OMB Reviewer: Michael Abrahams (202) 395–6880, Office of Management and Budget, Room 3208, New Executive Office Building, Washington, D.C. 20503.

* * * * *

Date Submitted: August 26, 1982.

Submitting Bureau: Internal Revenue Service.

OMB Number: 1545–0174.

Form Number: 4625.

Type of Submission: Revision.

Title: Computation of Minimum Tax—Individuals.

Purpose: Form 4625 is used by individuals who have certain tax preference items exceeding $10,000 ($5,000 for married individuals filing separately). The information is needed to help verify whether taxpayers are complying with the law and have paid the correct minimum tax.

OMB Reviewer: Michael Abrahams (202) 395–6880, Office of Management and Budget, Room 3208, New Executive Office Building, Washington, D.C. 20503.

* * * * *

Date Submitted: August 26, 1982.

Submitting Bureau: Internal Revenue Service.

OMB Number: 1545–0099.

Form Number: 1065 and Schedule K–1 (Form 1065).

Type of Submission: Revision.

Title: U.S. Partnership Return of Income Partner's Share of Income, Credits, Deductions, etc.

Purpose: Section 6031 of the IRC requires that partnerships file returns each tax year showing: gross income items; allowable deductions; names, addresses, and partners distributive shares; and other information the Secretary prescribes by forms and regulations. This information is used to verify correct reporting of partnership items and for general statistics.

OMB Reviewer: Michael Abrahams (202) 395–6880, Office of Management and Budget, Room 3208, New Executive Office Building, Washington, D.C. 20503.

* * * * *

Date Submitted: August 26, 1982.

Submitting Bureau: Internal Revenue Service.

OMB Number: 1545–0493.

Form Number: 6522.

Type of Submission: Revision.

Title: Volunteer Assistance Card.

Purpose: This form is prepared by each volunteer who assists an individual under the Voluntary Income Tax Assistance or Tax Counseling for the Elderly Programs. The purpose of the form is to measure the type and extent of assistance provided to the public. This card also captures the number of Form 1040, 1040A and 1040 EZ questions only, state and local returns, and TCE returns.

OMB Reviewer: Michael Abrahams (202) 395–6880, Office of Management and Budget, Room 3208, New Executive Office Building, Washington, D.C. 20503.

* * * * *

Date Submitted: August 26, 1982.

Submitting Bureau: Internal Revenue Service.

OMB Number: 1545–0436.

Form Number: 6729.

Type of Submission: Reinstatement.

Title: Site Visitation Sheet.

Purpose: This form is used to monitor the activities of the volunteer at the VITA/TCE Site to ensure that quality service is being given. Site visits will ensure that VITA volunteers and TCE sponsors are complying with program guidelines. Visitation checksheets should be available for regional and national office review.

OMB Reviewer: Michael Abrahams (202) 395–6880, Office of Management and Budget, Room 3208, New Executive Office Building, Washington, D.C. 20503.

Joy Tucker,

Departmental Reports Management Officer.

August 27, 1982.

[FR Doc. 82–24147 Filed 9–1–82; 8:45 am]

BILLING CODE 4810–25–M

VETERANS ADMINISTRATION

Special Medical Advisory Group; Meeting

The Veterans Administration gives notice under Pub. L. 92–463 that a meeting of the Special Medical Advisory Group will be held in the Administrator's Conference Room at the Veterans Administration Central Office, 810 Vermont Avenue, NW, Washington, DC, on September 28 and 29, 1982. The purpose of the Special Medical Advisory Group is to advise the Administrator and the Chief Medical Director relative to the care and treatment of disabled veterans, and other matters pertinent to the Veterans Administration's Department of Medicine and Surgery.

The sessions will convene at 8:30 a.m. both days. These sessions will be open to the public up to the seating capacity of the room. Because this capacity is limited, it will be necessary for those wishing to attend to contact Ms. Von Schneibel, Program Assistant, Office of the Chief Medical Director, Veterans Administration Central Office (phone 202/389–2298) prior to September 10, 1982.

Dated: August 25, 1982.

Rosa Maria Fontanez,

Committee Management Officer.

[FR Doc. 82–24136 Filed 9–1–82; 8:45 am]

BILLING CODE 8320–01–M

Sunshine Act Meetings

Federal Register
Vol. 47, No. 171
Thursday, September 2, 1982

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

CONTENTS

1

COMMODITY FUTURES TRADING COMMISSION

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: Vol. 47, No. 168, Monday, August 30, 1982.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: 2 p.m., Tuesday, August 31, 1982.

CHANGES IN THE MEETING: Cancelled. Changed to: 1 p.m., Tuesday, September 7, 1982.

[S-1247-82 Filed 8-30-82; 4:45 pm]

BILLING CODE 6351-01-M

2

COMMODITY FUTURES TRADING COMMISSION

TIME AND DATE: 10 am, Tuesday, September 7, 1982.

PLACE: 2033 K Street, N.W., Washington, D.C., Fifth floor hearing room.

STATUS: Open.

MATTERS TO BE CONSIDERED: 1984 Budget Discussion.

CONTACT PERSON FOR MORE INFORMATION: Jane Stuckey, 254-6314.

[S-1246-82 Filed 8-30-82; 4:32 pm]

BILLING CODE 6351-01-M

3

COMMODITY FUTURES TRADING COMMISSION

TIME AND DATE: 11 a.m., Friday, September 17, 1982.

PLACE: 2033 K Street, N.W., Washington, D.C., Eighth floor conference room.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Surveillance Briefing.

CONTACT PERSON FOR MORE INFORMATION: Jane Stuckey, 254-6314.

[S-1245-81 Filed 8-30-82; 4:32 pm]

BILLING CODE 6351-01-M

4

FEDERAL DEPOSIT INSURANCE CORPORATION

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that at 3:20 p.m. on Sunday, August 29, 1982, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session, by telephone conference call, to consider a bid for the purchase of certain assets of and the assumption of the liability to pay deposits made in Western National Bank, Santa Ana, California, which was closed by the Comptroller of the Currency as of the close of business on Friday, August 27, 1982.

In calling the meeting, the Board determined, on motion of Chairman William M. Isaac, seconded by Director Irvine H. Sprague (Appointive), concurred in by Mr. Doyle L. Arnold, acting in the place and stead of Director C. T. Conover (Comptroller of the Currency), that Corporation business required its consideration of the matter on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matter in a meeting open to public observation; and that the matter could be considered in a closed meeting pursuant to subsections (c)(8), (c)(9)(A)(ii), and (c)(9)(B) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(8), (c)(9)(A)(ii), and (c)(9)(B)).

Dated: August 30, 1982.

Federal Deposit Insurance Corporation.

Margaret M. Olsen,

Assistant Executive Secretary.

[S-1250-82 Filed 8-31-82; 3:16 pm]

BILLING CODE 6714-01-M

5

FEDERAL DEPOSIT INSURANCE CORPORATION

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that at 7:25 p.m. on August 27, 1982, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session, by telephone conference call, to (1) receive bids for the purchase of certain assets of and the assumption of the liability to pay deposits made in First Security Bank of North Arkansas, Horseshoe Bend, Arkansas, which was closed by the Arkansas State Bank Commissioner as of the close of business on Friday, August 27, 1982; (2) accept the bid for the transaction submitted by The Bank of Melbourne, Melbourne, Arkansas; (3) approve the application of The Bank of Melbourne, Melbourne, Arkansas, for consent to purchase the asset of and assume the liability to pay deposits made in First Security Bank of North Arkansas, Horseshoe Bend, Arkansas, and for consent to establish the main office and two branches of First Security Bank of North Arkansas as branches of the resultant bank; and (4) provide such financial assistance, pursuant to section 13(e) of the Federal Deposit Insurance Act (12 U.S.C. 1823(e)), as was necessary to effect the purchase and assumption transaction.

At that same meeting the Board of Directors (1) received sealed bids for the purchase of certain assets of and the assumption of the liability to pay deposits made in Security Bank and Trust Company, Cairo, Illinois, which was closed by the Illinois Commissioner of Banks and Trust Companies as of the close of business on Friday, August 27, 1982; (2) accepted the bid for the transaction submitted by First Bank and Trust Company, Cairo, Illinois; (3) approved the application of First Bank and Trust Company, Cairo, Illinois, for consent to purchase the assets of and to assume the liability to pay deposits made in Security Bank and Trust Company, Cairo, Illinois, and for consent to establish the sole office of Security Bank and Trust Company as a facility of the resultant bank; and (4) provide such financial assistance, pursuant to section 13(e) of the Federal Deposit Insurance Act (12 U.S.C. 1823(e)), as was necessary to effect the purchase and assumption transaction.

In calling the meeting, the Board determined, on motion of Chairman William M. Isaac, seconded by Director Irvine H. Sprague (Appointive), concurred in by Mr. Doyle L. Arnold, acting in the place and stead of Director

C. T. Conover (Comptroller of the Currency), that Corporation business required its consideration of the matters on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting pursuant to subsections (c)(8), (c)(9)(A)(ii), and (c)(9)(B) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(8), (c)(9)(A)(ii), and (c)(9)(B)).

Dated: August 30, 1982.

Federal Deposit Insurance Corporation.

Alan J. Kaplan,

Deputy Executive Secretary.

[S-1251-82 Filed 8-31-82; 3:16 pm]

BILLING CODE 6714-01-M

6

FEDERAL DEPOSIT INSURANCE CORPORATION

Change in Subject Matter of Agency Meeting

Pursuant to the provisions of subsection (e)(2) of the "Government in the Sunshine Act" (5 U.S.C. 552b(e)(2)), notice is hereby given that at its closed meeting held at 2:30 p.m. on Monday, August 30, 1982, the Corporation's Board of Directors determined, on motion of Chairman William M. Isaac, seconded by Director Irvine H. Sprague (Appointive), that Corporation business required the addition to the agenda for consideration at the meeting, on less than seven days' notice to the public, of a resolution making funds available for the payment of insured deposits in Western National Bank, Santa Ana, California, which was closed by the Comptroller of the Currency on Friday, August 27, 1982, if a purchase of the assets of and assumption of the liability to pay deposits made in the closed bank cannot be arranged.

The Board further determined, by the same majority vote, that no earlier notice of the change in the subject matter of the meeting was practicable; that the public interest did not require consideration of the matter in a meeting open to the public observation; and that the matter could be considered in a closed meeting by authority of subsections (c)(8) and (c)(9)(B) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(8) and (c)(9)(B)).

Dated: August 31, 1982.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[S-1252-82 Filed 8-31-82; 3:17 pm]

BILLING CODE 6714-01-M

7

FEDERAL DEPOSIT INSURANCE CORPORATION

Change in Subject Matter of Agency Meeting

Pursuant to the provisions of subsection (e)(2) of the "Government in the Sunshine Act" (5 U.S.C. 522b(e)(2)), notice is hereby given that at its open meeting held at 2:00 p.m. on Monday, August 30, 1982, the Corporation's Board of Directors determined, on motion of Chairman William M. Isaac, seconded by Director Irvine H. Sprague (Appointive), concurred in by Mr. Doyle L. Arnold, acting in the place and stead of Director C. T. Conover (Comptroller of the Currency), that Corporation business required the addition to the agenda for consideration at the meeting, on less than seven days' notice to the public, of the following matter:

Recommendation regarding the liquidation of a bank's assets acquired by the Corporation in its capacity as receiver, liquidator, or liquidating agent of those assets:

Case No. 45,373-NR—Penn Square Bank, N.A., Oklahoma City, Oklahoma

By the same majority vote, the Board further determined that no earlier notice of this change in the subject matter of the meeting was practicable.

Dated: August 31, 1982.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

S-1253-82 Filed 8-31-82; 3:18 pm]

BILLING CODE 6714-01-M

8

FEDERAL DEPOSIT INSURANCE CORPORATION

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that at 2:30 p.m. on Tuesday, September 7, 1982, the Federal Deposit Insurance Corporation's Board of Directors will meet in closed session, by vote of the Board of Directors pursuant to sections 552b(c)(2), (c)(6), (c)(8), and (c)(9)(A)(ii) of Title 5, United States Code, to consider the following matters:

Summary Agenda: No substantive discussion of the following items is anticipated. These matters will be resolved with a single vote unless a member of the Board of Directors requests that an item be moved to the discussion agenda.

Recommendations with respect to the initiation, termination, or conduct of administrative enforcement proceedings (cease-and-desist proceedings, termination-of-insurance proceedings, suspension or removal proceedings, or assessment of civil money penalties) against certain insured banks or officers, directors, employees, agents or other persons participating in the conduct of the affairs thereof:

Names of persons and names and locations of banks authorized to be exempt from disclosure pursuant to the provisions of subsections (c)(6), (c)(8), and (c)(9)(A)(ii) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(6), (c)(8), and (c)(9)(A)(ii)).

Note.—Some matters falling within this category may be placed on the discussion agenda without further public notice if it becomes likely that substantive discussion of those matters will occur at the meeting.

Discussion Agenda:

Personnel actions regarding appointments, promotions, administrative pay increases, reassignments, retirements, separations, removals, etc.:

Names of employees authorized to be exempt from disclosure pursuant to provisions of subsections (c)(2) and (c)(6) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(2) and (c)(6)).

The meeting will be held in the Board Room on the sixth floor of the FDIC Building located at 550 17th Street N.W., Washington, D.C.

Requests for information concerning the meeting may be directed to Mr. Hoyle L. Robinson, Executive Secretary of the Corporation, at (202) 389-4425.

Dated: August 31, 1982.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[S-1254-82 Filed 8-31-82; 3:18 pm]

BILLING CODE 6714-01-M

9

FEDERAL DEPOSIT INSURANCE CORPORATION

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that the Federal Deposit Insurance Corporation's Board of Directors will meet in open session at 2:00 p.m. on Tuesday, September 7, 1982, to consider the following matters:

Summary Agenda: No substantive discussion of the following items is anticipated. These matters will be resolved with a single vote unless a member of the Board of Directors

requests that an item be moved to the discussion agenda.

Disposition of minutes of previous meetings.

Recommendations regarding the liquidation of a bank's assets acquired by the Corporation in its capacity as receiver, liquidator, or liquidating agent of those assets:

Case No. 45,370—Central Savings Bank, New York, New York

Memorandum and Resolutions re: Banco Credito y Ahorro Ponceno, Ponce, Puerto Rico; Banco Economias, San German, Puerto Rico; Banco Regional, Bayamon, Puerto Rico; and Banco de Ahorro de Puerto Rico, San Juan (Hato Rey), Puerto Rico

Recommendations with respect to payment for legal services rendered and expenses incurred in connection with receivership and liquidation activities:

Morrison, Hecker, Curtis, Kuder & Parrish, Kansas City, Missouri, in connection with the liquidation of The Mission State Bank and Trust Company, Mission, Kansas.

Trubin, Sillcocks, Edelman & Knapp, New York, New York, in connection with the liquidation of The Greenwich Savings Bank, New York, New York.

Reports of committees and officers:

Minutes of actions approved by the standing committees of the Corporation pursuant to authority delegated by the Board of Directors.

Reports of the Division of Bank Supervision with respect to applications or requests approved by the Director or Associate Director of the Division and the various Regional Directors pursuant to authority delegated by the Board of Directors.

Discussion Agenda:

Recommendation regarding a proposed collection of information from insured State nonmember commercial banks.

The meeting will be held in the Board Room on the sixth floor of the FDIC Building located at 550 17th Street, N.W., Washington, D.C.

Requests for information concerning the meeting may be directed to Mr. Hoyle L. Robinson, Executive Secretary of the Corporation, at (202) 389–4425.

Dated: August 31, 1982.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[S–1255–82 Filed 8–31–82; 3:19 pm]

BILLING CODE 6714–01–M

10

FEDERAL RESERVE SYSTEM

Board of Governors

TIME AND DATE: 10 a.m., Wednesday, September 8, 1982.

PLACE: 20th Street and Constitution Avenue, N.W., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Joseph R. Coyne, Assistant to the Board, (202) 452–3204.

Dated: August 31, 1982.

William W. Wiles,

Secretary of the Board.

[S–1249–82 Filed 8–31–82; 3:11 pm]

BILLING CODE 6210–01–M

11

FOREIGN CLAIMS SETTLEMENT COMMISSION

[FCSC Meeting Notice No. 4–82]

Announcement in Regard to Commission Meetings and Hearings

The Foreign Claims Settlement Commission, pursuant to its regulations (45 CFR Part 504), and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice in regard to the scheduling of open meetings and oral hearings for the transaction of Commission business and other matters specified, as follows:

Date, Time, and Subject Matter

Monday, September 13, 1982 at 10:30 a.m.

Redetermination decisions involving claims against the Government of the Czechoslovak Socialist Republic; claim for prisoner of war compensation.

Subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

All meetings are held at the Foreign Claims Settlement Commission, 1111 20th Street, NW., Washington, D.C. Requests for information, or advance notices of intention to observe a meeting, may be directed to: Administrative Officer, Foreign Claims Settlement Commission, 111 20th Street, NW., Room 409, Washington, D.C. 20579. Telephone (202) 653–6155.

Dated at Washington D.C. on August 30, 1982.

Judith H. Lock,

Administrative Officer.

[S–1256–82 Filed 8–31–82; 3:59 pm]

BILLING CODE 4410–01–M

12

POSTAL RATE COMMISSION

TIME AND DATE: 10 a.m., Wednesday, September 8, 1982.

PLACE: Conference Room, Room 500, 2000 L Street, N.W., Washington, D.C.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Warshawsky and Company v. Postal Rate Commission and Board of Governors, USPS (Suit filed 3–26–82 in United States District Court for the Northern District of Illinois—Docket No. 82C1895).

2. Warshawsky and Company v. U.S. Postal Service—Docket No. C82–1.

Closed pursuant to 5 U.S.C. 552b(c)(10).

CONTACT PERSON FOR MORE INFORMATION: Dennis Watson, Information Officer, Postal Rate Commission, Room 500, 2000 L Street, N.W., Washington, D.C. 20268, Telephone (202)254–5614.

[S–1248–82 Filed 8–31–82; 9:35 am]

BILLING CODE 7715–01–M

federal register

Thursday
September 2, 1982

Part II

Department of Transportation

Federal Aviation Administration

Ultralight Vehicles; Operating Requirements

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 103

[Docket No. 21631; New Part 103]

Ultralight Vehicles; Operating Requirements

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment establishes rules governing the operation of ultralight vehicles in the United States. The rule defines ultralight vehicles in two categories: powered and unpowered. To be considered an ultralight vehicle, a hang glider must weigh less than 155 pounds; while a powered vehicle must weigh less than 254 pounds; is limited to 5 U.S. gallons of fuel; must have a maximum speed of not more than 55 knots; and must have a power-off stall speed of not more than 24 knots. Both powered and unpowered ultralight vehicles are limited to a single occupant. Those vehicles which exceed the above criteria will be considered aircraft for purposes of airworthiness certification and registration, and their operators will be subject to the same certification requirements as are aircraft operators. These rules for ultralight vehicles are needed to achieve an acceptable level of air safety by reducing potential conflict with other airspace users and to provide protection to persons and property on the ground.

The rule governs the operation of ultralight vehicles by specifying the airspace which requires prior authorization of Air Traffic Control (ATC), prohibiting operations over congested areas, and providing for operations during twilight hours with proper lighting. Right-of-way and minimum visibility rules are also established.

The FAA has chosen not to promulgate Federal regulations regarding pilot certification, vehicle certification, and vehicle registration, preferring that the ultralight community assume the initiative for the development of these important safety programs. The ultralight community is expected to take positive action to develop these programs in a timely manner and gain FAA approval for their implementation. Should this approach fail to meet FAA safety objectives, further regulatory action will be necessary.

EFFECTIVE DATE: October 4, 1982.

FOR FURTHER INFORMATION CONTACT:

Ken Peppard, Airspace and Air Traffic Rules Branch (AAT-220), Federal Aviation Administration, Washington, DC 20591, telephone (202) 426-3128, or

Gary Perkins, General Aviation Operations Branch (AFO-820), Federal Aviation Administration, Washington, DC 20591, telephone (202) 426-8194.

SUPPLEMENTARY INFORMATION:

Background

The FAA issued Advisory Circular No. 60-10, entitled "Recommended Safety Parameters for Operation of Hang Gliders" on May 16, 1974. That advisory circular contained recommended safety parameters for the operation of sport hang gliders, in lieu of formal Federal regulation. The advisory circular defined "hang glider" as "an unpowered, single place vehicle whose launch and landing capability depends on the legs of the occupant and whose ability to remain in flight is generated by natural air currents only."

The sport of hang gliding has advanced dramatically since Advisory Circular No. 60-10 was issued. There is now widespread use of powerplants, landing gear, and movable control surfaces to increase the speed, altitude, and distance capabilities of the vehicles. Many models have passenger-carrying capability. As a result of those developments, many hang gliding vehicles no longer fall within the scope envisioned by Advisory Circular No. 60-10. The addition of powerplants and controllable aerodynamic surfaces has created vehicles which can approximate the operational capabilities of fixed-wing and rotary-wing aircraft.

The increasing performance capabilities of these vehicles, and their greatly increased number, have created a potential hazard to other aircraft and operators, as well as to the ultralight operators themselves. As the result of aerodynamic improvements, many unpowered hang gliders are now capable of extended soaring to altitudes exceeding 10,000 feet above the point of launch and distances of over 100 miles. The powered hang gliders now have the capability of sustained flight above 10,000 feet and forward speed exceeding 50 knots. The operations of these vehicles are now a significant factor in aviation safety. The vehicles are routinely operated, without authorization, into regulated airspace, such as airport traffic areas, terminal control areas, positive control areas, and prohibited and restricted areas. Many operations have also taken place over congested areas and spectators and into adverse weather conditions in which operations may be conducted by pilots and aircraft which are qualified for instrument flight (IFR conditions). The midair collision potential presented by unauthorized operations is contrary to the FAA responsibility of ensuring the safety of all airspace operations including air carrier aircraft.

To illustrate the potential for hazardous situations that can arise, the FAA has recorded data detailing numerous instances of ultralight vehicles in controlled airspace causing near-miss situations with aircraft. The following examples highlight the problem:

(1) On March 24, 1981, an MU-2 flew between two ultralights operating off the end of the runway at Winter-Haven, Florida. Both ultralights were equipped with floats and were operating at night without lights.

(2) On April 11, 1981, a Western Airlines 727 captain reported a near-miss with an ultralight vehicle in the vicinity of Phoenix Sky Harbor Airport.

(3) In May of 1981, the pilot of a single engine aircraft reported a near-miss with an ultralight vehicle near Paso Robles, California. According to the report filed under the FAA Aviation Safety Reporting Program, the ultralight was operating at 7000 feet in IFR weather conditions. The airplane pilot, who was operating on an IFR flight plan, was forced to take evasive action to avoid a collision.

To establish regulations to deter flights which present a serious danger to aircraft and to provide a basis for necessary enforcement action, the FAA published Notice of Proposed Rulemaking No. 81-6 on July 27, 1981 (46 FR 38472). That notice proposed to include both powered and unpowered hang gliders under the generic term "ultralight vehicle" and included proposed weight and fuel limitations for those vehicles. The notice proposed a number of operational limitations for ultralight vehicles, while recognizing that the vehicles are used primarily for sport purposes. More than 2,500 persons and organizations submitted comments to that proposed rule. This rule is the result of FAA consideration of those comments in light of its responsibility for safety in the National Airspace System. Because of the growing significance of this segment of the aviation community, the new rules have been codified under a new part of the Federal Aviation Regulations, Part 103.

The Rule

Subpart A—General

Section 103.1 Applicability (proposed § 101.1(a)(3)).

This section defines the term "ultralight vehicle." The proposed rule would have limited the term to single-occupant designs weighing less than 155 pounds, with a fuel capacity of 15 pounds or less, and which had no U.S. or foreign airworthiness certificate. The final rule expands the definition to differentiate between powered and unpowered ultralight vehicles. The 155-pound weight limitation has been retained for unpowered designs and is the only criterion for those vehicles. Those ultralights equipped with powerplants must weigh less than 254 pounds empty weight. In addition, powered ultralight vehicles must have a fuel capacity not exceeding 5 U.S. gallons and be incapable of more than 55 knots calibrated airspeed at full power in level flight. The power-off stall speed of a powered ultralight must not exceed 24 knots calibrated airspeed.

The rule restricts both powered and unpowered vehicles to single occupants and requires that the aircraft be used exclusively for sport or recreational purposes.

The FAA estimates that nearly all unpowered vehicles currently on the market will fall within the definition of ultralight vehicle. The new criteria will exclude approximately 7% of the powered vehicle designs currently being marketed as ultralights, although many of those may be suitable for modifications to bring them within the scope of the definition.

Unpowered Ultralight Vehicles

A number of commenters, including the United States Hang Gliding Association (USHGA), object to the inclusion of "pure" hang gliders in the same definition as powered hang gliders. They raise the point that there are a number of distinctive operational differences between a pure hang glider and a powered vehicle which should be considered when assessing the necessity for regulations for these vehicles. The USHGA emphasizes its own self-regulation program and safety record.

The FAA recognizes that the measures taken by the USHGA to promote safety at USHGA launch sites have been effective, particularly those measures taken to protect the participants. However, the basic rationale for issuance of this rule is the safety of all users of national airspace, not just the ultralight operators. The great majority of hang gliding operations will not be affected by these regulations because, as a number of commenters indicate, they are usually conducted in rural or remote areas, at low altitudes, away from areas where safety of other persons in the air or on the ground is compromised. It is only in congested areas, airport traffic areas, and other areas frequented by aircraft involved in air commerce that these rules would restrict operations of unpowered ultralight vehicles.

The USHGA's self-regulation program lacks the legal authority to enforce requirements to ensure the safety of others. There is no requirement for any hang glider operator to be a member of the USHGA. Current hang glider publications have carried a number of articles describing hang glider operations which violate Part 91 regulations as well as the recommendations of Advisory Circular No. 60–10. Those descriptions have included operations near and into clouds, low-altitude operations over open-air assemblies of persons, and flights in close proximity to airports with large concentrations of airline and general aviation aircraft operations. Those potentially hazardous operations created the requirement for Federal regulatory limitations on hang gliders.

The proposed maximum weight restriction of less than 155 pounds was retained for unpowered ultralight vehicles to: (1) recognize the unpowered vehicles as a separate entity from those that are powered; and (2) ensure that the unpowered vehicles continue to meet essentially the same criteria that prevented their being classified as conventional gliders. Under this rule, those unpowered vehicles weighing 155 pounds or more must be certificated under the appropriate FAR's. No specific comments were received which objected to the 155-pound limitation on unpowered vehicles.

Powered Ultralight Vehicles

A large number of commenters request that the proposed maximum empty weight of 155 pounds be raised for powered ultralight vehicles. The suggestions range from 180 to 350 pounds. The reasons offered include greater structural integrity, more opportunity for design innovations, and the fact that many of the vehicles presently operated exhibit all of the other characteristics generally attributed to ultralights but weigh more than the proposed weight limit.

The FAA, by review of ultralight advertisements as of March 1982, has concluded that the empty weights of most of those vehicles range from 150 to 250 pounds. It was further concluded that the higher weights resulted from improvements which provide greater structural integrity, better stability, more positive controllability, and other safety-oriented additions which do not derogate the characteristics commonly associated with ultralight operations. Those characteristics are identified as low forward speeds, low wing loadings, low stall speeds, short takeoff and landing capability, and on enclosures around the pilot.

Some commenters suggest that limitations of 220 pounds or 330 pounds be adopted because they are "international standards." This is not correct. Canada, England, and Australia adopted 220 pounds as the maximum weight for a particular category of aircraft. In those countries, even if the weight limitation is met, the aircraft must be certificated and the pilots licensed. The 330-pound limit was established by the Federation Aeronautique Internationale for a category called "microlight aircraft." That category was established merely for the purpose of recording performance achievements of a particular group of aircraft.

The FAA agrees that the weight limitation for powered ultralight vehicles should be raised from the proposed 155 pounds. The 254-pound limitation was established because it closely corresponds to commenters' recommendations that the weight limitation be raised to at least 115 kilos, and because the vast majority of current vehicles on the market weigh less than 254 pounds. This weight does not include floats or safety devices intended for deployment in an emergency situation, e.g., parachutes and the harnesses and ballistic package necessary for deployment.

A large number of commenters recognize that, if the weight were raised, some restriction would have to be imposed to ensure that the characteristics associated with ultralights would be preserved. Those commenters include organizations such as the Experimental Aircraft Association (EAA), the Aircraft Owners and Pilots Association (AOPA), and the Professional Ultralight Manufacturers Association (PUMA).

The restrictions they propose range from simple wing loading values to complex aerodynamic formulas. They include maximum wing loading suggestions, minimum wing areas in relation to weight, maximum power capabilities in relation to weight, and calculations of launch mass. Some commenters suggest, and the FAA considered, that the pilot be required to

be exposed fully to the relative wind. This requirement was dropped to accommodate cold weather operations and to avoid stifling design and efficiency improvements within the parameters of an ultralight vehicle.

The maximum forward airspeed limitation was selected by the FAA because it is faster than almost all ultralight vehicles currently being sold but still places those vehicles in a significantly slower performance category than conventional aircraft. The determination and enforcement of this speed limitation is within the capability and resources of the FAA under the inspection requirements of the rule.

A number of commenters suggest maximum stall speed restrictions ranging from 18 to 25 miles per hour, believing that this limitation would continue to ensure the safe nature of ultralight vehicles. The FAA believes that the ability of those vehicles to operate from surfaces other than those designed for aircraft is a factor which lessens the potential for collisions and reduces the interference with aircraft operations. A relatively slow stall speed is a major contributing factor in allowing ultralight pilots to operate in a safe manner.

A maximum power-off stall speed of 24 knots was chosen because it encompasses most of the vehicles currently on the market. The stall is easily determined through a simple calculation using information which is readily available to the FAA inspector when inspecting a specific vehicle.

The total allowable fuel capacity was raised from the proposed 15 pounds to 5 U.S. gallons. The decision to increase the volume of fuel is a direct result of the desire by the FAA, in response to public comments, to ensure that adequate fuel reserves are available for safe flight.

Single Occupant

The rule limits both powered and unpowered ultralight vehicles to a single occupant. A few commenters suggest that two-seat versions be available for carrying passengers or for training purposes. The basis for allowing ultralight vehicles to operate under special rules which do not require pilot and aircraft certification is the "sport" aspect of the operation. For example, the assumption can be made that a person who elects, without pilot qualifications, to operate an uncertificated vehicle alone is fully aware of the risks involved. This assumption does not hold true of a passenger selected randomly from the general public. Persons in the general public will likely assume that the operator has certificated pilot qualifications. Because pilot qualifications are not controlled or monitored, the single-occupant requirement is a necessary component in the continuation of the policies which allow the operation of ultralight vehicles free from many of the restrictions imposed on aircraft. Persons wishing to operate two-place vehicles have the availability of existing provisions of the FAR's for conducting such operations.

Recreation or Sport Purposes Only

Recent activities and advertisements in ultralight-oriented publications (included in the docket) imply that commercial operations may be conducted by an uncertificated pilot in an ultralight which has not been certificated as an aircraft. Those types of operations are not allowed under the rule.

Several commenters suggest that ultralight vehicles be limited to sport or recreational purposes only. The position of the FAA had consistently been that these vehicles may be operated for sport and recreation purposes only. The justification for allowing the operation of these vehicles without requiring aircraft and pilot certification has been that this activity is a "sport" generally conducted away from concentrations of population and aircraft operations. Like any sport, the participants are viewed as taking personal risks which do not affect others not involved in the activity.

Section 103.3 Inspection requirements (proposed § 101.55).

This section ensures that FAA's authority to inspect ultralight vehicles for compliance with the limits specified in § 103.1 and is retained in the final rule as proposed in Notice No. 81–6.

A large number of commenters object to the inspection requirements, believing that considerable FAA manpower and resources would be required in this effort. The USHGA and its membership contributed a majority of the objecting comments, citing the remoteness of hang gliding sites as impractical for the FAA to monitor.

Given the current level of ultralight activity, the FAA is confident that enforcement of the provisions of Part 103 can be accomplished with the existing resources. As is the case today, many investigations of suspected violations are prompted by reports received from pilots, air traffic controllers, citizens, and other sources. The FAA foresees no appreciable increase in the number of these reports as a result of this rule.

Section 103.5 Waivers

In proposing to include ultralight operations under Part 101, ultralights would have been eligible for the waiver provisions applicable to all operations under that part. By removing the ultralight proposal from Part 101, the waiver eligibility for ultralights would have been lost. The FAA has concluded that the ultralight industry and the public would be best served by retention of waiver eligibility for these vehicles.

Thus, § 103.5 is added to the final rule, giving the ultralight operator the opportunity to apply for a certificate of waiver from any provisions of Part 103.

Section 103.7 Certification and registration

The intent of the FAA is to provide for safety in the national airspace with a minimum amount of regulation. Accordingly, those vehicles which meet the definition of "ultralight vehicle" will be exempt from FAA certification and registration requirements. Similarly, pilots of ultralight vehicles, as defined in this part, will not be required to possess FAA pilot certificates or airman medical certificates.

While this rule does not, at this time, require airman/aircraft certification or vehicle registration and is premised on the absolute minimum regulation necessary to ensure safety in the public interest, a continuation of burgeoning growth of the ultralight population could necessitate further regulation. The best practices and methods to preclude the need for further Federal regulation appear to at least include: self-regulation and self-policing, safety standards, membership in organizations and associations equipped to function and operate programs approved by the FAA, markings and identification of vehicles, programs including provisions similar to Federal Aviation Regulations relating to aircraft (both operation and airworthiness), etc.

FAA will continue to monitor performance of the ultralight community in terms of safety statistics, growth trends, and maturity and, if indicated, will take additional regulatory actions to preclude degradation of safety to the general public while allowing maximum freedom for ultralight operation. In summary, it should be emphasized that the individual ultralight operator's support and compliance with national self-regulation programs is essential to the FAA's continued policy of allowing industry self regulation in these areas.

Pilot Certification

A large number of commenters believe that there should be some requirement that pilots of ultralights be required to exhibit some knowledge and/or experience before being allowed to operate these vehicles. The suggestions range from no requirements to pilot certification under the requirements of Part 61. The general groupings of the comments are: (1) No certification; (2) required ground training on regulations and conventional aircraft operations; (3) required ground training and instructor sign-off for unsupervised solo operations; (4) successful passage of a written test, such as the FAA glider pilot written examination, (5) issuance of an Ultralight Pilot Certificate by the FAA based on satisfactory completion of an examination, and observed performance as the pilot of an ultralight; and (6) conforming to the certification requirements of Part 61 for student and private pilots.

The FAA endorses the ultralight community's efforts to develop and administer, under FAA guidelines, a national pilot certification program. At this time, however, pilots of ultralight vehicles are not required by Federal regulation to be certificated.

Aircraft Registration

Some commenters, primarily State and local governments, recommend that these vehicles be registered and be required to display their registration number. The reasons center around identification of any offenders. The FAA's experience in identification of offenders and processing enforcement action validates their recommendations. The FAA endorses the ultralight community's efforts to develop and maintain, under FAA guidelines, a national registration system which would be immediately accessible to the FAA. However, registration of ultralight vehicles will not be required by Federal regulation at this time.

Aircraft Certification

There are a small number of commenters who recommend additional Federal regulations requiring certification of ultralight vehicles to some design standards. The FAA has consistently refrained from the certification of these vehicles because they were operated by a single occupant for sport or recreational purposes. This policy is in accord with Federal regulatory policies regarding other sport activities. The pilots of these vehicles accept the responsibility for assuring their personal safety much as the driver of a moped street vehicle or a scuba diver does when engaged in his sport. The FAA has noted and commends the efforts of the USHGA to eatablish design standards and flight testing of new hang glider designs. The FAA endorses the development of similar standards and testing of new powered designs by the ultralight community. However, the FAA presently has no intent to require certification of these vehicles by Federal regulation.

Subpart B—Operating Rules

Section 103.9 Hazardous operations (proposed § 101.7).

This section prohibits any ultralight operator from engaging in activity which jeopardizes the safety of persons or property on the ground or in the air. The prohibition against hazardous flight or dropping of objects is common to the regulations pertaining to civil aircraft, and the FAA is addressing ultralight operations with equivalent stringency.

Section 103.11 Daylight operations (proposed § 101.43).

The proposed rule would have limited the operation of ultralights to the hours between official sunrise and official sunset. The limitation on daytime operations was retained with an added provision for twilight operations under certain conditions. Other night-time operations are not allowed.

A large number of commenters request that flight during the twilight periods of the day be allowed since those are prime times to conduct ultralight operations. They state that meteorological conditions are often best during those periods and are characterized by a lack of wind and turbulence. The AOPA believes that calm air is particularly important for the novice flyer and provides an increased safety factor, especially during training when confidence building is essential. Many commenters believe that the available light is generally adequate to allow operations during those periods and that other craft could be safely avoided.

There are some commenters who believe that operations in Alaska should be excluded from the daylight operations section. They allude to the uniqueness of their "normal" day and how ultralight operations would be adversely affected.

Several comments support the original proposal and do not want operations during the night-time hours. The primary concern centers around the difficulty in seeing these vehicles, especially at the higher altitudes, and the perceived inability of these operations to be conducted safely.

The FAA has observed ultralight operations during the twilight periods and has found the light available for such operations to be adequate in many instances. Operators were able to maneuver safely to avoid each other and also effect safe takeoffs and landings. Since most vehicles are operated at nearly the same altitude, they could be easily seen silhouetted against the lighted sky. Operations were conducted in relatively close proximity to each other, and each operator was readily aware of the others' presence. The mild weather conditions which generally prevailed during the twilight periods combined with the controllability and maneuverability of these vehicles to enhance the safety factor for flight.

The FAA is concerned, however, that unlimited operations of this type could pose a threat to aircraft which operate at higher speeds and higher altitudes. The number of potential encounters between aircraft and ultralights increases significantly as ultralights operate into areas normally traversed by certificated aircraft. Also, the ability of aircraft pilots descending into the lower altitudes to see ultralights would be minimal due to the darkened backdrop of the ground. Pilots would often not be aware of such operations taking place and could easily overrun an ultralight without ever having visual contact.

The FAA has adopted an alternative which provides an acceptable level of safety to aircraft while still allowing ultralights to operate in uncontrolled airspace during this period of the day. The FAA's conclusion on this issue is to disallow ultralight operations in controlled airspace during the period from sunset to sunrise. This affords aircraft operators the margin of safety to which they are entitled and, at the same time, leaves adequate airspace to the ultralight operator during a 30-minute twilight period.

The FAA has determined that the occasional aircraft operation in uncontrolled airspace during the twilight period should not entirely preclude ultralight operations. The visibility from above of ultralights operating at very low levels can be significantly enhanced by the addition of an anticollision light on these vehicles. Such a light would provide the descending aircraft pilot with a distinct indication of the ultralight's presence. Additionally, it would enable ultralight operators to better see and avoid each other.

For the purposes of ultralight operation, an anticollision light is defined as any flashing or stroboscopic device that is of sufficient intensity so

as to be visible for at least 3 statute miles. This regulatory approach does not impose on the ultralight owner the economic burden associated with a certificated lighting system. The ultralight must remain in uncontrolled airspace, and the anti-collision light must be operating during the twilight periods whenever the vehicle is in motion.

With respect to twilight operations in Alaska, the FAA recognizes that the periods of twilight are significantly different from those experienced in the lower latitudes. A review of the Air Almanac reveals that, in the upper latitudes, some days have no daylight periods but have over 4 hours of civil twilight. Civil twilight is defined as the period between official sunset and sunrise when the sun is less than 6 degrees below the horizon.

Regulations currently exist in Parts 91 and 101 which acknowledge the need to grant special allowances for operations in Alaska after sunset, and the FAA has determined that ultralights are entitled to the same consideration. Therefore, a provision to permit ultralight operations in Alaska during civil twilight has been added to § 103.11. The requirement to have an operating anticollision light during twilight operations is applicable to operations during this period in Alaska.

Section 103.13 Operations near aircraft and other ultralight vehicles; Right-of-way rules (proposed § 101.49).

The proposed regulations with respect to ultralight vehicle right-of-way are adopted. An additional provision is added to clarify the right-of-way requirements in situations involving powered and unpowered ultralight vehicles.

The comments regarding right-of-way range from those who believe that unpowered ultralight vehicles should have the right-of-way over all other vehicles and aircraft to those who believe that the requirements of § 91.67 should be adopted, with unpowered ultralights being grouped with gliders and the powered ultralights grouped with airplanes. The most salient reasons cited include lack of maneuvering ability and inability to change location in the air quickly.

The suggestions and associated rationale do not reveal any areas which has not been considered during the fomulation of the NPRM. The FAA has determined that uncertificated sport operations should not be given the right-of-way over all other aircraft. The small size and sport nature of the operations is a major factor in that determination. It is unlikely that the pilot of aircraft will be able to see the ultralight vehicle as readily as the pilot of the ultralight vehicle will be able to see or hear the large aircraft. Due to the forward speeds of the majority of aircraft, it may be impossible for the aircraft to make sudden changes of direction required to avoid small objects sighted at close quarters. The FAA recommends that operators engaged in ultralight operations avoid, if possible, areas where significant operations of aircraft are occurring so as to minimize the risk of midair collisions.

Some ultralight operators express concern that, if they are not given the right-of-way over aircraft, the pilots of those aircraft might deliberately fly in close proximity to the ultralights. In situations where this act can be substantiated, an investigation will be initiated to determine whether the pilot of the conventional aircraft operated in a careless or reckless manner in violation of § 91.9.

Some commenters recommend the establishment of areas where ultralight operations could be conducted and all aircraft operations would be prohibited. While the FAA has undertaken to identify locations on aeronautical charts where a specialized aeronautical activity, such as parachute jumping or gliding, is being conducted, no action is anticipated which would restrict other types of aeronautical activities in those areas and, similarly, no such action is contemplated for ultralights.

Section 103.15 Operations over congested areas (proposed § 101.47).

The proposed prohibition of ultralight vehicle operations over congested areas is retained in the final rule. The comments favoring an easing of the proposed rule focus on three main areas: (1) Those who favor permitting operations with a minimum altitude ranging from 1,000 to 3,000 feet AGL; (2) those requesting that the minimum altitude requirements of § 91.79 be allowed; and (3) those who believe that no minimum altitude should be specified, especially for unpowered vehicles, due to the short field landing ability and small size of the vehicles.

The representatives of cities and towns who commented generally favor the prohibition, believing that uncertificated aviation activities have no place over congested areas.

The FAA's position is based on the fact that ultralight vehicles are not certificated as airworthy by any approved method and are flown by uncertificated pilots for sport or recreational purposes only. Similar limitations apply to the operations of experimental and restricted category aircraft based on catastrophic incidents which have occurred in the past. The potential for such an incident makes the general issuance of the suggested authorization unacceptable. The FAA believes that concentrations of the general public must be protected from the possible dangers inherent in the operations of vehicles of uncertificated, possibly unproven designs. In specific limited instances, with appropriate operational limitations, ultralight operations may be approved over congested areas, through the waiver provisions of § 103.5.

Section 103.17 Operations in certain airspace (proposed § 101.45).

The NPRM proposed to require the ultralight operator to obtain authorization prior to operating within airport traffic areas, control zones, terminal control areas, and positive controlled airspace.

Operators of aircraft commented that the speed and visibility of ultralights are incompatible with other operations and that they should not be allowed at all in those areas. Some even suggest that a maximum operating altitude, such as 3,000 feet AGL, be imposed on all ultralight operations.

The FAA shares the concern expressed by pilots who are wary of the ability to intermix faster aircraft safely with the relatively slow ultralights; but, experience has shown that aircraft of significantly different performance characteristics can be accommodated when operations are conducted in accordance with specific authorizations. There is considerable precedence in the form of glider operations, hot air ballooning, and parachuting being conducted while aircraft safely transit the area. Historically, the greatest danger comes not from performance variables, but from operations unknown to the pilot or controller. The requirement to gain authorization before entering these airspace areas enhances the safety to all airspace users. The FAA has concluded that ultralight vehicles in compliance with the provisions of § 103.19 will be able to operate safely in those airspace areas.

Although the subject was not addressed in the NPRM, some commenters voice concern about ultralight operations conducted at or near uncontrolled airports, with many persons noting a need to develop standard operating procedures. The FAA agrees with the need to establish a compatible method of operation at uncontrolled airports but believes that the variables associated with each locality (terrain, runway configuration,

and the physical properties of the airport) combine in such a manner to preclude a generalized nationwide regulatory approach. The FAA has concluded that such operations could be handled much more efficiently by airport managers developing local procedures in concert with the ultralight community. In this way the available facilities can be used to the full extent while operational safety is maintained. Additionally, the interaction of the ultralight operators and the airport managers will serve as a basis for mutual understanding of the role this growing segment of aviation will play in the years ahead. The FAA encourages and supports efforts to reach such agreements and has been working with user groups in the development of guidelines for ultralight operations at uncontrolled airports.

Section 103.19 Operations in prohibited or restricted areas.

In the NPRM, requirements for operations of ultralights were included under the provisions of § 101.5.

In the final rule, the requirement for ultralight operators to obtain authorization prior to operating in prohibited or restricted areas is retained and restated under § 103.21.

Prohibited areas have been developed to provide for the safety and security of operations being conducted and to segregate activities, considered to be hazardous to nonparticipating aircraft. Such operations in these areas include military and presidential security, flight training and testing, experimental weapons testing, and the launch and recovery of rocket-powered vehicles.

Many commenters recognize the need to limit access to these operating areas and accept the requirement to obtain permission prior to operating in these areas. A few commenters believe that this restriction should not apply to them and that ultralight vehicles should be allowed to operate at their own risk.

The FAA has determined that allowing any aeronautical activity to enter prohibited or restricted areas without prior authorization would derogate the purpose for which these areas were established. Avoidance of such areas by ultralight operators is not viewed as imposing a significant burden on ultralight operations.

Section 103.21 Visual reference to the surface (proposed § 101.51).

NPRM No. 81–6 proposed that ultralight operators be required to maintain visual reference to the surface during all flight operations. This would ensure that the operator of an ultralight would have the opportunity to descend and land safely at any time without entering obscuring weather phenomena.

Many commenters support the proposal as reasonable and representative of normal ultralight operations. they recognize the possibility of being caught "on top" and the danger, both to themselves and to other airspace users, of trying to descend through a layer of clouds. A few commenters believe that visual reference to the surface is necessary only while climbing or descending and not while in level flight.

The FAA has determined that visual reference with the surface is necessary at all times. Experience with certificated aircraft has shown that many pilots, with fully instrumented aircraft, have been caught "on top" and have required assistance from Air Traffic Control to descend safely. Flying "on top" or between cloud layers often presents visual illusions which cannot be verified without instrumentation. The effect of these illusions is to disorient the airman spatially, with a resulting loss of control of the craft. It takes a well-trained and disciplined pilot to ignore what information the human senses are providing and rely on the instrumentation aboard the aircraft.

In the case of ultralights, there is relatively little, if any, instrumentation with which to confirm the flight attitude of the vehicle. Further, if the ultralight operator should get caught "on top," there is no alternative available but to descend unannounced through the clouds. The ultralight operator would be risking not only his own life, but the lives of persons who rely on the safeguards inherent in certificated aviation.

The FAA has determined that inclusion in the final rule of the requirement to maintain visual reference with the surface is necessary to reduce the potential for collisions and insure the safe operation of ultralight vehicles.

Section 103.23 Flight visibility and cloud clearance requirements (proposed § 101.53).

The flight visibility and cloud clearance requirements proposed in the NPRM are the same as those under § 91.105, the basic minima for VFR flight operations by fixed-wing aircraft. Since ultralight vehicles will be sharing the same airspace, the FAA has determined it is practical to apply the same operating minima.

Many commenters to this proposal are receptive to the similarity in visibility requirements for all airspace users. Many ultralight operators indicate an appreciation for the inherent safety in being able to see and avoid obstructions and other aeronautical activities. Establishment of specific visibility standards is viewed as enhancing the legitimacy and utility of ultralight operations.

Some commenters believed that the distance from clouds should be reduced to "clear of clouds." Their basis for such a change centers around the difficulty in determining actual distances from clouds.

Other commenters suggest that hang gliders be allowed to continue their practice of operating near and in the base of clouds. Their rationale is based on the added lift available from being in close proximity to cumulus clouds. Some hang glider operators fear that the restriction on in-cloud operations would eliminate their ability to vie for long-distance and high-altitude records.

The FAA cannot support the operation of ultralights in or near clouds. A specific distance from clouds is required when operating in controlled airspace, primarily due to the presence of aircraft conducting instrument flight operations through the clouds. The cloud clearance requirements serve as a practical buffer to reduce the possibility of having an aircraft exit the clouds on an unalterable collision course. Operating too close to clouds does, in effect, cause a blind side in the aviator's vision. Operation in and near clouds severely restricts the ultralight operator's ability to see and avoid, an ability that is paramount in allowing ultralight operations to take place.

In maintaining a safe distance from clouds, the FAA has concluded that ultralight operators can reasonably approximate, when operations are being conducted, the required distance from clouds. Experience with other segments of aviation has shown that it is readily apparent that, when operations approach an unsafe distance from clouds and adherence to the prescribed minimum distance determination becomes relatively easy. Therefore, retention of the flight visibility and clouds clearance requirements, as proposed, is essential for maintaining airspace safety.

List of Subjects in 14 CFR Part 103

Aviation safety, Ultralight vehicles.

Adoption of the Amendment

Accordingly, the Federal Aviation Regulations (14 CFR Chapter I) are amended, effective October 4, 1982, by adding to Subchapter F (14 CFR Chapter I) a new Part 103 as follows:

PART 103—ULTRALIGHT VEHICLES

Subpart A—General

Subpart B—Operating Rules

Authority: Secs. 307, 313(a), 601(a), 602, and 603, Federal Aviation Act of 1958 (49 U.S.C. 1348, 1354(a), 1421(a), 1422, and 1423); sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c)

Subpart A—General

§ 103.1 Applicability.

This part prescribes rules governing the operation of ultralight vehicles in the United States. For the purposes of this part, an ultralight vehicle is a vehicle that:

(a) Is used or intended to be used for manned operation in the air by a single occupant;

(b) Is used or intended to be used for recreation or sport purposes only;

(c) Does not have any U.S. or foreign airworthiness certificate; and

(d) If unpowered, weighs less than 155 pounds; or

(e) If powered:

(1) Weighs less than 254 pounds empty weight, excluding floats and safety devices which are intended for deployment in a potentially catastrophic situation;

(2) Has a fuel capacity not exceeding 5 U.S. gallons;

(3) Is not capable of more than 55 knots calibrated airspeed at full power in level flight; and

(4) Has a power-off stall speed which does not exceed 24 knots calibrated airspeed.

§ 103.3 Inspection requirements.

(a) Any person operating an ultralight vehicle under this part shall, upon request, allow the Administrator, or his designee, to inspect the vehicle to determine the applicability of this part.

(b) The pilot or operator of an ultralight vehicle must, upon request of the Administrator, furnish satisfactory evidence that the vehicle is subject only to the provisions of this part.

§ 103.5 Waivers.

No person may conduct operations that require a deviation from this part except under a written waiver issued by the Administrator.

§ 103.7 Certification and registration.

(a) Notwithstanding any other section pertaining to certification of aircraft or their parts or equipment, ultralight vehicles and their component parts and equipment are not required to meet the airworthiness certification standards specified for aircraft or to have certificates of airworthiness.

(b) Notwithstanding any other section pertaining to airman certification, operators of ultralight vehicles are not required to meet any aeronautical knowledge, age, or experience requirements to operate those vehicles or to have airman or medical certificates.

(c) Notwithstanding any other section pertaining to registration and marking of aircraft, ultralight vehicles are not required to be registered or to bear markings of any type.

Subpart B—Operating Rules

§ 103.9 Hazardous operations.

(a) No person may operate any ultralight vehicle in a manner that creates a hazard to other persons or property.

(b) No person may allow an object to be dropped from an ultralight vehicle if such action creates a hazard to other persons or property.

§ 103.11 Daylight operations.

(a) No person may operate an ultralight vehicle except between the hours of sunrise and sunset.

(b) Notwithstanding paragraph (a) of this section, ultralight vehicles may be operated during the twilight periods 30 minutes before official sunrise and 30 minutes after official sunset or, in Alaska, during the period of civil twilight as defined in the Air Almanac, if:

(1) The vehicle is equipped with an operating anticollision light visible for at least 3 statute miles; and

(2) All operations are conducted in uncontrolled airspace.

§ 103.13 Operation near aircraft; Right-of-way rules.

(a) Each person operating an ultralight vehicle shall maintain vigilance so as to see and avoid aircraft and shall yield the right-of-way to all aircraft.

(b) No person may operate an ultralight vehicle in a manner that creates a collision hazard with respect to any aircraft.

(c) Powered ultralights shall yield the right-of-way to unpowered ultralights.

§ 103.15 Operations over congested areas.

No person may operate an ultralight vehicle over any congested area of a city, town, or settlement, or over any open air assembly of persons.

§ 103.17 Operations in certain airspace.

No person may operate an ultralight vehicle within an airport traffic area, control zone, terminal control area, or positive control area unless that person has prior authorization from the air traffic control facility having jurisdiction over that airspace.

§ 103.19 Operations in prohibited or restricted areas.

No person may operate an ultralight vehicle in prohibited or restricted areas unless that person has permission from the using or controlling agency, as appropriate.

§ 103.21 Visual reference with the surface.

No person may operate an ultralight vehicle except by visual reference with the surface.

§ 103.23 Flight visibility and cloud clearance requirements.

No person may operate an ultralight vehicle when the flight visibility or distance from clouds is less than that in the following table, as appropriate:

Flight altitudes	Minimum flight visibility [1]	Minimum distance from clouds
1,200 feet or less above the surface regardless of MSL altitude:		
(1) Within controlled airspace	3	500 feet below, 1,000 feet above, 2,000 feet horizontal.
(2) Outside controlled airspace	1	Clear of clouds.
More than 1,200 feet above the surface but less than 10,000 feet MSL:		
(1) Within controlled airspace	3	500 feet below, 1,000 feet above, 2,000 feet horizontal.
(2) Outside controlled airspace	1	500 feet below, 1,000 feet above, 2,000 feet horizontal.
More than 1,200 feet above the surface and at or above 10,000 feet MSL.	5	1,000 feet below, 1,000 feet above, 1 statute mile horizontal.

[1] Statute miles.

Note.—The FAA has determined that this regulation is not a major rule under Executive Order 12291. Because the rule will regulate a new user segment and because of substantial public interest, it has been determined that it is a significant rule pursuant to the Department of Transportation Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). The total projected costs of this rule may be found in a copy of the regulatory evaluation contained in the public docket. A copy of that evaluation may be obtained by contacting the person identified above under the caption **"FOR FURTHER INFORMATION CONTACT."** It is certified under the criteria of the Regulatory Flexibility Act that this rule will not have a significant economic impact on a substantial number of small entities. There are very few small entities involved in ultralight vehicle activities and the majority of those will be unaffected by the implementation of this rule.

Issued in Washington, DC, on July 30, 1982.

J. Lynn Helms,

Administrator.

[FR Doc. 82-23936 Filed 8-27-82; 1:02 pm]

BILLING CODE 4910-13-M

federal register

Thursday
September 2, 1982

Part III

Environmental Protection Agency

Health and Safety Data Reporting; Submission of Lists and Copies of Health and Safety Studies

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 716

[OPTS-84003A; TSH-FRL 2112-2]

Health and Safety Data Reporting; Submission of Lists and Copies of Health and Safety Studies

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule requires the submission of unpublished health and safety studies on specifically listed chemicals by chemical manufacturers, processors, and others in possession of such studies. The rule is issued under section 8(d) of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2607(d). The Administrator will issue amendments in the **Federal Register** to add to the list of chemicals subject to the rule. Amendments to add chemicals recommended for testing by the Interagency Testing Committee (ITC), established under section 4 of TSCA, will be effective upon publication. Amendments to add other chemicals will be subject to a thirty-day comment period. This notice promulgates the final version of regulations proposed on December 31, 1979 at 44 FR 77470.

EFFECTIVE DATE: October 4, 1982.

FOR FURTHER INFORMATION CONTACT: Douglas Bannerman, Acting Director, Industry Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-511, 401 M Street, SW., Washington, DC 20460; toll free (800-424-9065); in Washington, DC (554-1404); outside the USA (Operator-202-554-1404).

SUPPLEMENTARY INFORMATION: OMB Control Number: 2070-0004.

Background

In the **Federal Register** of July 18, 1978 (43 FR 30984), EPA promulgated a previous version of this rule under section 8(d) of TSCA (43 FR 30984) requiring reporting of studies of chemicals listed on the first ITC report. That rule was challenged by the Dow Chemical Company and was subsequently revoked (see 44 FR 77470). Two provisions of that rule were the subject of a lawsuit, *Dow Chemical Company* v. *EPA*, 605 F.2d 673 (1979). The two provisions concerned obtaining studies on chemicals manufactured or processed for research and development purposes and obtaining copies of studies on a chemical from companies that do not manufacture, process or distribute that chemical. The Court upheld EPA's authority for both provisions.

Purpose and Use of the Rule

Under this rule, EPA will acquire unpublished health and safety studies on specified chemicals from manufacturers and processors of the chemicals. The Agency will use the studies to support its investigations of the risks posed by chemicals and, in particular, to support its decisions whether to require industry to test chemicals under section 4 of TSCA. The addition of chemicals to the rule will occur by notice of amendment in the **Federal Register**. In the case of chemicals recommended for testing by the ITC, the amendment will be effective thirty days after publication. For other chemicals, the amendment will be subject to a thirty-day public comment period before promulgation.

Studies of health and environmental effects, including studies of exposures of people or the environment, are the fundamental ingredients of any assessment of chemical risk. For this reason, EPA will require reporting under this rule for specific chemicals that are under investigation either in early stages of risk assessment or when action to control exposure is being considered. Furthermore, EPA expects to require submission of unpublished health and safety studies for all chemicals under consideration for required testing under section 4 of TSCA. EPA will evaluate the studies reported under this rule together with other available data to construct a picture of the effects of chemicals and their associated risks.

The studies submitted under the previously issued section 8(d) rule (43 FR 30984, July 18, 1978), have been very useful in the Agency's investigation of the effects of the ITC-recommended chemicals covered by that rule. The studies have been used in designing appropriate tests, and in support of the basic decision whether testing for a particular biological effect should be carried out. For example, studies submitted on chlorinated benzenes contributed significantly to EPA's design of a testing scheme for mutagenicity. The Agency, itself, will conduct these tests. Similarly, studies submitted on monochlorobenzene supported our decisions on the need for testing of the reproductive effects of that substance. These are examples of two important contributions that submitted studies can make to testing decisions.

Overview of Rule Requirements

Extensive comment was received on the question of what records a company should search to comply with this rule. The proposal spoke of information "known to" or in the "possession" of respondents. The definitions given for these terms were broad, and comments indicated that, under these definitions, companies would feel obliged to search many more records than we believe necessary. We have decided to replace the definitions with a description of the scope of a search that will be adequate for this rule. The rule now says that respondents are responsible for searching only the company files in which they ordinarily keep studies and the records kept by employees whose assigned duty is to advise the company on health and environmental effects of chemicals. Moreover, for all compliance purposes, respondents need not consult any records that they retired prior to December 31, 1979, the date on which this rule was proposed.

The rule has two basic requirements: Submission of copies of studies in the possession of persons subject to the rule and submission of lists of studies ongoing at the time of submission or known to but not possessed by the submitter. Persons who are manufacturing or processing a chemical at the time it is listed in the rule, or are proposing to do so, are required to submit both copies and lists of studies for that chemcial. EPA decided to exempt distributors from reporting, because we believe that very few distributors perform these studies and that the burden to these persons outweighs making them subject to the rule. An examination of the respondents to the previous section 8(d) rule revealed that no distributors submitted studies. These reporting requirements remain applicable until the sunset date for the chemical (three years after the chemical is made subject to the rule) to cover studies begun during that period, and to cover persons who begin, or are proposing to begin, manufacturing or processing a listed chemical during that period.

Persons who are not involved with a chemical when it is listed but manufactured or processed it or proposed to do so any time during the ten years prior to the time it is listed, are required to submit copies of studies for that chemical, but are not required to list studies.

Since the proposal, changes have been made regarding the types of studies that must be submitted. Several types have been exempted. The final requirements represent the Agency's effort to reduce the burden of the rule while still obtaining the most useful studies for our assessments. EPA received many good comments that allowed the Agency to

identify the studies that were most burdensome to submit and least useful for its assessments. Therefore, the Agency has added to the exemptions originally proposed. The final rule has the following overall exemptions: (1) Physical and chemical properties other than ten that are specifically listed; (2) studies of a substance or mixture that a person has manufactured or processed, or proposed to manufacture or process as an impurity; (3) published studies; (4) non-confidential studies submitted previously to another Federal agency; (5) all studies previously submitted to EPA (this includes studies voluntarily submitted during section 4 proceedings or under the previous section 8(d) rule); (6) studies of chemical substances which are not on the TSCA Chemical Substance Inventory, i.e., research and development studies on new chemical substances, and (7) underlying data such as medical records, monitoring data, and lab notebooks (unless the EPA requests the data later, by personal letter). In addition, certain types of studies of mixtures are exempted as stated below.

In summary, the reportable studies are: (1) Studies of listed chemicals with the seven exclusions noted above; and (2) studies of mixtures containing listed chemicals with the seven exclusions noted above and also excluding: acute oral toxicity studies, acute dermal toxicity studies, acute inhalation toxicity studies, primary eye irritation studies, primary dermal irritation studies, and physical and chemical properties.

Organization of This Preamble

EPA received more than 100 responses to the proposed rule, each containing multiple comments. Several aspects of the rule received numerous comments; other aspects, only one or a few. In this preamble, the Agency discusses the major comment areas: specific definitions; chemical substances subject to the rule; lists and copies to be submitted and who should submit them; studies not subject to mandatory reporting; file search; reporting schedule and sunset provision; confidentiality; and economic impact. The subjects that received only one or a few comments are individually discussed in a document entitled "General Comments on the Proposed Section 8(d) Rule" which is part of the public record.

I. Specific Definitions

A. Manufacture and Process for Commercial Purposes

EPA interprets the term "manufacture or process for commercial purposes" to refer to such activities conducted, in whole or in part, for the purpose of obtaining a commercial advantage for the manufacturer or processor as distinguished from charitable or academic purposes. Therefore, chemicals manufactured for product research and development (R & D), as well as byproducts and impurities of commercial manufacturing and processing, are "for commercial purposes."

EPA received comments saying that the Agency's interpretation is wrong because these substances themselves are not actually marketed, and, in the case of byproducts and impurities, are not desired for the market. However, the Agency considers it undeniable that products of commercial endeavors are made for commercial purposes. Moreover, the reason that section 8 of TSCA exists is to give the Agency access to information from which it can assess the nature and significance of chemical hazards and risks. TSCA is intended to address these hazards and risks to health or the environment whether or not the chemicals are desired commercial products.

The commenters thought that the Inventory Rule exempted reporting of byproducts, impurities, and R & D chemicals because they were not considered to be "for commercial purposes." On the contrary, this section 8(d) rule is completely consistent with the Inventory rule, both rules define these chemicals as "for commercial purposes." The Inventory Rule exempted such substances only because they were not appropriate for inclusion in the Inventory. In this final rule the Agency has limited the potential reach of this interpretation. A description of the applicability of the rule to impurities, byproducts, and R & D chemicals follows.

(1) *Impurities.* Under this rule, EPA has excluded from reporting any studies of chemicals that the person reporting has manufactured or processed or has proposed to manufacture or process only as impurities.

Since the chemicals presently listed in the rule are marketed most widely as desirable products, rather than as impurities, EPA expects that the excluded studies will be so few as not to justify the burden of searching for them. However, in other circumstances, the Agency may propose to require the excluded studies to be reported for some chemicals.

(2) *Byproducts.* It should be noted that the definition of "manufacture for commercial purposes" includes only byproduct substances and mixtures that are separated from the other substance or mixture that is being manufactured, processed, used, or disposed of. Other substances that are produced as byproducts, but not separated from the product, are impurities of the product and are thus not covered in the present rule.

This rule requires manufacturers of these separated byproducts to report studies on them and on mixtures containing them. Thus, persons who manufacture a listed chemical as a known byproduct that they separate during manufacture, processing, use, or disposal of another chemical must report studies on the known byproduct. EPA equates these studies with studies of the same chemicals as desired products. The studies will be just as telling on the effects of the chemicals.

(3) *R & D Chemicals.* The Third Circuit has upheld EPA in its view that substances manufactured for R & D purposes are manufactured for commercial purposes, *Dow* v. *EPA*, 605 F. 2d 673 (3rd Cir. 1979). EPA discussed the importance of these studies in the preamble to the proposed rule and continue to regard them as important resources in investigating the effects and risks associated with substances. However, to minimize the burden of this requirement, EPA has exempted persons from reporting studies on chemical substances that are not on the TSCA Chemical Substances Inventory, e.g., new chemical substances. When a premanufacture notice (PMN) is submitted on a new substance, any health and safety data on the substance would be submitted.

B. Propose to Manufacture, Process, or Distribute

"Propose to manufacture, process, or distribute" is defined in this rule to mean that a person has made a management decision to commit financial resources toward the manufacture, processing, or distribution of a chemical substance or mixture. A company could commit financial resources by, for example, hiring additional personnel, commissioning a construction engineering plan, purchasing land to construct manufacturing or processing facilities, purchasing production equipment, or contracting for raw materials.

One commenter stated that EPA should exempt persons that propose to manufacture, process, or distribute the listed substances because they would not have many studies. EPA has not adopted this suggestion. Valuable studies might be missed if these persons are exempted. The Agency would be particularly interested in the results of a

study which prompted a decision not to manufacture, process, or distribute a substance.

Some commenters felt that the proposed definition covered actions too early in a company's deliberations and that "propose to" should not hinge on a management decision to commit resources toward manufacture, but should require an actual management decision to manufacture the chemical, e.g., building a plant. The Agency recognizes that there are many individual decisions made prior to actual manufacture. Building a plant, for instance, only moves a person toward the manufacture of a chemical. Until the substance is actually manufactured, all the actions management might make only move the company toward manufacture of the substance. These actions are considered here as "proposed" manufacture.

Other commenters asserted that the meaning of "propose" is clear in the premanufacture notification provisions of section 5 where the requirement is to submit the notice at least ninety days before production. EPA disagrees. Section 5 requires a notice when a person "intends" to manufacture a new chemical substance, not when he "proposes" to manufacture. When a person is ready to submit a section 5 notice, he is beyond the initial stage in which he "proposes" to manufacture for purposes of section 8.

The Agency has not changed the definition. The Agency believes it is as specific as a definition of such a concept can be, given the variability of businesses covered.

C. Health and Safety Study

Many commenters argued that some of the examples of health and safety studies given in the proposed definition are not "studies" in their view. They argued that only studies designed to provide a direct measure of effects on human health or the environment should be included. They cited two kinds of studies they would exclude as not being direct measures.

One kind was measurement of a chemical's concentration in the workplace or environment. Another kind was measurements of properties of chemicals, such as: biological, photochemical, and chemical degradation; air, water, and soil transport; and water solubility, vapor pressure, and octanol/water partition coefficient.

The Agency disagrees with this narrow view. The legislative history of TSCA indicates that Congress expects the Agency to collect a broad range of information relevant to health and environmental effects.

It is intended that the term (health and safety studies) be interpreted broadly. Not only is information which arises as a result of a formal, disciplined study included, but other information relating to the effects of a chemical substance or mixture on health and the environment is also included. Any data which bears on the effects of a chemical substance on health or the environment would be included. H.R. Rep. No. 94–179, 94th Cong., 2nd Sess. 58 (1976) (Conference Report).

All of the data EPA will obtain under this rule, bear on the effects of chemical substances on health or the environment.

When measurements of a chemical's concentration have been analyzed to draw conclusions about occupational or environmental exposure, a "health and safety study" has been done. Similarly, determinations of physical and chemical properties that relate to a chemical's potential for affecting health or the environment are "health and safety studies."

(1) *Measures of concentration.* The final rule requires the submission of analyzed aggregates of measurements monitoring concentrations of a chemical in the workplace or environment. These are limited to analyses of data gathered within five years of the effective date for reporting on the chemical. These studies bear significantly on the effects of a chemical on health or the environment. For instance, if the Agency knows that a chemical never reaches the environment, it would know that it will not have an effect on the environment.

Some of the concerns commenters had about submitting monitoring data were because they understood the proposal to say that all underlying data were to be initially submitted. This would have meant submitting a very large amount of material. As explained below, underlying data are not to be initially submitted.

(2) *Properties of chemicals.* The final rule requires reporting on studies of ten properties when those studies are for the purpose of determining the environmental or biological fate of the substance: (a) Water solubility; (b) adsorption/desorption on particulate surfaces (e.g., soil); (c) vapor pressure; (d) octanol/water partition coefficient; (e) density/relative density (specific gravity); (f) particle size distribution for insoluble solids; (g) dissociation constant; (h) degradation by photochemical mechanisms—aquatic and atmospheric; (i) degradation by chemical mechanisms—hydrolytic, reductive, and oxidative; and (j) degradation by biological mechanisms—aerobic and anaerobic.

These properties of a chemical are very important elements to consider in assessing its potential biological effects. For example, water solubility and partition coefficient bear on the question of whether a chemical could become deposited in body fat tissues. For another example, all of the properties are informative on the questions of whether a chemical released into the environment would remain for a long time and be transported over a large area.

EPA decided to narrow the requirements for submitting properties in an effort to reduce the reporting burden. There are other properties that are very useful, but the Agency focused on these ten properties as being particularly informative, individually and together.

Determinations of physical and chemical properties, together with the other studies, will give a picture of the chemical's exposure and effects which will permit effective evaluation of potential risks. An evaluation of the environmental fate of a chemical, which is based on physical and chemical properties, that may be released to the envirionment is of critical importance. It is possible that a highly toxic, easily degradable substance will be less an object of concern than a less toxic, persistent chemical. Recent technical reports have indicated the importance of environmental fate testing.

For chemicals that are likely to be released to the environment, environmental fate testing is equally as important as biological effects testing. For many chemicals, adverse biological effects were discovered following extensive testing undertaken only after the discovery of widespread environmental contamination. (See Howard, P. H., et. al, Environmental Science and Technology, 12(4), 407 (1978)).

Determining the fate of a chemical substance in the environment and, thus, its effects, may involve investigating the nature of dispersal and ultimate distribution, and the types and rates of reactions in which the chemical participates during transport. Fate determinations help to identify the chemical form(s), the environmental compartments or concentration ranges to which the environment will be exposed, and the organisms exposed to the chemical. (See 45 FR 77332, (proposed environmental test standards) for a further discussion of the importance of physical and chemical properties in determining the environmental effects of chemicals.)

(3) *Underlying data.* Data such as individual monitoring records or employee medical records that may underlie an epidemiological or exposure study are not required to be submitted as initial reports under the rule. EPA may request these and other underlying data such as lab notebooks as a follow up to its examination of a study. The Agency does not anticipate making such requests very frequently. It will do so when a question of interpretation arises (such as when the Agency has studies whose results appear to conflict) and an examination of the underlying data may clarify the problem.

D. Known to and Possession

As previously discussed, the Agency has decided to delete definitions of "known to" and "possession" and, instead, describe the kind of file search that will suffice for compliance with this rule. From comments received on the proposed definitions, it is apparent that the definitional approach to delineating a responsibility to search for studies is too indirect. The matter is discussed further under the preamble section titled "File Search."

II. Chemical Substances Subject to the Rule

Section 716.17 of the rule contains a list of chemical substances subject to the rule. A subsection of § 716.17 is reserved for future listing of designated mixtures subject to the rule.

The majority of the chemicals presently listed are ones for which the ITC has recommended that EPA propose testing rules. It is important that EPA review unpublished studies on these chemicals to avoid unknowingly proposing testing under section 4 that may already have been done, and to base judgments about testing on as full an overview of existing information as practicable. The goal is to focus proposals for testing as efficiently as present knowledge will permit.

The list in § 716.17 contains two groups of chemicals. One group consists of the chemicals recommended by the ITC for testing. The other group of chemicals includes the asbestiform varieties of chrysotile, crocidolite, amosite, anthophyllite, tremolite, and actinolite, i.e., asbestos, which is being considered for control.

The bisazobiphenyl (BAB) dyes were recommended for testing, and are the subject of a broader Federal effort. Assessment actions are underway at CPSC and OSHA. In addition, the BAB dyes are being tested by CPSC (skin absorption) and at the National Center for Toxicological Research (metabolism studies).

Several chemicals in the proposed list have been removed in the final rule. A subset of one category of chemicals, listed in the proposal as "organotins" (selected by EPA) was subsequently recommended for testing by the ITC, 45 FR 78432 (November 25, 1980). The ITC had recommended the subset "alkyltins." However, the ITC has subsequently removed this category from the section 4(a) Priority List for reconsideration (47 FR 5459). EPA has deferred reporting on these and the other organotins for a later proposal. Another category of chemicals, acrylic acid and methylacrylic acid and their esters, has been removed from the rule. EPA will propose the category in a future iteration of this rule after it has better defined the category. Dioxin and related substances have also been removed from the rule. Since proposing their inclusion in this rule, the Agency has carried out administrative proceedings dealing with dioxin issues which have covered the ground that would have been covered by having the chemicals reported under this rule. Other chemicals removed from the rule include acrylonitrile, alphachlorotoluene, benzene, benzene (epoxyethyl), chlorendic anhydride, chlorodifluoromethane, 1,2-dichloroethane, 2-chloro-1,3-butadiene, ethyl benzene, iodomethane (methyl iodide), morpholine, nitrosodiethanolamine, 2-nitropropane, and vinylbenzene (styrene). These chemicals were removed for a number of reasons. Some (e.g., benzene, styrene) were the subject of earlier section 8(e) submissions and have since been referred to other EPA program offices or Federal agencies for study. The remainder were under early stages of assessment when they were added to the proposed rule. In the intervening time, however, the Agency has brought some of these assessments to near completion, e.g., 2-nitropropane.

Several comments argued that EPA did not provide adequate public notice and opportunity for comment because the Agency did not state in its proposal a reasoned explanation of how or why each particular chemical was selected. These comments said that the Agency must, for each chemical, show that the information to be reported will contribute to articulated regulatory objectives. In particular, they stated that EPA must show why it believes that each chemical might pose a risk to health or the environment and why published studies provide insufficient information for conducting a risk assessment, evaluating the need for testing, or considering other regulatory options. These comments also claimed the Agency must show for each chemical subject to the rule that the information requested is not available from other sources.

EPA believes it has justified, to the extent required by section 8(d), the need for reporting on the chemicals subject to the final rule. The Agency disagrees with the comments on the level of detail required to justify reporting. The comments would require that the Agency prepare an extensive chemical specific determination that would require a search of the entire scientific literature and all available sources and a complete hazard analysis of the chemical. Thus, according to the comments, section 8(d) could be used only to obtain information as a last resort. This is contrary to the intent of TSCA. There is nothing in the language or legislative history of the Act to indicate that section 8(d) is to be used in such a manner. On the contrary, section 8(d) is meant to reveal information early in the investigation phase. (See Report of the Senate Committee on Commerce, S. Rep. No. 698, 94th Cong., 2d Sess. 8 (1976).)

TSCA requires the Agency to provide only a general explanation of its concern before requesting unpublished studies on a chemical under section 8(d). Sufficient justification is provided if the chemical is recommended for testing by the Interagency Testing Committee or if EPA staff judges that further data on the chemical are needed for assessment. EPA should not ignore the possibility of obtaining data under section 8(d) when a chemical is under evaluation by the Agency staff.

EPA particularly disagrees that it must show during a section 8(d) proceeding that a chemical may present a risk. Congress could not have intended the Agency to make a risk finding under a section of the statute that is designed to reveal the hazards of a chemical.

As to the comment that EPA must indicate for each chemical that information required by this rule cannot be obtained from other sources, the final rule in fact accommodates this comment by excluding from rule requirements any studies available from sources to which EPA has access—published studies and studies submitted to other Federal agencies without confidentiality claims. The studies subject to the rule are those not otherwise available to the Agency.

Several comments argue that to provide adequate public notice and opportunity for comment EPA must in the proposed rule state for each chemical subject to section 8(d) that the information requested is not more detailed or extensive than necessary,

and will not burden more persons than necessary with reporting obligations.

EPA concurs that as a matter of sound policy these factors should be considered by the Agency for this section 8(d) rule, but disagrees that it can prepare detailed assessments of these factors at the time it proposes a section 8(d) rule. In fact, EPA has proposed this rule to solicit from the companies that obtain commercial advantage from the subject chemicals comments on whether reporting on their particular chemicals will be unnecessarily burdensome. These companies have or should have the knowledge to enable the Agency to make this decision. Indeed, the Agency has, in response to comments, eliminated some types of studies and some chemicals that were originally part of the proposal.

Many comments objected to the Agency's automatically making subject to the rule chemicals recommended for testing by the ITC. These comments claim that recommendation for testing by the ITC is not sufficient to justify an automatic reporting requirement. They argue that EPA must allow the public to present reasons why unpublished studies should not be collected in order to avoid imposing unnecessary or overly burdensome reporting requirements. The comments stated the following examples of situations in which the public should be able to comment on EPA's decision to obtain studies under this rule for ITC chemicals; EPA may be able to obtain unpublished studies on a voluntary basis; EPA may be able to make a decision to proceed with or abandon testing on the basis of information in hand; EPA and the public may need to consider whether studies should be submitted on effects in addition to those of concern to the ITC; the ITC may have overlooked a crucial study in the literature; voluntary testing may have been initiated or all manufacture and processing may have ceased.

EPA does not find this reasoning persuasive. Within one year after the ITC recommends a chemical for testing, the Agency must initiate a rulemaking proceeding to require testing under section 4 of TSCA or publish its reasons for not initiating such a proceeding. Because it has such a short period of time to make this decision, the Agency must proceed as rapidly as possible to gather available data on a chemical.

To decide whether to propose a test rule within one year, the Agency needs to be able to complete its assessment of the known health and environmental effects of a chemical no later than the first four to five months after the ITC recommendation. If studies are reported automatically under this rule, the Agency will receive them by the end of the fourth month. On the other hand, if the chemicals were proposed for comment, an additional two to three months would be required to give time for the comment period, EPA writing of responses to the comments, and EPA preparation and publication of a final rule. The Agency would then receive the studies by the end of the sixth or seventh month after the ITC recommendation. However, by this time EPA staff must complete their analyses for EPA decisionmakers to consider. EPA has previously discussed in this preamble the importance of section 8(d) studies in deciding whether to initiate proceedings to require testing and has discussed examples showing that unpublished studies submitted previously have been valuable in section 4 proceedings. Receipt of significant studies at this late stage that could cause fundamental revision of the basic analyses would make it impossible to meet the Agency's one-year deadline.

The Agency has also considered in this section 8(d) proceeding a large number of issues relating to reporting of unpublished studies. The Agency has been unable to determine, and no comments have been presented to indicate, that any other issues would be raised in a comment period that would lead the Agency not to require section 8(d) studies on ITC-recommended chemicals. Most of the examples described above of situations in which the public should be able to comment on decisions under section 8(d) on ITC chemicals are reasons why chemicals should or should not be tested under section 4. This section 8(d) rule is not for determining whether to proceed with testing under section 4, but is to be used to obtain information to assist in section 4 decisions. Most of the situations described by the comments, therefore, would not be relevant to a section 8(d) proceeding.

Further, EPA will not delay section 8(d) proceedings while it considers whether to wait for studies to be submitted voluntarily. The Agency has found that, while studies may be voluntarily submitted in some cases, all companies will not do so. Inquiring after voluntary submissions is a highly inefficient use of Agency time and resources and would unnecessarily delay input into the section 4 test rule process.

EPA's economic analysis shows that the costs of searching for studies on ITC chemicals in accordance with the procedures set forth in this rule will be very small. Further, the Agency expects that in the future companies will establish a system to enable more efficient retrieval of studies requested under section 8(d). After considering these costs against the relatively quick need the Agency has for studies of ITC chemicals, EPA has determined that such chemicals should become subject to the section 8(d) rule as soon as possible after the ITC recommends them.

III. Lists and Copies to be Submitted and Who Should Submit Them

The rule includes two types of submission requirements—the requirement to submit copies of health and safety studies, with an appropriate index, and the requirement to submit lists of certain additional health and safety studies.

A. Requirements for Submitting Copies of Studies

Two requirements to submit copies of studies will apply. First, any person who has manufactured or processed or who has proposed to manufacture or process a substance or designated mixture listed in § 716.17, within the ten years preceding and including the date the chemical is listed, will be required to submit copies of any unpublished studies he possesses on that chemical. Second, EPA may request copies from persons other than manufacturers and processors of the chemical when such persons are identified as possessing studies listed by someone else in accordance with § 716.12. Such persons would be requested to submit these studies voluntarily, but would be subject to subpoena under section 11 of TSCA if they do not comply.

This represents a change from the proposal which would have made all manufacturers, processors, and distributors subject to the copy submission requirement. Now, only those who actually have dealt with the chemical must report (except distributors).

Many comments suggested ideas for limiting the persons subject to the rule and limiting the types of studies to be submitted. These ideas were:

(1) Limit the copy submission requirement to past and present manufacturers, processors, and distributors of the chemicals selected by EPA since, in the commenters' view, these would obviously be the parties with the greatest interest in developing data, and thus the ones most likely to possess it.

EPA agrees and has changed the initial reporting under the rule accordingly. However, EPA may later

request any person, who is listed pursuant to § 716.7 as possessing a study, to submit that study.

(2) Limit the copy submission requirement of past manufacturers to those who have manufactured since 1965, 1970, 1975, or presently manufacture instead of since 1950 as proposed. The commenters maintain that these "cut-off" dates would tend to reduce the volume of studies collected and would maximize the quality of the studies being collected since, in the commenters' view, older studies tend to be of less value.

EPA retained the reporting requirements for past manufacturers and processors because they are just as likely to have good studies as present manufacturers and processors. EPA proposes the January 1, 1950 date because persons who have dealt with the chemical and performed studies in the last thirty years would have utilized more advanced analytical techniques. The Agency received comments basically agreeing with EPA's view that there is a time in the past beyond which techniques were not so good as they are now. However, commenters suggested cut-off dates from 1965 to 1975, with most commenters suggesting 1970 as a cut-off date because they believe that information more than ten years old may be outdated and of little value.

Commenters agree that more advanced analytical techniques were used after 1950, but they maintain that most of the more sensitive detectors and techniques for gas chromatography, atomic absorption spectroscopy, and infra-red spectroscopy were developed during the last decade.

For instance, the late 1960's saw the first commerically available liquid chromatography unit, while the first gas chromatography unit with infra-red spectrophotography was not available until 1972. Also, many of the screening tests used today, such as the Ames Test, were developed during the last decade. The commenters were persuasive that thirty years is inappropriate and that a shorter time span would be appropriate. Therefore, the final rule states the period as ten years prior to the effective date for reporting on a chemical. This will keep the ten-year period constant for the future. Holding to the 1950 date would result in an ever-lengthening span as this rule is used in the future.

Most of the concerns expressed about the long time span were concerns about companies potentially having to search retired files either for studies or to find out whether the company had dealt with the chemical in the past. To avoid this problem of retired files, the Agency has specified in the rule that a company need only consult its records not retired prior to December 31, 1979, either for studies or for answering the question of whether it dealt with a chemical in the past. The more valuable, older studies will likely have been preserved in current files, rather than being retired. In addition, searching long-retired files could be very costly; too costly for purchase of this rule. December 31, 1979 is the date on which potential respondents to this rule were put on notice of the Agency's intention to require this reporting, and it is therefore an appropriate date to define the limits of the file search.

(3) Limit the rule to persons who reported the chemicals for the Inventory. This would reduce the company's burden in determining its responsibility under a section 8(d) rule merely to checking the list of chemicals it reported for the Inventory, and would yield the higher quality data developed by the manufacturer or processor.

EPA did not adopt this suggestion for two reasons. Complete reporting for the Inventory was limited to manufacturers whereas section 8(d) also applies to processors. In addition, the implicit assumption that only those who reported for the Inventory would have a list of their Inventory chemicals is not valid. All manufacturers and processors of chemicals must know if the chemicals they make are on the Inventory, whether they reported for the Inventory or not. They must know, because they must submit a premanufacture notice to EPA under section 5 of TSCA, before making or processing a chemical that is not on the Inventory.

(4) Decrease the burden of section 8(d) rulemaking and subsequent regulations by asking major manufacturers voluntarily to submit studies. If manufacturers refuse to do so, then the Agency could proceed with section 8(d) rulemaking, or go directly to section 4 rulemaking.

EPA did not adopt this suggestion. Although some companies may submit certain studies voluntarily, it is important that EPA receive all relevant studies. Only a section 8(d) rule can ensure this. In addition, many commenters stated that many studies contain trade secret information which companies are very reluctant to submit voluntarily.

(5) First require lists or titles of studies that have been performed by manufacturers or processors of the listed chemicals and then later request copies of selected studies.

This suggestion was not adopted because insufficient information is contained in the titles of studies to give a basis for study selection.

(6) Limit initial reporting to key studies relevant to specified effects (such as those the ITC recommends be tested) in order to produce studies most valuable to risk assessment, and to reduce reporting burdens and EPA's review burden.

This suggestion was not adopted. EPA plans to investigate a full range of properties and effects of the listed chemicals. Effects of a substance are not discrete items, unrelated to one another. On the contrary, certain effects and properties are predictive of other effects and properties. For instance, fate and persistence studies will help in predicting environmental effects. Acute toxicity studies generally provide data to determine the median lethal dose (LD50) of a chemical substance (its relative toxicity), but also may provide data to judge its mode(s) of action, to determine its specific toxic effect(s) on target organs and functions, and to determine the existence and extent of species differences in sensitivity to a chemical. Acute effects studies designed to measure potential ecological effects are especially valuable since there is comparatively less information in this field than in others. Also, the submission of acute effects studies will be used to determine the need for and character of acute effects testing rules.

A broad range of studies is well recognized as necessary to judge the adverse effects of a chemical substance. For example, the Organization for Economic Cooperation and Development (OECD) has developed a base set of recommended tests containing a range of tests of physical and chemical properties and toxicity for assessing the hazards of chemicals. It has selected many physical and chemical properties that, in its view, constitute "information for degradation, accumulation and even noxious *effects* assessment * * * . For example, the shape of a particle can, in itself, be indicative of its carcinogenic nature (e.g., asbestos fibers) and the partition coefficient is indicative of likely accumulation in lipid tissues." OECD Chemicals Testing Programme, Expert Group, Physical Chemistry, Final Report Vol. I, p. 41. In addition to physical and chemical properties, the OECD has also included many acute, subacute, and chronic tests in the base set of tests.

(7) Limit the chemicals subject to the rule to "high priority" chemicals such as ITC chemicals to match exactly the ITC recommendations and reduce the reporting burden.

EPA did not adopt this suggestion. The chemicals recommended by the ITC may be in fact the majority group on the

rule, but they are not the only chemicals on which EPA will need studies. The hazards of other chemials are and will be under investigation.

B. Requirements for Submitting Lists of Studies

The final rule adopts the proposed requirement that only current manufacturers and processors of listed chemicals and those who propose to manufacture or process these chemicals must submit lists of studies.

Several comments objected to listing records kept on employees exposed to chemicals. They assert that record systems and data do not constitute a study unless an intention to correlate certain data to evaluate results and reach conclusions is declared. A record listing requirement would move the scope of the requirements into the realm of conjecture, and render the proposal, in this respect at least, impracticable, even if the thrust of this listing requirement falls within TSCA's authority. Quite simply, according to the comments, there is no way to determine to which particular chemicals any given employee might be exposed. Interpreted literally, this requirement would encompass the records for all employees, a result surely not intended by the EPA.

The Agency agrees and has modified the proposed listing requirements. The studies to be listed do not include record systems. Persons will not have to list medical record systems or daily or routine monitoring records. These types of data could constitute underlying data for an epidemiological study for example, but are not by themselves treated as studies.

Other commenters asserted that protocols for ongoing studies should not be submitted, as the proposed rule would have required, since protocols are not health and safety studies and contribute no relevant health and safety information regarding chemicals.

EPA has adopted the limitations suggested. Copies of protocols do not have to be submitted since they will usually be described in the study eventually reported.

Some comments objected to listing ongoing studies. They maintained that section 8(d) applies only to completed studies. EPA disagrees with this comment. Section 8(d) authorizes listing of a study "conducted or initiated by or for" a company. EPA may require listing once a study has begun because it has been "initiated" within the meaning of the statute.

A few comments questioned the need for listing ongoing studies and for submitting preliminary reports, if requested, when an ongoing study is listed. They asserted that partial and incomplete data can be extremely misleading. Also, they said a scientist should not be required to disclose the results of his research until the scientist is satisfied with the accuracy, reliability, and scientific significance of the data.

The Agency disagrees. It requires a list of ongoing health and safety studies to tailor testing rules to fill real gaps in knowledge. If industry has started enough research of a particular type, the Agency could exclude that type of testing from a testing rule or delay it until the test data are available to the Agency. For chemicals for which testing is not contemplated, the submission of lists of ongoing studies will help the Agency determine the scope of possible control regulations. If, for example, the Agency is considering control of a particular use of a substance, the knowledge that a person is testing that substance to determine its effects or potential for exposure to man or the environment would be valuable information.

The Agency will not routinely require preliminary reports to be submitted. However, under procedures stated in § 716.8, EPA may ask for the submission of preliminary reports when necessary. The Agency understands the concern a scientist might have about releasing preliminary data. However, sometimes it is necessary to track the progress of a long-term animal study, for example, so that the Agency can order its assessment priorities. It is far more cost-effective to monitor a study industry is performing than to propose a testing rule or take regulatory action that might be found to be unnecessary when the final test results are reported.

IV. Studies Not Subject To Mandatory Reporting

A. Exemptions for Studies of Mixtures

The proposed rule provided four exceptions to the reporting requirements. Persons did not have to submit: (1) Copies or lists of published studies; (2) copies of studies previously submitted to Federal agencies with no claims of confidentiality; (3) copies of studies conducted by other persons subject to the rule; or (4) copies or lists of studies of mixtures containing small amounts of listed substances when the studies clearly did not reflect effects of the listed substances. Comments addressing items (1) through (3) above, and EPA's responses, appear in "General Comments on the Proposed Section 8(d) Rule."

The exemption for reporting mixture studies (number 4 above) generated the greatest number of comments. The commenters were almost evenly divided on whether the proposed exemption or a modified version of it should appear in the final rule. Some comments stressed the difficulty of predicting the effects of a single component of a mixture from results obtained from testing the entire mixture. Therefore, they suggested the Agency should not require the submission of any mixture studies.

Other comments suggested that the Agency fine-tune the exemption by requiring only submittal of a study on a mixture containing a listed chemical when the study was undertaken for the express purpose of determining the effects of the listed chemical or when data in the study were originally aggregated and analyzed in a manner that directly and specifically relates to such effects.

Weighing all of the above, EPA decided to approach the problem differently. As before, only studies of mixtures in which a listed chemical is known to be present will be submitted, but in place of the proposed exemption, the Agency has provided exemptions for:

(1) Physical and chemical properties of mixtures;

(2) Certain types of acute studies on mixtures; and

(3) Certain aggregations of monitoring data on mixtures. See § 716.11 (e) through (h) of the rule for the particular studies that are not subject to reporting. The remaining studies to be reported must be reported regardless of the submitter's view of whether the studies reflect effects of the pertinent substance. EPA will make this judgment. By expanding the list of studies that do not have to be submitted and removing the review necessary to determine which mixture studies should be submitted, the reporting burden on persons will be significantly reduced.

B. "Substance" Versus "Mixture"

In the final rule (§ 716.4), EPA clarifies how certain preparations of substances should be treated. For example, one commenter indicated that he considered an aqueous solution of a substance to be a mixture. Since one often puts a substance into aqueous solution before testing it for biological activity, the commenter's view could result in many tests being reported as tests of mixtures. This would be an absurd result in the context of this rule. Studies of the following preparations of a chemical substance must be reported as studies of the chemical substance itself, not as studies of mixtures containing the substance:

(1) The chemical substance in aqueous solution.

(2) The chemical substance containing a small amount of an additive, such as a stabilizer, emulsifier, or other chemicals added for purposes of maintaining the integrity or physical form of the substance.

(3) The chemical substance at any grade of purity.

Studies of these preparations of substances are classified for reporting as studies of the substance. EPA does not, and need not, at this time reach the issue of whether these preparations are defined as mixtures or chemical substances under TSCA.

V. File Search

Because of the considerable confusion on the part of commenters regarding the file search required by the proposed rule, the final rule contains a provision describing the file search required. Persons can satisfy the requirements of this rule if they limit their search for information to files in which such information is expected to be found in the ordinary course of their business, and the files of employees whose assigned duty is to advise the company on the health and environmental effects of chemicals.

The actual mechanics of the search can be approached in a number of ways depending on the size of the company and the type of chemicals for which studies will be submitted. EPA includes the following discussion to convey how it believes a satisfactory search might reasonably be conducted with the least expenditure of resources. The Agency is not saying that this is how companies must search.

For small to medium size companies that believe they are subject to the rule and have few studies of any kind, it may be more cost effective to scan the titles of the studies they possess and then check to see if the chemical studied is on the list of chemicals subject to the rule. EPA's experience has been that smaller companies submit few studies and will find it easier to match studies against the chemical list. Large companies might use the same approach depending on how their files of studies are indexed. Alternatively, they might determine the chemicals they handle(d) then search for studies.

The Agency expects the search for physical and chemical properties to be minimal for all companies because of the very limited number of properties that are subject to the rule. Also, the Agency expects that companies will have a special reference file for the most standard properties such as solubility or vapor pressure. For other, special purpose properties, such as octanol/water partition coefficients and degradation properties, the company will not be determining these on a routine basis and should be able to check with one or two key personnel to see if these studies were performed.

Companies possibly subject to the rule because a listed substance is a component of a mixture should be able to examine the mixture studies they possess to see if any components of the mixture studied are on the section 8(d) chemical list. Since most of the studies normally performed on mixtures are exempted by the rule, most companies will only have to examine a handful of subchronic and chronic studies on mixtures to determine which studies should be submitted.

VI. Reporting Schedule and Sunset Provision

Persons must submit lists and copies of studies no later than sixty days after the effective date of promulgation of the list of chemcial substances and mixtures in § 716.17. The rule also provides for extending the submission deadline for a reasonable period, if a company requests such an extension because of long file searches.

Because they assumed a very extensive file search was required, many commenters suggested that sixty days was insufficient time to comply with the rule. EPA is retaining the proposed schedule because it has made significant changes to reduce the search burden. The scope of this final rule is less than that of the previous section 8(d) rule under which companies reported in 1979 since many exemptions to the required studies and the responsibilities of respondents have been made. No company requested an extension of time for reporting under the rule's sixty-day schedule. Based on the 1979 experience, and because of the reduced scope of this rule, the Agency believes that sixty days is an appropriate period.

As proposed, the rule would have required that persons subject to the list submission requirement inform EPA of any study initiated during the five years prior to the sunset date. Comments considered this to be too burdensome since it would require them to search continuously for all new studies. EPA agrees that the proposed provision was too broad. The Agency has changed the requirement. Under the final rule, these persons will be responsible only for informing EPA of studies initiated by or for them, rather than of any new study. This includes studies directly contracted for by the company or studies sponsored through a company's membership in an association that contracts for testing (including trade associations such as the Chemical Industry Institute of Toxicology). EPA considers this to be a reasonable change. Since only those studies under a company's control and sponsorship are covered, there will be no need for a search; the report to EPA will be made when the study is ordered to be done. In addition, EPA has limited this continuing reporting requirement to chronic studies; long- and short-term tests of mutagenicity, carcinogenicity, or teratogenicity; and the biological and environmental fate tests listed in § 716.10(h) through (j).

Another concern of the comments was that the five-year period for reporting completion of ongoing studies or initiation of new ones is too long, especially since EPA must act on chemicals recommended by the ITC within twelve months.

The Agency believes that a multiyear period is necessary. The action required within twelve months is to initiate rulemaking, or give EPA's reasons for not doing so. Promulgating a test rule or entering into a voluntary testing agreement will require consideration over a longer period during which new data of the initiation of new studies could affect EPA's final action. Even after a test rule is promulgated or a voluntary testing agreement is reached, new data on substances under test will be important in the Agency's evaluation of the chemical subsequent to testing and could contribute to a decision whether control action for the chemical is indicated. However, to balance EPA's needs against the burden of this requirement, EPA has decided to maintain a multiyear approach but to limit it to three years. EPA believes that this represents a minimal reporting burden since the only studies covered by this requirement would be presently ongoing studies which are completed and studies initiated during the three-year period. Also, the rule now allows the Assistant Administrator to terminate the requirement for reporting about a particular chemical if he decides that further reporting is not needed.

VII. Confidentiality

EPA is aware of the need to protect confidential business information. Several commenters suggested that the regulations should contain a specific statement about the means EPA would use to protect the confidentiality of information in the unedited copy of a study.

The TSCA Confidential Business Information Securuty Manual contains the procedures for physically

safeguarding confidential business information submitted under TSCA. (The manual is available from the OPTS Industry Assistance Office—see **FOR FURTHER INFORMATION CONTACT.**) EPA will share confidential information with contractors, other EPA offices, and other Federal agencies only in accordance with these procedures. In addition, all information claimed as confidential is subject to the legal procedures in 40 CFR Part 2 with respect to disclosure by EPA.

A person submitting a health and safety study may claim all or part of the study confidential. However, health and safety information about a chemical that has been offered for commercial distribution or is subject to testing under section 4 or notice under section 5 can be withheld from disclosure only to the extent that disclosure would reveal (1) processing information and (2) percent composition of mixtures, or contains information the disclosure of which would clearly be an unwarranted invasion of personal privacy (such as individual medical records), as provided in 5 U.S.C. 552(b)(6).

Any claims of confidentiality must be made at the time of submission, as provided in 40 CFR 2.203(a)(2) and in the manner specified in § 716.16 of this regulation. This rule requires submission of two copies of studies containing confidential material—one copy indicating what data are claimed as confidential and one copy without the confidential information. EPA will presumptively consider failure to submit the second copy as a waiver of the confidentiality claim. However, EPA will notify respondents who claim parts of studies confidential that they did not submit the required second copy. This provision affords persons the opportunity to correct errors within 30 days.

Commenters raised a number of issues concerning specific provisions of the proposed regulation that detail the methods for submitting confidential information.

One assertion was that submitters should not be burdened with "up front" substantiation for claims of confidentiality, and that such substantiation should be required only if EPA receives a Freedom of Information Act (FOIA) request for the information.

The Agency will not require "up front" substantiation. The language of § 716.16(c) has dropped the requirement that the basis of the claim be "explicitly" explained at the time of submission. The claim must still be explained briefly. However, this explanation should merely be a simple statement indicating that the reason for the claim is, for example, related to mixture proportion or process information, or that the information is clearly irrelevant to the health and safety study. EPA does not expect detailed substantiation of confidentiality claims at the time the study is submitted. The Agency believes that this simple statement is justified, because EPA needs some understanding of the claim to have a basis for initial denial or granting of FOIA requests and to protect the information.

Another suggestion was that failure to provide a nonconfidential second copy of a study for which claims are made should not be considered a presumptive waiver of the claim. The commenter asserted that the claim to a trade secret is a property right and cannot be taken away by the operation of a presumption. In their view, once the claim is made, it must stand unless a disclosure request is made and FOIA principles require that it be granted.

EPA will not place confidential information in the public file automatically if a second copy is not received. The Agency will notify the respondent that it has not received a second copy. This will allow the company to correct the situation.

Another commenter claimed that the 20-day grace period for correcting incomplete confidentiality submissions does not allow the respondent sufficient time to respond.

The rule has been changed to extend the proposed 20-day grace period to 30 days. This should be adequate for such a straightforward response, even given mail delays, because the only step needed is to provide a second, non-confidential copy for the public file.

A final specific comment was that the Agency must not allow confidentiality claims for submitted health and safety studies. To do so, is, in the commenter's view, a direct, illegal contradiction of section 14(b) which exempts the results of health and safety studies from such claims.

EPA disagrees that it should not allow confidentiality claims. Respondents may claim any information as confidential; however, the only information which the Agency may actually keep confidential is listed in § 716.16(c).

VIII. Economic Impact

EPA estimates that the total cost to industry of submitting lists and copies of health and safety studies under the present rule is approximately $537,000.

The major cost to a firm will be the cost of a file search to determine what health and safety studies it possesses. This cost will, of course, vary directly with the size of the firm, assuming that larger firms have more files at more locations which must be accessed. Once the studies are located, the remaining compliance costs involve copying and processing the studies, making lists of studies which are in progress or not in the possession of the respondent, and reviewing the studies for confidential information. The Agency's cost estimates are based on the cost to an average firm. EPA recognizes that actual costs will be larger or smaller for larger or smaller firms. Each of these costs is tabulated below.

	Total
Corporate rule review	$89,000
Corporate review (site identification)	67,000
File search	121,000
Title listing	7,000
Photocopying (materials)	9,000
Photocopying (labor)	28,000
Managerial review	189,000
Ongoing reporting	27,000
Total cost of this rule	537,000

This represents a cost of approximately $2,000 to $4,000 per chemical. When the Agency adds to the list of chemicals subject to the rule, these cost per chemical estimates can be used to determine the cost of the additional reporting.

If the studies submitted allow EPA to eliminate even one potential section 4 mandated test on a subject chemical, the cost avoided could exceed the total cost of this rule. For example, EPA estimates that it will cost industry from $700,000 to $1,300,000 to perform the proposed testing (see 45 FR 48557) for chloromethane and up to $4,900,000 for chlorobenzenes (see 45 FR 48557).

The Agency received many comments suggesting that its original estimate of $410,000 total cost was too low. The comments pointed to many features of the proposed rule that they believed would cause much greater burdens than the Agency had assumed. However, only a few comments actually gave EPA estimates of the time or money they would expend in complying with the proposal. For example, the Chemical Manufacturers Association suggested from a survey of thirteen of its members that the cost per company would be $400 to $10,000 per chemical, but this range estimate was not accompanied by data to indicate how the figures were generated.

The following is a list of the most burdensome features of the proposal as cited by comments. For each feature, a description follows for the changes made in the final rule to reduce the burden.

(1) One large burden commenters perceived was in searching for routine monitoring records and for medical

records. The commenters read the proposal to require submission of these data. However, EPA has made it clear in the final rule that these records are not to be submitted as studies. The Agency may request them in the future, but only if they are underlying data to a study.

(2) The proposed requirement to submit all studies on mixtures containing a listed substance would have caused several problems, according to many comments. The problems would have come in searching through records to determine whether a listed substance could be present in a studied mixture and in then deciding whether the listed substance was responsible for whatever effect the study showed.

The Agency has substantially changed the requirements for submitting studies on mixtures. It has excluded most acute studies from the requirement; it has excluded all physical/chemical properties of mixtures; and the Agency has excluded studies of mixtures that contain the listed chemical only as an impurity. In addition, the Agency has removed the requirement for respondents to decide whether the effect studied was caused by the listed substance—EPA will make that judgment. These changes should cut the cost of submitting mixture studies substantially. The changes mean that companies can go directly to their copies of studies on mixtures to see if a listed chemical was in a mixture tested. The number of studies to be looked at has been much reduced. And, most importantly, companies will not have to search records to find out what impurities may have been present in the studied mixture.

(3) The proposal would have required companies who may never have dealt with a chemical to submit studies on it if they had then. EPA has removed this burden by changing the requirements to apply to those who have manufactured or processed or have proposed to manufacture or process the chemical. Moreover, the Agency has said that companies can determine their association with the chemical by looking at their current files. This will alleviate a concern expressed by companies whose ownership or activities have changed and whose records have been retired.

(4) Perhaps the greatest burden cited was that of potentially searching every company file for studies or references to studies. The proposal was broadly worded in this respect. The final rule contains a section describing the much more limited search that will be enough to comply with the rule. Companies will comply if they search the files where studies are kept in the ordinary course of their business, and the files of those employees whose assigned duty is to advise the company about health and environmental effects of chemicals.

(5) Comments have requested that studies on research and development chemicals be exempted. They requested the exemption for a number of reasons, one being that these studies may be in a different set of files at different locations than other studies. EPA has not fully exempted these studies (see R & D Chemicals) because, as previously discussed in this preamble, the Agency does not believe that the fact that a studied chemical has been in research and development is relevant to the value of the study. However, by better defining the file searches required for compliance with the rule the Agency has reduced the burden of searching for such studies.

(6) The report's impact analysis for the proposal did not include the burden to a company to familiarize itself with the rule. Commenters remarked on this, and the Agency has included this item in the final analysis.

(7) The report's impact analysis for the proposal did not consider the cost of file searches which must be conducted by firms which will not actually find submittable studies in their file. Commenters suggested EPA account for these costs.

In the first analysis, EPA attempted to base cost estimates upon the prior experience of firms which reported for the original section 8(d) rule. These data did not reflect the experience of firms which conducted futile file searches, and did not report. The Agency believes that for the purposes of a report impact analysis, the previous experience of the prior section 8(d) rule is the firmest estimate that the Agency can utilize. However, EPA has now attempted to estimate costs for those companies that handle the listed substances, but have no studies to report. The Agency did this by searching the TSCA Inventory to determine the number of companies that reported the listed substances and then multiplying this number by a factor of three to account for processors and distributors.

Although some commenters indicated that the scope of the rule extends beyond the "chemical industry" and woudl therefore increase the potential number of processors of the listed substances beyond our estimate, EPA believes that its estimates or respondents is proper for the following reasons. First, over 85 percent of the companies that reported for the first section 8(d) rule were concentrated in the chemical, allied products, and petroleum refining industries. Second, most of the comments received from companies on the proposed rule were from companies in those industries, which EPA believes is an indicator of the respondent population for the final rule. Third, EPA believes that almost all of the studies performed on the listed substances are initiated by the manufacturers and primary processors of the substances, which is the reason EPA exempted distributors from reporting. These companies are heavily concentrated in the chemical, allied products, and petroleum refining industries.

Furthermore, the changes, exemptions, and limited file search prescribed in this rule should eliminate the possibility of a substantial burden of unavailing searches.

(8) The analysis accompanying the proposal did not consider the ongoing cost of reviewing newly completed studies during the multiyear follow-up period.

EPA does not believe that consideration of ongoing studies poses a substantial burden that would appreciably alter the report's impact analysis. Since firms would review newly completed studies for their effects regardless of this rule, no file retrieval costs associated with other health and safety studies would be incurred for these new ones.

(9) Comments criticized continued reliance on the assumption that 2.6 firms will respond per chemical, which was based on EPA's experience with the first section 8(d) rule, even though the additional chemicals subject to the rule are qualitatively different (high volume, extremely prevalent) than the chemicals subject to the first section 8(d) rule.

EPA's continued reliance on data from the first section 8(d) rule is valid. There is no real qualitatively difference in the chemicals subject to the original or present section 8(d) rules—many of the chemicals subject to both rules are high volume and extremely prevalent. Further, approximately 6.2 firms reported for the Inventory on chemicals that were listed on the first section 8(d) rule (this figure represents the average number of firms or companies, not the average number of sites), whereas only 2.6 firms responded per chemical for the original section 8(d) rule. For the subsequent ITC-recommended chemicals on the proposed rule, 1.1 firms reported for the Inventory. An average of 2.2 firms reported for the Inventory on chemicals selected by the EPA on the proposed rule. This indicated that the Agency's reliance on the 2.6 figure would actually tend to overstate the

number of expected respondents for the present rule.

(10) Comments were also concerned about the categories of chemicals in the rule. They specifically asked for better definitions of the categories or for lists of the chemical in the categories for which EPA wants studies. Because of chemical nomenclature complexities, the commenters suggested that the burden of deciding whether a given chemical should be counted in or out could be great.

EPA has eliminated one of the more troublesome categories from the list—acrylic acid and methylacrylic acid and their esters. In addition, the Agency has given better descriptions and more examples to define the categories. EPA believes that these steps, plus the fact that the categories now on the rule are ones that companies have become familiar with in following ITC recommendations for testing, should reduce the cited burden. A company that has a question about whether a particular chemical is included in a category should call the information number given at the beginning of this notice. EPA staff will be available to return these calls and answer questions.

The basic elements EPA has included in the final Reports Impact Analysis are:

(a) Corporate rule review—2 hours at $50 per hour.

(b) Corporate identification of pertinent files—3 hours at $50 per hour.

(c) File search at plant site—6 hours at $30 per hour.

(d) Listing study titles—1 hour at $15 per hour.

(e) Photocopying per study—½ hour at $15 per hour.

(f) Final review before submission—1 hour at $50 per hour.

EPA's estimate of total cost of the rule uses the above figures and assumes that 891 firms will perform an initial review; 447 firms will submit 3,784 reports of 50 pages each; and each firm has, on a weighted average, 1.5 plant sites.

The corporate rule review step was suggested by commenters, as was the corporate identification of locations to be searched. EPA has increased the hourly costs of managerial review and file searches by $10 each from previous estimates, and increased the file search time per site from four to six hours. These new estimates are based upon suggestions from commenters and the changes EPA has made to rule requirements. One caveat that must be kept in mind is that these are average costs. Individual firms may experience greater or lesser costs depending on their size.

EPA received comment that one hour for final review before submission would not be enough to accommodate decisions on confidentiality. The Agency's estimate of an average of one hour review per study is reasonable. EPA does not expect that a company should have to scrutinize a study for confidential information just before it is submitted to EPA. Confidential information in a study should already have been identified as such by the company. For example, to get a court to prevent disclosure of confidential information, a company must be able to show that the information was given special treatment by the company, i.e., marked confidential, or kept in limited access files. Therefore, the Agency believes that most of the information in a study that is confidential will have been previously identified as such by the company, and it should not be necessary to check with virtually every department of the company, as some commenters suggested, to check whether each data element is confidential.

IX. Public Record

EPA has established a public record (docket number OPTS–84003A) for this rulemaking document, which along with a complete index is available for inspection in the OPTS Reading Room, Rm. E–107, 401 M Street, SW, Washington, DC, 20460, from 8:00 a.m. to 4:00 p.m. Monday through Friday, except legal holidays. This record includes basic information considered by the Agency in developing this rule. Following is a list of the documents which constitute the record for this rulemaking. Public comments on the proposed rule are not individually listed, but will be available upon request in the OPTS reading room. EPA requests that it be notified of any additions or deletions to this record within the next 30 days.

(1) Health and Safety Study Reporting Regulations, July 18, 1978, Public Record, Docket No. 084001.

(2) Manufacturing Chemists Association—Petition under section 21 of TSCA, September 12, 1978.

(3) Denial of Citizens' Petition, 43 FR 56724–56727.

(4) The entire docket in *Dow Chemical Company* v. *United States Environmental Protection Agency, et al. Docket No. 78–2203 (3rd Cir.).*

(5) Revocation of Rule, 44 FR 6099.

(6) Reports Impact Analysis of this rulemaking.

(7) All comments on this rule, including any comments received from the Office of Management and Budget during Paperwork Reduction Act review.

(8) General Comments on the Proposed Section 8(d) Rule.

(9) All relevant support documents and studies.

(10) Records of all communications between EPA personnel and persons outside the Agency pertaining to the development of this rule. (This does not include any inter- or intra-agency memoranda unless specifically noted in the index of the rulemaking record.)

(11) Minutes, summaries, or transcripts of any public meetings held to develop this rule.

(12) Any factual information considered by the Agency in developing the rule.

X. Regulatory Assessment Requirements

Executive Order 12291

Under Executive Order 12291, EPA must judge whether a regulation is "major" and therefore requires a Regulatory Impact Analysis. EPA has determined that this regulation is not major because it does not have an effect of $100 million or more on the economy. It is expected to have a one-time cost of about $725 thousand. It does not have a significant effect on competition, or costs or prices.

This regulation was submitted to the Office of Management and Budget for review as required by Executive Order 12291.

Regulatory Flexibility Act

Since this rule was proposed before the effective date of the Regulatory Flexibility Act, 5 U.S.C. 601 et seq., the Act's requirements do not apply. However, based on the Agency's experience with a previous section 8(d) rule, it expects that only about 1 percent of the respondents will have gross sales of less than 20 million dollars.

Paperwork Reduction Act

Information collection requirements contained in this regulation (§§ 716.6 and 716.7) have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980 U.S.C. 3501 *et seq.* and have been assigned OMB Control Number 2070–0004.

This rule requires manufacturers and processors of 40 chemicals and categories of chemicals to submit unpublished health and safety studies relating to these chemicals. The studies to be submitted will be used by EPA evaluating health and environmental effects of chemicals for purposes of assessing risks associated with the chemicals, as well as in determining whether the chemicals should be included in testing rules issued under section 4 of TSCA.

Lists of Subjects in 40 CFR Part 716

Chemicals, Health and safety, Environmental protection, Hazardous materials, Recordkeeping and reporting.

Dated: August 19, 1982.

John E. Daniel,

Acting Administrator.

Therefore, Chapter I of Title 40 of the Code of Federal Regulations is amended by adding a new part 716 consisting at this time of Subpart A to read as follows:

PART 716—HEALTH AND SAFETY DATA REPORTING

Subpart A—General Provisions

Authority: Sec. 8(d), Pub. L. 94–469, Stat. 2029 (15 U.S.C. 2607(c)).

Subpart A—General Provisions

§ 716.1 Scope and compliance.

(a) This Subpart sets forth requirements for the submission of lists and copies of health and safety studies on chemical substances and mixtures selected for priority consideration for testing rules under section 4(a) of the Toxic Substances Control Act (TSCA) and on other chemical substances and mixtures for which EPA requires health and safety information in fulfilling the purposes of TSCA.

(b) Section 15(3) of TSCA makes it unlawful for any person to fail or refuse to submit information required under this Subpart. Section 16 provides that a violation of section 15 renders a person liable to the United States for a civil penalty and possible criminal prosecution. Under section 17, the district courts of the United States have jurisdiction to restrain any violation of section 15.

§ 716.3 Definitions.

The definitions in section 3 of TSCA apply to this Subpart. In addition, the following definitions are provided for the purposes of this Subpart:

(a) "Byproduct" means a chemical substance produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance(s) or mixture(s).

(b) "Co-product" means a chemical substance produced for a commercial purpose during the manufacture, processing, use, or disposal of another chemical substance(s) or mixture(s).

(c) "Copy of study" means the written presentation of the purpose and methodology of a study and its results.

(d) "EPA" means the United States Environmental Protection Agency.

(e) "Health and safety study" or "study" means any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying data and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological or other studies of a chemical substance or mixture, and any test performed under TSCA.

(1) It is intended that the term "health and safety study" be interpreted broadly. Not only is information which arises as a result of a formal, disciplined study included, but other information relating to the effects of a chemical substance or mixture on health or the environment is also included. Any data that bear on the effects of a chemical substance on health or the environment would be included. Chemical identity is part of, or underlying data, to, a health and safety study.

(2) Examples are:

(i) Long- and short-term tests of mutagenicity, carcinogenicity, or teratogenicity; data on behavioral disorders; dermatoxicity; pharmacological effects; mammalian absorption, distribution, metabolism, and excretion; cumulative, additive, and synergistic effects; and acute, subchronic, and chronic effects.

(ii) Tests for ecological or other environmental effects on invertebrates, fish, or other animals, and plants, including: acute toxicity tests, chronic toxicity tests, critical life stage tests, behavioral tests, algal growth tests, seed germination tests, plant growth or damage tests, microbial function tests, bioconcentration or bioaccumulation tests, and model ecosystem (microcosm) studies.

(iii) Assessments of human and environmental exposure, including workplace exposure, and impacts of a particular chemical substance or mixture on the environment, including surveys, tests and studies of: Biological, photochemical, and chemical degradation; structure/activity relationships; air, water, and soil transport; biomagnification and bioconcentration; and chemical and physical properties, e.g., boiling point, vapor pressure, evaporation rates from soil and water, octanol/water partition coefficient, and water solubility.

(iv) Monitoring data, when they have been aggregated and analyzed to measure the exposure of humans or the environment to a chemical substance or mixture.

(f) "Importer" means any person who imports a chemical substance, including a chemical substance as a part of a mixture or article, into the customs territory of the United States and includes the person primarily liable for the payment of any duties on the merchandise or an authorized agent acting on his behalf (as defined in 19 CFR 1.11). Importer also includes, as appropriate:

(1) The consignee.

(2) The importer of record.

(3) The actual owner, if an actual owner's declaration and superseding bond has been filed in accordance with 19 CFR 141.20.

(4) The transferee, if the right to draw merchandise in a bonded warehouse has been tranferred in accordance with Subpart C of 19 CFR Part 144.

For the purpose of this definition, the customs territory of the United States consists of the 50 States, Puerto Rico, and the District of Columbia.

(g) "Impurity" means a chemical substance which is unintentionally present with another chemical substance.

(h) "Manufacture" and "Process" mean manufacture or process for commercial purposes.

(i) "Manufacture for commercial purposes" means:

(1) To import, produce, or manufacture with the purpose of obtaining an immediate or eventual commercial advantage for the manufacturer, and includes, among other things, such "manufacture" of any amount of a chemical substance or mixture:

(i) For commercial distribution, including for test marketing.

(ii) For use by the manufacturer, including use for product research and development, or as an intermediate.

(2) The term applies to substances that are produced coincidentally during the manufacture, processing, use, or disposal of another substance or mixture, including both byproducts and coproducts that are separated from that other substance or mixture and impurities that remain in that substance or mixture. Byproducts and impurities may not in themselves have commercial

value. They are nonetheless produced for the purpose of obtaining a commercial advantage since they are part of the manufacture of a chemical product for a commercial purpose.

(j) "Person" includes any individual, firm, company, corporation, joint-venture, partnership, sole proprietorship, association, or any other business entity, any State or political subdivision thereof, any municipality, any interstate body, and any department, agency, or instrumentality of the Federal government.

(k) "Process for commercial purposes" means the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce with the purpose of obtaining an immediate or eventual commercial advantage for the processor. Processing of any amount of a chemical substance or mixture is included. If a chemical substance or mixture containing impurities is processed for commercial purposes, then those impurities are also processed for commercial purposes.

(l) "Propose to manufacture, process, or distribute" means that a person has made a management decision to commit financial resources toward the manufacture, processing, or distribution of a chemical substance or mixture.

(m) "Substance" means "chemical substance" as defined at section 3(2)(A) of TSCA, 15 U.S.C. 2602(2)(A).

(n) "TSCA" means the Toxic Substances Control Act 15 U.S.C. 2601 et. seq.

§ 716.4 Overview of subpart requirements.

This section highlights basic requirements. For additional procedures and qualifications, refer to pertinent, individual sections.

(a) *Adequate file search for compliance with this subpart.* Persons are not required to search any records retired prior to December 31, 1979 for information to comply with this subpart. In addition, the scope of a company's responsibility to search records is limited to records in which it ordinarily keeps the required information and to records kept by individual employees whose assigned duty is to advise the company of the health and environmental effects of chemicals under § 716.12.

(b) *Persons who must report.* (1) A person who manufactures or processes a substance or designated mixture listed in § 716.17 at the time it is listed, or proposes to do so, must do the following for that substance or designated mixture—(i) Submit copies of all non-exempted studies in his possession at the time he becomes subject to the rule under § 716.6. Under § 716.14 the copies must be submitted within 60 days after the addition of the substance or designated mixture to § 716.17.

(ii) Under § 716.7 submit a list of studies that are ongoing when the substance or designated mixture is added to § 716.17. The list must be submitted within 60 days after the addition of the substance or designated mixture to § 716.17 and copies of such studies must be submitted within 30 days of their completion under § 716.14.

(iii) Inform EPA within 30 days of any study initiated by or for him after the initial 60 day reporting period and submit a copy of the study when it is completed. This requirement continues until the sunset date specified in § 716.19; it applies not only to persons who manufacture or process a substance or designated mixture when it is added to the list, but also to persons who begin to manufacture or process, or propose to do so at any time prior to the sunset date.

(2) A person who is not covered under paragraph (b)(1) of this section, but has manufactured or processed a substance or designated mixture listed in § 716.17, or has proposed to do so, anytime in the preceding ten years, must submit copies of studies in his possession on the substance or designated mixture within 60 days of when it is added to § 716.17.

(c) *Studies to be reported.* In general, studies, as defined at § 716.3(d), that are unpublished are reportable, i.e., must be submitted or listed, for any substance or designated mixture listed in § 716.17. However, this requirement has limitations according to the nature of the material studied, so that—(1) All studies of substances and designated mixtures are reportable. However, in the case of physical and chemical properties, only those studies listed in § 716.10 must be submitted.

(2) Studies of mixtures known to contain substances or designated mixtures listed in § 716.17 are reportable except for studies of physical and chemical properties and the studies exempted at § 716.11(f) (1) through (6).

(3) Studies of substances or designated mixtures that a person who is reporting has manufactured or processed or proposed to manufacture or process only as impurities are not generally reportable under § 716.11(i).

(4) Research and development studies on chemical substances not on the TSCA Chemical Substance Inventory are not reportable under § 716.11(e).

(5) Underlying data, such as medical or health records, individual files, lab notebooks, and daily monitoring records are not reportable except by special request under § 716.8.

§ 716.6 Submission of copies of studies.

(a)(1) Except as provided in §§ 716.10 and 716.11, persons must send to EPA copies of any health and safety studies in their possession for the substances or designated mixtures listed in § 716.17. Persons are responsible for submitting copies on only the substances or designated mixtures which they have manufactured or processed or proposed to manufacture or process (including as known byproducts) within the ten years preceding the effective date for reporting on the substances or designated mixtures. Persons who list studies as ongoing under § 716.7(a)(1) must submit them when they are completed.

(2) Underlying data, such as medical or health records, individual files, lab notebooks, and daily monitoring records supporting studies, do not have to be submitted initially. EPA may request underlying data later under § 716.8.

(b) Submissions under paragraph (a) of this section must be indexed by chemical name, including CAS number if known, and must be accompanied by a cover letter containing the name, job title, address and telephone number of the submitting official, and the name and address of the manufacturing or processing establishment on whose behalf the submission is made. In the cover letter, respondents must identify any impurity or additive known to have been present in the substance as studied unless its presence is specifically noted in the study itself.

(c) Copies of health and safety studies and the accompanying cover letter must be submitted, preferably by certified mail, to: U.S. Environmental Protection Agency, TSCA–8D1, P.O. Box 2060, Rockville, Maryland 20852.

§ 716.7 Submission of lists of studies.

(a) Except as provided in §§ 716.10 and 716.11, persons must send the lists described in paragraphs (a) (1) and (2) of this section to EPA for each of the substances or designated mixtures listed in § 716.17 which they manufacture or process or propose to manufacture or process (including as known byproducts).

(1) A list of ongoing health and safety studies being conducted for or initiated by them, noting for each entry the purpose of the study, type of data collected, and progress and anticipated date of completion. This requirement continues until the sunset date specified by § 716.19. Studies initiated after the initial 60 day reporting period must be listed if they included one or more of the following tests: chronic tests; long- and short-term tests or mutagenicity, carcinogenicity or teratogenicity; and

the biological and environmental fate tests listed in § 716.10 (h) through (j).

(2) A list of unpublished studies known to them of which they do not have copies. The name and address of any person known to them to possess a copy of the unpublished study must accompany each entry on the list. For purposes of this section only, an unpublished study will be considered to be "known to" a person, if the study can be discovered by a file search in accordance with § 716.12.

(b) Submissions under paragraph (a) of this section must be indexed by chemical, including CAS number if known, and must be accompanied by a cover letter containing the name, job title, address and telephone number of the submitting official, and the name and address of the manufacturing or processing establishment on whose behalf the submission is made.

(c) The list of health and safety studies should be submitted, preferably by certified mail, to: U.S. Environmental Protection Agency, TSCA–8D1, P.O. Box 2060, Rockville, Maryland 20852.

§ 716.8 EPA requests for submission of further information.

EPA may request the following submissions after the initial reporting under §§ 716.6 and 716.7. If the requested submissions are not made, EPA may subpoena them under section 11 of TSCA, 15 U.S.C. 2610.

(a) Submission of underlying data of the kind described in § 716.6(a)(2) by persons who submit copies of studies under § 716.6 or list studies under § 716.7(a)(1).

(b) Submission of preliminary reports of ongoing studies by persons who list the studies under § 716.7(a)(1).

(c) Submission of copies of studies by persons listed under § 716.7(a)(2) as possessing them.

§ 716.9 How to report on substances and mixtures.

Section 716.17 contains two lists, one of substances and one of designated mixtures. Studies of listed substances and designated mixtures shall be reported as follows:

(a) When a substance is individually listed under § 716.17(a), studies of the substance and studies of mixtures known to contain the substance must be reported as studies of that substance.

(b) When two or more substances are listed as a designated mixture under § 716.17(b), studies of the designated mixture and studies of any mixture known to contain the designated mixture must be reported as studies of the designated mixture.

(c) Studies of the following preparations of a substance must be reported as studies of the substance itself, not as studies of mixtures known to contain the substance.

(1) The substance in aqueous solution.

(2) The substance containing a small amount of an additive, such as a stabilizer, emulsifier, or other chemical added for purposes of maintaining the integrity or physical form of the substance.

(3) The substance at any grade of purity.

§ 716.10 Reporting physical and chemical properties.

Studies of physical and chemical properties must be reported under this subpart if performed for the purpose of determining the environmental or biological fate of a substance, and only if they investigated one or more of the following properties:

(a) water solubility.

(b) Adsorption/desorption on particulate surfaces, e.g., soil.

(c) Vapor pressure.

(d) Octanol/water partition coefficient.

(e) Density/relative density (specific gravity).

(f) Particle size distribution for insoluble solids.

(g) Dissociation constant.

(h) Degradation by photochemical mechanisms—aquatic and atmospheric.

(i) Degradation by chemical mechanisms—hydrolytic, reductive, and oxidative.

(j) Degradation by biological mechanisms—aerobic and anaerobic.

§ 716.11 Exemptions to reporting requirements.

The following are exempt from the copy and list submission requirements of §§ 716.6 and 716.7.

(a) Studies which have been published in the scientific literature.

(b) Studies previously submitted to EPA, e.g., studies voluntarily submitted during section 4 proceedings or under the previous section 8(d) rule.

(c) Studies previously submitted to any Federal agency with no claims of confidentiality.

(d) Studies conducted or initiated by or for another person who is subject to §§ 716.6 and 716.7.

(e) Studies of chemical substances which are not on the TSCA Chemical Substance Inventory, e.g., research and development studies on new chemical substances.

(f) The following types of studies when the subject of the study is a mixture known to contain a substance or designated mixture listed in § 716.17.

(1) Acute oral toxicity studies.

(2) Acute dermal toxicity studies.

(3) Acute inhalation toxicity studies.

(4) Primary eye irritation studies.

(5) Primary dermal irritation studies.

(6) Dermal sensitization studies.

(7) Physical and chemical properties.

If the substance or designated mixture is an impurity, no reporting is required (see § 716.11(i), below).

(g) Analyzed aggregations of monitoring data based on monitoring data acquired more than five years preceding the date the substance or designated mixture was added to the list in § 716.17.

(h) Analyzed aggregations of monitoring data on mixtures known to contain one or more substance or designated mixtures listed in § 716.17, when the monitoring data are not analyzed to determine the exposure or concentration levels of the substances or designated mixture listed in § 716.17.

(i) Studies on a substance or designated mixture listed in § 716.17 that the person who is reporting has manufactured or processed or proposed to manufacture or process only as an impurity. When reporting of such studies is to be required, that reporting will be separately proposed in the **Federal Register.**

§ 716.12 File search.

Persons will satisfy the requirements of this Subpart if they limit their search for the required information to records in which such information is expected to be found in the ordinary course of their business, and to information kept by employees whose assigned duty is to advise the company on the health or environmental effects of chemicals. For purposes of this rule, persons do not have to search files retired prior to December 31, 1979.

§ 716.14 Reporting schedule.

(a) Except as provided in paragraphs (b) and (c) of this section, submissions under §§ 716.6 and 716.7 must be postmarked on or before 60 days after the effective date of the listing of a substance or designated mixture in § 716.17 or within 60 days of proposing to manufacture or process a substance or designated mixture if first done after the effective date of the substance's or designated mixture's listing in § 716.17.

(b) Persons subject to the listing requirement of § 716.7 must inform EPA of any study initiated by or for them within the three-year reporting period described in § 716.19 within 30 days of initiation of the study. Copies of studies listed as ongoing under § 716.7(a)(1), or studies initiated within the reporting

period, must be submitted within 30 days of their completion.

(c) Respondents who cannot meet a deadline under this section may apply for a reasonable extension of time. Requests for extensions should be addressed to: Document Control Officer, Office of Pesticides and Toxic Substances, (TS-793), Environmental Protection Agency, 401 M Street, SW, Washington, D.C. 20460, Attn: Section 8(d) extension.

§ 716.16 Confidentiality claims.

(a) Any person submitting a document under this Subpart may assert a business confidentiality claim covering all or part of the submitted material. Any information covered by a claim will be disclosed by EPA only as provided in procedures set forth at Part 2 of this title.

(b) If no claim accompanies a document at the time it is submitted to EPA, the document will be placed in an open file available to the public without further notice to the respondent.

(c)(1) Section 14(b) of TSCA states that EPA may not withhold from disclosure, on the grounds that they are confidential business information, health and safety studies of any substance that has been offered for commercial distribution or for which testing is required under TSCA section 4 or for which notice is required under TSCA section 5, except to the extent that disclosure of data from such studies would reveal: (i) processes used in the manufacturing or processing of a substance or mixture, or (ii) the portion of a mixture comprised by any of the substances in the mixture.

(2) Any respondent who wishes to assert a claim that part of a study should be withheld from disclosure because disclosure would reveal a confidential process or quantitative mixture composition or other confidential information, should briefly state the basis of the claim, i.e., by saying "reveals confidential process information" or "reveals confidential mixture proportion data," and clearly identify the material subject to the claim. Information in a study, such as company name or address, financial statistics, or product codes used by a company, which is irrelevant to any health or environmental effect of a chemical, may be claimed confidential and not subject to the disclosure requirements of section 14(b) of TSCA. Other information contained in a study, the disclosure of which would clearly be an unwarranted invasion of personal privacy (such as individual medical records), will be considered confidential as provided in Title 5, United States Code, section 552(b)(6).

(d) To assert a claim of confidentiality for data contained in a submitted document, the respondent must submit two copies of the document.

(1) One copy must be complete. In that copy, the respondent must indicate what data, if any, are claimed as confidential by marking the specific information on each page with a label such as "confidential," "proprietary," or "trade secret" and briefly state the basis of the claim.

(2) If some data are claimed as confidential, the respondent must submit a second copy. The second copy must be complete, except that all information claimed as confidential in the first copy must be deleted.

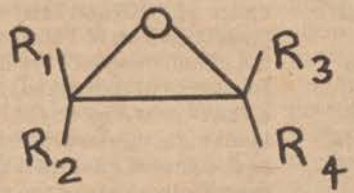
(3) The first copy will be for internal use by EPA. The second copy will be placed in an open file to be available to the public.

(4) Failure to furnish a second copy when information is claimed as confidential in the first copy will be considered a presumptive waiver of the claim of confidentiality. EPA will notify the respondent by certified mail that a finding of a presumptive waiver of the claim of confidentiality has been made. The respondent will be given 30 days from the date of receipt of notification to submit the required second copy. If the respondent fails to submit the second copy within the 30 days EPA will place the first copy in the public file.

§ 716.17 Substances and designated mixtures to which this subpart applies.

(a)(1) Substances. The following substances are subject to this subpart as of October 4, 1982.

Substances	CAS Numbers (examples for groups)
Acetonitrile.	75-05-8
Acrylamide.	79-06-1
Alkyl epoxides -- including all noncyclic aliphatic hydrocarbons with one or more epoxy functional groups.	75-21-8 75-56-9 106-88-7 1464-53-5



R_1 = H or alkyl
R_2 = H or alkyl
R_3 = H or alkyl
R_4 = H or alkyl

Groups R_1-R_4 may contain one or more epoxide functions

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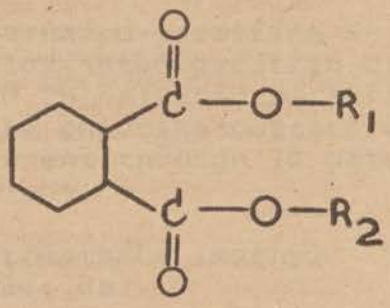
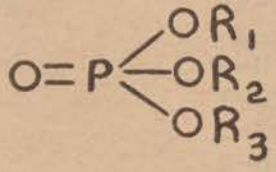
Substances	CAS Numbers (examples for groups)
Alkyl phthalates -- all alkyl esters of 1,2-benzene dicarboxylic acid (orthophthalic acid).	84-61-7 84-66-2 84-74-2 117-81-7 117-84-0 119-06-2 119-07-3 131-11-3 26761-40-0 27554-26-3



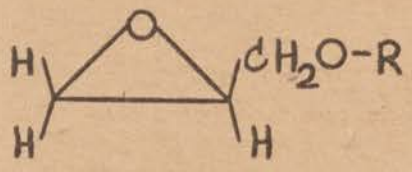
R_1 = alkyl
R_2 - alkyl

Aniline and chloro-, bromo-, and/or nitro-anilines.	62-53-3	108-42-9
	88-74-4	121-87-9
	89-63-4	141-85-5
	95-51-2	147-82-0
	95-76-1	554-00-7
	95-82-9	608-27-5
	97-02-9	626-43-7
	99-09-2	634-93-5
	99-29-6	635-22-3
	99-30-9	827-94-1
	100-01-6	1817-73-8
	106-40-1	5388-62-5
	106-47-8	6283-25-6
	3531-19-9	
Antimony.	7440-36-0	
Antimony trioxide.	1309-64-4	
Antimony sulfide.	1345-04-6	
Aryl phosphates - phosphate esters of phenol or of alkyl-substituted phenols. Try-aryl and mixed alkyl and aryl esters are included but trialkyl esters are excluded.	78-30-8	2528-36-1
	78-32-0	25155-23-1
	78-33-1	26444-49-5
	115-86-6	28108-99-8
	563-04-2	29761-21-5
	1241-94-7	51363-64-5
	1330-78-5	56803-37-3



Substances	CAS Numbers (examples for groups)
R_1 = phenyl, either unsubstituted or substituted with one or more alkyl or aralkyl groups	
R_2 = alkyl; or phenyl, either unsubstituted or substituted with one or more alkyl or aralkyl groups	
R_3 = alkyl; or phenyl, either unsubstituted or substituted with one or more alkyl or aralkyl groups	
Asbestos - Asbestiform varieties of: chrysotile (serpentine); crocidolite (riebeckite); amosite (cummingtonite-grunerite); anthophyllite; tremolite; and actinolite.	1332-21-4 12001-29-5 12172-73-5 17068-78-9
Bisazobiphenyl dyes derived from benzidine and its congeners, orthotolidine (dimethylbenzidine) and dianisidine (dimethoxybenzidine).	72-57-1 91-92-9 91-96-3 573-58-0 992-59-6 1937-37-7 2150-54-1 2429-71-2 2429-73-4 2429-74-5 2429-79-0 2429-81-4 2429-82-5 2429-83-6 2429-84-7 2586-57-4 2586-58-5 2602-46-2 2610-05-1 2893-80-3 3530-19-6 3567-65-5 3626-28-6 4335-09-5 6358-29-8 6360-54-9 6449-35-0 6637-88-3 6656-03-7 6739-62-4 8014-91-3 10401-50-0 16071-86-6 16143-79-6 20282-70-6
Chlorinated benzenes, mono- and di-.	95-50-1 106-46-7 108-90-7 541-73-1
Chlorinated benzenes, tri-, tetra- and penta-.	87-61-6 95-94-3 108-70-3 120-82-1 608-93-5 634-66-2 634-90-2

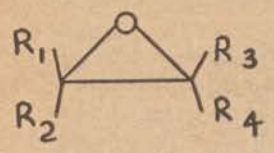
Substances	CAS Numbers (examples for groups)
Chlorinated naphthalenes -- chlorinated derivatives of naphthalene (empirical formula $C_{10}H_xCl_y$ where x+y=8).	90-13-1 1321-64-8 1321-65-9
Chlorinated paraffins -- chlorinated paraffin oils and chlorinated paraffin waxes, with chlorine content of 35 percent through 70 percent by weight.	61788-76-9 63449-39-8 68920-70-7
Chloromethane (methyl chloride).	74-87-3
Cresols -- ortho, meta-, and para-cresol.	95-48-7 106-44-5 108-39-4
Cyclohexanone.	108-94-1
Dichloromethane. (methylene chloride)	75-09-2
1,2-Dichloropropane.	78-87-5
Glycidol and its derivatives.	77-83-8 101-90-6 106-90-1 106-91-2 106-92-3 121-39-1 122-60-1 556-52-5 930-37-0 2238-07-5 2425-79-8 2426-08-6 2461-18-9 4016-11-9 4016-14-2 13236-02-7 13561-08-5 25085-99-8 26447-14-3



R = H; alkyl, alkenyl or alkynyl; aryl; acyl

Where R = alkyl, alkenyl, alkynyl, aryl, or acyl; any substituents or functional groups may be present with the alkyl, etc., groups.

Substances	CAS Numbers (examples for groups)
Halogenated alkyl epoxides -- halogenated noncyclic aliphatic hydrocarbons with one or more epoxy functional groups.	106-89-8 428-59-1 3083-25-8 3132-64-7



R_1 = X or $C_nH_{2n+1-y}X_y$ (y=1 to 2n+1)
R_2 = H or X or $C_nH_{2n+1-y}X_y$ (y=0 to 2n+1)
R_3 = H or X or $C_nH_{2n+1-y}X_y$ (y=0 to 2n+1)
R_4 = H or X or $C_nH_{2n+1-y}X_y$ (y=0 to 2n+1)

X = halogen

Groups R_1 - R_4 may contain one or more epoxide functions.

Hexachloro-1,3-butadiene.	87-68-3
Hexachlorocyclopentadiene.	77-47-4
Hydroquinone.	123-31-9
Isophorone.	78-59-1
Mesityl oxide.	141-79-7
4,4'-Methylenedianiline.	101-77-9
Methyl ethyl ketone.	78-93-3
Methyl isobutyl ketone.	108-10-1
Nitrobenzene.	98-95-3
p-Phenylenediamine.	106-50-3
Polychlorinated terphenyls -- polychlorinated ortho-, meta-, and para-terphenyls.	11126-42-4 12642-23-8 61788-33-8
Pyridine.	110-86-1
Quinone.	106-51-4
Toluene.	108-88-3
1,1,1-Trichloroethane (methyl chloroform).	71-55-6
Vinyl fluoride.	75-02-5
Vinylidene fluoride.	75-38-7
Xylenes -- ortho-, meta-, and para-xylene.	95-47-6 106-42-3 108-38-3

(2) [Reserved]

(b) [Reserved]

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§ 716.18 Additions to lists of substances and designated mixtures to which this subpart applies.

The requirements of this Subpart will periodically be extended to cover additional substances and designated mixtures. Two procedures will be used to add substances and mixtures.

(a) Except as provided in paragraph (b) of this section, substances and designated mixtures will be added after publication in the **Federal Register** of a notice of proposed amendment of this subpart. There will be a 30-day public comment period on the notice; after consideration of the comments, a final amendment will identify the substances and mixtures added.

(b) Substances and designated mixtures that have been recommended for testing by the Interagency Testing Committee, established under section 4 of TSCA, will become subject to this subpart 30 days after publication of a notice to that effect in the **Federal Register.**

§ 716.19 Sunset provision.

The reporting period on a substance or designated mixture will terminate no later than three years after that substance or designated mixture is added to the list in § 716.17. The automatic termination date for the three year reporting period on a substance or mixture will be the annual sunset date (May 1 or November 1) that falls no later than three years after reporting begins, e.g., a reporting requirement taking effect on January 1, 1982 would expire not later than November 1, 1984. A notice will be published in the **Federal Register** announcing the termination date for reporting for the substances and designated mixtures listed in § 716.17 (a) and (b). An earlier termination date may be published for a substance or designated mixture at the discretion of the Assistant Administrator for Pesticides and Toxic Substances.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 716

[OPTS-84003B; TSH-FRL 2112-3]

Health and Safety Data Reporting; Submission of Lists and Copies of Health and Safety Studies

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This is a proposal to add to the list of chemical substances and mixtures for which lists and copies of unpublished health and safety studies must be submitted under section 8(d) of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2607(d) (40 CFR Part 716 Subpart A). The chemical substances proposed to be added were recommended for testing by the Interagency Testing Committee (ITC), in their sixth through tenth reports to EPA (45 FR 35897, 45 FR 78432, 46 FR 28138, 47 FR 5456, and 47 FR 22585). The ITC was established under section 4 of TSCA.

DATE: Comments must be submitted on or before October 4, 1982.

ADDRESS: Written comments should bear the document control number OPTS-84003B and should be submitted to: Document Control Officer (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Room E-409, 401 M St., SW., Washington, D.C. 20460.

All written comments filed under this notice will be available for public inspection in Rm. E-107 from 8:00 a.m. to 4:00 p.m. Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: Douglas Bannerman, Acting Director, Industry Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-511, 401 M St., SW., Washington, D.C. 20460, Toll free: (800-424-9065); in Washington, D.C.: (554-1404); Outside the U.S.A.: (Operator-202-554-1404).

SUPPLEMENTARY INFORMATION: Elsewhere in today's **Federal Register** EPA is promulgating regulations under section 8(d) of TSCA to require submission of unpublished health and safety studies on specifically listed chemicals by chemical manufacturers and processors. Other persons in possession of such studies may be asked to submit them voluntarily. This rule establishes standardized reporting requirements and provides for amending the list of chemicals subject to the rule.

Under this proposal EPA would amend the list of chemicals by adding the chemicals recommended for testing by the ITC in its sixth through tenth reports. Comments are solicited on this amendment. In the future, all ITC-recommended chemicals will be subject to the rule effective 30 days after publication of a notice in the **Federal Register** to that effect. (See 40 CFR 716.18.)

We propose to add the following chemical substances and categories of chemical substances to 40 CFR 716.17. The ITC report number in which the recommendation was made follows each chemical substance or category of substances listed below.

Chemicals Proposed for Addition to Rule

Categories of Chemical Substances

Phenylenediamines—6th Report
Fluoroalkenes—7th Report

Chemical Substances

Benzyl butyl phthalate—7th Report
Biphenyl—10th Report
Butyl glycolyl butyl phthalate—7th Report
Chlorendic acid—9th Report
4-Chlorobenzotrifluoride—9th Report
2-Chlorotoluene—8th Report
Diethylenetriamine—8th Report
Ethyltoluene—10th Report
Formamide—10th Report
Hexachloroethane—8th Report
1,2,4-Trimethylbenzene—10th Report
Tris (2-Chloroethyl) phosphite—9th Report

Under the rule implementing section 8(d) of TSCA, EPA will acquire unpublished health and safety studies on these chemicals from manufacturers and processors of the chemicals. The Agency will use the studies to support its investigations of the risks posed by the chemicals and, in particular, to support its decisions whether to require industry to test chemicals under section 4 of TSCA. Use of the studies in this way was the subject of comment during the rulemaking proceeding for the rule. Our responses to section 8(d) issues raised in response to the proposal are part of the rulemaking record for that rule.

Economic Impact

EPA estimates that these additional chemicals will cost industry $195,000 to submit the required data. This consists of the following:

Corporate Rule Review	$22,000
Corporate Review (site identification)	26,000
File Search	46,000
Title Listing	3,000
Photocopying (materials)	4,000
Photocopying (labor)	11,000
Managerial Review	73,000
Ongoing Reporting	10,000
Total	195,000

If we assume ±30 percent margin of error in these estimates the range of probable cost varies from $136,000 to $254,000.

Public Record

EPA has established a public record (docket number OPTS-84003B) for this proposed rulemaking document which, along with a complete index, is available for inspection in Rm. E-107 from 8:00 a.m. to 4:00 p.m. on working days (401 M Street, SW., Washington, D.C., 20460). This record includes basic information considered by the Agency in developing this proposed rule. The Agency will supplement the record with additional information as it is received. The record includes the following categories of information:

(1) Health and Safety Study Reporting Regulations (40 CFR Part 716), Public Record, Docket No. 084003.

(2) Reports Impact Analysis for 40 CFR Part 716 and this proposed rulemaking.

(3) 6th-10th Reports of the Interagency Testing Committee (ITC); 45 FR 35897 (6th Report), 45 FR 78432 (7th Report), 46 FR 28138 (8th Report), 47 FR 5456 (9th Report), and 47 FR 22585 (10th Report).

EPA anticipates adding to the rulemaking record the following types of information:

(1) All comments on this proposed amendment.

(2) All relevant support documents and studies.

(3) Records of all communications between EPA personnel and persons outside the Agency pertaining to the development of this rule. (This does not include any inter- or intra-agency memoranda unless specifically noted in the index of the rulemaking record.)

(4) Minutes, summaries, or transcripts of any public meetings held to develop this rule.

(5) Any factual information considered by the Agency in developing the rule.

(6) Comments received from OMB under the Paperwork Reduction Act.

EPA will identify the complete rulemaking record on or before the date of promulgation of the regulation, as prescribed by section 19(a)(3) of TSCA, and will accept additional material for inclusion in the record at any time between this notice and such designation. The final rule will also permit persons to point out any errors or omissions in the record.

Regulatory Assessment Requirements; Paperwork Reduction Act

The reporting provisions of the final section 8(d) rule have been submitted for approval to the Office of Management and Budget (OMB) under section 3504(b) of the Paperwork Reduction Act of 1980 U.S.C. 3501 *et seq.* The final rule will explain how its

reporting provisions respond to any OMB or public comments.

This rule requires manufacturers and processors of eight chemicals and two chemical categories to submit unpublished health and safety studies relating to these chemicals. The studies to be submitted will be used by EPA in evaluating health and environmental effects of chemicals for purposes of assessing risks associated with the chemicals, as well as in determining whether the chemicals should be included in testing rules issued under section 4 of TSCA.

Regulatory Flexibility Act

This rule (amendment), if promulgated, will not have a significant economic impact on a substantial number of small entities. Based on our experience with a previous section 8(d) rule, we expect that only about 1 percent of the respondents will have gross sales of less than $20 million. Further, approximately 90 percent are expected to have gross sales over $100 million. Thus, of the approximately 172 companies expected to report under this rule, 156 are expected to have sales greater than $100 million. Only two companies are expected to have gross sales under $20 million. Therefore, in accordance with the Regulatory Flexibility Act (Pub. L. 96–354), EPA has determined that this rule will not have a significant economic impact on a substantial number of small entities.

Executive Order 12291

Under Executive Order 12291, EPA must judge whether a regulation is "major" and therefore requires a Regulatory Impact Analysis. EPA has determined that this regulation is not major because it does not have an effect of $100 million or more on the economy. It is expected to have a one-time cost of about $195,000. It does not have a significant effect on competition, costs or prices.

This regulation was submitted to the Office of Management and Budget for review as required by Executive Order 12291.

List of Subjects in 40 CFR Part 716

Chemicals, Health and safety, Environmental protection, Hazardous materials, Recordkeeping and reporting.

Dated: August 23, 1982.

John E. Daniel,

Acting Administrator.

PART 716—HEALTH AND SAFETY DATA REPORTING

Therefore, it is proposed that Title 40, Chapter I, be amended by adding § 716.17(a)(2) to read as follows:

§ 716.17 Substances and designated mixtures to which this subpart applies.

(a) * * *

(2) As of the date of publication of the final rule (amendment) in the **Federal Register**, the following chemical substances are subject to this subpart.

Substances	CAS numbers
Benzyl butyl phthalate	85–68–7
Biphenyl	92–52–4
Butyl glycolyl butyl phthalate	85–70–1
Chlorendic acid	115–28–6
4-Chlorobenzotrifluoride	98–56–6
2-Chlorotoluene	95–49–8
Diethylenetriamine	111–40–0
Ethyltoluene	25550–14–5
Fluoroalkenes:	
This category is defined as fluoroalkenes of the general formula: $C_nH_{2n-x}F_x$ where n equals 2 or 3 and x equals 1 to 6. This category includes the following six fluoroalkenes but is not limited to them:	
Tetrafluoroethene	116–14–3
Trifluoroethene	359–11–5
Vinylidine fluoride	75–38–7
Vinyl fluoride	75–02–5
Hexafluoropropene	116–15–4
Trifluoromethylethene	677–21–4
Formamide	75–12–7
Hexachloroethane	67–72–1
Phenylendiamines:	
This category is defined as all nitrogen-unsubstituted phenylendiamines and their salts with zero to two substituents on the ring selected from the same or different members of the group of halo, nitro, hydroxy, hydroxy-lower alkoxy, lower-alkyl, and lower-alkoxy. For this purpose, the term "lower" is defined as a group containing between one and four carbons This category includes the following phenyendiamines but is not limited to them:	
o-Diaminobenzene	95–54–5
2,5-diaminotoluene	95–70–5
1,3-Diamono-4-methylbenzene	95–80–7
o-Phenylendiamine, 4-chloro-	95–83–0
o-Phenylenediamine, 4-nitro-	99–56–9
p-Diaminobenzene	106–50–3
m-Diaminobenzene	108–45–2
3,5-Diaminotoluene	108–71–4
2,4-Diaminophenol dihydrochloride	137–09–7
1,2-Diamino-4-methylbenzene	496–72–0
m-Phenylenediammonium dichloride	541–69–5
m-Phenylenediamine, sulfate (1:1)	541–70–8
m-Phenylenediamine, 4-methoxy, dihydrochloride	614–94–8
m-Phenylenediamine, 4-methoxy	615–05–4
1,2-Phenylenediamine dihydrochloride	615–28–1
1,4-Benzenediamine, 2-methyl-, dihydrochloride	615–45–2
p-Phenylenediamine, 2-chloro-, dihydrochloride	615–46–3
2,5-Diaminotoluene sulfate	615–50–9
p-Phenylenediamine, dihydrochloride	624–18–0
2,6-Diamino-1-methylbenzene	823–40–5
o-Phenylenediamine, 4.ethoxy-	1197–37–1
1,2-Diamino-3-methylbenzene	2687–25–4
o-Phenylenediamine, 4-butyl-	3663–23–8
m-Phenylenediamine, 5-nitro	5042–55–7
m-Phenylenediamine, 4-nitro	5131–58–8
m-Phenylenediamine, 4-chloro-	5131–60–2
p-Diaminoanisole	5307–02–8
p-Phenylenediamine, 2-nitro	5307–14–2
m-Phenylenediamine, 2-nitro-	6219–67–6
p-Phenylenediamine, 2-nitro-	6219–71–2
o-Phenylenediamine, 4-nitro-, sulfate	6219–77–8
1,4-Benzenediamine, 2-methyl-, dihydrochloride	6369–59–1
4,6-Diamino-o-cresol	15872–73–8
p-Phenylenediamine, sulfate	16245–77–5
p-Phenylenediamine, 2-nitro-, dihydrochloride	18266–52–9
p-Phenylenediamine, 2,5-dichloro-	20103–09–7
Diaminotoluene	25376–45–8
2,4-Diaminoanisole sulfate	39156–41–7
1,2-Benzenediamine, 5-chloro-3-nitro	42389–30–0
1,4-Benzenediamine, ethanedioate (1:1)	62654–17–5
4,6-Diamino-2-methylphenol, hyrohloride	65679–44–9
Ethanol, 2-(2,4-diaminophenoxy-, dihydrochloride	66422–95–5
1,3-Benzenediamine, 4-ethoxy-, dihydrochloride	67801–06–3
1,3-Benzenediamine, 4-ethoxy-, sulate (1:1)	68015–98–5
m-Phenylenediamine, 4-chloro-, sulfate	68239–80–5
1,2-Benzenediamine, 4-nitro-, sulfate (1:1)	68239–82–7
1,4-Benzenediamine, 2-nitro-, sulfate (1:1)	68239–83–8
1,2-Benzenediamine, 4-chloro, sulfate (1:1)	68459–98–3
1,3-Benzenediamine, ar-ethyl-methyl	68966–84–7
1,2,4-Trimethylbenzene	95–63–6
/Tris (2-Chloroethyl) phosphite	140–08–9

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