improvement in air service, DOT will consider the following factors:

(1) Which hub or hubs the applicant proposes to serve from the eligible point;

(2) The number of stops that the applicant will make between the designated hub and the eligible point;

(3) The size and type of aircraft, including whether they are pressurized, that the applicant intends to use at the eligible point;

(4) An increase in the number of flights or seats that the applicant proposes to provide at the eligible point, if:

(i) The increased frequencies are combined with a change in aircraft so as not to result in the Department paying a subsidy for more than essential air transportation; or

(ii) A petition has been filed under § 325.10 of this chapter to raise the eligible point's essential air transportation level.

(5) Service-related advantages held by the applicant such as computerized reservation systems or joint fares.

(d) In addition to the factors described above, the Department, in evaluating an application, will consider the following:

(1) The desirability of developing an integrated linear system of air transportation whenever such a system most adequately meets the air transportation needs of the eligible point involved;

(2) The experience of the applicant in providing scheduled air service in the vicinity of the eligible point involved;

(3) The relative efficiency of the aircraft that the competing carriers use or propose to use;

(4) The relative financial strength of the competing carriers;

(5) The time necessary for the applicant to begin providing the service it proposes;

(6) The performance of the incumbent carrier in serving the eligible point involved;

(7) The amount of time that the incumbent carrier was on the subsidy rate to question;

(8) The effect of granting the bumping application on other points in the incumbent carrier's system;

(9) The availability of slots for the applicant at the hub or hubs that it proposes to serve; and

(10) In Alaska, the experience of the applicant in providing scheduled air service, or significant patterns of nonscheduled air service under Part 298 of this chapter, in that State.

(e) In evaluating the standards described above, the Department will give great weight to the views of representatives of the eligible point involved.

§ 326.8 Transition from the incumbent carrier to the applicant.

(a) If an applicant is successful in its bid to replace an incumbent carrier and receive a subsidy for serving the eligible point, it shall notify DOT and the incumbent carrier of the date that it is prepared to begin service at the eligible point. It shall allow the incumbent 45 days to close down its operation at the eligible point, unless another date is agreed on.

(b) The incumbent carrier shall continue service at the eligible point until the successful applicant begins service there.

(c) The Department will continue to pay the subsidy to the incumbent carrier for at least 45 days after it grants the bumping application, unless the two carriers agree to a different date for the transfer of service. DOT will continue to pay the subsidy to the incumbent carrier thereafter until the successful applicant begins service at the eligible point.

§ 326.9 Conformity with Subpart A of Part 302.

Except where they are inconsistent, the provisions of Subpart A of Part 302 of this chapter shall apply to proceedings under this part.

[FR Doc. 84-30193 Filed 11-20-84; 8:45 am]

BILLING CODE 4910-62-M

federal register

Wednesday
November 21, 1984

Part III

Environmental Protection Agency

40 CFR Part 723

Premanufacture Notification Exemptions; Exemptions for Polymers; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 723

[OPTS-50033A; TSH-FRL 2439-1]

Premanufacture Notification Exemptions; Exemptions for Polymers

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Section 5(a)(1) of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture or import a new chemical substance for commercial purposes to submit a notice to EPA before manufacture or import begins. Section 5(h)(4) of TSCA authorizes the Administrator, upon application and by rule, to exempt any person from the provisions of section 5 if the Administrator determines that the chemical substance will not present an unreasonable risk of injury to health or the environment when manufactured, processed, distributed, used, or disposed of under the exemption. This rule grants a section 5(h)(4) exemption for persons who manufacture or import certain polymers. To ensure that these polymers will not present an unreasonable risk, EPA has included procedural safeguards and other conditions in the exemption.

DATES: This rule shall be promulgated for purposes of judicial review under section 19 of TSCA at 1 p.m. eastern daylight time on December 5, 1984. This rule is effective January 4, 1985.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS-794), Office of Toxic Substances, Environmental Protection Agency, Room E-511, 401 M St., SW., Washington, D.C. 20460, Toll-free: (800-424-9065), In Washington, D.C.: (554-1404), Outside the USA: (Operator-202-554-1404).

SUPPLEMENTARY INFORMATION: This rule exempts, under section 5(h)(4) of TSCA, manufacturers and importers of certain polymers from certain premanufacture notice (PMN) requirements. EPA has determined that these chemical substances will not present an unreasonable risk of injury to health or the environment under conditions of the exemption.

I. Background

Under section 5 of TSCA, any person who intends to manufacture or import a new chemical substance for commercial purposes must notify EPA at least 90 days before manufacture or import begins. A new chemical substance is any substance that is not on the inventory of existing substances compiled by EPA under section 8(b) of TSCA.

The requirement to submit premanufacture notices (PMNs) for new chemical substances became effective on July 1, 1979, 30 days after the publication of the Initial Inventory. EPA issued the final Premanufacture Notice Requirements and Review Procedures in the **Federal Register** of May 13, 1983 (48 FR 21722). In the **Federal Register** of September 13, 1983 (48 FR 41132), the Agency clarified certain provisions of the rule, made a non-substantive amendment to the timing of the submission of the notice of commencement of manufacture, and stayed certain other provisions of the rule. Several of the stayed or amended provisions of the PMN Rule have been referenced in this exemption rule, and therefore are stayed or amended to the same extent. The rule became effective October 26, 1983. Since the beginning of the program in 1979, EPA has reviewed more than 4,000 notices.

Section 5(h)(4) of TSCA provides that the Administrator may, upon application and by rule, exempt a new chemical substance or category of new substances from any requirement of section 5 if he or she determines that the manufacture, processing, distribution, use, or disposal of the chemical substance(s) will not present an unreasonable risk of injury to human health or the environment.

This exemption was developed in response to petitions from the Chemical Manufacturers Association (CMA) and other industry trade groups. Notice of receipt of the petitions from CMA and others was published in the **Federal Register** of November 3, 1981 (46 FR 54688); the proposed exemption rule was published in the **Federal Register** of August 4, 1982 (47 FR 33924). The 60-day comment period on this proposal ended on October 4, 1982. EPA received 51 comments from trade associations, chemical manufacturers, environmental organizations, and other interested persons.

At the request of the Natural Resources Defense Council and other groups, a public hearing was held on November 1, 1982, in Washington, D.C. Seven organizations and individuals made oral comments on the proposal at the hearing. EPA reopened the public comment period at that time, extending it for 30 days, to give participants at the hearing an opportunity to answer questions from EPA on their comments on the proposal. Eleven organizations provided comments during the extended comment period.

EPA has summarized its response to the major public comments received during the rulemaking. This summary, together with copies of the public comments and a transcript of the hearing, is included in the public record.

A. Exemption Requests

On May 21, 1981, the Agency received a petition from CMA requesting exemptions for: (1) Site-limited intermediates; (2) chemical substances produced in quantities of 25,000 pounds or less per year; and (3) polymers whose precursor monomers are on the TSCA Chemical Substance Inventory. In addition, CMA requested an exemption that would authorize EPA to allow manufacture of new chemical substances if review was completed before the end of the 90-day PMN review period. CMA also requested that EPA promulgate a rule to establish procedures for processing individual section 5(h)(4) exemption applications. The Synthetic Organic Chemical Manufacturers Association (SOCMA) submitted a petition to exempt the same categories of substances on June 28, 1981. Six other trade associations submitted endorsements of the CMA petition.

Ashland Chemical Company submitted a petition on July 28, 1981 to exempt unsaturated polyester resins made from the list of acids, polyols, polyepoxides, and modifiers identified in their petition. On October 8, 1981, Cargill, Incorporated petitioned EPA to exempt (1) new polymers made by the substitution of a natural oil or mixture of oils, derived from natural sources, in polymers listed on the Inventory, and (2) alkyd and polyester resins whose monomers used a greater than two weight percent are on a list of Inventory-listed substances compiled by Cargill. Mobil Research and Development Corporation submitted a petition to exempt alkyd and polyester resins on April 7, 1982. Mobil included a list of starting materials for these resins, many of which appear on the Ashland and Cargill lists.

On June 22, 1982 the Kelco Division of Merck and Company submitted an exemption request for a class of substances that Kelco defined as "biosynthetic polysaccharide gums." The rule published with this notice addresses only polymers and responds to the CMA, Ashland, Mobil, and Cargill petitions. The Kelco petition has been considered separately.

B. Alternatives Proposed

In response to the petitions from CMA, EPA began separate rulemakings

for polymers and for site-limited intermediates and low volume chemicals. The rule issued today addresses polymers. A rule to exempt site-limited intermediates and low volume chemicals is still under consideration. At this time, EPA has decided not to begin rulemaking to allow manufacture of new chemical substances when review is completed before the 90-day period has expired because (1) it believes that the exemptions for site-limited intermediates, low volume chemicals, and polymers will substantially reduce or eliminate the need for such an exemption; and (2) there is a legal uncertainty as to whether the Act permits early manufacture as a general approach to PMN review either by rule or policy statement. In addition, because of limited resources, EPA has deferred consideration of section 5(h)(4) procedural rules.

In developing the exemption proposals for polymers, EPA considered five alternative approaches. These alternatives were discussed in the preamble to the proposed rule. EPA also considered several other alternatives identified in the comments on the proposal. These alternatives are summarized below.

Under Alternative 1, EPA would have denied CMA's exemption petition to exempt polymers and instead would have addressed individual petitions for exemption categories defined more narrowly in terms of exposure or chemical class. For example, EPA could have responded only to exemption petitions for polymers with certain toxicological characteristics. The Agency did not adopt this approach in the final rules because of the difficulty of identifying narrow classes of new chemical substances that, based solely on potential exposure or inherent toxicity, would not present an unreasonable risk and that, at the same time, would provide an economically useful exemption category. Other alternatives offer broader, more immediate relief and apply to a large number of categories and combinations of categories, while not presenting unreasonable risks.

Alternative 2 would have exempted all polymers made from monomers on the TSCA Chemical Substance Inventory without restrictions. EPA rejected this approach because it could not make the "no unreasonable risk" finding for all polymers manufactured from monomers on the Inventory. The hazard assessment performed in support of this rule illustrates that under some circumstances polymers manufactured under such an exemption may present significant risks to human health and the environment.

Under Alternative 3, EPA would have exempted all polymers which met certain criteria based on physical or chemical properties. For exemple, the Agency could establish a minimum number-average molecular weight or a criterion for maximum levels of residual monomers and other reactants for all exempt polymers. EPA did not adopt this approach because the criteria that would be necessary to support a "no unreasonable risk" finding vary with the specific reactants used as well as with the class of polymer being considered. To establish criteria that would be sufficient for an exemption for many classes of polymers would unnecessarily limit the applicability of the exemption. However, as described in Alternative 5, EPA did adopt a variation of this approach.

Alternative 4 would have exempted certain classes of polymers, such as polyolefins with or without chemical property criteria, and without EPA review of individual substances. This approach would have allowed EPA to focus its assessment of potentially exempt polymers on the specific characteristics of the polymers. However, the Agency has found that the existing data are generally too limited to identify economically useful categories of polymers that present low risks and to identify criteria appropriate to exempt these classes, particularly without EPA review. Again, EPA included a modification of this alternative in its final approach.

Alternative 5 is the approach the Agency adopted in the August 4, 1982 proposed exemption. Under this alternative, EPA would exclude from the exemption (1) certain categories of polymers for which the Agency had inadequate experience or data to judge their potential risks, and (2) certain categories of polymers for which there was concern for hazard sufficient to warrant EPA review under the full statutory provisions. EPA also proposed to exempt certain high molecular weight polymers and polyesters made from a list of reactants from all premanufacture notification requirements. Other polymers that were not excluded from exemption eligibility and had a number-average molecular weight of at least 1,000 would undergo a limited premanufacture review.

Based on comments received on the proposed polymer exemption rule, the Agency considered two more major alternatives for exemption polymers. First, some commenters suggested that a "qualified expert" provision, similar to that for the site-limited intermediate and low volume chemicals exemption, be incorporated into the polymer exemption rule. The "qualified expert" would evaluate each potentially eligible substance for toxicological properties. Such a provision might have provided a further level of protection and might have allowed EPA to eliminate some of the exclusion criteria or further shorten the length of the review period specified in the proposal. However, unlike the site-limited intermediate and low volume exemption, the polymer exemption is based in part on the inherent physical properties of polymers as a class. EPA believes that this characteristic limits the risks associated with substances under the exemption such that the broad overview of the risks of the substances that a qualified expert would provide is not necessary. The Agency believes its limited review of specific risk concerns is more effective and less burdensome than this proposed approach.

Second, many commenters stated that EPA should exempt without review the category of polymers approved for food use by the Food and Drug Administration (FDA) on the basis that their safety in food use renders them low risk chemicals in all circumstances. Many commenters also said that the exclusion criteria in the proposed exemption excludes from exemption eligibility many substances which are approved for food use and thus should be eligible for exemption. The Agency believes it cannot make the no unreasonable risk finding for food use polymers approved by FDA because the standards for review under the Food, Drug, and Cosmetic Act are different from those under TSCA and because substances manufactured outside the FDA restrictions may present significant risks. First, substances approved for food use are subject to specific use restrictions to ensure low risk which would be difficult to impose in a broad exemption under 5(h)(4). Typically, food-use approval includes restrictions on extractability and residual content which, if included in the section 5(h)(4) exemption, would limit its applicability. Second, polymers may be subject to a broad range of processing and use application that may present potential exposure and risk concerns not considered by FDA. Therefore, EPA has chosen not to exempt, as a class, polymers solely because they are approved for food use by FDA. However, many such polymers will be eligible for exemption under EPA's selected approach.

Many commenters also suggested specific classes of polymers that could be exempt. In addition, commenters identified many reactants that could be added to the polyester reactant list. EPA has not included these additional classes or reactants in the final exemption. Adequate review of their potential risk would have unduly delayed the promulgation of the final rule. In addition, inclusion of these classes and reactants in the final rule would not have allowed for adequate public comment. EPA will consider inclusion of these polymers or reactants in an amendment to this final rule or in separate rulemakings if exemption petitions that fully assess the potential risks associated with those substances are submitted.

This rule adopts the general approach described in Alternative 5: polymers which have a number-average molecular weight greater than 1,000 are exempt. Because this characteristic does not in itself eliminate or reduce to a reasonable level all concerns for risk that have been identified for polymers, the Agency has excluded from the exemption (1) certain polymers for which the Agency has inadequate experience or data to judge their potential risks, and (2) certain polymers for which there was a concern for hazard that could lead to potential risks and that EPA believes should be reviewed under the statutory 90-day review period. Second, the rule requires that all exempt polymers undergo a limited 21-day review prior to manufacture. Finally, the Agency has also allowed one exception to the molecular weight requirement. Polyesters made from a list of reactants for which the Agency has low concern are exempt even if their number-averaged molecular weight is less than 1,000.

The final rule and the Agency's reasons for adopting this approach are described in Units II through IV.

II. Final Exemption

A. Summary of the Rule

1. *Definition of exemption category.* To be considered for exemption, substances must meet the definition of polymer in the final rule. This definition ensures that exempt substances have the structural characteristics common to the category of substances on which EPA has based its no unreasonable risk finding.

2. *Classes of polymers ineligible for exemption.* Certain classes of polymers are ineligible for the exemption. These classes are (1) cationic polymers; (2) polymers that contain less than 32 percent carbon; (3) polymers that contain certain other elements; (4) polymers made from reactants that contain halogen atoms or cyano groups; (5) polymers that contain certain reactive functional groups that are intended or reasonably anticipated to undergo further reaction; (6) polymers that substantially degrade, decompose, or depolymerize; and (7) biopolymers, their synthetic equivalents, and modifications and derivatives of biopolymers.

3. *Polymers eligible for the exemption.* Polymers meeting the criteria listed above receive expedited premanufacture review by the Agency if they are: (1) Polyesters that are made from a specified list of reactants, or (2) polymers with a number-average molecular weight of greater than 1,000.

4. *General provisions.* To qualify for the exemption, manufacturers of exempt polymers must submit a limited premanufacture notice (PMN) 21 days before the date that manufacture begins. The limited PMN must contain manufacturer's identity, type of exemption, site of manufacture, chemical identity, number-average molecular weight, levels of residual monomers and other reactants and low molecular weight species contained in the polymer, identity of impurities, production volume, use information, generic chemical identity and use if these items are claimed confidential, any test data or other data concerning the polymer's health or environmental effects that are in the possession or control of the submitter, and a certification.

EPA may also extend the review period to a full 90 days if unresolved issues concerning toxicity or exposure remain at the end of the expedited review period. The manufacturer must then submit the additional information required under full premanufacture review. EPA may further extend the review period up to an additional 90 days under section 5(c) of TSCA. The Agency retains the authority to act under section 5(e) or 5(f) of TSCA during the review period.

Substances which have undergone expedited review will be added to the Inventory after receipt of a notice of commencement of manufacture or import. Substances added to the Inventory will be subject to the exclusion criteria, the applicable exemption conditions, and the weight percent of the residual monomers, reactants, and low molecular weight species reported in the notice.

The rule also establishes recordkeeping requirements for all exempt polymers. Additionally, the rule identifies procedures for determining that a substance is ineligible for exemption if the substance as manufactured does not meet the polymer definition or exemption conditions, or is excluded by the exclusion criteria.

In this preamble and under the rule, references to "manufacture" and "manufacturer" include "import" and "importer," respectively, as defined in the Premanufacture Notification Rule and as referenced in this rule.

B. Discussion of the Final Rule

The final rule adopts many of the provisions of the proposed rule published in the **Federal Register** of August 4, 1982 (47 FR 33924). The following sections discuss the differences between the final rule and the proposal, and clarify the provisions of the final rule.

1. *Definition of polymer, subunits, and reactant.* To identify the category of substances addressed in the exemption, the proposed rule defined the term "polymer." The proposal defined "polymer" as a chemical substance predominantly composed of molecules that contain at least two structural units derived from functioning monomers. The final rule modifies the definition of polymer in response to public comment; however, the meaning and purpose originally intended has been retained.

EPA received many comments suggesting modifications of the definition of "polymer." Several commenters stated that EPA should broaden the definition of polymer because it excludes substances commonly thought of as polymers. However, the Agency's review of the information submitted in PMNs to date (the PMN data base) indicates that few substances identified as polymers by PMN submitters do not meet the definition in the proposed rule. Some commenters also suggested that the other provisions of the rule (e.g., the 1,000 number-average molecular weight criterion) already limit the exemption to polymers, thus eliminating the need for the definition. However, if the definition were not retained, some substances (e.g., certain dyes), which are not considered polymers, would qualify for the exemption under the greater than 1,000 number-average molecular weight criteria. The Agency, therefore, has not broadened the definition of polymer, but has revised it to remove ambiguities in the proposed approach.

Some of the misunderstanding associated with EPA's approach to defining "polymer" resulted from the proposed rule's use of terms which have

multiple meanings when used by polymer chemists. As a result, the Agency has developed a definition which does not rely on these terms.

First, EPA has replaced the term "functioning monomer" with the term "internal subunit," to eliminate the confusion surrounding the use of the term "functioning monomer." The term "subunit," which refers to the basic building blocks of a polymer, means an atom or group of associated atoms chemically derived from "reactant" substances. The term "internal subunit" means a "subunit" that is covalently linked to at least two other "subunits." Thus, an internal subunit cannot be a pendant group.

Second, the Agency has redefined the term "polymer" used in defining the category of substances which are potentially eligible for exemption. "Polymer" means a chemical substance that consists of at least a simple weight majority of "polymer molecules." A "polymer molecule" is a molecule of at least four covalently linked "subunits," which contains at least two "internal subunits." To form a polymer, polymer molecules must be distributed over a range of molecular weights. Differences in molecular weight among polymer molecules must be primarily attributable to differences in the number of "internal subunits," and not solely to changes in the number of pendant groups or similar subunits. Finally, a "polymer" cannot consist of less than a simple weight majority of "polymer molecules" with the same molecular weight. The definition for polyester has been revised to be consistent with this terminology.

Finally, in response to several comments, EPA also has included in the final rule a definition of reactant. This definition in consistent with the term as it has been used in reporting for the Inventory and premanufacture notification program. "Reactant" is defined as a chemical substance which is used intentionally in the manufacture of a polymer and which becomes part of the polymer composition. Reactants include monomers, chain transfer and crosslinking agents, monofunctional groups that act as modifiers, and other end groups that are not also monomers if they are incoporated into the polymer molecule.

In order to illustrate this terminology, EPA has developed the following example:

A "polymer" is manufactured from the starting materials phthalic anhydride, ethylene glycol, and 1-hexanol. The reaction product consists of various molecules distributed over a broad molecular weight range. Most of the reaction product molecules are "polymer molecules."

One of these "molecules" consists of seven "subunits" which are linearly connected. The seven "subunits" are chemically derived from three phthalic anhydride molecules, two ethylene glycol molecules, and two 1-hexanol molecules. The phthalate "subunits" are linked to the glycol "subunits" in an alternating order with each end terminated by a 1-hexanoxy "subunits." Thus, in this case the starting materials are "reactants" because they become part of the polymer composition.

In this molecule, the phthalate and glycol "subunits" are considered "internal subunits" because each of them is covalently bonded to two other "subunits." The "subunits" derived from 1-hexanol are not considered "internal subunits" because they are covalently linked to only one other "subunit." In other reaction product molecules, pendant "subunits" can be derived from 1-hexanol, ethylene glycol, or phthalic anhydride. However, "internal subunits" can only be derived from ethylene glycol and phthalic anhydride, because a subunit derived from 1-hexanol can covalently link to only one other molecule. Because this molecule contains five "internal subunits" and seven "subunits," it qualifies as a "polymer molecule," which must have at least two "internal subunits" out of a minimum of four subunits.

The reaction product molecules in this polymer differ primarily by the number and identity of "internal subunits." Some of the reaction product molecules are not "polymer molecules." For example, the linear combination of one molecule of 1-hexanol, linked to one molecule of phthalic anhydride, which is in turn linked to one molecule of ethylene glycol, is not a polymer molecule because it contains only one "internal subunit" and only three "subunits."

The minimum content for "polymer molecules" in a "polymer" is 50 weight percent; the remainder may consist of reaction products that have too few "subunits" or "internal subunits." Also, the polymer must consist of less than 50 weight percent of any molecules with the same molecular weight. In this example, the difference in the number of "internal subunits" derived from ethylene glycol and phthalic anhydride are primarily responsible for the differences in molecular weight among the "polymer molecules." The range of the total number of "internal subunits" is sufficiently broad that there is not 50 weight percent or more of any molecules with the same molecular weight.

2. *Substances ineligible for exemption.* The proposed rule excluded seven categories of polymers, regardless of whether they met the other conditions of the exemption. These polymers were excluded because of data indicating potential for adverse health and/or environmental effects because EPA lacked experience in reviewing them.

Several commenters supported EPA's approach of excluding categories of polymers from the exemption. However, many commenters stated that the exclusion criteria were too broad and had specific recommendations for changing each criterion. Some commenters suggested that these exclusions should apply only to those substances exempt from all premanufacture review requirements and not to those which are subject to expedited review.

The final rule retains the proposed approach of excluding certain polymers from the exemption. Such exclusions are an important component of EPA's finding that polymers manufactured under the terms of the exemption will not present an unreasonable risk. The Agency, however, has modified some of the exclusions based on public comments and additional analysis during the comment period, as described in unit II.B.2.a. through g.

EPA has not determined that the manufacture, processing, use, distribution in commerce or disposal of excluded polymers will present an unreasonable risk. The Agency has simply found that it cannot at this time make the no unreasonable risk finding for the categories of substances excluded from this exemption.

a. *Cationic polymer exclusion.* The proposed rule would have excluded from exemption polymers that are designed, intended, or reasonably anticipated to be soluble in water. This exclusion was developed because the Agency was concerned that water-soluble polymers could be widely distributed in the environment, resulting in a wide range of exposures that the Agency could not assess. In addition, EPA had toxicity concerns for some classes of polymers that are also water soluble.

Several commenters supported this exclusion and stated that the Agency should also exclude polymers that are water-extractable. Other commenters, however, stated that the exclusion was too broad and that water-soluble polymers are not necessarily toxic. Still other commenters stated that the one percent water solubility level proposed by the Agency would not be appropriate across a range of polymers because

polymers vary in toxicity. They also stated that for some polymers such a level is difficult to measure.

After further review of the literature, EPA has concluded that the exclusion of all water-soluble polymers is unnecessarily broad. The Agency also agrees that, in many cases, there is no direct correlation between high water solubility or high extractability in water and high exposure. EPA has revised its approach to exclude only cationic polymers for which it has identified is an aquatic toxicity concern.

The final rule excludes from exemption eligibility polymers that are cationic or that are reasonably anticipated to become cationic in the aquatic environment. Such polymers are typically used in drinking water treatment, municipal and industrial wastewater treatment, and petroleum recovery. As such, they have a high potential for release to the environment. The available literature demonstrates that some cationic polymers are highly toxic to fish and to other aquatic organisms. Although controlled use in water and wastewater treatment systems can limit exposure to these polymers, there is potential for such polymers to be used outside of these controlled conditions. EPA believes that a careful review of exposure conditions is necessary for cationic polymers, a review that often could not be completed within the expedited exemption review period. As a result, the Agency has excluded cationic polymers from exemption eligibility.

The rule defines "cationic polymer" as a polymer whose molecules contain one or more covalently bound "subunits" that bear net positive charge. Non-polymeric counterions alone, such as ammonium ions, are not covalently linked subunits of polymer molecules and therefore do not make an otherwise non-cationic polymer cationic. Examples of cationic polymers include quaternary ammonium polyelectrolytes and alkyl sulfonium or alkyl phosphonium polymers. The exclusion applies not only to cationics soluble in water, but also to cationics that are insoluble, such as water-dispersible polymers that are components of electrostatically-applied coatings. In addition, the rule excludes polymers that are not cationic as manufactured, but which are reasonably anticipated to become cationic in an aquatic environment. Examples of such polymers are those that contain aliphatic amine moieties. By "aquatic environment" EPA means water in a natural environment, usually having a pH between 5 and 8, as opposed to deionized water often used in the laboratory. The Agency believes that manufacturers can easily determine from the structure of the new substance, without costly testing, whether or not it may become cationic in an aquatic environment.

b. *Exclusion of polymers containing less than 32.0 percent carbon.* The proposed and the final rule exclude from exemption eligibility polymers with less than 32.0 weight percent of the atomic element carbon. The Agency proposed this exclusion because of lack of information and review experience concerning polymers that contain less than 32.0 percent carbon. By excluding such polymers, the Agency intends to limit availability of the exemption to the types of polymers that have been frequently reviewed in the PMN program.

Several commenters felt that the exclusion was arbitrary. Many commenters suggested that the carbon content level should be lowered from the proposed level to recognize the current commercial production of certain teflons and silicones. Other commenters stated that polymers of known low toxicity would be excluded.

EPA's review of the PMN data base found that only a very low percentage of polymers would be excluded. Consequently, this exclusion will provide an added safeguard and at the same time is not expected to have a significant impact on the availability of the exemption. EPA believes that polymers containing at least 32.0 percent carbon are typical of the vast majority of polymers in commerce. While polymers have been developed and are in use that contain less than 32.0 percent carbon, EPA does not have toxicity or exposure information to characterize the risks associated with low carbon content polymers. Therefore, without risk data or agency review experience, the Agency cannot make the no unreasonable risk finding for such polymers. EPA believes that the full 90-day review period will often be necessary to adequately assess the risks of polymers containing less than 32.0 weight percent carbon.

c. *Exclusion of polymers that contain certain elements.* The proposed rule excluded exemption eligibility polymers containing as an integral part of the polymer more than 0.10 weight percent of any atomic element other than hydrogen, carbon, nitrogen, oxygen, sodium, magnesium, aluminum, silicon, phosphorus, sulfur, potassium, calcium, titanium, iron, or tin. A polymer containing more than a total of 0.20 weight percent of any elements not listed above would also have been excluded. The proposed exclusion applied only to those elements intended or reasonably anticipated to be incorporated into the polymer composition. The Agency proposed this approach because there is a wide variety of polymers that could be made containing the excluded elements. Since the Agency has insufficient review experience or data on such polymers, EPA believes that full 90-day review will often be required. While several commenters stated that polymers of known low toxicity would be excluded by this approach, EPA's review of the PMN data base found that only a low percentage of polymers would be excluded by this provision.

Several commenters felt that these exclusions were arbitrary and suggested that certain elements should be added to the list of unrestricted elements. The Agency generally did not revise the exclusion based on these comments because EPA does not have sufficient review experience or data to exempt substances containing these elements on a categorical basis.

Another commenter suggested that the exclusion should limit even further the level of elements such as lead, beryllium, and cadmium that are known to be toxic to humans and the environment even at levels lower than the proposed permissible levels. The elemental exclusion was designed to restrict exemption eligibility to polymers which are similar in composition to those which have been reviewed in the PMN program. EPA's PMN review experience has indicated that polymers that are eligible for this exemption can be adequately reviewed within an expedited review period. In addition, EPA typically does not receive PMN's on polymers containing such elements. In addition, if an exempt polymer contains an eligible element at levels that present any unresolved issues about toxicity or exposure, the expedited review period will be extended and these risks will be addressed.

The final rule retains the basic approach of limiting the elemental content of polymers eligible for exemption with minor modifications that clarify the provision and better reflect Agency review experience. EPA's analysis of the PMN data base has shown that these modifications have negligible effect on the number of substances that would be eligible for exemption. The Agency believes it can adequately review the resulting eligible polymers in 21 days because of previous PMN review experience.

First, polymers that do not contain at least two of the following elements—hydrogen, carbon, nitrogen, silicon, sulfur and oxygen—are excluded from the exemption. According to the PMN data base, typical organic polymers have these elements as their primary constituents. In addition, many conventional polymers that have been reviewed in the PMN program also contain the atomic ions of sodium, magnesium, aluminum, potassium, and calcium as the monatomic counterions: Na^{+}, Mg^{+2}, Al^{+3}, K^{+} and Ca^{+2}. The final rule provides that polymers that contain these counterions as an integral part of the polymer composition may also be eligible for exemption.

Second, the Agency has reviewed polymers in PMN program that retain minor components chemically incorporated lithium, boron, phosphorus, titanium, manganese, iron, nickel, copper, zinc, tin, and zirconium due to the use of catalysts, solvents, initiators, and other substances used in the manufacture of polymers. Since EPA has experience with polymers containing such minor components, the exclusion was modified so polymers that contain an individual or combined concentration of less than 0.20 weight percent of these minor elements would be eligible. Polymers that contain any other elements, except as impurities are ineligible for exemption.

As noted in the proposal, the elemental exclusion is intended to address only those elements intended or reasonably anticipated to be incorporated into the polymer composition, either because they were constituent elements in the monomers or reactants, or because the polymer was deliberately reacted to incorporate them (for example, if a solvent or catalyst was partially reacted with a polymer). EPA's analysis of PMN data demonstrated that the level of elements allowed in the final rule typically will not exclude polymers as a result of the use of such elements in catalysts, chain transfer agents, adjuvants, and similar reactive agents. Elements not on the list that are present in the final polymer in the form of impurities from catalysts, additives, adjuvants, and so forth are not considered "part of the polymer composition" and thus would not result in the exclusion of such polymers. However, such impurities must be reported in the PMN and will be considered by EPA when reviewing exempt polymers. If the presence of any such impurities present an unresolved issue concerning toxicity or exposure at the conclusion of the expedited review period, or if EPA believes that such impurities may cause significant risks, the review period will be extended so that the Agency thoroughly considers the need for regulatory action.

d. *Exclusion of polymers made from reactants containing halogen atoms or cyano groups.* Under the proposed rule, polymers that contain covalently bonded fluorine, chlorine, bromine, or iodine atoms or cyano groups would be excluded from the exemption. The intent of this exclusion was to exclude polymers that contain residual substances composed of halogen atoms or cyano groups. Significant toxicity concerns have been identified for certain halogen- and cyano-containing chemical substances. The final rule retains this approach with a minor modification to reflect EPA's risk concerns.

Several commenters supported EPA's exclusion of halogen- and cyano-containing polymers because of the documented risk concerns associated with some halogen- and cyano-containing reactants. However, many commenters stated that EPA should not extrapolate concern for several existing monomers to an entire class of polymers. One commenter said that halogen- and cyano-containing polymers are unreactive, unabsorbable, and insoluble that thus generally do not present risk. Several commenters suggested that the Agency establish a residual monomer limit instead of unconditionally excluding these polymers. Other commenters suggested that fluorine should not be on the list of excluded halogens, because the fluorine-carbon bond is more stable than the carbon bond with other halogens.

EPA's primary concern is not with the larger polymer molecules containing halogen atoms and cyano groups, but the low molecular weight species and residual material containing such atoms or groups that may be present in the polymer as manufactured. Information from the PMN data base and other sources demonstrates that polymers that contain halogen atoms and cyano groups may be produced in substantial volumes and used in many industrial and consumer applications with potential for significant exposure and release. Levels of residuals in these polymers can also vary widely. The Agency believes that it cannot make the no unreasonable risk finding for this class of polymers given the documented toxicity of unbound low molecular weight species containing vinyl chloride, vinyl bromide, and acrylonitrile contained in the polymer. Additionally, the documented concern for monomers such as vinylidene fluoride, vinyl fluoride, tetrafluoroethylene, and those containing perfluorinated alkyl groups supports the presence of fluorine on the exclusion list, even though the fluorinated polymer molecule itself may be unreactive. Finally, EPA does not have information to indicate that a given residual reactant level that is economically reasonable, such as the 0.1 percent level suggested by some commenters, would adequately limit the risks associated with halogen- and cyano-containing species of low molecular weight.

Upon further analysis, EPA has found that reactants that contain halogen atoms or cyano groups, but that do not result in the incorporation of such atoms or groups in the polymer, may be found in significant levels in the final polymer. The Agency believes that such residuals may cause adverse health and environmental effects. Therefore, the final rule broadens the proposed exclusion to exclude polymers made from reactants containing halogen atoms or cyano groups whether or not the halogen atom or cyano groups are incorporated into the polymer. In addition, since cyano groups may form during reactions even when they are not present in the reactants, the final rule excludes any polymer which contains cyano groups other than as impurities. This provision does not exclude polymers if non-reactants that contain halogen atoms or cyano groups (e.g., certain catalysts) are used in the manufacture of the ploymer and retained only as impurities. Potential risks associated with non-reactant impurities will be considered during the expedited review period. The final rule requires that the level of all reactant and non-reactant impurities, such as catalysts be reported in the limited PMN. If the presence of any such impurities presents an unresolved issue concerning toxicity or exposure at the conclusion of the expected review period, EPA would extend the review period to thoroughly consider the need for regulatory action.

Finally, some reactants that do not contain halogen atoms or cyano groups as their primary constitutents may contain very low levels of halogen atoms or cyano groups as trace impurities. This exclusion is not intended to exclude polymers made from reactants containing such trace impurities since EPA believes it can review the risks associated with trace impurities within the limited review period. If the levels of halogen atoms or cyano groups as impurities in the polymer are high enough to be known to or reasonably ascertainable by the

submitter, they must be identified in the limited PMN for EPA's review.

e. *Reactive functional group exclusion.* The proposed rule would have excluded polymers containing at a greater than one in 10,000 concentration certain reactive functional groups that are intended to further react to produce other polymers. This exclusion reflects the Agency's concern that such substances may react with the tissues or chemical constituents of living organisms and may increase the potential for absorption due to irritation as a result of their reactivitiy.

Many commenters agreed that it is reasonable to exclude polymers containing reactive functional groups. However, some stated that the proposed exclusion was too broad and that the list of permissible reactive functional groups should be expanded. The Agency has not obtained additional data adequate to mitigate its concerns and consequently the final rule returns this exclusion. The final rule slightly expands the scope of the exclusion to more fully address potential risks.

The final rule excludes not only polymers containing reactive functional groups that are intended to react to produce other polymers, but also those that are reasonably anticipated to react. Examples of excluded polymers are those that contain groups such as isocyanates, pendant acrylates and methacrylates, epoxides, acid anhydrides, acid halides, aldehydes, amines, phenols, thiophenols, sulfur acids and their reactive derivatives, aziridines, blocked isocyanates, imines, isothiocyanates, vinyl sulfones, halosilanes, alkoxysilanes, and 3- and 4-membered ring lactones and other reactive groups. EPA has added the "reasonably anticipated" language to address those situations where such groups are present to impart particular properties and can be expected to react but may not necessarily be intended to further react to form other polymers. Such groups would include groups capable of chelating metals, phenolic groups in phenol/formaldehyde type resins, or esters manufactured from an aromatic alcohol.

Consistent with the proposal, the final rule specifically states that polymers containing as reactive groups carboxylic acid groups, aliphatic hydroxyl groups, unconjugated olefinic groups, butenedioic groups, and those containing conjugated olefinic groups in naturally-occurring fats, oils, and carboxylic acids are not excluded from the exemption. These polymers generally lack reactivity in biological settings and therefore are eligible for exemption. EPA did not expand the list of non-excluded functional groups because it did not have sufficient information to support the addition of other groups. Polymers containing these groups and other reactive functional groups are excluded.

EPA has retained and clarified the equivalent weight criteria which allow low concentrations of reactive functional groups in the polymer molecule. Under the final rule, polymers may contain reactive functional groups if the weight of the polymer that is equivalent to one gram-formula weight of reactive functional groups is 10,000 grams or greater. As stated in the proposal, the Agency believes that this level ensures that each reactive functional group is substantially diluted by polymeric material, reducing the likelihood of exposure. EPA did not receive sufficient information to alter this level.

Several commenters stated that EPA should lower the maximum permissible equivalent weight of functional groups from 1 in 10,000 to 2 in 100 to be consistent with the rule for reporting polymers on the TSCA Chemical Substance Inventory. Polymers listed on the Inventory may be manufactured from additional reactants not included in the polymer identity if the composition of such reactants does not exceed 2.0 weight percent of the polymer (40 CFR Part 710). This "2 percent" rule was established to limit the reporting of minor modifications of polymers, but does not affect PMN information requirements. If a manufacturer submits a notice on a new polymer, the manufacturer must report the identity and composition of all monomers and other reactants regardless of their weight percent in the final polymer. The Agency assesses the risks associated with all monomers and reactants in the notice, even though some may be present at two weight percent or less.

The Agency believes that it is appropriate to apply a more stringent requirement for limiting reactive functional group content in polymers eligible for exemption. The 1 in 10,000 standard was applied in part to allow EPA to review eligible polymers in 21 days. Higher concentrations of reactive functional groups could raise a higher level of concern to the Agency. EPA believes that such concerns should be addressed in a full PMN review where potential toxicity and exposure can be addressed at the level of detail warranted for such polymers.

f. *Exclusion of polymers that degrade.* The proposed rule would have excluded from eligibility polymers that are designed to substantially degrade, decompose, or depolymerize. Examples of polymers that are intended to substantially degrade, decompose, or depolymerize include temporary protective layer coatings that are subject to rapid removal, certain kinds of time release media, propellants, and polymers whose degradation is intentionally accelerated in the environment. The final rule retains this exclusion with minor modification.

Several commenters supported this exclusion as reasonable and suggested that polymers that are reasonably anticipated to degrade, decompose, or depolymerize should also be excluded. Other commenters suggested either that such polymers not be excluded or, alternatively, that those made exclusively from carbon, hydrogen, oxygen, and nitrogen should not be excluded.

In over 1,200 PMN submissions on polymers, EPA has received and reviewed an extremely limited number of polymers that substantially degrade, decompose, or depolymerize. The Agency thus has little experience reviewing the mechanism by which breakdown may occur, the decomposition products that may result, and the potential uses of such polymers. Some of these polymers, however, are likely to degrade to low molecular weight species and/or residual reactants which present some of the major risks associated with such polymers. Even polymers made exclusively of carbon, hydrogen, nitrogen, and oxygen may decompose into products which are toxic, such as formaldehyde, phthalic acid, acrylonitrile, hydrogen cyanide, acetaldehyde, and p-dioxane. Because of the complexity of review necessary for many of these polymers and the lack of EPA review experience, the Agency did not believe that an expedited review period was sufficient to adequately characterize risk.

The final rule was revised to exclude also polymers that are "reasonably anticipated" to substantially degrade, decompose, or depolymerize. Thus, polymers that could substantially decompose after manufacture and use, even though they are not actually intended to do so, are excluded. Such polymers include certain pH-labile polyesters and structural analogues to polymers that are known to substantially degrade, decompose, or depolymerize.

Only those polymers designed or anticipated to substantially degrade, decompose, or depolymerize are excluded by this provision. The Agency acknowledged that essentially all polymers degrade or decomposed to a

limited degree over times as typified by the normal fate of polymers in landfills or ordinary weathering of conventional paint layers. The exclusion is not intended to address such degradation. EPA believes the other provisions of the exemption adequately address concerns associated with low molecular weight species and residual monomers and reactants.

g. *Exclusion of biopolymers.* The proposed rule excluded from exemption eligibility biopolymers, synthetic equivalents of biopolymers, and derivatives and modifications of biopolymers if the biopolymer remains substantially intact. The biopolymer exclusion was developed because of the Agency's limited experience with biopolymers, the variety of substances within the class, and the potential wide range of novel uses for such polymers. Consequently, EPA cannot make a no unreasonable risk finding for biopolymers, their synthetic equivalents, and derivatives and modifications of them as a broad class.

Several commenters stated that the exclusion as proposed was too broad because there are many biopolymers which are not toxic, such as cellulose. Some commenters proposed categories of biopolymers that should be eligible for exemption. Other commenters suggested limiting the exclusion to those biopolymers which are biologically active. Another commenter supported the exclusion of biopolymers, stating that production of such polymers is a new area of polymer chemistry about which little is known. While EPA acknowledges that there are some biopolymers in commerce that may not present significant risks, the Agency cannot narrow the exclusion because of the general lack of EPA review experience.

This exclusion applies only to polymers that are directly produced by living or from once-living cells or cellular components. Therefore, petroleum does not meet the definition of a biopolymer because petroleum is not directly produced by living or from once-living cells. Consequently, polymers manufactured from petroleum are also not excluded from the exemption, because these polymers are not derivatives or modifications of a biopolymer. Natural oils are also not polymers, and therefore substances derived from them are not derivatives or modifications of a biopolymer.

EPA has included in the rule further clarifications of the terms "modification of a biopolymer" and "derivative of a biopolymer." Both modified biopolymers and derivatives of biopolymers contain recognizable remnants of a biopolymer in their structure so that the original biopolymer is substantially intact. A biopolymer is substantially intact if it contains at least two original adjacent repeating internal subunits that are not pendant units. A "modification of a biopolymer" is a polymer created by a non-additive chemical change or transformation such as oxidation, hydrolysis, thermal degradation, regeneration, or deacylation (e.g., acid-hydrolyzed amylopectin, thermal hydrolyzed starch, and regenerated callulose). A "derivative of a biopolymer" is a polymer created by an additive chemical change or transformation such as either formation, esterification, oxidation, boration, nitration or graft polymerization (e.g., methyl cellulose, borated caseins, palmitoyl derivatives of collagen, and cellulose nitrate).

3. *Exemption criteria.* The exemption criteria identify categories of polymers that the Agency believes present low risk. The criteria were developed based on the Agency's judgment concerning potential risks, its review experience, and the economic impact of the criteria. To provide additional safeguards, certain classes of polymers have been excluded when EPA had specific concerns for hazards, or when EPA had insufficient experience to allow the Agency to conduct an adequate review within an expedited review period.

Under the proposed approach, polyesters made from certain reactants, polymers of 20,000 number-average molecular weight or greater, and polymers with certain polydispersity criteria could be manufactured without any premanufacture review by EPA. Polymers over 1,000 number-average molecular weight would have been exempt after a 14-day expedited premanufacture review. In the final rule, EPA has modified certain criteria to reduce potential risks from polymers manufactured under the exemption. Following is an explanation of the modifications adopted in the final rule and the reasons for such modifications.

a. *Polyesters.* The proposed rule would have exempted from all premanufacture notice and review requirements polyesters made from a specified list of reactants. Residual content of certain of the reactants would have been limited to 1.0 percent to address EPA's concern about their toxicity.

Many commenters supported this approach. Commenters also generally agreed that residual content of high concern reactants should be limited. However, several commenters viewed the 1.0 percent level as too restrictive. Other commenters stated that the level was inadequate for more toxic precursors and identified reactants of high concern that they thought should be removed from the list.

Based on these comments and further analysis, EPA has adopted a revised approach to exempt certain polyesters in the final rule. First, EPA has removed from the list of eligible polyester reactants those reactants that were limited to 1.0 percent residual content in the proposed rule based on human or aquatic toxicity concerns. Second, the final rule requires expedited PMN review of those polyesters that are made from the revised list of reactants for which the Agency has low concern. Unlike other polymers that undergo expedited PMN review under the final rule, polyesters made from the specified list of reactants are not required to meet the minimum number average molecular weight criterion of 1,000 although they must meet the polymer definition and exclusion criteria.

EPA believes that the approach adopted in the final rule is necessary because it does not have enough information to make the no unreasonable risk finding for polyesters without review before manufacture. While EPA believes that the list of reactants contained in the final rule present low hazard potential, the Agency considers an expedited PMN review period to be necessary to assess risks associated with low molecular weight reaction products that may be present in an exempt polyester. In addition, because polyesters manufactured from the list of specified reactants are not required to meet a minimum number average molecular weight criteria, EPA believes it is appropriate to review actual reactant residual levels and potential exposure on a case-by-case basis. Given the generally low hazard for these reactants, EPA believes that an adequate review can be conducted on an expedited basis.

Finally, the Agency believes that it cannot review polyesters made from medium or high toxicity reactants within the limited expedited review period adopted in the final rule there may be a need to conduct a detailed exposure review to assess potential risks. The Agency agrees with commenters that a 1.0 percent residual reactant limit may be too restrictive in some cases and too lenient in others and therefore does not provide adequate risk protection. The document "Response to Comments" in the public record identified the reactants removed from the proposed list and EPA's reasons for removing them.

EPA has included three reactants on the list which were identified by petitioners as potential starting materials, but which are not on the TSCA Inventory. These new reactants are asterisked on the list of polyester reactants in the rule. The Agency included these reactants in its assessment and found that they are of low hazard concern. However, neither these reactants, nor a polyester made from these reactants, may be manufactured or imported until manufacturers submit a full PMN for the reactant and it is added to the Inventory after submission of a commencement of manufacture notice.

b. *Polymers with number-average molecular weight greater than 1,000.* The proposal and final rule exempt polymers with number-average molecular weight greater than 1,000 from certain premanufacture notice and review requirements. Substances with a molecular weight of 1,000 or less (other than polyesters made from the list of acceptable reactants) would not be eligible. Limiting the exemption to polymers with a number-average molecular weight of at least 1,000 is necessary because the Agency believes that as absolute molecular weight decreases, the likelihood that molecules will cross cell membranes significantly increases. Most commenters supported the proposed expedited review for such polymers.

The information available to the Agency indicates that as the number-average molecular weight of polymers decreases, the concentration of low molecular weight species in such polymers significantly increases. Such low molecular weight species may be more readily absorbed by biological organisms. The Agency believes that the 1,000 number-average molecular weight level reduces the amounts of readily absorbable low molecular weight species that may be present in such polymers. At the same time, the Agency also acknowledges that exempt polymers with number-average molecular weights in the low range may contain significant amounts of potentially absorbable low molecular weight species and unreacted residuals. However, the risk from polymers of greater than 1,000 number-average molecular weight is related not only to the amount of potentially absorbable low molecular weight species and residual reactants, but also to their toxicity. To limit potential toxicity concerns, the rule excludes certain specific polymers for which the Agency has such concerns or little review experience. Thus, EPA believes the combined effects of the 1,000 number average molecular weight criterion and the polymer exclusion categories sufficiently narrows risk concerns to allow adequate review within an expedited review period.

Finally, some commenters suggested that the molecular weight level should be raised to 5,000 molecular weight to limit the potential for gastrointestinal absorption. EPA believes that, while a higher molecular weight level such as 5,000 would provide further reduction of the amount of low molecular weight species, it would unnecessarily render a number of polymers ineligible. EPA has retained the 1,000 number-average molecular weight level not as a level that guarantees low absorption and potential risk, but as a level that narrows the Ageny's risk concerns to the degree that, along with the exclusion criteria, allows the Agency to review new polymers during the expedited review period.

c. *Polymers over 20,000 number-average molecular weight.* The proposed rule would have exempted polymers with number average molecular weights of 20,000 or greater without any EPA review. EPA considered several factors that led to the preliminary conclusion that polymers over 20,000 molecular weight present risks that are sufficiently low to preclude the need for case-by-case review. Polymers of this number-average molecular weight typically contain a majority of polymer molecules of a molecular weight above the range where they are likely to be absorbed. The lower absorption potential in these polymers limited the possibility that they may cause toxic effects upon exposure to them. Additionally, because of their structure, these substances are generally resistant to degradation, further reducing the potential for exposure to residual monomers and low weight species.

Many commenters supported this exemption criterion. Other commenters stated that the 20,000 number-average molecular weight level should be lowered to 5,000 arguing that this level would still ensure inertness, nonreactivity and low toxicity. However, other commenters noted that absorption may occur even at the 5,000 molecular weight level and therefore the molecular weight cutoff should not be lowered.

EPA has not included the 20,000 number-average molecular weight criterion in the final rule. The Agency continues to believe that, in general, polymers with number-average molecular weight greater than 20,000 are not absorbed and that low molecular weight species content is low. However, further analysis of the PMN data base has indicated that some polymers with molecular weights greater than 20,000 also contain high levels of unreacted low molecular weight species. EPA no longer believes that the available data adequately support the contention that polymers in the 20,000 number-average molecular weight range can be expected to have insignificant levels of unreacted species such as monomers and other reactants. For this reason the Agency has concluded that a finding of no unreasonable risk cannot be made without an expedited EPA review prior to manufacture.

Polymers that would have been eligible for the 20,000 number-average molecular weight criterion under the proposed rule are now eligible for exemption under the expedited review procedures in the final rule. EPA believes that the expedited review period will allow EPA to adequately review each polymer (including those with number average molecular weights greater than 20,000) and its low molecular weight species content on a case-by-case basis.

d. *Polymers with certain polydispersity.* EPA proposed a class of ploymers with certain polydispersity and molecular weight criteria to be exempt without review before manufacture. The polydispersity criterion would theoretically limit the amount of low molecular weight species that would be present in the polymer. Some commenters stated that the approach was too complex and costly and thus would provide little relief. Other commenters stated that polydispersity is an inadequate mechanism for limiting low molecular weight content. As a result of these comments, EPA has not included a polydispersity provision in the final rule. Substances that would have been eligible under the proposal for this exemption without review because they met the polydispersity criteria will still be eligible for expedited review.

4. *Data requirements and determination of eligibility.* Many commenters expressed concern about the amount of data that manufacturers would have to develop to determine that a substance was eligible for the exemption and to support information submitted in a limited PMN. Following is the clarification of a manufacturer's responsibilities in these areas.

EPA will review limited PMN's under the standard of section 5(d)(1)(A) of TSCA. This section states that information related to the submission must be provided to the extent that it is

"known to or reasonably ascertainable by the submitter." The Premanufacture Notification Rule (40 CFR 720.2(p)) defines known to or reasonably ascertainable information as "all information in a person's possession or control plus all information that a reasonable person similarly situated might be expected to possess, control, or know." This standard is flexible so that varying circumstances among submitters (such as low versus high volume manufacturers, manufacturers of specialty chemicals versus manufacturers of bulk feed stock chemicals) are taken into consideration. (The effective date of the definition of "possession or control" has been stayed by the PMN clarification 48 FR 41132).

EPA does not require that submitters perform analytical measurements of the physical and chemical properties of polymers solely for the purpose of providing information in limited PMN. Manufacturers may be able to determine compliance with the polymer definition, exclusion criteria, the exemption conditions, or to provide information required in the limited PMN, for example, low molecular weight species information, on some other basis. Such a basis may be using past experience by correlating observed or measured values of the properties of similar polymers to the polymer in question, using stoichiometric relationships based on knowledge of the starting materials and expected reactions, or using knowledge or process and purification steps.

If the information in question is related solely to that required in the limited PMN but not to eligibility, such as low molecular weight species information or use information, the submitter may indicate in the limited PMN that the information is not known or reasonably ascertainable if he or she cannot provide meaningful estimates for this information. In such cases, the submitter should be prepared to provide a rationale for why the information cannot be provided. Where EPA does not have sufficient information in the limited PMN to complete its risk assessment, it will make reasonable worst-case assumptions as needed.

Where the information in question is related to a submitter's determination the polymer meets the terms of the exemption (for example that the polymer has an average molecular weight of greater than 1,000), the Agency believes that the manufacturer's knowledge of the structure of the substance and nature of reactant and reaction process will generally be adequate to make the determination. However, there may be circumstances where the polymer is significantly different from previously manufactured polymers or where the value of a specific parameter approaches the level established in the exemption. In these cases, the Agency expects the manufacturer to take the steps necessary to ensure that the chemical is eligible. For example, a manufacturer may want to produce a low molecular weight polymer for which, either because of the variability in the nature of the production process, or because of the potential margin for error in the technique used to estimate molecular weight, the manufacturer is uncertain that the polymer will meet the 1,000 number-average molecular weight criterion to be eligible for the exemption. In such cases, it may be necessary to use an analytical method rather than past experience or an analytical method of greater certainty to determine molecular weight or to take process steps to ensure compliance with the exemption. A similar situation may occur when determining whether a polymer is excluded by its elemental content or content of reactive function groups. The Agency believes that, when the polymer is manufactured with properties near the parameters in the exemption, it is reasonable for the manufacturer to take a greater burden to demonstrate eligibility.

EPA believes that where intent or design determines eligibility (for example, certain substances "intended to further react" or "designed to degrade" or ineligible), this intention or design will be clear from the structure and intended use of the substance. In several provisions of the exemption, EPA also uses the standard of "reasonably anticipated" to describe eligibility requirements for the exemption. The Agency uses this phrase in cases where a determination must be made of the composition or a particular characteristic of the polymer. In using this phrase, EPA recognizes that there are circumstances in which a property may be imparted to a substance without specific intention or design. The final rule defines the phrase "reasonably anticipated" to mean that a knowledgeable person familiar with the nature of the precursors to the polymer, the type of reaction, the type of manufacturing process, the products produced in polymerization, the intended uses of the substance, or associated use conditions would expect such a composition or characteristic to occur. By using the term "reasonably anticipated," EPA is not requiring that costly analysis be undertaken. Rather, as with the term "reasonably ascertainable," all the information developed in bringing the substance to commercial production, and any other information a reasonable person similarly situated would know, must be considered in determining the substance's eligibility.

The Agency will apply these standards flexibly. For example, if because of an ambiguous feature in a substance's structure, EPA believes that the substance is likely to be cationic in a natural environment, the Agency will attempt to clarify the feature in the structure before using ineligibility procedures. Section 723.250(q) of the final rule requires manufacturers to maintain records documenting information provided in the limited PMN and information demonstrating that the new polymer is not excluded from the exemption. EPA expects that such records would provide an adequate explanation of the basis and rationale for the manufacture's determination of eligibility.

5. *Information requirements.* The final rule has adopted, with minor modifications, the information requirements outlined in the proposed rule for limited PMN's. Under the proposal limited PMN's would contain submitter identity, site of manufacture, chemical identity, type of exemption, number-average molecular weight, low molecular weight species and residual monomer and reactant content, production volume, descriptions of uses, generic information if chemical identity or uses are claimed as confidential, a certification, available test data and technical contact. The final rule has added synonyms, trade names, and impurities information; "other data" on health and environmental effects; and data on related chemicals.

Many commenters stated that the proposed notification requirements are not justified for substances which the Agency agrees are inherently non-toxic. Thus, notification under the exemption should only be to ensure that a substance meets the criteria for exemption. The Agency agrees that many polymers appear to be of low risk concern and that the polymer definition, exclusion criteria, and exemption categories will eliminate many high concern polymers from eligibility. However, as the risk assessment demonstrates, there are instances in which some members of the polymer class are capable of presenting significant risks. The information requirements of the limited PMN are critical to EPA's review of specific polymers during the abbreviated review period.

Other commenters stated that the proposed information requirements were insufficient for assessment of the risks associated with polymers. The Agency believes that the information in the limited PMN is sufficient for an adequate assessment of the new polymer, given the exclusions, exemption criteria, and generally low level of concern for polymer molecules. Additionally, polymers eligible for exemption are representative of polymers for which EPA has had PMN review experience. If EPA believes additional review is necessary after its initial 21-day assessment, the Agency will extend the review period and obtain the additional information required under full PMN review from the submitter. If the Agency still has insufficient information on the substance to evaluate health and environmental effects and the substance may present significant risks or exposures, the Agency will consider action under section 5(e). If EPA determines that there is a reasonable basis to conclude that the substance will present an unreasonable risk, it will consider action under section 5(f).

One commenter stated that molecular weight information is not needed because of the certification that the substance qualifies for the exemption. EPA believes this information is essential to its review of the risks associated with polymers. Some commenters also stated that it is unnecessarily burdensome to require information on low molecular weight species content. However, low molecular weight species content is one of the major risk concerns associated with polymers. Therefore, EPA believes such information is essential to assessment of risks during the expedited review. Additionally, EPA has found in full premanufacture review that submitters are typically able to provide this information without undue burden or cost.

Another commenter stated that a structural diagram is often impossible to provide for polymers and is unnecessary for EPA's risk assessment. Structure is a necessary component of the Agency's toxicity review. EPA requires only a representative structural diagram because in some cases it is not possible to wholly characterize a polymer's structure. Another commenter stated that a structural diagram is unnecessary to determine compliance. However, the Agency has found that this information is often essential to ascertain the identity of the new chemical substance.

In the proposed rule, manufacturers were not required to provide EPA with any information on impurities in the limited PMN. This information, however, is required in full premanufacture notices as part of the description of chemical identity. On several occasions impurities information has proved critical in the Agency's assessment of risks posed by a new chemical substance. Therefore, EPA believes that it is necessary to require information on impurities in the final exemption rule. Section 723.10(f)(2)(vii) of the final rule requires the manufacturer to identify impurities anticipated to be present in the exempt substance and their weight percent. EPA has also added the requirement that manufacturers submit trade names and synonyms related to the new polymer, consistent with the full premanufacture notification requirements. This information will allow the Agency to perform a more complete literature search on the new polymer within the 21-day review period. The final rule also has modified production volume information requirements to be consistent with full PMN review.

Many commenters stated that the information requirements for reactants are inconsistent with Inventory Reporting Rules because the Inventory Rules do not require monomers and other reactants used in the manufacture of a polymer at 2 weight percent or less to be reported as part of chemical identity information. However, § 720.45(a)(3) of the Premanufacture Notification Rules and the PMN form require the reporting of monomers or other reactants used at any weight percent. The submitter may then choose which, if any, of those monomers and reactants used at 2 weight percent or less are to be included as part of the identity of the polymer to be entered on the Inventory. The reporting of reactants at 2 weight percent or less, even though they might not be included in the description of the polymer, allows EPA to review the potential toxicity of minor components reported in the notice.

EPA has referenced the test data and other data requirements in the final Premanufacture Notification Rule (the PMN rule) (§ 720.50) to guide submitters on what test data and other data should be submitted with a limited PMN. Although the proposed rule did not include the requirement that manufacturers submit other data related to the health and environmental effects of the new substance and data on chemicals related to the new chemical substance, including impurities and byproducts, EPA believes that it is essential that manufacturers provide these data with the limited PMN given the limited time that EPA has to obtain and review information on the new polymer. Additionally, as previously stated, the risks associated with related chemicals are a major concern associated with new polymers (the requirements concerning § 720.50(c), data on related chemicals, have been stayed by the PMN clarification (48 FR 41132)).

One commenter stated that test data should be redefined to exclude data that have not been developed for the specific purpose of evaluating the health or evironmental effects of a new polymer. However, EPA believes that all test data and other data that may be relevant to its assessment of health and environmental effects, not simply test data specifically developed to evaluate those effects, are essential for an adequate assessment of the risks associated with the substance. Another commenter stated that manufacturers should be required to report the leaching rates of residual monomers. The Agency believes, however, that such information is necessary only after its initial assessment of the toxicity of the new polymer. EPA can obtain this information during the extended review period if necessary.

The final rule requires that submitters use the appropriate sections of the Premanufacture Notification form (EPA Form 7710-25, 48 FR 21755). This requirement will not place any additional burden on submitters since the information requirements in the exemption rule are identical to the corresponding requirements in the PMN rule. EPA believes that the standard format presented by the form is essential to completing its expedited review and to ensuring that proper confidentiality is maintained. Submitters must clearly indicate on the first page of the form that the notice is a limited PMN and whether the submission applies to the polyester or to the greater than 1,000 molecular weight exemption. Submitters of limited PMN must complete the following sections of Part I of the form: Certification; Section A—Submitter Identification; Section B.2—Chemical Identity Information—Polymers; Section B.3-6—Impurities, Synonyms, Trade Identification, Generic Chemical Name; Section C.1—Production Volume; Section C.2a(1) Description of Category of Use; Section C.2a(4)—Type of Use; Section C.2b—Generic Use Description. Submitters should also complete Part III—List of Attachments. Submitters should add to the certification a statement that the substance satisfies the polymer definition, the exclusion criteria, and the exemption criteria and

will be manufactured under the terms of the exemption. The "Instructions Manual for Premanufacture Notification," available from the TSCA Assistance Office, gives information on completing these sections of the form.

6. *Length of review period.* The proposed rule would have required that manufacturers notify EPA 14 calendar days before manufacturing a new chemical substance under the exemption. In the final rule, however, manufacturers are required to notify EPA 21 calendar days before manufacture begins. After carefully reviewing public comments and evaluating its experience in the premanufacture notice review process, the agency has concluded that 14 calendar days is not sufficient to ensure a substance is eligible for an expedited review; to assess potential toxicity of low molecular weight species and residual monomers and reactants, and to make a general assessment of exposure. Instead, 21 days is the minimum reasonable period in which EPA can adequately review the substance and, if necessary, inform the manufacturer that EPA has extended the review period.

EPA recognizes that one of the major benefits of this exemption is that it allows companies to respond more rapidly to market demand and to introduce new chemical substances more quickly into commerce. Although extending the review period from 14 to 21 calendar days may reduce this benefit to a cerain extent, EPA does not believe this impact will be substantial.

7. *Extension of the review period.* The proposed rule would have given EPA the authority to extend the 14-day review of a limited PMN for any period up to an additional 76 days for an aggregate period of 90 days. EPA would have retained the authority of section 5(c) of TSCA to further extend the review period by an additional 90 days.

Under the final rule, EPA will not extend the 21-day expedited review for any incremental periods less than a total of 90 days. Rather, the period will automatically be extended to 90 days if the Administrator determines that the polymer should be considered for regulatory action under sections 5(e) or 5(f) of the Act or that unresolved issues concerning toxicity or exposure require further review. Like the authority to extend the PMN review period under section 5(c), the authority to extend the exemption review will be delegated to the Director of the Office of Toxic Substances. Under the final rule EPA also retains the authority to use section 5(c) of TSCA to extend the review period an additional 90 days for good cause.

The authority to extend the review period is essential in cases for which the Agency has significant questions about the toxicity of the polymer based on the information available during expedited review. The extended review period allows the Agency to obtain additional information and perform additional review on the new polymer. Under the final rule, if EPA extends the review period, the manufacturer must either withdraw the PMN or must suspend the review period and submit additional information so that all the information required in a full PMN is provided. EPA will suspend the review period for any period up to 60 days. If EPA receives the additional information, the Agency will review the notice under the procedures in 40 CFR Part 720 as if it is a complete PMN. However, the initial 90-day review period will include the number of days that have elapsed in the limited review period. If the manufacturer withdraws the limited PMN, fails to suspend the review period, fails to submit the additional information within 60 days or submits incomplete information, within that period, he or she may not begin manufacture before submitting a full PMN and before the statutory review period is complete.

The automatic extension provided for in the final rule will eliminate the uncertainty and potential arbitrariness that could be associated with the proposed approach. This approach also eliminates a potential inequity. A substance may be reviewed for an extended period under the exemption and be placed on the Inventory with restrictions, while a similar substance that completed a full 90-day review would be placed on the Inventory without restriction. In this case, both substances would have essentially the same review time but would be treated differently with respect to Inventory listing. Finally, it is clear that the Agency only has sufficient time within the 21-day expedited review period to review the specific polymer as defined by the exemption category, exclusions, and residuals content. Under the final approach, when the review period is extended to the full 90 days the Agency will have sufficient time to review the specific use conditions for the polymer as it would be defined by placement on the Inventory without restrictions.

Additionally, EPA believes that such an approach will rarely result in a longer period of review. In most cases, the Agency would have required close to the additional 69 days to obtain additional data from the submitter and to analyze that data.

EPA will not extend the review period simply for speculative reasons. EPA may extend, for example, if an impurity in the polymer is an analog of a suspected carcinogen, but the significance of the analogy or the strength of the case against the analog might be open to question. In another instance, the review period may be extended because of serious unresolved issues concerning exposure (particularly exposure outside the control of the manufacturer) to a substance known or likely to be a serious hazard.

8. *Review of notices.* Many commenters requested clarification of EPA's exemption review procedures. EPA will generally follow the review procedures established in the final PMN Rule, with modifications appropriate for the shortened review period. The sections of the PMN rule relating to the review of limited PMN's have been referenced in the rule.

All notices will be received by the Office of Toxic Substances Document Control Officer and will be assigned to a Notice Manager. The Notice Manager will be the official Agency contact with the submitter and will also coordinate the expedited review. Each notice will be reviewed for completeness. The Agency has retained authority to act on errors in the notice and incomplete notices similar to that under full premanufacture review. EPA will publish a notice of receipt of the limited PMN in the **Federal Register**. The TSCA Inventory will be searched for the identity of each substance.

If the substance is on the Inventory, EPA will notify a submitter that neither a premanufacture notice nor a limited PMN must be submitted. Therefore, the substance may be manufactured without restriction, subject to other rules promulgated under TSCA.

After it has been reviewed for completeness, a chemist will review the notice to determine whether the polymer meets the criteria for exemption. If EPA determines that the substance is ineligible for the exemption, it will follow the procedures outlined in paragraph (q) of the Rule.

As stated in the proposal, EPA's review of the limited PMN will focus on the toxicity of the new polymer as manufactured for commercial purposes, and particularly on the residual reactants and low molecular weight species associated with the polymer. EPA will also make a general evaluation of exposure, given the information provided in the notice. The Notice Manager will contact the submitter if

there are errors in the notice, if EPA determines that the notice is incomplete, and if other questions arise during the review. Submitters may submit any information in addition to that required in the notice at any time during the Agency's review. Submitters may withdraw a limited PMN following paragraph (m) of the rule. Submitters may also suspend the review period, with EPA's consent, for limited periods of time but only during the extended review period.

If serious concerns regarding the potential health and environmental effects of the manufacture, processing, use, distribution, or disposal of the new polymer cannot be resolved before the end of the 21-day review period, EPA will extend the review period. The manufacturer must submit the additional information on the substance that is necessary to constitute a full PMN or withdraw the limited PMN. EPA will make reasonable worst case assumptions when information on exposure and toxicity is limited. The Agency will extend the 90-day review period under section 5(c) if it is considering action under section 5(e) or 5(f).

If the initial review period or any subsequent review period expires without notice of further extension from EPA, manufacture or import of the new substance may begin. However, the manufacturer must submit a notice of commencement of manufacture or import when manufacture or import begins under § 720.102 of the PMN rule as amended by the PMN clarification (48 FR 41132).

9. *Inventory.* Under the proposal, EPA would have added substances that had completed a limited PMN review to the TSCA Inventory without restrictions. Polymers exempt without EPA review would not have been added to the Imventory. The proposal also did not contain an approach for informing the public of the identity of substances manufactured under the exemption. The final rule not only specifies a 21-day limited PMN review period for all eligible polymers but also requires that all exempt polymers be listed on the Inventory with exclusion criteria, exemption category restrictions, and residual monomer and low molecular weight species content limitations.

Many commenters stated that once EPA has completed its review of an exempted substance it should be placed on the Inventory without restriction. To do otherwise would require frequent and unnecessary reporting of minor changes in composition.

EPA believes that it cannot make its no unreasonable risk finding unless it ensures that the exempt substance is manufactured under the terms of the exemption. EPA has based this finding in part on its ability to review risks of these chemical substances during the 21-day review period. An Agency determination made during the expedited review period that a polymer should be exempt and that no regulatory action is warranted is largely based on the fact that the polymer meets the exemption conditions. If such a polymer were added to the Inventory without restriction, it could be manufactured in a form or manner other than those which EPA reviewed and thus could potentially present an increased risk. To preserve the integrity of the no unreasonable risk finding for exempt polymers that complete expedited review without the review period being extended, EPA will list their identities on the Inventory with restrictions. The substance will be added to the Inventory when EPA receives a notice of commencement of manufacture. The Agency will list these substances on the Inventory qualified by the exclusion criteria. In addition, exempt polymers will be listed by monomer and reactant identity (in accordance with the inventory two percent rule), the maximum content of each residual monomer, the maximum content of molecular weight species below 500 and below 1,000 absolute molecular weight, and the minimum allowable number-average molecular, weight criteria, if applicable. Subsequent manufacturers of the polymer must comply with these criteria, or a new limited PMN or full PMN must be submitted. Substances for which the expedited review period is extended will be added to the Inventory without restriction when review is complete and a notice of commencement of manufacture is submitted, unless the Agency has taken action under sections 5(e) or 5(f). The extended review period will provide EPA with the opportuntiy to conduct a more detailed toxicity, use, and exposure assessment.

While manufacturers must report in the limited PMN all monomers and other reactants used to manufacture the polymer, manufacturers may choose which monomers or other reactants used at two weight percent or less should be included in the identity added to the Inventory. Following the Inventory Rules, other manufacturers may manufacture an exempt polymer made from the reactants listed on the Inventory for that polymer in any proportion provided that the polymer complies with the polymer definition, the exemption category, exclusion criteria, residual monomer restrictions, and low molecular weight species restrictions. A polymer may also be made from the same reactants and other reactants used at two percent or less. However, regardless of the proportion of the reactants in the polymer and the reactants used at less than two percent, the polymer must meet the exclusion criteria, the category criteria, and appropriate residual reactant and low molecular weight species restrictions identified on the Inventory. Otherwise, the manufacturer must submit a limited PMN or full PMN, as appropriate, before manufacture may begin. If a limited PMN is submitted for a polymer listed under an exemption category on the Inventory which broadens the definition of that polymer, and if EPA allows manufacture or import to begin, EPA will revise the restrictions, as appropriate. If a manufacturer submits a full PMN on a polymer listed as an exempt substance on the Inventory and EPA completes review of the PMN without taking action under sections 5(e) or 5(f), the Agency will, after receiving a notice of commencement or manufacture, replace the restricted description of the exempt substance with the unrestricted description in the full PMN.

10. *Notification of ineligibility.* Under the proposal, EPA would have the authority to determine that a substance is ineligible for exemption if it failed to meet the criteria for exemption (i.e., the polymer definition, the exclusion criteria, and the exemption conditions). The proposed rule established different procedures by which EPA would declare substances ineligible that had not yet been manufactured under the exemption and those that had been manufactured. The final rule has retained this basic division, but the procedures have been changed for the period after manufacture because of other changes in the rule.

Several commenters stated that EPA should not have the authority to determine that a substance is ineligible after the limited review period ends and before manufacture begins. The Agency believes that, where serious questions exist about whether a substance meets the terms of the exemption, the questions should be resolved before manufacture begins without elaborate procedures for obtaining manufacturers' objections. If EPA makes a determination that the substance is ineligible before manufacture of the substance begins, EPA will notifiy the manufacturer by telephone, and subsequently, by certified letter, that the substance is ineligible. The manufacturer has the option of (1) submitting another limited PMN if he or

she makes the modifications necessary to resolve eligibility issues and identifies those modifications in the notice, or (2) complying with section 5(a)(1) of the Act and the Premanufacture Notification Rule by submitting a full PMN at least 90 days before manufacturing the substance.

After the manufacturer submits a notice of commencement of manufacture for an exempt polymer, EPA will enter the substance on the Inventory by the criteria and exclusions of the rule and the molecular weight and low weight species information supplied by the manufacturer. Although EPA believes that in most cases questions about the eligibility of a polymer will be raised in the limited review period EPA may, after manufacture begins, obtain additional information that calls into question the substance's eligibility. This could occur, for example, as a result of the Agency's TSCA inspections program. If EPA determines that the substance actually being manufactured does not comply with the description on the Inventory, and that the substance is not otherwise listed on the Inventory, the manufacturer would be in violation of section 5(a)(1) of TSCA. In effect, the company would be manufacturing the substance without having submitted a notice on that substance. As with any section 5 violation, EPA could bring an enforcement action against the manufacturer for the violation.

As in the proposal, EPA recognizes that it is possible for a manufacturer to diligently and in good faith attempt to comply with this exemption and still be in violation. For example, a manufacturer can determine that a substance meets the exemption criteria by relying on past experience with similar substances and making reasonable estimates. Subsequent testing of the substance might indicate that it does not meet one or more of the criteria which appear in the Inventory description. In the situation where the manufacturer has made a diligent, good faith effort to comply with the rule and EPA's guidance, EPA has concluded that the manufacturer should be allowed a short period of time to submit a full PMN under the PMN rule and to continue manufacture, processing, distribution in commerce, and use during the review of that PMN.

EPA has retained the basic approach of the proposal for treating manufacturers whose violations happened in spite of due diligence and good faith efforts to comply. Similar to the proposed rule, EPA will notify the manufacturer by telephone, followed by certified letter, that the Agency believes the substance does not comply with the Inventory description. The manufacturer will have the opportunity to submit objections to the determination or an explanation of its diligence and good faith in attempting to comply with the rule and the Inventory description, or both. The manufacturer must submit the objections or explanation within 15 days of receiving the written notification. EPA will review the submission and, within 15 days, notify the manufacturer of its final determination by telephone followed by certified letter.

Under the final rule, the manufacturer may continue commercial activity with the new polymer while EPA makes its final determination if the manufacturer was manufacturing, processing, distributing in commerce, or using the substance at the time of the telephone notification and if the manufacturer submits written objections or an explanation. If the Agency brings an enforcement action in such instances, it will not levy a penalty for continuing commercial activities the days between the date of the first telephone notification and the date of its final determination. As with a substance that undergoes full premanufacture review, EPA could take action under section 7 of TSCA if it determined that continued commercial activity presented an imminent hazard to health or the environment.

Manufacturers not engaged in manufacture, processing, distribution in commerce, or use of the substance at the time of telephone notification may not begin manufacture until EPA makes its final determination. Many commenters stated that this approach discriminates against batch manufacturers as opposed to continuous manufacturers. However, the Agency believes it is inappropriate to allow companies to resume commercial activity with a chemical substance under the exemption after EPA has initially determined that the substance is in violation of the rule and the Inventory description.

EPA may bring an enforcement action if (a) no objections or explanations are filed, or (b) EPA concludes that the substance is in violation and the manufacturer did not act diligently and in good faith to comply with the rule and the Inventory description.

If EPA concludes that the manufacturer has acted with due diligence and in good faith, the manufacturer may continue manufacturing, processing, distributing in commerce, or using the substance if it submits a full PMN under the Premanufacture Notification Rule within 15 days of the final notification by the Agency. EPA believes that 15 days is adequate to submit a full PMN since the manufacturer will know of this possibility when EPA notifies it that the Agency believes the substance is ineligible. If such a manufacturer were to continue to manufacture, process, distribute in commerce, or use the substance without submitting a full PMN, EPA would bring an enforcement action. The manufacturer would also be in violation from the date of the Agency's final determination.

In determining whether a manufacturer exercised due diligence and good faith in attempting to comply with the rule and the Inventory description, the Agency would consider many factors, and decisions would be made on a case-by-case basis as an exercise of the Agency's discretion. For example, a manufacturer would not be considered to have exercised due diligence and to have acted in good faith if it: (1) Failed to consider information it knew concerning process chemistry or physical/chemical properties in determining eligibility, (2) deliberately falsified information in the limited PMN, or (3) knowingly altered production parameters after submitting the limited PMN so that the actual substance manufactured would not meet the Inventory description.

Several commenters stated that a 15-day period is not adequate to allow objections to be filed. However, the Agency intends to have prepared specific questions about the substance's eligibility so that a manufacturer familiar with the exemption criteria will be able to respond based on the analysis he or she has already performed. EPA believes that 15 days is adequate time for the manufacturer to submit objections and/or an explanation of its due diligence and good faith efforts to comply with the rule and the Inventory description.

11. *Recordkeeping.* In the final rule, the Agency modified the recordkeeping requirements for limited PMN's to include documentation of information in the notice; production volume during the first three years of manufacture; and the date of commencement of manufacture. The Agency agrees with commenters who stated that requirements should be no more burdensome than under the Premanufacture Notification Rule (40 CFR Part 720) and has modified the final exemption requirements to be consistent with them.

One commenter stated that recordkeeping requirements are unnecessary because the manufacturer certifies compliance, the information required is included in the exemption

notice, and the manufacturer could submit information to the Agency upon request. However, EPA believes that recordkeeping requirements are an essential component of an effective exemption enforcement program; documentation of information in the notice would be used by enforcement inspectors to determine compliance. (Such documentation would include data or supporting rationale concerning molecular weight, low molecular weight species, and impurities determinations, the bases for the production volume estimate and potential uses, etc.)

Several commenters stated that recordkeeping to demonstrate continuing compliance was unnecessary and so burdensome as to preclude use of the exemption. The Agency agrees that specific recordkeeping provisions that require documentation of continuing compliance may be overly burdensome and are not necessary. However, it is the responsibility of the manufacturer to ensure that the exempt polymer being manufactured complies with the Inventory listing, just as it would be when manufacturing any non-exempt chemical listed on the Inventory. The Agency believes that information manufacturers normally maintain and develop for purposes such as quality control, product specification data, and product evaluation will in many cases be useful in determining compliance. EPA expects that if conditions, such as reaction temperature or sources for feedstock change, manufacturers will take steps to determine the effect of such a change so as to ensure continued compliance with the exemption. If EPA discovers at a later date that the chemical being manufactured is not covered by the notice, or otherwise not on the Inventory, the submitter will be in violation of section 5.

12. *Confidentiality.* The final rule has retained essentially the same provisions for confidentiality as the proposed rule and the final premanufacture notice rule (§§ 720.80, 720.85, 720.87, and 720.90).

The confidentiality provisions in the final rule take into account various requirements under the Act, including the need to provide nonconfidential information to the public, to give EPA information it needs to respond to FOIA requests, and to allow persons to assert claims of confidentiality with minimum burden. In determining final confidentiality provisions, EPA also considered its experience with notices submitted under section 5(a)(1) of TSCA.

A person may assert a claim of confidentiality for any information submitted to EPA under this rule. To do so, submitters must clearly indicate on the limited PMN or attached document (e.g., by circling, underlining, or bracketing) the information that they wish to claim as confidential. Only the information claimed as confidential should be identified as confidential. A submitter should not simply stamp "confidential" on the page which contains a piece of confidential information.

The final rule requires that submitters provide a sanitized copy of the limited PMN in which all confidential information has been deleted. This requirement is especially essential for this exemption rule given the limited period of EPA reveiw. The final rule requires companies to develop generic descriptions if they claim chemical identity and use information confidential. The generic name and use information will be published in the **Federal Register** notice of receipt of the limited PMN. (See II.B.6. of this preamble.) The generic chemical identity will be published in an appendix to the TSCA Inventory. In some cases, companies may develop a generic name that EPA believes is more generic than necessary to protect confidential chemical identity. In this case, EPA will propose to the submitter a more specific name. If that name is unacceptable, the submitter must explain why EPA's name is not sufficiently generic to protect confidential chemical identity and propose an alternative. EPA will publish the submitter's alternative name if it is acceptable. Otherwise, EPA will put the generic name it devises on the Inventory Appendix, 30 days after giving notice to the submitter.

13. *Enforcement.* Several commenters stated that EPA should establish an exemption audit program. The exemption for polymers does not require a report such as the qualified expert's report required by the site-limited intermediate and low volume exemption. Review of the performance of the qualified expert was the main reason for establishing an audit program for the site-limited intermediate and low volume exemption. Therefore, EPA believes that an adequate enforcement program will preclude the need for a special audit program for this exemption. EPA intends to periodically inspect all companies which have made TSCA section 5 submissions, including exemptions. Those submitters with violations may be inspected more frequently.

To determine compliance with the exemption, the EPA inspector will focus on the information in the exemption notice and limited PMN and whether the substance actually produced is consistent with the Inventory description. For example, he or she may examine the techniques used to determine or estimate molecular weight or may review reaction materials used to ensure compliance with the exemption exclusion categories. If the initial inspection reveals a violation or significant questions about compliance, a follow-up investigation may be conducted. This may involve compliance monitoring for all exempt chemicals manufactured at the manufacturer's sites and interviews with employees.

III. Regulatory Analysis

To support the August 4, 1982 proposal, EPA prepared a risk assessment of polymers and an economic analysis of the various alternatives considered. These alternatives are summarized in unit I.C. of this preamble. After reviewing public comments on the risk assessment and the economic analysis, EPA revised these documents, modifying them where necessary to reflect changes in the final rule. The final documents are available in the public record of this rulemaking. The documents are summarized briefly below. This section also explains the basis for the Agency's finding that the manufacture, processing, use, distribution, and disposal of the polymers manufactured under the exemption will not present an unreasonable risk.

A. Summary of Risk Assessment

1. *Introduction.* The Agency originally considered an exemption rule for polymers because it is generally agreed within the Agency and the scientific community that many of these substances are of low concern due to their lack of reactivity and their molecular size. The hazard analysis for this rule provides the evaluation of information relevant to the Agency's conclusions that: (1) Polymers eligible for this exemption are generally of low concern, (2) sufficient uncertainty exists about this conclusion to warrant a limited Agency review of all exempt polymers, (3) sufficient information exists on the potential toxicity of several classes of polymers to warrant their exclusion from the exemption, and (4) certain additional polyesters of number-average molecular weight below 1000 can be exempt.

2. *Approach to risk analysis.* The first step the Agency took to confirm the assumption of the low risk of polymers was to identify and characterize the hazards associated with them. A relatively extensive literature search for information on the toxicity of major types of existing polymers revealed that such data is very limited. Review of the

available data did not allow clear identification or characterization of hazards (or lack thereof) for existing polymers.

Because EPA could not make a finding of low concern for polymers based on knowledge of their hazard potential, the Agency attempted to confirm that certain polymers would be of low concern for risk because of their molecular weight. The selection of molecular weight as a risk-limiting criteria rests on two well-known and accepted principles of toxicology. The first principle states that in general, in order to cause an adverse health or ecological effect, other than direct contact effects, a chemical must first be absorbed by an organism. The second states that absorption of a chemical generally decreases with increasing molecular weight (size). Based on these two principles, the Agency reasoned that potential risks should generally be expected to decrease with increasing molecular weight.

3. *Molecular weight as a determinant of risk.* In its anaslysis of the use of molecular weight as a determinant of the risks associated with polymers, the Agency evaluated the relationship between toxicity and absorption and between absorption and molecular weight. It also considered the factors measured by the average molecular weight of polymers and the molecular weight limit above which absorption generally is not expected to occur.

a. *Toxicity/absorption.* For a chemical to elicit a toxic response within an organism, it must come into direct contact with the biological cells from which it elicits the response. Because all organisms are encased in protective membranes, a chemical must usually penetrate these membranes and be translocated to various parts of the organism to gain access to its target sites. Therefore, it can be reasoned that if a chemical cannot penetrate the protective membranes to gain access to a target site, it usually cannot elicit a response in the organism no matter what inherent potential it may have to do so. It can be further reasoned that if a chemical cannot elicit a response, it will generally not present a risk.

b. *Absorption/molecular weight.* The key factors which appear to determine absorbability of a chemical by an organism are its molecular weight and its lipophilicity. These are considered key factors because current evidence indicates that any chemical that penetrates a membrane does so by one or more of three possible mechanisms: (1) Passive diffusion through the spaces and pores of the membrane (dependent on molecular weight/size) or by dissolving in the lipoid material of the membrane (dependent on lipophilicity); (2) filtration through the spaces and pores in the membrane (dependent on molecular weight/size); and (3) specialized transport through systems which carry water-soluble substances across membranes by a lipid-soluble "carrier" molecule. As can be observed, the ability of a chemical to penetrate a membrane is dependent on its molecular weight/size. From this, the Agency reasoned that by increasing the molecular weight/size of a chemical, its absorption by an organism will generally be expected to decrease.

c. *The use of average molecular weight.* Analysis of absorption potential is usually made in terms of a single molecule of a given weight. However, polymers do not generally consist exclusively of molecules of one specific molecular weight. They are usually composed of homologous molecules spanning a range of molecular weights. As a result, the molecular weight of polymers can be best characterized by: (1) An average of the weight of the molecules making up the polymer, and (2) a measure of the distribution of weights, which is called polydispersity.

As polydispersity decreases in a polymer of a given average molecular weight, the distribution of molecular weights narrows, so that the amount of low molecular weight species in the polymer decreases. EPA has observed in the PMN data base that as molecular weight increases, polydispersity decreases. This indicates that as molecular weight increases, the importance of polydispersity as a parameter in characterizing polymer absorbability decreases. Although the amount of low molecular weight species may in some circumstances be significant, EPA believes that the average molecular weight of a polymer is a reasonable parameter to use when assessing the potential for absorbability. The Agency has chosen to use the number-average molecular weight of polymers for its assessment because the number-average is more sensitive than other measures of average weight to the amount of low molecular weight species in the polymer.

d. *The choice of a molecular weight criterion.* Because of limited data, known exceptions to the principle that as molecular weight increases absorption decreases, and the polydispersity of polymeric substances, it is not possible to identify any single molecular weight limit above which no absorption will take place. However, available data on the relationship between absorbability and molecular weight does suggest that substances with molecular weights greater than 400 are generally not readily absorbed through the intact skin and that substances with molecular weights greater than 1,000 are generally not readily absorbed through the intact gastrointestinal (GI) tract. The relationship between absorption through the GI tract and molecular weight of somewhat more tenuous than it is for dermal absorption because other factors, such as active transport and metabolism, may play a key role in affecting absorption from the GI tract. Based on the above data, the Agency believes that except for polymers that contain significant quantities of low molecular weight substances, polymers will generally not be absorbed through the skin or GI tract to a significant extent.

4. *Limitations to approach.* The Agency recognizes that there are limitations to the general rule that high molecular weight substances will not be readily absorbed and therefore, will be of low concern. First, there are exceptions to the rule, and second, there may be potential toxicity due to toxic residual feedstocks or to formation of particulates.

a. *Exceptions.* There are known exceptions to the general principle that increasing molecular weight decreases absorbability. For example, high molecular polyester diamines are able to penetrate skin. Bovine serum albumin and bovine milk xanthine oxidase can be taken up by the GI tract. Possible explanations for these exceptions are that: (1) A polymer may cause irritation sufficient to disrupt the integrity of the membrane; (2) it may have unique physicochemical properties which enable it to be absorbed; or (3) it may have an appropriate steric configuration which enables it to be transported on one of the specialized transport systems.

b. *Residual feedstocks.* In some cases there may be a substantial amount of residual starting material in the final polymeric substance. These reactants are typically low molecular weight (i.e., absorbable), reactive substances. To the extent that reactivity combined with absorbability suggests potential hazards, the presence of residual reactants may present risk not addressed by risk analysis based on molecular weight. The Agency prepared a quantitative risk estimate for several residual monomers in different exposure scenarios. The risk estimates indicate that under certain conditions there may be potential for significant risk due to residual monomers.

c. *Particulates.* Another potential source of toxicity not covered by the

molecular weight approach is toxicity due to particulates. Some polymers may be in particulate form and as a result may upon inhalation present potential health risks due to development fibrosis of the lung or other pulmonary effects. Although the Agency's PMN review experience has demonstrated that exposure to polymer particulates is generally limited and therefore expected to be of low concern, there is still the potential for this hazard to occur.

d. *Oil-soluble polymers.* The molecular weight approach does not address some factors which may alter a polymer's typical potential to be absorbed. In particular, it does not address the fact that polymers could come in contact with oils which could extract both polymer molecules and residual materials which, if lipophilic, could be absorbed and bioaccumulate. Although few significant risk concerns in PMN review have resulted from the oil solubility of polymers, the potential for absorption and biomagnification does exist.

e. *Pyrolysis products of polymers.* Finally, the molecular weight approach does not address the potential toxicity of pyrolysis and combustion products of polymers. Polymers, like other substances, decompose in the presence of heat, releasing byproducts that, with significant exposure, may produce significant risk. Such decomposition is generally associated with accidental occurrences (e.g., fires) or process errors. (e.g, thermal degradation of a polymer due to excessive molding temperatures). Because pyrolysis and combustion products from polymers have not been well characterized and may vary with temperature and conditions, the Agency believes that these risks cannot generally be addressed within the scope of a broad exemption rule.

f. *Conclusion.* Based on the above analysis, the Agency believes that although exempt polymers are generally of low concern, there may be specific instances of concern, and therefore it is appropriate that all exempt polymers undergo a limited Agency review. Such a review is necessary for EPA to make the no unreasonable risk finding. This review allows the Agency to determine if any of the above concerns might apply to a given polymer. If these concerns do apply, the polymer should not be exempt from a more detailed EPA review.

5. *Exclusions.* Several classes of polymers have been excluded on the basis of information that suggests potential risk. The classes are cationic polymers, polymers manufactured from reactants containing halogen or cyano groups, and polymers containing certain reactive functional groups.

a. *Cationic polymers.* Review of data on polymers submitted under the PMN program revealed that certain cationic polymers, such as polyamines, are likely to be toxic to aquatic organisms even when their molecular weight is greater than 10,000.

b. *Polymers containing halogen or cyano groups.* There is sufficient concern regarding the toxicities of certain low molecular weight halogenated and cyanated monomers (e.g., vinyl bromide, vinyl chloride, and acrylonitrile) for the Agency to be unable to make a general finding of low risk for polymers made from such reactants.

c. *Polymers containing reactive functional groups.* Certain polymers containing reactive functional groups are intended to undergo further reaction to produce high molecular weight polymers. Because many of these groups are capable of reacting with tissues or other chemical constituents of living organisms, polymers containing such groups may be biologically active. Absorption of polymers with reactive groups is also plausible since reactive groups often cause sufficient irritation to disrupt normal cell membrane barriers and facilitate penetration. Because of the possibility of both absorption and reactivity with biological cells, polymers with reactive functional groups may be toxic.

For these reasons, the Agency believes that there is sufficient concern about the hazard potential of these three classes of polymers to exclude them from the exemption.

6. *Polyesters.* The polyester exemption, unlike the rest of the general polymer exemption, does not impose a minimum number-average molecular weight as a criterion for eligibility. The potential toxicity of residual reactants was addressed by limiting the reactants from which polyesters can be made under the exemption. A list of reactants that are commonly used in the manufacture of polyesters was evaluated for their potential toxicity. The evaluation was conducted by a panel of senior Agency scientists, who relied upon available scientific literature, information from other Federal agencies, knowledge of structure-activity principles, and general experience in identification and evaluation of hazardous substances. (This is the major hazard identification step in the normal PMN review process.) Under the exemption, polyesters may be made only from those reactants identified as presenting low concern in this review. These reactants are identified in § 723.250(e)(2) of the rule.

7. *Risk under exemption conditions.* There are several factors about polymers and the proposed exemption that reduce risks to human health and the environment presented by exempt polymers.

Many polymers are relatively unreactive and stable when compared to most other chemical substances. As a polymer's molecular weight increases, its potential to cause adverse health or ecological effects is generally reduced. This occurs because an increase in molecular weight generally reduces the rate of polymer absorption by biological systems. The Agency believes that these inherent properties of polymers, when combined with the provisions of this exemption, will significantly reduce the potential risks to human health and the environment that exempt polymers may present.

Under the exemption there are three main elements that will reduce risks: (1) The exemption criteria, (2) the expedited PMN and review provisions, and (3) the exclusion categories.

First, the exemption criteria will limit risk. Only polyesters manufactured from a list of low concern monomers are eligible for exemption without meeting the minimum number-average molecular weight criterion. Other polymers with a number-average molecular weight over 1,000 (if not otherwise excluded) would be exempt. EPA believes that this minimum number-average molecular weight, when combined with the exclusion categories and expedited review, sufficiently narrows potential risk concerns.

Second, certain polymers which may present significant risks or for which little is known about risk would be excluded from eligibility. For instance, polymers made from reactants that contain halogens or cyano groups would be excluded as a result of concerns for unreacted residuals. Polymers designed or reasonably anticipated to degrade or depolymerize would be excluded because EPA has limited review experience with such polymers. Cationic polymers, some of which are believed to present significant aquatic risks, are excluded. Other exclusions would similarly eliminate categories of polymers for which the Agency cannot make the finding of no unreasonable risk. Polymers that are not excluded must then meet the exemption criteria to be exempt.

Third, no polymers can be manufactured under this exemption without submission of a limited PMN to EPA at least 21 days prior to

manufacture. The Agency believes that, with the above exemption exclusions and criteria, EPA will be able within the 21-day period to identify problematic substances requiring more extended review. If significant risk issues are raised, the Agency may extend the review period and may exercise its authority under sections 5(e) and 5(f).

EPA believes that the exemption exclusions, conditions, and notice and review procedures will reduce potential risks by excluding certain polymers for which the Agency has limited review experience and some polymers which may often have hazard concerns, and by providing the Agency an opportunity to review all polymers prior to manufacture. In addition, the Agency believes that there will be no increase in potential risks beyond what would have occurred if a full PMN review was conducted. Polymers that are eligible for this exemption are usually identified as having low risk potential early in PMN review and consequently are dropped from consideration before the 21st day of the review period.

B. Summary of Economic Analysis

1. *Introduction.* To perform the economic analysis of the polymer exemption, the Agency created a data base from a sample of about 500 polymer PMN's submitted in 1980 and 1981. This data base provides an overview of the Agency's recent experience with the PMN program. The Agency analyzed the PMN's in this data base to determine the types of polymers being submitted for review, their projected production volumes, their intended uses, and in some cases their potential toxicity. This information was used to estimate the number of new chemicals that would likely be eligible for an exemption.

The Agency also reviewed the current cost of PMN requirements for manufacturers of new polymers; it estimated the direct relief to industry, reflected in decreased reporting costs and decreased time in bringing a new chemical to the market, that would result from different exemption alternatives; and it estimated direct savings to EPA resulting from decreased PMN review costs. These figures were used to derive quantitative estimates of benefits.

In assessing benefits, EPA also considered nonquantifiable benefits, such as the potential for increase in chemical innovation due to the promulgation of a polymer exemption. Although the Agency could not attach specific figures to these benefits, they may be substantial. EPA's analysis of the impact on industry of its proposed PMN rules suggests that the nonquantifiable costs of the program may be greater than quantifiable costs. By extension, it appears reasonable to assume that the nonquantifiable benefits of an exemption may be greater than those that can be quantified.

The complete economic analyses can be found in the economic support document in the public file for this rulemaking.

2. *Current impact on PMN program.* As a baseline for its economic analysis, EPA estimated the annual direct costs of submitting PMN's on polymers. A review of the sample of 500 polymer PMN's indicates that about 49 percent of all PMN's submitted are for polymers. Using the current direct PMN reporting costs of $1,300 to $7,500 per PMN, EPA estimated the annual direct reporting costs for polymers to be between $.64 and $3.7 million. Besides these direct filing costs, industry is also faced with additional costs from the TSCA-imposed 90-day PMN review period (delay costs), from having to establish confidential business information claims, and from uncertainty as to whether EPA will take regulatory action. Considering all current PMN reporting costs, the annual reporting costs to submitters of polymer PMN's are estimated to be between $1.8 and $4.9 million.

3. *Benefits of the exemption.* The Agency estimated the number of new chemical substances that would be eligible for the exemption. From this base, EPA then calculated the annual net benefits of the exemption. These benefits include the indirect savings from the reduction of the 90-day delay. The costs of having to submit limited PMN's and the cost of the delay associated with expedited review are subtracted from the gross savings to obtain the net savings to industry. The polymer exemption would make about 216 substances eligible for limited reviews per year. However, we expect that some firms would continue to submit PMN's for all new polymers while others would take advantage of the exemption for only a portion of the new polymers they develop. The polymer exemption would thus result in the filing of about 85 to 216 limited PMN's per year; net benefits to industry would therefore be between $0.165 and $1.65 million per year. However, the Agency will expend approximately the same resources reviewing limited polymer PMN's as it now expands reviewing polymer PMN's; any savings in EPA resources due to the exemption are expected to be negligible.

In addition to the benefits which EPA has quantified, there are certain benefits which the Agency has examined qualitatively. Chief among these are the benefits of reduced uncertainty and of increased innovation for manufacturers of new chemical substances. The reduction in the length of the review period (from 90 to 21 days) would reduce the period of uncertainty about the outcome of EPA's review of the notice (whether the chemical would be manufactured, when, and under what restrictions, if any, etc.). Also, by reducing direct PMN filing costs and delay costs, the exemption will encourage chemical innovation. These reductions will mean that chemicals which formerly were not profitable to introduce would now be acceptable investments. The net value of this additional innovation would constitute additional benefits, both to the chemical industry and to society.

C. Finding of No Unreasonable Risk

1. *Statutory background.* Under section 5(h)(4) of TSCA, EPA is authorized to exempt the manufacturer of any new chemical substance from all or part of the requirements of section 5 if EPA determines that the manufacture, processing, distribution in commerce, use, and disposal of the substance will not present an unreasonable risk of injury to health or the environment. Section 26(c) TSCA provides that any action authorized under TSCA for an individual chemical substance may be taken for a category of such substances.

The term "unreasonable risk" is not defined in TSCA. The legislative history indicates that determination of whether a risk is unreasonable requires a balancing of the probability and severity of harm from the substance or category of substances against the costs of the regulatory action to society. Because EPA's determination of the reasonableness of risk involves a consideration of factors such as environmental effects, use patterns, and market potential which are frequently difficult to define and quantify precisely, EPA must rely not only on the available data but also its professional judgment. Congress recognized that the implementation of the unreasonable risk standard "will vary depending on the specific regulatory authority which the Administrator seeks to exercise." [Legis. Hist. at 422]

2. *EPA's approach to making the no unreasonable risk finding.* To determine whether the category of substances manufactured under the exemption presents an unreasonable risk, the Agency should consider not only the inherent risks presented by the overall category of polymers, but also the extent to which specific exclusions or

adjustments of the overall category definition have mitigated such potential risks. EPA must then analyze the effect on risk of any further conditions imposed on the exemption. For example, manufacturers who intend to use the exemption must submit a PMN containing only limited information, which may affect the Agency's ability to identify risk. Because the effect of the exemption is to modify general PMN requirements, EPA should also compare the absolute risk posed by the exemption with the risks which would have resulted from the same substances if the substances had been subject to full notice submission requirements and minimum 90-day EPA review period.

Congress did not intend the section 5 review process to eliminate entirely all risk resulting from manufacture, processing distribution in commerce, use, and disposal or new chemical substances, nor is it possible to do so. While section 5 gives EPA the opportunity to review all new chemical substances, the Agency is authorized to ban such substances or otherwise control against risks only when it can show the substances will present an unreasonable risk of injury to health or the environment (section 5(f) of TSCA) or when there is insufficient information to evaluate the risks and EPA finds either that the manufacture, processing, distribution in commerce, use, or disposal may present an unreasonable risk or that the substance will be produced in substantial quantities and will be released in substantial amounts or will result in significant or substantial human exposure (section 5(e) of TSCA). To the extent that certain risks presented by members of a category of substances would not have been regulated by EPA during a full PMN review, based on EPA's maximum exercise of its section 5 authorities, such risks could not be considered to be risks posed by an exemption rule.

There are two methods of calculating the benefits of the exemption which should be weighed in determining whether exempt substances will present an "unreasonable" risk. First, CPA can consider the benefits in a manner analogous to the way it would consider them if the Agency were evaluating a particular member of the category during the full PMN period. Under this approach the evaluation would focus on the benefits of the chemicals to society, and the extent to which any regulation of the substances necessary to address remaining risk concerns would reduce or eliminate such benefits. The basis for considering this type of benefits information is that Congress arguably did not intend to exempt from PMN requirements any substances which were likely to have been subject to control under section 5(e) or 5(f). EPA thus would not consider the reduced burden of the PMN or other benefits of reducing PMN requirements, because these costs would not be considered in making a regulatory decision on a PMN substance. One problem with focusing on the benefits of the substances in the category is that, while section 5(h)(4) clearly contemplates granting exemptions by category, it is difficult or impossible to predict accurately the nature of those benefits.

Under the second approach, EPA could consider benefits beyond those considered in an actual PMN review. As discussed in the proposed rule, a broader consideration of benefits would analyze, in addition to the benefits of the substances themselves, the reduction in the costs to society imposed by the full PMN requirements. There are strong arguments for taking such an approach in making a no unreasonable risk finding in the context of a 5(h)(4) exemption. The legislative history indicates that EPA's unreasonable risk consideration should include effects on society beyond the benefits of a substance. In addition, unlike the review of an individual PMN, the costs of PMN's for substances which would be addressed by this exemption have not already been paid. Such direct costs would include the cost of preparing and submitting the PMN, and the cost of the delay in the introduction of the benefits of a new chemical. In addition, economic analyses have indicated that reporting and delay costs may discourage the introduction of new chemicals. While elimination of these costs would not be a benefit that EPA would take into account in making an individual control decision on a new substance, they are real effects on society which result from EPA's exercise of its exemption authority and are thus appropriately considered in a section 5(h)(4) unreasonable risk finding for a category of substances.

3. *Application of no unreasonable risk factors.* Following is an explanation of EPA's consideration of the factors relevant to the finding of no unreasonable risk.

a. *Risks associated with exempt polymers.* As discussed in Unit III. A of the preamble, there are several characteristics about polymers as a category of substances and several elements of the proposed exemption that would significantly limit the risks to human health and the environment that exempt polymers may present. First, polymers are relatively unreactive and stable compared to other chemical substances and typically are not readily absorbed. These properties generally limit a polymer's ability to cause adverse effects. Supporting these conclusions are the available, although limited, data and EPA's professional judgment and its experience in reviewing over 1,200 polymer PMN's. Second the exemption excludes polymers that are believed to present potential risk concerns as well as certain polymers about which little is known. Third, the exemption provisions include eligibility criteria that further limit potential risks. Finally, the exemption includes notice and review procedures that would allow EPA to exclude individual polymers from the exemption if unresolved issues concerning toxicity or exposure remain at the end of the 21-day review period or if EPA believes that it should consider regulatory action under section 5(e) or 5(f). The Agency believes that these factors provide reasonable assurances that exempt polymers will not present unreasonable risks to human health or the environment.

b. *Relative risks of expedited review and full PMN review.* In deciding whether to grant this exemption, EPA has carefully considered the potential decrease in the Agency's ability to identify risks in the exemption review process, compared with its ability to do so in full PMN review. Such additional risks could result from: (1) The inclusion of less information in the limited PMN, or (2) failure to recognize a problem in the 21-day review period that EPA would have recognized during the 90-day review period. EPA has several reasons for concluding that, in fact, the exemption review process would not result in any such increase in risk. First, as discussed above, EPA believes that the potential for significant risks among the class is reduced. Second, based on EPA's review experience, the information required to be submitted for limited PMN review, and the 21-day review period, will be sufficient to identify any problems that were likely to have been identified in a full PMN review. Under the present process for PMN's, EPA performs an initial review of all PMN substances to identify possible health or environmental effects. Within a few weeks after receipt of the notice, if EPA has any significant suspicions about a PMN substance, or if there are unresolved questions about toxicity, the chemical substance is referred for a more thorough review. For the vast majority of substances, for which no such issues are raised, little or

no assessment occurs after this initial review. The experience of the PMN program to date is that very few polymeric substances are identified for more detailed assessment.

The review process for exempt polymers will be very similar to that now followed for PMN's. The limited PMN will contain information sufficient for EPA to evaluate those aspects of polymeric substances which could potentially cause effects of concern, primarily focusing on the presence of low molecular weight species, the toxicity of such species and general exposure conditions. If EPA did identify toxicity concerns during this 21-day review, the exemption rule would allow EPA to extend the review period, and conduct a full PMN review. EPA is confident that any such problems can be identified during the 21-day period. If no such problems are identified, there is virtually no chance that they would have been identified by EPA during a more extensive review.

There is one aspect of EPA's expedited review that in the abstract would not be equivalent to a full 90-day PMN review. Under section 5(a), when EPA receives a PMN, it publishes a notice in the **Federal Register**, seeking information on risks which may be presented by the substance. The 21-day review period under the exemption rule, would not be adequate to allow the submission by the public of information on the substance which was not available to EPA. EPA, however, does not believe that this problem is significant because the Agency very rarely receives comments in response to such notices. In addition, no information has ever been received from the public during the 90-day PMN review period which caused the Agency to reverse its initial evaluation of a polymer.

c. *Benefits.* It is impossible to quantify the total benefits which may accrue to society from the individual substances subject to this exemption. Uncertainty about benefits is inherent in any action under TSCA which deals with a category of substances whose structure and uses are unknown. However, it is clear that the field of polymer chemistry has been the source of many recent technological advances. In addition, it is obvious that a new polymer must present benefits to society by performing a new function, or performing an old function more efficiently or less expensively, or with less risk, or it would not have been developed or used. Therefore, EPA has concluded that the new polymers eligible for exemption, as a category and as individual substances, will present some significant benefits to society.

EPA has been able to quantify some of the benefits to society which will result from this exemption that do not depend on specific knowledge about the benefits of the individual substances. First, as is indicated above, manufacturers submitting notices under this exemption will incur reduced reporting costs. Second, for the vast majority of substances submitted under this exemption, for which the 21-day review period is not extended, there will be a potential for significant reduction in the delay in introducing new polymers. Manufacturers, and the general public, will be able to take advantage of the benefits of individual polymeric substances more quickly, including any increases in efficiency and decrease in cost.

Assuming that from 85 to 216 polymers a year would take advantage of the exemption, net benefits would be between $0.165 and $1.65 million annually. Of this amount, a significant portion consists of the savings in costs due to delay. The delay cost savings for polymers range from about $0.1 to $0.25 million annually. Total industry costs associated with the PMN program are presently estimated at $3.715 to $9.915 million annually. The final polymer exemption rule will therefore reduce the program cost to industry by about 4 to 17 percent.

4. *Conclusion.* As discussed above, a finding concerning the existence or absence of an unreasonable risk under section 5 requires a balancing of risks and benefits which result from a particular action. As explained above, EPA has determined that the risks likely to result from substances manufactured under this exemption are very low, based on the inherent properties of the category of substances considered for exemption, the conditions in the rule limiting the polymers eligible for the exemption, and the procedural safegrards EPA has included in the exemption, including the limited PMN, the 21-day review period, and the Agency's authority and intention to extend the review period if there are significant questions about the risks posed by the substance.

Under EPA's interpretation of section 5(h)(4), because the risks of the exemption are small, EPA could make a finding that the substances would not present an unreasonable risk even if the benefits of the exemption were small. However, EPA believes that there are substantial benefits to be considered. First, substances addressed by the rule have clear benefits to society. While these benefits are difficult to quantify, the Agency believes that they by themselves outweigh any risks which are presented by the exemption. In addition, the exemption will result in a reduction in PMN reporting costs for eligible polymers, reduction in the delay between submission of notices to EPA and commencement of manufacture, and increase in innovation because of lesser costs and lesser potential for regulatory delay. The fact that not all of these benefits are subject to precise quantification does not prevent EPA from considering them, because Congress recognized the limitations of quantitative solutions to such inherently judgmental decisions as "unreasonable risk". When these benefits are added to the benefits of the substances themselves, they even more strongly outweigh the risks posed by this exemption.

Finally, the Agency believes that it is prudent public policy to focus society's limited resources on chemical substances that have greater potential to present significant risks. Other regulatory bodies and society as a whole have largely recognized that polymers present limited risk potential and EPA has rarely identified significant risk concerns in reviewing PMN's on new polymers. The exemption of relatively low risk categories of substances, such as polymers, allows EPA to focus its attention on the review and control of chemical substances that may present more serious risks.

Given the above considerations, EPA has concluded that the manufacture, processing, distribution in commerce, use, and disposal of the substances eligible for this exemption will not, taking into account all the terms of the exemption, present and unreasonable risk of injury to health and the environment.

IV. Judicial Review

Judicial review of this final rule may be available under section 19 of TSCA in the United States Court of Appeals for the District of Columbia Circuit or for the circuit in which the person seeking review resides or has its principal place of business. To provide all interested persons an equal opportunity to file a timely petition for judicial review and to avoid so called "races to the courthouse," EPA has decided to promulgate this rule for purposes of judicial review two weeks after publication in the **Federal Register**, as reflected in **DATES** in this notice. The effective date has, in turn, been calculated from the promulgation date.

V. Record

EPA has established a record of this final rulemaking (Docket Number: OPTS–50033A): the public version of this record is available for inspection in the OPTS Reading Room, Rm. E–107, 401 M St., SW, Washington, D.C. 20460 from 8 a.m. to 4 p.m. Monday through Friday, except legal holidays. Persons who do not have access to the record in the public reading room should contact Edward A. Klein, Director, TSCA Assistance Office (TS–799), at the above address for assistance.

The preamble to the proposed rule (47 FR 33896) lists items entered into the record through June 1982. The list below identifies items entered into the record after that date.

61. Adhesives Manufacturers Association (AMA), Letter to USEPA-OTS, August 13, 1981.

62. USEPA-OTS, Letter to AMA, September 14, 1981.

63. National Paint and Coatings Association, "Coatings Polymers: General Properties and Uses. A General Mortality Study of Production Workers in the Paint and Coatings Manufacturing Industry," October 22, 1981.

64. Cargill Incorporated Reasearch Department, "Cargill PMN Exemption Petition," November 13, 1981.

65. Shell Oil Company, Documents from CIBA-GEIGY and Shell supporting CMA proposed exemption for epoxy resins, February 3, 1982.

66. American Cyanamid Company, "Studies on Water Soluble Polymers (I)," July 29, 1982.

67. USEPA-OTS, "Methodology for Estimating Aquatic Safety with Minimal Data," August 1982.

68. USEPA-OTS, "Proposed Rule: Exemption of Certain Polymers from Premanufacturing Notification Requirements," August 4, 1982.

69. Comments after Proposed Rule (51 comments).

70. Public Meeting on Proposed PMN Exemptions (Six Exhibits), November 1, 1982.

71. A letter summarizing a conversation between E. Klein and J. Derbeck of Keller and Heckman, August 26, 1982.

72. USEPA/OTS, "Summary of Meeting with Burlin and Co., Inc.," September 14, 1982.

73. Tretolite Division, Petrolite Division, "Data on Cationic Polymers (II)," November 29, 1982.

74. American Cyanamid Company, "Toxicity Studies in Water Soluble Polymers," December 16, 1982.

75. Post Hearing Comments (10 comments).

76. USEPA-OTS, "Polymer Exemption Bibliography," October 1, 1982.

77. USEPA-OTS, "Technical Support Document: Risk Analysis of Polymers," July 12, 1983.

78. USEPA-OTS, "Economic Analysis of Final Section 5(h)(4) Polymer Exemption Rule," May 1983.

In accordance with section 19(a)(13) of the Act, the above lists together identify the complete rulemaking record. The public version of the record does not include confidential business information.

VI. Application of Executive Order 12291, Paperwork Reduction Act, and Regulatory Flexibility Act

This regulation does not satisfy any of the criteria for a major regulation described in Executive Order 12291; therefore, EPA has determined that a Regulatory Impact Analysis is not necessary. The annual impact of the rule on the economy will not exceed $100 million; instead it will provide substantial relief to the regulated industry. The rule will not burden any one particular geographic region and will not affect government agencies, except that it may slightly reduce the burden of PMN review for EPA. The exemption will not adversely affect the ability of domestic manufacturers to compete with foreign manufacturers, and it will encourage chemical innovation. EPA expects that the net effect of this exemption rule on the economy will be positive.

This regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Also, the information requirements contained in this rule have been submitted to OMB under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* and have been assigned OMB control number 2070–0012.

As required by the Regulatory Flexibility Act (5 U.S.C. 605(b)), EPA hereby certifies that this rule will not have a significant adverse economic impact on a substantial number of small businesses. Instead, it will provide relief from the present PMN requirements, which is likely to be particularly beneficial to small businesses. Since the exemption will reduce PMN filing costs and shorten production delays, small manufacturers will benefit from the rule. As stated in the document "Economic Analysis of TSCA section 5(h)(4) Exemptions: Polymers," the exemption will potentially benefit all manufacturers by reducing direct notification uncertainty, and delay costs associated with premanufacture review. Although it is difficult to determine the reduction in costs specific to small business, the exemption will not benefit large companies at the expense of small manufacturers, and may tend to improve small firms ability to compete and innovate by reducing their more critical direct costs.

Authority: Sec. 5, TSCA, 15 U.S.C. 2604.

List of Subjects in 40 CFR Part 723

Chemicals, Environmental protection, Premanufacture notification exemption, Hazardous materials, Reporting and recordkeeping requirements.

Dated: November 9, 1984.

William D. Ruckelshaus,

Administrator.

PART 723—[AMENDED]

Therefore, 40 CFR Part 723 is amended by adding a new § 723.250 to Subpart B to read as follows:

§ 723.250 Polymers.

(a) *Purpose and scope.* (1) This section grants an exemption from certain of the premanufacture notice requirements of section 5(a)(1)(A) of the Toxic Substances Control Act (15 U.S.C. 2604(a)(1)(A)) for the manufacture of certain polymers.

(2) To manufacture a new chemical substance under the terms of this section, a manufacturer must: (i) Determine that the substance meets the definition of polymer in paragraph (b)(12) of this section.

(ii) Determine that the substance is not specifically excluded by paragraph (d) of this section.

(iii) Ensure that the substance meets the exemption criteria of paragraph (e) of this section.

(iv) Submit a notice as required under paragraph (f) of this section.

(v) Comply with the recordkeeping requirements of paragraph (r) of this section.

(b) *Definitions.* In addition to the definitions under section 3 of TSCA, 15 U.S.C. 2602, the following definitions apply to this Part.

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

(2) "Administrator" and "environment," have the same meanings as in section 3 of the Act (15 U.S.C. 2602).

(3) "Biopolymer" means a polymer directly produced by living or once-living cells or cellular components.

(4) "Category of chemical substances" has the same meaning as in section 26(c)(2) of the Act (15 U.S.C. 2625).

(5) "Cationic polymer" means a polymer that contains one or more covalently linked subunits that bear a net positive charge.

(6) "Chemical substance," "Director," "EPA," "importer," "impurity," "Inventory," "known to or reasonably ascertainable," "manufacture," "manufacturer," "mixture," "new chemical substance," "person," "possession or control," "process," and

"test data" have the same meanings as in § 720.3 of this chapter.

(7) "Internal subunit" means a subunit that is covalently linked to at least two other subunits. "Internal subunits" of polymer molecules are chemically derived from monomer molecules that have formed covalent links between two or more other subunits.

(8) "Monomer" means a chemical substance that has the capacity to form links between two or more other molecules.

(9) "Number-average molecular weight" means the arithmetic average (mean) of the molecular weight of all molecules in a polymer.

(10) "Polyester" means a chemical substance that meets the definition of polymer and whose polymer molecules contain at least two carboxylic acid ester linkages, at least one of which links internal subunits together.

(11) "Polymer" means a chemical substance that consists of at least a simple weight majority of polymer molecules but consists of less than a simple weight majority of molecules with the same molecular weight. Collectively, such polymer molecules must be distributed over a range of molecular weights wherein differences in molecular weight are primarily attributable to differences in the number of internal subunits.

(12) "Polymer molecule" means a molecule which includes at least four covalently linked subunits, at least two of which are internal subunits.

(13) "Reactive functional group" means an atom or associated group of atoms in a chemical substance that is intended or can reasonably be anticipated to undergo facile chemical reaction.

(14) "Reactant" means a chemical substance that is used intentionally in the manufacture of a polymer to become chemically a part of the polymer composition.

(15) "Reasonably anticipated" means that a knowledgeable person would expect a given physical or chemical composition or characteristic to occur based on such factors as the nature of the precursors used to manufacture the polymer, the type of reaction, the type of manufacturing process, the products produced in polymerization, the intended uses of the substance, or associated use conditions.

(16) "Subunit" means an atom or group of associated atoms chemically derived from corresponding reactants.

(c) *Applicability.* This section applies to manufacturers of new chemical substances that otherwise must submit a premanufacture notice to EPA under § 720.22 of this chapter. New substances are eligible for exemption under this section if they meet the definition of polymer in paragraph (b)(11) of this section, and the criteria in paragraph (e) of this section, and if they are not excluded from the exemption under paragraph (d) of this section.

(d) *Polymers that cannot be manufactured under this section*—(1) *Cationic polymers.* A polymer cannot be manufactured under this section if the polymer is a cationic polymer as defined under paragraph (b)(5) of this section or if the polymer is reasonably anticipated to become a cationic polymer in a natural aquatic environment (e.g., rivers, lakes).

(2) *Polymers containing less than 32.0 percent carbon.* A polymer cannot be manufactured under this section if the polymer contains less than 32.0 percent by weight of the atomic element carbon.

(3) *Elemental limitations.* (i) A polymer manufactured under this section must contain as an integral part of its composition at least two of the atomic elements carbon, hydrogen, nitrogen, oxygen, silicon, and sulfur.

(ii) A polymer cannot be manufactured under this section if it contains as an integral part of its composition, except as impurities, any elements other than the following:

(A) the elements listed in paragraph (d)(3)(i) of this section;

(B) Sodium, magnesium, aluminum, potassium, or calcium as the monatomic counterions Na^{+}, Mg^{+2}, Al^{+3}, K^{+}, or Ca^{+2};

(C) Less than 0.20 weight percent of any combination of the atomic elements lithium, boron, phosphorus, titanium, manganese, iron, nickel, copper, zinc, tin, and zirconium.

(4) *Biopolymers.* A polymer cannot be manufactured under this section if the polymer is:

(i) A biopolymer as defined under paragraph (b)(3) of this section.

(ii) The synthetic equivalent of a biopolymer.

(iii) A derivative or a modification of a biopolymer if the initial biopolymer is substantially intact. A derivative of a biopolymer is a polymer that results from an additive chemical change of a biopolymer. A modification of a biopolymer is a polymer that results from a non-additive chemical change of a biopolymer. A derivative or a modification of biopolymer is substantially intact if it contains two or more internal subunits of a biopolymer in its structure.

(5) *Polymers manufactured from reactants containing halogen atoms or cyano groups.* A polymer cannot be manufactured under this section:

(i) If the polymer is manufactured from reactants containing, other than as impurities, fluorine, chlorine, bromine, or iodine atoms or cyano groups, or

(ii) If the polymer contains cyano groups other than as impurities.

(6) *Polymers containing reactive functional groups.* A polymer cannot be manufactured under this section if the polymer contains reactive functional groups that are intended or reasonably anticipated to undergo further reaction unless:

(i) The weight of the polymer that is equivalent to one gram-formula weight of reactive functional groups is 10,000 grams or greater.

(ii) The reactive functional groups are carboxylic acid groups, aliphatic hydroxyl groups, unconjugated olefinic groups, butenedioic acid groups; or conjugated olefinic groups in naturally-occurring fats, naturally-occurring oils, or naturally-occurring carboxylic acids.

(7) *Polymers which degrade, decompose, or depolymerize.* A polymer cannot be manufactured under this section if the polymer is designed or reasonably anticipated to substantially degrade, decompose, or depolymerize.

(e) *Exemption criteria.* To be manufactured under this section, the polymer must meet one of the following criteria:

(1) *Polymers over 1,000 number-average molecular weight.* The polymer has a number-average molecular weight greater than 1000.

(2) *Polyester polymers.* The polymer is a polyester as defined in paragraph (b)(10) of this section and is manufactured solely from one or more of the reactants in the following Table:

Table—List of Reactants From Which Polyesters May be Made

Monobasic Acids and Natural Oils

Benzoic acid (65-85-0)
Coconut oil (8001-31-8*)
Corn oil (8001-30-7*)
Cottonseed oil (8001-29-4*)
Dodecanoic acid (143-07-7)
Fatty acids, coco (61788-47-4*)
Fatty acids, linseed oil (68424-45-3*)
Fatty acids, safflower oil**
Fatty acids, soya (68308-53-2*)
Fatty acids, sunflower oil** (84625-38-7*)
Fatty acids, tall-oil (61790-12-3*)
Fatty acids, tall-oil conjugated**
Fatty acids, vegetable oil (61788-66-7*)
Heptanoic acid (111-14-8)
Hexanoic acid (142-62-1)
Hexanoic acid, 3,3,5-trimethyl- (3302-10-1)
Linseed oil (8001-26-1*)
Nonanoic acid (112-05-0)
Oils, *Cannabis*
Oils, anchovy
Oils, babassu palm
Oils, herring (68153-06-0*)
Oils, menhaden (8002-50-4*)
Oils, oiticica (8016-35-1*)
Oils, palm kernel (8023-79-8*)

Oils, perilla (68132-21-8*)
Oils, walnut (8024-09-7*)
Oils, sardine
Safflower oil (8001-23-8*)
Soybean oil (8001-22-7*)
Sunflower oil (8001-21-6*)
Tung oil (8001-20-5*)

Di and Tri Basic Acids and Anhydrides

1,2-Benzenedicarboxylic acid (88-99-3)
1,3-Benzenedicarboxylic acid (121-91-5)
1,4-Benzenedicarboxylic acid (100-21-0)
1,2,4-Benzenetricarboxylic acid (528-44-9)
Butanedioic acid (110-15-6)
2-Butenedioic acid (*E*) (110-17-8)
Decanedioic acid (111-20-6)
Hexanedioic acid (124-04-9)
Nonanedioic acid (123-99-9)

Polyols

1,3-Butanediol (107-88-0)
1,4-Butanediol (110-63-4)
1,4-Cyclohexanedimethanol (105-08-8)
1,2-Ethanediol (107-21-1)
1,6-Hexanediol (629-11-8)
1,3-Pentanediol, 2,2,4-trimethyl- (144-19-4)
1,2-Propanediol, (57-55-6)
1,3-Propanediol, 2,2-bis(hydroxymethyl)- (115-77-5)
1,3-Propanediol, 2,2-dimethyl- (126-30-7)
1,3-Propanediol, 2-ethyl-2-(hydroxymethyl)- (77-99-6)
1,3-Propanediol, 2-(hydroxymethyl)-2-methyl- (77-85-0)
1,2,3-Propanetriol (56-81-5)
1,2,3-Propanetriol, homopolymer (25618-55-7)
2-Propen-1-ol, polymer with ethenylbenzene (25119-62-4)

Modifiers

Acetic acid, 2,2'-oxybis- (110-99-6)
1-Butanol (71-36-3)***
Cyclohexanol (108-93-0)
Cyclohexanol, 4,4,-(1-methylethylidene)bis- (80-04-6)
Ethanol, 2-(2-butoxyethoxy)- (112-34-5)
1-Hexanol (111-27-3)
Methanol, hydrolysis products with trichlorohexylsilane and trichlorophenylsilane (72318-84-4*)
1-Phenanthrenemethanol, tetradecahydro-1,4a-dimethyl-7-(1-methylethyl)- (13393-93-6)
Phenol, 4,4'-(1-methylethylidene)bis-, polymer with 2,2'-[(1-methylethylidene)bis(4,1-phenyleneoxymethylene)] bis[oxirane] (25036-25-3)
Siloxanes and Silicones, di-Me, di-Ph, polymers with Ph silsesquioxanes, methoxy-terminated (68440-65-3*)
Siloxanes and Silicones, di-Me, methoxy Ph, polymers with Ph silsesquioxanes, methoxy-terminated (68957-04-0*)
Siloxanes and Silicones, Me Ph, methoxy Ph, polymers with Ph silsesquioxanes, methoxy- and Ph-terminated (68957-06-2*)
Silsesquioxanes, Ph Pr (68037-90-1*)

* The * is used to designate chemical substances of unknown or variable composition, complex reaction products, and biological materials (UVCB). The CAS Registry Numbers for UVCB substances are not used in CHEMICAL ABSTRACTS and its indexes.

** These substances and polyesters made from them may not be manufactured until notices for them are submitted under sections 5(a)(1) or 5(h)(4) of TSCA.

*** These substances may not be used in a substance manufactured from fumaric or maleic acid because of potential risks associated with esters, which may be formed by reaction of these reactants.

(f) *Limited premanufacture notice*—The manufacturer must submit to the Administrator a limited premanufacture notice at least 21 calendar days prior to the date of manufacture. (1) *Notice form.* The information set forth in paragraph (f)(2) of this section must be submitted on the corresponding sections of Appendix A, 40 CFR Part 720 (EPA Form No. 7710-25) as identified below. The manufacturer must indicate clearly on the form that he or she is claiming an exemption from full premanufacture notice requirements under this section.

(2) *Contents of notice.* For substances exempt under paragraph (e) of this section the notice must include to the extent known to or reasonably ascertainable by the manufacturer:

(i) *Manufacturer's name.* This includes the name and address of the manufacturer and the name and telephone number of a technical contact. (Part I, Section A, Appendix A, 40 CFR Part 720).

(ii) *Type of exemption.* A designation of whether the manufacturer is claiming an exemption under paragraph (e) (1) or (2) of this section. (Identify on page 1 of the notice.)

(iii) *Site of manufacture.* (Except for chemical substances that are imported.) The name and address of the site or sites of manufacture. (Identify as an attachment to the notice.)

(iv) *Chemical identity.* (A) The identity (by chemical name and CAS Registry Number) and the maximum percent (by weight) of each reactant as defined in paragraph (b)(14) of this section, used at any weight percent to manufacture the polymer. The manufacturer must specify any reactants used at 2 weight percent or less that should be included as part of the polymer description on the Inventory. (Part I, Section B.2b, Appendix A, 40 CFR Part 720.)

(B) A representative structural diagram of the polymer, if possible. The notice must also indentify synonyms and trade names of the new polymer. (Part I, Sections B.2c, B.4, B.5, Appendix A, 40 CFR Part 720.)

(v) *Number-average molecular weight.* The number-average molecular weight, as defined under paragraph (b)(9) of this section, of the lowest molecular weight composition of the substance anticipated to be manufactured under the exemption and a description of the method used to determine the molecular weight. (Part I, Sections B.2a, Appendix A, 40 CFR Part 720.)

(vi) *Residual monomer and other reactants and low molecular weight species content.* (A) The maximum weight percent of each monomer or other reactant that will be present as residual in the polymer as manufactured for commercial purposes. (Part I, Sections B.2b, Appendix A, 40 CFR Part 720.)

(B) The total maximum weight percent of all material below 500 absolute molecular weight and below 1,000 absoulute molecular weight in any composition of the polymer that will be manufactured. (Part I, Section B.2a, Appendix A, 40 CFR Part 720.)

(vii) *Impurity information.* The identity, by chemical name and CAS Registry Number, and estimated maximum weight percent of each impurity anticipated to be present in the polymer as manufactured for commercial purposes. If there are unidentified impurities, the notice must include an estimate of their total weight percent. (Part I, Section B.3, Appendix A, 40 CFR Part 720.)

(viii) *Maximum annual production volume.* The maximum production volume during the first 12-month period of production and the maximum production volume for any consecutive 12-month period during the first three years of production. (Part I, Section C.1, Appendix A, 40 CFR Part 720.)

(ix) *Category of use.* A description of each use for which the polymer would be manufactured, including its function and application (e.g., spray adhesive in the manufacture of laminates). The description of use must also indicate whether the use in industrial, commercial, consumer, and/or site-limited. (Part I, Section C.2a(1)–(4), Appendix A, 40 CFR Part 720.)

(x) *Generic chemical identity and use.* If chemical identity or use information provided under this section is claimed as confidential under paragraph (g) of this section, the notice must provide a non-confidential description of this information which is only as generic as necessary to protect the confidentiality of the information. (Part I, Sections B.6, C.2b, Appendix A, 40 CFR Part 720.)

(xi) *Test data and other data.* Test data on the polymer in the possession or control of the manufacturer, a description of other data concerning the health and environmental effects of the polymer that are known to or reasonably ascertainable by the manufacturer, and a decription of data on related chemicals, as required in § 720.50 of this chapter. (Identify as an attachment to the notice.)

(xii) *Cetification.* A certification that:

(A) The notice includes all test data and other data required.

(B) The person submitting the notice intends to manufacture or import the polymer for a commercial purpose other than for research and development.

(C) All information provided in the notice is complete and truthful as of the date of submission.

(D) The new chemical substance meets the definition of polymer, is not specifically excluded from the exemption, and meets the conditions of the exemption. (Certification, Appendix A, 40 CFR Part 720, plus statement (xii)(D).)

(xiii) *List of Attachments.* The notice must include a list of attachments submitted with the notice. (Part III, Appendix A, 40 CFR Part 720.)

(g) *Notice Procedures.* The following sections of Part 720 of this chapter apply to the review and handling of notices under this section.

(1) Section 720.25 *Determining whether a chemical substance is on the Inventory.*

(2) Section 720.40 *General.* (Notice Form, Paragraphs (e) through (h)).

(3) Section 720.57 *Imports.*

(4) Section 720.62 *Notice that notification is not required.*

(5) Section 720.70 *Notice in the* **Federal Register.**

(6) Section 720.80 *General Provisions.*

(7) Section 720.85 *Chemical Identity.*

(8) Section 720.87 *Categories or proposed categories of uses of a new chemical substance.*

(9) Section 720.90 *Data from health and safety studies.*

(10) Section 720.95 *Public file.*

(11) Section 720.102 *Notice of commencement of manufacture or import.*

(h) *Notification of receipt of notice.* EPA will notify the manufacturer by telephone of the date on which the Agency received the notice. This acknowledgement does not constitute a finding by EPA that the notice, as submitted, is in compliance with this section. EPA will consider a person to have submitted the notice on the date the notice is received by the EPA Document Control Officer for the Officer of Toxic Substances.

(i) *Errors in the notice. (1) Within 10 calendar days or receipt of the notice, EPA may request that the manufacturer remedy errors in the notice.*

(2) In the request to correct the notice, EPA will explain the action which the manufacturer must take to correct the notice.

(3) If the manufacturer fails to correct the notice within eight days of receipt of the requests, EPA may determine that the notice is incomplete under paragraph (j) of this section.

(j) *Incomplete submissions.* (1) *A submission is not complete, and the notification period does not begin, if:*

(i) The wrong person submits the notice form.

(ii) The manufacturer does not sign the notice form.

(iii) Some or all of the information in the notice or the attachments are not in English, except for published scientific literature.

(iv) The manufacturer does not use the notice form.

(v) The manufacturer does not provide information that is required by paragraph (f)(2)(xi) of this section.

(vi) The manufacturer does not provide information required or indicate that is is not known to or reasonably ascertainable by the manufacturer.

(vii) The manufacturer does not submit a second copy of the submission with all confidential information deleted for the public file, as required by § 720.80(b)(2) of this chapter.

(viii) The manufacturer does not include any information required by section 5(b)(1) of the Act and pursuant to a rule promulgated under section 4 of the Act, as required by § 720.40(g) of this chapter.

(ix) The manufacturer does not submit data which the manufacturer believes show that the chemical substance will not present an unreasonable risk of injury to health or the environment, if EPA has listed the chemical substance under section 5(b)(4) of the Act, as required in § 720.40(h).

(2) If EPA determines that a submission is incomplete, the Director, or his or her delegate, will notify the manufacturer within 21 days of receipt that the submission is incomplete and that the notice review period will not begin or continue until EPA receives a complete notice.

(3) The notification that a submission is incomplete under paragraph (j)(2) of this section will include:

(i) A statement of the basis for EPA's determination that the submission is incomplete.

(ii) The requirements for correcting the incomplete submission.

(iii) Information on procedures under § 720.65(c)(4) of this chapter for filing objections to the determination or requesting modification of the requirements for completing the submission.

(4) If EPA determines that a submission is incomplete under this paragraph, it will follow the procedures outlined in § 720.65(c) (4) and (5) of this filing objections to this determination.

(k) *Review period.* The notice review period runs for 21 calendar days from the date the EPA Document Control Officer for the Office of Toxic Substances receives a complete limited premanufacture notice submitted according to paragraph (f) of this section, unless the period is extended under paragraph (l) of this section. If EPA determines that the notice is incomplete as specified in paragraph (j) of this section, the 21-day review period will not begin until a compete notice is submitted to the Agency Document Control Officer.

(l) *Extension of the review period.* (1) At any time during the review period specified in paragraph (k) of this section, EPA may extend the review period to a total of 90 days from the date of notice submission if the Administrator determines that the polymer should be considered for regulatory action under sections 5(e) or 5(f) of the Act or that unresolved issues concerning toxicity or exposure require further review.

(i) If the Administrator makes this determination, the Director or his or her designee will notify the manufacturer by telephone, followed by a letter, that the notice review period has been extended. The letter will explain the reasons for the extension.

(ii) On receipt of such notification, the manufacturer must withdraw the limited premanufacture notice or suspend the review period and submit the additional information on the substance necessary to constitute a full notice under Part 720 of this chapter. If the manufacturer suspends the review period, the manufacturer must submit the required additional information within 60 days of the date of telephone notification. If EPA receives the information, EPA will review the information following the procedures in Part 720 of this chapter, except that the review period identified in § 720.75(a) will be shortened by an amount equal to the days already elapsed in the review period under paragraph (k) of this section. If the manufacturer withdraws the limited notice or fails to suspend the review period or fails to submit complete additional information within 60 days, manufacture of the polymer may not begin until the manufacturer complies with section 5(a)(1) of the Act and Part 720 of this chapter.

(2)(i) At any time during the review period specified in paragraph (l)(1) of this section, EPA may determine that good cause exists to extend the notification period under section 5(c) of the Act. If EPA makes such a determination, the Director will:

(A) Notify the manufacturer by telephone followed by a letter, that EPA is extending the period for a specified length of time. The letter will specify the length of the extension and state the reasons for the extension; and

(B) Publish a notice in the Federal Register, which states that EPA is extending the review period and gives the reasons for the extension.

(ii) The extension under paragraph (l)(2)(i) of this section may be for a period of up to 90 days. If the extension is for less than 90 days, EPA may make additional extensions. However, the total period of extensions under paragraph (l)(2) of this section may not exceed 90 days for any notice.

(m) *Withdrawal of a notice by the manufacturer.* (1) A manufacturer may withdraw a notice during the notice review period specified in paragraph (k) or (l) of this section. A statement of withdrawal must be made in writing to the Document Control Officer (TS-793), Office of Pesticides and Toxic Substances, 401 M Street, SW., Washington, D.C. 20460. The withdrawal is effective upon receipt of the statement by the Document Control Officer (OMB Control No. 2070-0012).

(2) If a manufacturer or importer who withdraws a notice later resubmits a notice for the same chemical sustance, a new notice review period begins.

(n) *Expiration of review period.* If the review period identified in paragraph (k) of this section expires without notification of extension by EPA, manufacture or import may begin under the terms of the exemption. The fact that EPA does not initiate regulatory action during the review period does not constitute EPA approval or certification of the substance, and does not mean that EPA may not take regulatory action on the substance in the future.

(o) *Inventory.* For any polymer for which the review period has expired under paragraph (k) of this section, and for which a notice of commencement of manufacture has been submitted under § 720.102 of this chapter, EPA will add the substance to the Inventory. The substance will be identified on the Inventory by:

(1) The name of each reactant used at greater than 2 percent by weight in the manufacture of the polymer and by those reactants used at 2 weight percent or less as identified under paragraph (f)(2)(iv) of this section.

(2) The criteria identified in paragraph (d) (1) through (7) of this section.

(3) The information provided in paragraph (f)(2)(vi) of this section.

(4) For substances exempt under paragraph (e)(1) of this section, the minimum permissible number-average molecular weight of 1,000.

(p) *Actions under sections 5(e) and 5(f) of the Act.* EPA will act under section 5(e) or 5(f) of the Act on a substance submitted under paragraph (e) of this section if the Agency determines that the statutory criteria for such action are met.

(q) *Notification of Ineligibility*—(1) *During the period from notice submission until commencement of manufacture.* If at any time between submission of a notice under paragraph (f) of this section and commencement of manufacture of the new chemical substance described in the notice, the Director determines that the new chemical substance does not meet the terms of this section, the Director or his or her designee will immediately notify the manufacturer by telephone, and subsequently by certified letter, that the substance does not meet the terms of this section and will explain the reasons for the determination. After receiving notice of such a determination, the manufacturer may not begin to manufacture the new chemical substance without complying with section 5(a)(1) of the Act and Part 720 of this chapter.

(2) *After commencement of manufacture.* (i)(A) If at any time after commencement of manufacture of a chemical substance which was the subject of a notice under paragraph (f) of this section, the Director determines that the chemical substance being manufactured does not comply with the identification entered on the Inventory under paragraph (o) of this section and that the substance is not otherwise on the Inventory, the Director or his or her designee will notify the manufacturer by telephone, and subsequently by certified letter, that EPA believes that the new chemical substance is being manufactured in violation of this section.

(B) The manufacturer may continue to manufacture, process, distribute in commerce, or use the chemical substance after receiving notification under paragraph (q)(2)(i)(A) of this section if the manufacturer was manufacturing, processing, distributing in commerce, or using the substance at the time of telephone notification and if the manufacturer submits objections or an explanation under paragraph (q)(2)(ii) of this section. Manufacturers not manufacturing, processing, distributing in commerce, or using the chemical substance at the time of telephone notification may not begin such activity until EPA makes its final determination under paragraph (q)(2)(iii) of this section.

(C) If EPA brings an enforcement action under this section, the manufacturer will not be subject to penalty under section 15 of the Act for continuing commercial activity from the date of telephone notification under paragraph (q)(2)(i)(A) of this section through the date of notification under paragraph (q)(2)(iii) of this section.

(ii) A manufacturer which has received notice under paragraph (q)(2)(i) of this section may submit detailed objections to the determination or an explanation of its diligence and good faith efforts in attempting to comply with the terms of this section and with the identification of the substance on the Inventory, or both, within 15 days of receipt of the written notification.

(iii) The Director will consider any objections or explanation submitted under paragraph (q)(2)(ii) of this section, will make a final determination, and will notify the manufacturer of the final determination by telephone within 15 days of receipt of the objections or explanation, and subsequently by certified letter.

(iv) EPA may begin an enforcement action against the manufacturer if:

(A) The Director does not receive objections or an explanation within the 15 days specified in paragraph (q)(2)(ii) of this section.

(B) The Director determines, after considering the objections or explanation, that the chemical substance does not comply with the identification on the Inventory and is not otherwise on the Inventory and that the manufacturer did not act with due diligence and in good faith to comply with all of the terms of this section and with the identification of the substance on the Inventory.

(C) The Director makes the determination specified in paragraph (q)(2)(v) of this section, but the manufacturer continues manufacture of the new chemical substance without submitting a full notice under Part 720 of this Chapter as specified in paragraph (q)(2)(v) of this section.

(v) The Director may determine, after considering the explanation and objections, if any, that, while the chemical substance does not comply with the identification on the Inventory and is not otherwise on the Inventory, the manufacturer acted with due diligence and in good faith to comply with the terms of this section and the identification of the substance on the Inventory. If the Director makes such a determination, the manufacturer may continue manufacturing, processing, distributing in commerce, and using the new chemical substance if:

(A) It was actually manufacturing, processing, distributing in commerce, or using the chemical substance at the time it received the telephone notification specified in paragraph (q)(2)(i) of this section.

(B) It submits a full notice on the new chemical substance under section 5(a)(1) of the Act and Part 720 of this chapter within 15 days of receipt of the telephone notification under paragraph (q)(2)(iii) of this section. Such manufacture, processing, distribution in commerce, and use may continue unless EPA takes action under sections 5(e) or 5(f) of the Act.

(3) Action under this paragraph does not preclude action under sections 7, 15, 16, and 17 of the Act.

(r) *Recordkeeping.* (1) A manufacturer of a new polymer under paragraphs (e) (1) or (2), of this section must keep the records described in this paragraph for 5 years from the date of commencement of manufacture.

(2) The records must include the following to demonstrate compliance with the terms of this section:

(i) Records of production volume for the first 3 years of manufacture, the date of commencement of manufacture, and documentation of this information.

(ii) Documentation of any other information provided in the limited premanufacture notice, including:

(A) Information to demonstrate that the new polymer is not specifically excluded from the exemption.

(B) Information to demonstrate that the polymer meets the exemption criteria in paragraph (e) (1) or (2) of this section.

(3) The manufacturer must submit the records listed in paragraph (r)(2) of this section to EPA upon written request by the Director of the Office of Toxic Substances. The manufacturer must provide these records within 15 working days of receipt of this request. In addition, any person who manufactures a new chemical substance under the terms of this section, upon request of any officer or employee of EPA designated by the Administrator, must permit such person at all reasonable times to have access to and to copy these records.

(s) *Submission of information.* Information submitted to EPA under this section must be sent in writing to: Document Control Officer (TS–793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Room E–401, 401 M St., SW., Washington, D.C. 20460.

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

(2) A person who manufactures or imports a new chemical substance before a notice is submitted and the notice review period expires is in violation of section 15 of the Act.

(3) Using for commercial purposes a chemical substance or mixture which a person knew or had reason to know was manufactured, processed, or distributed in commerce in violation of section 5 or this rule is a violation of section 15 of the Act (15 U.S.C. 2614).

(4) Failure or refusal to establish and maintain records or to permit access to or copying of records, as required by this section and section 11 of the Act, is a violation of section 15 of the Act (15 U.S.C. 2614).

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

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

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

(u) *Inspections.* EPA will conduct inspections under section 11 of the Act to assure compliance with section 5 and this section, to verify that information submitted to EPA under this section is true and correct, and to audit data submitted to EPA under this section.

[FR Doc. 84–30427 Filed 11–20–84: 8:45 am]

BILLING CODE 6560–50–M

federal register

Wednesday
November 21, 1984

Part IV

Environmental Protection Agency

40 CFR Part 265

Interim Status Standards for Owners and Operators of Hazardous Waste Treatment, Storage and Disposal Facilities; Technical Amendment

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 265

[SWH-FRL 2656-8]

Interim Status Standards for Owners and Operators of Hazardous Waste Treatment, Storage and Disposal Facilities

AGENCY: Environmental Protection Agency.

ACTION: Technical Amendment.

SUMMARY: The Environmental Protection Agency is today promulgating a technical amendment to the interim status standards for owners and operators of hazardous waste facilities. This amendment merely clarifies the existing interim status standards regarding the applicability of requirements to facilities whose interim status is terminated. Today's amendment does not change any substantive requirements.

DATE: These amendments are effective December 5, 1984.

ADDRESS: Background material relating to this amendment is maintained by the Docket Clerk, Office of Solid Waste (WH-562), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460. The docket is available for viewing from 9:00 a.m. to 4:00 p.m., Monday thru Friday, excluding holidays.

FOR FURTHER INFORMATION CONTACT: The RCRA Hotline, toll-free at (800) 424-9346 or 382-3000 in Washington, D.C.; or Libby Scopino in the Office of Waste Programs Enforcement, U.S. Environmental Protection Agency, Washington, D.C., (202) 475-8731.

SUPPLEMENTARY INFORMATION: EPA has promulgated regulations implementing Subtitle C of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976, as amended (RCRA), 42 U.S.C. 6901 *et seq.*, establishing a comprehensive program for the handling and management of hazardous waste (40 CFR Parts 260-265, 270, 271, and 124). Pursuant to Section 3005(a) of RCRA, the regulations require owners or operators of hazardous waste management facilities to have a permit.

Recognizing that EPA would not be able to issue permits to all hazardous waste management facilities at once, Section 3005(e) of RCRA provides that a hazardous waste management facility that meets certain requirements will be treated as having been issued a permit. EPA refers to such an owner or operator as one who has interim status.

Section 3004 of RCRA requires EPA to promulgate performance standards applicable to owners and operators of facilities that treat, store or dispose of hazardous wastes. These Section 3004 standards are independently enforceable national standards which are separable from the Section 3005 permit/interim status provisions. See 45 FR 33158 (May 19, 1980).

EPA promulgated both Part 264 general permitting standards and Part 265 interim status standards under the authority of Section 3004. EPA has, by regulation, limited the requirements for facilities with interim status to those found in 40 CFR Part 265. See 40 CFR 270.71(b). Pursuant to § 265.1 of the RCRA regulations, the standards in Part 265 apply "during the period of interim status." These standards apply to owners and operators of hazardous waste facilities who have fully complied with the interim status requirements, "until final administrative disposition of their permit application is made." (§ 265.1(b)).

The wording of § 265.1(b) implies that once a facility's interim status is terminated the facility would no longer have to meet the Part 265 interim status standards including the closure, post-closure and financial responsibility requirements. However, EPA has the statutory authority under Section 3004 to enforce the Part 265 standards at facilities which no longer have interim status. Some sections of the regulations clearly reflect that authority. For example, the provisions in § 265.112(c) and § 265.118(c) clearly require facilities whose interim status has been terminated to meet certain Part 265 closure and post-closure requirements. Section 265.112(c) requires that,

> The owner or operator must submit his closure plan to the Regional Administrator at least 180 days before the date he expects to begin closure. The owner or operator must submit his closure plan to the Regional Administrator no later than 15 days after:
>
> (1) *Termination of interim status* (except when a permit is issued to the facility simultaneously with termination of interim status; (emphasis added))
>
> (2) Issuance of a judicial decree or order under Section 3008 of RCRA to cease receiving wastes or close.

Clearly, § 265.112(c) envisioned that facilities would submit closure plans for approval subsequent to the termination of the facilities' interim status.

Further, many of the other substantive requirements of Part 265 are clearly stated to be applicable until final closure of the facility is certified. For instance, § 265.147(e) requires that liability insurance be maintained by the owner or operator of a facility until the certification of final closure is received by the Regional Administrator. A facility's interim status may be terminated prior to certification of final closure. In those instances, the Agency requires the facility whose interim status has been terminated to maintain liability insurance in spite of the language in § 265.1.

As stated above, EPA believes that it has both the statutory and regulatory authority to apply the Part 265 standards to those facilities whose interim status has been terminated. However, in order to clarify the Part 265 standards, the Agency is amending Section 265.1 to state specifically that the Part 265 requirements apply to an interim status facility until either a permit is issued under Section 3005 of RCRA or until all applicable Part 265 closure and post-closure responsibilities are fulfilled.

Good Cause Exception

This technical amendment is published without prior notice and comment because the Agency believes that such notice and comment is unnecessary pursuant to the good cause exception in the Administrative Procedures Act, 5 U.S.C. Section 553(APA). Today's amendment merely clarifies an existing Agency rule and as such is a routine, insignificant technical amendment. The impact of the amendment on the public is insignificant because the amendment does not impose any new substantive requirements. It merely codifies the already implied requirement that owners and operators of facilities whose interim status is terminated must comply with the applicable Part 265 standards until final closure and post-closure responsibilities are fulfilled.

Effective Date

RCRA Section 3010(b) provides that regulations and amendments to regulations under RCRA take effect six months from the date of promulgation. The purpose of this requirement is to allow sufficient lead time for regulated communities to prepare for compliance with major new regulations. Section 553(d) of the Administrative Procedures Act (APA) prohibits "publication or service of a substantive rule . . . less than 30 days before its effective date except for good cause."

For the amendment proposed today, EPA believes that an effective date six months or 30 days after promulgation would be unnecessary. These amendments simply clarify existing regulatory language and do not impose any new substantive requirements. Therefore, the Agency finds that there is

good cause that this amendment be effective two weeks after publication.

Compliance With Executive Order 12291

Under Executive Order 12291, EPA must judge whether a regulation is "major" and therefore subject to the requirement of a Regulatory Impact Analysis. This proposed regulation is not major because it will not result in an effect on the economy of $100 million or more, nor will it result in an increase in costs or prices to industry. There would be no adverse impact on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. Because this amendment is not a major regulation, no Regulatory Impact Analysis is being conducted.

These amendments were submitted to the Office of Management and Budget for review as required by Executive Order 12291. Any comments from OMB to EPA and any response to those comments are available for viewing at the Office of Solid Waste Docket, Room S269–C, U.S.E.P.A., 401 M Street, SW., Washington, D.C. 20460.

Paperwork Reduction Act

There is no recordkeeping or reporting burden associated with today's action.

Regulatory Flexibility Act

The Regulatory Flexibility Act requires that Federal Agencies prepare regulatory flexibility analyses assessing the impacts of proposed rules on entities such as small businesses, small organizations, and small governmental jurisdictions. Such an analysis is not required, however, when the head of an Agency certifies that a proposed rule will not have a significant economic impact on a substantial number of small entities.

I find that today's proposal, if promulgated, would have no impact on small entities because it does not impose any additional substantive requirements. Accordingly, I certify that this amendment will not have a significant impact on a substantial number of small entities.

List of Subjects in 40 CFR Part 265

Hazardous materials, Packaging and containers, Reporting and recordkeeping requirements, Security measures, Surety bonds, Waste treatment and disposal, Water supply.

Dated: October 25, 1984.

William D. Ruckelshaus,

Administrator.

PART 265—[AMENDED]

40 CFR Part 265 is amended as follows:

§ 265.1 [Amended]

1. Section 265.1 (a) is revised to read as follows:

(a) The purpose of this part is to establish minimum national standards that define the acceptable management of hazardous waste during the period of interim status and until certification of final closure or, if the facility is subject to post-closure requirements, until post-closure responsibilities are fulfilled.

2. Section 265.1(b) is revised to read as follows:

(b) The standards of this part apply to owners and operators of facilities that treat, store or dispose of hazardous waste who have fully complied with the requirements for interim status under Section 3005(e) of RCRA and § 270.10 of this Chapter until either a permit is issued under Section 3005 of RCRA or until applicable Part 265 closure and post-closure responsibilities are fulfilled, and to those owners and operators of facilities in existence on November 19, 1980 who have failed to provide timely notification as required by Section 3010(a) of RCRA and/or failed to file Part A of the permit application as required by 40 CFR 270.10 (e) and (g). These standards apply to all treatment, storage and disposal of hazardous waste at these facilities after the effective date of these regulations, except as specifically provided otherwise in this Part or Part 261 of this Chapter.

Comment: As stated in Section 3005(a) of RCRA, after the effective date of regulations under that Section (i.e., Parts 270 and 124 of this Chapter), the treatment, storage and disposal of hazardous waste is prohibited except in accordance with a permit. Section 3005(e) of RCRA provides for the continued operation of an existing facility that meets certain conditions, until final administrative disposition of the owner's and operator's permit application is made.

(Secs. 1006, 2002(a), 3004, and 3005 of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976, as amended, 42 U.S.C. 6905, 6912(a), 6924, 6925)

[FR Doc. 84–29121 Filed 11–20–84; 8:45 am]

BILLING CODE 6560–50–M