

SNUR notice submitters were small firms, the number of small businesses affected by this rule will not be substantial.

C. Paperwork Reduction Act

There is no additional reporting burden associated with this amendment. The information collection requirements in this rule have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3502 et seq., and have been assigned OMB control number 2070-0012.

List of Subjects in 40 CFR Part 721

Chemicals, Environmental protection, Hazardous materials, Recordkeeping and reporting requirements, Significant new uses.

Dated: March 21, 1995.

Carol M. Browner,
Administrator.

Therefore, 40 CFR Chapter I, part 721 is amended as follows:

PART 721 — [AMENDED]

1. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

2. By revising §721.170(c)(1) to read as follows:

§721.170 Notification requirements for selected new chemical substances that have completed premanufacture review.

* * * * *

(c) * * *

(1) When EPA decides to establish significant new use reporting requirements under this section, EPA may designate as a significant new use any one or more of the activities set forth in subpart B of this part. In addition, EPA may designate specific recordkeeping requirements described under subpart C of this part that are applicable to the substance.

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[FR Doc. 95-7710 Filed 3-24-95; 3:32 pm]

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40 CFR Part 723

[OPPTS-50594B; FRL-4929-8]

RIN 2070-AC14

Premanufacture Notification Exemptions; Revisions of Exemptions for Polymers; Final Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is promulgating amendments to the polymer exemption rule to expand the exemption criteria and exempt manufacturers of eligible polymers from certain section 5 premanufacture notification (PMN) requirements. EPA has determined that the manufacture, processing, distribution in commerce, use, and disposal of new chemical substances meeting the revised polymer exemption criteria will not present an unreasonable risk of injury to human health or the environment under terms of the exemption. These final amendments reflect criteria developed and used by EPA to assess the hazards associated with new polymeric substances over the past 15 years the New Chemicals Program has been in place. EPA believes that these amendments will encourage the manufacture of safer polymers by reducing industry's reporting burden for this category of chemical substances.

DATES: This rule will become effective May 30, 1995. In accordance with 40 CFR 23.5 (50 FR 7271), this rule shall be promulgated for purposes of judicial review at 1 p.m. eastern time on April 12, 1995.

FOR FURTHER INFORMATION CONTACT: James B. Willis, Acting Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Telephone: (202) 554-1404; TDD: (202) 554-0551.

SUPPLEMENTARY INFORMATION: The polymer exemption rule was originally promulgated on November 21, 1984. The supporting rationale and background for that exemption was published at 49 FR 46066 on November 21, 1984 and 46 FR 54688 on November 3, 1981. On February 8, 1993, EPA proposed amendments to the 1984 polymer exemption rule (58 FR 7679). Consult those documents for further information on the objectives, rationale, and procedures for the rule and the basis for the finding that polymers eligible for exemption will not present an unreasonable risk of injury to human health and the environment under terms of the exemption. The docket control number for this document is OPPTS-50594B.

The amended rule allows manufacture and distribution of polymers meeting the exemption criteria without submission of a PMN or an exemption notice prior to commencement of manufacture for a commercial purpose under terms of the exemption. However, manufacturers of

exempted polymers are required to submit an annual report on exempted polymers for which manufacture or importation commenced for the first time under terms of the exemption during the preceding calendar year. Recordkeeping requirements are retained as part of the rule to document compliance with the exemption criteria. Overall, these amendments constitute a substantial revision of the existing polymer exemption rule.

I. Background

A. Statutory Authority

Section 5(a)(1) of TSCA requires that persons notify EPA at least 90 days before they manufacture or import a new chemical substance for commercial purposes. A "new chemical substance" is any substance that is not on the Inventory of Chemical Substances compiled by EPA under section 8(b) of TSCA. Section 5(h)(4) of TSCA authorizes EPA, upon application and by rule, to exempt the manufacturer or importer of any new chemical substance from part or all of the provisions of section 5 if the Agency determines that the manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance will not present an unreasonable risk of injury to human health or the environment. In this preamble and under the rule, references to "manufacture" and "manufacturer" include "import" and "importer", respectively, as defined in TSCA section 3 and the PMN rule.

B. History/Rationale

In 1984, the Agency published a TSCA section 5(h)(4) rule granting an exemption for persons who manufacture or import certain polymers, set forth at 40 CFR 723.250. Since promulgation of the 1984 polymer exemption rule (the "1984 exemption"), the Agency has reviewed over 2,000 polymers submitted as polymer exemption notices in the 21-day review process in addition to over 10,000 polymers submitted as PMNs since the initiation of the 90-day PMN review process in 1979. In the course of performing hazard and risk assessments for these polymers, the Agency has developed internal guidelines for identifying polymeric substances that do not present an unreasonable risk of injury to human health or the environment. These guidelines are based on (1) EPA's ongoing review of the available literature on the toxicity of polymers, (2) EPA's analyses of various samples of the PMN polymer data base, (3) information provided to EPA by outside groups

during and subsequent to development of the 1984 exemption, and (4) professional judgment of EPA staff scientists. The final rule will bring the 1984 polymer exemption criteria into close alignment with the internal criteria currently being used by EPA to assess hazards and risks of polymers. The eligibility criteria in the final rule, which are based on the 1984 polymer exemption criteria, have been refined and expanded to allow more low-risk polymers to qualify for exemption. While expanding the category of safer polymers, the exemption continues to exclude or restrict those polymers that the Agency believes should be reviewed under the 90-day PMN process.

Both the Agency and the polymer industry have had 10 years of practical experience with the polymer exemption. Since the current exemption criteria define what the Agency considers to be low-risk polymers, eligible polymers generally receive only a cursory Agency review to validate that the polymer meets the eligibility criteria. Consequently, most polymers eligible for the exemption present no issues and manufacture can commence when the 21-day review period expires.

Based on the Agency's review and analysis of polymer exemption applications submitted to date, EPA has determined that an overwhelming number of submitters correctly determined the eligibility status of the polymer. Consequently, the Agency believes that it is no longer necessary for EPA to expend its limited resources to validate a polymer's eligibility under the exemption. The Agency would like to shift the resources currently expended on analytical screening of this class of low-risk substances to the substantive review of substances that present unknown or potentially higher risks. Moreover, the Agency believes that industry has become sufficiently familiar with the criteria over the past 10 years and is capable of correctly determining the eligibility of a polymer under the exemption. Therefore, EPA has decided to eliminate the requirement that a company submit an exemption application prior to the manufacture or importation of an exempted polymer under terms of the exemption. Instead, the final rule requires submission of an annual report on polymers for which manufacture or importation under terms of the exemption commenced for the first time during the preceding calendar year. However, to increase the level of assurance that polymers manufactured under the exemption meet the eligibility criteria, EPA has prepared a draft technical guidance document and will

hold workshops on determining eligibility of exempted polymers for polymer manufacturers. In addition, the final rule requires that records documenting an exempted polymer's eligibility under terms of the exemption be maintained at the manufacturing site.

The Agency believes that expanding the 1984 exemption criteria and eliminating routine EPA review will increase the number of polymeric substances eligible for exemption, encourage the manufacture of safer polymers, and result in resource savings to industry and the EPA without decreasing or compromising the level of risk reduction/management afforded by a 21-day or 90-day review of these same substances.

II. Final Amendments

A. Summary of Final Amendments

1. *Definition of polymer.* To be considered for exemption, substances must meet the definition of polymer in the rule. EPA is amending the definition of "polymer" to adopt the exact wording of the internationally recognized definition of polymer which was developed at the Organization of Economic Cooperation and Development (OECD) Expert Group Meetings on Polymers held in Toronto, Canada (January, 1990), Paris, France (October, 1991), and Tokyo, Japan (April, 1993) and agreed upon in May, 1993 by the OECD Member Countries. (Copies of the OECD Chairperson's reports are available in the docket for this rulemaking.) The definition, which is based on the Agency's 1984 polymer definition at 40 CFR 723.250, ensures that exempt substances have the structural characteristics common to the category of substances on which EPA has based its no unreasonable risk finding. Minor revisions are included in the definition in response to comments.

2. *Classes of polymers ineligible for exemption.* Section 723.250(d) of the 1984 exemption established certain classes of polymers that were ineligible for exemption. As with the 1984 exemption, polymers that are designed or reasonably anticipated to substantially degrade, decompose, or depolymerize will remain ineligible for exemption in this final rule. In addition, polymers that are prepared from monomers or other reactants that are included in the polymer identity must be existing chemical substances on the TSCA Inventory or otherwise excluded or manufactured under terms of another TSCA section 5 exemption. The final rule excludes from eligibility water-absorbing polymers with molecular weights (MW) equal to or greater than

10,000 daltons; moreover, the term "water-absorbing" has been re-defined to describe more specifically the category of polymers that the Agency believes should remain subject to the full PMN review process. The final rule also amends certain restrictions contained in the 1984 exemption for cationic polymers and polymers that contain certain elements. Restriction on polymers that contain certain reactive functional groups have been amended and are part of the eligibility criteria for polymers with MW equal to or greater than 1,000 and less than 10,000 daltons (§720.250(e)(1)).

3. *Polymers eligible for the exemption.* Polymers with number-average MW greater than 1,000 daltons and polyesters that are made from a specified list of reactants remain eligible for exemption. The final rule sets limits on oligomer content and reactive functional groups for polymers with number-average MW equal to or greater than 1,000 and less than 10,000 daltons. In addition, polymers with number-average MW equal to or greater than 10,000 daltons and restricted oligomer content are also eligible for exemption. In the 1993 proposal, the Agency requested comment on its proposal to impose certain restrictions relating to potential inhalation exposure of respirable water-insoluble polymer particles, along with several alternatives for dealing with potential lung effects associated with the inhalation of water-insoluble particles of respirable size. Based on comments and further analysis of the available data, the Agency has removed the restrictions on water-insoluble polymers with MW of 10,000 daltons or greater, with the exception of water-absorbing polymers which are ineligible for exemption.

Polyesters remain eligible as in the current exemption; however, in response to comments that the Agency should expand the category of polyester polymers eligible for exemption, the final rule includes a number of additional substances in the list of acceptable polyester reactants.

Finally, the following classes of polymers are now eligible for exemption: (a) polymers that contain less than 32 percent carbon; (b) biopolymers, their synthetic equivalents, and modifications and derivatives of biopolymers; and (c) polymers made from reactants that contain halogen atoms or cyano groups.

4. *General provisions.* In the 1993 proposal, manufacturers and importers would have been required to submit an abbreviated notice within 30 calendar days following the first manufacture or import of an eligible polymer rather

than 21 days prior to manufacture (import) as required in the 1984 exemption. However, the final rule further modifies the notification provisions and now requires only that manufacturers of exempt polymers submit an annual report on all exempted polymers for which manufacture or importation under terms of the exemption commenced for the first time during the preceding calendar year. This annual report would provide the Agency with information concerning use of the exemption. Manufacturers are required to maintain specific records to document a polymer's eligibility under the exemption rule.

With the elimination of the obligation to notify EPA in advance of manufacture of an exempted polymer, the use of EPA Form 7710-25 will not be required. However, the final rule requires that certain information be maintained at the site of manufacture including chemical identity and structure, records of production volume for the first 3 years of manufacture, date of commencement of manufacture or import, certification that the polymer meets the conditions of the exemption, and information that demonstrates compliance with the exemption, including analytical data or other information that substantiates the manufacturer's claim of eligibility under criteria established for minimum number average MW and restricted oligomer content.

EPA proposed but is not requiring that polymer identity be described by a Chemical Abstracts (CA) Index Name or CA Preferred Name, since manufacturers are not required to submit an exemption notice to the Agency under the final rule. Finally, the Agency has determined, for the reasons outlined in the discussion below, that the revocation provisions in the 1993 proposal are not necessary for the Agency to make its determination that this category of substances will not present unreasonable risk to human health and the environment and has deleted these provisions in their entirety.

B. Discussion of the Amendments and Response to Comments

The final rule adopts many of the proposed amendments without changes. However, as indicated above, certain provisions of the proposed amendments have been revised in light of the Agency's consideration of comments received. A discussion of the major comments, the Agency's responses, and the amended provisions follow:

1. *Definition of polymer.* Under the proposal, EPA proposed to revise the definition of polymer in the 1984

exemption to conform with the international definition of polymer recently adopted by OECD Member Countries, including the United States, Canada, Japan, and the member nations of the European Union. The revised definition retains the meaning and purpose of the 1984 exemption definition of polymer. For purposes of this exemption, the term "polymer" means "a chemical substance consisting of molecules characterized by the sequence of one or more types of monomer units and comprising a simple weight majority of molecules containing at least 3 monomer units which are covalently bound to at least one other monomer unit or other reactant and which consists of less than a simple weight majority of molecules of the same molecular weight. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units."

The term "monomer unit," which replaces the non-standard term "internal subunit" used in the 1984 exemption, means the reacted form of the monomer in a polymer, i.e., the monomer must have formed at least one covalent bond with another like or unlike molecule under the conditions of the relevant polymer-forming reaction. The fact that a monomer must be capable of forming two or more such bonds is not a requirement that it do so to be considered "the reacted form;" one is sufficient. Consequently, "polymer molecules," defined as containing "at least 3 monomer units which are covalently bound to at least one other monomer unit or other reactant," continue to require at least 4 precursor units, as in the 1984 definition. The difference is that, under the proposal, at least 3 of the units must be in a "sequence," and further, one of the groupings could come from an "other reactant" as well as from a monomer. The first change ("sequence") is slightly more restrictive and the second ("other reactant") slightly less restrictive than the present definition. The net effect of the change, made to be consistent with protocols of the OECD, is expected to be minimal. The term "sequence" is defined as part of the polymer definition in the final rule. "Monomer" and "reactant" remain consistent with the terms used for purposes of Inventory reporting and premanufacture notification, wherein "reactants" include monomers, chain transfer and cross-linking agents, monofunctional groups that act as modifiers, and other

end groups if incorporated into the polymer molecule.

Comment. The Society of the Plastics Industry (SPI) commented that the new polymer definition should be clear and complete. By using wording that strays from the OECD definition, EPA has rendered its definition unclear and made interpretation difficult. The definition of "polymer molecule" that uses the term "monomer unit" cannot be equated with the earlier definition that used "internal subunit" because a "monomer unit" does not have to be internal. The term "polymer molecule" defined at §723.250(b), requiring at least two internal monomer units, is in conflict with the statement in the preamble that "at least three of the units must be internal."

Response. The polymer definition in the proposed rule represents a version proposed before an OECD meeting held in April 1993 in which the participants agreed upon an interpretation of the polymer definition. (The definition of the term "polymer molecule", which is responsible for some of the confusion, was introduced to assist in defining "polyester," which is not relevant to the OECD definition of polymer.) EPA has therefore made changes in the relevant provisions of the rule.

Comment. SPI commented that the definition of "reactant" is inconsistent with the definition of "reactive functional group" and is problematic because of EPA's dependence on subjective intent; it recommends that the language "reasonably be anticipated" and "reasonably ascertainable" be used instead of depending on intent.

Response. The Agency does not believe there is an inconsistency between the definitions, nor any particular reason why they should be consistent, since they are describing different things and addressing different issues. Sodium hydroxide may be a reactant, but it can hardly be a reactive functional group. Furthermore, many chemically reactive substances are not "reactants" in this context because they are not intended (or reasonably anticipated) to become chemically part of the polymer.

2. *Polymers ineligible for exemption—*
(a) *Exclusion of certain polymers that are cationic or anticipated to become cationic in aquatic environments.* The Agency continues to have ecotoxicity concerns for cationic polymers with specific characteristics but believes that certain restrictions in the 1984 exemption can be modified as discussed in the 1993 proposal. No comments were received on this provision. Accordingly, under the final rule, the

current restriction on cationic polymers at §723.250(d)(1) is amended to provide that certain cationic polymers will be eligible for exemption if:

(i) The polymer is a solid material that is not soluble or dispersible in water and will be used only in the solid phase (e.g., polymers that will be used as ion exchange beads), or

(ii) The combined (total) functional group equivalent weight of cationic groups (e.g., primary, secondary and tertiary amines, quaternary ammonium, phosphonium, and sulfonium) in the polymer is equal to or greater than 5,000. "Equivalent weight" of a functional group means the ratio of the molecular weight to the number of occurrences of that functional group in the molecule. It is the weight of substance that contains one formula-weight of the functional group. In addition, the definition of "cationic polymer" was rephrased in the final rule to replace the term "subunit," which as discussed previously in this unit under Definition of Polymer is considered a non-standard term.

(b) *Exclusion of polymers with certain weight content of certain elements.* The rule continues to exclude from eligibility polymers containing certain levels of particular elements from the exemption if the elements are present as an integral part of the polymer structure, or present as counterions in the polymer. However, as proposed, the Agency is expanding the list of allowable elements set forth at §§723.250(d)(2)(ii)(B) and (C) to include chlorine, bromine, and iodine as the monatomic counterions; and fluorine, chlorine, bromine, and iodine as covalently bound to carbon. The Agency received no comments on this specific provision.

(c) *Exclusion of polymers that degrade, decompose, or depolymerize.* The rule continues the exclusion at §723.250(d)(3) for polymers that are designed or reasonably anticipated to substantially degrade, decompose, or depolymerize, including those polymers that could substantially decompose after manufacture and use, even though they are not actually intended to do so. A description of what the Agency considers degradation, decomposition and depolymerization for purposes of this exemption is contained in the final rule. No specific comments were received on this provision.

(d) *Exclusion of polymers that are prepared from monomers or other reactants that are not already on the TSCA Inventory.* As proposed, polymers that are manufactured using monomers or other reactants that are not on the TSCA Inventory, or that are not

manufactured under an applicable section 5 exemption are not eligible for exemption at §723.250(d)(4). Some confusion surrounded the Agency's position on the use of non-Inventory listed monomers or other reactants at levels of 2 percent or less, as evidenced at the public hearing on the proposed rule held in Washington, D.C. on April 26-27, 1993 and written comments on this proposal. EPA is making clear that this provision relates specifically to monomers or other reactants that would be considered part of the polymer's identity, if the same substance was reported in a PMN, i.e., those substances charged to the reaction vessel or incorporated in the polymer at levels greater than 2 percent. The provision will not restrict the use of non-Inventory listed reactants that are not considered part of the polymer identity, provided that those reactants do not introduce into the polymer elements, properties, or functional groups that would render the polymer ineligible for the exemption. In other words, the "two percent rule" affects only the identity of the polymer, not its eligibility. This is consistent with the 1984 exemption. However, in practice, the use of non-Inventory listed monomers or reactants at 2 percent or less may be applicable only to imported polymers since chemical substances used as feedstocks in domestic manufacture must be on the Inventory or otherwise excluded or exempted from the section 5 requirements. In a separate rulemaking being published concurrently with this document [Revisions of Premanufacture Notification Regulations], EPA amended the "Two Percent Rule" to allow submitters greater flexibility in determining the amount of monomer or other reactant used in the manufacture of a polymer. Please consult that rule for further information.

As stated in the proposal, hazard concerns for polymers are often based on a concern for residual monomers or other reactants in the polymer. Since residual levels of monomers or other reactants are not restricted under the exemption and EPA is not reviewing exempt polymers, the Agency is restricting this exemption to those polymers manufactured using only Inventory-listed (or otherwise excluded or manufactured under an applicable section 5 exemption) constituent monomers or other reactants that are part of the polymer's chemical identity. This ensures that the Agency will review polymers that contain new chemical monomers or other reactants through the full PMN process and can regulate any new polymer that may

cause concern as a result of residual monomers or reactants that are new chemical substances.

Comment. The Synthetic Organic Chemical Manufacturers Association (SOCMA), The Dow Chemical Company (Dow), Monsanto Company, and SPI commented that imported polymers should be treated as polymers produced in the United States. That is, if the imported polymer meets the polymer exemption criteria but contains a non-Inventory listed monomer or reactant (at greater than 2 percent), that polymer should be eligible for the polymer exemption as long as the residual monomer or reactant level is kept below 1 percent (0.1 percent if a carcinogen). The importer may have no reason to ever bring the monomer or other reactant into the United States, and thus no PMN would be filed on that material. This would reduce the burden on those companies importing polymers that meet the exemption criteria since PMNs would not have to be filed for the monomers that these polymers contain. The residual monomer level limit would address any potential risk to health and the environment.

Response. Imported polymers are being treated the same under this exclusion as polymers manufactured in the United States. As stated above, the Agency wants to be able to assess new monomers and reactants if present as residuals. Further, the Agency has not considered setting a specific level for residuals nor concluded that polymers made with presently unknown monomers (i.e., chemicals not on the Inventory or exempted) will not present an unreasonable risk to health or the environment.

(e) *Exclusion of water-absorbing polymers with number-average MW equal to or greater than 10,000 daltons.* The final rule excludes from the exemption water-absorbing polymers having MW of 10,000 daltons or greater (§723.250(d)(5)). In the proposal, EPA had defined a water-absorbing polymer as a polymeric substance that, either in whole or in part, increases its volume when in contact with water. Numerous comments were received by the Agency concerning this definition and the MW restriction. Commenters argued that this restriction represented a very narrow approach by the Agency since it was based on the TSCA section 8(e) study, designated 8(e)-1795 and FYI-470, on a water-absorbing polyacrylate polymer with a MW in excess of 1 million daltons. The section 8(e) data on the toxicity of the water-absorbing polyacrylate polymer included a 1-year chronic inhalation study, a 2-year chronic/oncogenicity study, and a

subchronic inhalation study. As discussed in the 1993 proposal, preliminary data from the 2-year chronic inhalation study reported squamous cell carcinoma and bronchioalveolar carcinomas. The exposure concentrations were 0.05, 0.2, and 0.8 mg/m³. Preliminary pathology reports state that cancer was observed in the two highest concentrations. Since the 1993 proposal, the final report on the 2-year chronic inhalation study has been received and reviewed by the Agency. The final report confirms the preliminary conclusions that under the conditions of the study, the water-absorbing polyacrylate polymer was carcinogenic to F344 rats, inducing lung tumors (bronchiolar/alveolar adenomas and adenocarcinomas) in both males and females. Statistically significant increased incidences of lung tumors were seen in both male and female rats exposed to 0.8 mg/m³ of the polymer. The tumor incidences in males and female rats also showed significant trends as analyzed using the Logistic Regression Test. At the present time published Agency guidelines state that cancer may be a non-threshold effect, i.e., that dose is cumulative over a lifetime (see Guidelines for Carcinogen Risk Assessment, 51 FR 33998, September 24, 1986 and Risk Assessment Guidelines of 1986, Document No. EPA/600/8-87/045). Consequently, EPA has excluded such polymers from the exemption and will review them in the full PMN process to ensure that they do not present an unreasonable risk of injury to human health or the environment. The subject polymer evaluated in the study has no reactive functionalities and no residuals below 1,000 daltons, conditions which might have excluded it from this exemption, and, if present, could have played a role in the reported carcinogenicity. In the absence of these factors, the Agency concluded that the water-absorbing properties of the polymer may have played a role in the reported carcinogenicity findings. The Agency intends to keep abreast of the scientific findings related to the inhalation toxicity of water-absorbing high MW polymers, which for purposes of this rule means polymers with MW equal to or greater than 10,000 daltons, and will consider modifying these conclusions as the data so warrant.

The Agency examined more closely its own databases to determine the MW range for water-absorbing polymers and their water-absorbing capabilities. The polymer that was the subject of the section 8(e) report is a so-called "super absorbent" material of the type used

primarily in applications such as disposable diapers and paper towels. It is the Agency's understanding that to be applicable for these types of uses, the polymers must absorb at least 60 - 100 times their weight of water. The Agency also has observed that these polymers have molecular weights (MW) in the 1 million dalton range. The Agency recognizes that although many other high MW polymers absorb water to some extent, they do not belong to the class identified as "super absorbent." To the Agency's knowledge, data showing adverse lung effects which include oncogenicity do not exist on other than the single high MW "super absorbent" type polymer that was the subject of this section 8(e) study. Based on the review of this polymer, the Agency, at this time, is still unable to establish an exact MW limit for water-absorbing polymers likely to cause effects similar to those reported in the section 8(e) study, but believes that it is reasonable to set the number-average MW exclusion for water-absorbing polymers at 10,000 daltons. Based on EPA's professional judgment, the Agency believes that a MW of 10,000 daltons is a reasonable value where absorption is slow enough that a compound can be considered to persist in the lung. In addition, this MW is two orders of magnitude less than the MW of the tested polymer. The Agency believes that polymers with a number-average MW less than 10,000 daltons, in general, can be expected to be absorbed by the lung and therefore have different detoxification mechanisms available to mitigate potential health hazards.

In response to comments requesting a definition of "water absorbing" that more accurately bounds the category of polymers of concern, EPA has defined a "water-absorbing polymer" as a polymer that is capable of absorbing its weight of water. Although the tested polyacrylate polymer absorbs 100 times its weight of water, the Agency lowered the threshold for exclusion in this rule to "absorbing its weight of water", a threshold which is 2 orders of magnitude less than that of the tested polymer. The hundredfold difference in water absorption is believed to be appropriate based in part on the limited data, duration of the studies, effects noted, dose levels at which effects were seen, extrapolation from animal to humans, and the professional judgment of EPA experts.

Comment. Monsanto comments that the definition of water-absorbing is entirely too broad. Nearly all polymers will absorb some minute amount of water which will alter its volume if the measurements are precise enough. A better approach might be to exclude from the exemption polymers that will

absorb more than 20 percent of their weight of water.

Response. The Agency agrees that the definition in the proposal, which defined a water-absorbing polymer as any polymeric substance that, either in whole or in part, increases its volume when in contact with water, was too broad and has narrowed the definition.

Comment. 3M states that the water-absorbing exclusion is based on a single section 8(e) report on a polyacrylate polymer with a MW of greater than 1 million daltons. While 3M understands the Agency's desire to develop an excluded class with an apparent safety factor in terms of MW, the company asks EPA to better define water-absorbing and review industry and scientific data to restrict the exclusion to water-absorbing polymer classes and MW ranges of true concern.

Response. As discussed above, based on the limited data received by EPA, the Agency was unable to establish an exact MW limit but believes it is reasonable to set the MW exclusion at 10,000 daltons.

3. *Elimination of specific exclusions contained in the 1984 exemption.* No comments were received on the Agency's proposal to remove three of the exclusion criteria present in the 1984 exemption including (a) polymers containing less than 32 percent carbon, (b) biopolymers, and (c) polymers manufactured from reactants containing halogen atoms or cyano groups. Therefore, these restrictions have been deleted from the final rule as proposed. Further discussion of this issue is contained in the proposed rule.

4. *Exemption criteria.* The Agency is amending the exemption criteria for polymers with MW of 1,000 daltons or greater by establishing two MW ranges with restricted oligomer content. Section 723.250(e)(1) sets out exemption criteria for polymers with number-average MW equal to or greater than 1,000 and less than 10,000 daltons, while §723.250(e)(2) sets out criteria for polymers with number-average MW equal to or greater than 10,000 daltons. The exemption criteria for polyester polymers manufactured using certain specified precursors have been retained and redesignated at §723.250(e)(3).

Under the final rule, polymers eligible for exemption include the following:

a. *Polymers with number-average MW equal to or greater than 1,000 and less than 10,000 daltons.* Section 723.250(e)(1) exempts polymers with number average MW equal to or greater than 1,000 and less than 10,000 daltons (and oligomer content less than 10 percent below MW 500 and less than 25 percent below MW 1,000) provided the polymer

also meets the following criterion: the polymer can not contain reactive functional groups except as specified in paragraph (e)(1)(ii).

i. *Restrictions on number average MW and oligomer content.* As discussed in the proposal, a chemical must be absorbed by an organism in order to cause an adverse health or ecological effect, other than direct contact effects; further, the ability of a molecule to pass through membranes and therefore be absorbed by organisms generally decreases with increasing MW (size).

Based on these principles, the Agency concluded that low MW species content provides an appropriate indication of the concerns that EPA has for polymers, namely, the content of potentially absorbable low MW compounds. As was proposed, the final rule includes restrictions on the percentage of low MW components directly derived from the monomers or other reactants for §723.250(e)(1) polymers. The criterion requires that oligomer content be less than 10 percent below MW 500 and less than 25 percent below MW 1,000.

Under the final rule, companies are free to manufacture any exempted polymer with any residual reactant content desired, as long as the percentages of low MW species do not exceed the levels specified in the exemption criteria.

Comment. SPI commented that number-average MW is a poor criterion for determining the amount of low MW oligomers present, and that the weight percentages of material with MW below 500 and 1,000 daltons are a better indicator of concern.

Response. While the Agency agrees that the number-average MW is by itself a less than perfect measure of the amount of low MW species present, a high statistical correlation of the two values was established by EPA in the course of preparing the criteria for the 1984 exemption, and EPA's experience since then has reinforced the correlation. In addition, the most frequently used method for determining the number-average MW, size-exclusion chromatography, also yields the percentages of material in given MW ranges. It should also be noted that because the Agency has concerns for possible lung effects associated with certain water-absorbing polymers with MW greater than 10,000 daltons, determination of number-average MW is needed for more than one criterion.

ii. *Allowable reactive functional groups.* The final rule excludes from eligibility under the §723.250(e)(1) criterion certain polymers that contain reactive functional groups (groups that are intended or can reasonably be

anticipated to undergo further reaction). The final rule also amends certain restrictions in the 1984 exemption.

As discussed in the proposal, polymers that contain reactive functional groups may be capable of reacting with tissues or other chemical constituents of living organisms. Absorption of polymers containing reactive functional groups is also plausible since reactive groups can cause sufficient irritation to disrupt normal cell membrane barriers and facilitate penetration.

There are no restrictions on polymers containing certain reactive functional groups that generally lack reactivity in biological settings. Under §723.250(e)(1)(ii)(A), polymers containing only the following reactive functional groups remain eligible for the exemption without restrictions on equivalent weight: carboxylic acid groups, aliphatic hydroxyl groups, unconjugated olefinic groups that are considered "ordinary" (i.e., not specially activated either by being part of a larger functional group, such as a vinyl ether, or by other activating influences, for example, strongly electron-withdrawing sulfone group with which the olefinic groups interact), butenedioic acid groups, and conjugated olefinic groups in naturally-occurring fats, oils, and carboxylic acids.

Certain other functional groups are also implicitly permitted. Obviously, carboxylic esters, ethers, amides, urethanes, and sulfones are among them, although not listed above, because polyesters, -ethers, -amides, -urethanes, and -sulfones are among the types of polymers allowed under the exemption. As long as these groups have not been modified to enhance their reactivity (for example, dinitrophenyl esters of carboxylic acids would be considered reactive; see also the related discussion of "ordinary" above), they are assumed not to be reactive. Please consult the draft technical guidance document for further discussion of this issue.

Further, as discussed in the proposal, EPA believes that the following groups generally lack or have low reactivity in biological settings and has therefore included them in §723.250(e)(1)(ii)(A): blocked isocyanates (including ketoxime-blocked isocyanates), thiols, unconjugated nitrile groups, and halogens (except reactive halogen-containing groups such as benzylic or allylic halides).

iii. *Allowable equivalent weights for other reactive functional groups.* In the 1984 exemption, the Agency established equivalent weight criteria which allowed low concentrations of reactive functional groups to be present in the

polymer molecules. At that time EPA believed that a level of less than 1 gram-formula weight of reactive functional groups in 10,000 grams of polymer was sufficient to ensure that the reactive functional group was substantially diluted by polymeric material. Based on the Agency's experience in reviewing polymers since the 1984 exemption was promulgated, EPA now believes that the reactive functional group equivalent weight can be lowered accordingly, because of EPA's lower level of concern. For example, data generated by companies through the PMN program (either as section 5(e) testing or via voluntary programs) and reviewed by EPA now indicate that epoxy resins with epoxide equivalent weights greater than 800 are negative in the Ames assay; and numerous so-called "engineering" plastics containing substantial concentrations of anhydride functional groups derived from maleic anhydride are essentially inert to water and other reagents that might ordinarily react with them by virtue of the overall insolubility and hydrophobicity of the polymer. The final rule establishes equivalent weights of 1,000 and 5,000 daltons for specific reactive functional groups, as discussed below.

Section 723.250(e)(1)(ii)(B) sets forth allowable equivalent weights at 1,000 for the combined weight of certain polymer reactive functional groups (other than those of lower concern identified in §723.250(e)(1)(ii)(A), which are not restricted), based on the Agency's lower level of concern for these reactive groups. These groups will include the following: acid halides; acid anhydrides; aldehydes; hemiacetals; methylolamides, -amines or -ureas; alkoxysilanes with alkoxy greater than C₂; allyl ethers, conjugated olefins; cyanates; epoxides; imines; and unsubstituted positions ortho or para to phenolic hydroxyl.

All other reactive functional groups (except those that are unrestricted) are required at §723.250(e)(1)(ii)(C) to have a combined equivalent weight of 5,000 daltons or greater, including pendant acrylates and methacrylates, aziridines, carbodiimides, halosilanes, hydrosilanes, hydrazines, isocyanates, isothiocyanates, alpha or beta lactones, methoxy or ethoxy silanes, vinyl sulfones or analogous compounds, and any other reactive functional group not listed at §§723.250(e)(1)(ii)(A) or (B).

EPA requested comment on the complexity of this specific provision and was concerned that smaller businesses or those with limited technical resources would have trouble interpreting the exemption criteria for reactive functional groups, if the groups

are complicated, and might choose not to use the exemption for eligible polymers. Such persons would, of course, have the option of using 5,000 as the equivalent weight if they are uncertain whether a particular reactive functional group is listed under §§723.250(e)(1)(ii)(A) and (B). No adverse comments were received on the Agency's specific approach. Therefore, the final rule includes this provision as proposed.

EPA believes that restrictions on reactive functional groups are not necessary for polymers with a number-average MW equal to or greater than 10,000 because, as stated in the proposed rule, polymers of this size are not expected to be absorbed by biological systems.

b. Polymers with number-average MW equal to 10,000 daltons or greater.

Section 723.250(e)(2) exempts polymers with number average MW equal to 10,000 daltons or greater (and oligomer content less than 2 percent below MW 500 and less than 5 percent below MW 1,000). The Agency established this separate category for polymers with number-average MW equal to or greater than 10,000 daltons because high MW polymers are not expected to be readily absorbable by any route of exposure because of their molecular size. As stated earlier in this unit, polymers with a number-average MW of less than 10,000 daltons, in general, can be expected to be absorbed by the lung and therefore have different detoxification mechanisms available to mitigate potential health hazards.

In the 1993 proposal, EPA proposed as a condition of the exemption that the submitter evaluate the potential for inhalation exposure to respirable particles of water-insoluble polymers and, if warranted, provide adequate notification and appropriate protective measures to exposed workers. At that time, EPA had expressed concern for potential health effects that may be caused by inhalation of respirable particles of water-insoluble high MW polymers of 10,000 daltons or greater based on section 8(e) data which are discussed below. In the 1984 exemption, the Agency also discussed a similar concern for potential health risks but in the preamble to the 1984 final polymer exemption rule, EPA concluded that such exposure to polymer particulates was generally limited and expected to be of low risk [49 FR 46082, November 21, 1984]. Following publication of the 1993 proposal, the Agency received numerous adverse comments regarding EPA's proposed conditions on this category of high MW polymers which,

as a class in general, is considered to be one of the safest categories of chemicals in commerce.

To address these comments, the Agency reviewed in detail its experience with polymers in the New Chemicals Program and in particular re-examined its database of polymers submitted under the 1984 polymer exemption rule to determine what percentage of these polymers afforded the potential for inhalation exposure. In particular, the Agency examined 553 polymer exemption notices received since 1991 and found that of the 18 polymers that fit the proposed exemption criteria for water-insoluble polymers, only 1 polymer presented a possible inhalation risk based on particle size and use considerations. The exemption application for this polymer was converted to a PMN to allow a full review in the 90-day PMN review process. The Agency's review did not result in a finding that the manufacture, processing, use, or disposal of the polymer "may present" an unreasonable risk to human health and the polymer was dropped from further review. In view of the Agency's experience over the last 3 years and its judgment that exposure patterns will not change appreciably, the Agency has concluded that there is an exceedingly low probability that potential exposure to high MW water-insoluble polymers, as a class, will result in unreasonable risk of injury to human health or the environment. In the 1993 proposal, EPA stated that it received TSCA section 8(e) data, designated 8(e)-0668, reporting irreversible lung damage linked with inhalation of respirable particles of water-insoluble polymers with MW of 70,000 daltons or greater. Of these data, the central study was contained in section 8(e)-0668. The subject chemical was a toner used in copy machines. This submission included chronic inhalation studies in both rats and hamsters and concluded that both species suffered similar lung damage when respirable dusts were inhaled at levels that also produced "lung overloading." In addition, studies were performed on clearance rates that demonstrated that impaired clearance occurred without regard to particle concentration once overloading had taken place. Other section 8(e) data on water-insoluble high MW polymers did not include chronic studies, but were shorter term studies that resulted in a similar type of lung damage. The 1993 proposal contains a full discussion concerning these data and the issues the data raised for the Agency.

In the 1993 proposal, EPA proposed an exposure level for respirable polymer

dust of 0.5 mg/m³ as an 8-hour time weighted average to provide an adequate margin of safety given the Agency's interpretation of the section 8(e) data and believed that this level was technologically feasible. EPA assumed that most companies would be in compliance with the Occupational and Safety and Health Administration's (OSHA) existing Permissible Exposure Limit (PEL) for respirable Particulates Not Otherwise Regulated (PNOR), as an 8-hour time weighted average of 5 mg/m³ and that EPA's proposed lower limit of 0.5 mg/m³ could be attained through additional engineering controls, work practices, good housekeeping practices, or different respiratory protection. While EPA is not imposing conditions on this category of high MW polymers as part of the final rule, the Agency believes that manufacturers and users of polymers and chemical substances, in general, where feasible should take appropriate action to mitigate exposure to all respirable particles. In addition, EPA has raised the general issue of particulate inhalation exposure to the attention of the "ONE" Committee, which is an intra-agency committee of OSHA, National Institute for Occupational Safety and Health, the Mine Safety and Health Administration, and EPA representatives, formed in 1988 as a focal point for coordination and information exchange related to occupational issues. When further research is conducted in the area of particulate inhalation exposure and the data gaps are addressed (see "Inhalation Toxicity of High Molecular Weight Polymers, Workshop Proceedings, by Technical Resources, Inc., 1993), EPA may refine the eligibility criteria further for the polymer exemption or may impose new restrictions, if necessary.

Comment. The American Fiber Manufacturers Association (AFMA) comments that it was unwarranted to impose restrictive evaluation criteria for products based on the limited data available. AFMA stated that since EPA has already restricted the introduction of polymers containing chemically reactive groups and water-absorbing polymers, the remaining polymers should not present any special hazard dependent solely upon MW. This restriction should be eliminated.

Response. As stated previously, EPA has concluded that there is an exceedingly low probability that potential exposure to high MW water-insoluble polymers as a class will result in unreasonable risk of injury to human health or the environment. Consequently, the final rule does not impose restrictive evaluation criteria on this class of polymers.

Comment. AFMA commented that the 1991 EPA workshop on Inhalation Toxicity of High MW Polymers recommended against using MW as a predictor of inhalation toxicity, stating that the workshop concluded that knowledge of MW alone does not provide enough information about the material for use in predicting inhalation toxicity and that lung toxicity seen in animals with excessive lung burdens of high MW polymers is likely the result of a particle overload mechanism. The Workshop did not believe there is a relationship between MW and particle overloading that would justify use of MW for the proposed criteria determinant.

Response. The Workshop was advisory in nature and the opinions of the participants are not necessarily those of EPA. Nevertheless, EPA has reconsidered its own experience with such polymers and the available data for water-insoluble polymers and concluded that the proposed MW criteria were unduly limited and its reliance on MW as a restricting factor is unnecessary. Therefore, the limitation on water-insoluble polymers has been removed.

Comment. AFMA cited a report (attached to AFMA's comments) where polypropylene fibers were tested in subchronic inhalation studies. Under the conditions of the study, these high MW water-insoluble polymers are not fibrogenic, yet would be needlessly and improperly regulated by EPA as proposed.

Response. The report cited by AFMA is a 90-day inhalation study of polypropylene fibers, not respirable particulate dust. The toxicity of fibers involves factors such as length and diameter which are unique to fibers and not applicable to respirable dust. The study therefore, has limited relevancy to the polymer exemption criteria.

Comment. AFMA states that data filed under TSCA section 8(e) HQ-0487-0668 and section 8(e) HQ-0983-0492 S both involve polymers which fall below the proposed 10,000 MW cut-off. Both polymers appear to be biologically-active (acutely toxic) with reactive functional groups associated with them, rendering each ineligible for PMN exemption regardless of their MW. In both cases, MW would be an inappropriate primary determinant of toxicity.

Response. EPA agrees that these polymers would not be eligible for the exemption under the criterion which restricts reactive functional groups. Further, these studies were not used by the Agency in assessing concerns for high MW water-insoluble polymer.

Comment. AFMA stated that data on the pulmonary toxicity of xerographic toner, as filed in TSCA section 8(e)HQ-0487-0668, should not be used in determining polymer toxicity criteria. The "toner" tested was a mixture of materials, not a single polymer. Approximately 10 percent of this mixture is reported to be carbon black. EPA should defend its rationale for including this mixture in the database for water-insoluble polymers. AFMA contends it is inappropriate for EPA to restrict use of an entire class of polymers based on extrapolation of the results of a toxicity study on a mixture.

Response. It is EPA's understanding that the carbon black was encased in the polymer and therefore not bioavailable. Only the polymer was available for contact with the experimental animal. Thus EPA does not consider the carbon black to be a factor in the toxicity described in TSCA 8(e)HQ487-0668. As discussed previously in this unit and in the preamble to the proposed rule, EPA did not rely solely on this particular study but also considered other data albeit shorter term studies. Based on EPA's experience in evaluating polymers as discussed above, EPA has decided to proceed as described in this rulemaking.

Comment. AFMA states that the inhalation data on super-absorbent polymers are inappropriate for use in determining exemption criteria in the water-insoluble polymer section of the proposed rule. It appears that TSCA section 8(e) filings reporting pulmonary toxicity [as reported hazardous in 8(e)HQ-0382-0438 S, section, 8(e)HQ-0683-0484 S, 8(e)HZ-1291-1795, and FYI-OTS-1285-0470] were used by EPA to propose conditions on water-insoluble polymers as part of the exemption. However, EPA has not provided relevant data to show that similar pulmonary toxicity would occur in water-insoluble and water-absorbent polymers. Accordingly, AFMA believes it inappropriate for EPA to use toxicity data obtained from water-absorbent polymers in a manner that affects the exemption eligibility of water-insoluble polymers. AFMA believes that in the absence of adequate supporting data, these polymers should be treated as nuisance particulates.

Response. EPA agrees that use of the data on super-absorbent polymers are not appropriate for use in determining exemption criteria for water-insoluble polymers. Further, in its proposal, EPA did not use the data on super-absorbent polymers in determining exemption criteria of water-insoluble polymers.

Comment. Elf Atochem commented that by setting a 0.5 mg/m³ dust

concentration level (a factor of 10 less than OSHA's PEL of 5 mg/m³), the acceptability of new polymers would be greatly reduced. To maintain consistency between Federal agencies, EPA should raise its workplace exposure level to be consistent with the OSHA standard. In addition, Exxon commented that the imposition of inhalation standards that are inconsistent not only with OSHA PEL levels but with existing polymers creates yet another disincentive for pursuing polymer exemptions.

Response. EPA agrees that consistency among Federal regulations regarding workplace exposure is desirable. EPA has elected not to establish an exposure limit for respirable particles at this time for reasons given above. However, TSCA provides authority to "protect human health and the environment" and authorizes EPA to establish limits on worker exposure for new chemical substances where such exposure may present an unreasonable risk of injury to human health. EPA has removed the proposed limitations on water-insoluble polymers for the reasons stated above. However, the Agency believes that manufacturers and users of polymers and other chemical substances should take appropriate actions to mitigate exposure to all respirable particles as part of good industrial hygiene practices.

c. Polyester polymers manufactured solely from reactants listed at §723.250(e)(3). The Agency has had sufficient experience in reviewing polymer exemption notices for polyester polymers that are prepared using reactants specified in the 1984 exemption rule that the Agency does not believe such polymers present an unreasonable risk of injury to human health or the environment. Accordingly, these polyester polymers continue to be eligible for exemption. As discussed in the 1993 proposal, EPA is deleting footnote No. 2 in §723.250(e)(3), which is no longer applicable, because under the final rule all monomers and reactants used to manufacture the polymer must be on the TSCA Inventory.

There are many polyester polymer reactants that are not included in the 1984 polyester exemption list, and the Agency requested comments on expanding the list of potential polyester reactants. Several companies identified reactants for Agency review. Agency scientists, using structure-activity relationships and their expert judgment, evaluated the candidate reactants and identified no health or ecological concerns for these reactants. Based on

the Agency's evaluation, the following substances have been added to Table 1 of this regulation: canola oil; castor oil fatty acids; dehydrated castor-oil fatty acids; C₁₆₋₁₈ and C₁₈-unsatd. fatty acids; C₁₈-unsatd. fatty acids, dimers; oxidized linseed oil; conjugated sunflower oil fatty acid; C₁₆₋₁₈ and C₁₈-unsatd. glycerides; butanedioic acid, dimethyl ester; butanedioic acid, diethyl ester; pentanedioic acid, dimethyl ester; pentanedioic acid, diethyl ester; hexanedioic acid, dimethyl ester; hexanedioic acid, diethyl ester; heptanedioic acid; heptanedioic acid, dimethyl ester; octanedioic acid; octanedioic acid, dimethyl ester; nonanedioic acid, dimethyl ester; nonanedioic acid, diethyl ester; decanedioic acid, dimethyl ester; undecanedioic acid; dodecanedioic acid; diethyl terephthalate; dimethyl terephthalate; dimethyl isophthalate; 2-methyl-1,3-propanediol; diethylene glycol.

One reactant, terephthaloyl chloride [CASRN: 100-20-9], was not approved for inclusion in the list of reactants because the Agency does not believe it has had sufficient experience with the reactant or ones of this type. The Agency has decided not to include the following substances in the list of eligible reactants for polyester because they are not on the TSCA Inventory: heptanedioic acid, diethyl ester [CASRN: 2050-20-6]; octanedioic acid, diethyl ester [CASRN: 2050-23-9]; undecanedioic acid, dimethyl ester [CASRN: 4567-98-0]; undecanedioic acid, diethyl ester [CASRN: 22543-29-9]; dodecane-dioic acid, dimethyl ester [CASRN: 1731-79-9]; dodecanedioic acid, diethyl ester [CASRN: 10471-28-0].

Comment. CMA commented that the list of eligible reactants for polyester polymers under the 1984 rule is extremely limited, that many analogous polyols and acids on the Inventory are worthy of inclusion, and that in practice polyesters are often made from esters rather than acids. CMA, Arco, and Eastman proposed expanding the list to include a number of additional substances. CMA, Arco, Dow, Quantum, and Rohm Haas recommended that EPA develop and publish procedures for periodic updating of the "approved" reactants list.

Response. The Agency agrees with the general tenor of the comments and notes that the original "approved" reactants list was compiled from suggestions submitted by manufacturers, after review by Agency scientists. The Agency believes that it would be appropriate in the future to propose amendments to this section to allow

expansion of the list of eligible precursors, when additional candidates have been identified. To support requests for additional reactants, petitioners should provide health and environmental effects information on the candidate reactants, which must be already on the Inventory.

5. *Determination of eligibility.* The Agency believes that, when a polymer is manufactured under the terms of the exemption, it is reasonable for the manufacturer to take on a greater burden to demonstrate eligibility than under the 1984 exemption because EPA is eliminating its premanufacture review of these polymers. Under the 1984 exemption, the Agency did not require that submitters perform analytical measurements of the physical and chemical properties of polymers, but allowed manufacturers to determine compliance with the exemption conditions on whatever basis the manufacturer deemed appropriate. These included 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 of process and purification steps.

Under the final rule, the Agency will no longer receive and review exemption notices prior to manufacture or import of exempted polymers nor verify a polymer's eligibility under terms of the exemption. Consequently, the manufacturer must take the steps necessary to ensure that a chemical substance is eligible for exemption. Therefore, the Agency is requiring that a manufacturer generate appropriate records and data to demonstrate that a substance meets the eligibility criteria set forth at §723.250(e) to ensure compliance with the exemption.

The final rule requires manufacturers of exempt substances at §723.250(e)(1) and (e)(2) to generate appropriate analytical data, if applicable, or theoretical calculations if it can be documented that an analytical determination can not be made or is not necessary, to demonstrate that the polymer meets the minimum number average MW and corresponding restrictions on oligomer content. The Agency has not specified a particular analytical method to demonstrate compliance with the eligibility criteria, but allows the manufacturer to use an appropriate method of analysis that generates the data to verify compliance with the criteria, such as gel permeation chromatography or vapor pressure osmometry. Performance of such

analysis is required prior to commencement of manufacture or import in accordance with the exemption. A number of commenters stated that manufacturers were concerned about the requirement to generate updated analyses and documentation to demonstrate that a given polymer continues to qualify for the exemption whenever a manufacturing process change occurs that could possibly cause the polymer to not meet the exemption criteria. Although the manufacturer is not required to generate updated analytical data on the exempted polymer under the final rule, 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. Obviously, if a new chemical substance is generated during subsequent manufacture, the manufacturer would be required to be in compliance with all the section 5 provisions.

Manufacturers are expected to follow the provisions of the exemption for research and development (R&D) activities during the period of evaluation of eligibility of a substance under the exemption criteria prior to actual manufacture under the exemption provisions. Such R&D activities will be subject to the R&D procedural and recordkeeping provisions in the PMN rule at 40 CFR 720.36 and 720.78, respectively. To enhance compliance with the criteria, EPA is publishing a draft technical guidance document for this rule and will hold a series of workshops on these criteria to facilitate understanding and compliance with this exemption.

6. *Reporting requirements.* The proposed rule would have required that a notice be filed with EPA within 30 days after manufacture or importation for commercial purposes instead of 21 days prior to manufacture of an eligible polymer as under the current exemption. The Agency also solicited comment on a "no reporting" option for this category of substances. In light of the Agency's determination that this class of polymeric substances will not present an unreasonable risk of injury to human health or the environment if manufactured under the criteria specified in this rule, and in the interests of reducing the reporting burdens for both industry and EPA, the final rule will require only annual reporting on polymers for which manufacture or importation under terms of the exemption has commenced for the first time during the preceding

calendar year. This reporting requirement will allow EPA inspectors to determine which companies have manufactured polymers under the exemption thereby allowing them to ensure compliance with the provisions of this rule during site inspections. The final rule requires that a company file a polymer exemption report to EPA, postmarked by January 31, that includes all chemical substances for which manufacture or importation commenced under the terms of the exemption during the preceding year [§723.250(f)]. Such report must include submitter identity information including company name and address, a technical contact (a person available in the United States) and telephone number, and the number of eligible substances for which manufacture commenced under the terms of the exemption during the previous calendar year.

A company may decide to report by plant site instead of submitting a single company report which consolidates reporting on the number of polymers manufactured for the first time under terms of the exemption; however, reporting on the number of polymers manufactured under the exemption should not be duplicated. EPA believes that an annual report on the number of polymers being manufactured for the first time under terms of the exemption will alleviate industry's reporting burden by reducing the information submission requirements while providing EPA with a direct mechanism for monitoring compliance. This type of reporting will also provide a useful measure of the utility of the polymer exemption.

7. Chemical identity information. As discussed above, an exemption notice is no longer required under the final rule. However, manufacturers of polymers under terms of the exemption are required to maintain certain information at the site of manufacture, including chemical identity and a structural diagram, to the extent known or reasonably ascertainable, as specified at §723.250(g). The 1993 proposal, if adopted, would have required a Chemical Abstracts (CA) Index Name or CA Preferred Name, CAS Registry number (or EPA Inventory accession or PMN number) for each reactant used at greater than 2 percent (by weight) to manufacture the polymer, or alternatively, incorporated at greater than 2 percent (by weight) in the polymer. Although the Agency encourages the use of CA nomenclature, the final rule does not require CA nomenclature since polymers manufactured under terms of the exemption will not be placed on the

TSCA Inventory. For purposes of determining chemical identity, the manufacturer may determine whether a reactant is used or incorporated at greater than 2 percent (by weight). However, as discussed earlier in unit II B.2(d) of this preamble, reactants that introduce into the polymer elements, properties, or functional groups that would render the polymer ineligible for the exemption are not allowed. The "two percent rule" affects only the polymer's identity, not its eligibility under the exemption criteria.

Under the final polymer exemption rule, the manufacturer is required to maintain appropriate analytical data or other supporting information to demonstrate that the exempted polymer meets the specific number-average MW and restricted oligomer content criteria at §723.250(e)(1) or (e)(2), as discussed under unit II.B.5 of this preamble. The final rule allows the company to make the polymer with MW ranges, or residual reactant concentrations, etc., as the company desires, provided that these values fall within the exemption criteria.

8. Certification. The final rule retains provisions that require that the manufacturer of an exempt polymer, as of the date of first manufacture, certify that the polymer meets the definition of a polymer, is not specifically excluded from the exemption, and meets the conditions of the exemption [§723.250(h)(3)]. Certification statements must be retained with the other required records at the manufacturing or import site.

9. Recordkeeping. EPA believes that recordkeeping requirements are an essential component of an effective exemption enforcement program and has retained this provision in the final rule at §723.250(j), while including some additional provisions proposed in 1993 since EPA will no longer receive exemption notices. These additional provisions include certification statements, chemical identity information, and analytical data, as discussed in this unit. Documentation of information would be used by enforcement personnel to determine compliance with the rule. The recordkeeping requirements have been amended to require that the manufacturer maintain certain information at the site of manufacture or the site of import.

Comment. Some commenters suggested that the present recordkeeping requirements for the polymer exemption would be adequate to ensure industry compliance.

Response. Since the Agency will not conduct any premanufacturing review

of exempted polymers, EPA believes that it is important for manufacturers to develop and maintain more detailed and comprehensive records than are required by the current polymer exemption. EPA believes that the recordkeeping requirements are necessary to ensure that manufacturers are able to demonstrate compliance by documenting that the exempted polymers meet the eligibility criteria.

10. Inspections. The Agency will continue to periodically inspect companies to ensure compliance with TSCA section 5. Those companies with past violations may be inspected more frequently. To determine compliance with the polymer exemption, the EPA inspector will focus on the information in the company's records, including the analytical data documenting the substance's eligibility under the exemption.

11. Deletion of proposed revocation provisions. The 1993 proposal contained provisions to allow EPA to revoke the exemption for an exempted polymer and require a full PMN review if EPA obtains information indicating that a particular polymer or category of polymers may present an unreasonable risk of injury to human health or the environment.

The Agency has determined, for the reasons outlined below, to delete the proposed revocation provision in its entirety. When the Agency proposed amendments to the polymer rule in 1993, development of the revocation provisions was predicated on EPA's evaluation of the section 8(e) data on certain high MW water-insoluble polymers previously discussed in this unit. EPA believed it was prudent, given its evaluation of the data at the time of the proposal, to ensure it had a mechanism in place to identify eligible polymers which may pose an unreasonable risk of injury to human health or the environment. Specifically, the Agency was concerned that additional section 8(e) data or other adverse data would be received which might compromise the ability of the Agency to prevent unreasonable risk of injury to human health or the environment in a timely fashion.

The Agency received numerous comments reflecting general dissatisfaction with the proposed revocation provisions. Specifically, the comments received by the Agency, both in writing and in conjunction with the public hearing on the proposed rule, were as follows:

(1) The provisions do not provide recourse for the submitter and allow insufficient time for objections to be lodged with the Agency;

(2) The provisions will discourage many companies from developing new products;

(3) Specialty chemical companies in particular would not be as willing to develop new products under the threat that they would be banned from the marketplace;

(4) The revocation provisions of the proposal reduce the commercial acceptability of the exemption process and business managers will prefer the stability and certainty of clearance through submission of a PMN, rather than risk potential business interruptions under the terms of the proposed exemption; and

(5) The provision will threaten the utility of the entire exemption procedure as a vehicle for reducing the number of PMNs that are filed for substances that pose no reasonable likelihood of harm to health or the environment.

Based on consideration of these adverse comments and in light of the Agency's conclusion that the likelihood of eligible polymers posing an unreasonable risk is low, the Agency has determined that these provisions are not necessary to support the Agency's statutory finding that polymers manufactured under terms of the exemption will not present an unreasonable risk of injury to human health and the environment. Should evidence be received by the Agency that casts reasonable doubt on the appropriateness of a criterion or set of criteria, the Agency has other regulatory options available, such as publication of a proposed amendment to the polymer exemption rule to either refine the criteria or impose new restrictions, similar to EPA's treatment of water-absorbing high MW polymers in this rulemaking. Specifically, EPA proposed an amendment to the 1984 exemption that would exclude this category of polymers from eligibility for the exemption based on the Agency's evaluation of certain section 8(e) data as discussed in unit II.B.2(e) of this preamble. After publishing its 1993 proposal and providing an opportunity for public comment, the Agency amended the 1984 exemption in this rulemaking to exclude high MW water-absorbing polymers from eligibility. Similarly, any future proposed revisions would also be subject to notice in the **Federal Register** and comment in accordance with the Administrative Procedure Act.

12. *Inventory status of exempted polymer.* Polymers that were reviewed under the terms of the 1984 polymer exemption rule and included on the Inventory will remain on the Inventory,

with the restrictions concerning low MW species content and maximum residual amounts of reactants specified for each exempted polymer still in force. Polymers manufactured under the amended exemption will not be included on the Inventory. A number of commenters argued that exempt polymers warrant inclusion on the TSCA Inventory, since customers rely on Inventory listings to confirm a product's regulatory compliance. Since the Agency will not be receiving information on the chemical identity of the exempted polymer as part of the reporting requirement, the Agency will not have a mechanism for including exempted polymers on the Inventory. However, the Agency recognizes that it is essential that manufacturers have an adequate method to assure their customers that their products are in compliance with TSCA regulations and agrees that an Inventory listing of the substance would simplify this process. Under the final rule, an exempted polymer remains a new chemical substance (although legitimately manufactured under terms of the exemption) until a PMN has been submitted for the substance and has completed the PMN review period, followed by manufacture for non-exempt commercial purpose and subsequent NOC. Nonetheless, it is current practice that manufacturers employ a variety of methods to assure customers that a chemical substance is in compliance, particularly in situations where the Agency does not include an exempted substance on the Inventory, as is the case for low volume, test marketing, and R&D substances. Since the Agency will neither be receiving notices for exempted polymers nor providing receipt numbers (similar to the status of R&D substances), manufacturers who use this exemption should rely on practices similar to ones currently used for R&D substances. These include appropriate labeling and reference to the polymer exemption rule at 40 CFR 723.250 and this **Federal Register** document. A company might also consider setting up a system for identifying exempted polymers which relates back to the exemption and use this identification code to identify polymers in any commercial activity or Material Safety Data Sheet (MSDS).

The Agency believes that use of the polymer exemption provides significant benefits to polymer manufacturers for a number of reasons discussed in this document. Moreover, polymers manufactured under this exemption have been identified by EPA as some of the least hazardous substances in

commerce. In light of pollution prevention and product stewardship initiatives undertaken by the regulated community, the Agency believes that the marketing of safer chemical substances should enhance the commercial viability of these substances.

Comment. CMA states that customers rely on TSCA Inventory listings to confirm a product's regulatory compliance. Elf Atochem argues that inclusion on a separate list leaves the regulatory status of exempt polymers rather ambiguous.

Response. As discussed above, the Agency believes that manufacturers who use the exemption will be able to develop adequate methods of assuring their customers that these polymers are not only in compliance with TSCA regulations but meet the Agency's low-risk criteria.

13. *Transition period until final rule becomes effective.* The Agency will continue to accept and review polymer exemption applications under the terms of the 1984 exemption at 40 CFR 723.250 until the effective date of this final rule. No new exemption applications will be accepted after the effective date of this rule.

If a manufacturer who submitted a polymer exemption application under the 1984 exemption rule but has not yet submitted a NOC wishes to add its polymer to the Inventory, the person may submit the NOC in accordance with 40 CFR 720.102. The exempt polymer will then be listed on the Inventory with the applicable 1984 polymer exemption criteria and exemption category restrictions on residual monomers/reactants and low MW species content. The manufacturer may instead choose to manufacture under the terms of the new exemption.

III. Response to Other Alternatives Considered

EPA requested comments and data on all aspects of the 1993 proposal, including the following specific issues discussed below:

Other Polymers Considered for Exemption

1. *Polymer salts.* The Agency has also considered a proposal to exempt certain salts of polymers that are listed on the TSCA inventory but was unable to make the determination that, as a class, all of these polymers will not present an unreasonable risk of injury to human health or the environment. However, EPA believes that many individual polymer salts will be eligible for exemption under the amended criteria.

2. *Polymers containing high cationic functional group.* The Agency considered allowing, under the exemption, polymers which contain high percentages of amine (low amine equivalent weight) in their structures but decided against this approach. Accordingly, polymers with high cationic functional groups continue to be subject to the restrictions under §723.250(d)(1) for the following reason. In the past, the main concern for cationic polymers was for ecotoxicity, specifically, aquatic toxicity. There has been a significant amount of data generated by industry in response to section 5(e) consent orders or on a voluntary basis, which after EPA review, was concluded to demonstrate that for the category of polymers with a high amine or cationic content, equivalent weight of 425 daltons or less, there is sufficient mitigation of the risk, through the mechanism of dissolved-organic-carbon (DOC), to render this polymer class of low risk for ecotoxicity if used according to current standard practices. The Agency believes that these data sufficiently support the conclusion that high amine content polymers, as specified above, will not pose an unreasonable risk of injury for aquatic toxicity.

However, as discussed in the 1993 proposal, EPA received section 8(e) data on a polymer with high cationic functional group content in which test results demonstrated lethality in standard eye irritation tests in rabbits. This study has resulted in high concerns for acute lethality as demonstrated by this polymer. The polymer used in the study met all provisions of the proposed polymer exemption and would have qualified for exemption if the low cationic functional group equivalent weight (high cationic content) provision was incorporated as part of the exemption criteria. It is for this reason that EPA believes that it would be inappropriate to include the high cationic functional group content allowance in the final rule at this time and will continue to restrict these polymers under the final rule.

Comment. One commenter stated that the exclusion of the polymers with high cationic functional group content is based upon the assumption that all high cationic charge polymers have similar physical-chemical, steric, structural and toxicological properties and that the concern should be more focused on the class of polymers that cause the adverse effect.

Response. The Agency agrees that it may be more appropriate to use the definition of the class of cationic polymers to exclude the polymers of

concern from the exemption in lieu of the broader-based exclusion. However, this preliminary assessment is based on section 8(e) data that are claimed as CBI. (At the time of the proposal, EPA believed that it would be able to resolve the CBI claim in a way that would allow the public an opportunity to comment on the data.) To date, the submitter of the 8(e) data has declined to rescind the CBI claim on the chemical structure despite repeated requests. Nor were publicly accessible data received during the comment period that support narrowing the category of polymers excluded from the exemption. Therefore, because the public has not had an opportunity to comment on the basis for such an exemption and in order not to delay issuance of this final rule until the CBI issues can be resolved, the Agency has elected not to include a more narrow category in this rulemaking. The Agency may continue discussions with the submitter of the section 8(e) data and amend this section as appropriate in the future.

IV. Regulatory Analysis

A. Summary of Risk Assessment

1. *Introduction.* The Agency has determined that polymers defined by the exemption criteria set forth in this rule are of low concern due to their lack of reactivity and their molecular size. These criteria have been developed based on the Agency's review of over 5,000 polymer submissions since the original polymer exemption rule in 1984 (49 FR 46066). The Agency believes that polymers eligible for this exemption are generally of low risk and that sufficient information exists on the potential risks of other polymers with certain characteristics to make them ineligible for the exemption.

2. *Approach to risk analysis.* The Agency based its risk analysis on (a) the effect MW has on the overall risk a polymer poses, (b) the specific concerns the Agency has had in the past for polymers submitted as PMNs, (c) toxicological data available on particular polymers, (d) an analysis of the Agency's database on over 500 polymers received in the last 3 years under the current polymer exemption to determine the potential for exposure to respirable particles of insoluble high MW polymers, and (e) an analysis of the Agency's experience to date in assessing potential risks of new polymers submitted as PMNs or exemption applications. The 1993 proposal contains an extensive discussion of the Agency's approach and limitations to that approach. The proposal also details EPA's extensive evaluation of

ecotoxicity considerations for polymers. The discussion below is limited to an analysis of the inhalation toxicity concerns associated with exposure to respirable polymeric particles.

3. *Inhalation toxicity.* As discussed in the 1993 proposal, health concerns exist for certain types of polymers that have been found to produce lung toxicity if inhaled. Based on section 8(e) data on a water-absorbing polyacrylate polymer with a MW in excess of 1 million daltons that indicated a potential oncogenic (cancer) concern for this type of high MW water-absorbing polymer, the Agency has excluded water-absorbing polymers of MW equal to or greater than 10,000 daltons from the exemption. Other section 8(e) data on high MW water-insoluble polymers were indicative of a lung-overload phenomenon and did not demonstrate any carcinogenic response under conditions of the studies. Please consult units II.B.4(b) and IV.C of this preamble and the preamble to the proposed rule for a full discussion of this issue.

The final rule does not impose a condition in the exemption on high MW water-insoluble polymers linked to the evaluation of the potential for inhalation exposure to respirable particles as was contemplated in the 1993 proposal. Based on numerous comments received on these proposed limitations on high MW water-insoluble polymers, the Agency reevaluated the existing scientific data and its own experience in reviewing the potential for inhalation exposure to such polymers submitted under the current polymer exemption. Based on these analyses, EPA has determined that there is an exceedingly low probability that potential inhalation exposure to high MW water-insoluble polymers, as a class, will result in unreasonable risk of injury to human health or the environment. This conclusion reaffirms EPA's finding at the time of promulgation of the 1984 exemption that exposure to polymer particulates was generally limited and expected to be of low risk.

Based on over 15 years experience with polymers, EPA considers that the criteria set forth in this exemption define polymers of low-concern and that the potential risk from respirable particles of high MW water-insoluble polymers is low. Therefore, the Agency has not retained in this rulemaking the requirement that companies evaluate the potential for inhalation exposure to respirable particles for this specific category. However, EPA believes that as part of responsible health and safety and product stewardship programs in general, manufacturers and their customers should be aware of the

potential for toxicity from any respirable particle and when producing or using such materials take measures to keep their workplace free of respirable dusts of any type.

B. Summary of Regulatory Impact Analysis

EPA has evaluated the potential costs of the final amendments for potential manufacturers of exempt polymers. The Agency's complete economic analysis is available in the public record for this rule (OPPTS-50594B).

The regulatory impact analysis estimates the costs and benefits attributable to the final regulation. In this case, the analysis also contains estimates for the three additional final amendments to section 5 regulations that are published elsewhere in this **Federal Register**. These rules amend the PMN regulations, the Low Volume Exemption Rule, and the Expedited Process for Issuing Significant New Use Rules. Because these final regulations are amendments to current regulations, the costs and benefits are incremental and estimate the effect of the final rule with respect to the current regulations.

The costs and benefits associated with the polymer exemption amendments are partially quantified; many of the benefits are unquantified but are expected to be of significant importance as discussed later in this unit. Considering only the quantified costs and benefits, there is a cost saving. Since the number of section 5 submissions received by the Agency varies, this analysis used three scenarios, assuming either 1,000, 2,000, or 3,000 annual submissions, to reflect the expected range of submissions. The savings as compared to the current regulation are estimated to be:

Annual Number of Submissions	Annual Cost Savings (\$ Million)	
	Industry	Government
1,000	4.7 - 6.8	0.2 - 0.4
2,000	9.4 - 13.5	0.4 - 0.8
3,000	14.2 - 20.3	0.6 - 1.2

The industry costs associated with these amendments are labor requirements for preparation of an annual report and recordkeeping costs. Reporting and delay costs are eliminated due to the elimination of submission requirements. The user fee is no longer applicable since exemption notices will not be required. Moreover, the amendment makes a larger number of polymers eligible for the exemption, further reducing the reporting and delay costs for those substances.

The unquantified benefits include increased flexibility for industry due to the expanded exemption criteria. In addition, Agency resources will be focused on those substances more likely to pose an unreasonable risk.

C. EPA's Approach to Making the No Unreasonable Risk Finding

1. *Statutory background.* Pursuant to 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, or disposal of the substance, or any combination of such activities, will not present an unreasonable risk of injury to human health or the environment. Section 26(c) of TSCA provides that any action authorized under TSCA for an individual chemical may be taken for a category of such substances.

While TSCA does not contain a definition of "unreasonable risk," the legislative history indicates that the determination of unreasonable risk requires a balancing of the considerations of both the severity and the probability that harm will occur against the effect of the final regulatory action on the availability to society of the benefits of the chemical substance [House Report 1341, 94th Cong., 2nd Session, 14 (1976)]. This analysis can include an estimate of factors such as market potential, the effect of the regulation on promoting or hindering the economic appeal of a substance, environmental effects, and many other factors which are difficult to define and quantify precisely. EPA may rely not only on data available to it, but also on its professional judgment. Congress recognized that the implementation of the unreasonable risk standard "will vary on the specific regulatory authority which the Administrator seeks to exercise" [Ibid.]

2. *EPA's approach.* In determining whether the category of polymeric substances being considered for exemption presents an unreasonable risk of injury to human health or the environment, the Agency considers more than just the inherent risks presented by the overall category of polymers. The Agency also considers how the criteria of the exemption maintain full regulatory oversight on higher risk polymers while promoting the manufacture of low-risk polymers by providing regulatory relief for them.

The amended polymer exemption modifies the requirements for eligible polymers from the current polymer exemption requirements and the general PMN requirements. EPA therefore

compares the risks posed by the substances being considered for an amended exemption with the risks which would have resulted from the same category of substances, if that category of substances had been subject to full notice submission requirements and 90-day EPA review or, where applicable, the reporting requirements of the current polymer exemption and the abbreviated 21-day review. Certainly it is not possible to eliminate all risks associated with the manufacture, processing, distribution in commerce, use, and disposal of any new chemical substance nor was this Congress' intent. The standard embodied by a section 5(h)(4) exemption does not require the Agency to ensure absolute safety from the activities associated with an exempted substance.

3. *Application of no unreasonable risk factors.* The following is an explanation of the factors and their analysis relevant to the no unreasonable risk finding. The design of the final polymer exemption together with intrinsic properties of polymers significantly limit the risks of injury to human health or the environment that exempt polymers may present. Polymers as a general class are relatively unreactive and, at or above a MW of 10,000, are not easily absorbed by body tissue because they do not easily transport across human membranes. As originally discussed in the Agency's 1984 polymer exemption rule:

...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 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. [49 FR 46081 (November 21, 1984)].

EPA's conclusions regarding low risk potential for polymers that meet the eligibility criteria are supported by the available data as well as EPA's scientific professional judgment based on 15 years experience reviewing polymers under the PMN and current polymer exemption requirements. Pursuant to the final rule, certain polymers will be automatically ineligible for the polymer exemption. EPA has excluded those polymers for which: (a) The Agency still has insufficient data and review

experience to find that they will not present an unreasonable risk of injury, or (b) the Agency has found that, under certain conditions, based on data on the polymers in question, a polymer, or subset of polymers, may present an unreasonable risk, thereby requiring a closer examination of the conditions of manufacturing, processing, distribution in commerce, use, and disposal during a full 90-day PMN review. This level of analysis would be necessary to make an appropriate determination about risk.

In 1982, when the Risk Analysis and Evaluation of PMN Regulatory Decisions for Polymers was performed for the original polymer rule, the Agency determined that high MW polymers containing small amounts of low MW species were not considered an unreasonable risk to humans or the environment. Extensive discussion on this topic can be found in the 1982 proposed polymer exemption rule and the preamble to the final rule promulgated in 1984. The Agency has assumed that monomers would be of greater concern than oligomers, and that oligomers would be of greater concern than polymers based on the probability that the monomer would be more readily absorbed and, on a weight basis, be more reactive than the resulting oligomer or polymer. In its 1982 proposal, the Agency proposed to allow polymers with MW greater than 20,000 daltons to be manufactured without any premanufacture review by EPA but determined in the final rule that an abbreviated review period was necessary due to concerns for unreacted monomers and low MW species. The Agency is now modifying this approach, based on the review and hazard assessment of polymers reviewed as PMNs or polymer exemptions since the 1984 polymer exemption was promulgated. The Agency now believes that it has sufficient experience with high MW polymers such that a "no unreasonable risk" finding may be made for a broader class of these substances without EPA premanufacture review.

Over the past 15 years, the Agency has reviewed over 10,000 polymers in the New Chemicals Program (over approximately 50 percent of all PMNs are polymers). Of these 10,000, the polymers that would have qualified for the final polymer exemption rule have consistently been characterized as posing low concern for both adverse health and environmental risks by the Agency during the course of PMN review. The characteristics of a significant number of polymers (i.e., their MW and/or physical/chemical properties), are such that they are neither absorbed by biological systems

nor do they interact with biological systems, as described above. (A more detailed discussion is provided in the preambles to the 1984 polymer exemption and the 1993 proposal.) Furthermore, these polymers do not degrade to toxic species in the environment.

The Agency has developed specific criteria which define low-risk polymeric substances. Such criteria include limitations on low MW species, reactive functional groups, and cationic polymers. Many of these criteria are outgrowths of the criteria used to determine eligibility under the current polymer exemption that has been in effect since 1984. Further, the Agency uses these same criteria to identify low-risk polymers in its PMN review process. The 1984 polymer exemption, which uses the same types of criteria as these final exemption criteria to determine eligibility, required a 21-day premanufacture review period. The Agency believes that this review period for polymers that meet the final exemption criteria is unnecessary based on EPA's finding that these exemption criteria place sufficient constraints on risk, such that EPA review of these eligible polymers would not result in any additional protection. Accordingly, exempting polymers that meet the low-risk eligibility criteria will allow the Agency to refocus its limited resources on those non-exempt substances which, by comparison, may pose a considerable risk to society.

In its 1993 proposal, the Agency expressed concern for potential lung toxicity due to inhalation of respirable high MW polymers. Toxicity studies, in the form of section 8(e) submissions on a water-absorbing high MW polymer and certain water-insoluble high MW polymers, indicated two areas of potential concern with high MW polymers.

The data set on the water-absorbing polymer, which is discussed in detail in unit II.B.2(e) of this preamble, included a 2-year chronic inhalation study reporting squamous cell carcinoma and bronchio-alveolar carcinomas at concentrations of 0.2 mg/m³ and 0.8 mg/m³ for the tested polymer, which was a water-absorbing polyacrylate polymer having a MW of greater than 1 million daltons. The tested polymer lacked both reactive functionalities and low MW species (below a MW of 1,000 daltons), factors that could have played a role in the reported carcinogenicity. In the absence of these factors, the Agency concluded that the water-absorbing properties of the polymer may have played a role in the reported carcinogenicity findings. Although the

Agency was unable to establish a link between MW and toxicity for water-absorbing polymers, the Agency set the number average MW exclusion at 10,000 daltons which the Agency believes is a reasonable value at which absorption is a sufficiently slow process that a substance can persist in the lung. This MW level is also two orders of magnitude below that of the tested polymer. At 10,000 daltons and greater, these water-absorbing polymers are not likely to be absorbed, so mechanisms for detoxification which are available for lower MW polymers may not be available. Thus the respirable particles are expected to remain in the lung for extended periods. As stated earlier in unit II of this preamble, EPA believes that polymers with MW less than 10,000 daltons can be expected to be absorbed by the lung and therefore have different detoxification mechanisms available to mitigate potential health hazards. Based on these findings, the Agency has determined that exposure to respirable fractions of these polymers might present an unreasonable risk to human health and has excluded water-absorbing polymers with MW of 10,000 daltons or greater from the exemption eligibility.

Moreover, in response to comments requesting a definition of "water-absorbing" that more accurately defines this parameter for polymers of concern and based on further evaluation of the 2-year inhalation study on the polyacrylate polymer, the final rule defines a "water-absorbing polymer" as a polymer capable of absorbing its weight of water. Although the subject polyacrylate polymer absorbs approximately 100 times its weight of water, the Agency lowered the threshold for exclusion in this rule to absorbing its weight of water by using a hundredfold factor. This definition more accurately bounds the category of polymers that the Agency believes should be subject to the full PMN review process, pending the development of data that would mitigate the Agency's concern. These two limitations allow the Agency to conclude that the non-excluded water-absorbing polymers will not present an unreasonable risk of injury to human health. Accordingly, the final rule defines the term "water-absorbing" and excludes such polymers with MW of 10,000 or greater from the exemption.

The section 8(e) data on high MW water-insoluble polymers, which are discussed in detail in the 1993 proposal, indicated that inhalation of respirable particles of certain high MW water-insoluble polymers resulted in irreversible lung damage (fibrosis) but, under the conditions of the study, no

carcinogenic response to experimental animals. Numerous comments received on this issue questioned the Agency's use of a limited set of data to impose restrictions on an entire class of water-insoluble high MW polymers that are generally recognized as polymers of low-concern. In the proposed rule, the Agency itself recognized that imposing conditions under the exemption on high MW water-insoluble polymers may not have been appropriate and had requested comments on the alternative of imposing no limitations on the exemption eligibility of this category of polymers. In light of this and in response to numerous comments, the Agency re-examined its proposal to impose conditions on this category of high MW water-insoluble polymers. Please consult unit II.B of this preamble for an extensive discussion of this issue.

Based on its evaluation of 553 polymers that were the subject of polymer exemption applications during the past 3 years, as previously discussed in unit II.B.4(b) of this preamble, EPA concluded that there is an exceedingly low probability that potential exposure to high MW water-insoluble polymers, as a class, would result in an unreasonable risk of injury to human health or the environment. EPA reached a similar conclusion during promulgation of the 1984 exemption that exposure to polymer particulates was generally limited and expected to be of low risk. In its 1984 rule, EPA had recognized that particulate inhalation exposure was a potential source of toxicity which was not explained by MW, stating then that the review experience developed in the PMN program had demonstrated that exposure to polymer particulates was generally limited and therefore expected to be of low concern. 49 FR 46082 (November 21, 1984).

Further, EPA reviewed the section 8(e) data that were the basis of the Agency's concern regarding potential inhalation toxicity of high MW water-insoluble polymers. The studies on a toner for copy machines that was a water-insoluble polymer with a MW of 70,000 daltons included chronic inhalation studies in both rats and hamsters. These studies indicated that both species suffered similar lung damage when respirable dusts were inhaled at levels that also produced lung overloading. Other studies were performed on clearance rates that demonstrated that impaired clearance occurred without regard to particle concentration in the air once overloading had taken place. Other section 8(e) data on water-insoluble high MW polymers did not include

chronic studies, but were shorter term studies that resulted in lung damage consistent with the damage seen when "lung overloading" occurred on a chronic basis.

Based on the above mentioned limited data and uncertainty as to all the factors contributing to the identified effects, the Agency determined that it could not draw any broad scientific conclusions in which lung toxicity is linked affirmatively with any specific chemical class or category of high MW water-insoluble polymers. In addition, it should be recognized that the chronic toxicity endpoint being addressed for water-insoluble polymers was only seen under conditions of lung overload (which suggests the presence of a threshold for this type of toxicity). In the case of the water-absorbing polymers, which exhibit a cancer endpoint, the exemption criteria reflect the more conservative approach which the Agency has historically adopted for oncogenicity concerns. Further, it is clear from the Agency's experience in assessing high MW water-insoluble polymers that members of this class of polymers have rarely been subject to control action as a result of PMN review.

In the present rulemaking, based on numerous comments on this issue and the Agency's finding that exposure to respirable particles of high MW water-insoluble particles is expected to be limited, the Agency has concluded that it can make its statutory finding that polymers meeting the eligibility criteria will not present an unreasonable risk of injury to human health or the environment. The Agency believes that the criteria set forth in this exemption are sufficient to mitigate risk, particularly when compared to the benefits, *in toto*, of encouraging further development of comparatively lower risk classes of chemicals, such as polymers. Furthermore, the expedited manufacture of eligible new polymers will provide essential benefits to industry and to the public, which comprise an important element in the finding of no unreasonable risk.

4. *Benefits.* The following discussion describes the benefits of this rule in a qualitative manner; for a more quantitative approach, see the economic analysis discussion in unit V.B of this preamble. It is reasonable to assume that a newly developed polymer will either possess a new function or serve an existing function more efficiently or less expensively. The reduction in delay for that polymer to be introduced into commerce is a benefit to both manufacturers and the general public,

who will have access to the substance in a more timely manner.

The benefits analyzed encompass more than the costs associated with submitting the polymer for review in a full PMN. Rather, EPA's benefit analysis included a consideration of the broader benefits of reduction of costs to society by providing a less burdensome alternative for polymer manufacturers, including a reduction in the burden associated with both full PMN and current polymer exemption requirements. EPA's unreasonable risk determination is based on broader benefits to society as well as those benefits attributable to the substance itself.

Some of the costs directly attributable to the substance include the preparation of the PMN or polymer exemption form as well as the delay in the commercial market introduction of the new chemical substance. On the other hand, there are broad societal benefits that can not be directly attributed to any one chemical substance or category of substances. Such benefits include a reduction in Agency review resources being dedicated to a category of compounds determined to be of low risk, and a concomitant shift in those resources to the review of substances of greater known concern. While factors such as these are generally not of the type that EPA would take into account when making an individual control decision on a new chemical substance, they have a significant effect on society which is directly linked to EPA's exercise of its exemption authority, and are therefore appropriately considered in a section 5(h)(4) unreasonable risk finding for a category of substances. The costs of reporting requirements will also be eliminated since companies will be able to manufacture polymers under terms of the exemption without submitting PMNs or exemption notices. These savings are detailed in the Regulatory Impact Analysis report which is available in the public docket for this rulemaking (docket control number OPPTS-50594B).

Manufacturers of polymers for which there is little concern bear a significant regulatory burden. By incorporating into the exemption those criteria that the EPA uses internally to judge the risks posed by polymers, the Agency removes the regulatory impediments to the design, manufacture, and commercialization of this large class of chemical substances and substantially reduces costs associated with industry's reporting burden for polymers meeting these low-risk criteria.

In addition, if the exemption is used to its greatest advantage, more than 31

percent of the resources allocated to the PMN program by EPA could be shifted from this category of low concern to those chemicals considered to pose a considerably greater risk to society. Finally, manufacturers of these polymeric substances will be given greater flexibility provided they meet the terms of the criteria of the exemption.

One of the benefits of the rule is that it incorporates exactly those criteria that delineate the areas of concern to EPA. By including this level of specificity in the rule, EPA provides industry with an understanding of which specific chemicals and chemical properties within the general class of polymers are considered to be hazards and which are considered relatively innocuous. Industry can use this information to design future polymeric products or classes of polymers that can supply the function that is desired while minimizing or eliminating any hazard. Supplying this information as criteria in the rule allows industry to engage in up-front risk-reduction activities by designing new products that conform with the provisions of the polymer exemption while reducing regulatory compliance costs.

Further, this rule provides pollution prevention benefits as well in three areas: the functional group equivalent weight specifications, the acceptable monomers list, and the water absorability criteria. Pollution prevention principles have the goal of reducing or eliminating the use or generation of hazardous feedstocks, by-products, or products. By adherence to the lists of feedstocks and reactants of low concern contained in this rule, companies will be able to accomplish these pollution prevention goals while minimizing their regulatory compliance costs.

In view of the extensive and continually increasing use of polymers in commerce, encouraging industry to expand the use of low risk polymers can result in significant benefits to society. In general, such low risk polymers can, and often do, function as replacements for heavy metals, many of which can cause detrimental human health effects to multiple organ systems as well as permanently contaminating the ecosystem with subsequent damage to the flora and fauna. The benefits of encouraging the development of new chemical substances of low concern in place of those existing substances with known hazards touch on all aspects of human activity and the environment including less hazardous work place environments, safer products available for the consumer, and materials that

will not decompose to toxic products in the disposal sites.

5. *Risk/benefit balance.* Determining the presence or absence of an unreasonable risk requires balancing of the benefits and risks posed by a regulatory action. EPA has determined that the risks are low based on the inherent properties of this class of substances and the additional safeguards provided by the risk-based ineligibility provisions.

EPA believes that the benefits of this action are quite significant. Promoting the development of this category of polymeric substances by reducing the regulatory burden in both reporting requirements and in eliminating the delay of these products into commerce will have discernible benefits to society. The added benefit of concentrating limited EPA resources on regulation of substances which have a greater potential to present significant risks, rather than a category such as polymers, which have a minimal potential for significant risk, is difficult to quantify, but is considered substantial nonetheless.

Given the above analysis, EPA concludes that the polymers covered by the scope of this final rule will not present an unreasonable risk of injury to human health or the environment when manufactured under the conditions of this exemption.

V. Rulemaking Record

EPA has established a record for this rulemaking (docket control number OPPTS-50594B). The record includes basic information considered by the Agency in developing this final rule. A public version of the record without any confidential business information is available in the TSCA Nonconfidential Information Center (also known as the TSCA Public Docket Office) from 12 noon to 4 p.m., Monday through Friday, except legal holidays. The TSCA Nonconfidential Information Center is located at EPA Headquarters in Rm. NE-B307, 401 M St., SW., Washington, DC.

VI. Regulatory Assessment Requirements

A. Executive Order 12866

Under Executive Order 12866 (58 FR 51835, October 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. Under section 3(f), the Order defines a "significant regulatory action" as an action that is likely to (1) have an annual effect on the economy of \$100

million or more, or adversely and materially affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as "economically significant") (2) create serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially alter the budgetary impacts of entitlement, grants, user fees, or load programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of this Executive Order, it has been determined that this rule is not a "significant regulatory action" under section 3(f) of the Order. This action is therefore not subject to OMB review.

B. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (5 U.S.C. 601 et seq.), the Agency has determined that this regulatory action will not impose any adverse economic impacts on small entities. EPA believes that, even if all of the polymer exemption notice submitters were small firms, the number of small businesses affected by this action will not be substantial. In addition, since this action will generally reduce the existing burden and cost imposed on PMN submitters, the impact of this action on small entities should be an overall positive one.

C. Paperwork Reduction Act

The information collection requirements in this rule have been approved under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3502 et. seq. and have been assigned OMB control number 2070-0012. The public reporting burden for this exemption has been eliminated. The public reporting burden for a PMN submission is estimated to vary from 95 to 110 hours; the burden for the 1984 polymer exemption is estimated to vary from 29.5 to 40 hours.

List of Subjects in 40 CFR Part 723

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

Dated: March 21, 1995.

Carol M. Browner,
Administrator.

Therefore, 40 CFR chapter I, subchapter R, part 723 is amended as follows:

PART 723—[AMENDED]

1. The authority citation for part 723 continues to read as follows:

Authority: 15 U.S.C. 2604

2. By revising §723.250 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) 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 report as required under paragraph (f) of this section.

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

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

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

Biopolymer means a polymer directly produced by living or once-living cells or cellular components.

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

Cationic polymer means a polymer that contains a net positively charged atom(s) or associated groups of atoms covalently linked to its polymer molecule.

Chemical substance, Director, EPA, importer, impurity, Inventory, known to or reasonably ascertainable, manufacture, manufacturer, mixture, new chemical, person, possession or control, process and test data have the same meanings as in §720.3 of this chapter.

Equivalent weight of a functional group means the ratio of the molecular weight to the number of occurrences of that functional group in the molecule. It is the weight of substance that contains one formula-weight of the functional group.

Internal monomer unit means a monomer unit that is covalently bonded to at least two other molecules. Internal

monomer units of polymer molecules are chemically derived from monomer molecules that have formed covalent bonds between two or more other monomer molecules or other reactants.

Monomer means a chemical substance that is capable of forming covalent bonds with two or more like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process.

Monomer Unit means the reacted form of the monomer in a polymer.

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

Oligomer means a polymer molecule consisting of only a few monomer units (dimer, trimer, tetramer)

Other reactant means a molecule linked to one or more sequences of monomer units but which, under the relevant reaction conditions used for the particular process, cannot become a repeating unit in the polymer structure.

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 monomer units together.

Polymer means a chemical substance consisting of molecules characterized by the sequence of one or more types of monomer units and comprising a simple weight majority of molecules containing at least 3 monomer units which are covalently bound to at least one other monomer unit or other reactant and which consists of less than a simple weight majority of molecules of the same molecular weight. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. In the context of this definition, sequence means that the monomer units under consideration are covalently bound to one another and form a continuous string within the molecule, uninterrupted by units other than monomer units.

Polymer molecule means a molecule which contains a sequence of at least 3 monomer units which are covalently bound to at least one other monomer unit or other reactant.

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

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 further chemical reaction.

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.

(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) 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) of this section or if the polymer is reasonably anticipated to become a cationic polymer in a natural aquatic environment (e.g., rivers, lakes) unless:

(i) The polymer is a solid material that is not soluble or dispersible in water and will be used only in the solid phase (e.g., polymers that will be used as ion exchange beads), or

(ii) The combined (total) functional group equivalent weight of cationic groups in the polymer is equal to or greater than 5,000.

(2) *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)(2)(i) of this section.

(B) Sodium, magnesium, aluminum, potassium, calcium, chlorine, bromine, and iodine as the monatomic counterions Na⁺, Mg²⁺, Al³⁺, K⁺, Ca²⁺, Cl⁻, Br⁻, or I⁻.

(C) Fluorine, chlorine, bromine, and iodine covalently bound to carbon.

(D) 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.

(3) *Polymers which degrade, decompose, or depolymerize.* A polymer

cannot be manufactured under this section if the polymer is designed or is reasonably anticipated to substantially degrade, decompose, or depolymerize, including those polymers that could substantially decompose after manufacture and use, even though they are not actually intended to do so. For the purposes of this section, degradation, decomposition, or depolymerization mean those types of chemical change that convert a polymeric substance into simpler, smaller substances, through processes including but not limited to oxidation, hydrolysis, attack by solvents, heat, light, or microbial action.

(4) *Polymers manufactured or imported from monomers and reactants not on the TSCA Chemical Substance Inventory.* A polymer cannot be manufactured under this section if the polymer being manufactured or imported is prepared from monomers and/or other reactants (that are either charged to the reaction vessel or incorporated in the polymer at levels of greater than 2 weight percent) that are not already included on the TSCA Chemical Substance Inventory or manufactured under an applicable TSCA section 5 exemption.

(5) *Water absorbing polymers with number average molecular weight (MW) 10,000 and greater.* A polymer cannot be manufactured under this section if the polymer being manufactured or imported is a water absorbing polymer and has a number average MW greater

than or equal to 10,000 daltons. For purposes of this section, a water-absorbing polymer is a polymeric substance that is capable of absorbing its weight of water.

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

(1) *Polymers with number average MW greater than or equal to 1,000 and less than 10,000 daltons (and oligomer content less than 10 percent below MW 500 and less than 25 percent below MW 1,000).* (i) The polymer must have a number average MW greater than or equal to 1,000 and less than 10,000 daltons and contain less than 10 percent oligomeric material below MW 500 and less than 25 percent oligomeric material below MW 1,000.

(ii) The polymer cannot contain reactive functional groups unless it meets one of the following criteria:

(A) The polymer contains only the following reactive functional groups: carboxylic acid groups, aliphatic hydroxyl groups, unconjugated olefinic groups that are considered "ordinary," (i.e., not specially activated either by being part of a larger functional group, such as a vinyl ether, or by other activating influences, e.g., strongly electron-withdrawing sulfone group with which the olefinic groups interact), butenedioic acid groups, those conjugated olefinic groups contained in naturally-occurring fats, oils, and carboxylic acids, blocked isocyanates (including ketoxime-blocked

isocyanates), thiols, unconjugated nitrile groups, and halogens (except that reactive halogen-containing groups such as benzylic or allylhalides cannot be included).

(B) The polymer has a combined (total) reactive group equivalent weight greater than or equal to 1,000 for the following reactive functional groups: acidhalides; acid anhydrides; aldehydes, hemiacetals; methylolamides, - amines or, - ureas; alkoxysilanes with alkoxy greater than C₂-alkoxysilanes; allyl ethers; conjugated olefins; cyanates; epoxides; imines; or unsubstituted positions *ortho* or *para* to phenolic hydroxyl; or

(C) If any reactive functional groups not included in paragraph (e)(1)(ii)(A) and (B) of this section are present, the combined (total) reactive group equivalent weight, including any groups listed in paragraph (e)(1)(ii)(B), is greater than or equal to 5,000.

(2) *Polymers with number average MW greater than or equal to 10,000 (and oligomer content less than 2 percent below MW 500 and less than 5 percent below MW 1,000).* The polymer must have a number average MW greater than or equal to 10,000 daltons and contain less than 2 percent oligomeric material below MW 500 and less than 5 percent oligomeric material below MW 1000.

(3) *Polyester polymers.* The polymer is a polyester as defined in paragraph (b) of this section and is manufactured solely from one or more of the reactants in the following Table 1:

TABLE 1.— LIST OF REACTANTS FROM WHICH POLYESTER MAY BE MADE

Reactant	CAS No.
Monobasic Acids and Natural Oils	
Benzoic acid	65-85-0
Canola oil	120962-03-0
Coconut oil	8001-31-8*
Corn oil	8001-30-7*
Cottonseed oil	8001-29-4*
Dodecanoic acid	143-07-7
Fats and glyceridic oils, anchovy	128952-11-4*
Fats and glyceridic oils, babassu	91078-92-1*
Fats and glyceridic oils, herring	68153-06-0*
Fats and glyceridic oils, menhaden	8002-50-4*
Fats and glyceridic oils, sardine	93334-41-9*
Fats and glyceridic oils, oiticica	8016-35-1*
Fatty acids, C ₁₆₋₁₈ and C ₁₈ -unsatd.	67701-08-0*
Fatty acids, castor-oil	61789-44-4*
Fatty acids, coco	61788-47-4*
Fatty acids, dehydrated castor-oil	61789-45-5*
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, sunflower-oil, conjugated	68953-27-5*
Fatty acids, tall-oil	61790-12-3*
Fatty acids, tall-oil, conjugated*	
Fatty acids, vegetable oil	61788-66-7*
Glycerides, C ₁₆₋₁₈ and C ₁₈ -unsatd.	67701-30-8*
Heptanoic acid	111-14-8

TABLE 1.— LIST OF REACTANTS FROM WHICH POLYESTER MAY BE MADE—Continued

Reactant	CAS No.
Hexanoic acid	142-62-1
Hexanoic acid, 3,3,5-trimethyl-	3302-10-1
Linseed oil	8001-26-1*
Linseed oil, oxidized	68649-95-6*
Nonanoic acid	112-05-0
Oils, Cannabis*	
Oils, palm kernel	8023-79-8*
Oils, perilla	68132-21-8*
Oils, walnut	8024-09-7
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:	
1,2-Benzenedicarboxylic acid	88-99-3
1,3-Benzenedicarboxylic acid	121-91-5
1,3-Benzenedicarboxylic acid, dimethyl ester	1459-93-4
1,4-Benzenedicarboxylic acid	100-21-0
1,4-Benzenedicarboxylic acid, diethyl ester	636-09-9
1,4-Benzenedicarboxylic acid, dimethyl ester	120-61-6
1,2,4-Benzenetricarboxylic acid	528-44-9
Butanedioic acid	110-15-6
Butanedioic acid, diethyl ester	123-25-1
Butanedioic acid, dimethyl ester	106-65-0
2-Butenedioic acid (E)-	110-17-8
Decanedioic acid	111-20-6
Decanedioic acid, diethyl ester	110-40-7
Decanedioic acid, dimethyl ester	106-79-6
Dodecanedioic acid	693-23-2
Fatty acids, C ₁₈ -unsatd., dimers	61788-89-4*
Heptanedioic acid	111-16-0
Heptanedioic acid, dimethyl ester	1732-08-7
Hexanedioic acid	124-04-9
Hexanedioic acid, dimethyl ester	627-93-0
Hexanedioic acid, diethyl ester	141-28-6
Nonanedioic acid	123-99-9
Nonanedioic acid, dimethyl ester	1732-10-1
Nonanedioic acid, diethyl ester	624-17-9
Octanedioic acid	(505-48-6)
Octanedioic acid, dimethyl ester	1732-09-8
Pentanedioic acid	(110-94-1)
Pentanedioic acid, dimethyl ester	1119-40-0
Pentanedioic acid, diethyl ester	818-38-2
Undecanedioic acid	1852-04-6
Polyols	
1,3-Butanediol	107-88-0
1,4-Butanediol	110-63-4
1,4-Cyclohexanedimethanol	105-08-8
1,2-Ethandiol	107-21-1
Ethanol, 2,2'-oxybis-	111-46-6
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
1,3-propanediol, 2-methyl	2163-42-0
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

TABLE 1.— LIST OF REACTANTS FROM WHICH POLYESTER MAY BE MADE—Continued

Reactant	CAS No.
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	168957-06-2*
Silsesquioxanes, Ph Pr	168037-90-1*

* Chemical substance 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 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) *Exemption report for polymers manufactured under the terms of this section.* For substances exempt under paragraphs (e)(1), (e)(2), and (e)(3) of this section a report of manufacture or import must be submitted (postmarked) by January 31 of the year subsequent to initial manufacture. The notice must include:

(1) *Manufacturer's name.* This includes the name and address of the manufacturer and the name and telephone number of a technical contact.

(2) *Number of substances manufactured.* Number of substances manufactured. The manufacturer must identify the number of polymers manufactured under terms of the exemption for the first time in the year preceding the notice.

(g) *Chemical identity information.* For substances exempt under paragraph (e) of this section the manufacturer must to the extent known to or reasonably ascertainable by the manufacturer identify the following and maintain the records in accordance with paragraph (j) of this section:

(1) A specific chemical name and CAS Registry Number (or EPA assigned Accession Number) for each "reactant," as that term is defined in paragraph (b) of this section, used at any weight in the manufacture of the polymer. For purposes of determining chemical identity, the manufacturer may determine whether a reactant is used at greater than two weight percent according to either the weight of the reactant charged to the reaction vessel or the weight of the chemically combined (incorporated) reactant in the polymer. Manufacturers who choose the "incorporated" method must have analytical data, or theoretical calculations (if it can be documented that an analytical determination cannot be made or is not necessary), to demonstrate compliance with this paragraph. Reactants that introduce into the polymer elements, properties, or functional groups that would render the

polymer ineligible for the exemption are not allowed at any level.

(2) A representative structural diagram, if possible.

(h) *Certification.* To manufacture a substance under the terms of this section, a manufacturer must as of the date of first manufacture, make the following certification statements and maintain them in accordance with paragraph (j) of this section:

(1) The substance is manufactured or imported for a commercial purpose other than for research and development.

(2) All information in the certification is truthful.

(3) The new chemical substance meets the definition of a polymer, is not specifically excluded from the exemption in paragraph (d) of this section, and meets the conditions of the exemption in paragraph (e) of this section.

(i) *Exemptions granted under superseded regulations.* Manufacturers granted exemptions under the superseded requirements of §723.250 (as in effect on May 26, 1995) shall either continue to comply with those requirements or follow all procedural and recordkeeping requirements pursuant to this section. If an exemption holder continues to follow the superseded regulations, the Notice of Commencement requirements apply and the exempt polymer will continue to be listed on the Inventory with exclusion criteria and exemption category restrictions on residual monomer/ reactant and low molecular weight species content limitations.

(j) *Recordkeeping.* (1) A manufacturer of a new polymer under paragraphs (e) of this section, must retain the records described in this paragraph at the manufacturing site for a period of 5 years from the date of commencement of manufacture or import.

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

(i) Chemical identity information as required in paragraph (g) of this section.

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

(iii) Records of production volume for the first 3 years of manufacture and the date of commencement of manufacture.

(iv) Information to demonstrate that the new polymer meets the exemption criteria in paragraphs (e)(1), (e)(2), or (e)(3) of this section.

(v) Analytical data, or theoretical calculations (if it can be documented that an analytical determination cannot be made or is not necessary), to demonstrate that the polymer meets the number-average MW exemption criteria in paragraphs (e)(1) or (e)(2) of this section. The analytical tests may include gel permeation chromatography (GPC), vapor pressure osmometry (VPO), or other such tests which will demonstrate that the polymer meets the number-average MW criterion.

(vi) Analytical data, or theoretical calculations (if it can be documented that an analytical determination cannot be made or is not necessary), to demonstrate that the polymer meets the criteria in paragraphs (e)(1) or (e)(2) of this section, meets the low MW content criteria in paragraphs (e)(1) or (e)(2) of this section.

(vii) If applicable, analytical data, or theoretical calculations (if it can be documented that an analytical determination cannot be made or is not necessary) required in paragraph (g) of this section for determining monomers or reactants charged to the reaction vessel at greater than 2 weight percent but incorporated at 2 weight percent or less in the manufactured polymer.

(viii) The certification statements as required under paragraph (h) of this section.

(3) The manufacturer must submit the records listed in paragraph (j)(2) of this section to EPA upon written request by EPA. 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 EPA, must

permit such person at all reasonable times to have access to and to copy these records.

(k) *Submission of information.* Information submitted to EPA under this section must be sent in writing to: TSCA Document Control Officer, (7407), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

(l) *Compliance.* (1) A person who manufactures or imports a new chemical substance and fails to comply with any provision of this section is in violation of section 15 of the Act (15 U.S.C. 2614).

(2) 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 of the Act is a violation of section 15 of the Act (15 U.S.C. 2614).

(3) 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).

(4) 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).

(5) 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.

(6) 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 the Act (15 U.S.C. 2606) or section 17 of the Act (15 U.S.C. 2616).

(m) *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.

(n) *Confidentiality.* If a manufacturer submits information to EPA under this section which the manufacturer claims to be confidential business information, the manufacturer must clearly identify the information at the time of submission to EPA by bracketing, circling, or underlining it and stamping it with "CONFIDENTIAL" or some other

appropriate designation. Any information so identified will be treated in accordance with the procedures in 40 CFR part 2. Any information not claimed confidential at the time of submission may be made available to the public without further notice.

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40 CFR Part 723

[OPTS-50596B; FRL-4923-1]

RIN 2070-AC14

Premanufacture Notification Exemption; Revision of Exemption for Chemical Substances Manufactured in Small Quantities; Low Release and Exposure Exemption; Final Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Section 5(a)(1) of the Toxic Substances Control Act (TSCA) requires that persons notify EPA before they manufacture or import a new chemical substance for commercial purposes. Section 5(h)(4) of TSCA authorizes EPA, upon application and by rule to exempt the manufacturer or importer of any new chemical substance from some or all of the provisions of section 5 if the Agency determines that the manufacture, processing, distribution in commerce, use, or disposal of the substance will not present an unreasonable risk of injury to health or the environment. EPA is amending the current TSCA section 5(h)(4) limited exemption defined at 40 CFR 723.50 for persons who manufacture certain chemical substances in quantities of 1,000 kilograms or less per year. This amendment will increase the volume limit to 10,000 kilograms or less a year. Also, this amendment adds a new section 5(h)(4) exemption category for certain chemical substances with low environmental releases and human exposures. This amendment will significantly reduce administrative burdens on EPA and industry and will expedite the Agency review process so that lower risk chemical substances may be marketed more quickly. To ensure that these chemical substances will not present an unreasonable risk, EPA has included procedural safeguards, including a 30-day review, and other conditions in the exemption.

DATES: This rule is effective May 30, 1995. This rule shall be promulgated for purposes of judicial review at 1 p.m. eastern time, on April 12, 1995.

FOR FURTHER INFORMATION CONTACT: Susan B. Hazen, Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Telephone: (202) 554-1404, TDD: (202) 554-0551.

SUPPLEMENTARY INFORMATION: The original exemption for chemical substances manufactured in quantities of 1,000 kilograms or less per year became effective on August 26, 1985. The supporting rationale and background for that exemption were published at 50 FR 16477 on April 26, 1985 and 47 FR 33896, August 4, 1982. This rule was proposed in the **Federal Register** on February 8, 1993 (58 FR 7646). Public hearings on this and related PMN exemptions were held in Washington, DC, on April 26-28, 1993. While general background information is presented here, readers should also consult the preambles for those notices for further information on the objectives and rationale for the rule and the basis for finding under TSCA section 5(h)(4) that activities involving the exempt chemical substances will not present an unreasonable risk of injury to human health or the environment.

I. Background

Section 5(a)(1) of TSCA (15 U.S.C. 2604 (a)(1)) requires any person who intends to manufacture or import a new chemical substance to notify EPA 90 days before manufacture or importation begins. Section 5(h)(4) of TSCA (15 U.S.C. 2604(h)(4)) allows the EPA, by rule, to grant an exemption from any or all of the requirements of section 5 if EPA determines that the manufacture, processing, distribution in commerce, use, or disposal of a substance will not present an unreasonable risk of injury to health or the environment.

II. Final Exemption

A. Summary of the Rule

1. *Chemical substances manufactured at 10,000 kg or less per year.* Manufacturers of all new chemical substances manufactured in quantities of 10,000 kilograms or less per year are eligible to apply for a new category of exemption. (Note that throughout 40 CFR parts 720, 721, and 723, the term "manufacturer" is defined in TSCA section 3(8), 15 U.S.C. 2602(8), to include persons who import the specified chemical substance; the term "manufacture" is defined to include importation.) Upon approval, manufacturers will be permitted to manufacture up to 10,000 kilograms of the new chemical substance during