required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and record keeping requirements.

Dated: March 19, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180 -- [AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

§ 180.442 [Amended]

2. In § 180.442, by amending the tolerance listed for ''Vegetables, Cucurbits'' in the table under paragraph (b) by changing the expiration date ''4/30/98'' to read ''4/30/99''.

[FR Doc. 98–8216 Filed 3–31–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 716

[OPPTS–42188B; FRL–5750–4]

RIN 2070–AD17

Revisions to Reporting Regulations Under TSCA Section 8(d)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: As a part of EPA's 1994 regulatory review, the reporting requirements under section 8(d) of the Toxic Substances Control Act (TSCA) were reviewed for burden reduction opportunities. As a result of this review, EPA is revising its TSCA section 8(d) health and safety data reporting rule that requires chemical manufacturers (including importers) and processors of listed substances and listed mixtures to report unpublished health and safety studies. Revisions include changes to the categories of persons required to report, the types of studies and the grade/purity of the substance for which reporting is required, the reporting period, and the measure of adequacy of the file search needed to comply with the requirements of TSCA section 8(d). Additionally, EPA is amending the sunset date for all chemical substances and mixtures listed in 40 CFR 716.120, for which reporting is currently required. Furthermore, because of this change in the reporting period, EPA will no longer conduct a biennial review of the chemical substances and mixtures listed in 40 CFR 716.120. The Agency's goal is to streamline the reporting requirements while maintaining the ability to protect human health and the environment through the collection of data regarding potential risks.

DATES: *Effective date*: June 30, 1998. *Comment date*: All comments must be received by EPA by May 1, 1998. If EPA receives adverse comments to this direct final rule by May 1, 1998, EPA will issue a notice to withdraw this direct final rule and seek comment on the issue raised. After considering the comments submitted, EPA will respond to comments received in a final rule that is published in the **Federal Register**. If no adverse comments to this direct final rule are received, this rule will become effective as a final rule on the date specified above.

ADDRESSES: Each comment must bear the docket control number OPPTS–42188B. All comments should be sent in triplicate to: OPPT Document Control Officer (7407), Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, 401 M St., SW., Room G–099, East Tower, Washington, DC 20460.

Comments and data may also be submitted electronically to: oppt.ncic@epamail.epa.gov. Follow the instructions under Unit IV. of this document. No Confidential Business Information (CBI) should be submitted through e-mail.

All comments which contain information claimed as CBI must be clearly marked as such. Three sanitized copies of any comments containing information claimed as CBI must also be submitted and will be placed in the public record for this rulemaking. Persons submitting information on any portion of which they believe is entitled to treatment as CBI by EPA must assert a business confidentiality claim in accordance with 40 CFR 2.203(b) for each such portion. This claim must be made at the time that the information is submitted to EPA. If a submitter does not assert a confidentiality claim at the time of submission, EPA will consider this as a waiver of any confidentiality claim and the information may be made available to the public by EPA without further notice to the submitter.

FOR FURTHER INFORMATION CONTACT: Susan B. Hazen, Director, Environmental Assistance Division (7408), Rm. ET–543B, Office of Pollution Prevention and Toxics, USEPA, 401 M St., SW., Washington, DC 20460; telephone: (202) 554–1404; TDD: (202) 554–0551; e-mail: TSCA-Hotline@epamail.epa.gov. For specific information regarding this rule, contact Keith Cronin, Project Manager, Chemical Control Division (7405), Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone: (202) 260–8157; fax: (202) 260–1096; e-mail: cronin.keith@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

Electronic Availability:

Internet

Electronic copies of this document are available from the EPA Home Page at the Federal Register - Environmental Documents entry for this document under ''Laws and Regulations'' (http://www.epa.gov/fedrgstr/TOX/).

Fax on Demand

Using a faxphone call 202–401–0527 and select item 4301 for a copy of this document and select item 4057 for a copy of 40 CFR 716.120 revised in its entirety.

Regulated persons. Potentially regulated persons are those that manufacture (including import) or process chemical substances and mixtures. Regulated categories and entities include:

Category	Examples of regulated persons
Industry	Chemical manufacturers (including importers),chemical processors, and petroleum refiners.

This table is not exhaustive, but lists the types of persons that could potentially be regulated by this action. Other types of persons may also be regulated. To determine whether a person is regulated by this action, carefully examine the applicability criteria in 40 CFR part 716. If you have questions regarding the applicability of this action to a particular person, consult the person listed under ''FOR FURTHER INFORMATION CONTACT'' at the beginning of this document.

EPA believes this revised rule will significantly decrease the reporting burden by eliminating many of the file

searches conducted in compliance with TSCA section 8(d), eliminating many of the reporting systems which have been designed to track TSCA section 8(d) chemical substances, and eliminating the submission of data that are typically unnecessary to determine data needs.

EPA is publishing this action as a direct final rule, without a proposal and prior opportunity for comment, because the action substantially reduces existing reporting requirements under TSCA section 8(d), the Agency views the action as noncontroversial, and the Agency anticipates there will be no significant adverse comments. EPA believes that there will be no adverse reaction to this action because it substantially reduces the reporting burden associated with TSCA section 8(d) Health and Safety Data reporting requirements while still providing EPA with the needed data. In addition, EPA discussed these changes with a majority of the information providers and users, and received a favorable response. It is in the interest of the regulated community and EPA to avoid delaying the implementation of this action due to the burden reduction that would be achieved from the time it becomes effective as a final rule. The shared interest of EPA and the regulated community in this action indicates that these revisions will be received favorably and without adverse comment. Therefore, notice and public procedure are unnecessary prior to the publication of this direct final rule.

Nonetheless, adverse comments may be submitted on this action as directed under ''ADDRESSES'' at the beginning of this document. If EPA receives adverse comments, this direct final rule will be withdrawn before the effective date through publication of a document in the **Federal Register**. If this direct final rule is withdrawn, any public comments received will be addressed in a subsequent proposed rule. Any parties interested in commenting on this action must do so at this time. If no adverse comments are received, the public is advised that this action will become effective on June 30, 1998.

I. Introduction

The TSCA section 8(d) Health and Safety Data Reporting rule (40 CFR part 716) 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 TSCA and on other substances and mixtures for which EPA requires health and safety information to identify data needs and/or to support chemical risk assessment/management activities. The rule requires manufacturers (including importers) and processors to submit to EPA unpublished health and safety studies on the substances and mixtures listed at 40 CFR 716.120. EPA is revising the categories of persons required to report, the types of studies and the purity/grade of the substance on which studies were performed for which reporting is required, the reporting period, and the measure of adequacy of the file search needed to comply with TSCA section 8(d).

A. Background

On October 11, 1976, the President signed the Toxic Substances Control Act (TSCA), 15 U.S.C. 2601 *et seq.*, to ''regulate commerce and protect human health and the environment by requiring testing and necessary use restrictions on certain chemical substances * * *.'' Section 8(d) of TSCA, 15 U.S.C. 2607(d), directs the EPA Administrator to promulgate rules that require the submission of lists of health and safety studies and copies of the studies pertaining to chemical substances and mixtures in commerce. This section of TSCA requires ''any person who manufactures (includes imports), processes, or distributes in commerce or who proposes to manufacture, process, or distribute in commerce any chemical substance or mixture'' to submit to EPA lists and copies of health and safety studies available to them. The regulations implementing TSCA section 8(d) are found at 40 CFR part 716.

Under the current section 8(d) regulations, EPA requires the submission of unpublished health and safety studies on specified chemicals from manufacturers (including importers) and processors of the chemicals. Studies of human health and environmental effects, including studies of exposures to people and the environment, are the fundamental ingredients of any assessment of chemical risk. EPA requires reporting under these regulations for specific chemicals that are under investigation either in the early stages of risk assessment or when action to control exposure is being considered.

As TSCA section 8(d) rules are promulgated, chemicals and mixtures are added and subtracted from the list in 40 CFR 716.120. The process by which these modifications are made has evolved over the years. Particularly significant changes in the process described at 40 CFR part 716 occurred on October 4, 1982, when a rule (47 FR 38780) was published that set up a process for adding chemicals recommended for testing by the TSCA Interagency Testing Committee (ITC) without the opportunity for prior notice and comment (40 CFR 716.105(b)). For such chemicals, amendments made to 40 CFR 716.120, the list of chemicals subject to section 8(d) reporting requirements, become effective as direct final rules thirty days after publication of a document in the **Federal Register**.

B. Role of the TSCA Interagency Testing Committee (ITC)

The TSCA Interagency Testing Committee (ITC) is an independent committee that was created in 1976 under section 4(e) of TSCA, 15 U.S.C. 2603(e), to make recommendations to the Agency about chemicals for which data are needed. The statute specifies that the ITC consists of eight statutory members, appointed by and drawn from the following organizations: Environmental Protection Agency (EPA), Department of Labor (DOL) (appointee is drawn from the Occupational Safety and Health Administration (OSHA)), Council on Environmental Quality (CEQ), National Institute for Occupational Safety and Health (NIOSH), National Institute of Environmental Health Sciences (NIEHS), National Cancer Institute (NCI), National Science Foundation (NSF), and the Department of Commerce (DOC). Currently, eight other Federal Agency members are participating on a liaison basis: Agency for Toxic Substances and Disease Registry (ATSDR), Consumer Product Safety Commission (CPSC), Department of Agriculture (USDA), Department of Defense (DOD), Food and Drug Administration (FDA), Department of the Interior (DOI), National Library of Medicine (NLM), and the National Toxicology Program (NTP).

The chemical substances and mixtures recommended by the ITC to the EPA for priority consideration for proposed test rules under TSCA section 4(a) comprise a list called the Priority List. Chemical substances and mixtures may be recommended to be added to the Priority List based on the ITC's consideration of factors such as production volume, exposure, and availability of data regarding health and environmental effects. When the ITC recommends chemicals for testing, EPA issues amendments in the **Federal Register** to add to the list of recommended chemicals subject to reporting requirements under TSCA section 8(a) (40 CFR 712.30) and TSCA section 8(d) (40 CFR 716.120).

The ITC provides an existing infrastructure to rapidly prioritize inter-Agency data needs on many industrial chemicals. The ITC has the authority to

designate chemical substances and mixtures on the Priority List with respect to which the ITC determines the Administrator should initiate rulemaking proceedings pursuant to TSCA section 4(a). Within 12 months of the date of first inclusion on the Priority List of a chemical substance or mixture designated by the ITC, TSCA directs the Administrator to initiate rulemaking proceedings or publish in the **Federal Register** the reasons for not doing so.

The ITC recommends chemicals to the Administrator to meet focused Federal data needs under TSCA section 4(e). EPA plans to focus its TSCA section 8(d) reporting requirements to reduce the resources that are consumed to retrieve and submit section 8(d) studies (on the part of industry), log-in, store and index studies (on the part of EPA), and summarize and review studies (on the part of ITC). Further, in its 40th Report to the Administrator, the ITC has recommended to EPA that procedures be established by the Agency that offer industry opportunities to submit voluntarily the types of data required under TSCA section 8(a) and 8(d) and establish cooperative efforts with the ITC to support ITC efforts in evaluating chemicals for testing under TSCA (62 FR 30580, June 4, 1997).

C. The Need for Change

As one part of its regulatory reinvention initiative, EPA has reviewed its reporting requirements under section 8(d) of TSCA. The Agency's goal is to streamline the reporting requirements while maintaining the availability of the data or its ability to acquire the data necessary to protect human health and the environment. The current opportunity to revise the section 8(d) rule is the result of the ''regulatory reform'' evaluation efforts undertaken as a result of a Presidential regulatory reform initiative of March 16, 1995 entitled ''Reinventing Environmental Regulation.'' The rationales for reinvention activities are manifold, however, a central principle is that ''[r]egulation must be designed to achieve environmental goals in a manner that minimizes costs to individuals, businesses, and other levels of government.'' (Ref. 1)

Over the years, EPA has received a variety of comments concerning the implementation of section 8(d). Extensive comments have been received on many topics, including the definition of the term ''processor,'' reporting requirements for waste streams, and reporting requirements for modeling and monitoring information. In December 1987, the Chemical Manufacturers Association (CMA) developed a comprehensive report (Ref. 2) suggesting a variety of revisions and, in June 1996, provided the following list of suggested revisions in descending order of importance to CMA and its members (Ref. 3):

(1) Reduce ten-year reporting period to one year for section 8(d) related information.

(2) Revise reporting of monitoring and modeling studies.

(3) Revise processor reporting requirements.

(4) Reduce reporting of studies on mixtures.

(5) Exempt reporting requirements for waste streams.

(6) Eliminate study initiation reporting.

(7) Clarify file search issue.

(8) Clarify guidance on reporting of international studies.

(9) Establish a voluntary call-in prior to issuing TSCA section 8(d) reporting rules.

(10) Establish an electronic up-to-date list of TSCA section 8(d) chemicals by CAS registry number.

(11) Exclude health and safety studies managed by other environmental regulations to avoid duplicate reporting.

(12) Eliminate reporting of quantitative risk assessment and structure-activity analysis.

(13) Eliminate less useful studies.

(14) Provide for alternative forms of required reporting.

D. The Public Meeting

On August 23, 1996, EPA published a **Federal Register** notice (61 FR 43546) inviting all interested parties to attend a public meeting in Washington, DC on September 12, 1996, to discuss possible amendments to the TSCA section 8(d) rule. The meeting was well attended with over 65 representatives of manufacturers, processors, trade associations, and other interested parties. Each of the above issues was discussed and time for comments was provided. At the meeting, EPA requested that comments on the above or any other issues be submitted in writing for consideration by the Agency. Additional comments were submitted, especially relating to the issue of definition of the term ''processor'' and whether processors should be required to submit health and safety data under section 8(d) of TSCA. The comments received from all sources have been analyzed and evaluated (Ref. 4) and the general issues are addressed in Unit II. of this document.

II. Revisions to TSCA Section 8(d) Regulations

A. Background

TSCA provides EPA with a variety of methods by which it can acquire chemical substance and mixture data needed to protect human health and the environment. Section 8(d) provides EPA with the authority to promulgate rules requiring the submission of studies that are initiated by the submitter, as well as studies conducted by the submitter in the past and studies the submitter knows of or may reasonably ascertain.

A chemical substance or mixture that is not subject to an section 8(d) rule may still be subject to other TSCA reporting requirements. Section 8(e) requires manufacturers, processors and distributors to report any information regarding a chemical substance or mixture which reasonably supports the conclusion that the substance or mixture presents a substantial risk of injury to health or the environment. Studies that are not otherwise required to be reported under section 8(e) are typically the kind of studies required to be reported under section 8(d). Data relating to chemical substances and mixtures that are not reportable under TSCA section 8 may be obtained by EPA through the promulgation of a test rule under section 4 of TSCA. Once findings are made by EPA under section 4(a), EPA must promulgate a rule requiring the testing of chemical substances and mixtures to develop health and environmental effects data.

B. Persons Who Must Report

Under the current TSCA section 8(d) regulations, any person who manufacturers (including imports) or processes a chemical substance or mixture listed under 40 CFR 716.120 must submit to EPA copies of available health and safety studies upon request by EPA. Currently, there is no category or sector limitation on reporting. By this rulemaking, reporting of health and safety studies would be required only by manufacturers (including importers) who fall under the North American Industry Classification System (NAICS) in effect as of January 1, 1997, replacing the 1987 Standard Industrial Classification ((SIC); 62 FR 17288, April 9, 1997), Subsector 325 (chemical manufacturing and allied products) and Industry Group 32411 (petroleum refiners), unless otherwise required in a specific rule. EPA believes that this narrowing of the scope of reporting, on a routine basis, will reduce the burden imposed on industry to comply with TSCA section 8(d), while still providing EPA and other Federal agencies with the

data necessary to protect human health and the environment.

A number of organizations have suggested that the definition of the term ''processor'' under TSCA section 8(d) should be reevaluated. Commentors suggested two options:

(1) Revise the definition to focus reporting requirements on manufacturers (including importers), rather than on ''chemical users,'' who buy chemicals and mixtures and then use them to manufacture non-chemical products, such as articles.

(2) Use appropriate Standard Industrial Classification (SIC) codes (replaced by the North American Industry Classification System, NAICS, in 1997).

At the present time, the term ''processor'' may be broadly defined to include a far larger audience than intended on a routine basis.

EPA has analyzed the approximately 300 submitters of the roughly 11,000 submissions of TSCA section 8(d) information received to date, and has categorized them by submitter type (Ref. 4). The vast majority of submitters are individual chemical manufacturers or associations representing chemical manufacturers falling under NAICS Subsector 325 and Industry Group 32411, which are heavily concentrated on the chemical, allied products, and petroleum refining industries. Examination of some of the processor submissions indicates very limited data have been submitted by them and typically only in the form of industrial hygiene/monitoring data. Thus, narrowing the overall scope of persons who must report on a routine basis would likely have a negligible impact on the type and comprehensiveness of the information submitted under section 8(d). The rule's focus on those entities that actually submit studies ensures that virtually all of the data that have been reported in the past will continue to be reported. Health and safety data submitted under section 8(d) are typically those studies that are not otherwise reportable under section 8(e), the ''substantial risk'' information reporting provision of TSCA. Further, studies reportable under section 8(e) must be submitted within a specific time frame by a broader range of persons, i.e., manufacturers, importers, processors, and distributors.

In a specific section 8(d) rule, EPA may require reporting of health and safety studies from all manufacturers (including importers) and processors of a chemical substance. In this way, EPA reserves the ability to require more information from a much wider audience in exceptional circumstances, while reducing the burden to industry on a routine basis.

C. Reporting Period

The reporting period for health and safety studies under TSCA section 8(d) is currently 60 days for existing data, and 10 years for new data, after the effective date on which a listed chemical substance or listed mixture is added to 40 CFR 716.120, unless the listed substance or listed mixture is removed from 40 CFR 716.120 prior to the lapse of the standard reporting period. EPA is revising 40 CFR 716.65, Reporting period, to only require a standard one-time reporting, which will include the requirement that all existing studies be reported within 60 days of the 40 CFR 716.120 listing, instead of the present 10 year reporting requirement. EPA believes this will provide a significant burden reduction for industry while having little effect on the availability of data to EPA and the ITC (Refs. 5 and 6).

When a substance from the TSCA section 4(e) Priority List is listed at 40 CFR 716.120, existing studies are required to be reported within 60 days of the listing, then the ITC examines the submitted data, usually within a year, to see if test data are already available in the areas of concern. The ITC has only rarely used data that have been submitted after the first year. Once the ITC recommends a chemical for testing, EPA may write a rule requiring testing or obtain the test data through specific enforceable consent agreements (ECA) with individual companies or groups of companies who volunteer to conduct the needed testing. This may take one to several years after the initial 40 CFR 716.120 listing. Although it is important for EPA to know about any testing initiated after the first year, EPA expects this information to still be forthcoming to EPA in a timely manner. Industry groups subject to a test rule, or with which EPA is negotiating an ECA, are likely to be knowledgeable about any relevant testing that is underway or will in fact be the ones conducting the testing.

Examination of the EPA's Toxic Substances Control Act Test Submissions (TSCATS) database (Ref. 4) indicates that most of the section 8(d) submissions are made shortly after the initial listing of a chemical substance. Any new studies that offer reasonable support for a conclusion of substantial risk, would still be required to be submitted immediately under TSCA section 8(e). In addition, many companies submit to EPA other new studies on a ''For Your Information'' (FYI) basis. The present revisions to the rule leave section 8(d) as the primary mechanism to obtain older studies, not new studies, and require that industry track the chemical for 60 days to make sure that any data that should be submitted under section 8(d) are collected and transmitted to EPA, within this new time frame. Should this direct final rule become effective, EPA will sunset all current reporting requirements for all chemicals listed at 40 CFR 716.120 for which reporting is currently required, except for those chemicals about which EPA was notified that a study had been initiated or is underway. For those chemicals, reporting is required until receipt of the final report is received by EPA. At the present time, the 60–day reporting period for all chemicals and mixtures listed at 40 CFR 716.120 has elapsed. Experience has shown prospective reporting to be very limited and therefore, it is likely that EPA has received all relevant data except for chemicals for which EPA has received notice of studies initiated during the initial 60–day period or those studies underway at that time.

D. Initiated Studies

The existing regulations at 40 CFR 716.35(a)(2) and 40 CFR 716.60(b)(1) require that EPA be notified within 30 days about studies initiated during the current 10–year reporting period and that the Agency be provided with information including the date on which the study was commenced, the purpose of the study, the types of data to be collected, the anticipated date of completion, and the name and address of the laboratory conducting the study. EPA is revising 40 CFR 716.65 to only require notification of study initiation that occurs during the 60–day reporting period. EPA believes that this revision will reduce the burden imposed on industry without reducing the data available to EPA and other Federal agencies to protect human health and the environment.

Several comments (Ref. 4) received in response to the public meeting held on September 12, 1996, have suggested that for short-term toxicity studies, any notification is of little value because within a short time the final versions of these studies would be submitted. It was also suggested that it would require considerable effort to track the initiation of other types of studies, such as monitoring studies. In addition, it was suggested by some industry groups that it would be to their benefit to voluntarily notify EPA of these planned studies in order to ensure the completeness of data known to EPA, as

the Agency will make decisions on required testing of a chemical substance or mixture under section 4 of TSCA based upon the data available.

Historically, few studies have been initiated during the TSCA section 8(d) reporting period. Thus, the revisions made in this rulemaking should result in a reduction in burden related to reporting by industry and in burden of reviewing by EPA. Persons who are subject to the rule under 40 CFR 716.35 (a)(2) or (a)(3) and who have submitted to EPA lists of ongoing or initiated studies under 40 CFR 716.35 (a)(1) or (a)(2) must still submit the final report of the study within 30 days after its completion regardless of the study's completion date.

E. Studies to be Reported

A present general requirement of 40 CFR part 716 is that all health and safety data available on a listed chemical substance or listed mixture must be reported when requested by EPA. EPA is narrowing the focus of the reporting requirements to specifically identify data needs on listed chemical substances or listed mixtures which meet or exceed certain grade/purity requirements. EPA believes that this approach reduces the amount of routine reporting of health effects studies and mixture studies which are in many cases of little value in Agency and ITC decision making.

Following the September 12, 1996, public meeting, EPA met with the ITC to discuss potential revisions to the Agency's regulations under TSCA section 8(d). The ITC recommended that the Agency focus its needs for section 8(d) data to reduce the resources that are spent by: industry to submit section 8(d) studies, EPA to computerize and store studies, and ITC to review studies. In order to facilitate such focused requests for information, EPA will require reporting of studies on particular effects of a chemical recommended by the ITC.

In order to facilitate the identification of data needs, the EPA will specify the type(s) of health and safety data needed by the ITC (see the following table for sample of effects data; environmental fate and exposure data may also be requested by the ITC). By being as specific as possible in identifying data needs, EPA will allow some companies that have indexed their health and safety studies to quickly identify relevant information for submission. Also, there may be some instances when the ITC cannot specifically identify the type of health and safety data needed (e.g., when a chemical has high exposure and little toxicity data). In such a situation, the reporting requirement may be significantly broader in scope. In all cases, the ITC will provide the rationale to EPA for its requests for studies of interest.

EPA will also specify the chemical grade/purity for which reporting is required. If studies meeting the EPA's chemical/grade purity specifications are not reported, the ITC may consider requesting studies on mixtures containing the recommended chemical, and EPA will reserve the ability to require that mixtures containing a listed chemical substance are subject to reporting under a specific TSCA section 8(d) rule. In the past, the ITC has typically only reviewed studies on mixtures if there were no available studies on the relatively pure chemical. The reduction in the routine reporting of studies on mixtures that would occur upon promulgation of this direct final rule should provide significant burden relief to industry, not because of the quantity of studies that are typically reported on mixtures, but because of the difficulty in identifying the mixtures that contain a listed substance. By no longer routinely requesting mixture studies, EPA will expend fewer resources computerizing and storing studies and ITC will spend less time reviewing studies that are in many cases of little value in Agency and ITC decision-making.

The following table is a hypothetical example of the types of existing studies for which EPA may be interested in obtaining for a chemical or mixture which meets or exceeds certain grade/purity criteria. This table should not be interpreted as setting forth future reporting requirements for a given chemical substance or mixture; rather it is a sample of the type of table which could be printed in the **Federal Register** setting forth certain identified data needs necessary for risk characterization for a specific chemical substance or mixture meeting specified grade/purity criteria in a new section of rules issued under section 8(d). Data needs and grade/purity would be indicated in the appropriate boxes. Data needs may include health, ecological, and/or environmental fate studies. A particular organism (e.g., rat) or route of exposure (e.g., inhalation) may provide the most relevant data for decision-making purposes, therefore, identification of a particular test species or route of exposure will be made where applicable.

Examples of Health, Ecological, and/or Environmental Effects Studies Which Can Be Requested Under TSCA Section 8(d)

Chemical name	CAS registry no.	Grade/purity of test substance	Study types	Test species	Route of exposure
1,chemical name	xxx–xx–x	technical grade or better (XX%).	HE[1]/subchronic EE[2]/acute toxicity EF[3]/hydrolysis	Mammals Fish-freshwater na[4]	Dermal/oral na na
2,chemical name	xxx–xx–x	99.9%	EE/reproductive toxicity	Fish-Marine	na
3,chemical name	xxx–xx–x	mixtures 75% or greater	EF/octanol Water partition Coefficient	na	na

[1] HE, health effects.
[2] EE, ecological effects.
[3] EF, environmental fate.
[4] na, not applicable.

F. Adequate File Search

The former approach for reporting TSCA section 8(d) studies requires searching all ''active'' files or records kept by the company personnel responsible for keeping such records or providing advice on health and environmental effects of chemicals. In this rulemaking, EPA is limiting 40 CFR 716.25 to require file searches only for reportable information dated on or after January 1, 1977, the effective date of TSCA, unless a subsequent section 8(d) rule requires a more extensive search.

EPA believes that this revision will also result in an additional reduction in burden to both industry and EPA.

Over the years, commenters have suggested that file searches have resulted in considerable burden due to the reporting of some rather old studies which are less likely to meet current needs due to changing protocols to achieve state-of-the-art science and lack of application of Good Laboratory Practice Standards (GLPS). The GLPS were promulgated in 1978 (Food and Drug Administration) and the mid 1980's (EPA, 40 CFR part 792). For example, in earlier studies, fewer animals were used for oncogenicity, developmental, reproductive, and subchronic studies; monitoring of animals' health status by breeders was less rigorous; and chemical analytical methods were not as sensitive. However, limiting reporting of studies to only a certain time frame preceding the date of the listing of the substance could result in useful studies not being reported to EPA and ITC. Consequently, EPA would reserve the right to request such studies through a more extensive search.

EPA believes that in all but exceptional circumstances, establishing a single date after which all files should be searched will remove the confusion that currently exists with respect to ''active'' and ''retired'' files. EPA will continue to accept the submissions of older studies that may meet the regulatory needs of EPA and ITC, but these would be submitted on a voluntary rather than obligatory basis by industry, unless a rule makes submission mandatory. However, because studies conducted prior to the effective date of TSCA may be the only source of relevant data on a chemical, EPA may, under certain circumstances, require file searches for reportable information dated before January 1, 1977. Industry will have a considerable incentive to voluntarily submit older ''good'' studies, because the alternative is that EPA may require testing under section 4 of TSCA if sufficient relevant test data are not forthcoming. Additionally, section 8(e) would remain applicable to studies, regardless of age, required to be reported pursuant to that section.

III. Refinements to the TSCA Section 8(d) Information Collection Program

A. The Voluntary Program

For over twenty years, the ITC has received voluntary data submissions from manufacturers, importers, processors and users of chemicals recommended by the ITC and has engaged in dialogue with several chemical industry trade associations and their members to discuss the needs for these data. Such dialogue provides opportunities to discuss in a more focused way data needed by ITC member organizations, and may in some cases result in the ITC obtaining sufficient information to remove a chemical from the Priority List provided by the ITC to EPA. The following are examples that illustrate the significance of these activities:

(1) Discussions between the ITC and CMA's Propylene Glycol Ethers Panel resulted in the provision of data and facilitated the removal of propylene glycol ethers from the Priority List (60 FR 42982, August 17, 1995).

(2) Discussions between the ITC and Silicones Environmental Health and Safety Council (SEHSC) resulted in the provision of data and facilitated the removal of many siloxanes from the Priority List (61 FR 4188, February 2, 1996).

Recently, most additions to the list of chemical substances and mixtures subject to TSCA section 8(d) reporting requirements (40 CFR 716.120) have been the result of additions by the ITC to the TSCA section 4(e) Priority List. Voluntary data submissions by numerous chemical companies and trade associations to the ITC have been helpful in identifying the important commercial chemicals that require testing and identifying the types of tests that need to be conducted. A request for the voluntary submission of health and safety data prior to the promulgation of a section 8(d) rule for a recommended chemical was issued by the ITC in its 40th Report to the EPA Administrator (62 FR 30580, June 4, 1997). Such requests provide an opportunity for industry representatives to voluntarily submit information related to the ITC's testing or informational needs. When responding to requests, a letter (or e-mail) of intent to submit the information must be received by the ITC no later than 30 days after the date the ITC Report is published in the **Federal Register**. If the ITC receives a ''letter of intent,'' followed by a voluntary information submission, the ITC will make a decision regarding the need for additional information following its review of all relevant information. If no ''letter of intent'' (or e-mail) is received, the ITC will request in its next Report that EPA promulgate a TSCA section 8(d) rule requiring the reporting of health and safety studies on the recommended chemical substance or mixture.

B. Electronic Submissions

The EPA, ITC, and industry have had an interest for a number of years in the development of a means for providing electronic submissions of TSCA section 8(d)-related data. This interest was stimulated for the following reasons:

(1) Electronic submissions would reduce costs to industry and the EPA by eliminating copying time and charges.

(2) Electronic submissions would cut the large amount of paper generated with each submission.

(3) Electronic submissions could be linked to tracking systems to ease document management efforts by EPA, ITC, and industry.

(4) Electronic submissions would have the potential to be searchable and permit easier review.

(5) Electronic submissions could be more easily and rapidly transferred to end users allowing potential real time assessment of submissions.

(6) Electronic submissions could be ''uploaded'' to existing databases.

(7) Electronic submissions may be readily made publicly available through existing and new information dissemination vehicles.

Currently, three areas related to electronic submissions of TSCA section 8(d) data are under consideration:

(1) Cover sheets for section 8(d) documents.

(2) Bibliographic data and abstracts of section 8(d) documents.

(3) Electronic copies of full text section 8(d) documents.

Documents containing confidential business information (CBI) must not be submitted electronically. Electronic submissions of section 8(d) data are considered public information by the Agency.

The current status of the above efforts is as follows:

Coversheets, bibliographic data and abstract submittal. Standardized coversheets have been designed by a committee consisting of members from EPA and industry. These coversheets provide the information required for entry of data into EPA's Toxic Substances Control Act Test Submissions (TSCATS) database as well as some additional data desired by the Agency. Currently EPA is investigating the possibility of placing templates of this coversheet on a World Wide Web page to permit easy access and a means for transmitting completed cover sheets to EPA, and matching transmitted coversheets to the paper copies of the section 8(d) documents when they are received by EPA. These coversheets will provide a standardized form for submittal of data whether used in

electronic form or as a paper attachment to a section 8(d) document.

As part of this effort, industry would submit bibliographic data (title, submitter, laboratory), indexing terms (as they are used in the TSCATS database) and abstracts of section 8(d) documents submitted. Some industry groups have indicated that there is little incentive to develop the means to submit these data electronically if they normally only submit a few studies or if their files are not currently in electronic form. EPA agrees that current incentives are lacking, but feels that, with time, industry (particularly large corporations) will have ''computerized'' file structures, and electronic filing may provide industry with a cost savings. If EPA establishes its data needs now, industry can accommodate them, at little expense, when developing electronic files. With advance knowledge of these data elements, industry can ensure that any database developed will be compatible with electronic submission of section 8(d) information.

Full text electronic documents. The development of systems to accommodate submission of full text documents in electronic form will assist in reducing storage space, providing easily read documents, and potentially allowing the searching of documents for specific subjects. EPA anticipates that electronic documents would be provided in a variety of file formats including, but not limited to, standard word processing files, images, and combinations of these, and any system developed would need to accommodate all formats. Information from laboratory studies, particularly raw data, is still typically maintained in handwritten form, and unless a specific company has its own reason for converting this material to electronic form, there is little incentive to convert for submission to EPA. In addition, industries who submit relatively few documents may initially prefer paper submission. For these reasons, industry has encouraged EPA to develop means for receiving submissions in electronic form, while also maintaining the current process for receiving paper copies of TSCA section 8(d) submissions.

EPA believes there are a number of advantages to developing the means to submit section 8(d) information in electronic form, thus the development of these procedures will continue. The current system of paper submissions will be continued because of the cost of converting to electronic submissions, particularly for those who submit relatively few documents or do not currently have their files computerized. It is anticipated, however, that in the future, more companies will have electronic files and that there will be a cost savings associated with the submission of section 8(d) documents by electronic filing. As the means to submit documents electronically progresses, EPA will address issues concerning document security, integrity, and authenticity.

C. Updated List of Chemicals for which TSCA Section 8(d) Reporting is Required

Currently, when a chemical or chemical class appears on the section 4(e) Priority List, an amendment to the section 8(d) regulations at 40 CFR 716.120, effective thirty days after publication in the **Federal Register**, requires submission of all health and safety studies for 10 years after the notice is published. EPA has also made the section 8(d) list at 40 CFR 716.120 available on EPA's Home Page through a World Wide Web Site (http://www.epa.gov). Under the revised section 8(d) rule, EPA has reduced the reporting period, in general, from 10 years to 60 days. Because of this change in the reporting period, EPA will no longer conduct biennial review of chemical substances and mixtures listed at 40 CFR 716.120. EPA is amending the sunset date for all chemical substances and mixtures listed at 40 CFR 716.120, for which reporting is currently required, to June 30, 1998. Nevertheless, EPA will continue to publish each chemical or mixture on the list at 40 CFR 716.120, including the sunset date, for a period of 5 years.

In a specific section 8(d) rule, EPA may, in certain circumstances in which it has identified a continuing need for information, continue to list chemical substances and mixtures at 40 CFR 716.120 for a period of time not to exceed 2 years. In this way, EPA reserves the ability to require the reporting of information during periods longer than 60 days where EPA believes that new and potentially significant data may be generated beyond the 60 day period, while reducing the burden of industry on a routine basis.

IV. Public Record and Electronic Submissions

The official record for this rulemaking, as well as the public version, has been established for this rulemaking under docket control number OPPTS-42188B (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 12 noon to 4 p.m., Monday through Friday, excluding legal holidays. The official rulemaking record is located in the TSCA Nonconfidential Information Center, Rm. NE–B607, 401 M St., SW., Washington, DC.

Electronic comments can be sent directly to EPA at:

oppt.ncic@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket control number OPPTS–42188B. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries.

A. Supporting Documentation

This record contains the basic information considered in developing this Rule and includes the following information:

Federal Register notice of Public Meeting for TSCA Section 8(d) Revision, (August 23, 1996, 61 FR 43546).

Communications consisting of:

(a) Written letters.

(1) AAMA & AIAM. 1996. Comments of the American Automobile Manufacturers Association and the Association of International Automobile Manufacturers on EPA's TSCA Section 8(d) Reinvention Initiative, November 1, 1996, Washington, DC.

(2) AIA. 1996. Letter from Roundtree, G. to Frank Kover, OPPT, EPA for TSCA Section 8(d) Revision Project, Aerospace Industries Association, October 15, 1996, Washington, DC.

(3) API. 1996. Comments of the American Petroleum Institute on EPA's Review of Reporting Requirements Under Section 8(d) of the Toxic Substances Control Act, November 1, 1996, Washington, DC.

(4) Adams, G.L. 1992. Letter to TSCA Public Document Office. ''OPPTS–82038 TSCA Section 8(d) Guidance on Modeling Health and Safety Studies.'' March 4, 1992, 3M, St. Paul, MN 55144.

(5) Adams, G.L. 1995. Letter to TSCA Public Document Office. ''OPPTS–84030 TSCA Section 8(d).'' October 19, 1995, 3M, St. Paul, MN 55144.

(6) Christman, M.H. 1992. Letter to TSCA Public Document Office. Comments on Docket Control Number OPPTS–82038: ''Questions and Answers: Applicability of the Toxic Substances Control Act (TSCA) Section 8(d) Model Health and Safety Reporting Rule (40 CFR Part 716) to Modeling

Studies.'' 57 FR 1723 (January 15, 1992), April 1, 1992, DuPont, Wilmington, Delaware 19898.

(7) CMA. 1988. Letter to Joseph Merenda, Director, Existing Chemical Assessment Division, EPA, May 2, 1988, Washington, DC.

(8) CMA. 1991. Letter to Mark Greenwood, Director, Office of Toxic Substances, EPA, August 26, 1991, Washington, DC.

(9) CMA. 1996. Recommendations of the Chemical Manufacturers Association for Reform in EPA's Reporting Requirements Under Section 8(d) of the Toxic Substances Control Act, October 15, 1996, Washington, DC.

(10) Green, D.H. 1994. Letter to Patricia A. Roberts, Office of General Counsel, EPA, for Regulations of Wastes Under TSCA, October 6, 1994, Piper & Marbury, Washington, DC.

(11) Green, D.H. 1996A. Letter to Patricia A. Roberts, Office of General Counsel, EPA, for TSCA section 4 Test Rules and Waste Imports, April 5, 1996, Piper & Marbury, Washington, DC.

(12) Green, D.H. 1996B. Letter to Keith Cronin, Chemical Control Division, OPPT, for Comments on Issues Raised at EPA Public Meeting on TSCA Section 8(d) Amendments (OPPTS–4218), October 15, 1996, Piper & Marbury, Washington, DC.

(13) Greenwood, M.A. 1996. Letter to Frank Kover, OPPT, US EPA for TSCA Section 8(d) Revision Project, Ropes & Gray, Washington, DC.

(14) Harvey, S.K. 1996. Letter to TSCA Docket Contol Number 42188 for Comments on Section 8(d) Notice, October 14, 1996, FMC Corporation, Philadelphia, PA.

(15) Kuryla, W.C. 1990. Letter to Charles Auer, Acting Director, Existing Chemical Assessment Division, Office of Toxic Substances, for Request for Interpretation of TSCA Section 8(d), March 29, 1990, Union Carbide Corporation, Danbury, CT 06817.

(16) Kuryla, W.C. 1995. Letter to Frank Kover, OPPT, US EPA for TSCA Section 8(d) Revision, December 21, 1995, Union Carbide Corporation, Danbury, CT 06817.

(17) Petke, F. D. 1996. Letter to Frank Kover, OPPT, US EPA, Comments on Revisions to TSCA Section 8(d), October 10, 1996, Eastman Chemical Company, Kingsport, TN 37662.

(18) Robinson, R.H. 1995A. Letter to Regulatory Coordination Staff, OPPTS, EPA, for Regulations Reinvention Initiative—Opportunity to Submit Comments in OPPTS, May 16, 1995, Hazardous Waste Management Association.

(19) Robinson, R.H. 1995B. Letter to Denise Keehner, Deputy Director, Chemical Control Division, OPPTS, EPA, for Meeting Concerning Applicability of TSCA to Wastes, May 31, 1995, Hazardous Waste Management Association.

(20) Sanders, W.H. III. Undated. Letter to Gary King, Regulatory Program Manager, Safety-Kleen Corporation, Elgin, Illinois, Office of Pollution Prevention and Toxics, EPA, Washington, DC.

(21) Wilson, J.D. 1992. Letter to TSCA Public Document Office. Comments on Docket Control Number OPPTS–82038: ''Questions and answers: Applicability of the Toxic Substances Control Act (TSCA) Section 8(d) model health and safety reporting rule to modeling studies.'' 57 FR 1723 (January 15, 1992), July 20, 1992, Monsanto Co., St. Louis, MO 63167.

(22) Zoll, D.F. 1988A. Letter to Charles L. Elkins, Director of Office of Toxic Substances. May 24, 1988, Guidance on Application of TSCA Section 8(d) to Community Health Standards and Modeling and Monitoring Reports Developed in Connection With Section 313 of EPCRA, Chemical Manufacturers Association, Washington, DC.

(23) Zoll, D.F. 1988B. Letter to Joseph J. Merenda, Director of the Assessment Division, EPA, June 28, 1988, Application of TSCA Section 8(d) to Modeling and Other Materials Developed in Connection With Section 313 of EPCRA, Chemical Manufacturers Association, Washington, DC.

(b) Meeting summary.

EPA. Agenda and Presentation; Public Meeting for Revisions's in EPA's Reporting Requirements under Section 8(d) of the Toxic Substances Control Act, September 12, 1996, Washington, DC.

B. References

(1) ''Reinventing Environmental Regulation,'' Clinton Regulatory ReformInitiative, Washington, DC (March 16, 1995).

(2) CMA. 1987. Recommendations of the Chemical Manufacturers Association for Modification of EPA's Regulations Under Section 8(d) of TSCA. December 28, 1987. Washington, DC.

(3) CMA. 1996. Regulatory Priorities of the Chemical Manufacturers Association for Modification of EPA's Regulations Under Section 8(d) of TSCA (Draft). June, 1996. Washington, DC.

(4) Syracuse Research Corporation. ''Support Document for Proposed Revisions to Section 8(d) of TSCA,'' Syracuse NY (April 30, 1997).

(5) Chemical Manufacturers Association. ''Recommendations of the Chemical Manufacturers Association for Reforms in EPA's Reporting Requirements Under Section 8(d) of the Toxic Substances Control Act'' (October 15, 1996).

(6) EPA. ''Analysis of the Proposed Streamlining of Section 8(d) Rule Requirements,'' Washington, DC (April 30, 1997).

V. Regulatory Assessment Requirements

The Office of Management and Budget (OMB) has exempted actions issued pursuant to section 8(d) of TSCA from OMB review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). In addition, this direct final rule is expected to provide significant reductions in the burden and costs associated with reporting under TSCA section 8(d) for those subject to reporting (i.e., manufacturers, importers, and processors of chemicals), as well as those who use the information reported (i.e., the ITC and EPA), and is not expected to result in any adverse impacts.

As a result, this action does not impose any enforceable duty or contain any unfunded mandate as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), or require prior consultation with State officials as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993). Moreover, it does not involve special considerations of environmental justice related issues as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

According to the Paperwork Reduction Act (PRA), 44 USC 3501 *et seq.*, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under the PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations, after initial display in the preamble of the final rules, are listed in 40 CFR part 9. The information collection requirements related to reporting under TSCA section 8(d) have already been approved by OMB pursuant to the PRA under OMB control number 2070–0004 (EPA ICR No. 575). This action does not impose

any new collections or burden requiring additional OMB approval.

The annual public burden for the existing requirements ranged between 2 and 23 hours per response (depending upon the individual respondent activities). The changes made to the requirements through this direct final rule reduce the annual public burden by 5,000 hours, for a new annual public burden of between 1 and 12 hours per response. If the Agency does not receive any adverse comments so that this direct final rule can become effective, EPA will then amend the total burden hours approved under OMB Control number 2070–0004 to reflect this reduction.

Under the PRA, burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Send any comments about the accuracy of this burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the Director, OPPE Regulatory Information Division, U.S. Environmental Protection Agency (Mail Code 2137), 401 M Street, SW., Washington, DC 20460, with a copy to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th St., NW., Washington, DC 20503, marked ''Attention: Desk Officer for EPA.'' Please remember to include the OMB control number in any correspondence, but do not submit any reports to these addresses.

In addition, pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that this action does not have a significant economic impact on a substantial number of small entities.

VI. Submission to Congress and the Comptroller General

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in today's **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 716

Environmental Protection, Chemicals, Hazardous substances, Health and Safety, Reporting and recordkeeping requirements.

Dated: March 18, 1998.

Lynn R. Goldman,

Assistant Administrator for Prevention, Pesticides and Toxic Substances.

PART 716—[AMENDED]

1. The authority for part 716 continues to read as follows:

Authority: 15 U.S.C. 2607(d).

2. By revising § 716.5 to read as follows:

§ 716.5 Persons who must report.

(a) Except as provided in paragraphs (b) and (c) of this section, only those persons described in this section are required to report under this part. Persons who must report include manufacturers (including importers) who fall within the North American Industry Classification System (NAICS) (in effect as of January 1, 1997) Subsector 325 (chemical manufacturing and allied products) or Industry Group 32411 (petroleum refineries), who:

(1) In the 10 years preceding the effective date on which a substance or mixture is added to § 716.120, either had proposed to manufacture (including import), or had manufactured (including imported) the listed substance or listed mixture (including as a known byproduct), are required to report during the reporting period specified in § 716.65.

(2) As of the effective date on which a substance or mixture is added to § 716.120, and who propose to manufacture (including import), or who are manufacturing (including importing) the listed substance or listed mixture (including as a known byproduct), are required to report during the reporting period specified in § 716.65.

(3) After the effective date on which a substance or mixture is added to § 716.120, and who propose to manufacture (including import) the listed substance or listed mixture (including as a known byproduct), are required to report during the reporting period specified in § 716.65.

(b) A rule promulgated under the authority of 15 U.S.C. 2607(d) may require that any person who does not fall within NAICS (in effect as of January 1, 1997) Subsector 325 or Industry Group 32411, and who had proposed to manufacture (including import) or process, had manufactured (including imported) or processed, proposes to manufacture (including import) or process, or is manufacturing (including importing) or processing a substance or mixture listed in § 716.120 must report under this part.

(c) Processors and persons who propose to process a substance or mixture otherwise subject to the reporting requirements imposed by this part are not subject to this part unless EPA specifically states otherwise in a particular notice or rule promulgated under the authority of 15 U.S.C. 2607(d).

3. By adding § 716.20(b)(5) to read as follows:

§ 716.20 Studies not subject to reporting requirements.

* * * * *

(b) * * *

(5) Rulemaking proceedings that add substances and mixtures to § 716.120 will specify the types of health and/or environmental effects studies that must be reported and will specify the chemical grade/purity requirements that must be met or exceeded in individual studies. Chemical grade/purity requirements will be specified on a per chemical basis or for a category of chemicals for which reporting is required.

4. By revising § 716.25 to read as follows:

§ 716.25 Adequate file search.

The scope of a person's responsibility to search records is limited to records in the location(s) where the required information is typically kept, and to records kept by the person or the person's individual employee(s) who is/are responsible for keeping such records or advising the person on the health and environmental effects of chemicals. Persons are not required to search for reportable information dated before January 1, 1977, to comply with this subpart unless specifically required to do so in a rule.

5. By revising the first sentence in § 716.30(a)(1) to read as follows:

§ 716.30 Submission of copies of studies.

(a)(1) Except as provided in §§ 716.5, 716.20, and 716.50, persons must send to EPA copies of any health and safety studies in their possession for the

substances or mixtures listed in § 716.120. * * *

* * * * *

6. By revising § 716.35(a), introductory text, to read as follows:

§ 716.35 Submission of lists of studies.

(a) Except as provided in §§ 716.5, 716.20, and 716.50, persons subject to this rule must send lists of studies to EPA for each of the listed substances or listed mixtures (including as a known byproduct) in § 716.120 which they are manufacturing, importing, or processing, or which they propose to manufacture (including import) or process.

* * * * *

7. By revising § 716.45(c)(3) to read as follows:

§ 716.45 How to report on substances and mixtures.

* * * * *

(c) * * *

(3) The substance of the grade/purity specified in each rule promulgated under 15 U.S.C. 2607(d).

8. By revising § 716.60(a) to read as follows:

§ 716.60 Reporting schedule.

(a) *General requirements.* Except as provided in § 716.5 and paragraphs (b) and (c) of this section, submissions under §§ 716.30 and 716.35 must be postmarked on or before 60 days after the effective date of the listing of a substance or mixture in § 716.120 or within 60 days of proposing to manufacture (including import) or process a listed substance or listed mixture (including as a known byproduct) if first done after the effective date of the substance or mixture being listed in § 716.120.

* * * * *

9. By revising the § 716.65 to read as follows:

§ 716.65 Reporting period.

Unless otherwise required in a rule promulgated under 15 U.S.C. 2607(d) relating to a listed chemical substance or listed mixture [hereinafter ''rule''], the reporting period for a listed chemical substance or listed mixture will terminate 60 days after the effective date on which the listed chemical substance or listed mixture is added to 40 CFR 716.120. EPA may require reporting for a listed chemical substance or listed mixture beyond the 60 day period in a rule promulgated under 15 U.S.C. 2607(d), however EPA will not extend any reporting period later than 2 years after the effective date on which a listed chemical substance or listed mixture is added to 40 CFR 716.120. After the applicable reporting period terminates, any person subject to the rule under 40 CFR 716.5 (a)(2) or (a)(3) and who has submitted to EPA lists of ongoing or initiated studies under 40 CFR 716.35 (a)(1) or (a)(2) must submit a copy of any such study within 30 days after its completion, regardless of the study's completion date.

§ 716.120 [Amended]

10. The tables in § 716.120 (a), (c), and (d) are amended by revising the dates in the ''Sunset date'' column that have not yet occurred as of April 1, 1998, to read ''June 30, 1998''.

[FR Doc. 98–8425 Filed 3–31–98; 8:45 am]

BILLING CODE 6560–50–F

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 87–268; FCC 98–23]

Advanced Television Systems

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This *Memorandum Opinion and Order on Reconsideration of the Fifth Report and Order* (''MO&O'') reaffirms & clarifies the Commission's rules to implement digital television. The intended effect of this action is to provide a host of new and beneficial services to the American public, while preserving and improving free universal television service that serves the public.

EFFECTIVE DATE: May 1, 1998.

FOR FURTHER INFORMATION CONTACT: Mania Baghdadi, Mass Media Bureau, Policy & Rules Division, 202–418–2130.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *MO&O*, MM Docket No. 87–268, FCC 98–23, adopted February 17, 1998 and released February 23, 1998. The full text of this *MO&O* is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 1919 M Street, N.W., Washington, DC, and also may be purchased from the Commission's copy contractor, International Transcription Service, Inc., 1231 20th Street, N.W., Washington, D.C., 20036, (202) 857–3800.

I. Introduction

1. In the *Fifth Report and Order*, 62 FR 26996 (May 16, 1997), in the digital television (''DTV'') proceeding, we adopted rules to permit the nation's broadcasters to implement the conversion to digital television in accordance with the Telecommunications Act of 1996 (''1996 Act''). Our goals were to preserve and promote free, universally available, local broadcast television in a digital world, as well as to advance spectrum efficiency and the rapid recovery of spectrum by fostering the swift development of DTV. Accordingly, we sought to maximize broadcasters' flexibility to provide a digital service to serve the needs and desires of the viewers, while adopting rules to ensure a smooth transition to digital television.

2. We established an aggressive but reasonable construction schedule, a requirement that broadcasters continue to provide free, over-the-air television service, a target date of 2006 for the completion of the transition, and a simulcasting requirement phased in at the end of the transition period. We also recognized that digital broadcasters remain public trustees of the nation's airwaves and have a responsibility to serve the public interest. In order to permit an opportunity to reassess the decisions we made in the *Fifth Report and Order,* we also noted our intention to conduct a review of the progress of the transition to DTV every two years. In response to petitions for reconsideration from various parties, we take this opportunity to reaffirm, revise, or clarify certain of our actions. Issues raised in the petitions for reconsideration that are not addressed here will be resolved in separate proceedings or future orders as noted.

II. Issue Analysis

A. Eligibility

3. *Background.* The 1996 Act expressly limited initial eligibility for DTV licenses to persons that, as of the date of the issuance of the licenses, hold either a construction permit or license (or both) for a television broadcast station. In the *Fifth Report and Order,* the Commission issued initial DTV licenses simultaneously to all eligible full-power permittees and licensees. We concluded that it more effectively effectuates the Congressional scheme to implement the statute through a streamlined three-phased licensing process, with the first phase consisting of the initial DTV license, rather than through the conventional two-phased licensing process. Use of the two-step process without the initial licensing phase would have prevented the establishment of a date certain at which to determine initial eligibility because, given the statutory directive that eligibility be limited to permittees and licensees as of the date of issuance of the DTV licenses, it could potentially