2).
12. 4-Nitroaniline (CAS No. 100-01-06).
13. 2,4-Dinitroaniline (CAS No. 97-02-9).
14. 2-Chloro-4-nitroaniline (CAS No. 121-87-9).
15. 2-Chloro-5-nitroaniline (CAS No. 6283-35-6).
16. 4-Chloro-2-nitroaniline (CAS No. 89-83-4).
17. 4-Chloro-3-nitroaniline (CAS No. 635-22-3).
18. 2,6-Dichloro-4-nitroaniline (CAS No. 99-30-9).
19. 2,6-Dibromo-4-nitroaniline (CAS No. 827-94-1).
20. 2-Bromo-4,6-dinitroaniline (CAS No. 1817-73-18).

II. Tentative EPA Decision And Issues

A. Development of Rulemaking

The Agency has reviewed available data which indicate that human and environmental exposure to and the toxicity of individual anilines category members may be sufficient to support a finding of potential unreasonable risk under TSCA section 4(a)(1)(A). EPA has previously indicated that although it would generally initiate rulemaking for testing through publication of a proposed rule, it may initiate action on chemical categories and certain complex chemicals through publication of an Advance Notice of Proposed Rulemaking (ANPR), as it is doing in this case. There are several reasons, both general to categories and specific to the anilines category, why the Agency has chosen to use this approach to initiate rulemaking with respect to this ITC designation of the anilines category.

The Agency has found that in developing rules for chemical categories, the issues that require attention are considerably more complex and numerous than in rulemaking for a single chemical. These issues thus require considerable additional time to resolve. For example, in order to avoid unnecessary or duplicative testing while assuring that adequate data are developed, the Agency needs to determine whether it is scientifically valid to test a set of representative chemicals rather than test each individual chemical substance in the category. One method of achieving this goal is through the use of structure-activity relationships (SAR). The Agency believes that there is a logical basis for pursuing SAR along the lines outlined in this notice (i.e., subcategorization according to the structures of the anilines). In addition, the Agency is setting forth for public comment a variety of other methods for selecting test substances (see Unit III. 8).

Identifying the appropriate means for selecting which anilines category compounds should be tested is only part of the effort necessary for development of a proposed test rule for this category. The Agency must also consider what the proper scope of the anilines category should be, because there are numerous anilines that are listed in the TSCA inventory but are not currently in production, and there is also a large number of anilines that are neither in production nor on the TSCA inventory, but which have been reported in the chemical literature (see Unit III.10). The Agency's decisions with regard to the scope of the testing category and the method for selecting test substances will have important effects on reimbursement and exemption issues that arise under TSCA section 4 test rules. Because of the complexity of these important issues, the Agency believes that the issuance of an ANPR is the most appropriate method to initiate rulemaking for the anilines category.

Furthermore, EPA must review data applicable to exposure, release, and unreasonable risk (including consideration of testing costs and economic impact) for many chemical substances when dealing with a category.

A major part of EPA's data-gathering efforts on chemical substances is completed through two rules under section 8 of TSCA. The first, published in the Federal Register of June 22, 1982 (47 FR 26992), required, pursuant to section 8(a) of TSCA, that manufacturers of specified chemicals supply the Agency with certain production data and other information relating to potential exposure and release of the substances in question. The second rule, published September 2, 1982 (47 FR 38780), required, pursuant to section 8(d) of TSCA, that manufacturers of the specified chemicals supply the Agency with all unpublished health and safety studies in their possession relating to the chemicals. All substances nominated for priority consideration for testing are subject to these rules.

The section 8(d) rule has resulted in the submission to EPA of important data during 1983. Moreover, the Aniline Association and the Substituted Anilines Task Force (SATF) of the Synthetic Organic Chemical Association have recently submitted important environmental release and human exposure information for the manufacturing situation (Refs. 20 and 27). However, the incomplete nature of the information, especially on human exposures and environmental releases resulting from the non-captive processing and use of anilines category members, as well as a lack of reliable environmental monitoring data has also prompted EPA to issue an ANPR for these chemicals, rather than issue a proposed test rule.

In addition to the conceptual difficulties EPA has in directly preparing a proposed rule on a category of this size, EPA believes there are positive advantages in using an ANPR to initiate the process of rulemaking for testing this category of chemical substances. Publication of such a notice provides an opportunity for public comment on the difficult issues involved in the use of subcategories based on chemical structure, the other methods for choosing representative test substances, the scope of the testing category, and the complex questions related to reimbursement and exemptions (see Unit III), before the agency expends its resources on developing a proposed test rule for the anilines category. Because of the complexity of the issues involved, development of a proposed rule before receiving such input may result in needless expenditure of Agency resources and considerable delay in rule promulgation because of the potential volume of public comments on the proposed rule. For these reasons EPA has chosen to initiate rulemaking by issuing an ANPR in response to the ITC designation of the anilines category.

EPA, in publishing this ANPR, wishes to receive comment on its tentative basis for requiring testing, on the tests the Agency believes necessary to characterize the health and environmental effects of the anilines, on EPA's tentative approach to a representative sample of chemicals for testing, and on certain technical and regulatory issues that bear significantly on the makeup of a future proposed rule for this category. The bases for the suggested findings, and for the tests under consideration, are discussed below.

B. Preliminary Findings

1. *Potential human and environmental exposure.* Production and import volumes for members of the anilines category, which are derived from the TSCA public inventory, are provided in Table 1. The most recent information available to the Agency indicates that aniline is produced in substantial quantities, that aniline may be released into the environment in substantial quantities and that there may be significant or substatial human exposure to this substance. Thus for this one category member the available data suggest that the Agency could make the section 4(a)(1)(B) findings for human and environmental exposure potential.

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TABLE 1. EXPOSURE, PRODUCTION, USE AND USAGE OF ANILINES (SUBSTITUTED AND UNSUBSTITUTED)

Chemical	Uses	Usage (10^6 lbs)		Production Volumes[d] (1977)		Dyes Produced Commercially: 1980[b]	NIOSH Worker Exposure Est.[c]
		JRB for 1978[a]	SRI for 1980[b]	US (10^6 lbs)	Import (10^3 lbs)		
aniline	Isocyanate synthesis	290	350-360	300-1500	1-10	15(1.3 x 10^6 lbs)	85,127 (16,191 to aniline derivatives)
	Rubber Chemicals	183	140				
	Dyes & Pigments Intermediate	315	28				
	Hydroquinone	325	17-20				
	Miscellaneous, Pharmaceuticals and Pesticides	24.2	55-65				
aniline hydrochloride	Dyes & Pigments Intermediate	.02	ND[e]	ND	ND	ND	537
	Photographic Chemicals	ND	ND				
2-chloroaniline	Dyes & Intermediates	ND	ND	0.1-1.0	200-2,000	2(>15,000 lbs)	18,138
3-chloroaniline	Dyes & Pigment Intermediate	ND	ND	.001-.01	100-1,000	1(>5000 lbs)	ND
	Herbicide Intermediate	ND	ND				
	Pharmaceutical Intermediate	ND	ND				
4-chloroaniline	Dyes & Pigments Intermediate	ND	ND	0.1-1.0	10-100	1(>10,000 lbs)	ND
	Pesticide Intermediate	ND	ND				
2,4-dichloroaniline	Pigment Intermediate	ND	ND	.001-.01	0-1.0	ND	110 (mixed isomers)
2,5-dichloroaniline	Dyes & Pigments Intermediate	ND	ND	ND	ND	4(>48,000 lbs)	
3,4-dichloroaniline	Pigment Intermediate	ND	ND	0.1-1.0	ND	ND	ND
	Herbicide Intermediate	ND	ND				
2,4,6-trichloroaniline	Pigment Intermediate	ND	ND	0.1-1.0	2	1(>10,000 lbs)	ND
4-bromoaniline	Azo Dyes	ND	ND	ND	ND	ND	1744
	Organic Synthesis Reagent	ND	ND				

[a] JRB (1980). JRB Associates, Inc. Level I materials balance for anilines, for office of Pesticides and Toxic Substances (OPTS), USEPA (Ref. 31)
[b] SRI (1982). SRI International Anilines by Kashiwase D and Rich P Technical Directive 60 for OPTS, USEPA. (Ref. 76)
[c] NIOSH (1983). National Institute for Occupational Health and Safety. Aniline and derivatives. In: Quarterly Hazard Summary Report (Ref. 62)
[d] USEPA (1983). Computer printout of nonconfidential TSCA inventory of anilines. Management Support Division, USEPA. (Ref. 81)
[e] ND - No Data.

TABLE 1. EXPOSURE, PRODUCTION, USE AND USAGE OF ANILINES (SUBSTITUTED AND UNSUBSTITUTED) - CONTINUED

Chemical	Uses	Usage (10^6 lbs)		Production Volumes[d] (1977)		Dyes Produced Commercially: 1980[b]	NIOSH Worker Exposure Est.[c]
		JRB for 1978[a]	SRI for 1980[b]	US (10^6 lbs)	Import (10^3 lbs)		
2-nitroaniline	Dye & Pigment	7.7	ND[e]	1.2-10	ND	6(>60,000 lbs)	336
	Pesticide Intermediate						
	Intermediate to phenylenediamine						
3-nitroaniline	Dye & Pigment Intermediate	ND	ND	ND	10-100	3(>15,000 lbs)	ND
	Organic Synthesis Intermediate						
4-nitroaniline	Dye & Pigment Intermediate	6.6	ND	10-50	10-100	17(2.6 x 10^6 lbs)	2813
	Intermediate to p-phenylenediamine	ND	ND				
	Rubber Chemicals	13.2	ND				
	Gasoline Antioxidant	2.2	ND				
	Funqicide Intermediate	6.6	ND				
2,4-dinitroaniline	Dye & Pigment Intermediate	ND	ND	.01-.1	100-1000	1(581,000 lbs)	ND
2-chloro-4-nitroaniline	Dye & Pigment Intermediate	ND	ND	ND	ND	5(741,000 lbs)	2938
	Pesticide Intermediate						
2,6-dichloro-4-nitroaniline	Dye & Pigment Intermediate	ND	ND	ND	ND	3(879,000 lbs)	3580
	Direct Funqicide	ND	0.4				
4-chloro-2-nitroaniline	Dye & Pigment Intermediate	ND	ND	0.2-2.0	10-100	10(521,000 lbs)	ND
		ND	0.4				
4-chloro-3-nitroaniline	Intermediate for Azo dyes, Pharmaceuticals and Organic Synthesis	ND	ND	0.1-1.0	1-10	ND	ND
2,6-dibromo-4-nitroaniline	Dye & Pigment Intermediate	ND	ND	ND	ND	ND	ND
2-bromo-4,6-dinitroaniline	Dye & Pigment Intermediate	ND	ND	ND	ND	2	ND
2-bromo-6-chloro-4-nitroaniline	Dye & Pigment Intermediate	ND	ND	ND	ND	ND	

[a]JRB (1980). JRB Associates, Inc. Level I materials balance for anilines, for office of Pesticides and Toxic Substances (OPTS), USEPA (Ref. 31)
[b]SRI (1982). SRI International Anilines by Kashiwase D and Rich P Technical Directive 60 for OPTS, USEPA. (Ref. 76)
[c]NIOSH (1983). National Institute for Occupational Health and Safety. Aniline and derivatives. In: Quarterly Hazard Summary Report (Ref. 62)
[d]USEPA, (1983). Computer printout of nonconfidential TSCA inventory of anilines. Management Support Division, USEPA. (Ref. 81)
[e]No Data.

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Other information available to the Agency indicates that some of the remaining category members are being produced in substantial quantities. Although certain category members are or may be produced in substantial quantities, available data do not clearly indicate that they are released into the environment in substantial quantities or that there is or may be significant or substantial human exposure to these chemical substances. Thus, without additional environmental release and/or human exposure information, the Agency does not believe that a TSCA section 4(a)(1)(B) finding can be made for the substituted anilines in the category. EPA requests the submission of additional data on the environmental release of anilines category members and information on the potential for human exposure to any of these substances. The Agency will review such information before making a determination as to whether a 4(a)(1)(B) finding can be made for anilines category members besides aniline itself.

However, the Agency does consider that publicly available and confidential information indicate that each of the twenty members of the anilines category currently in production may have sufficient human and environmental exposure to meet the criterion for a finding under section 4(a)(1)(A)(i): That the manufacture, distribution in commerce, processing, use, or disposal of anilines category members, or any combination of such activities may present an unreasonable risk of injury to health and the environment. Summaries of the available data on human exposure and environmental release are set forth below and in Unit II.B.3, respectively.

Current (1983) NIOSH estimates of the number of workers potentially exposed to the anilines addressed in this notice range from 110 to 85,127 (Ref. 62) and are summarized in Table 1. The ACGIH-recommended 8-hour, time-weighted-average (TWA) limits for aniline and 4-nitroaniline are 2 ppm and 1 ppm, respectively (Ref. 2). The OSHA-required 8-hour TWA limit for aniline is 5 ppm (Ref. 65).

The Aniline Association, which deals solely with unsubstituted aniline, has reported to EPA that a total of 344 operators and 532 other workers were potentially exposed to aniline during production and internal use by manufacturers. According to the Association, the measured level of exposure to aniline by operators was below 1 ppm in all cases (Ref. 27). The SATF reported to EPA on the numbers of workers potentially exposed and levels of exposure to the substituted anilines; however, this information is claimed confidential (Ref. 20). The Aniline Association and the SATF are compiling information on worker exposure from the distribution and processing of aniline and the substituted anilines. This information should be available to the Agency in the near future. The Agency also has confidential information on the number of workers exposed to aniline and substituted anilines submitted by manufacturers under section 8(a) of TSCA.

There is very little information on the potential for consumer exposure to the anilines. The publicly available information on usage volume and major end-uses of aniline and substituted anilines is listed in Table 1. The major TSCA uses include gasoline additives, rubber chemicals, and intermediates in the production of dyes and pigments, pesticides, isocyanates and photographic chemicals. There is no information on the presence of aniline or the substituted anilines as impurities in other chemicals.

There may be some potential for human exposure due to inadvertent aniline production (Ref. 32). Aniline has been detected in the retort water from oil shale processing and in product water from coal gasification. Reported concentrations vary widely because of differences in nitrogen content and process conditions. Aromatic amines, including aniline, have been identified as a major class of organics in effluents from coal liquefaction processes. Aniline also has been detected in cigar and cigarette smoke. However, at this time EPA has insufficient exposure-related information to suggest that it will be able to make a section 4(a)(1)(B) finding of significant or substrantial human exposure to members of the anilines category other than aniline itself.

2. *Adequacy of information and need for health effects testing.* The ITC recommended that the anilines category be considered for health effects testing in the areas of carcinogenicity, mutagenicity, teratogenicity, and chronic effects, with special emphasis on blood disorders and neurotoxicity, and for epidemiology studies. EPA has approached its analysis of these recommendations on the anilines from the standpoint of potential unreasonable risk (section 4(a)(1)(A)). Table 2 summarizes the tentative testing needs for the twenty anilines currently in production. In both Table 2 and in the discussions of specific testing needs that follow, the testing needs are presented in terms of all 20 commercial substances. However, EPA is considering whether testing a smaller number of representative substances is a possible option for this category. An application of this approach is discussed in Unit II.C; issues related to the scope of the category and what chemicals should be tested are raised for public consideration in Unit III.8 through 10.

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TABLE 2. HEALTH EFFECTS FOR WHICH TESTING IS BEING CONSIDERED*

Chemical (CAS No.)	Onco-genicity	Muta-genicity[c]	Terato-genicity	Reproductive Effects	Acute Effects	Chronic Effects[d]	Neurotoxic Effects	Epidemi-ology[e]
aniline (62533)	-	x	x[a]	x	-	x	x	x
2-chloroaniline (95512)	x	x	x	x	-	x	x	-
3-chloroaniline (108429)	x	x	x	x	-	x	x	-
4-chloroaniline (106478)	-	x	x	x	-	x	x	-
2,3-dichloroaniline (608275)	x	x	x	x	x	x	x	-
2,4-dichloroaniline (554007)	x	x	x	x	-	x	x	-
2,5-dichloroaniline (95829)	x	x	x	x	-	x	x	-
3,4-dichloroaniline (95761)	x*	x	x	x	-	x	x	-
2,4,6-Trichloroaniline (634935)	x	x	x	x	-	x	x	-
2-nitroaniline (88744)	x	x	x	x	-	x	x	-
3-nitroaniline (88744)	x	x	x	x	-	x	x	-
4-nitroaniline (100016)	-[b]	-	-	-[b]	-	x	x	-
2,4-dinitroaniline (97029)	x	x	x[a]	x	-	x	x	-
2-chloro-4-nitroaniline (121879)	x	x	x	x	x	x	x	-
2-chloro-5-nitroaniline (6283256)	x	x	x	x	-	x	x	-
4-chloro-2-nitroaniline (89634)	x	x	x	x	-	x	x	-
4-chloro-3-nitroaniline (635223)	x	x	x	x	-	x	x	-
2,6-dichloro-4-nitroaniline (99309)	x	x	x	x	-	x	x	-
2,6-dibromo-4-nitroaniline (827941)	x	x	x	x	-	x	x	-
2-bromo-4,6-dinitroaniline (1817738)	x	x	x	x	x	x	x	-

*x = Testing being considered.

a. Testing with second species being considered.

b. On test [Dickson B. (1983). Report to USEPA by Substituted Anilines Task Force on health and environmental effects of anilines. NTP. 1983. On-going and planned testing by National Toxicology Program (Ref. 21)].

c. Tests to evaluate gene mutational and cytogenetic potentials are being considered.

d. With emphasis on blood effects.

e. Study being considered for aniline only, no cohort currently identified for substituted anilines [Dickson B. 1983. (Ref. 21)].

a. *Hematologic disorders.* Studies have been conducted on different anilines using several test species and various routes of administration (Refs 30, 44, 58, 70 through 72 and 85). Aniline and many of the substituted anilines cause methemoglobinemia (elevation of methemoglobin, the oxidized form of hemoglobin) as well as effects on the spleen (an organ that take part in red blood celll production and destruction) and changes in the populations of various blood elements. In addition to aniline itself, other anilines shown to cause methemoglobinemia in one or more species include all three monochloroanilines, 2,4,- and 3,4-dichloroaniline, 2,4,6-trichloroaniline, and 4-nitroaniline.

Methemoglobin induction appears to be related to the formation of N-oxidized metabolites such as phenyl hydroxylamines and nitrosobenzenes (Ref. 35). Thus, any anilines category member has the potential to cause this effect, but among those tested there is considerable variation in potency and in species sensitivity. For example, 2,4,6-trichloroaniline does not induce methemoglobin in the rat but induces 44 percent methemoglobin in the cat at a single dose of 49 mg/kg (Refs. 39 and 44); 4-chloroaniline at 8 mg/kg induces 61 percent methemoglobin in the cat but somewhat less effective in the dog, rat and monkey (Refs. 44, 70 and 75). The Agency believes that species other than the rat may be preferred for testing of anilines category members for effects that may be related to methemoglobinemia; for further discussion see Unit III.5.

The Agency believes that the decrease in the oxygen-carrying capacity of the blood that accompanies methemoglobin formation and possibly causes anoxia may cause or contribute to the development of adverse health effects [i.e., teratogenicity (see Refs. 19, 16, 56 and 63) and neurotoxicity (Refs. 6, 77 through 79, 83 and 84)]. The available data on teratogenic and neurotoxic effects raise only limited concern that the anilines category members may cause these effects. However, the potential for these substances to induce methemoglobinemia, possibly leading to anoxia, in combination with the data on neurotoxicity and teratogenicity suggests that exposures to sufficiently high levels may cause either or both of these latter effects. The available information is insufficient to evaluate the potential effects of the anilines category members *per se* or to correlate any observed teratogenic or neurotoxic effects with induction or specific levels of methemoglobin. Therefore, the Agency is considering requiring testing to adequately characterize the teratologic, hematologic and systemic (including neurotoxic) effects of the anilines category members.

The Agency is also raising for public consideration and comment the issue of whether available positive oncogenicity data on aniline and 4-chloroaniline permit regulatory alternatives that would render further health effects testing for these chemicals unnecessary (see Unit III. 4).

b. *Reproductive effects.* Aniline and the substituted anilines were not recommended by the ITC for testing for reproductive effects. On the basis of information that repeated subcutaneous injection of aniline interferes with steroidogenesis in the rat uterus and that repeated oral administration of 4-chloro-3-nitroaniline causes sperm degeneration and an increase in testes weights in rats (Ref. 28 and 69), the Agency believes that other anilines category members may cause adverse reproductive effects, and is considering requiring testing to adequately characterize the reproductive effects of these substances.

c. *Mutagenicity.* Many of the commercially available anilines have been tested in either the Ames assay or other lower-tier mutagenicity assays; in most cases, positive results were obtained in at least one system (Refs. 5, 7, 17, 25, 57, 64, 73, 74 and 89). However, few data on the anilines have been developed using higher-tier mutagenesis test systems necessary to adequately characterize the mutagenic potential of a chemical that is positive in a lower-tier test. Thus, EPA is considering requiring a set of mutagenicity tests on the anilines category members, to determine or reasonably predict their gene-mutational and cytogenetic potentials. Such tests may include short-term mutagenicity tests for those category members that have not been adequately tested in such systems, as well as higher-tier mutagenicity tests for some or all of the anilines. Examples of additional mutagenicity tests include, but are not necessarily restricted to, specific-locus gene mutation tests on cells in culture, tests for induction of chromosomal aberrations in cells in culture, and tests for induction of mutations in drosophila, rats or mice.

d. *Oncogenicity.* EPA believes at this time that human exposure to anilines category members may present an unreasonable risk of oncogenicity. Three oral chronic toxicity studies have reported on the oncogenic effects of aniline hydrochloride on rats or rats and mice (Ref. 18, 59 and 87). The final report on the study sponsored by CIIT (Ref. 18) indicates that dietary intake of aniline hydrochloride for 104 weeks at levels of 10, 30 and 100 mg/kg/diet is associated with an increased incidence of primary splenic sarcomas, principally in male F344 rats. Similar effects of aniline hydrochloride exposure were observed in rats and mice in studies completed by Ward and Reznick (Ref. 87) and NCI (Ref. 59). Comparable results were noted in the two oral chronic toxicity studies on the oncogenic effects of 4-chloroaniline and 4-chloroaniline hydrochloride (Ref. 60, 61 and 87). A study completed by NCI in 1978 (Ref. 59) also reported an increase in splenic neoplasms in male rats exposed to 250 and 500 mg/kg/day and both sexes of mice after chronic dietary exposure to 4-chloroaniline hydrochloride; a confirmatory study sponsored by NTP is in progress (Ref. 64).

In a study by Weisburger *et al.* (Ref. 88), a significant dose-related increase in vascular tumors in male mice was observed after chronic oral exposure to dietary levels of 6,000 and 12,000 mg/kg/day of 2,4,6-trichloroaniline hydrochloride.

EPA believes that the available positive oncogenicity data on three anilines raise a suspicion that oncogenic effects may result from human exposure to the remaining anilines category members, but that the sum of available evidence is insufficient to reasonably determine the oncogenic effects of the untested chemicals. Therefore, EPA is considering requiring testing of untested anilines for oncogenic effects. In addition, whereas for aniline and 4-chloroaniline the data from completed or ongoing studies should be sufficient to support oncogenicity risk assessments, the study of 2,4,6-trichloroaniline may be inadequate for this purpose. For example, the authors did not report actual consumption of test compound by the animals or the relationship of the doses to the maximum tolerated dose; further, no dose-response relationship was observed. Therefore, the Agency is also considering whether to require further oncogenicity testing of this compound.

e. *Epidemiology.* The SATF has reported to EPA that based on their information there is no suitable cohort of workers available on which to conduct an epidemiology study for the substituted anilines currently produced or imported (Ref. 20). However, EPA has information which suggests that an adequate cohort of workers can be defined for the conduct of an epidemiology study on aniline. This chemical has been reported by NIOSH

(Ref. 62) to have the greatest occupational exposure among the anilines category members. In addition, the major uses of aniline are representative of the major uses of the substituted anilines. Hence EPA believes that an epidemiological study of workers exposed to aniline may be justified in light of the health effects exhibited by laboratory animals. Unless information indicating the existence of a suitable cohort becomes available for one or more of the substituted anilines, EPA will conclude that epidemiological studies of category members other than aniline may not be feasible at this time and will not propose that epidemiological studies be undertaken on those category members.

3. *Environmental release.* The Agency has tentatively concluded that aniline and the 19 substituted anilines are released into the environment from their manufacture, distribution, processing, use or disposal. The Agency has arrived at this tentative conclusion using information on the release of these substances reported by manufacturers under the TSCA section 8(a) Preliminary Assessment Information Rule (40 CFR Part 712), information provided by the SATF and the Aniline Association, and other published and unpublished data available to the Agency.

JRB Associates (Ref. 31) has estimated for EPA that the total emission of aniline from manufacture, processing and on-site use was approximately 19 million pounds in 1978. Of this amount, 18.5 million pounds was estimated to be released into water and 222,000 pounds into the air. No information was available on the disposal of solid residues.

The Aniline Association has reported to EPA that the environmental release of aniline itself from production and internal use by manufacturers was approximately 638,000 pounds in 1982. Approximately 481,000 pounds was released to air and approximately 174,000 pounds was released to water (Ref. 27).

There is little monitoring information available on environmental concentrations of anilines category members in soil. One probable source of release of residues of some of these compounds is from their direct application to soil for pesticidal uses (e.g. 2,6-dichloro-4-nitroaniline, a nematocide). However, control over the potential for exposure of plants and animals to residues of aniline or substituted anilines in the terrestrial compartment from the application of pesticides falls under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

Another potential source of residues of anilines category members is from treated or untreated solid wastes generated from chemical reaction processes, because these chemicals are used almost exclusively as chemical intermediates. Because there is no information on the manner in which treated or untreated solid wastes that may contain anilines are disposed of, it is not possible to estimate the release of anilines to the soil from solid wastes. If it is assumed that the disposal of these solid wastes is localized either in controlled landfills or monitored sites of agricultural fertilizer application (aniline is regulated under the Resource Conservation and Recovery Act (RCRA) as a hazardous waste, while the substituted anilines are not) there would not be a reason to assume a significant uncontrolled release of anilines into soil from solid waste disposal, nor significant exposure of terrestrial plants or animals to the anilines.

The total emissions of 2-nitro-, 3-nitro-4-nitro-aniline for 1978 were estimated to be 152,000, 5,240, and 1,738,000 pounds, respectively (Ref. 31). Of these emissions, nearly all (152,000, 5,000, and 1,580,000 pounds, respectively) were estimated to be released into water. No estimates were available for releases to land. The SATF has reported to EPA on the environmental release of the 19 substituted anilines currently in production (Ref. 20). The Agency also has confidential information on the production and release of anilines category members submitted by manufacturers under section 8(a) of TSCA. Although this information is claimed confidential it does support EPA's tentative conclusion that releases of some category members occur in connection with manufacturing and on-site uses. The SATF has agreed to supply EPA with results of its survey of downstream users of anilines.

Limited data were found on residue levels for aniline and five substituted anilines in water and sediments. Wastewater, the receiving waters and sediments near a specialty manufacturing plant that manufactures a broad range of chemicals were analyzed for organic pollutants (Ref. 34). One sample of wastewater contained 0.02 ppm of aniline. Aniline was not detected in river water or sediments. Monochloroanilines (isomers unspecified) were not detected in wastewater or river water but were found in sediments at 1–2 ppm. Games and Hites (Ref. 24) studied organic compounds in the untreated and final effluent of wastewater originating from a dye manufacturing plant near Charleston Bay, South Carolina. Results of a 2.5-month compositing study for both treated and untreated plant effluent showed the presence of six of the substituted aniline compounds. USEPA data on the STORET system include a total of 78 data points or observations on environmental levels of anilines in streams (Ref. 80). The mean residue level was 188.5 ppb, with maximum and minimum values of 2,800 and 100 ppb, respectively. The STORET data were collected from August 29, 1978 to August 4, 1980.

While the available monitoring studies and the data from the EPA STORET data base have not reported large amounts of aniline or the substituted anilines in water, wastewaters, and sediments, the Agency is concerned about the potential for exposure of aquatic organisms to anilines resulting from estimated and reported releases and the reports that the chloroanilines and possibly other substituted anilines bind to organic components in water and sediments, possibly reaching concentrations sufficient to cause acute and chronic effects on these organisms.

4. *Chemical fate.* The Agency is concerned about the chemical fate of anilines category members in water and sediment because of the estimated and reported release and dispersion of these compounds into water and because of the known toxic effects of some anilines on aquatic organisms. Therefore chemical fate testing as outlined in Table 3 is being considered by the Agency. The following is a summary of the available information on chemical fate of anilines category members.

The Agency believes there are sufficient data to reasonably determine or predict the hydrolysis of anilines category members (Ref. 20). These data suggest that, because of their chemical structure, anilines would not be susceptible to hydrolysis. The Agency also believes that there are sufficient data to reasonably determine or predict the partitioning of anilines into an organic phase from water (Refs. 36, 40 through 42). These data suggest that, because of their low to moderate octanol-water partition coefficients (log P), anilines would not partition into an organic phase in water, such as the fatty tissues of aquatic organisms.

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TABLE 3. CHEMICAL FATE TESTING BEING CONSIDERED

TABLE 3. CHEMICAL FATE TESTING BEING CONSIDERED*

Chemical (CAS No.)	Aquatic Photolysis Rates	Aquatic Volatility Rate	Aerobic Aquatic Biodegradation Rate	Sediment Adsorption	Aerobic Sediment Biodegradation Rate	Anaerobic Sediment Biodegradation Rate
aniline (62533)	x	-	-	x	x	x
2-chloroaniline (95512)	x	x	x	x	x	x
3-chloroaniline (108429)	x	x	x	x	x	x
4-chloroaniline (106478)	x	-	x	x	x	x
2,3-dichloroaniline (608275)	x	x	x	x	x	x
2,4-dichloroaniline (554007)	x	x	x	x	x	x
2,5-dichloroaniline (95829)	x	x	x	x	x	x
3,4-dichloroaniline (95761)	-	-	x	x	x	x
2,4,6-trichloroaniline (634935)	x	x	x	x	x	x
2-nitroaniline (88744)	x	x	x	x	x	x
3-nitroaniline (99092)	x	x	x	x	x	x
4-nitroaniline (100016)	x	x	x	x	x	x
2,4-dinitroaniline (97029)	x	x	x	x	x	x
2-chloro-4-nitroaniline (121879)	x	x	x	x	x	x
2-chloro-5-nitroaniline (6283256)	x	x	x	x	x	x
4-chloro-2-nitroaniline (89634)	x	x	x	x	x	x
4-chloro-3-nitroaniline (635223)	x	x	x	x	x	x
2,6-dichloro-4-nitroaniline (99309)	x	x	x	x	x	x
2,6-dibromo-4-nitroaniline (827941)	x	x	x	x	x	x
2-bromo-4,6-dinitroaniline (1817738)	x	x	x	x	x	x

*(x)=Testing being considered.
(-)=No testing being considered.

The Agency believes that there are insufficient data to reasonably determine or predict the persistence of anilines category members in the aquatic environment. Sufficient data exist to predict the aquatic photolysis rate of 3,4- dichloroaniline (Tp½=0.3–2 days; Ref. 46) and the aquatic volatility rates of aniline, 4-chloroaniline and 4-nitroaniline (Tv½=15.5, 44.5 and 106 days, respectively) (Refs. 22 and 23). Additional experimental data developed for 4-chloroaniline and 3,4-dichloroaniline suggest that their aquatic volatilization rates are low (Refs. 22, 23 and 38). Sufficient data exist to predict the aerobic aquatic biodegradation rate of aniline since it is recommended as a reference substance for aerobic biodegradation testing by EPA (Ref. 82). The predicted aquatic half-life of aniline in one mathematical model is 3 days (Refs. 22 and 23). The Agency believes that aniline should be used as a reference substance for any of the aerobic biodegradation rate tests being considered in this ANPR to provide an adequate internal standard for comparing test results. The Agency also believes that aquatic photolysis, aquatic volatility and aerobic aquatic biodegradation rate testing should be considered for the anilines listed in Table 3 to evaluate their potential as rate-limiting processes influencing the persistence of anilines in the aquatic environment.

The Agency believes that there are insufficient data to reasonably determine or predict the persistence of anilines in the sediment environment. Data exist to predict that a number of chloroanilines bind chemically to soil (Refs. 8, 10, 29, 35, 66, 67 and 87). These data indicate that binding of chloroanilines is greater than would be predicted from water solubilities and the algorithms of Kenega and Goring (Ref. 36) to estimate their partitioning to soil organic matter. Data also exist to predict that aniline and a number of chloroanilines are biodegraded by soil microorganisms (Refs. 10 through 13, 16, 26, 35) and activated sludge microorganisms (Refs. 43 and 68). However, the existing data do not allow the Agency to reasonably determine or predict the adsorption of anilines to sediment or the rate at which anilines may be biodegraded aerobically or anaerobically in sediment. Therefore, the Agency believes that sediment adsorption as well as aerobic and anaerobic sediment biodegradation rate testing should be considered for the anilines listed in Table 3 to evaluate their potential as rate-limiting processes influencing the persistence of anilines in the sediment environment.

5. *Environmental Effects.* The Agency has tentatively concluded that the available information indicates that aniline and the 19 substituted anilines may cause acute and chronic effects in aquatic organisms, and therefore is considering proposing the environmental effects testing listed in Table 4 under TSCA section 4(a)(1)(A). Sufficient data exist to predict the toxicity of aniline and 3,4-dichloroaniline to freshwater algae. The reported 48-hour LC_{50}'s are 0.16 mg/l and 2.2–3.2 mg/l for aniline and 3,4-dichloroaniline, respectively (Refs. 4 and 14). In addition, sufficient data exist to predict the toxicity of 3,4-dichloroaniline to marine algae. The reported 48-hour LC_{50} is 0.48 mg/l (Ref. 14). However, the Agency believes data are insufficient to reasonably determine or predict the toxicity of other anilines category members to freshwater and marine algae. The Agency believes that algal toxicity testing should be considered for the anilines category members indicated in Table 4 to determine the potential adverse effects of these substances on algae.

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TABLE 4. ENVIRONMENTAL EFF[illegible] FOR WHICH TESTING IS BEING CONSIDERED*

Chemical (CAS No.)	Algal Bioassay		FW Invertebrates		Marine Invertebrates			FW Vertebrates				Marine Vertebrates		Benthic Invertebrates			
	FW	Marine	Daphnid Acute	Daphnid Chronic	Mysid Acute	Mysid Chronic	Oyster Acute	FHM Acute	FHM-ELS	RT Acute	RT-ELS	SHM Acute	SHM-ELS	FW Acute	FW Chronic	Marine Acute	Marine Chronic
aniline (62533)	-	X	-	X	-	X	X	-	-	-	X	X	X	X	X	X	X
2-chloroaniline (95512)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
3-chloroaniline (108429)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
4-chloroaniline (106478)	X	X	-	X	-	X	-	-	X	X	X	X	X	X	X	X	X
2,3-dichloroaniline (608275)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
2,4-dichloroaniline (554007)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
2,5-dichloroaniline (95829)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
3,4-dichloroaniline (95761)	-	-	-	-	-	X	-	-	X	-	X	X	X	X	X	X	X
2,4,6-trichloroaniline (634935)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
2-nitroaniline (88744)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
3-nitroaniline (99092)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
4-nitroaniline (100016)	X	X	-	X	-	X	X	-	X	-	X	X	X	X	X	X	X
2,4-dinitroaniline (97029)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
2-chloro-4-nitroaniline (121879)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
2-chloro-5-nitroaniline (6283256)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
4-chloro-2-nitroaniline (89634)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
4-chloro-3-nitroaniline (635223)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
2,6-dichloro-4-nitroaniline (99309)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
2,6-dibromo-4-nitroaniline (827941)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
2-bromo-4,6-dinitroaniline (1817738)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

*Key to Abbreviations: (X) = Testing being considered, (-) = No testing being considered, FW = Freshwater, FHM = Fathead minnow, ELS = Early life stage, RT = Rainbow Trout, SHM = Sheepshead Minnow.

The Agency believes there are insufficient data to reasonably determine or predict the toxicity of most of the anilines to freshwater and marine invertebrates. However, sufficient data do exist to predict the acute toxicity of aniline, 4-chloroaniline, 3,4-dichloroaniline and 4-nitroaniline to daphnids. The reported 48- or 24-hour LC_{50}'s are 0.65 mg/l, 6.2 mg/l, 0.23–0.29 mg/l and 20–24 mg/l (24-hour), respectively (Refs. 3, 15, 51 through 53). Sufficient daphnid chronic toxicity data exist for 3, 4-dichloroaniline. The reported 21-day LC_{50} is 0.1 mg/l (Ref. 4). Sufficient acute toxicity data to marine invertebrate species *(Crangon septemspinosa,* shrimp) exist for aniline, 4-chloroaniline, 3,4-dichloroaniline, and 4-nitroaniline. The reported 48-hour LC_{50}'s are 28.4 mg/l, 12.5 mg/l, 3.6 mg/l and 12.6 mg/l, respectively (Ref. 45). Sufficient data exist to predict the toxicity of 4-chloroaniline and 3,4-dichloroaniline to oysters. The reported 48-hour LC_{50}'s are 10 mg/l and 24 mg/l, respectively (Ref. 48). The Agency believes that toxicity testing using freshwater and marine invertebrates should be considered for the anilines category members indicated in Table 4.

Data are not sufficient to reasonably determine or predict the toxicity of anilines to freshwater and marine vertebrates although sufficient data exist to predict the acute toxicity of 4-chloroaniline and 3,4-dichloraniline to the fathead minnow, and aniline and 4-nitroaniline to the golden orfe. The 48-hour LC_{50}'s are 61–65 mg/l and 106 mg/l for aniline and 4-nitroaniline, respectively (Ref. 33). The 48-or 96-hour LC_{50}'s for 4-chloroaniline and 3,4-dichloroaniline are 44–50 mg/l and 5.6 mg/l (96h), respectively (Refs. 49 and 50).

Sufficient data also exist to predict the acute toxicity of aniline, 3,4-dichloroaniline, and 4-nitroaniline to rainbow trout. The 48-or 96-hour LC_{50}'s are 28.3 mg/l, 2.4-3.2 mg/l (96h), and 45 mg/l (96h) (Refs. 1, 47, 54). Sufficient data exist to predict the fish early life stage toxicity of aniline to the bass, catfish and goldfish. The LC_{50}'s are 43.2-47.3, 5.6-7.4 and 10.2 mg/l, respectively (Ref. 9). There are no data on the acute or early life stage toxicity of anilines category members to marine vertebrates. The Agency believes that acute and early life stage testing of freshwater and marine vertebrates should be considered for the anilines category members indicated in Table 4 to determine their potential adverse effects on these organisms.

Finally, the Agency believes there are incomplete data to determine or predict the toxicity of anilines category members to freshwater and marine sediment-dwelling invertebrates. There are data indicating that anilines bind to soils, and the Agency believes that anilines have the potential to bind to sediments. Therefore, the Agency believes that testing of sediment-dwelling invertebrates should be considered for the anilines category members indicated in Table 4 to determine their potential adverse effects of on these organisms.

C. Subcategorization of the Anilines Category.

1. *Technical analysis.* EPA is considering whether it should require testing of all anilines category members or adopt an approach in which tests are performed on substances chosen to represent smaller groups (i.e., subcategories) of anilines. In considering this issue, the Agency developed a number of alternatives as set forth in Unit III.6–8. The Agency has tentatively concluded, for the reasons outlined below, that the most feasible approach to developing test data sufficient to determine or reasonably predict the health and environmental effects of the anilines is subcategorization of the larger category and selection of representative test candidates from among the smaller subcategories.

The anilines category is rather strictly defined. The three allowed substituents are all electron-withdrawing in nature and thus tend to deactivate aromatic molecules. They (particularly the halogens) also are generally less reactive than the amino group. The amino group common to all the anilines is so reactive compared to the other substituents that it can be expected in many respects to dominate the chemistry and the toxicology of the category. Thus, the category presents the picture of a general type of behavior modified in roughly predictable ways by the various substituents. Certain effects do in fact appear to be common to several anilines—examples are hematologic effects (methemoglobinemia), mutagenesis in short-term *in vitro* assays, and tumor formation. However, the relationship between the degree and complexity of substitution and the probability and potency of a given effect is unclear. Therefore, EPA believes it may be appropriate to subdivide the anilines category into smaller, more homogeneous subcategories. The Agency is tentatively defining these subcategories by chemical structure type, in the belief that the differences in chemical structure thus emphasized can reasonably be expected to be reflected in the toxicological data. The rationale supporting the definition of the Agency's tentative subcategories is as follows:

a. Aniline is the only category member not bearing an electron-withdrawing (deactivating) substituent, and therefore comprises a one-chemical subcategory.

b. Chlorinated anilines are less reactive chemically than aniline because chlorine atoms are deactivating substituents. Increases in degree of chlorination lead to corresponding decreases in reactivity and increases in lipid solubility, as with most haloaromatic compounds. Thus, differences in metabolic reaction rates and pharmacokinetic properties can reasonably be expected for chlorianted anilines versus aniline, and to some extent among chloroanilines having different numbers of chlorine atoms. The Agency therefore believes that chloroanilines can be represented by two subcategories: monochloroanilines and polychloroanilines.

c. For nitroanilines the situation is similar to that for chloroanilines: deactivating nitro substituents are expected to result in lowered amino and ring reactivity with increasing substitution leading to still lower reactivity. However, in contrast to the unreactive chloro substituent, the nitro group can be reduced to hydroxylamino, nitroso or amino functions, thus making possible new families of metabolites that may produce unique toxic effects. The Agency is tentatively proposing two nitroanilines subcategories: mononitroanilines and polynitroanilines.

d. Halonitroanilines are again deactivated anilines, but the mix of substituent types complicates the chemistry as well as the potential toxicological picture. The degree to which the toxicology of a halonitroaniline might be predicted from data on individuals halo- and nitroanilines is unknown. Therefore, EPA is tentatively proposing a subcategory of halonitroanilines.

The Agency is considering proposing testing of one substance from each of the first five subcategories. While this approach may not remove all the uncertainties as to the toxicity of untested subcategory members, it may suffice to provide a reasonable basis for characterizing the risk to human health and the environment presented by members of that subcategory. Because of the complexity of the halonitroanilines subcategory, the Agency is considering proposing testing of two substances from this group.

The subcategories and chemicals under consideration for testing by EPA are as follows:

Category identification	Test substance
Subcategory A: Aniline	Aniline.
Subcategory B: Monochloroaniline	4-chloroaniline.
Subcategory C: Polychloroanilines	3,4-dichloroaniline.
Subcategory D: Monochloroaniline	4-nitroaniline.
Subcategory E: Polychloroanilines	2,4-dinitroaniline.
Subcategory F: Halonitroanilines	2-chloro-4-nitro-aniline and 2-bromo-4,6-dinitroaniline.

2. *Legal/regulatory implications of subcategorization.* The obligation to test and exemption and reimbursement implications of this approach are discussed in this section.

Two of the subcategories—aniline and polynitroanilines—have only a single member on the Inventory and currently in commercial production—aniline and 2,4-dinitroaniline, respectively. Consequently, the testing of those two substances raises no issues about equivalence or exemptions. However, EPA believes that data developed on 2,4-dinitroaniline could be used in the future to predict the effects of other polynitroanilines that might enter commerce.

The remaining four subcategories have three or more members on the Inventory and currently in commercial production. For three subcategories—monochloroanilines, polychloroanilines, and mononitroanilines—EPA is considering proposing the testing of a single member of the subcategory—4-chloroaniline, 3,4-dichloroaniline, and 4-nitroaniline, respectively. EPA believes that within these three subcategories all members are likely to be similar toxicologically and, consequently, that testing any member of the subcategory will reasonably predict the effects of the others. EPA believes the test substance in each of these three subcategories should be a substance that is among the highest in production volume. The choice of test substances based on production volume would also result in structural variations among the entire set of seven substances that will enable EPA to compare data between subcategories to verify the effects of substituent changes in certain positions.

EPA believes that data on the three test substances in subcategories B, C and D could be used to reasonably predict the effects of all the other members and that EPA could regulate the other members of each subcategory on the basis of data produced for the designated test substance. This approach presents the advantage of avoiding unnecessary, duplicative testing and allowing industry to spread its testing resources further.

For purposes of exemptions and reimbursement, EPA is considering proposing that each member of the three subcategories B, C and D be considered equivalent to the designated test substance for that subcategory. Thus, manufacturers and processors of substances in the subcategory who apply for an exemption would not be required to show equivalence. The cost of testing the single test substance would be spread among all the manufacturers and processors of members of the subcategory and would probably be weighted on the basis of production volume.

However, EPA recognizes that a company making another substance in one of these subcategories might wish to test its own substance for some or all of the effects of concern rather than contribute to testing of the designated test substance. Accordingly, EPA is considering allowing a manufacturer or processor to test the substance it manufactures or processes, rather than the designated test substance in its subcategory, for any or all of the effects of concern. Such a manufacturer or processor would not be required to test the designated test substance or seek an exemption for any designated test that it performs with the chemical substance it manufactures or processes.

The final subcategory—halogenated nitroanilines—presents a different problem. EPA believes that to characterize adequately the effects of all the members of this subcategory it is necessary to test at least two representative substances—2-bromo-4,6-dinitroaniline and 2-chloro-4-nitroaniline—because the variations in structure are greater within this subcategory. Here again, EPA is considering proposing as the test substances two of the highest production members of the subcategory, which also reflect the variations in structure within the subcategory. EPA's tentative conclusion is that data on the two test substances will reasonably predict the effects of the other members in the subcategory and that EPA could regulate the other members on the basis of these data.

EPA is considering proposing that the other members of the subcategory be considered equivalent to the two test substances together. Thus, a manufacturer or processor of another member of the category must seek an exemption from the testing requirements for both test substances and would be required to reimburse for testing of both test substances. However, a demonstration of equivalence would not be necessary in the exemption application. As with the three subcategories discussed above, EPA is considering that a manufacturer or processor of another member of the subcategory could instead test its own substance for some or all of the effects of concern and that it would not be required to test the test substances or seek an exemption for any designated test that if performs with the substance it manufactures or processes.

In addition, EPA is considering proposing that manufacturers and processors of only one of the two designated test substances for this subcategory not be required to perform tests for the other test substance, to contribute to that testing, or to seek exemption from testing the other test substance. The reason is that data on the substance that person manufactures or processes are all that is necessary to predict its health effects.

This testing scheme is predicated on EPA's belief that data on the designated test substances can be used to predict the effects of the other members of each subcategory and that it can regulate the other members on the basis of those data. EPA believes the intent of section 4 of TSCA is to provide enough information to regulate substances of concern. EPA also believes that the section 4 equivalence finding is inextricably intertwined with the conclusion that the data from one substance can be used to regulate another. Thus, if the data for the test substances cannot be used to predict the effects of the other members of each subcategory and, therefore, cannot be used to regulate the other members of the subcategory, testing of each of the twenty substances individually would be necessary.

III. Issues for Comment

1. For a given test organism, should some or all of the test substances be administered as salts rather than free bases? This would be expected to increase the stability of the materials, but changes the possible exposure routes and pharmacokinetic properties (for example, vapor pressures of the salts are lower than those of the free bases while water solubilities are much greater). What would be appropriate test sample purity requirements?

2. Should all the test substances to be tested in the anilines category be administered by the same route? This approach would increase comparability of test results, but might result in some discrepancies between actual and experimental exposure routes. Would comparative pharmacokinetic studies be useful?

3. EPA's analysis to date of exposure-related information shows that information on processing and use practices by non-manufacturers of anilines will be a very important factor in the Agency's eventual determinations under TSCA section 4. The SATF and the Aniline Association have told EPA that they are collecting such information and intend to supply it to the Agency. EPA wishes to hear directly from processors and users of anilines and from any other knowledgeable persons about specific uses of individual anilines, amounts of anilines devoted to particular uses, numbers of employees potentially exposed, quantities of anilines disposed, treatment of anilines-containing wastes, and any other information bearing on potential release and exposure for the anilines.

4. The Aniline Association has suggested that the Agency consider existing oncogenicity data on aniline as a sufficient basis for defining exposure controls to adequately protect human health, thereby obviating the need for further health effects testing on aniline.

Three studies show that aniline hydrochloride is oncogenic in rodents (see Unit II B.2.d), and they provide sufficient information to reasonably assess the oncogenic risk from known exposures to aniline. Consequently, as an alternative to requiring additional health effects testing of aniline EPA, is considering evaluating the need for additional exposure controls to limit the levels of aniline to which workers can be exposed on the basis of the oncogenicity data (the Occupational Safety and Health Administration (OSHA) in 1978 promulgated an 8-hour time-weighted-average (TWA) standard of 5 ppm for aniline (Ref. 65), and the American Conference of Governmental Industrial Hygienists (ACGIH) has recommended an 8-hour TWA standard of 2 ppm (Ref. 2); these standards are intended to protect workers from methemoglobinemia and related effects).

Similarly, positive oncogenicity data on 4-chloroaniline may also be sufficient for a risk assessment (See Unit II B.2.d). EPA requests comments on exposure controls as an alternative to requiring testing of aniline or 4-chloroaniline for effects other than oncogenicity—i.e., will oncogenicity-based controls be sufficiently protective against the other effects?

5. The Agency believes that methemoglobin formation and the attendant oxygen depletion resulting from exposure to aniline or the substituted anilines may cause or contribute to effects such as teratogenicity and neurotoxicity.

Laboratory studies using rats do not report structural teratologic effects after exposure to aniline or 4-nitroaniline at doses that produce significant maternal and tetal toxicity. However, the rat may be an inappropriate test species since fetal rats have 10 times the methemoglobin reductase of adult rats, while human cord blood contains 0.7 times the methemoglobin reductase found in human blood (Reg. 8). Thus, human fetal effects could occur at a dose lower than rat fetal effects in the absence of maternal methemoglobin toxicity. EPA has received comment from industry representatives on this issue; however, EPA is requesting further comment to determine which species of laboratory animals are the most appropriate for reproductive, teratological, neurotoxicological and possibly other studies of aniline and the substituted anilines.

6. The environmental effects testing being considered by the Agency may provide sufficient data to reasonably determine the environmental effects of aniline category chemicals. Is the testing being considered sufficient? Are there existing data that the Agency has not obtained on the environmental effects of aniline category compounds? Are there existing validated structure-activity data to predict the environmental effects of these compounds? Are there benthic organisms that are true detritivores for which validated protocols are available to determine the environmental effects of sediment-adsorbed aniline category members? Would testing in a model benthic ecosystem be a useful approach to testing for toxicity to benthic organisms? Are there available data to indicate the bioavailability of sediment-bound category members?

7. The chemical fate testing being considered by the Agency may provide sufficient data to reasonably determine the chemical fate of anilines category chemicals in the aquatic environment. Are there available data on the fate or these chemcials that the Agency has not obtained? Are there methods of which the Agency is unaware for extracting these types of chemicals from sediments? Are there additional tests that the Agency should be considering? Since anilines may be released to the aquatic environment from waste treatment facilities, should the Agency consider additional testing to evaluate the fate of anilines in treatment plants, e.g., sorption to primary and secondary sludge solids, losses through volatilization under conditions of high aeration and mixing, biodegradation under simulated waste treatment conditions and sorption or other removal in tertiary treatment processes? Finally, should the Agency require testing to identify major transformation products of anilines resulting from environmental fate processes?

8. There are several alternatives for defining the size and scope of the anilines category for test rule purposes. As set forth in Unit II, for this ANPR EPA has focused on the twenty anilines that are on the Inventory and currently imported or in commercial production, and could limit the testing to those twenty substances. However, there are 34 anilines on the Inventory. The 14 anilines on the Inventory not now in commercial production could be put into commercial production at any time without notice to EPA. In addition, 56 anilines have been assigned CAS registry numbers, indicating that someone has explored the use of substances in addition to those on the Inventory. Theoretically, there are over one hundred more aniline structures that would fit the definition of the category recommended by the ITC.

From EPA's analysis, it appears that the twenty anilines currently in production have the same or very similar uses. Thus, the Agency believes that anilines not now in production would have uses similar to anilines now being produced. Anilines not on the Inventory may be produced in volumes and give rise to exposures and releases during production in the same ranges as those currently in production. In view of this EPA has also considered two other alternatives for defining which anilines would be subject to a test rule.

a. *All anilines on the inventory.* One alternative approach to including only the twenty anilines in commercial production would be to include in the category for the test rule all the anilines on the Inventory. All these are or have been in commercial production. They can be made at any time in any quantity without notification of EPA. Since production, uses, exposures, and releases would be similar to those currently in production, EPA believes that it could make a section 4(a)(1)(A) finding that the manufacture, processing, use, and disposal of each aniline on the Inventory "may present an unreasonable risk of injury" to human health and the aquatic environment for the effects of concern even though some of them are not now in commercial production.

Under the approach set forth in Unit II, a person could begin to manufacture a category member on the Inventory, other than the twenty covered by the proposed rule, without being required to test that chemical or to reimburse those

undertaking the testing of the anilines currently in production. The alternative discussed here, which make the test rule applicable to all anilines in the Inventory, would bring those persons into the coverage of the rule and would more fairly distribute the cost and burden of testing. A person beginning manufacture of another aniline on the Inventory would be subject to the testing requirement, but the requirement would not prevent manufacture from beginning. Rather, testing or seeking an exemption would take place as manufacture began in a manner similar to that for new manufacturers of any chemical substance under a test rule.

b. *All anilines within the ITC's category definition.* A still broader approach would be to include in the category for the test rule all the anilines that have been assigned CAS registry numbers or all those possible structures that fit the ITC category definition, regardless of whether they are on the Inventory.

EPA would make a section 4(a)(1)(A) finding in a manner similar to that discussed above for all anilines on the Inventory. The Agency believes that new anilines would probably be made for the same or very similar uses as the existing anilines. Consequently, production, use, exposures, and releases are likely to be within the same ranges. EPA believes such a finding would be appropriate for new anilines not on the Inventory because section 5(b) of TSCA clearly contemplates that new chemical substances will be subject to secton 4 test rules, and thus it is clear that EPA has the authority to subject them to such rules. In this case, a finding of "may present an unreasonable risk" based on knowledge of production, use, exposures, and releases of other members of the category would be appropriate.

This alternative would present the advantages of alternative III.8.a discussed above in that all manufacturers and processors of anilines, whether on the Inventory or not, would be required to test equally. There is, however, an impact of this approach that is inherent in TSCA. Under section 5(b) of TSCA a person required to submit a premanufacture notice under section 5(a) of TSCA for a new chemical substance that is the subject of a test rule may not submit the notice until that person has either performed and submitted the required testing or submitted the data upon which an exemption has been granted. Thus, the manufacturer of the new chemical substance may be at a competitive disadvantage relative to new manufacturers of substances subject to the test rule but already on the Inventory.

EPA is interested in comments on the advantages and disadvantages of adding substances to the category for this test rule and, in particular, on the ability of the Agency to make the "may present an unreasonable risk" finding for substances not in commercial production, whether on the Inventory or not.

9. EPA is considering proposing that rather than require testing on all members of the anilines category, it adopt an approach in which testing is performed on a selected number of representative category members and that these test results be used to predict the toxicity of all other category members. This type of an approach may be justified when the physicochemical and biological properties of category members are similar in important respects or change more or less regularly across the category, or when the category can be divided into smaller groups of similar chemicals. When this is the case, data obtained on a properly chosen subset of chemicals can be expected to allow reasonable predictions about the behavior of untested category members. The Agency is requesting comment on the appropriateness of using this approach to evaluate the health and environmental effects of the anilines category. The Agency also requests comment on other aspects of its overall approach as outlined in Unit II.C; for example, is the number of chemical substances to be tested adequate? Are the substances the Agency has selected the most appropriate to be tested and is the category appropriately subdivided?

10. EPA has tentatively decided to propose to require testing of seven anilines as representative of the substances in six subcategories. However, the Agency has considered the following alternatives to the subcategorization and the choice of test substances discussed in Unit II. Each alternative has certain exemption, reimbursement and regulatory consequences.

a. *Require testing of all category members.* One alternative would be to require testing of each substance subject to the test rule. This alternative would be appropriate if EPA finds that data from one or more representative test substances cannot be ued to predict the effects of other members of the category, that EPA could not regulate other members of the category on the basis of data from the test substances, or that the members of the subcategories are not equivalent to the test substances. This alternative would be appreciably more burdensome and would consume a far greater amount of industry testing resources.

EPA could perhaps reduce this burden by allowing any manufacturer or processor to seek an exemption by showing in its exemption application that its substance is equivalent to one or more substances being tested. This alternative would preserve the possibility that testing of selected category members could be used to predict the effects of other members and to support regulation of those other members, but it would shift the burden of showing equivalence for those purposes to the individual manufacturer or processor seeking an exemption.

b. *Base set testing for all category members and follow-up testing on one or more category members.* In this approach a set of base set testing such as mutagenicity and subchronic testing would be required of all category members. These data would be used to select one or more test substances for longer term testing. This approach offers an advantage over that described in unit II in that subcategorization and the selection of test substances would be based on toxicity data on all category members as well as relying on chemical structure considerations. The disadvantage is that this approach may add substantially to the time required for rulemaking by necessitating an additional proposal after the base set testing is completed.

In the case of base set testing, the exemptions and reimbursement implications would be the same as for individual chemicals; that is, manufacturers and processors would pay for the testing of the chemicals they manufacture or process. The exemptions and reimbursement provisions for the long term testing would be the same as for the subcategorization option if subcategories are used, or for one of the alternatives if subcategories are not used and more than one test substance is selected.

c. *Require testing of all category members but make generic equivalence decision in rulemaking.* Another alternative would be to require testing of all members of the category but to find in the rulemaking that, within the five subcategories where EPA is proposing to require testing of only a single test substance, all members of the subcategory are equivalent. Thus, manufacturers and processors of substances in those subcategories woud choose the test substances by deciding to perform testing. Other manufacturers

and processors in the subcategory could seek exemptions without having to show equivalence to the substances actually being tested.

This approach presents many of the advantages of the approach set forth in Unit II.C and provides additional flexibility for affected industry to choose the test substances. However, to the extent the EPA-chosen test substances provide a scientific cross check between the variations in structure across the subcategories, industry-chosen test substances might not provide the same cross checks.

d. *Require testing of seven representative test substances without subcategories.* Another alternative would be to require testing of the seven suggested test substances (see Unit II.C) as representative of the aniline category as a whole. Such an approach would recognize that it might be necessary to examine variations in effects across the variations in structure within the category to adequately characterize the effects of untested members of the category. Under this alternative, EPA would find that the other members of the aniline category are equivalent to the seven test substances collectively. Manufacturers and processors of other members of the category would receive exemptions without showing equivalence, but they would be obligated to reimburse for their share of testing all seven test substances. However, any manufacturer or processor could choose to test the substance it manufactures or processes instead of testing the test substances.

e. *Test the seven test substances and make a decision not to test the other category members.* A final alternative would be to require testing of the seven suggested test substances and to make a decision not to require testing of the other anilines on the basis that testing is not necessary. The finding that testing the other anilines is not necessary would be based on the conclusion that data on the seven tested anilines could be used to predict the effects of any other anilines and to regulate those other anilines. The effect of this alternative would be to limit exemptions and reimbursement to the manufacturers and processors of the seven test substances. Manufacturers and processors of other anilines would not be required to test or to pay for testing even though their substances would be evaluated using the data on the seven test substances. This would reduce the complexity of the exemptions and reimbursement but would also reduce the pool of persons obligated to pay for testing, and may be less equitable since the burden of paying for testing would not be borne by all manufacturers and processors.

EPA is particularly interested in comments on approaches to exemptions and reimbursement in light of the other issues on which substances to test and how to define the category.

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V. Rulemaking Record

The EPA has established a record for this testing decision (docket number OPTS-42054). The record includes the following information:

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

(a) Advance notice of proposed rulemaking for aniline and chloro-, bromo- and/or nitroanilines.

(b) Notice containing the ITC designation of the anilines to the Priority List.

(c) Notices relating to EPA's health effects test guidelines and GLP standards.

(d) Notice of proposed rule on exemption policy and procedures.

(e) Final rule on reimbursement policy and procedures.

(2) Minutes of informal meetings.

(3) Communications before proposal consisting of:

(a) Written public and intra- or interagency memoranda and comments.

(b) Telephone conversations.

(c) Meetings.

(d) Reports: Published and unpublished factual materials, including contractor's reports and information submitted by industry.

The record enumerated above includes basic information considered by the Agency in developing this decision. The Agency will supplement the record periodically with additional relevant information received.

A public version of the record with CBI deleted is available for inspection in the OPTS Reading Room from 8:00 a.m. to 4:00 p.m. Monday through Friday (except legal holidays) in Rm. E-107, 401 M St., SW., Washington, D.C. 20460.

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

Dated: December 21, 1983.

William D. Ruckelshaus,

Administrator.

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Adminstration

50 CFR Part 628

Bluefish Fishery Management Plan; Public Hearing

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public hearing.

SUMMARY: The Mid-Atlantic Fishery Management Council (Council) will hold a public hearing on the proposed revised bluefish Fishery Management Plan (FMP). The public hearing is being held in conjunction with the public meetings that the Council is holding from January 11 to January 13, 1984. A notice for these meetings was published in the **Federal Register** on December 21, 1983 (48 FR 56424).

DATES: Written comments on the FMP will be accepted at the public hearing. The hearing will be held on Thursday, January 12, 1984, from 11:15 to 11:45 a.m. Copies of the summaries can be requested from the Council. The revised FMP will ba available at the Council meeting. The hearing will be taped recorded and the tapes will be filed as an official transcript of the proceedings. A written summary will be prepared at the hearing.

ADDRESS: The hearing will be held at the Tidewater Inn, Dover and Harrison Streets, Easton, Maryland 21601: phone 301-822-1300.

FOR FURTHER INFORMATION CONTACT: John C. Bryson (302-674-2331), Executive Director, Mid-Atlantic Fishery Management Council, Room 2115, Federal Building, 300 South New Street, Dover, Delaware 19901.

SUPPLEMENTARY INFORMATION: This hearing will provide the public with a final opportunity to comment on the revised bluefish FMP before Council adoption. The revisions involve the establishment of an allocation system for the commercial fishery and reporting requirements that have been revised from the earlier draft.

Dated: December 29, 1983.

Carmen J. Blondin,

Deputy Assistant Administrator for Fisheries, National Marine Fisheries Service.

[FR Doc. 84-33739 Filed 12-30-84; 8:45 am]

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