its entirety, effective on December 29, 1991.

B. Regulatory Flexibility Act

The Department of Defense, the General Services Administration, and the National Aeronautics and Space Administration, certify that this final rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, because it merely removes the sanctions imposed by Executive Order 12661 which will expire on December 28, 1991. Effects on small entities, if any, would result from the expiration of the Executive Order and not from this regulatory change.

C. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the changes to the FAR do not impose recordkeeping information collection requirements or collection of information from offerors, contractors, or members of the public which require the approval of OMB under 44 U.S.C. 3501, *et seq.*

List of Subjects in 48 CFR Parts 25 and 52

Government procurement.

Dated: December 23, 1991.

Harry S. Rosinski,

Acting Director, Office of Federal Acquisition Policy.

Federal Acquisition Circular (FAC) 90–10 amends the Federal Acquisition Regulation (FAR) as specified below:

Removal of Toshiba Sanctions

FAR Subpart 25.10, Sanctions for Violations of Export Controls, the provision at FAR 52.225–12, Notice of Restrictions on Contracting with Sanctioned Persons, and the clause at FAR 52.225–13, Restrictions on Contracting with Sanctioned Persons, are being deleted, in their entirety, from the FAR because the sanctions imposed by Executive Order 12661 dated December 27, 1988, will expire on December 28, 1991. Therefore, the regulatory policy contained in the subpart, the provision, and the clause no longer applies after December 28, 1991.

Therefore, 48 CFR parts 25 and 52 are amended as set forth below:

1. The authority citation for 48 CFR parts 25 and 52 continues to read as follows:

Authority: 40 U.S.C. 486(c); 10 U.S.C. chapter 137; and 42 U.S.C. 2473(c).

PART 25—FOREIGN ACQUISITION

25.10 [Removed]

2. Supart 25.10, consisting of §§ 25.1000 through 25.1005, is removed.

PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

52.225–12 and 52.225–13 [Removed and reserved]

3. Sections 52.225–12 and 25.225–13 are removed and reserved.

[FR Doc. 91–31083 Filed 12–27–91; 8:45 am]
BILLING CODE 6820–34–M

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 33 and 52

[FAC 90–10; FAR Case 91–62; Item III]

Federal Acquisition Regulation; Alternative Dispute Resolution

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Interim rule with request for comment.

SUMMARY: Federal Acquisition Circular (FAC) 90–10 amends the Federal Acquisition Regulation (FAR) to revise subpart 33.2 and section 52.233–1 to implement the Administrative Dispute Resolution Act (Pub. L. 101–552) and recommendations from the Defense Advisory Panel on Government-Industry Relations (DAPGIR). The revisions encourage the use of alternative dispute resolution (ADR) techniques to resolve issues in controversy.

DATES: *Effective Date:* December 30, 1991.

Comment Date: Comments should be submitted to the FAR Secretariat at the address shown below on or before February 28, 1992 to be considered in the formulation of a final rule.

ADDRESSES: Interested parties should submit written comments to: General Services Administration, FAR Secretariat (VRS), 18th & F Streets, NW, Room 4041, Attn: Ms. Deloris Baker, Washington, DC 20405.

Please cite FAC 90–10, FAR case 91–62 in all correspondence related to this case.

FOR FURTHER INFORMATION CONTACT: Mr. Jack O'Neill at (202) 501–3856 in reference to this FAR case. For general information, contact the FAR Secretariat, room 4041, GS Building, Washington, DC 20405, (202) 510–4755. Please cite FAC 90–10, FAR case 91–62.

SUPPLEMENTARY INFORMATION:

A. Background

Revisions to FAR subpart 33.2 and 52.233–1 have been made in this interim rule. FAR 33.201, Definitions, is revised to add definitions of the terms "Alternative dispute resolution," "Issue in controversy," and "Neutral person." FAR 33.202, Contract Disputes Act of 1978, is revised to include a reference to Public Law 101–552 and to clarify the language. FAR 33.204, Policy, is revised to encourage use of alternative dispute resolution (ADR) techniques. FAR 33.207, Contractor claim certification, is revised at paragraph (a) to require that any claim subject to ADR, regardless of dollar amount, be certified by the contractor. A new section is added at 33.214, Alternative dispute resolution. It describes the objective of ADR, sets forth criteria for use of such techniques, authorizes agencies to establish ADR procedures, and suggests use of a neutral person. FAR 52.233–1, Disputes, is revised to encourage consideration of ADR to resolve disputes.

B. Regulatory Flexibility Act

This interim rule is not expected to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, because less than 20% of small entities are affected by the disputes process and the economic impact on small businesses is expected to be less than significant. An Initial Regulatory Flexibility Analysis has, therefore, not been performed. Comments are invited from Small Businesses and other interested parties. Comments from small entities concerning the affected FAR subpart will also be considered in accordance with 5 U.S.C. 610. Such comments must be submitted separately and cite 5 U.S.C. 601, *et seq.* (FAC 90–10, FAR Case 91–62) in correspondence.

C. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the changes to the FAR do not impose recordkeeping information collection requirements or collection of information from offerors, contractors, or members of the public which require the approval of OMB under 44 U.S.C. 3501, *et seq.*

D. Determination to Issue an Interim Rule

A determination has been made under the authority of the Secretary of Defense (DOD), the Administrator of General Services (GSA), and the Administrator of the National Aeronautics and Space Administration (NASA) that compelling reasons exist to promulgate this interim

rule without prior opportunity for public comment. This action is necessary to implement the Administrative Dispute Resolution Act (Pub. L. 101–552). The Act requires that FAR regulations be promulgated by November 15, 1991. Pursuant to Public Law 98–577 and FAR 1.501, public comments received in response to this notice will be considered in formulating the final rule, however.

List of Subjects in 48 CFR Parts 33 and 52

Government procurement.

Dated: December 23, 1991.

Harry S. Rosinsky,

Acting Director, Office of Federal Acquisition Policy.

Federal Acquisition Circular (FAC) 90–10 amends the Federal Acquisition Regulation (FAR) as specified below:

Alternative Dispute Resolution

This interim rule revises FAR subpart 33.2 and section 52.233–1 to add policy, guidance, and criteria for use of alternative dispute resolution techniques.

Therefore, 48 CFR parts 33 and 52 are amended as set forth below:

1. The authority citation for 48 CFR parts 33 and 52 continues to read as follows:

Authority: 40 U.S.C. 486(c); 10 U.S.C. chapter 137; and 42 U.S.C. 2473(c).

PART 33—PROTESTS, DISPUTES, AND APPEALS

2. Section 33.201 is amended by adding, in alphabetical order, definitions to read as follows:

33.201 Definitions.

Alternative dispute resolution means any procedure or combination of procedures voluntarily used to resolve issues in controversy without the need to resort to litigation. These procedures include, but are not limited to, settlement negotiations, conciliation, facilitation, mediation, fact-finding, minitrials, and arbitration.

Issue in controversy means a material disagreement between the Government and the contractor related to a claim or which could result in a claim. An issue in controversy can be all or part of a claim.

Neutral person, as used in this subpart, means an impartial third party, who serves as a mediator, fact finder, or arbitrator, or otherwise functions to assist the parties to resolve the issues in controversy. A neutral person may be a permanent or temporary officer or employee of the Federal Government or any other individual who is acceptable to the parties. A neutral person shall have no official, financial, or personal conflict of interest with respect to the issues in controversy, unless such interest is fully disclosed in writing to all parties and all parties agree that the neutral person may serve (5 U.S.C. 583).

3. Section 33.202 is revised to read as follows:

33.202 Contract Disputes Act of 1978.

The Contract Disputes Act of 1978 (41 U.S.C. 601–613) (the Act), as amended by the Administrative Dispute Resolution Act (Pub. L. 101–552), establishes procedures and requirements for asserting and resolving claims subject to the Act. In addition, the Act provides for: (a) the payment of interest on contractor claims; (b) certification of contractor claims; and (c) a civil penalty for contractor claims that are fraudulent or based on a misrepresentation of fact.

4. Section 33.204 is revised to read as follows:

33.204 Policy.

The Government's policy is to try to resolve all contractual issues in controversy by mutual agreement at the contracting officer's level. Agencies are encouraged to use alternative dispute resolution (ADR) procedures to the maximum extent practicable in accordance with the authority and the requirements of the Administrative Dispute Resolution Act (Pub. L. 101–552) and agency policies.

5. Section 33.207 is amended by revising paragraph (a) introductory text to read as follows:

33.207 Contractor claim certification.

(a) A contractor claim exceeding $50,000, or any claim regardless of amount when using alternative dispute resolution procedures, shall be accompanied by a certification that—

* * * * *

33.214 [Redesignated as 33.215]

6. Section 33.214 is redesignated as 33.215 and a new 33.214 is added to read as follows:

33.214 Alternative dispute resolution.

(a) The objective of using alternative dispute resolution (ADR) procedures is to increase the opportunity for relatively inexpensive and expeditious resolution of issues in controversy. Essential elements of ADR include—

(1) Existence of an issue in controversy;

(2) A voluntary election by both parties to participate in the ADR process;

(3) An agreement on alternative procedures and terms to be used in lieu of formal litigation;

(4) Participation in the process by officials of both parties who have the authority to resolve the issue in controversy; and

(5) Certification by the contractor in accordance with 33.207.

(b) ADR procedures may be used at any time that the contracting officer has authority to settle the issue in controversy and may be applied to a portion of a claim. When ADR procedures are used subsequent to issuance of a contracting officer's final decision, their use does not alter any of the time limitations or procedural requirements for filing an appeal of the contracting officer's final decision and does not constitute a reconsideration of the final decision.

(c) When appropriate, a neutral person may be used to facilitate resolution of the issue in controversy using the procedures chosen by the parties.

PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

7. Section 52.233–1 is amended by—

(a) Revising the introductory text, the date of the clause, and paragraph (a);

(b) Redesignating paragraphs (g) and (h) as (h) and (i) and adding a new paragraph (g);

(c) Removing the date "APR 1984" in Alternate I and inserting in its place "DEC 1991.";

(d) Redesignating paragraph (h) of Alternate I as paragraph (i);

(e) Removing from the introductory paragraph of Alternate I the words "paragraph (h)", everytime they appear, and inserting in their place "paragraph (i)"; and

(e) Removing the derivation lines following "(End of clause)" and Alternate I to read as follows:

52.233–1 Disputes.

As prescribed in 33.215, insert the following clause:

Disputes (Dec 1991)

(a) This contract is subject to the Contract Disputes Act of 1978, as amended (41 U.S.C. 601–613).

* * * * *

(g) At the time a claim by the Contractor is submitted to the Contracting Officer or a claim by the Government is presented to the Contractor, the parties, by mutual consent,

may agree to use alternative means of dispute resolution. When using alternative dispute resolution procedures, any claim, regardless of amount, shall be accompanied by the certification described in paragraph (d)(2) of this clause, and executed in accordance with paragraph (d)(3) of this clause.

(End of clause)

* * * * *

[FR Doc. 91–31084 Filed 12–27–91; 8:45 am]

BILLING CODE 6820–34–M

federal register

Monday
December 30, 1991

Part VIII

Department of Education

34 CFR Parts 300 and 303

Assistance to States for Education of Handicapped Children and Early Intervention Program for Infants and Toddlers With Handicaps; Proposed Rule

DEPARTMENT OF EDUCATION

34 CFR Parts 300 and 303

Assistance to States for Education of Handicapped Children and Early Intervention Program for Infants and Toddlers With Handicaps

AGENCY: Department of Education.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Secretary proposes to amend the regulations at 34 CFR part 300, implementing the Assistance to States for Education of Handicapped Children program authorized by part B of the Individuals with Disabilities Education Act (part B), and the regulations at 34 CFR part 303, implementing the Early Intervention Program for Infants and Toddlers with Handicaps authorized by part H of the Individuals with Disabilities Education Act (part H), by removing from their nonsupplanting regulations the provisions that prohibit the use of funds awarded under those programs to displace State or local funds for any "particular cost".

DATES: Comments must be received before March 30, 1992.

ADDRESSES: All comments concerning these proposed regulations should be addressed to Ms. Lucille Sleger, Program Administration Branch, Division of Assistance to States, Office of Special Education Programs, Department of Education, 400 Maryland Avenue, SW., Switzer Building, room 3615, Washington, DC 20202–2720; telephone: (202) 732–1104; (202) 732–1090 for TDD services.

FOR FURTHER INFORMATION CONTACT: Ms. Rhonda Weiss; telephone: (202) 732–1375; (202) 732–1090 for TDD services.

SUPPLEMENTARY INFORMATION: Part B authorizes formula grants to States, and through them to local educational agencies, to help provide special education and related services to children with disabilities. To receive Part B funds from the State, each local educational agency is required to submit an application that contains specified assurances regarding use of those funds, including an assurance that Part B funds will be used to supplement and, to the extent practicable, increase the level of State and local funds expended for the education of children with disabilities, and in no case to supplant those State and local funds. The statutory requirement prohibiting local educational agencies from supplanting State and local funds with part B funds is implemented by 34 CFR 300.230 of the part B regulations.

Part H authorizes assistance to States to help them plan, develop, and implement a State-wide system of early intervention programs for infants and toddlers with disabilities and their families. Each participating State must make an application to the Secretary for its Part H grant award. The statute requires this application to contain specified assurances regarding the use of part H funds, including an assurance, similar to the assurance in part B, that part H funds will be used to supplement, and not supplant, State and local funds expended for early intervention services for infants and toddlers with disabilities. The statutory requirement prohibiting States from supplanting State and local funds with part H funds is implemented by 34 CFR 303.124 of the part H regulations.

During the Education Summit held in September 1989, President Bush made a commitment to the State Governors that the Federal Government would give States more flexibility in the use of Federal education program funds while ensuring accountability in the use of those funds by recipients. These proposed regulatory changes, which would continue to require that States maintain or increase the total amount of funds spent to meet Part B and Part H requirements, are being made consistent with this commitment. These proposed regulatory changes also are supportive of the goals of the AMERICA 2000 Education Strategy, because they will increase the ability of State and local educational agencies to develop and implement innovative strategies to meet the needs of children with disabilities more effectively. The part B and part H nonsupplanting provisions, which are virtually identical, currently include the following two-pronged test for determining compliance with the nonsupplanting requirements for these programs:

Aggregate Test: The total amount of State and local funds budgeted for expenditures in the current fiscal year for the education of children with disabilities under Part B or for early intervention services for infants and toddlers with disabilities and their families under part H must be at least equal to the amount of those funds actually expended in the most recent preceding fiscal year for which information is available.

Particular Cost Test: Funds awarded under part B and Part H may not be used to displace State or local funds for any "particular cost".

The "particular cost" test was included in the part B regulations, first published in 1977, to assist in ensuring that part B funds would be used to increase State and local efforts for the education of children with disabilities. Because the Secretary sought to coordinate the fiscal requirements in Part H with those of part B as closely as possible, the nonsupplanting provisions in the part H regulations published in 1989 were modeled after those in the part B regulations. However, based on the Secretary's experience in administering part B, the Secretary has found that under the "particular cost" test, local educational agencies have been found out of compliance with the part B nonsupplanting requirement, even in instances in which the total amount of State and local funds budgeted for the education of children with disabilities in a fiscal year was maintained at, or increased from the amount expended in the most recent preceding fiscal year. For example, if a local educational agency spends part B funds to pay for a teacher's salary that was previously paid for with State or local funds, a supplanting violation would occur, even though the total amount of State and local funds spent on special education is greater than the amount spent the previous year.

The Secretary believes that the particular cost test is unnecessary to ensure compliance with the statutory requirements that Federal funds be used to supplement, or increase, the level of State and local funds expended to meet the special educational needs of children with disabilities and the early intervention needs of infants and toddlers with disabilities and their families, and not to replace those State and local funds. The Secretary also believes that the particular cost provision limits the ability of State and local agencies to make financial adjustments that could assist in improving the quality of services for children with disabilities and for infants and toddlers with disabilities and their families.

Therefore, to give States and local educational agencies more flexibility in the use of part B and part H funds, while still requiring States to maintain or increase the total amount of State and local funds expended to meet part B and part H requirements, the Secretary proposes to amend the part B regulations at 34 CFR 300.230 by deleting the particular cost provision at § 300.230(b)(2) and to amend the part H regulation at 34 CFR 303.124 by deleting the particular cost provision at § 320.303.124(b)(2). Also, the Secretary proposes to delete the comment following § 300.230 of the Part B regulations and the note following § 303.124 of the part H regulations since

this comment and note were intended primarily to distinguish between the "aggregate" and "particular cost" tests. The Secretary believes that these proposed regulatory changes will serve to enhance State and local efforts to meet the special educational needs of children with disabilities and the early intervention needs of infants and toddlers with disabilities and their families, and will in no way serve to diminish the rights and protections guaranteed to children with disabilities and their parents by part B of the Act and the rights and protections guaranteed to infants and toddlers with disabilities and their families by part H of the Act.

Executive Order 12291

These proposed regulations have been reviewed in accordance with Executive Order 12291. They are not classified as major because they do not meet the criteria for major regulations established in the order.

Regulatory Flexibility and Certification

The Secretary certifies that these proposed regulations would not have a significant impact on a substantial number of small entities.

To the extent that these proposed regulations would affect States and State agencies, the regulations would not have an impact on small entities, since States and State agencies are not defined as "small entities" in the Regulatory Flexibility Act.

The few small entities that would be affected by these proposed regulations are small local educational agencies receiving Federal funds under this program. However, the regulations would not have a significant economic impact on the small local educational agencies affected because the regulations would not impose excessive regulatory burdens or require unnecessary Federal supervision. The regulations would impose minimal requirements to ensure the proper expenditure of program funds.

Paperwork Reduction Act of 1980

These proposed regulations have been examined under the Paperwork Reduction Act of 1980 and have been found to contain no information collection requirements.

Intergovernmental Review

This program is subject to the requirements of Executive Order 12372 and the regulations in 34 CFR part 79. The objective of the Executive order is to foster an intergovernmental partnership and a strengthened federalism by relying on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

In accordance with the order, this document is intended to provide early notification of the Department's specific plans and actions for this program.

Invitation to Comment

Interested persons are invited to submit comments and recommendations regarding these proposed regulations. All comments submitted in response to these proposed regulations will be available for public inspection, during and after the comment period, in room 3615, Switzer Building, 330 C Street, SW., Washington, DC, between the hours of 8:30 a.m. and 4 p.m., Monday through Friday of each week except Federal holidays.

To assist the Department in complying with the specific requirements of Executive Order 12291 and the Paperwork Reduction Act of 1980 and their overall requirement of reducing regulatory burden, the Secretary invites comments on whether there may be further opportunities to reduce any regulatory burdens found in these proposed regulations.

List of Subjects

34 CFR Part 300

Administrative practice and procedures, Education, Education of individuals with disabilities, Grant programs—education, Privacy, Private schools, Reporting and recordkeeping requirements.

34 CFR Part 303

Education, Education of the handicapped, Grant programs–education, Medical personnel, State educational agencies.

Dated: November 1, 1991.

Lamar Alexander,

Secretary of Education.

(Catalog of Federal Domestic Assistance Number 84.027; Assistance to States for Education of Handicapped Children and 84.181; Early Intervention program for Infants and Toddlers with Handicaps)

The Secretary proposes to amend title 34 of the Code of Federal Regulations by amending parts 300 and 303 as follows:

PART 300—ASSISTANCE TO STATES FOR EDUCATION OF HANDICAPPED CHILDREN

1. The authority citation for part 300 continues to read as follows:

Authority: 20 U.S.C. 1411–1420, unless otherwise noted.

§ 300.2 [Amended]

2. Section 300.230 is amended by removing the colon after the word "section" in paragraph (b); removing "(1) The" in paragraph (b)(1) and adding in its place ", the"; removing paragraph (b)(2) and redesignating paragraphs (b)(1)(i) and (ii) as (b)(1) and (2), respectively; and removing the Comment following the section.

PART 303—EARLY INTERVENTION PROGRAM FOR INFANTS AND TODDLERS WITH HANDICAPS

3. The authority citation for part 303 continues to read as follows:

Authority: 20 U.S.C. 1471–1485, unless otherwise noted.

§ 303.124 [Amended]

4. Section 303.124 is amended by removing the dash after the word "section" in paragraph (b); removing the "(1) The" in paragraph (b)(1) and adding in its place ", the"; removing paragraph (b)(2) and redesignating paragraphs (b)(1)(i) and (ii) as (b)(1) and (2), respectively; and removing the Note following the section.

[FR Doc. 91-31074 Filed 12-27-91; 8:45 am]

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federal register

Monday
December 30, 1991

Part IX

Environmental Protection Agency

Twenty-Ninth Report of the Interagency Testing Committee to the Administrator; Notice

ENVIRONMENTAL PROTECTION AGENCY

[OPPTS-41036; FRL 4007-6]

Twenty-Ninth Report of the Interagency Testing Committee to the Administrator; Receipt of Report and Request for Comments Regarding Priority Testing List of Chemicals

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Interagency Testing Committee (ITC), established under section 4(e) of the Toxic Substances Control Act (TSCA), transmitted its Twenty-Ninth Report to the Administrator of EPA on November 27, 1991. As noted in this Report, which is included with this notice, the Committee revised the Priority Testing List by adding one chemical, white phosphorus, and one chemical group, the alkyl-, bromo-, chloro-, hydroxymethyl diaryl ethers. These chemicals are recommended. There are no designated or recommended with intent-to-designate chemicals.

The ITC removed six chemicals from the Priority Testing List in the 29th Report as a result of EPA actions. Five brominated flame retardants, designated in the 25th ITC Report, were removed because EPA issued a proposed rule on June 25, 1991 (56 FR 29140). 4-Vinylcyclohexene, designated in the 26th Report, was removed because EPA issued a consent order on September 23, 1991 (56 FR 47912).

EPA invites interested persons to submit written comments on the Report.

DATES: Written comments should be submitted by January 29, 1992.

ADDRESSES: Send four copies of written submissions to: TSCA Public Docket Office (TS-793), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. NE G-004, 401 M St., SW., Washington, DC 20460. Submissions should bear the document control number (OPPTS-41036; FRL 4007-6). The public record supporting this action, including comments, is available for public inspection in Rm. NE G-004 at the address noted above from 8 a.m. to noon and 1 p.m. to 4 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: David Kling, Acting Director, Environmental Assistance Division (TS-799), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. E-543B, 401 M St., SW., Washington, DC 20460, (202) 554-1404, TDD (202) 554-0551.

SUPPLEMENTARY INFORMATION: EPA has received the TSCA Interagency Testing Committee's Report to the Administrator.

I. Background

TSCA (Pub. L 94-469, 90 Stat. 2003 et seq; 15 U.S.C. 260l et seq.) authorizes the Administrator of EPA to promulgate regulations under section 4(a) requiring testing of chemicals and chemical groups in order to develop data relevant to determining the risks that such chemicals and chemical groups may present to health or the environment. Section 4(e) of TSCA established the Interagency Testing Committee to recommend chemicals and chemical groups to the Administrator of EPA for priority testing consideration. Section 4(e) directs the ITC to revise the TSCA section 4(e) Priority Testing List at least every 6 months. The ITC's most recent revisions to this List are included in the Committee's Twenty-Ninth Report. The Report was received by the Administrator on November 27, 1991, and is included in this Notice. The Report adds one chemical and one chemical group to the TSCA section 4(e) Priority Testing List.

II. Written and Oral Comments

EPA invites interested persons to submit detailed comments on the ITC's new recommendations. The Agency is interested in receiving information concerning additional or ongoing health and safety studies on the subject chemicals as well as information relating to the human and environmental exposure to these chemicals.

A notice will be published at a later date in the **Federal Register** adding the substances recommended in the ITC's Twenty-Ninth Report to the TSCA section 8(d) Health and Safety Data Reporting Rule (40 CFR part 716), which requires the reporting of unpublished health and safety studies on the listed chemicals. The delay in publishing this notice is necessary to avoid an overlap in the reporting period for chemicals included in the ITC's 28th list. That notice will also add the chemicals to the TSCA section 8(a) Preliminary Assessment Information Rule (40 CFR part 712). The section 8(a) rule requires the reporting of production volume, exposure, and release information on the listed chemicals.

III. Status of List

The ITC's Twenty-Ninth Report notes the addition of one chemical and one chemical group to the Priority Testing List, and the removal of 5 brominated flame retardants and 4-vinylcyclohexene from the List. The current Priority Testing List contains 26 chemicals and 21 chemical groups, 13 of these chemicals are designated.

Authority: 15 U.S.C. 2603.

Dated: December 16, 1991.

Charles M. Auer,

Director, Existing Chemical Assessment Division, Office of Pollution Prevention and Toxics.

Twenty-Ninth Report of the TSCA Interagency Testing Committee to the Administrator, Environmental Protection Agency

Summary

The U.S. Congress created the Interagency Testing Committee (ITC) under the Toxic Substances Control Act (TSCA) to recommend chemicals and chemical groups to the Administrator of the U.S. Environmental Protection Agency (EPA) for priority testing consideration and to facilitate coordination of chemical testing sponsored or required by U.S. Government organizations represented on the Committee. Congress directed the Committee to: (1) Organize their recommendations as the Priority Testing List, (2) revise the Priority Testing List at least every 6 months and (3) transmit these revisions to the EPA Administrator for publication in the **Federal Register**.

As a result of its deliberations during this reporting period (5/16/91 to 11/27/91), the Committee is revising the TSCA section 4(e) Priority Testing List by recommending one chemical and one chemical group. The Committee's computerized, substructure-based chemical selection expert systems were used to identify the chemicals in groups that are likely to satisfy multiple data needs of Member Agencies and others. During this reporting period, the Committee (1) considered available information on 5 chemicals and 14 chemical groups, (2) discussed information on Committee activities at the North American Benthological Society Technical Information Workshop on Toxicity Assessment Techniques for Aquatic Invertebrates, (3) participated in CPSC's, EPA's and NCI's chemical testing meetings, (4) met with the Synthetic Organic Chemical Manufactures Association and the Chemical Manufactures Association to discuss completed, ongoing and planned testing of chemical groups, (5) processed chemicals nominated by Maryland's Department of the Environment, (6) prepared testimony for U.S. Senate hearings on chemicals causing adverse reproductive effects, (7) published

unambiguous tables of the 124 chemicals and 39 chemical groups on or removed from the Priority Testing List, (8) initiated a review of 350 studies submitted to the EPA or retrieved from recent literature for chloroalkyl phosphates, (9) shared test data resulting from EPA's implementation of ITC's testing recommendation with a permitting authority and (10) deferred one chemical from testing consideration.

Chemicals or chemical groups (entries) on the Priority Testing List are designated, recommended with intent-to-designate or recommended by the Committee. Designations were created by the U.S. Congress when they drafted TSCA. Recommendations with intent-to-designate were established by the Committee in their 17th Report (50 FR 47603; November 19, 1985). Recommendations were established by the Committee in their 11th Report (47 FR 54626; December 3, 1982).

Revisions to the Priority Testing List

Revisions to the Priority Testing List are presented, together with the types of testing recommended, in Table 1. The footnote letters following Table 1 acknowledge the Committee's efforts to comprehensively search ongoing testing-related activities for chemicals under section 110 of the Superfund Amendments and Reauthorization Act (SARA), section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA), section 301 of the Clean Air Act Amendments, Priority 1 substances in the Organization for Economic Cooperation and Development's chemical testing program and available information previously submitted under TSCA section 8(a) and 8(d). Table 1 reads as follows:

TABLE 1.—REVISIONS TO THE SECTION 4(E) PRIORITY TESTING LIST

Group	CAS No.	Chemical	Action	Date	Recommended Tests
	7723-14-0	White phosphorus[1] [2]	Recommended	11/91	Chemical fate: Persistence in surface waters and sediments. Health effects: None. Ecological effects: Toxicity to migratory birds and other wildlife.
Alkyl-, bromo-, chloro-, hydroxymethyl diaryl ethers.			Recommended	11/91	Chemical fate: Physical and chemical properties and biodegradation screening. Health effects: Screening for subchronic, mutagenic, reproductive, developmental and neurotoxic effects, except diphenyl oxide. Ecological effects: Screening for toxicity to algae, aquatic invertebrates and fish.

[1] Superfund Amendments and Reauthorization ACt (SARA) Section 110.
[2] Emergency Planning and Community Right-to-Know Act (EPCRA) section 313.

Listed below are the individual chemicals for the diaryl ethers in Table 1. Chemical nos. 1 through 7 are alkyldiaryl ethers, chemical no. 8 is a bromodiaryl ether, chemical nos. 9 through 12 are chlorodiaryl ethers, chemical nos. 13 and 14 are hydroxymethyl diaryl ethers.

No.	Chemical Name	CAS No.
1.	Benzene, 1,1'-oxybis-	101-84-8[1] [2]
2.	1,4-Diphenoxybenzene	3061-36-7
3.	Benzene, 1-methyl-3-phenoxy-	3586-14-9
4.	Benzene, 1,1'-oxybis[methyl-	28299-41-4
5.	1,1'-Biphenyl, phenoxy-	28984-89-6
6.	Benzene, 1,1'-oxybis[(1,1,3,3-tetramethylbutyl)-	61702-88-3
7.	Benzene, 1,1'-oxybis[dodecyl-	69834-19-1
8.	Benzene, 1-(bromomethyl)-3-phenoxy-	51632-16-7
9.	2-Chloro-l-(3-methylphenoxy)-4-(trifluoromethyl)benzene	42874-96-4
10.	Phenol, 3-[2-chloro-4-(trifluoromethyl)phenoxy]-,acetate	50594-77-9
11.	Benzoic acid, 3-[2-chloro-4-(trifluoromethyl)phenoxy]-	63734-62-3
12.	Benzoic acid, 3-[2-chloro-4-(trifluoromethyl)phenoxy]-,potassium salt	72252-48-3
13.	Benzenemethanol, 3-phenoxy-,	13826-35-2
14.	Benzenemethanol, 3-phenoxy-, acetate	50789-44-1

[1] Toxic Substances Control Act (TSCA) section 8(a) Preliminary Assessment Information Rule (PAIR).
[2] TSCA section 8(d) Health and Safety Data Reporting Rule.

TSCA Interagency Testing Committee

Statutory Member Agencies and Their Representatives

Council on Environmental Quality
Larry Clark, member (see Note 1)

Department of Commerce
Willie E. May, member (see Note 2)

Environmental Protection Agency
James B. Willis, member (see Note 3)
John S. Leizke, alternate (see Note 4)

National Cancer Institute
Thomas P. Cameron, member (see Note 5)
Richard Adamson, alternate (see Note 6)

National Institute for Environmental Health Sciences
Errol Zeiger, member (see Note 7)
James K. Selkirk, alternate

National Institute for Occupational Safety and Health
Robert W. Mason, member and Chairperson
Rodger L. Tatken, alternate

National Science Foundation
Carter Kimsey, member (see Note 8)
Jarvis L. Moyers, alternate

Occupational Safety and Health Administration
Christine Whittaker, member (see Note 9)
Stephen Mallinger, alternate

Liaison Agencies and Their Representatives

Agency for Toxic Substances and Disease Registry
Sharunda Buchanan (see Note 10)

Consumer Product Safety Commission
Lakshmi C. Mishra

Department of Agriculture
Donald Derr, member (see Note 11)
Richard M. Parry, Jr., alternate

Department of Defense
Randall S. Wentsel

Department of the Interior
Clifford P. Rice, member
Barnett A. Rattner, alternate

Department of Transportation
James O'Steen, member
George Cushmac, alternate

Food and Drug Administration
Charles J. Kokoski, member
Raju Kammula, alternate

National Library of Medicine
Vera Hudson

National Toxicology Program
Miriam Davis, member
Victor A. Fung, alternate and Vice Chairperson

U.S. International Trade Commission
James Raftery, member
Edward Matusik, alternate

Committee Staff

John D. Walker, Ph.D., Executive Director
Norma S.L. Williams, Executive Assistant

Support Staff

Alan Carpien, office of the General Counsel, EPA

Notes:
1. Appointed on November 21, 1991.
2. Appointed on November 8, 1991.
3. Appointed on August 5, 1991.
4. Appointed on August 5, 1991.
5. Appointed on November 22, 1991.
6. Appointed on November 22, 1991.
7. Appointed on November 15, 1991.
8. Appointed on September 28, 1991; on an IPA from August 1990 to August 1991.
9. Appointed on August 15, 1991
10. Appointed on September 11, 1991.
11. Appointed on November 26, 1991

The Committee very much appreciates the efforts of former members and alternates from ATSDR (Deborah Barsotti, member from 3/89-11/91), EPA (Letitia Tahan, member from 8/89-8/91 and Vince Nabholtz, alternate from 8/89-8/91), NSF (Bill Pengelly, member from 8/90-8/91), and OSHA (Loretta Schuman, member from 9/89-8/91). These members and alternates were responsible for initiating and sustaining intraagency efforts that resulted in Member Agency nomination of chemical groups (brominated flame retardants, isocyanates, IRIS (RfC/RfD) chemicals, aldehydes, alkynes, nitroalcohols, phophoniums, hydrazines, oxiranes, alkoxysilanes, aldehyde hydrates and isothiocyanates) and chemicals (1,1' methylenebis-4-isocyanatocyclohexane and *N*-phenyl-1-naphthylamine) that were included in the Committee's 25th, 26th, 27th and 28th Reports. The ITC acknowledges the assistance and support given by the staff of Syracuse Research Corp. (technical support contractor) and personnel of the EPA Office of Pollution Prevention and Toxics.

Chapter 1—Introduction

1.1 *Background.* The U.S. Congress created the TSCA Interagency Testing Committee (ITC) in 1976 and provided the ITC with statutory authority to screen, select and recommend chemicals and chemical groups to the EPA Administrator for priority health effects, chemical fate, and ecological effects testing consideration. When screening chemicals or chemical groups for consideration, Congress directed the Committee (which consists of members from 8 statutory and 10 liaison U.S. Government organizations) to consider 8 statutory factors including: (1) Quantities manufactured or released, (2) numbers of individuals exposed, (3) duration of exposure, (4) extent of human exposure, (5) structural relationships to known toxic substances, (6) availability of existing toxicity data, (7) reliability of available toxicity data to predict hazard, and (8) availability of testing facilities to develop data for the recommended tests. Congress also directed the Committee to give priority attention to those chemicals or chemical groups known to cause or suspected of causing cancer, gene mutations or birth defects. Based on these Congressional directives, the Committee recommends chemicals or chemical groups that appear to have insufficient health effects, chemical fate, or ecological effects test data and that may present an unreasonable risk of injury to health or the environment, reasonably be anticipated to enter the environment in substantial quantities or involve significant or substantial human exposure.

Congress also created the ITC to facilitate coordination of chemical testing sponsored or required by U.S. Government organizations and to enhance information exchange to promote cost-effective use of U.S. Government chemical testing resources by recommending testing of chemicals or chemical groups that are likely to satisfy multiple data needs of Member Agencies and others. The Committee's statutory responsibilities are described in section 4(e) of the Toxic Substances Control Act (TSCA; Public Law 94-469, 90 Stat. 2003 et seq., 15 U.S.C. 2601 et seq.).

The Committee prepares the Priority Testing List of chemicals or chemical groups recommended for testing (by the chemical's manufacturers), transmits the Priority Testing List to the Administrator of the U.S. Environmental Protection Agency (EPA) and determines the order in which the EPA Administrator shall implement the testing recommendations under TSCA section 4(a) by designating those chemicals, from among its recommendations, to which the Administrator should respond within 12 months. Congress directed the Committee to revise the Priority Testing List at least every 6 months and required the EPA Administrator to publish the Committee's Reports in the **Federal Register**.

1.2 *Committee's previous reports.* Twenty-eight previous Reports to the EPA Administrator have been issued by the Committee and published in the **Federal Register**. In these 28 Reports, the Committee recommended testing for 123 chemicals and 38 chemical groups. Chemical groups consist of one or more chemicals, isomers, congeners, mixtures, and so on that have a common substructure, use, testing information deficiency, exposure scenario, etc., and for which there is one common testing recommendation, e.g., aldehydes

recommended for ecological effects testing in the 27th Report. Chemicals can be members of chemical groups, but each is counted as a single chemical if their testing recommendations are different, e.g., the five chloroalkyl phosphates recommended in the 23rd Report.

1.3 *Committee's activities during this reporting period.* Between May 16, 1991 and November 27, 1991, the Committee examined lists of ongoing activities related to reducing testing information deficiencies for commercial chemicals, used their computerized, substructure-based, chemical selection expert systems to identify chemical groups in need of testing, identified chemicals that appeared to have insufficient health effects, chemical fate or ecological effects test data, considered the multiple data needs of Member Agencies and others, and recommended chemicals and chemical groups with insufficient test data based on concerns for potential toxicity, exposure or environmental release.

1.3.a *Chemical and chemical group selections.* The Committee recommended one chemical (white phosphorus) and one chemical group (alkyl-, bromo-, chloro-, hydroxymethyl diarylethers) for testing (Table 1). White phosphorus and alkyl-, bromo-, chloro-, hydroxymethyl diarylethers were recommended, not designated, because the Committee wants to review the TSCA section 8(a) and 8(d) information and any use exposure and release information as well as any physical chemical property information that is voluntarily submitted, before deciding whether to designate or withdraw these chemicals for testing. When the Committee recommended white phosphorus for chemical fate and ecological effects testing, it considered the data needs of the U.S. Department of the Interior, the ongoing activities of the Department of Defense and the regulatory authorities of the Department of Transportation. Test data needs are considered during selection of chemicals and chemical groups for testing. However, it may be difficult to identify test data needs or to anticipate how test data might be used until EPA implements the ITC's testing recommendations and industry develops sufficient data to distinguish between hazardous versus non-hazardous chemicals (e.g., see third paragraph of chapter 1.3.c below). When the Committee recommended alkyl-, bromo-, chloro-, hydroxymethyl diarylethers for health effects, chemical fate and ecological effects screening tests, it considered the uncertainties related to production and use, potential exposures and releases from production, processing and use, potential for persistence in the environment, potential to cause adverse health or ecological effects and the paucity of publicly-available data for over 90 percent of these chemicals. These recommendations are consistent with the Committee's comprehensive approach of using their computerized processes to: (1) Identify chemicals in substructure-based groups in need of screening tests, (2) review recently requested production and exposure data and non-public health and safety studies, (3) meet with interested groups to identify commercially-important chemicals that need to be tested (4) withdraw chemicals or tests to avoid unnecessary or duplicative testing, (5) characterize testing information deficiencies identified by Member Agencies as well as others, and (6) integrate available information into a consolidated testing program likely to serve multiple users.

There are numerous advantages associated with nominating chemicals to the Committee. These were described in detail in chapter 1.3.a of the 27th Report (56 FR 9534, March 6, 1991). Further information about nominating chemicals or chemical groups to the Committee can be obtained by calling the Committee's Executive Director at area code 202/260-1820 or the Committee's Executive Assistant at area code 202/260-1825.

1.3.b *Comprehensive information processing.* During this reporting period, several For Your Information (FYI), TSCA section 8(d) and 8(e) documents were reviewed. These documents are stored on microfiche in the TSCA Public Docket Office, Office of Pollution Prevention and Toxics, Environmental Protection Agency, Room G-004 NE Mall, 401 M Street, SW., Washington, D.C. 20460. These microfiched documents are also available from the National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia 22161 (1-800-336-4700), and from Chemical Information Systems, Inc., 7215 York Road, Baltimore, Maryland 21212 (1-800-CIS-USER). The Committee referenced several of these documents in chapter 2 of this report and readers are referred to the above addresses to obtain further information. Interested parties can also obtain, from the EPA address, copies of publicly-available reports, letters and published references supporting recommendations of chemicals in this report.

The Committee continues to comprehensively search available domestic and international lists of ongoing activities related to reducing testing information deficiencies on chemicals under review. Efforts to conduct these searches have identified numerous chemicals previously reviewed or recommended by the Committee. Many of the chemicals previously reviewed or recommended by the Committee are on ATSDR's list, the Toxics Release Inventory or the list of Hazardous Air Pollutants because of test data developed, in part, as a response to EPA's implementation of ITC's testing recommendation or as a result of other testing after ITC review. Committee recommendations have resulted in the submission of: (1) Substantive TSCA section 8(a) production, exposure and release information, (2) thousands of non-public TSCA section 8(d) studies and (3) hundreds of TSCA section 4(a) and (d) studies that were conducted as a result of the EPA's implementation of the Committee's testing recommendations. The Committee continues to review information on these and other lists. Efforts to conduct searches also identified chemicals for which TSCA information-gathering activities are ongoing (see Table 1 footnotes). The Committee makes the results of these searches publicly available by referencing TSCA submissions in Reports to the EPA Administrator or making tables and references of these submissions available in the public dockets supporting a Report to the EPA Administrator.

During this reporting period, the Committee considered available information on 5 chemicals and 14 chemical groups. Chemical groups under consideration include: alkenes, alkylamines, alkylethers, alkylsulfonates, amino aromatics, anhydrides, anthraquinones, aromatic dianhydrides, aromatic sulfhydryls, aromatic sulfonates, aryl ethers, benzothiazoles, carbamates, dialkylamines, dihydroxybenzenes, ethylhexyl derivatives, fluorinated and iodinated organics, glycol ethers, haloalkyl ethers, heterocyclics, hindered phenols, imidazoles, inorganics, isoindoles, isophthalic acids, IRIS chemicals, nitriles, nitroaromatics, nitroparaffins, *N*-phenylenediamines, phenolic antioxidants, phosphates, pyrrolidinones, sulfenamides, sulfonic acids, thiocarbamates, thiols, triazines, and xanthenes. The Committee recommended one chemical and one chemical group to the TSCA section 4(e) Priority Testing List. Review of the remaining chemicals and chemical groups is ongoing.

1.3.c *Information dissemination.* To emphasize the Committee's efforts to promote public understanding of the ITC's functions and purposes, the Committee is listing some of the Committee-related activities that occurred during this reporting period. On May 23, 1991, the Executive Director presented a keynote speech at the North American Benthological Society Technical Information Workshop on Toxicity Assessment Techniques for Aquatic Invertebrates. On several occasions, the Committee's Chairperson, Vice-Chairperson, Executive Director or Members participated in CPSC's, EPA's and NCI's meetings to discuss chemical testing.

To facilitate coordination of chemical testing and to promote conservation of chemical testing resources the Executive Director met with the Synthetic Organic Chemical Manufactures Association and the Chemical Manufactures Association to discuss completed, ongoing and planned testing of chemical groups. The Committee processed chemicals referred to the ITC by Maryland's Department of the Environment. The Executive Director prepared testimony for U.S. Senate hearings on chemicals causing adverse reproductive effects.

To enhance communication, the Executive Director and Executive Assistant frequently respond to questions related to chemicals reviewed or recommended by the ITC. During this reporting period, the Executive Director responded to a call from Peter Howe of EPA's Region V, who called to learn if the ITC had recommended 4-(1,1,3,3-tetramethylbutyl)phenol (TMBP) for testing. TMBP was recommended for testing in November 1982 as part of the Committee's 11th Report. EPA's implementation of the ITC's testing recommendation and industry testing of TMBP produced chemical fate and ecological effects data (TMBP is persistent and highly toxic to aquatic organisms) that Region V used as part of the Agency's National Pollutant Discharge Elimination System permitting activities.

To promote a comprehensive evaluation of recent exposure information similar to that requested in the 28th Report, the Committee is soliciting voluntary use exposure and release information that is unlikely to be submitted in response to the TSCA Section 8(a) rule that is promulgated for any chemical or chemical group recommended for testing. In this 29th Report, the Committee is soliciting voluntary use exposure and release information for the one chemical and one chemical group recommended for testing and listed in Table 1.

To promote a comprehensive evaluation of recent physical and chemical property information similar to that requested in the 28th Report, the Committee is soliciting voluntary submission of this information for the one chemical and one chemical group recommended for testing and listed in Table 1.The Committee is soliciting voluntary submissions, because under 40 CFR 716.50, TSCA Section 8(d) studies of physical and chemical properties must be submitted only if they are performed for the purpose of determining the environmental or biological fate of a substance, and only if they investigated water solubility, adsorption/desorption on particulate surfaces, vapor pressure, octanol/water partition coefficient, density, dissociation constant, etc. The Committee recognizes that before chemicals are manufactured, many physical and chemical properties are measured (including those mentioned above, but also including flash point, melting point, boiling point, etc.), but not for the purpose of determining the environmental or biological fate of a substance. Member Agencies often need these physical and chemical properties that would not be developed as part of an environmental or biological fate assessment.

The Committee hopes that a voluntary approach for use exposure data and physical chemical property information will prove more efficient than pursuing notice-and-comment rulemaking under a TSCA section 8(a) Comprehensive Assessment Information Rule.

1.3.d *Referrals.* During this reporting period, the Committee did not refer any chemicals to Member Agencies or other organizations for testing consideration.

1.3.e *Deferrals.* The Committee is deferring 5-chloro-2-(2,4-dichlorophenoxy) phenol (CAS No. 3380–34–5), because of uncertainties related to testing under TSCA. Deferred and other chemicals are recycled through the Committee's computerized processes to identify chemicals whose production volumes have substantially changed.

1.3.f *Removals.* Six chemicals were removed from the Priority Testing List as a result of EPA responses to Committee recommendations. Five brominated flame retardants designated in the Committee's 25th Report were removed from the Priority Testing List on June 25, 1991 when EPA promulgated a Notice of Proposed Rulemaking. 4-Vinylcyclohexene, designated in the Committee's 26th Report was removed from the Priority Testing List on September 23, 1991 when EPA published a negotiated Consent Order.

In addition, the Committee is providing a complete list of 98 chemicals and 18 chemical groups that have been recommended and removed from the Priority Testing List since the ITC's 1st Report in October 1977 (Table 2). Reasons for removing chemicals from the Priority Testing List as well as the reference for the original Committee designation or recommendation are contained in the FR citations listed in Table 2. The Report numbers for the original Committee designation or recommendation are listed in Table 2. Reports have been consistently published every 6 months since October 1977. Table 2 reads as follows:

TABLE 2.—REMOVALS FROM THE TSCA SECTION 4(E) PRIORITY TESTING LIST

Report	Chemical/Group	Citation	Publication Date
1	Alkyl epoxides	49 FR 449	January 4, 1984
1	Alkyl phthalates	46 FR 53775	October 30, 1981
1	Chlorinated benzenes (mono and di-health)	45 FR 48524	July 18, 1980
1	Chlorinated benzenes (mono and di-environmental)	49 FR 1760	January 13, 1984
1	Chlorinated paraffins	47 FR 1017	January 8, 1982
1	Chloromethane	45 FR 48524	July 18, 1980
1	Cresols	48 FR 31812	July 11, 1983
1	Hexachloro-1,3-butadiene	47 FR 58029	December 29, 1982
1	Nitrobenzene	46 FR 30300	June 5, 1981

TABLE 2.—REMOVALS FROM THE TSCA SECTION 4(E) PRIORITY TESTING LIST—Continued

Report	Chemical/Group	Citation	Publication Date
1	Toluene	47 FR 56391	December 16, 1982
1	Xylenes	47 FR 56392	December 16, 1982
2	1,1,1-Trichloroethane	46 FR 30300	June 5, 1981
2	Acrylamide (health)	45 FR 48510	July 18, 1980
2	Acrylamide (environmental)	48 FR 725	January 6, 1983
2	Aryl phosphates	46 FR 57452	December 29, 1983
2	Chlorinated naphthalenes	46 FR 54491	November 2, 1981
2	Dichloromethane	46 FR 30300	June 5, 1981
2	Halogenated alkyl epoxides	48 FR 57695	December 30, 1983
2	Polychlorinated terphenyls	46 FR 54482	November 2, 1981
2	Pyridine	47 FR 58031	December 29, 1982
3	1,2-Dichloropropane	49 FR 899	January 6, 1984
3	Chlorinated benzenes (tri, tetra and penta-health)	45 FR 48524	July 18, 1980
3	Chlorinated benzenes (tri, tetra and penta-environmental)	49 FR 1760	January 13, 1984
3	Glycidols	48 FR 57562	December 30, 1983
4	4,4'-Methylenedianiline	48 FR 31806	July 11, 1983
4	Acetonitrile	47 FR 58020	December 29, 1982
4	Aniline and bromo-, chloro- or nitroanilines	49 FR 108	January 3, 1984
4	Antimony metal	48 FR 717	January 6, 1983
4	Antimony sulfide	48 FR 717	January 6, 1983
4	Antimony trioxide	48 FR 717	January 6, 1983
4	Cyclohexanone	49 FR 136	January 3, 1984
4	Hexachlorocyclopentadiene	47 FR 58023	December 29, 1982
4	Isophorone	48 FR 727	January 6, 1983
4	Mesityl oxide	48 FR 30699	July 5, 1983
4	Methyl ethyl ketone	47 FR 50025	December 29, 1982
4	Methyl isobutyl ketone	47 FR 58025	December 29, 1982
5	Benzidine-, o-dianisidine and o-tolidine based dyes	46 FR 55004	November 5, 1981
5	Hydroquinone	49 FR 438	January 4, 1984
5	Quinone	49 FR 456	January 4, 1984
6	Phenylenediamines	47 FR 973	January 8, 1982
7	Alkyltins	47 FR 5456	February 5, 1982
7	Butyl benzyl phthalate	46 FR 53775	October 30, 1981
7	Butyl glycolyl butyl phthalate	46 FR 54487	November 2, 1981
7	Fluoroalkenes	46 FR 53704	October 30, 1981
8	2-Chlorotoluene	47 FR 3596	January 26, 1982
8	Diethylenetriamine	47 FR 18386	April 29, 1982
8	Hexachloroethane	47 FR 18175	April 28, 1982
9	4-Chlorobenzotrifluoride	47 FR 50555	November 8, 1982
9	Chlorendic acid	47 FR 44878	October 12, 1982
9	Tris(2-chloroethyl) phosphite	47 FR 49466	November 1, 1982
10	1,2,4-Trimethylbenzene	48 FR 23088	May 23, 1983
10	Biphenyl	48 FR 23080	May 23, 1983
10	Ethyltoluene	48 FR 23088	May 23, 1983
10	Formamide	48 FR 23098	May 23, 1983
11	1,3-Dioxolane	48 FR 51839	November 14, 1983
11	4-(1,1,3,3-Tetramethylbutyl)phenol	48 FR 51971	November 15, 1983
11	Bis(2-ethylhexyl)terephthalate	48 FR 51845	November 14, 1983
11	Carbofuran intermediates	50 FR 29761	July 22, 1985
11	Dibutyltin bis(isooctyl maleate)	48 FR 51361	November 8, 1983
11	Dibutyltin bis(isooctyl mercaptoacetate)	48 FR 51361	November 8, 1983
11	Dibutyltin bis(laurel mercaptide)	48 FR 51361	November 8, 1983
11	Dibutyltin dilaurate	48 FR 51361	November 8, 1983

TABLE 2.—REMOVALS FROM THE TSCA SECTION 4(E) PRIORITY TESTING LIST—Continued

Report	Chemical/Group	Citation	Publication Date
11	Dimethyltin bis(isooctyl mercaptoacetate)	48 FR 5 361	November 8, 1983
11	Monobutyltin tris(isooctyl mercaptoacetate)	48 FR 51361	November 8, 1983
11	Monomethyltin tris(isooctyl mercaptoacetate)	48 FR 51361	November 8, 1983
11	Tris(2-ethylhexyl)trimellitate	48 FR 51824	November 14, 1983
12	2-Phenoxyethanol	49 FR 21407	May 21, 1984
12	Calcium naphthenate	49 FR 21411	May 21, 1984
12	Cobalt naphthenate	49 FR 21411	May 21, 1984
12	Lead naphthenate	49 FR 21411	May 21, 1984
12	Methylolurea	49 FR 21371	May 21, 1984
13	1,2,3,4,7,7-Hexachloronorbornadiene	49 FR 45654	November 19, 1984
13	Diethyleneglycol butyl ether acetate	49 FR 45606	November 19, 1984
13	Ethylene bis(oxyethylene) diacetate	49 FR 45651	November 19, 1984
13	Oleylamine	49 FR 45610	November 19, 1984
14	1,2-Dibromo-4-(1,2-dibromoethyl)cyclohexane	50 FR 19460	May 8, 1985
14	2-Ethylhexanoic acid	50 FR 20678	May 17, 1985
14	3,4-Dichlorobenzotrifluoride	52 FR 23547	June 23, 1987
14	Bisphenol A	50 FR 20691	May 17, 1985
14	Diisopropylbiphenyl	50 FR 18920	May 3, 1985
14	Isopropylbiphenyl	50 FR 18920	May 3, 1985
15	9,10-Anthraquinone	50 FR 46090	November 6, 1985
15	Chloroprene	50 FR 29761	August 26, 1985
15	Cumene	50 FR 46104	November 6, 1985
15	2-Mercaptobenzothiazole	50 FR 46121	November 6, 1985
15	Octamethylcyclotetrasiloxane	50 FR 45123	October 30, 1985
15	Pentabromoethylbenzene	50 FR 46785	November 13, 1985
15	Sodium *N*-methyl-*N*-oleoyltaurine	50 FR 46178	November 6, 1985
16	Methylcyclopentane	51 FR 17854	May 15, 1986
16	Tetrabromobisphenol A	51 FR 17872	May 15, 1986
16	Triethylene glycol monobutylether	51 FR 27883	May 15, 1986
16	Triethylene glycol monoethylether	51 FR 27883	May 15, 1986
16	Triethylene glycol monomethylether	51 FR 27883	May 15, 1986
17	Diisodecyl phenyl phosphite	54 FR 8112	February 24, 1989
18	2,6-Di-tert-butylphenol	52 FR 23862	June 25, 1987
18	Cyclohexane	52 FR 19096	May 20, 1987
19	Disperse blue dye 79 (bromo ethoxy substituted)	54 FR 48102	November 21, 1989
19	Methylethyl ketoxime	53 FR 35838	September 15, 1988
19	Tributylphosphate	52 FR 43346	November 12, 1987
20	Disperse blue dye (chloro ethoxy substituted)	54 FR 48102	November 21, 1989
20	Disperse blue dye (chloro methoxy substituted)	54 FR 48102	November 21, 1989
20	Disperse blue dye 79:1 (bromo methoxy substituted)	44 FR 48102	November 21, 1989
20	Ethylbenzene	53 FR 46262	November 16, 1988
20	Isopropanol	53 FR 8638	March 16, 1988
20	Methyl *tert*-butyl ether	53 FR 10391	March 31, 1988
21	Acid blue 40	53 FR 18196	May 20, 1988
21	Acid blue 45	53 FR 18196	May 20, 1988
21	Acid form of Acid blue 40	53 FR 18196	May 20, 1988
21	Acid form of Acid blue 45	53 FR 18196	May 20, 1988
21	Disperse blue 56	53 FR 18196	May 20, 1988
21	Disperse red 60	53 FR 18196	May 20, 1988
22	1,6-Hexamethylene diisocyanate	54 FR 21240	May 17 1989
23	Crotonaldehyde	54 FR 47062	November 9, 1989
25	1,2-Bis(2,4,6-tribromophenoxy)-ethane	56 FR 29140	June 25, 1991
25	Hexabromocyclododecane	56 FR 29140	June 25, 1991

TABLE 2.—REMOVALS FROM THE TSCA SECTION 4(E) PRIORITY TESTING LIST—Continued

Report	Chemical/Group	Citation	Publication Date
25	Pentabromodiphenyl ether	56 FR 29140	June 25, 1991
25	Octabromodiphenyl ether	5FR 29140	June 25, 1991
25	Decabromodiphenyl ether	56 FR 29140	June 25, 1991
26	4-Vinylcyclohexene	56 FR 47912	September 23, 1991

1.4 *The TSCA section 4(e) Priority Testing List.* Section 4(e)(1)(B) of TSCA directs the Committee to: "* * * make such revisions in the [priority] list as it determines to be necessary and * * * transmit them to the Administrator together with the Committee's reasons for the revisions." Under this authority, the Committee is revising the Priority Testing List by recommending one chemical and one chemical group. These revisions are listed in Table 1.

The Priority Testing List (Table 3) includes 26 chemicals and 21 chemical groups designated, recommended with intent-to-designate or recommended for testing. Individual chemicals in Priority Testing List chemical groups are listed in Table 1 or the paragraph following Table 1 of this and previous Reports with appropriate notes that minimize ambiguities related to TSCA section 8(a) and 8(d) reporting requirements. Tables 2 (Removals from the Priority Testing List) and 3 (the Priority Testing List) list the 124 chemicals and 39 chemical groups that have been recommended or designated for testing since the Committee's 1st Report in October 1977. Table 3 reads follows:

TABLE 3.—THE TSCA SECTION 4(E) PRIORITY TESTING LIST

Date	Entry	Action
May 1988	Ethoxylated quaternary ammonium compounds	Recommended
May 1988	Imidazolium quaternary ammonium compounds	Recommended
November 1988	Tetrakis(2-chloroethyl)ethylene diphosphate	Recommended with intent-to-designate
November 1988	Tris(1,3-dichloro-2-propyl) phosphate	Recommended with intent-to-designate
November 1988	Tris(1-chloro-2-propyl) phosphate	Recommended with intent-to-designate
November 1988	Tris(2-chloro-1-propyl) phosphate	Recommended with intent-to-designate
November 1988	Tris(2-chloroethyl)-phosphate	Recommended with intent-to-designate
November 1988	Butyraldehyde	Recommended
November 1989	Brominated flame retardants	Recommended
May 1990	Isocyanates	Recommended with intent-to-designte
May 1990	Brominated flame retardants	Recommended
May 1990	Alkyl phosphates	Recommended
November 1990	Sodium cyanide	Designated
November 1990	Acrylic acid	Designated
November 1990	Acetophenone	Designated
November 1990	Phenol	Designated
November 1990	*N,N*-Dimethylaniline	Designated
November 1990	Ethylacetate	Designated
November 1990	2,6-Dimethylphenol	Designated
November 1990	Aldehydes	Recommended with intent-to-designate
November 1990	2,4-Dinitrophenol	Recommended
November 1990	3,4-Dimethylphenol	Recommended
November 1990	*N*-phenyl-1-naphthylamine	Recommended
November 1990	Sulfones	Recommended
November 1990	Substantially produced chemicals in need of subchronic tests	Recommended
May 1991	Acetone	Designated
May 1991	*n*-Butanol	Designated
May 1991	Isobutanol	Designated
May 1991	Di-(2-ethylhexyl)adipate	Designated
May 1991	Dimethyl terephthalate	Designated
May 1991	Thiophenol	Designated
May 1991	*m*-Dinitrobenzene	Recommended
May 1991	Allyl alcohol	Recommended
May 1991	2,4-Dichlorophenol	Recommended

TABLE 3.—THE TSCA SECTION 4(E) PRIORITY TESTING LIST—Continued

Date	Entry	Action
May 1991	Alkynes	Recommended
May 1991	Nitroalcohols	Recommended
May 1991	Phosphoniums	Recommended
May 1991	Hydrazines	Recommended
May 1991	Oxiranes	Recommended
May 1991	Alkoxysilanes	Recommended
May 1991	Aldehyde hydrates	Recommended
May 1991	Propylene glycol ethers and esters	Recommended
May 1991	Methyl ethylene glycol ethers	Recommended
May 1991	Isothiocyanates	Recommended
May 1991	Cyanoacrylates	Recommended
November 1991	White phosphorus	Recommended
November 1991	Alkyl-, bromo-, chloro-, hydroxymethyl diarylethers	Recommended

Chapter 2—Recommendations of the Committee

2.1 *Chemicals recommended for priority consideration by the EPA Administrator.* As provided by section 4(e)(1)(B) of TSCA, the Committee is adding to the section 4(e) Priority Testing List one chemical and one chemical group (see Table 1). The recommendation of these chemicals is made after considering the factors identified in section 4(e)(1)(A) and other relevant information, such as the chemical testing data needs of Member Agencies.

2.2 *Designated chemicals.* None.

2.3 *Recommended with intent-to-designate chemicals.* None.

2.4 *Recommended chemicals—2.4.a White phosphorus.* White Phosphorus is recommended for testing based on concerns of the Department of Interior (DOI). DOI is concerned about and has few data on the persistence of white phosphorus in wetland sediments, the adverse effects of persistent white phosphorus to birds and wildlife that feed on sediments contaminated with white phosphorus, the potential for food chain effects and potential elimination of endangered species that may feed on carcasses of birds and wildlife that die from white phosphorus poisoning. The Department of Defense (DOD) is also concerned about the persistence and adverse effects of white phosphorus and has a task force that is developing a strategy for remediation of military sites contaminated with white phosphorus. The ITC is working with DOI and DOD to facilitate coordination of testing efforts and is aware of the Department of Transportation's regulation of white phosphorus as a flammable solid.

Summary of recommended studies. It is recommended that white phosphorus be tested for:

Chemical fate. Persistence in surface waters and sediments.

Health effects. None.

Ecological Effects. Toxicity to migratory birds and other wildlife.

White phosphorus

Physical and Chemical Information

CAS Number: 7723-14-0
Synonyms: Yellow phosphorus
Empirical Formula: P_4
Molecular Weight: 123.9
Physical State at 25 °C: Solid.
Description of Chemical: Colorless off white waxy solid, cubic crystals that spontaneously inflame in air at 30 °C. (Ref. 32, Windholz et al., 1983)
Melting Point: 44.1 °C
Vapor Pressure: 0.023 torr 25 °C (Ref. 26, Spanggord et al., 1985)1 atm at 76.6 °C (Ref. 3, Berkowitz et al., 1981)
Specific Gravity: Not Applicable
Log Octanol/Water
Partition Coefficient: 1200 ± 100 (Ref. 26, Spanggord et al., 1985)
Water Solubility at 25 °C: 4.1 mg/L (Ref. 26, Spanggord et al., 1985)
Log K_{oc}: 2,400 (Ref. 17, Lyman et al., 1990)
Henry's Law Constant: 2.1×10^{-3} atm m^3 $mole^{-1}$ at 25 °C.

Rationale for Recommendations

A. *Exposure information—Production/use/disposal/exposure/release.* In 1990, approximately 700 million pounds of white phosphorus were produced (Ref. 5, CMR, 1991); 1991 production is expected to be 792 million lbs (Ref. 27, SRI International, 1991).

Direct use of P_4 is mainly restricted to military applications (Ref. 30, Van Wazer, 1982); however, white phosphorus is commercially available for other applications such as in rodenticides (Ref. 23, Sax and Lewis, 1987). Otherwise white phosphorus is converted to phosphorus sulfides, halides, phosphorus pentoxide, phosphoric acid, and red phosphorus. The major uses of phosphorus compounds are in detergents, in the food and beverage industry and as fertilizers.

B. *Evidence for exposure—Human exposure.* The NOES conducted during 1981-83 by NIOSH reported that 135,453 workers (6811 females) were exposed to white phosphorus at 7,697 production and use facilities involving 83 occupations in 86 industries. The OSHA Permissible Exposure Limit for occupational exposure to white phosphorus is 0.1 mg/m^3 8-hour Time Weighted Average.

C. *Environmental exposure.* Catastrophic waterfowl mortality has been observed in the Eagle River Flats firing range, a salt marsh in Cook inlet in Alaska. Careful study of dying birds indicated that white phosphorus residues were present in their fat, gizzard contents and other digestive tissues, liver, skin, and breast muscle. White phosphorus was also found in the sediments on which they were feeding. Other munitions-derived chemicals were also found, but not at levels high enough to cause death. Feeding studies at levels similar to those found in the sediment produced death (Ref. 21, Racine et al., 1991). Other sites of exposure would be manufacturing operations and munitions packaging facilities. Direct release occurs during the production of white phosphorus (Ref. 15, Idler, 1969) and during the manufacture and combustion of white phosphorus/felt smoke-producing devices (Ref. 2, Bentley et al., 1978). During deployment of munitions, about 10 percent of the white phosphorus is not oxidized; thus it is

available for release in the environment (Ref. 26, Spanggord et al., 1985).

Test firing of U.S. Army munitions, especially smokes, into marshy areas may have serious consequences to waterfowl inhabiting these areas. A memorandum from the Regional Contaminants Coordinator (Region 7 - Alaska) describing the problem of white phosphorus in Eagle River Flats contained the following description (Ref. 22, Robinson-Wilson, 1991):

> White phosphorus is used in both flares and smokes by the U.S. Army. Shells are fired out over the impact area where they explode in the air, releasing the burning white phosphorus into the atmosphere. At ERF [Eagle River Flats], the falling particles of burning white phosphorus fall either onto snow or water, where they are quenched. Waterfowl, mainly dabbling ducks and swans, pick up white phosphorus particles during feeding. The particles are believed to have an oxidized coating and the birds are not exposed to the white phosphorus until the particles are ground up in their gizzards and released during digestion.

According to the TRI, 19,097 lbs were released to air, 11,569 lbs were discharged to water, 3,719,412 lbs were released to land, and 219,456 lbs were transferred to other off-site locations in 1988 (Ref. 29, TRI, 1991). In 1989, 16,174 lbs were released to air, 3,033 lbs were discharged to water, 3,291,402 lbs were released to land, and 85,573 lbs were transferred to other off-site locations (Ref. 29, TRI, 1991).

I. Chemical Fate Information

A. *Persistence.* In the few studies conducted near discharge sites, rapid dissipation out from the source was noted; however, it was determined in studies on the sediments from these locations that the surface deposits of a few parts per million probably oxidized quickly; whereas deeper deposits of higher concentrations could be stable for years (Ref. 1, Ackman et al., 1971; Ref. 26, Spanggord et al., 1985). This persistence is ascribed to the fact that most sediments are anaerobic a short distance below the surface, (Ref. 26, Spanggord et al., 1985; Ref. 8, Davidson et al., 1987; Ref. 28, Sullivan et al., 1979). This type of persistence is especially of concern to waterfowl which feed in these areas, since the particles of white phosphorus which are embedded in the sediment of the shallow water are believed to be ingested by ducks and swans.

B. *Rationale for chemical fate testing.* The U.S. Department of Interior is concerned about the fate of white phosphorus in sediments of a dabbling duck feeding environment. Release and persistence under these conditions is only poorly understood and further testing is needed.

II. Health Effects Information

The Committee is not recommending health effects testing at this time because it wants to review non-public health effects studies that may be submitted in response to the TSCA section 8(d) rule that EPA will publish for chemicals in the ITC's 29th Report.

A. *Metabolism and pharmacokinetics.* White phosphorus is rapidly absorbed from the digestive tract of mice, rats, and rabbits (complete within 24 hours). When radioactive P_4 is administered, radioactivity accumulates primarily in the liver, kidney, lung, bone, and skeletal muscle (Ref. 4, Cameron and Patrick, 1966; Ref. 13, Ghoshal et al., 1971; Ref. 16, Lee et al., 1975). Elimination is mainly via urinary excretion as inorganic and organic phosphates; some fecal elimination also occurs (Ref. 4, Cameron and Patrick, 1966; Ref. 16, Lee et al., 1975). It does not appear that white phosphorus is absorbed from the lungs or skin of laboratory animals (Ref. 7, Dalhamn and Holma, 1959).

There is no direct pharmacokinetic information for humans, but absorption from the digestive tract can be inferred by toxicity data (Ref. 20, Polson et al., 1983). There is no convincing evidence that white phosphorus is absorbed as a result of exposure by inhalation or dermal contact (Ref. 8, Davidson et al., 1987).

B. *Acute and subchronic (short-term) effects.* White phosphorus is highly toxic to humans and laboratory animals exposed by the oral route. Oral LD_{50} values for male and female rats are 3.76 and 3.03 mg/kg, and for male and female mice, 4.85 and 4.82 mg/kg, respectively (Ref. 16, Lee et al., 1975). The estimated minimal lethal oral dose in humans is 50 mg (0.7 mg/kg), but 15 mg (0.2 mg/kg) may cause serious toxicity (gastrointestinal, liver, renal, cardiovascular, and CNS effects) (Ref. 25, Sollman, 1957; Ref. 18, McCarron et al., 1981; Ref. 9, Diaz-Rivera et al., 1950).

Acute inhalation LC_{50} values for rats and mice are 1,400 and 660 mg/m^3, respectively. Because white phosphorus ignites spontaneously, (Ref. 30, Van Wazer, 1982), its contact with skin can cause serious burns. Dermal exposure of humans to white phosphorus via industrial accidents and on the battlefield has led to 3rd degree burns and death, massive hemolysis, and low plasma calcium (Ref. 31, Walker et al., 1947).

Young female rats fed diets containing median daily doses of white phosphorus of 0.075 mg/kg/day for 22 weeks showed severely depressed weight gain and weight loss, leading to a final weight less than the starting weight. Male rats fed 0.0027 mg per kg per day showed fluctuations in growth prior to the 15th week, but from the 15th to 25th week of exposure growth was rapid and was 13 percent above that of controls by the 25th treatment week (Ref. 24, Sollman, 1925).

C. *Genotoxicity.* White phosphorus was negative in Ames/*Salmonella* tests when evaluated as an undiluted saturated solution in distilled water; a concentration of up to 100 μL/plate in both the presence and absence of S9 fraction of liver did not induce increased incidence of mutations (Ref. 10, Ellis et al., 1978).

No data were located regarding the genotoxicity of white phosphorus in humans.

D. *Chronic toxicity.* Oral exposure of groups of 6 rats to 0.2, 0.4, 0.8, or 1.6 mg per kg per day of white phosphorus dissolved in peanut oil and mixed with stock diet for their lifetimes (up to 512 days) caused dose-related mortality. Retarded growth (effect level not reported) was believed due to inanition rather than systemic toxicity. Histopathological evaluation showed changes in the long bones (thickening of the epiphyseal line; extension of the trabeculae into the shaft). White phosphorus (0.05 mg per kg per day) dissolved in peanut oil and administered by subcutaneous injection to rats and guinea pigs for their lifetimes caused the same effects on bone, but to a lesser degree in the guinea pigs. Livers of these treated rats showed mild fatty degeneration, and lungs were also affected (bronchopneumonia, pneumonitis, bronchitis). These effects were not seen in guinea pigs (Ref. 11, Fleming et al., 1942).

Chronic exposure of humans to white phosphorus causes a characteristic lesion, necrosis of the jaw, which has been documented through numerous cases involving occupational exposure. In one study, the incidence of this condition was less than 5 percent of those exposed (Ref. 25, Sollman, 1957), and the estimated mortality rate from white phosphorus necrosis was about 20 percent, according to another study (Ref. 14, Hunter, 1969). Levels of exposure were not quantified.

E. *Reproductive and developmental effects.* Elemental yellow phosphorus was administered by gavage in corn oil to 8-week-old male and female rats in doses of 0, 0.005, 0.015, or 0.075 mg per kg per day for 80 days prior to mating, and continued through mating, gestation and lactation, then through a second

cycle from mating through lactation. Seven of the 30 high-dose females died during parturition, and hair loss was noted on both forelimbs of the high-dose males and females. No effects were seen on body weights or reproductive indices. No evidence of developmental toxicity was noted. The NOAEL was 0.015 mg per kg per day (Ref. 19, Monsanto, 1985).

No data were found on the reproductive or developmental toxicity of white phosphorus in humans.

III. Ecological Effects Information.

A. *Acute and subchronic (short-term) effects.* Both laboratory and field studies indicated that white phosphorus is highly toxic to aquatic organisms. The effluent from white phosphorus production contains both suspended and dissolved white phosphorus, and environmental release can occur from the combustion of munitions with remobilization from aquatic sediments as well as sinks in anaerobic soils. The LC_{50} values for five freshwater fish species range from 2.4 to 73 μg/L; the most sensitive species is *Lepomis macrochirus*. The LC_{50} values for five invertebrate species range from 30 to >560 μg/L; the most sensitive species is *Daphnia magna*. Available LC_{50} data for fish and invertebrates indicate that the toxicity of white phosphorus is cumulative. Single doses of 3 to 6 mg/kg have been reported to cause death in mallards and black ducks within 24 hours (Ref. 6, Coburn et al., 1950). A memo from the Regional Contaminants Coordinator (Region 7 - Alaska) describing the problem of white phosphorus in Eagle River Flats contained the following description (Ref. 22, Robinson-Wilson, 1991).

> Birds typically go through protracted convulsions before death, indicating a possible nervous system involvement. Birds that are affected are often taken by bald eagles and/or gulls before they die. However, few bald eagles or gulls have been found dead on ERF [Eagle River Flats] to date. ..[one] bald eagle was found and subsequent analysis of tissues found that WP [white phosphorus] was present. Since no data are available on WP toxicity in raptors and since no data exists on transfer of WP between trophic levels, we cannot state that WP was the toxic agent, but all the circumstantial evidence points to WP as the toxic agent.

B. *Chronic (long-term) effects.* Chronic white phosphorus exposure in *Pimephales promelas* reduced survival at 1.5 μg/L, and hatchability was reduced at 0.4 μg/L. In studies with macroinvertebrates, exposure to 8.7 μg/L reduced survival in *Daphnia magna* (Ref. 8, Davidson et al., 1987).

C. *Other ecological effects (biological, behavioral, or ecosystem processes).* The issue of wildlife toxicity was raised when it was discovered that a long-standing problem of waterfowl mortality at Eagle River Flats in Alaska was apparently being caused by the ingestion of particles of white phosphorus that had settled into marsh sediments. This has resulted in the death of 1000 to 2000 migratory dabbling ducks and 10 to 50 swans per year for the last 10 years (Ref. 21, Racine et al., 1991).

D. *Bioconcentration and Food-chain transport.* Bioconcentration in 3 species of fish ranged from 11.7 to 67.7 in muscle and from 51.5 to 2,000 fold in liver (Ref. 8, Davidson et al., 1987). In 6 species of invertebrates, bioconcentration ranged from 10.5 to 1,267 fold. In 2 species of seaweed the factor was 22.2 to 22.8 fold (Ref. 12, Fletcher, 1971).

E. *Rationale for ecological effects testing recommendation.* The U.S. Department of Interior is concerned about the toxicity of white phosphorus to migratory birds that seasonally reside on bodies of water containing white phosphorus particles in the water and in the sediment. Ecological effects testing is recommended because data are insufficient to reasonably determine or predict the toxicity of white phosphorus to migratory birds and other wildlife.

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2.4.b *Alkyl-, bromo-, chloro-, hydroxymethyl diaryl ethers.* The Committee is recommending 14 alkyl-, bromo-, chloro-, hydroxymethyl diaryl ethers for physical chemical property, biodegradation rate, health effects and ecological effects screening tests. These chemicals will allow the Committee to evaluate the persistence and toxicity of the diaryl ether substructure. Alkyl-, bromo-, chloro-, hydroxymethyl diaryl ethers are defined as any two aromatic rings joined by an oxygen (i.e., Ar-*O*-Ar where Ar is any aryl group) where there are alkyl, bromo, chloro or hydroxymethyl substituents on one or both of the aromatic rings or on a methyl group attached to one of the aromatic rings. One minor exception to this definition is an acetate ester of hydroxymethyl diaryl ether. This chemical was included because the Committee believed that the ester would be metabolized to the alcohol. The Committee is making this recommendation based on: (1) concerns for potential persistence and toxicity, (2) the paucity of publicly-available data for a majority of these chemicals, and (3) the need to carefully review any studies that may be submitted under TSCA section 8(d), before designating or withdrawing recommended testing for any of these diaryl ethers.

Several diaryl ethers were previously reviewed. Diphenyl oxide was previously nominated for oncogenicity testing by the National Cancer Institute's Chemical Selection Working Group. The chemical was not selected for testing, pending the results of industry testing (Helmes et al., 1983, Ref. 13). 1-Amino-4-hydroxy-2-phenoxy-9,10-anthraquinone was recommended in ITC's 21st Report. Penta-, octa- and decabromodiphenyl ethers were designated in the ITC's 25th Report. 3-Phenoxybenzaldehyde was recommended in the ITC's 27th Report. Benzenesulfonic acid, 4,4'-oxybis-, dihydrazide was recommended in the ITC's 28th Report.

The 14 chemicals being recommended at this time were selected from a TSCA Inventory group of 55 diaryl ethers that have the general formula Ar-*O*-Ar. Of the 55 diaryl ethers that were considered, all but 16 were eliminated on the basis of substructural characteristics which indicated they would be better considered along with other chemical groups such as xanthenes, anthraquinones, sulfonic acids, isoindoles, amino and nitro aromatics, etc. Nonabromodiphenyl ether was not recommended because the Committee wanted to review any data developed for bromodiphenyl ethers. 5-Chloro-2-(2,4-dichlorophenoxy) phenol was deferred because of pesticide uses.

The Committee hopes that manufacturers, processors, and users will voluntarily provide use, exposure, and release data not required under TSCA section 8(a). Uncertainties related to production, toxicity and persistence may be clarified after the Committee's review of the data obtained from the automatic 8(a) and 8(d) rules.

Summary of recommended studies. Testing recommendations for the 14 diaryl ethers listed in the paragraph following Table 1 are summarized in Table 1.

Physical and Chemical Information

The Committee found limited information on measured physical and chemical properties for the diaryl ethers listed in the paragraph following Table 1: four boiling points, one log octanol/water partition coefficient, three melting points, one water solubility, and one vapor pressure (Ref. 1, Aldrich, 1988; Ref. 2, Ambrose et al., 1976; Ref. 4, Banerjee et al., 1980; Ref. 5, Bein, 1985; Ref. 9, Dean, 1985; Ref. 12, Hansch and Leo, 1985; Ref. 24, Weast, 1985).

Rationale for Recommendation

A. *Exposure information—Production/use/disposal/exposure/release.* The Committee believes that the diaryl ethers listed in the paragraph following Table 1 are commercially available, and that some of them may be produced in substantial quantities. Composite production volume for this group exceeds 70 million pounds; actual production volumes are confidential business information.

Alkyl diaryl ethers are used as heat transfer fluids, resins for laminated electrical insulators, chemical intermediates and antioxidants; the bromodiaryl ether is used as an intermediate in production of pyrethroids; chlorodiaryl ethers are used as bacteriostatic and preservative agents for cosmetics and detergents (Ref. 7, Chemcyclopedia 91, 1990; Ref. 8, Dagani, 1985; Ref. 11, Gusten et al., 1973; Ref. 18, Sax and Lewis, 1987). No use information was found for the hydroxymethyl diaryl ethers.

B. *Evidence for exposure—Human exposure.* The National Occupational Exposure Survey (NOES) conducted during 1981-83 by NIOSH reported that 90,789 workers were potentially exposed to diphenyl oxide in 24 industries and 145 workers were potentially exposed to 1-methyl-3-phenoxybenzene in business services (Ref. 16, NIOSH, 1989). Only diphenyl oxide has an OSHA Permissable Exposure Limit.

C. *Environmental exposure.* Diphenyl oxide has been detected in 1 of 14 treated drinking water supplies (Ref. 10, Fielding et al., 1981) and detected at concentrations of 69 and 388 μg/L in wastewater extract from the organics and plastics industry, 12 μg/L from the plastics and synthetics industry, 18 μg/L

from rubber processing industry, 30 and 38 μg/L from the soaps and detergents industry, 35 μg/L from the electronics industry, and 1620 μg/L in wastewater extract from the organic chemicals industry (Ref. 6, Bursey and Pellizzari, 1982). Diphenyl oxide has been identified in wastewater, river and estuary water, and river, estuary and bay sediment (Ref. 14, Hites and Lopez-Avila, 1980).

I. Chemical Fate Information

The Committee searched published and unpublished chemical fate literature and found that there were studies on only one of the recommended diaryl ethers. In acclimated river water, diphenyl oxide (23.8 mg/L initial concentration) exhibited approximately 20 percent biodegradation under aerobic conditions during an 80 day incubation period (Ref. 15, Ludzack and Ettinger, 1963). In a review, diphenyl oxide was characterized as "unlikely to be removed during biological sewage treatment even after prolonged exposure" (Ref. 19, Thom and Agg, 1975). A degradation half-life in soil of 11 days was estimated from analysis of percolate groundwater samples; biodegradation is expected to be the primary fate process contributing to environmental degradation (Ref. 25, Zoeteman et al., 1981).

Alkyl-, bromo-, chloro-, hydroxymethyl diaryl ethers are recommended for physical and chemical property and biodegradation rate screening tests because there are insufficient data to reasonably determine or predict environmental persistence.

II. Health Effects Information

A search of published and unpublished health effects literature revealed that there were studies on six of the recommended diaryl ethers. The majority of health effects studies were published on diphenyl oxide or mixtures containing diphenyl oxide including: 18 oral, dermal and inhalation acute toxicity studies on 5 mammalian species (Ref. 17, RTECS 1991, Ref. 22, TSCATS 1991); 6 oral and inhalation prechronic studies on 3 mammalian species (Ref. 20, TOXLINE 1991); 9 genotoxicity studies, including those on mutagenicity in bacteria and yeast (Ref. 20, TOXLINE 1991, Ref. 22, TSCATS 1991), negative cytogenetics in hamsters (Ref. 22, TSCATS 1991), and DNA effects in rats (Ref. 22, TSCATS 1991); 1 negative developmental toxicity study in rats that used 77 percent diphenyl oxide and 33 percent biphenyl as the test substance (Ref. 20, TOXLINE 1991);1 positive developmental toxicity study in sea urchins (Ref. 20, TOXLINE); and 3 oral and intraperitoneal pharmacokinetics studies in rats (Ref. 20, TOXLINE 1991).

For the other five diaryl ethers recommended for testing [benzene, 1-methyl-3-phenoxy-; benzenemethanol, 3-phenoxy-; benzene, 1,1'-oxybis[methyl-; 1,1'-biphenyl, phenoxy-; benzene, 1(bromomethyl)-3-phenoxy-], there were 7 oral and dermal acute toxicity studies on 4 mammalian species (Ref. 20, TOXLINE 1991, Ref. 21, TOXLIT 1991, Ref. 17, RTECS 1991); 2 prechronic studies in rats (Ref. 22, TSCATS 1991, Ref. 20, TOXLINE 1991); and six genotoxicity studies, including those on mutagenicity in bacteria and cytogenetics in mice (Ref. 21, TOXLIT 1991, Ref. 20, TOXLINE 1991).

Alkyl-, bromo-, chloro-, hydroxymethyl diaryl ethers are recommended for health effects screening tests (except for diphenyl oxide) because there are insufficient data to reasonably determine or predict health effects.

III. Ecological Effects Information

Except for acute aquatic toxicity data for diphenyl oxide (LC_{50} values ranged from 3 to 4 mg/L for freshwater fish and 0.67 to 1.4 mg/L for freshwater invertebrates, Ref. 3, AQUIRE 1991) and 3-phenoxy-benzenemethanol (EC_{50} values ranged from 1.4 to 95.0 mg/L for freshwater algae, Ref. 3, AQUIRE 1991), no ecological effects testing information was located for the other 12 diaryl ethers.

Alkyl-, bromo-, chloro-, hydroxymethyl diaryl ethers are recommended for ecological effects screening tests because there are insufficient data to reasonably determine or predict ecological effects.

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Monday
December 30, 1991

Part X

Department of Health and Human Services

Food and Drug Administration

21 CFR Chapter I

Withdrawal of Certain Pre-1986 Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. 91N-0300]

Withdrawal of Certain Pre-1986 Proposed Rules; Final Action

AGENCY: Food and Drug Administration, HHS.

ACTION: Withdrawal of proposed rules.

SUMMARY: The Food and Drug Administration (FDA) announces that it is withdrawing 89 proposed rules that were published in the **Federal Register** on or before December 31, 1985. In many cases, these proposals have been superseded by subsequent actions or events or no longer reflect the agency's regulatory objectives or priorities. In other cases, sufficient time has elapsed that it would be appropriate to publish a new proposal or tentative final rule before proceeding to final action. Accordingly, the agency concludes, after considering the public comments submitted in response to a notice published in the **Federal Register** of August 28, 1991 (56 FR 42778) announcing its intent to withdraw 115 proposed rules, that further action to issue final rules based on 89 of these proposals is not warranted, and that the proposals should be formally withdrawn. The agency also announces that it is deferring a decision on withdrawal of 26 of the 115 proposals listed in that notice of intent.

DATES: The proposed rules are withdrawn on December 30, 1991.

FOR FURTHER INFORMATION CONTACT: Robert L. Spencer, Office of Policy, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3480.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the **Federal Register** of August 28, 1991 (56 FR 42668), FDA announced that it had begun a comprehensive review of the agency's regulations process, including a review of the backlog of advance notices of proposed rulemaking, notices of proposed rulemaking, and other notices for which no final rule or notice of withdrawal has been issued. The review was begun partly in response to criticism that the agency's backlog of pending proposals dilutes the agency's ability to concentrate its attention on higher priority regulations mandated by statute or necessary to protect public health.

As a first step, FDA reviewed all of the proposals that the agency published in the **Federal Register** prior to December 31, 1985, but for which no final rules or notices of withdrawal have been published. The agency then tentatively concluded that 115 of these pre-1986 proposals should be withdrawn. The August 28, 1991, notice of intent (hereafter referred to as the notice of intent) identified these 115 pre-1986 proposals and invited interested persons to submit comments on FDA's intent to withdraw these proposals.

FDA received 34 written comments regarding the agency's intent to withdraw the 115 pre-1986 proposed rules. These comments were from a member of Congress, consumer organizations, trade associations, professional associations, law firms, consultants, individuals and commercial organizations. The comments generally supported the agency's efforts to withdraw the pre-1986 proposals; however, the comments requested additional procedures to provide for increased opportunity for public comment on the proposed withdrawals. Many of the comments concerned one or more of the specific proposals identified for withdrawal in the notice of intent. The comments specifically addressed 30 of the 115 proposals listed in the notice of intent; no specific comments were received regarding the other 85 proposals listed in the notice. The agency is deferring action on 9 of the 85 proposals on which no comments were received as well as 17 of the proposals on which comments were received.

The following is a summary of the comments received and the agency's response to these comments.

II. Summary of and Responses to Comments

A. General Comments

1. Six of the comments submitted expressed general support for FDA's action to withdraw pre-1986 proposed rules that have low priority or are outdated. One of these comments suggested that FDA consider the withdrawal of any proposal that is more than 4 years old because, with the advances being made in understanding the toxicology of chemical substances, issues more than 4 years old may well be scientifically and technically outdated. Another comment stated that, because of the long time that elapsed since the proposals were published, circumstances require a reexamination of these proposals to determine whether they are relevant and whether the factual basis and applicable science and policy still apply. Still another of these comments suggested that, in the future, FDA should not initiate proposed rulemaking unless it intends to complete the rulemaking in a timely manner.

As noted in the preamble to the notice of intent (56 FR 42668), FDA agrees that many of these pre-1986 proposals have become outdated in the time that has elapsed since their publication and that, before the agency could proceed further, it would be necessary to reexamine the factual and scientific bases for the proposals, the agency would publish a new proposal or tentative final rule before proceeding to final action.

The agency disagrees, however, with the comment that the agency should consider withdrawing a proposal solely on the basis of age, e.g., if it is more than 4 years old. Although the amount of time that has elapsed since publication of the proposal should be one of the criteria used in an initial screening of proposals for consideration to withdraw, a final decision to withdraw a proposal or to proceed to final rulemaking must address other factors including, but not limited to, statutory requirements and the public health.

The agency also agrees in principle with the comment that the agency should not initiate proposed rulemaking unless it intends to complete the rulemaking in a timely manner. Although the need for a particular rule may change with changes in the circumstances that caused the agency to initiate the rulemaking proceeding, the agency intends in the future to adhere to the general principle that any rulemaking activity important enough to initiate is important enough to be accompanied by a plan, timetable, and agency-level commitment sufficient to ensure its timely completion. This goal of timely completion includes not only the promulgation of a final rule but also recognizing when the time has come to withdraw a proposal.

2. One comment asked that FDA clarify that it is not disavowing any positions or standards established in the proposed rules the agency intends to withdraw.

Preambles to proposed rules are advisory opinions under 21 CFR 10.85(d) until they are amended or revoked. The agency's withdrawal of the pre-1986 proposals listed below constitutes a revocation of these preambles as advisory opinions under 21 CFR 10.85(g). As FDA acknowledged in the notice of intent, some of the withdrawn proposals still reflect current agency views and thus may still provide useful guidance. However, the withdrawn proposals no longer necessarily represent the formal position of FDA, and do not bind or

otherwise obligate or commit the agency to the views expressed. Interested persons who believe that guidance provided in the preambles to the withdrawn proposals should be restated in the form of an advisory opinion should submit a request for an advisory opinion as provided in 21 CFR 10.85.

3. One comment asked that FDA reconsider the approach taken in inviting public comment on the agency's notice of intent to withdraw proposed rules. The comment suggested that FDA should describe the substance of the proposal at issue so that the public could intelligently comment on the agency's action. Another comment stated that the mere publishing of the titles and other references provides little assistance to persons reviewing the list of pre-1986 proposals, particularly where some of the proposals were more than 30 years old. This comment suggested that it would have been helpful if FDA had included brief summaries of the essence of the proposals on the withdrawal list, and possibly the reasons for their proposed withdrawal.

The notice of intent identified each of the proposals being considered for withdrawal by title, docket number, and the **Federal Register** publication date and cite. The agency believes that, in almost all cases, the title described the substance of the proposed rule sufficiently to allow readers to make an initial determination as to whether the proposed withdrawal might affect an issue in which they were interested. Any interested person could obtain additional, detailed information by reading the specific proposal in the cited **Federal Register** issue.

In addition, to assist persons interested in obtaining additional information about a certain proposal, the agency included in the notice the name, address, and telephone number of an agency contact. This employee was prepared to answer any questions and to provide copies of each of the listed proposals upon request.

The agency considered providing more information concerning the substance of each of the 115 proposals in the notice of intent. FDA believed, however, that persons interested in commenting would want to read the underlying proposals themselves, regardless of how detailed a summary the agency had provided in the notice of intent. In the end, the agency decided to move ahead with this initiative to reduce the backlog of pre-1986 proposals in a manner it judged to be efficient, expeditious, and more than adequately protective of the interests of affected parties. Based on the comments received, it appears that interested persons understood the intent of the notice and were able to formulate comments addressing their concerns.

Any person who believes that the subject of a withdrawn proposal still should be addressed by regulation is free to petition the agency to recommend rulemaking. Any such petition must be in accordance with § 10.30 (21 CFR 10.30) or other applicable FDA procedure and must present the legal, factual, and public health rationale for devoting FDA resources to the promulgation of such a rule.

4. One comment recommended that FDA make copies of the proposals listed in the notice of intent available to the public for a period of 1 year before removing the proposed regulations. Alternatively, the comment requested that the comment period for eight specific proposals remain open for a period of not less than 90 days to allow interested persons to review the substance of the proposals and present comments if appropriate.

Copies of all of the proposals listed in the notice of intent have been available to the public at all times since the documents were published in the **Federal Register**. Any member of the public may visit FDA's Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday, and review and/or obtain copies of all proposed rules, received comments, and other reference materials. After reviewing these documents, interested persons may submit comments on the proposals or on the received comments.

Because the 115 proposals listed in the notice of intent to withdraw have been available to the public for more than 5 years, and in some cases for more than 25 years, the agency believes that it would unnecessarily delay final action to withdraw these pre-1986 proposals the comment period was extended as requested in the comment.

5. One comment stated that it is not appropriate to withdraw a proposed rule simply because it is more than 6 years old and has not been designated as high priority. The comment added that each proposal should be considered independently, to be pursued if it has merit and withdrawn if it does not.

The proposals listed in the notice of intent were not proposed for withdrawal simply because they were published in the **Federal Register** before 1986. Each of the pre-1986 proposals, including those that were not included in the notice of intent, was reviewed on its merits by the appropriate program officials in each of FDA's Centers, by the Office of the General Counsel, and by other senior agency officials. The intent of the notice was not to withdraw proposed rules simply on the basis of age. Although the notice was confined to announcing the agency's intent to withdraw only proposed rules that had been published prior to 1986, the date of publication was not the sole or most important criterion for inclusion in the notice.

The agency had initially identified a larger number of pre-1986 proposals, all of which were considered for withdrawal. Where reviewers determined that further agency action to issue a final rule based on the pre-1986 proposal might be appropriate, the proposal was deleted from the list of proposals included in the notice of intent. Only those pre-1986 proposals that the agency found not to warrant the issuance of a final rule based on the proposal were included in the final list published in the notice of intent.

B. Specific Comments

The agency received specific comments concerning 30 of the 115 proposals listed in the notice of intent. These comments generally supported FDA's action to withdraw 11 of these 30 proposals and objected to FDA's action to withdraw 19 of these 30 proposals.

The specific comments received regarding these 30 proposals and the agency's response are as follows:

1. Methyl Salicylate; Oil of Wintergreen; Notice of Proposal to Establish Tolerance for Residues—Docket No. 91N-0301—September 26, 1962, 27 FR 9521.

One comment supporting the withdrawal of this proposal argued that data demonstrate that methyl salicylate is generally recognized as safe (GRAS) under its intended conditions of use, that FDA is fully justified in withdrawing this 1962 proposal, and that no further action is warranted.

FDA is withdrawing this proposal. Although FDA agrees that the proposal should be withdrawn, the agency's decision is not based on the merits of the argument that methyl salicylate (oil of wintergreen) is GRAS. The agency has not yet made such a determination. The agency's decision to withdraw this 1962 proposal is because the agency would initiate new notice and comment rulemaking before proceeding further in any determination concerning the GRAS status of methyl salicylate. The agency would not issue a final rule based solely on the proposal, which was issued almost 30 years ago.

2. Xylitol; Proposed Revocation of Food Additive Regulation—Docket No. 89-0421—October 20, 1971, 36 FR 20306.

One comment from a commercial organization stated that the firm previously had an interest in this product for many years and had made a number of submissions to the Agency in connection with this proposed rule to revoke the food additive regulation providing for the use of xylitol in foods for special dietary use. The comment added that the firm no longer has a commercial interest in this product and supports withdrawal of the 1971 proposal. The comment suggested, however, that FDA should consider revising 21 CFR 172.395 to include additional uses of xylitol in candies, chewing gums, jams, and jellies.

FDA has decided to defer a decision as to whether this proposal should be withdrawn. Although the only comment received regarding this specific proposal supports the agency's initial decision to withdraw it, the agency has reconsidered the issues involved. In a future issue of the Federal Register, FDA will either publish a final rule based on the proposal, repropose the amendment in a new rulemaking proceeding, or withdraw the proposal.

3. Legal Status of Approved Labeling for Prescription Drugs; Prescribing for Uses Unapproved by the Food and Drug Administration—Docket No. 91N–0312—August 15, 1972, 37 FR 16503.

After further examination of this proposal, the agency, on its own initiative, has decided not to withdraw this proposed rule at this time. Although the agency does not intend to proceed to a final rule on the basis of this 1972 proposed rule, the agency has established an Unlabeled Use Task Force to examine the promotion and use of prescription drugs for indications not included in their approved labeling. (The agency's position concerning the veterinary use of human drugs is set forth in Compliance Policy Guide 7125.35 "Human Drugs Distributed to Veterinarians for Animal Use.") Therefore, the agency will defer consideration on the withdrawal of this proposed rule until after the task force has completed its review.

4. Infant Foods; Percentage Declaration of Ingredients—Docket No. 76P–03290–September 7, 1976, 41 FR 37595; and,

5. Infant and Junior Foods; Establishment of Common or Usual Name—Docket No. 76P–0330–September 7, 1976, 41 FR 37593.

One consumer organization objected to the withdrawal of these two proposed rules to require percentage-ingredient labeling of baby foods and a percentage declaration of the characterizing ingredient(s) as part of the common or usual name of such foods. The comment urged FDA to finalize these two proposals instead of rescinding them.

FDA does not intend to issue final rules on the basis of these two proposals and, therefore, has decided to withdraw the proposed rules. As noted in the preamble to the notice of intent (56 FR 42668), this action does not mean that the agency has no interest in the issues concerning percentage-ingredient labeling of baby foods. The agency is in the process of reviewing and revising all food labeling, in part in response to the Nutrition Labeling and Education Act of 1990. If the agency decides to proceed further to require percentage-ingredient labeling for baby foods, it will do so through new notice and comment rulemaking.

6. Saccharin and Its Salts—Docket No. 76N–0510—January 7, 1977, 42 FR 1486; and,

7. Saccharin and Its Salts—Docket No. 77N–0065—April 15, 1977, 42 FR 19996.

Two comments supported the withdrawal of these two proposals. The first proposal was to amend the interim food additive regulation for saccharin and its salts to establish a tolerance for toluenesulfonamide of 25 parts per million. The second proposal would ban the use of saccharin and its salts in foods, drugs, and cosmetics. These comments asserted that the safety of saccharin is no longer of concern and that these 1977 proposals have become outdated. One comment from a consumer organization asked the agency to keep the docket on these two proposals open for at least 90 days to allow for additional public comments if appropriate.

While not addressing the issue concerning the safety of saccharin and its salts, the agency has decided to withdraw these two proposals. The Saccharin Study and Labeling Act enacted on November 23, 1977, prohibited for 18 months any new regulations restricting or banning the sale of saccharin or products containing it. Congress has extended the legislative moratorium several times. Most recently, it was extended to May 1, 1992. Even if it were not extended further, the agency would have to consider any new data concerning the safety of saccharin and its salts and initiate new rulemaking proceedings prior to taking any action to alter the regulatory status of saccharin. This decision to withdraw these two 1977 proposals does not preclude the agency from reproposing a ban or other restrictions on the use of saccharin and its salts at a later date should such action be warranted.

8. Over-the-Counter Drugs; General Conditions for Use and Labeling of Inactive Ingredients—Docket No. 77N–0010—April 12, 1977, 42 FR 19156.

One comment objected to FDA's proposal to withdraw this proposal to amend regulations which establish the general conditions for use of inactive ingredients in over-the-counter (OTC) drug products so that these products are generally recognized as safe, effective, and not misbranded. The comment stated that the proposed rule has become an industry standard for the 15 years since it was first proposed. The comment added that inactive ingredient manufacturers and users have a problem with uncertainty as to the regulatory status of inactive ingredients that will be exacerbated if the proposed rule is withdrawn.

FDA concludes that the proposed rule should not be withdrawn at this time. FDA agrees with the comment that the principles set forth in the proposed rule have utility and should be retained in some manner. The agency intends to reevaluate the issues addressed in the proposed rule and determine whether to proceed with the rulemaking, repropose the requirements and provide new opportunity for comment, or to withdraw the proposed rule.

9. Ionizing Radiation Therapy Equipment; Notice of Intent to Propose Rules and Develop Guidelines—Docket No. 77N–0031—March 22, 1977, 42 FR 15428;

10. X-Ray Intensifying Screens; Intent to Develop a Radiation Protection Recommendation—Docket No. 78N–0074—June 2, 1978, 43 FR 24066;

11. Diagnostic Ultrasound Equipment; Intent to Propose Rules and Develop Regulations—Docket No. 78N–0288—February 13, 1979, 44 FR 9542; and

12. Procedures to Minimize Medical X-Ray Exposure of the Human Embryo and Fetus; Recommendations for Medical Radiation Exposure of Women of Childbearing Potential—Docket No. 75N–0340—November 20, 1979, 44 FR 66616.

Two professional associations supported FDA's action to withdraw these four proposals for which final rules were never developed. One of these comments stated that other FDA regulations and Nuclear Regulatory Commission regulations have significantly improved radiation equipment safety and superseded the need to develop regulations concerning ionizing radiation therapy equipment.

The agency agrees that these four proposals, three of which were only announcements of FDA's intent to issue proposed rules, should be withdrawn. If the agency decides that rulemaking is

required in the future, it will initiate new proceedings.

13. Butylated Hydroxytoluene; Use Restrictions—Docket No. 77N–0003—May 31, 1977, 42 FR 27603.

One consumer organization urged FDA to ban the use of the food preservative butylated hydroxytoluene (BHT) until its safety has been established. The comment stated that conflicting and inconclusive studies regarding BHT's safety demand that FDA reappraise the safety of this food additive.

The agency is deferring a decision as to the withdrawal of this proposal. Although the 1977 proposal would have restricted the use of BHT as a direct and indirect food additive and not have banned the use of BHT as requested in the comment, the agency is in the process of reviewing the conflicting data and information it has received concerning the safety of BHT. After further review of this data and information concerning the safety of BHT, the agency will either initiate a new rulemaking proceeding or withdraw the 1977 proposal.

14. New Drugs for Investigational Use; Prompt Reporting of Animal Studies and Data—Docket No. 77N–0059—July 15, 1977, 42 FR 36490.

One consumer organization asked that FDA keep the docket on this proposal open for at least 90 days to allow the organization and other interested parties to review the substance of the proposal and present comments if appropriate.

The agency has decided to withdraw this proposed rule. The proposal was intended to ensure prompt reporting of animal studies and data following the submission of an investigational new drug application. The proposed requirements are superseded by the existing regulations at 21 CFR Part 312—Investigational New Drug Applications. Requirements for reporting of animal studies and data are set forth under §§ 312.23(a)(8), 312.32, and 312.33.

15. Skim Milk Cheese for Manufacturing; Proposal to Amend Identity Standard—Docket No. 77P–0071—October 4, 1977, 42 FR 53979.

One consumer organization asked that FDA keep the docket on this proposal open for at least 90 days to allow the organization and other interested parties to review the substance of the proposal and present comments if appropriate. The commercial organization that filed the petition on which this proposal was based did not submit comments on the notice of intent to withdraw this proposal.

The agency has decided to withdraw this 1977 proposal to amend the identity standard for skim milk cheese for manufacturing. The amendment would have provided for the use of skim milk cheese in producing lower fat cheese products. The agency's decision to withdraw the proposal is based primarily on the time that has elapsed since the proposal was issued and the apparent lack of interest on the part of the petitioner to pursue this action. In addition, circumstances have changed with the publication on November 27, 1991, of a proposed amendment to FDA's standard of identity regulations that will reduce regulatory barriers to the marketing of low fat substitutes for standardized cheese products (56 FR 60512). The agency's decision to withdraw the proposal does not, however, address the merits of the use of skim milk cheese in producing lower fat cheese products. If the agency, on its own initiative or in response to a new petition, decides that an amendment to the food standards regulations is warranted, it will initiate new rulemaking proceedings.

16. Sorbic Acid and Its Salts; Proposed Affirmation and Deletion of GRAS Status—Docket No. 77G–0379—March 10, 1978, 43 FR 9823.

One commercial organization urged the agency to complete this proposed rulemaking to affirm potassium sorbate and sorbic acid as GRAS as direct human food ingredients, to delete calcium and sodium sorbates from the GRAS list, and to amend the standards of identity for some cheeses, fruit jellies, jams and preserves, and margarine. The comment argued that sufficient scientific data were submitted to FDA on the safety of sorbic acid and its potassium salt during the rulemaking to enable the agency to affirm the GRAS status of these direct food additives for use as chemical preservatives. The firm stated that it was unaware of any new safety information on the calcium and sodium salts or on the stability of the sodium salt of sorbic acid to alter the agency's earlier conclusion that the GRAS status of calcium and sodium sorbates should be revoked.

The agency has reconsidered the issues involved in the agency's GRAS review program and has decided to defer a decision as to whether this proposal should be withdrawn. In a future issue of the **Federal Register**, FDA will publish a final rule based on the proposal, repropose the amendment in a new rulemaking proceeding, or withdraw the proposal.

17. Ethylene Oxide, Ethylene Cholohydrin, and Ethylene Glycol; Proposed Maximum Residue Limits and Maximum Daily Levels of Exposure—Docket No. 77N–0424—June 23, 1978, 43 FR 27474.

Two comments from commercial organizations objected to FDA's action to withdraw this proposal to impose restrictions on the continued use of ethylene oxide as a sterilant for certain drug products and medical devices for human use. The comments stated that this proposed rule is commonly used by medical device manufacturers as a guideline for product residual levels and patient exposure limits. The comments also stated that elimination of this guidance would not only serve to create chaos in the regulatory review process (both domestic and international) and in product development activities as well. The comments urged FDA to maintain its acceptance of the 1978 residue limits until such time as appropriate guidance documents can be issued. One of these comments, noting the shortcomings of the 1978 proposal, suggested that the International Standards Organization document developed by ISO/TC 198 and ISO/TC 194, "Sterilization of Health Care Products," be used as a reference document for establishing product residual levels.

FDA has decided to defer its decision to withdraw this proposal. The agency is evaluating toxicological studies on the affects of ethylene oxide residuals conducted subsequent to the issuance of the proposal. In addition, FDA is considering the utility of international standards already being proposed in this area as an alternative to promulgation of an agency rule. The decision concerning the necessity of an FDA rule will await the outcome of that process which is not expected to be completed until early 1993. Therefore, FDA's decision to issue a final rule based on the proposal and the received public comments; to repropose the rulemaking proceeding based on the toxicological studies conducted subsequent to the issuance of the proposal; or to withdraw the proposal will be announced in a future issue of the **Federal Register**.

18. Common or Usual Names for Vegetable Protein Products and Substitutes for Meat, Seafood, Poultry, Eggs, or Cheese Which Contain Vegetable Protein Products as Sources of Protein; Tentative Final Rule—Docket No. 75N–0205—July 14, 1978, 43 FR 30472.

One trade association supported FDA's announced intent to withdraw this tentative final regulation to establish common or usual names for all use of vegetable protein products. The comment stated that 13 years of experience, in which significant advances have been made in the utilization of soy proteins, have

reconfirmed that the tentative final regulation is not workable (in whole) or desirable.

Without addressing the merits of the comment, FDA agrees that the tentative final rule should be withdrawn. The agency's decision to withdraw this 1978 tentative final rule is based on the time that has elapsed since publication of the tentative final rule. If the agency determines that rulemaking is warranted, it will initiate a new proceeding.

19. Tocopherols and Derivatives; Proposed Affirmation of GRAS Status for Certain Tocopherols and Removal of Certain Others from GRAS Status as Direct Human Food Additives—Docket No. 78N-0213—October 27, 1978, 43 FR 50193.

Three comments supported the agency's action to withdraw this proposal to affirm the GRAS status of certain tocopherols and derivatives as direct human food ingredients and to remove certain other tocopherols and derivatives from GRAS status as direct human food ingredients provided that this withdrawal does not constitute a finding that these tocopherol forms are not GRAS as human food ingredients.

The agency has reconsidered the issues involved in the agency's GRAS review program and has decided to defer a decision as to whether this proposal should be withdrawn. In a future issue of the **Federal Register**, FDA will either publish a final rule based on the proposal, repropose the amendment in a new rulemaking proceeding, or withdraw the proposal.

20. Cellulose Derivatives; Affirmation of GRAS Status—Docket No. 78N-0144—February 23, 1979, 44 FR 10751.

Four comments objected to FDA's intent to withdraw this proposal to affirm the GRAS status of cellulose derivatives and urged FDA to complete the rulemaking proceeding. These comments stated that sufficient data have been submitted to establish the safety of cellulose and to allow the agency to issue a final rule affirming the GRAS status of cellulose derivatives.

The agency has reconsidered the issues involved in the GRAS status of cellulose derivatives and has decided to defer a decision as to whether this proposal should be withdrawn. Among the issues that the agency is considering is whether dioxins or furans that may be formed during the bleaching of cellulose for paper may be present in cellulose or cellulose derivatives intended for food additive use. In a future issue of the **Federal Register**, FDA will either publish a final rule based on the proposal, repropose the amendment in a new rulemaking proceeding, or withdraw the proposal.

21. Requirements for Estrogen Labeling Directed to Patients—Docket No. 78N-0303—April 17, 1979, 44 FR 22752.

One consumer organization asked that the docket for this proposal remain open for at least 90 days to allow interested persons to review the substance of the proposal and present comments if appropriate to the FDA.

FDA is withdrawing this proposal. This proposed rulemaking would have exempted distribution of estrogen patient warning labeling to male patients and would have allowed distribution of the labeling after administration of the drug when, at the time of administration, the patient is unable to read and understand the labeling because of impaired consciousness. The agency has seen no sustained interest in this issue from physicians or pharmacists. If the agency in the future decides that a regulation is required, it will initiate a new rulemaking proceeding.

22. Lakes of Color Additives; Intent to List—Docket No. 79N-0043—June 22, 1979, 44 FR 36411.

Two trade associations and an individual objected to FDA's announced intent to withdraw this 1979 advance notice of proposed rulemaking announcing its intention to propose regulations concerning lakes of color additives. The comments argued that substantial years of work by the industry to resolve issues concerning this matter with FDA would be wasted if the proceeding were substantially delayed. One comment argued that agency action concerning the issue is one that must eventually be addressed in a rulemaking proceeding.

The agency has decided not to withdraw this advance notice of proposed rulemaking at this time.

23. Caffeine; Deletion of GRAS Status; Proposed Declaration That No Prior Sanction Exits, and Use on an Interim Basis Pending Additional Study—Docket No. 80N-0418—October 21, 1980, 45 FR 69817.

One consumer organization opposed recision of this proposal that would, among other things, delete caffeine used as an added food ingredient from the list of substances that are GRAS and declare that no prior sanction exists for the use of caffeine as an added food ingredient. The comment stated that there is evidence to suggest that the consumption of caffeine interferes with reproduction and urged FDA to revive its program to alert pregnant women to the dangers proposed by caffeine.

The agency agrees that the proposal should not be withdrawn at this time. The Agency will defer its decision until such time as it has reviewed all data and information it has received concerning the safety of caffeine. The agency then will either issue a final rule based on the proposal and the received comments, repropose a rule concerning the use of caffeine as a food ingredient, or withdraw the proposal.

24. Ascorbic Acid and Its Sodium and Calcium Salts, Erythorbic Acid and Its Sodium Salt, and Ascorbyl Palmitate; Proposed Affirmation of GRAS Status and Removal of Calcium Ascorbate From the List of GRAS Ingredients—Docket No. 82N-0246—January 14, 1983, 48 FR 1735.

One commercial organization suggested that this proposal to affirm that ascorbic acid and sodium ascorbate, its sodium salt; erythorbic acid and sodium erythorbic acid and sodium erythorbate, its sodium salt; and ascorbyl palmitate are GRAS as direct human food ingredients not be withdrawn. This comment added that this proposal remains the most recent FDA statement that the agency regards sodium erythorbate as GRAS and asked that the proposal not be withdrawn until further action by FDA with respect to GRAS affirmation of erythorbates. One other commercial organization stated that, although it would not object to the withdrawal of this proposal, if the agency decides at some point to reinstate the GRAS affirmation procedure for these ingredients, the agency should consider the comments submitted to the agency in response to the original proposal.

FDA has decided to defer its decision to withdraw this GRAS proposal. FDA's decision to issue a final rule based on the proposal and the received public comments, to repropose the rulemaking proceeding, or to withdraw the proposal will be announced in a future issue of the **Federal Register**.

25. Biotin; Proposed Affirmation of GRAS Status—Docket No. 78N-0308—January 14, 1983, 48 FR 1739.

One commercial organization stated that it has no objection to the withdrawal of this proposal to affirm that biotin is GRAS as a direct human food ingredient because the regulation at 21 CFR 182.8159 is quite adequate. The comment added, however, that if the agency decides at some point to reinstate a GRAS affirmation proposal for biotin, the agency should consider the comments that the firm submitted in response to the original proposal.

FDA has decided to defer its decision to withdraw this GRAS proposal. FDA's

decision to issue a final rule based on the proposal and the received public comments, to repropose the rulemaking proceeding, or to withdraw the proposal will be announced in a future issue of the Federal Register.

26. Glycerin; Affirmation of GRAS Status as a Direct Human Food Ingredient—Docket No. 78N-0348, February 8, 1983, 48 FR 5758.

One commercial organization commented on this proposal to affirm glycerin as GRAS as a direct human food ingredient. The firm stated that it had responded to all FDA requests for information concerning the synthetic glycerin it produced in compliance with 21 CFR 182.1320 and other applicable regulations. These requests began in 1989 and the most recent submission was March 11, 1991. The firm stated that this information was provided at significant cost to the firm and that it was puzzled by the decision to withdraw this proposed rule when the review was quite active.

FDA has decided to defer its decision to withdraw this GRAS proposal. FDA's decision to issue a final rule based on the proposal and the received public comments, to repropose the rulemaking proceeding, or to withdraw the proposal will be announced in a future issue of the Federal Register.

27. Regenerated Collagen; Proposed GRAS Status as a Direct Human Food Additive—Docket No. 82N-0219—April 26, 1983, 48 FR 18833.

Two commercial organizations urged FDA to complete this rulemaking procedure to affirm that regenerated collagen is GRAS as a direct human food ingredient. These comments stated that a codified regulation for regenerated collagen would serve the needs of U.S. industry and protect the public from regenerated collagen produced in a manner different from the specifications in the GRAS affirmation proposal.

FDA has decided to defer its decision to withdraw this GRAS proposal. FDA's decision to issue a final rule based on the proposal and the received public comments, to repropose the rulemaking proceeding, or to withdraw the proposal will be announced in a future issue of the Federal Register.

28. Protein Hydrolysates and Enzymatically Hydrolyzed Animal (Milk Casein) Protein; Proposed GRAS Status—Docket No. 82N-0008—December 8, 1983, 48 FR 54990.

On behalf of its client, one consulting organization objected to FDA's announced intent to withdraw this proposal to affirm that certain protein hydrolysates and enzymatically hydrolyzed animal (milk casein) protein are GRAS for use as direct human food ingredients. The comment stated that the rulemaking process should be completed as proposed because the withdrawal of the proposed rule will convey a message of uncertainty regarding the regulatory status of these ingredients.

FDA has decided to defer its decision to withdraw this GRAS proposal. FDA's decision to issue a final rule based on the proposal and the received public comments, to repropose the rulemaking proceeding, or to withdraw the proposal will be announced in a future issue of the Federal Register.

29. Hydrochloric Acid; Proposed Affirmation of GRAS Status as Direct Human Food Ingredient—Docket No. 80N-0148—April 26, 1984, 49 FR 17966.

A law firm, on behalf of its client, commented that the 1984 proposal to affirm that hydrochloric acid is GRAS as a direct human food ingredient should be withdrawn because it is scientifically, administratively, and economically unsound. The comment stated that the proposal, which would not permit byproduct hydrochloric acid as a direct food ingredient, would cause significant economic disruption within the fluorocarbon industry. Although not objecting to the agency's action to withdraw this proposal, another law firm stated that its client understood that if the proposal is withdrawn, current regulations support its client's determination that byproduct hydrochloric acid is GRAS. A commercial organization recommended that the agency amend the proposal to include types of hydrochloric acid consistent with the Food Chemical Codex definition of food-grade acid or, alternatively, expand the list of acceptable processes to include byproduct hydrochloric acid from the fumed silica process and other suitable manufacturing processes.

FDA has decided to defer its decision to withdraw this GRAS proposal. FDA's decision to issue a final rule based on the proposal and the received public comments, to repropose the rulemaking proceeding, or to withdraw the proposal will be announced in a future issue of the Federal Register.

30. Margarine; Proposal to Amend the Standard of Identity—Docket No. 82P-0186—October 30, 1984, 49 FR 43560.

A trade association urged FDA to finalize the proposed rule as originally published, or to issue a tentative final rule and proceed to final rulemaking as expeditiously as possible. The proposal would amend the standard of identity for margarine to remove the list of permitted emulsifiers and the maximum use level restrictions for each from the current standard and to retain the provision for the use of safe and suitable emulsifiers without specified limitations.

The agency expects to complete this rulemaking proceeding. Therefore, the agency is deferring its decision to withdraw this proposed rule until a later date.

III. Additional FDA-Initiated Actions

In addition, the agency, on its own initiative, has further reviewed the proposals listed in the notice of intent and is deferring its decision to withdraw the following nine proposals:

1. Glycerophosphates; Proposed Affirmation and Deletion of GRAS Status—Docket No. 78N-0335—May 15, 1979, 44 FR 28336.

This proposal was inadvertently included in the notice of intent. On March 14, 1991, FDA issued a tentative final rule in the Federal Register (56 FR 10843) tentatively affirming the GRAS Status of glycerophosphates. This tentative final rule was based on the proposed rule published on May 15, 1979 (44 FR 28336) and the received comments. The agency is in the process of completing this rulemaking proceeding.

2. Brown and Yellow Mustard and Their Derivatives; Proposed Affirmation of GRAS Status as Direct Human Food Ingredient—Docket No. 77N-0033—August 26, 1977, 42 FR 43092;

3. Gelatin; Affirmation of GRAS Status as a Direct and Indirect Human Food Ingredient—Docket No. 77N-0232—November 11, 1977, 42 FR 58763;

4. Lard and Lard Oil; Proposed Affirmation of GRAS Status as Indirect Human Food Ingredients—Docket No. 78N-0336—May 18, 1979, 44 FR 29102;

5. Sodium Dithionite and Zinc Dithionite; Proposed Affirmation of GRAS Status—79N-0095—January 25, 1980, 45 FR 6117;

6. Japan Wax; Proposed Deletion from GRAS Status as an Indirect Human Food Ingredient—Docket No. 80N-0196—July 9, 1982, 47 FR 29985;

7. Thiodipropionic Acid and Dilaural Thiodipropionate; Proposed Removal of GRAS Status—Docket No. 80N-0361—August 13, 1982, 47 FR 35240;

8. Zinc Salts; Proposed Affirmation of GRAS Status—Docket No. 82N-0167—October 26, 1982—47 FR 47441; and

9. Unmodified Food Starches and Acid Modified Starches; Proposed Affirmation of GRAS Status as Direct and Indirect Human Food Ingredients—Docket No. 84N-0341—April 1, 1985, 50 FR 12821.

After considering the comments received on other proposals to implement the agency's GRAS review

program, FDA has decided to defer its decisions on the withdrawal of all of the GRAS proposals included in the notice of intent. The agency is in the process of reexamining the issues involved in each of these proposed regulations that implement the agency's GRAS review program and expects to decide, in the near future, to either issue a final rule based on the proposal and the received public comments, repropose the rulemaking proceeding, or withdraw the proposal. The agency's decision in each case will be the subject of a future **Federal Register** publication.

Therefore, for the reasons set forth above, and under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, the agency announces that it is withdrawing the following proposed rules, published in the **Federal Register** on the dates indicated:

Title	Docket No.	FR publication date and cite
Prescription Drugs; Proposed Changes in Labeling Requirements Prescription Drugs	85N-0358	Nov. 10, 1961, 26 FR 10601.
Prescription Drugs; Further Proposals to Amend Labeling Requirements	85N-0358	May 10, 1962, 27 FR 4482.
Methyl Salicylate; Oil of Wintergreen; Notice of Proposal to Establish Tolerances for Residues	91N-0301	Sept. 26, 1962, 27 FR 9521.
Antibiotics in Combination with Analgesic Substances, Antihistaminics, and Caffeine; Proposal to Delete from List of Oral Drugs Acceptable for Certification.	91N-0302	Aug. 17, 1963, 28 FR 8471.
Food Additives in Animal Feed; Proposed Antibiotics for Growth Promotion and Feed Efficiency	91N-0304	Nov. 19, 1964, 29 FR 15538.
Tests, Methods of Assay and Certification of Certain Antibiotic Drugs	85N-0380	Oct. 6, 1965, 30 FR 12746.
Certain Drug-Labeling Exemptions; Proposed Termination	85N-0356	Nov. 23, 1966, 31 FR 14840.
Drugs; Current Good Manufacturing Practice in Manufacture, Processing, Packing or Holding; Repackaged Tablets or Capsules.	85N-0359	Mar. 2, 1967, 32 FR 3470.
Time-Release Dosage Forms of Drugs; Statement Regarding New-Drug Status	91N-0307	Sept. 6, 1967, 32 FR 12756.
Promotional Labeling of Oral Contraceptives; Proposed Statement of Policy	85N-0383	Sept. 13, 1967, 32 FR 13008
Drugs for Human Use; Drug Efficacy Study Implementation; Announcement and Proposal Regarding Methylergonovine Maleate Tablets and Methylergonovine Maleate Injection.	91N-0309	June 5, 1968, 33 FR 8348.
Kanamycin Sulfate; Kanamycin B Content Testing Method	91N-0310	Apr. 26, 1969, 34 FR 6983.
Pyrimethamine, Sulfaquinoxaline; Proposal to Revoke Exemption from Certification	91N-0311	Mar. 25, 1971, 36 FR 5619.
Food Additives; Proposed Revocation of Use of Morpholine	85N-0363	Nov. 3, 1972, 37 FR 23456.
Labeling or Misbranding of Drugs; Misleading Proprietary or Trade Names	85N-0357	Mar. 27, 1974, 39 FR 11298.
2-Mercaptoimidazoline; Use in Closures and Product Delivery Systems for Drugs and Cosmetics and In Components of Medical Devices.	91N-0255	May 2, 1974, 39 FR 15306.
Intramammary Infusion Products for Treating Mastitis; Proposed Revocation and Amendment of Antibiotic Certification Provisions and Related Regulations.	85N-0360	Aug. 30, 1974, 39 FR 31647
Aflatoxin in Shelled Peanuts and Peanut Products Used as Human Food; Proposed Tolerance	78N-0048	Dec. 6, 1974, 39 FR 42748.
Conditions for Marketing Human Prescription Drugs; Proposed Rulemaking and Notice of Enforcement Policy for Drugs Subject to the Effectiveness Requirements of the Drug Amendments of 1962.	75N-0052	June 20, 1975, 40 FR 26142.
Animal Food and Feed; Prohibited Substances	75N-0180	Sept. 9, 1975, 40 FR 41797.
Methadone; Proposal to Amend Procedures for Denying or Revoking Approval of Applications to Receive Shipments.	75N-0151	Nov. 7, 1975, 40 FR 52049
Drained Weights for Processed Fruits and Vegetables; Standards of Fill of Container and Label Statement	75P-0166	Nov. 7, 1975, 40 FR 52172.
Chloroform in Contact With Food; Proposal to Amend Food Additive Regulations	76N-0097	Apr. 9, 1976, 41 FR 15029.
Human Drugs; Current Good Manufacturing Practice in the Manufacture, Processing, Packing, or Holding of Large Volume Parenterals.	76N-0099	June 1, 1976, 41 FR 22202.
Infant Foods; Percentage Declaration of Ingredients	76P-0329	Sept. 7, 1976, 41 FR 37595.
Infant and Junior Foods; Establishment of Common or Usual Name	76P-0330	Sept. 7, 1976, 41 FR 37593.
Saccharin and its Salts	76N-0510	Jan. 7, 1977, 42 FR 1486.
Administrative Practices and Procedures; Publicity Policy	76N-0478	Mar. 4, 1977, 42 FR 12436.
Saccharin and its Salts	77N-0085	Apr. 15, 1977, 42 FR 19996.
Ionizing Radiation Therapy Equipment; Notice of Intent to Propose Rules and Develop Guidelines	77N-0031	Mar. 22, 1977, 42 FR 15428.
Enriched Rice; Proposal to Revise Standard	77N-0116	July 15, 1977, 42 FR 36487.
Drugs for Human and Veterinary Use; Public Disclosure of Specifications	77N-0124	July15, 1977, 42 FR 36485.
New Drugs for Investigational Use; Prompt Reporting of Animal Studies and Data	77N-0059	July 15, 1977, 42 FR 36490.
New Animal Drugs; Bovine Teat Dips	76N-0286	Aug. 9, 1977, 42 FR 40217.
New Drugs for Investigational Use; Availability of Draft of Bioresearch Monitoring Data Collection Form	77N-0190 Aug. 16, 1977, 42 FR 41301.	
Annatto Extract, Paprika Oleoresin, and Turmeric Oleoresin; Removal of Provisions for Trichloroethylene	75P-0132	Sept. 27, 1977, 42 FR 49464.
Trichloroethylene; Removal from Food Additive Use	76N-0469	Sept. 27, 1977, 42 FR 49465.
Trichloroethylene in Human Drug and Cosmetic Products; Declaration of New Drug Status and Determination of Status in Cosmetics.	77N-0029	Sept. 27, 1977, 42 FR 49467.
Trichloroethylene; Prohibition in Animal and Pet Food	75P-0132	Sept. 27, 1977, 42 FR 49468.
Trichloroethylene in Animal Drug Products; Proposed Declaration of New Animal Drug Status	76N-0476	Sept. 27, 1977, 42 FR 49470.
Clinical Investigators; Proposed Establishment of Regulations on Obligations of Sponsors and Monitors	77N-0195	Sept. 27, 1977, 42 FR 49612.
Pasteurized Process Cheese and Cheese Products; Proposed Revision of Definitions and Standards of Identity.	77P-0070	Oct. 4, 1977, 42 FR 53970.
Skim Milk Cheese for Manufacturing; Proposal to Amend Identity Standard	77P-0071	Oct. 4, 1977, 42 FR 53979.
Preservation of Cosmetics Coming In Contact With The Eye; Intent to Propose Regulations and Request for Information.	77N-0105	Oct. 11, 1977, 42 FR 54837.
Drained Weight or Solid Content Weight for Canned Fruits and Vegetables; Label Statement, Standards of Fill of Container, and Temporary Labeling Exemption.	77P-0097	Dec. 9, 1977, 42 FR 62282.
Public Information; Disclosure of Existence	77N-0248	Mar. 28, 1978, 43 FR 12869.
Food Labeling; Ingredient Labeling Exemptions	76P-0430 77P-0123 77P-0357	Apr. 7, 1978, 43 FR 14675.
X-Ray Intensifying Screens; Intent to Develop a Radiation Protection Recommendation	78N-0074	June 2, 1978, 43 FR 24066.
Common or Usual Names for Vegetable Protein Products and Substitutes for Meat, Seafood, Poultry, Eggs, or Cheeses Which Contain Vegetable Protein Products as Sources of Protein; Tentative Final Rule.	75N-0205	July 14, 1978, 43 FR 30472.
Obligations of Clinical Investigators of Regulated Articles; Proposed Establishment of Regulations	77N-0278	Aug. 8, 1978, 43 FR 35210.
Bioresearch Monitoring Program; Clarification of Part Designation	78N-0282	Sept. 26, 1978, 43 FR 43468.

Title	Docket No.	FR publication date and cite
Orange B; Termination of Listing	78C-0216	Oct. 3, 1978, 43 FR 45611.
Estrogenic, Oral Contraceptive, and Progestational Drug Products; Proposed Requirements for Patient Labeling.	78N-0274	Oct. 13, 1978, 43 FR 47198.
2-Nitropropane; Proposed Removal from Food Additive Use	78N-0112	Dec. 1. 1978, 43 FR 56247.
Estrogens to Treat Postpartum Breast Engorgement; Proposed Requirements for Patient Labeling	78N-0383	Dec. 5, 1978, 43 FR 56906.
Status of Injectable Animal Drugs; Intent Regarding Sterility and Pyrogenicity of Injectable Animal Drugs	78N-0267	Dec. 15, 1978, 43 FR 58591.
Recombinant DNA; Intent to Propose Regulations	78N-0012	Dec. 22, 1978, 43 FR 60134.
Estradiol Benzoate, Progesterone, Testosterone Propionate, and Estradiol Monopalmitate for Use in Food-Producing Animals.	78N-0435	Jan. 5, 1979, 44 FR 1381.
Diagnostic Ultrasound Equipment; Intent to Propose Rules and Develop Regulations	78N-0288	Feb. 13, 1979, 44 FR 9542.
New Animal Drugs for Use in Animal Feeds; Definitions and General Considerations; Postponement of Final Action.	77N-0076	Mar. 6, 1979, 44 FR 12208.
Medical Devices; Classification of pH Catheter Probes	78N-1419	Mar. 9, 1979, 44 FR 13303.
Medical Devices; Classification of Catheter Guide Holders	78N-1425	Mar. 9, 1979, 44 FR 13309.
Medical Devices; Classification of Electrocardiograph Conducting Media	78N-1455	Mar. 9, 1979, 44 FR 13337.
Requirements for Estrogen Labeling Directed to Patients	78N-0303	Apr. 17, 1979, 44 FR 22752.
Protection of Human Subjects; Proposed Establishment of Regulations	78N-0031	Apr. 24, 1979, 44 FR 24106.
Hydrazine; Proposed Removal from Food Additive Use	78N-0208	June 12, 1979, 44 FR 33693.
Hydrazine in Human Drug Products; Declaration of New Drug Status	78N-0384	June 12, 1979, 44 FR 33694.
Medical Devices; Classification of Iron Kinetics Tests	78N-1870	Sept. 11, 1979, 44 FR 52992.
Medical Devices; Classification of Red Cell Survival Tests	78N-1875	Sept. 11, 1979, 44 FR 52997.
Medical Devices; Classification of Systems for the Identification fo Hepatitis B Antigen	78N-1934	Sept. 11, 1979, 44 FR 53056.
Medical Devices; Classification of Nonindwelling Blood Nitrogen Partial Pressure (PN2) Analyzer	78N-1661	Nov. 2, 1979, 44 FR 63309.
Medical Devices; Classification of Gas Cylinders	78N-1801	Nov. 2, 1979, 44 FR 63421.
Medical Devices; Classification of Gas Cylinder Holders	78N-1802	Nov. 2, 1979, 44 FR 63422.
Procedures to Minimize Medical X-Ray Exposure of the Human Embryo and Fetus; Recommendations for Medical Radiation Exposure of Women of Childbearing Potential.	75N-0340	Nov. 20, 1979, 44 FR 66616.
Biological Products; Labeling Standards; Position and Prominence of Proper Name	79N-0263	Jan. 25, 1980, 45 FR 6120.
Medical Devices; Voluntary Standards Development; Requests for Data and Information on In Vitro Diagnostics.	80N-0100	Feb. 1, 1980, 45 FR 7493.
Devices Used as a Radiation Source (In Combination With a Psoralen Drug) in the Photochemotherapy for Psoriasis; Intent to Propose Rules and Develop Recommendations.	79N-0013	Feb. 8, 1980, 45 FR 8870.
Additional Standards for Human Blood and Blood Products; Antihemophilic Factor (Human)	79N-0326	Apr. 4, 1980, 45 FR 22975.
Diluents for Cosmetic Color Additive Mixtures; Intent to Propose Rules; Request for Information	78N-0390	Apr. 22, 1980, 45 FR 26977.
Substances Prohibited from Use in Animal Food or Feed; Tentative Final Rule	75N-0180	Apr. 29, 1980, 45 FR 28349.
Allergenic Products; Proposed Testing and Labeling Requirements	79N-0410	May 2, 1980, 45 FR 29305.
Quality Control Testing of Platelet Concentrate (Human) and Cryoprecipitated Antihemophilic Factor (Human)	80N-0035	July 8, 1980, 45 FR 45924.
Blood and Blood Components; Error and Accident Reports	79N-0094	Aug. 8, 1980, 45 FR 52821.
Food Labeling; Net Weight Labeling Requirements	79N-0292	Aug. 8, 1980, 45 FR 53023.
Shipping Temperature Requirements for Certain Biological Products	80N-0497	Dec. 30, 1980, 45 FR 85785.
Apple Juice and Concentrated Apple Juice; Possible Establishment of Standards	82N-0218	Aug. 13, 1982, 47 FR 35234.
Medical Devices; Notice of Intent to Initiate Proceedings to Require Premarket Approval of Preamendments Devices.	83N-0240	Sept. 6, 1983, 48 FR 40272.
Clarification of Potency Standard for Certain Antibiotic Drugs	83N-0301	Dec. 2, 1983, 48 FR 54364.
Cheese and Related Cheese Products; Repeal of Four Class Standards of Identity	80N-0372	Apr. 23, 1984, 49 FR 17017.

Dated: December 19, 1991.

Michael R. Taylor,

Deputy Commissioner for Policy.

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