A/C Pipe
Producers Association

Internal Correspondence

TO Executive Committee
International Affairs Committee

FROM J.F. Welch, Vice President

DATE September 8, 1982

SUBJECT U.S. Environmental Protection Agency (EPA) - Section 8 (d), Toxic Substances Control Act (TSCA)

REF: JFW correspondence, EPA-Proposed Rule on Submission of Health and Safety Studies, January 4, 1980

ACTION REQUIRED: Review for information

BACKGROUND

Section 8 (d) of TSCA authorizes the Administrator to promulgate rules requiring manufacturers, processors and distributors to submit lists and copies of health and safety studies on chemical substances or mixtures. EPA would use these studies to assess health and environmental effects of chemicals and the need for and character of testing rules promulgated under Section 4 (a) of TSCA.

On December 31, 1979, EPA proposed such rules and listed asbestos, among other chemicals, as a substance for which unpublished studies should be gathered.

CURRENT STATUS

On September 2, 1982, EPA issued a final rule requiring submission of unpublished health and safety studies and lists of studies on asbestos and a number of other chemicals. As of October 4, 1982, all commercial forms of asbestos and mixtures containing asbestos are subject to the enclosed regulations. Lists and copies of studies must be submitted no later than sixty (60) days after October 4, 1982.

COMPARISON WITH 1979 PROPOSED RULE

In contrast to the proposal, the final rule states "...respondents are responsible for searching only the company files in which they ordinarily keep studies and records kept by employees whose assigned duty is to advise the company on health and environmental effects of chemicals... ." Respondents need not consult any records retired prior to December 31, 1979. Distributors are exempted from the reporting requirements.

HEALTH AND SAFETY STUDY DEFINED

The term "health and safety study" is broadly interpreted to mean "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... ." Virtually any data that bear on health and environmental effects, including studies of air, water and soil transport of asbestos, fall withi the meaning of the term.

When a substance such as asbestos is individually listed, studies of mixtures known to contain asbestos must be reported as studies of asbestos.

STAFF ANALYSIS

The AACPP report on asbestos exposures during the cutting and machining of A/C pipe should not be subject to the reporting requirements because it was published in whole or in part in a number of AACPP publications or position statements.

However, the results of TAC-01-80, "Recommended Work Practices Phase 2: Transient Asbestos," may be subject to the reporting requirements because it could be construed to be an assessment of "human and environmental exposure...including surveys, tests and studies of...air, water and soil transport" of asbestos. This matter will be discussed with Kirkland & Ellis and AACPP counsel, and appropriate action taken.

If you have any questions, please do not hesitate to call.

JFW/ccw

cc: A. Kahn, Esq.
Tim Hardy, Esq.

copies:

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 716

[OPTS-34003A; 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 addresses the major comment areas: specific definitions; chemical substances subject to the rule; lists and copies to be submitted and who should submit them; persons 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 Proposed Section 8(d) Rule" which is part of the public record.

Specific Definitions

Manufacture and Process for Commercial Purposes

EPA interprets the term "manufacture or process for commercial purposes" to include 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 environment 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 into 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 dated 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 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 would 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 . 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 20352.

§ 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.

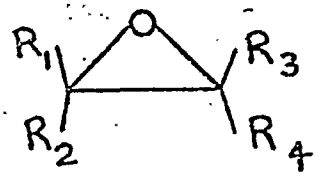
(3) The first copy will be for internal use by EPA. The second copy will be placed in an open file to be available to the public.

(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

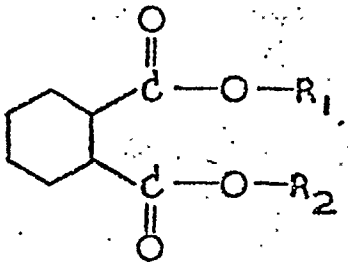


R_1 = H or alkyl
R_2 = H or alkyl
R_3 = H or alkyl
R_4 = H or alkyl

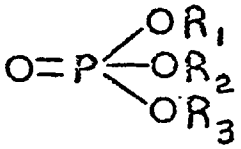
Groups R_1-R_4 may contain one or more epoxide functions

BILLING CODE 6560-50-M

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
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

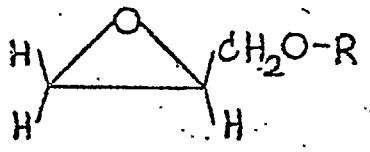


R_1 = alkyl
R_2 - alkyl



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 20282-70-6 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
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

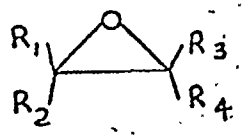
Substances	CAS Numbers (examples for groups)
Chlorinated naphthalenes -- chlorinated derivatives of naphthalene (empirical formula $C_{10}H_xCl_y$ where x+y=8).	90-13-1 1321-64-8 1321-65-9
Chlorinated paraffins -- chlorinated paraffin oils and chlorinated paraffin waxes, with chlorine content of 35 percent 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.

[FR Doc. 82-24058 Filed 9-1-82; 8:45 am]

BILLING CODE 6560-50-M