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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 723

[EPA-HQ-OPPT-2002-0051; FRL-8805-5]

RIN 2070-AD58

Premanufacture Notification Exemption for Polymers; Amendment of Polymer Exemption Rule to Exclude Certain Perfluorinated Polymers

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is amending the polymer exemption rule, which provides an exemption from the premanufacture notification (PMN) requirements of the Toxic Substances Control Act (TSCA), to exclude from eligibility polymers containing as an integral part of their composition, except as impurities, certain perfluoroalkyl moieties consisting of a CF₃- or longer chain length. This exclusion includes polymers that contain any one or more of the following: Perfluoroalkyl sulfonates (PFAS), perfluoroalkyl carboxylates (PFAC), fluorotelomers, or perfluoroalkyl moieties that are covalently bound to either a carbon or sulfur atom where the carbon or sulfur atom is an integral part of the polymer molecule (affected polymers). In general, any person who intends to manufacture (which is defined by TSCA to include import into the customs territory of the United States) any of these polymers not already on the TSCA Inventory (Inventory) must complete the TSCA PMN review process prior to commencing the manufacture or import of such polymers. Alternatively, manufacturers or importers may submit a request for a different exemption, such as the Low Volume Exemption (LVE) or Low Release and Exposure Exemption (LoREX), for affected polymers that they reasonably believe may qualify for such exemptions. Those persons who are currently manufacturing or importing affected polymers, or who have previously manufactured or imported them but are not doing so now, in full compliance with the 1995 polymer exemption rule, may continue manufacturing or importing them until

January 27, 2012. After that date, manufacture of these polymers will no longer be authorized under the polymer exemption rule, and continued manufacture or import must be authorized under a different TSCA section 5(h)(4) exemption or under a different TSCA section 5 authority, such as TSCA section 5(a)(1) or section 5(e). This change is necessary because, based on current information, EPA can no longer conclude that these polymers “will not present an unreasonable risk to human health or the environment” under the terms of the polymer exemption rule, which is the determination necessary to support an exemption under TSCA section 5(h)(4).

DATES: This final rule is effective February 26, 2010.

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPPT-2002-0051. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

FOR FURTHER INFORMATION CONTACT: For general information contact: Colby Lintner, Regulatory Coordinator, Environmental Assistance Division

(7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 554-1404; e-mail address: TSCA-Hotline@epa.gov.

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SUPPLEMENTARY INFORMATION:

I. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture or import polymers that contain as an integral part of their composition, except as impurities, certain perfluoroalkyl moieties consisting of a CF₃- or longer chain length (affected polymers). As specified in the regulatory text of this final rule (40 CFR 723.250(d)(6)), these perfluoroalkyl moieties include any one or more of the following: PFAS, PFAC, fluorotelomers, or perfluoroalkyl moieties that are covalently bound to either a carbon or sulfur atom where the carbon or sulfur atom is an integral part of the polymer molecule. Persons who import or intend to import polymers that are covered by this final rule would be subject to TSCA section 13 (15 U.S.C. 2612) import certification requirements, and to the regulations codified at 19 CFR 12.118 through 12.127 and 127.28. Those persons must certify that they are in compliance with the PMN requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. Importers of formulated products that contain a polymer that is subject to this final rule as a component (for example, for use as a water-proof coating for textiles or as a top anti-reflective coating (TARC) used to manufacture integrated circuits) may also be potentially affected. A list of potential monomers and reactants that could be used to manufacture polymers that would be affected by this final rule may be found in the public docket (Ref. 7). Potentially affected entities may include, but are not limited to: Chemical manufacturers or importers (NAICS code 325), e.g., persons who manufacture (defined by statute to include import) one or more of the subject chemical substances.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in 40 CFR 723.250. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

II. Background

A. What Action is the Agency Taking?

In the **Federal Register** issue of March 7, 2006 (Ref. 26), the Agency proposed to exclude from the polymer exemption rule (40 CFR 723.250), which exempts certain chemical substances from TSCA section 5 PMN requirements, polymers containing as an integral part of their composition, except as impurities, certain perfluoroalkyl moieties consisting of a CF₃- or longer chain length. The proposed exclusion included polymers that contain any one or more of the following: PFAS, PFAC, fluorotelomers, or perfluoroalkyl moieties that are covalently bound to either a carbon or sulfur atom where the carbon or sulfur atom is an integral part of the polymer molecule. EPA is finalizing the rule as proposed, with two changes related to the implementation of the final rule. The first applies to the effective date of the final rule, which will be 30 days after date of publication in the **Federal Register** instead of 12 months, as was proposed. The second will allow persons who are currently manufacturing or importing affected polymers, or who have previously manufactured or imported them but are not doing so now, in full compliance with the 1995 polymer exemption rule, 24 months to complete the TSCA section 5 review process instead of 12 months, as was proposed. EPA is also clarifying that manufacturers and importers of affected polymers may submit a request for a different TSCA section 5(h)(4) exemption, such as a LVE or LoREX request, in lieu of a PMN, if they reasonably believe that the subject polymers may qualify for those exemptions. See Unit III.E. for additional information on implementation of the final rule.

Non-confidential information related to this final rule may be found in

administrative record number (AR) AR-226, which is the public administrative record that the Agency has established for perfluorinated chemical substances generally. Interested parties should consult AR-226 for additional information on PFAS, PFAC, fluorotelomers, or other perfluoroalkyl moieties. To receive an index of AR-226, contact the EPA/DC by telephone: (202) 566-1744 or e-mail: *docket-customerservice@epa.gov*.

Additional information may be found in docket ID number EPA-HQ-OPPT-2003-0012 which covers the Agency's enforceable consent agreement (ECA) process for certain of these chemical substances. See **ADDRESSES** for instructions on accessing a public docket.

B. What is the Agency's Authority for Taking this Action?

Section 5(a)(1)(A) of TSCA requires persons to notify EPA at least 90 days before they manufacture or import a new chemical substance for commercial purposes. Section 3(9) of TSCA defines a "new chemical substance" as any chemical substance that is not on the Inventory compiled by EPA under TSCA section 8(b). 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 TSCA section 5 if the Agency determines that the manufacture, processing, distribution in commerce, use, or disposal of such chemical substance, or any combination of such activities will not present an unreasonable risk of injury to human health or the environment. Section 5(h)(4) of TSCA also authorizes EPA to amend or repeal such rules. EPA has acted under these authorities to amend the polymer exemption rule at 40 CFR 723.250.

C. Why is the Agency Taking this Action?

1. *Polymers containing PFAS or PFAC.* EPA is amending the polymer exemption rule, last amended in 1995, to exclude polymers containing PFAS or PFAC, because the Agency has received information which suggests that polymers containing PFAS or PFAC may degrade and release fluorochemical residual compounds into the environment. Once released, PFAS or PFAC are expected to persist in the environment, may bioaccumulate, and may be highly toxic. Accordingly, EPA can no longer make the determination that the manufacturing, processing, distribution in commerce, use, or disposal of polymers containing PFAS

or PFAC "will not present an unreasonable risk to human health or the environment" under the terms of the polymer exemption rule, as required under TSCA section 5(h)(4).

2. *Polymers containing fluorotelomers or other perfluoroalkyl moieties.* EPA is also excluding polymers that contain fluorotelomers, or that contain perfluoroalkyl moieties consisting of a CF₃- or longer chain length that are covalently bound to either a carbon or sulfur atom where the carbon or sulfur atom is an integral part of the polymer molecule. Initial studies have demonstrated toxic effects of certain compounds containing fluorotelomers (derived from the 8-2 alcohol, Chemical Abstracts Service Registry Number (CAS No.) 678-39-7). Preliminary investigations have found that fluorotelomer alcohols were present in the air above several cities, indicating that these chemical substances may be widely distributed and that air may be a route of exposure. Based on the available data, EPA expects that polymers containing fluorotelomers or perfluoroalkyl moieties that are covalently bound to either a carbon or sulfur atom where the carbon or sulfur atom is an integral part of the polymer molecule may degrade in the environment thereby releasing fluorotelomer alcohols or other perfluoroalkyl-containing chemical substances. It is possible that, once released, such moieties may potentially degrade to form PFAS or PFAC. Accordingly, EPA can no longer conclude that polymers containing fluorotelomers and these other perfluoroalkyl moieties "will not present an unreasonable risk of injury to health or the environment" under the terms of the polymer exemption rule, as required for an exemption under TSCA section 5(h)(4). Therefore, EPA is excluding such polymers from the polymer exemption at 40 CFR 723.250.

III. Final Rule

A. History Subsequent to the 1995 Amendment to the Polymer Exemption Rule

The 1995 amendments to the polymer exemption rule published in the **Federal Register** issue of March 29, 1995 (Ref. 28) expanded the polymer exemption to include polymers made from reactants that contain certain halogen atoms, including fluorine. The best available information in 1995 indicated that most halogen containing compounds, including unreactive polymers containing PFAS and PFAC chemical substances, were chemically and environmentally stable and would not

present an unreasonable risk to human health and the environment. In 1999, however, the 3M Company (3M) provided the Agency with preliminary reports that indicated widespread distribution of perfluorooctane sulfonate (PFOS) in humans, the environment and wildlife (Refs. 8–10). In addition, on May 16, 2000, 3M announced that it would phase out perfluorooctanyl chemistry in light of the persistence of certain fluorochemicals and their detection at extremely low levels in the blood of the general population and wildlife. 3M indicated that production of these chemical substances would be substantially discontinued by the end of 2000 (Ref. 11). Based on this information from 3M, EPA began to investigate potential risks from PFOS and other perfluorinated chemical substances, as well as polymers containing these chemical substances. It is possible that polymers containing PFAS or PFAC chemical substances may degrade, releasing these chemical substances into the environment where they are expected to persist. The number of carbon atoms on the PFAS or PFAC molecule, whether as a single compound, or as a component of a polymer, may influence bioaccumulation potential and toxicity. Based on the available data, EPA expects that polymers containing fluorotelomers or perfluoroalkyl moieties that are covalently bound to

either a carbon or sulfur atom where the carbon or sulfur atom is an integral part of the polymer molecule may degrade, releasing these chemical substances into the environment where they may further degrade into PFAS or PFAC.

B. EPA's Responses to Comments Received on the Proposed Rule

EPA specifically requested comments on the following issues in the proposed rule:

- Whether exemption is appropriate under the polymer exemption rule for polymers containing perfluoroalkyl moieties that are covalently bound to either a carbon or sulfur atom where the carbon or sulfur atom is an integral part of the polymer molecule and where the perfluoroalkyl moiety consists of a CF₃- or longer chain length.

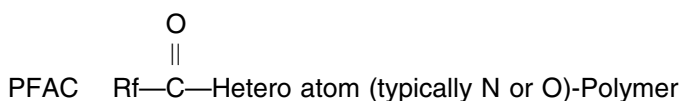
- Alternatives for implementing the final rule that would achieve the purposes of TSCA section 5 without disrupting ongoing manufacture or import of currently exempt polymers.

The Agency received comments on these and other aspects of the proposed rule. Comments were submitted by the Society of the Plastics Industry, E.I. DuPont de Nemours and Company, 3M Company, the People's Republic of China, International Imaging Industry Association, Peach State Labs, Inc., Dainippon Ink & Chemicals, Inc., and Clariant Corporation. Summaries of significant comments and EPA's

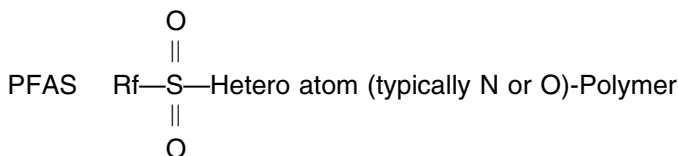
responses to them are included in a separate document entitled "Response to Comments on the Polymer Exemption Rule Amendment" (Ref. 2). This document is available in the public docket established for this final rule.

C. Defining Polymers that are Subject to this Final Rule

1. *Polymers containing PFAS or PFAC.* This final rule applies to a large group of polymers containing one or more fully fluorinated alkyl sulfonate or carboxylate groups. None of these polymers occur naturally. Such polymers are considered "new chemical substances" under TSCA if they have not been included in the Inventory compiled and published under TSCA section 8(b) (15 U.S.C. 2607(b)). For a list of examples of the Ninth Collective Index of Chemical Abstracts of chemical names and CAS numbers of chemical substances used to make polymers that are subject to this final rule, see Ref. 7. EPA has concerns for the perfluorinated carbon atoms in the Rf (Rf=Perfluoroalkyl CF₃- or greater) substituent, in this unit, when that Rf unit is associated with the polymer through the carbonyl (PFAC) or sulfonyl (PFAS) group. How these materials are incorporated into the polymer is immaterial (they may be counter ions, terminal/end capping agents, or part of the polymer backbone).



Rf=Perfluoroalkyl CF₃- or greater



This final rule specifically excludes from the polymer exemption at 40 CFR 723.250 polymers that contain any PFAS or PFAC group consisting of a CF₃- or longer chain length. EPA has increasing concerns as the number of carbon atoms that are perfluorinated in any individual Rf substituent increases. PFOA (perfluorooctanoate) is a PFAC (see top structure) which has 7 carbon atoms in the Rf moiety (CAS nomenclature rules count the carbonyl carbon atom as the eighth carbon for

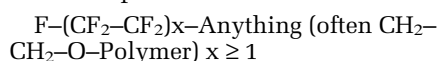
naming purposes, hence the octanoate terminology). PFOS is a PFAS (see bottom structure) which has 8 carbon atoms in the Rf moiety. Generally, the longer the chain of perfluorinated C atoms, the greater the persistence and retention time in the body; furthermore, the C8 chain length has been associated with adverse health effects in laboratory animals.

Most of the toxicity data currently available on PFAS and PFAC chemical substances pertain to the PFOS

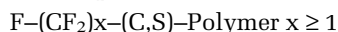
potassium salt (PFOSK) and the PFOA ammonium salt (APFO). There is some evidence that PFAS/PFAC moieties with longer carbon chains may present greater concerns than PFAS/PFAC moieties with shorter-carbon chains (Refs. 3, 12–14). However, EPA has insufficient information at this time to determine a limit for which shorter chain lengths "will not present an unreasonable risk to human health or the environment" under the terms of the polymer exemption rule.

2. *Polymers containing fluorotelomers or other perfluoroalkyl moieties.* EPA is also excluding from the polymer exemption at 40 CFR 723.250 polymers that contain fluorotelomers, or that contain perfluoroalkyl moieties of a CF₃- or longer chain length that are covalently bound to either a carbon or sulfur atom where the carbon or sulfur atom is an integral part of the polymer molecule.

i. *Fluorotelomers.* One method that is commonly used to incorporate perfluorinated compounds into polymers is to use fluorotelomers, such as perfluoroalkyl ethanol or its derivatives. Telomerization is the reaction of a telogen with a polymerizable ethylenic compound to form low molecular weight polymeric compounds, commonly referred to as a telomer. For example, the reaction of pentafluoroethyl iodide (a telogen) with tetrafluoroethylene forms a fluorotelomer iodide intermediate which is then reacted with ethylene and converted into perfluoroalkyl ethanol. This chemical substance can be further reacted to form a variety of useful intermediates which may subsequently be incorporated into the polymer (Ref. 15). The fluorochemical group formed by the telomerization process is predominantly straight chain, and depending on the telogen used produces a product having an even number of carbon atoms. However, the chain length of the fluorotelomer varies widely. A representative structure for these compounds is:



ii. *Other perfluoroalkyl moieties.* Perfluoroalkyl moieties that are covalently bound to either a carbon or sulfur atom where the carbon or sulfur atom is an integral part of the polymer molecule can be attached to the polymers using conventional chemical reactions. A representative structure for these compounds is:



D. Concerns with Respect to Polymers Containing PFAS, PFAC, Fluorotelomers, or Other Perfluoroalkyl Moieties

1. *Polymers containing PFAS or PFAC.* EPA has received and reviewed data on the PFAS and PFAC chemical substances PFOS and PFOA, respectively, and on other perfluoroalkyl acids. PFAS and PFAC are used in a variety of polymeric chemical substances to impart oil and water resistance, stain and soil protection, and reduced flammability. The same features that make the

polymeric coatings containing PFAS or PFAC useful, allow the polymeric compound to be stable to the natural environmental conditions that produce degradation. However, it has been demonstrated in certain circumstances that PFAS and PFAC-containing compounds will undergo degradation (chemical, microbial, or photolytic) of the non-fluorinated portion of the molecule leaving the remaining perfluorinated acid untouched (Ref. 22). Further degradation of the perfluoroalkyl residual compounds is extremely difficult. In particular, EPA has evidence that polymers containing PFAS or PFAC may degrade, possibly by incomplete incineration, and that these perfluorinated chemical substances may be released into the environment (Ref. 16). Under routine conditions of municipal waste incinerators (MWIs), incinerated chemical substances are exposed to 1,000°C temperature for long retention times. Those conditions are sufficient to cleave the normally stable C–F bonds. However, when MWIs do not maintain sufficiently high temperatures or sufficiently long retention times to cleave the stable C–F bond, it is possible that the PFAS and PFAC produced by oxidative thermal decomposition of the polymers will remain intact and can be released into the environment (Ref. 16).

PFOS and PFOA have been found in the blood of workers exposed to the chemical substances and in the general populations of the United States and other countries (Refs. 3, 17, and 18). They have also been found in many terrestrial and aquatic animal species worldwide (Refs. 3, 17, and 18). As discussed in this unit, PFAS and PFAC chemical substances used in the production of polymers may be released into the environment by degradation. It is possible, therefore, that the widespread presence of PFOS and PFOA in the environment may be due, in part, to the degradation of such polymers and the subsequent release of the PFAS and PFAC components into the environment. However, the method of degradation and global distribution is uncertain. The widespread distribution of the chemical substances also suggests, and biomonitoring studies confirm, that human exposure to PFOS and PFOA may be widespread. In particular, in a 2007 National Health and Nutrition Examination Survey (NHANES) report, PFOS, PFOA, perfluorohexane sulfonic acid (PFHxS) and perfluorononanoic acid (PFNA) were detected in > 98% of the serum samples from a representative sample of the general U.S. population ≥ 12 years

of age (Ref. 21 and see also the Response to Comments Document (Ref. 2)).

PFOS and PFOA have shown liver, developmental, and reproductive toxicity in animal studies (Ref. 3). Animal test data indicate that PFOS and PFOA may cause cancer (Ref. 3). An occupational study reported an excess of bladder cancer in a small number of workers at a plant that manufactured perfluorinated chemical substances; however, follow up studies have not confirmed an increase in bladder cancer incidence in workers (Ref. 3). EPA included a comprehensive discussion of use and production volume data, exposure data, and environmental fate and health effects data for PFOS and PFOA and other PFAS and PFAC chemical substances in the proposed rule (Ref. 26, pp. 11489–11497). That comprehensive discussion is incorporated here as modified by EPA's responses to public comments received by the Agency on aspects of that discussion (Ref. 2). Although the Agency has far more data on PFOS and PFOA than on other PFAS and PFAC chemical substances, EPA expects that, based on available data, other PFAS and PFAC chemical substances of CF₃- or longer chain length may share similar toxicity, persistence, and bioaccumulation characteristics that need to be evaluated.

Some commenters objected to EPA's statement in the proposed rule that it believes other PFAS and PFAC chemical substances of CF₃- or longer chain length may share similar toxicity, persistence, and bioaccumulation characteristics that need to be evaluated and what they asserted were other "generalized" statements in the proposed rule, noting that each PFAS and PFAC chemical substance should be examined on its own merits with respect to toxicity, bioaccumulation, and persistence. EPA agrees that individual PFAS and PFAC chemical substances, like the polymers that contain them, should be evaluated based on their own merits. That is precisely why it has excluded affected polymers from the polymer exemption rule. This action will allow EPA to evaluate affected polymers individually, based on their own merits, through the PMN process or under other appropriate exemption criteria. EPA also emphasizes that it has not stated in the preambles to the proposed rule or this final rule that other PFAS or PFAC chemical substances categorically share similar toxicity, bioaccumulation, and persistence characteristics with PFOS and PFOA. EPA has only stated that it believes that they may, or are expected to, share similar characteristics, based

on available information and its professional judgment and experience.

Consideration of available information on specific chemical substances in light of EPA's professional judgment and expertise, in order to draw reasonable conclusions about the potential risks of similar chemical substances, has long been an integral component of EPA's implementation of the polymer exemption rule. This has been the case whether EPA is expanding the scope of the exemption (see, for example, Ref. 27, pp. 7679, 7682–7683, in which EPA explained the basis for expanding the scope of the exemption to include polymers that contain halogen groups, based on analysis of health and ecotoxicity data for specific polymers that previously had been evaluated under the PMN program) or narrowing it (see, for example, Ref. 28, pp. 16316, 16319–16320, in which EPA excluded a category of water-absorbing polymers from the exemption, based on a single toxicity study submitted under TSCA section 8(e)).

In this instance, EPA stated in the proposed rule that, based on currently available information, EPA believed that, while all PFAS and PFAC chemical substances are expected to persist, the length of the perfluorinated chain may have an effect on the other areas of concern for these chemical substances, such as bioaccumulation and toxicity. EPA also stated that there was evidence that PFAS/PFAC moieties with longer carbon chains may present greater concerns for bioaccumulation potential and toxicity than PFAS/PFAC moieties with shorter-carbon chains. However, carbon chain length may only be one factor in determining retention time. As discussed in the Response to Comments document (Ref. 2), data received since the proposed rule was published generally supports these statements.

The Agency continues to investigate the physicochemical properties, the environmental fate and distribution, and the toxicity of PFAS and PFAC chemical substances, including polymers already in production. A recent journal article provides an overview of the monitoring data available for the environment, wildlife, and humans, as well as recent advances in the toxicology and mode of action for this class of compounds (Ref. 3). These data help the Agency to evaluate these polymers to ascertain any potential risks on a case-by-case basis. However, available data are still insufficient to determine the carbon number below which PFAS and PFAC chemical substances “will not present an unreasonable risk.” At this time, therefore, EPA can no longer conclude that polymers containing PFAS or PFAC

will not present an unreasonable risk to human health or the environment under the terms of the polymer exemption rule. Therefore, this final rule excludes polymers containing PFAS or PFAC from eligibility for exemption from TSCA section 5(a)(1)(A) reporting requirements for new chemical substances under the polymer exemption rule.

2. *Polymers containing fluorotelomers or other perfluoroalkyl moieties.* EPA has received data on various perfluorinated chemical substances that indicate that the Agency should evaluate polymers that contain these perfluoroalkyl moieties through the PMN process. As discussed in the proposed rule (Ref. 26, p. 11497), there is a growing body of data demonstrating that fluorotelomer alcohols metabolize or degrade to generate PFOA. For example, the fluorotelomer alcohol [CA Index Name:

3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-Heptadecafluorodecan-1-ol; CAS No. 678–39–7], also known as 8–2 alcohol, has been shown to degrade to form PFOA when exposed to activated sludge during accelerated biodegradation studies (Refs. 3, 19, and 20).

Initial test data from a study in rats dosed with fluorotelomer alcohol and other preliminary animal studies on various telomeric products containing fluorocarbons structurally similar to PFAC or PFAS have demonstrated a variety of adverse effects including liver, kidney and thyroid effects (Refs. 3 and 5).

Preliminary investigations have demonstrated the presence of fluorotelomer alcohols in the air in six different cities (Ref. 6). This finding is significant because it is indicative of not only widespread fluorotelomer alcohol distribution, but also it further indicates that air may be a route of direct or indirect exposure to these chemical substances, which can be degraded or metabolized to form PFOA. Fluorotelomer alcohols are generally incorporated into the polymers via covalent ester linkages, and it is possible that degradation of the polymers may result in release of the fluorotelomer alcohols to the environment.

Based on the presence of fluorotelomer alcohols in the air, the growing data demonstrating that fluorotelomer alcohols metabolize or degrade to generate PFOA, the preliminary toxicity data on certain compounds containing fluorotelomers (such as the 8–2 alcohol), and the possibility that polymers containing fluorotelomers as an integral part of the polymer composition may degrade in

the environment thereby releasing fluorotelomer alcohols or other perfluoroalkyl-containing chemical substances, EPA can no longer conclude that polymers containing fluorotelomers as an integral part of the polymer composition “will not present an unreasonable risk of injury to health or the environment” under the terms of the polymer exemption rule as required for an exemption under TSCA section 5(h)(4).

Although EPA does not have specific data demonstrating that polymers containing perfluoroalkyl moieties other than PFAS, PFAC, or fluorotelomers present the same concerns as those containing PFAS, PFAC, or fluorotelomers, EPA is nevertheless excluding polymers containing perfluoroalkyl groups, consisting of a CF₃- or longer chain length, that are covalently bound to either a carbon or sulfur atom where the carbon or sulfur atom is an integral part of the polymer molecule from the polymer exemption. Based on available data which indicate that compounds containing PFAS or PFAC may degrade in the environment thereby releasing the PFAS or PFAC moiety, and that fluorotelomers may degrade in the environment to form PFAC, it is possible that polymers containing these other types of perfluoroalkyl moieties may also degrade over time in the environment thereby releasing the perfluoroalkyl moiety. Based on available data, EPA expects that once released, such moieties may potentially degrade to form PFAS or PFAC. EPA therefore cannot continue to make the “will not present an unreasonable risk of injury to health or the environment” finding under the terms of the polymer exemption rule for such polymers.

E. Implementation

The proposed rule would have established an effective date for the final rule that was 1 year after the date of publication of the final rule. This would have allowed manufacturers or importers of affected polymers who were already manufacturing or importing such polymers in full compliance with the terms of the polymer exemption rule, to continue manufacture or import for a period of 1 year after the date of publication of the final rule. However, in order to continue manufacturing or importing affected polymers after the 1-year period, manufacturers or importers would have had to complete the PMN review process within the 1-year period before the final rule became effective.

As an alternative to the 1 year effective date, EPA also specifically

sought comment on an implementation approach that would have established an effective date 30 days after publication of the final rule, but provide an extended compliance date for those who, prior to the effective date, had already initiated the manufacture or import of affected polymers (see Ref. 26, pp. 11484, 11488). Under the alternative approach, the TSCA section 5(a)(1)(A) requirement to submit a PMN for a new chemical substance would have been re-established with respect to affected polymers beginning 30 days after publication of the final rule. However, those who were manufacturing or importing affected polymers in full compliance with the existing exemption would have had 1 year from the effective date to complete the PMN process. EPA specifically requested comment on these or other implementation approaches.

Commenters generally asserted that 1 year was not enough time to develop a PMN and to complete the PMN review process. Several commenters suggested as an alternative that EPA require submission of a PMN within a year or that it extend the 1-year "grace period" to 3 years. One commenter also requested clarification regarding whether a LVE request could be submitted in lieu of a PMN in order to comply with this final rule. Upon review of these comments and proposed alternatives, EPA agrees that 1 year would likely not provide sufficient time to complete the PMN review process for all affected polymers currently being manufactured or imported under the polymer exemption rule. The Agency has therefore changed the proposed approach, and is also clarifying that requests for different TSCA section 5(h)(4) exemptions, such as a LVE or LoREX request, may be submitted to comply with the final rule, if manufacturers or importers reasonably believe affected polymers may qualify for such exemptions.

The effective date of this final rule will be 30 days after its publication in the **Federal Register**, which is the minimum required by section 553(c) of the Administrative Procedure Act. Accordingly, the TSCA section 5(a)(1)(A) requirement to submit a PMN (or alternate exemption request, if appropriate) for a new chemical substance applies to all affected polymers beginning 30 days after publication of the final rule in the **Federal Register**. However, EPA is providing an extended compliance date for those who, prior to the effective date of the final rule, had already initiated the manufacture or import of affected polymers in full compliance with the

1995 polymer exemption rule. Specifically, this final rule allows manufacturers or importers of affected polymers, who are in full compliance with the terms of the 1995 polymer exemption rule, to continue manufacture or import of such polymers under the polymer exemption rule until January 27, 2012. If PMNs for these polymers have not been reviewed by the Agency and the polymers have not been listed on the TSCA Inventory or, in the case of exemption requests, EPA has not granted the exemption request by January 27, 2012, such manufacture or import must cease. With respect to PMN submissions, the company must submit a notice of commencement (NOC) within 30 days of commencing non-exempt manufacturing (see 40 CFR 720.102), so that the polymer can be placed on the TSCA Inventory where appropriate, after the review of the PMN submission. The NOC must be filed as a condition of continued manufacture or import. A company may at any time during the review process elect to withdraw its PMN or exemption request. If a manufacturer or importer elects to withdraw its PMN or exemption request, all manufacturing or importing activity must cease as of January 27, 2012.

EPA will strive to complete the review of the PMN (or alternate exemption request) submitted in response to this final rule promptly. For those PMNs for which EPA determines that action under TSCA section 5(e) may be necessary, the 90-day review period is generally suspended by the reviewer as the consent order is developed/negotiated. In addition, at any time in the review period, EPA may determine that good cause exists to extend the PMN notice review period for a total period of extension not to exceed 90 days (see 40 CFR 720.75). However, for polymers currently being manufactured under the terms of the existing polymer exemption rule, the TSCA section 5 review process must be completed by January 27, 2012. Therefore, the Agency recommends that manufacturers currently manufacturing affected polymers under the polymer exemption rule submit their PMNs early in the 24 months following the publication of this final rule. In particular, manufacturers intending to submit an LVE or LoREX should do so as soon after the effective date as possible to ensure that they have adequate time to submit a PMN in case the Agency denies the LVE or LoREX. In addition to reviewing the applicable regulations pertaining to submission of PMNs and alternate TSCA section 5(h)(4) exemption requests,

manufacturers may consult with the OPPT New Chemicals Management Branch ((202) 564-9373) in the TSCA New Chemicals Program to determine what information will enable timely review.

EPA decided on this approach because the proposed rule would have inadvertently allowed polymers not already being manufactured under the polymer exemption rule to be manufactured or imported for a year without going through the PMN or other TSCA section 5 review process. As noted in the proposed rule, the delayed effective date was intended to provide current manufacturers or importers of affected polymers who are in full compliance with the terms of the existing polymer exemption rule additional time to come into compliance with the final rule, without disrupting their ability to manufacture or import those polymers. (Ref. 26, p. 11487). Those who are not currently manufacturing or importing affected polymers would not experience such disruptions. Accordingly, EPA believes it is reasonable to make the effective date of the final rule 30 days after publication in the **Federal Register**, but provide additional time to complete the TSCA section 5 review process for manufacturers or importers who began manufacturing or importing affected polymers in full compliance with the terms of the existing polymer exemption rule prior to the effective date of the final rule.

EPA has extended by 12 months the time that manufacturers and importers who are currently manufacturing or importing affected polymers would have had under the proposed rule to complete the TSCA section 5 review process. Under the proposed rule, such manufacturers would have had to submit a PMN to EPA within 6 months after publication of the final rule in order for EPA to have had the entire 180 day period authorized by TSCA section 5 to complete the PMN review. This time frame may have been too short in some circumstances. For example, one trade group indicated that notifications for imported affected polymers might take longer than normal to prepare because its members would need to coordinate with non-domestic suppliers to obtain information, which may be proprietary, on formulations that they import. Another commenter observed that manufacturers or importers may need to submit bona fide letters of intent prior to submitting a PMN to determine whether affected polymers that they manufacture or import are already listed on the Inventory.

Under this final rule, such manufacturers and importers will have up to 18 months to submit a PMN in order for EPA to have the entire 180 day review period (90 days plus opportunity for up to a 90-day extension under TSCA section 5(c)) to complete the review. This approach will allow such manufacturers and importers additional time to compile the information necessary to prepare and submit PMNs or exemption requests. However, EPA encourages manufacturers and importers to submit PMNs or alternate exemption requests as soon as possible after publication of the final rule. Doing so will provide EPA with more time to complete consent orders and, if necessary, establish testing requirements for those polymers for which EPA may have concerns of potential unreasonable risk to human health or the environment.

The proposed regulatory text in 40 CFR 723.250(d)(6)(i) has therefore been changed from "Except ... may no longer be manufactured after January 27, 2011 unless that polymer has undergone a premanufacture review ..." to: "Any polymer that has been manufactured previously in full compliance with the requirements of this section prior to February 26, 2010 may no longer be manufactured under this section after January 27, 2012."

Manufacturers or importers of affected polymers that are already on the Inventory compiled and published under TSCA section 8(b) (15 U.S.C. 2607(b)) are not impacted by this final rule. The PMN requirements in TSCA section 5(a) apply only to new chemical substances which are those that are not included on the Inventory of Chemical Substances.

IV. Objective and Rationale for this Final Rule

The objective of this final rule is to amend the polymer exemption rule to exclude polymers containing as an integral part of the polymer composition, except as impurities, any one or more of certain perfluoroalkyl moieties consisting of a CF₃- or longer chain length from eligibility for the exemption from TSCA section 5 reporting requirements allowed under the 1995 amendments to the polymer exemption rule. In TSCA section 5(a)(1)(A), Congress prohibited persons from manufacturing (including importing) new chemical substances unless such persons submitted a PMN to EPA at least 90 days before such manufacture. Pursuant to TSCA section 5(h)(4), EPA is authorized to exempt the manufacturer of any new chemical substance from all or part of the

requirements of TSCA section 5 if the Agency determines that the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance, or any combination of such activities, will not present an unreasonable risk of injury to health or the environment. Section 5(h)(4) of TSCA also authorizes EPA to amend or repeal such rules.

The polymer exemption rule is intended to exempt certain polymers from certain TSCA section 5 requirements polymers because EPA believes those exempted polymers pose a low risk of injury to health or the environment. The exemption criteria are therefore designed to exempt polymers that are of low concern because of their stability, molecular size, and lack of reactivity, among other properties. EPA has excluded certain polymers from the exemption where:

- The Agency has insufficient data and review experience to support a finding that they will not present an unreasonable risk; or
- The Agency has found that under certain conditions, the polymers may present risks which require a closer examination of the conditions of manufacturing, processing, distribution, use, and disposal during a full 90-day PMN review (i.e., the Agency has information suggesting that the conditions for an exemption under TSCA section 5(h)(4) are not met).

This approach allows the Agency to maintain full regulatory oversight over potentially higher risk polymers while streamlining the review process for low-risk polymers.

Based on the data currently available, for the reasons stated herein, EPA can no longer make a generally applicable finding, without additional information, that the manufacture, processing, distribution in commerce, use, and/or disposal of affected polymers will not present an unreasonable risk of injury to health or the environment under the terms of the polymer exemption rule.

V. Economic Considerations

EPA has evaluated the potential costs of eliminating the polymer exemption for the chemical substances described in this final rule. The results of this evaluation are contained in a document entitled "Economic Analysis of the Amendment to the Polymer Exemption Rule to Exclude Certain Perfluorinated Polymers" (Ref. 1). A copy of this economic analysis is available in the public docket for this action, and is briefly summarized here.

The industry costs for completing and submitting a PMN reporting form are

estimated to be \$8,269 per chemical substance. Because the final rule would eliminate the cost of complying with the recordkeeping and reporting requirements of the polymer exemption rule, the cost for completing and submitting a PMN as a result of this amendment is reduced by \$372, for a net cost of \$7,897 per chemical substance (Ref. 1).

Companies that currently manufacture an affected polymer under the exemption are estimated to incur a total net cost of \$7,897 per chemical substance. Companies that do not currently manufacture an affected polymer, but begin to manufacture such polymers in the future, may also incur potential net costs of \$14,522 associated with potential delays in commercialization of the new chemical substance. These companies are estimated to incur a total cost of \$22,419 per chemical substance as a result of this final rule (Ref. 1). These net costs do not include the following per chemical substance costs that would have been incurred had a manufacturer of an affected polymer been allowed to continue to submit an exemption notification under the polymer exemption rule (i.e., had this amendment to the polymer exemption rule not been finalized):

- \$372 for recordkeeping and reporting costs.
- \$9,572 commercialization delay cost.

The potential number of PMNs that may be submitted each year under the final rule was estimated using the 292 polymer reports received by EPA annually between 1996 and 2006 under the polymer exemption rule. EPA estimates this final rule could affect a maximum of 6% of the 292 polymers reported annually, and, therefore, estimates that a maximum of 18 PMNs may be submitted each year under the final rule. Using the same estimated number of 18 chemical substances per year for the 14 years (1996 through 2009) during which affected polymers were exempt from PMN requirements under the polymer exemption rule, 252 previously exempt chemical substances (18 chemical substances x 14 years) could be expected to have a PMN submitted under the final rule. EPA expects to receive the majority of PMNs for previously exempt chemical substances during the second year of the proposed rule. However, because EPA has no way of predicting accurately the actual timing of the submissions, EPA is averaging the 252 PMNs over the 2-year period and is assuming that 126 PMNs for previously exempt chemical substances will be submitted in each of

the first 2 years after publication of the final rule.

In addition, EPA is expecting a maximum of 18 PMNs to be submitted to the Agency each year for new chemical substances. Therefore, the Agency estimates that a maximum of 144 PMNs (126 + 18) might be submitted during each of the first 2 years after the effective date of the final rule, and that a maximum of 18 PMNs might be submitted in each subsequent year.

Using the estimated per chemical substance costs and the estimated number of PMNs anticipated, EPA estimates the potential PMN submission costs to industry in each of the first 2 years of the final rule for manufacturers of 144 chemical substances (126 previously exempt new chemical substances and 18 new chemical substances) to be \$1,398,564, or \$1.4 million per year, including \$995,022 for previously exempt chemical substances (126 chemical substances x \$7,897 per chemical substance) + \$403,542 (18 new chemical substances x \$22,419). This will decrease to an estimated annual cost of \$403,542 in the third year and beyond for the maximum of 18 PMNs that EPA believes could be submitted annually by manufacturers and importers of new chemical substances that are no longer eligible for the exemption.

While the final rule clarifies that other TSCA section 5(h)(4) exemption requests may be submitted, EPA estimates that the cost of preparing an LVE or a LoREX is equal to the cost of preparing a PMN. However, LVEs and LoREXs are not subject to the \$2,500 user fee. Accordingly, if the Agency receives no LVE or LoREXs notices as a result of this clarification, then Agency estimated costs are not affected by this clarification. However, if the Agency does receive any LVE or LoREX notices, then estimated costs would be overstated because these notices would not be subject to the user fee. The Agency has never received a photographic film exemption request and does not expect to as a result of this final rule.

In addition, as was the case prior to the promulgation of the polymer exemption rule in 1995, the Agency recognizes that the submission of a PMN may lead to other regulatory actions under TSCA, for example consent orders issued under TSCA section 5(e). Any such actions are highly dependent on the circumstances surrounding the individual PMN (e.g., available information and scientific understanding about the chemical substance and its risks at the time the

PMN is being reviewed). Such potential actions and any costs associated with them would not be a direct result of this final rule. Nevertheless, the economic analysis does contain a brief discussion of the Agency's previous and ongoing regulatory activities with respect to potentially affected polymers.

VI. References

As indicated under **ADDRESSES**, a docket has been established for this final rule under docket ID number EPA-HQ-OPPT-2002-0051. The following is a listing of the documents that are specifically referenced in this final rule. References from the proposed rule that have not been referenced in the final rule are relevant to EPA's decisions in this final rule and can also be found in this docket. The docket includes these documents and other information considered by EPA in developing this final rule, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

Reference documents identified with an "AR" designation are cross-indexed to non-regulatory, publicly accessible information files maintained in the EPA/DC. Copies of these documents can be obtained as described in **ADDRESSES**.

1. EPA. Economic Analysis of the Amendment to the Polymer Exemption Rule To Exclude Certain Perfluorinated Polymers. Wendy Hoffman (EPA/OPPT/Economics, Exposure and Technology Division (EETD)). October 19, 2009.

2. EPA. Response to Comments on the Polymer Exemption Rule Amendment. July 14, 2009.

3. Lau, C.; Anitole, K.; Hodes, C.; Lai, D.; Pfahles-Hutchens, A.; Seed, J. Perfluoroalkyl Acids: A Review of Monitoring and Toxicological Findings. *Toxicological Sciences*. Vol. 99(2), pp. 366-394. 2007.

4. (AR-226-1440) Hagen, D.F.; Belisle, J.; Johnson, J.D.; Venkateswarlu, P. Characterization of fluorinated metabolites by a gas chromatographic-helium microwave plasma detector—the biotransformation of 1H, 1H, 2H, 2H-perfluorodecanol perfluorooctanoate. *Analytical Biochemistry*. Vol. 118(2), pp. 336-343. 1981.

5. (AR-226-1147) DuPont presentation to the Agency at the meeting held on November 25, 2002.

6. (AR-226-1281) Scott Mabury, P.I. Interim Annual Report of Activities for TRP Grant to University of Toronto;

Project years: 1 September, 2001 to 1 September, 2002.

7. Memo from Dr. Gregory Fritz (EPA/OPPT/EETD) to Mary Begley (EPA/OPPT/Chemical Control Division (CCD)) re: Polymer Feedstocks Resulting in Excluded Polymers. April 18, 2002.

8. (AR-226-0620) Sulfonated Perfluorochemicals in the Environment: Sources, Dispersion, Fate, and Effects. 3M. St. Paul, MN. March 1, 2000.

9. (AR-226-0547) The Science of Organic Fluorochemistry. 3M. St. Paul, MN. February 5, 1999.

10. (AR-226-0548) Perfluorooctane Sulfonate: Current Summary of Human Sera, Health and Toxicology Data. 3M. St. Paul, MN. January 21, 1999.

11. (AR-226-0600) Weppner, William A. Phase-out Plan for PFOS-Based Products. 3M. St. Paul, MN. July 7, 2000.

12. Kudo, Naomi, et al. Comparison of the Elimination Between Perfluorinated Fatty Acids with Different Carbon Chain Lengths in Rats. *Chemico-Biological Interactions*. Vol. 134(2), pp. 203-216. 2001.

13. Goeke-Flora, Carol M. and Nicholas, V. Reo. Influence of Carbon Chain Length on the Hepatic Effects of Perfluorinated Fatty Acids, A ¹⁹F- and ³¹P-NMR Investigation. *Chemical Research in Toxicology*. Vol. 9(4), pp. 689-695. 1996.

14. (AR-226-1030a109) Fluorochemical Decomposition Processes. 3M. St. Paul, MN. April 4, 2001.

15. Bultman, David and Pike, Myron. The Use of Fluorochemical Surfactants in Floor Polish. 3M. St. Paul, MN.

16. (AR-226-0550) Fluorochemical Use, Distribution and Release Overview. 3M. St. Paul, MN. May 26, 1999.

17. (AR-226-1093) Seed, Jennifer. Hazard Assessment of Perfluorooctanoic Acid and Its Salts, Revised Draft (EPA/OPPT/Risk Assessment Division (RAD)). Washington, DC. November 4, 2002.

18. (AR-226-1140) Organization for Economic Co-operation and Development (OECD), Hazard Assessment of Perfluorooctane sulfonate (PFOS) and its Salts. OECD Publication No. ENV/JM/ RD(2002)17/FINAL. November 21, 2002.

19. (AR-226-1149) Biodegradation screen studies for telomer type alcohols. 3M. November 6, 2002.

20. (AR-226-1262) DuPont Executive Summary—Biodegradation Screening Studies of 8-2 Telomer B Alcohol. March 20, 2003.

21. Calafat, A.; Wong, L.; Kuklenyik, Z.; Reidy, J.; Needham, L. Polyfluoroalkyl Chemicals in the U.S. Population: Data from the National Health and Nutrition Examination

Survey (NHANES) 2003–2004 and Comparisons with NHANES 1999–2000. *Environmental Health Perspectives*. Vol. 115(11), pp. 1596–1602. 2007.

22. Remde, A. and Debus, R. Biodegradability of Fluorinated Surfactants Under Aerobic and Anaerobic Conditions. *Chemosphere*. Vol. 32(8), pp. 1563–1574. 1996.

23. OECD. Screening Information Data Sets (SIDS). Ammonium Perfluorooctanoate & Perfluorooctanoic Acid, SIDS Initial Assessment Report (SIAR). April 2006.

24. United Nations Environment Program/Persistent Organic Pollutants/Persistent Organic Pollutants Review Committee (UNEP/POPS/POPRC). Draft risk profile: Perfluorooctane sulfonate (PFOS). July 2006.

25. Ellis, D.A.; Mabury, S.A.; Martin, J.W.; Muir, D.C.G. Thermolysis of fluoropolymers as a potential source of halogenated organic acids in the environment. *Nature*. Vol. 412, pp. 321–324. 2001.

26. EPA. Premanufacture Notification Exemption for Polymers; Amendment of Polymer Exemption Rule to Exclude Certain Perfluorinated Polymers; Proposed Rule. **Federal Register** (71 FR 11483, March 7, 2006) (FRL–7735–5).

27. EPA. Premanufacture Notification Exemptions; Revisions of Exemptions for Polymers; Proposed Rule. **Federal Register** (58 FR 7679, February 8, 1993) (FRL–3890–1).

28. EPA. Premanufacture Notification Exemptions; Revisions of Exemptions for Polymers; Final Rule. **Federal Register** (60 FR 16316, March 29, 1995) (FRL–4929–8).

VII. Statutory and Executive Order Reviews

A. Executive Order 12866

This action is not a “significant regulatory action” under section 3(f) of Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), and was not therefore reviewed by the Office of Management and Budget (OMB) under Executive Order 12866.

EPA has prepared an economic analysis of the potential impacts associated with this action. A copy of this economic analysis, “Economic Analysis of the Amendment to the Polymer Exemption Rule to Exclude Certain Perfluorinated Polymers” (Ref. 1) is available in the public docket for this action and is briefly summarized in Unit V.

B. Paperwork Reduction Act

The information collection requirements related to the submission

of PMNs are already approved by OMB under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.* That Information Collection Request (ICR) document has been assigned EPA ICR number 0574 and OMB control number 2070–0012. This final rule does not impose any new requirements that require additional OMB approval.

Under PRA, “burden” means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required PMN, and maintain the required records.

Based on the estimated burden in the existing ICR, if an entity were to submit a PMN to the Agency, the annual reporting burden is estimated to average between 95 and 114 hours per response, with a midpoint respondent burden of 107 hours. This estimate was adjusted to account for the elimination of the existing burden related to the recordkeeping and reporting requirements in the polymer exemption rule, which is estimated to impose a burden on industry of 6 hours per chemical substance, i.e., 2 hours for reporting, and 4 hours for recordkeeping. The net paperwork burden for submitting a PMN as a result of this final amendment is therefore estimated to be 101 hours per PMN submission. The net cost to submit a PMN under the final rule is estimated to be \$5,397. In addition, PMN submissions must be accompanied by a user fee of \$2,500 (set at \$100 for small businesses with annual sales of less than \$40 million). These net paperwork hours and associated costs do not include the per chemical substance 6 hour burden and \$372 associated cost that would have been incurred had a manufacturer of an affected polymer been allowed to continue to submit an exemption notification under the polymer exemption rule (i.e., had this amendment to the polymer exemption rule not been finalized).

The final rule clarifies that other TSCA section 5(h)(4) exemption requests may be submitted in lieu of PMNs. EPA estimates that the cost of preparing an LVE or a LoREX is equal to the cost of preparing a PMN. However, LVEs and LoREXs are not subject to the \$2,500 user fee.

Accordingly, if the Agency receives no LVE or LoREXs notices as a result of this clarification, then Agency estimated costs are not affected by this

clarification. However, if the Agency does receive any LVE or LoREX notices, then estimated costs would be overstated because these notices would not be subject to the user fee. The Agency has never received a photographic film exemption request and does not expect to as a result of this final rule.

For the first 2 years after publication of the final rule, EPA estimates that the one-time burden for the companies that submit PMNs for chemical substances already in production will be a maximum of 12,726 hours (126 chemical substances x 101 hours per submission). Based on the high-end assumption of 18 PMNs for new chemical substances annually, the annual burden is estimated to be 1,818 hours (18 x 101 hours). Therefore, EPA estimates that the burden in each of the first two years for the 144 PMNs will be 14,544 hours. The burden is expected to decrease to 1,818 hours in the third year of the final rule and beyond.

An agency may not conduct or sponsor, and a person is not required to respond to an information collection request subject to PRA unless it displays a currently valid OMB control number. The OMB control numbers for EPA’s regulations are listed in 40 CFR part 9 and included on any related collection instrument (e.g., on the form or survey).

C. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that this action will not have a significant adverse economic impact on a substantial number of small entities. The Agency’s basis is briefly summarized here and the analysis is detailed in the economic analysis (Ref. 1).

Small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impacts of this final rule on small entities, small entity is defined as:

1. A small business as defined by the Small Business Administration’s (SBA) regulations at 13 CFR 121.201 based on the applicable NAICS code for the business sector impacted.

2. A small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000.

3. A small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

The regulated community does not include any small governmental jurisdictions or small not-for-profit

organizations. For small businesses, the Agency assessed the impacts on small chemical manufacturers in NAICS codes 325 and 324110. The SBA size standards for sectors under NAICS code 325 range from 500 to 1,000 employees or fewer in order to be classified as small. The size standard for NAICS code 324110, petroleum refineries, is 1,500 employees.

As summarized in Unit V., the industry costs for completing and submitting a PMN reporting form are estimated to be \$7,897 per chemical substance (Ref. 1). Small businesses with less than \$40 million in annual sales are entitled to a reduced user fee of \$100 for submitting a PMN, rather than the \$2,500 user fee, which would reduce the per PMN costs for small businesses to \$5,497 per chemical substance.

Based on estimates of the number of PMNs expected to be submitted as a result of this action, it appears that 12 or fewer businesses would be affected per year (Ref. 1). The five companies that manufacture the majority of the volume of chemical substances that will be affected by the polymer exemption rule belong to either or both of the Fluoropolymer Manufacturers Group and the Telomer Research Program. These two groups, which have no other members beyond the five companies, have negotiated TSCA section 4 ECAs and other voluntary testing arrangements with the Agency for testing specific chemical substances that would be affected by the polymer exemption rule. The two groups have told the Agency that their member companies manufacture the majority of the volume of chemical substances that would be affected by the final rule. None of these five companies meet the definition of small under the Small Business Administration employee size criteria. The remaining volume of chemical substance that could be affected by the final rule is low enough so that even if a small company were to be affected, a significant number of businesses would not be affected, nor would any individual small business experience significant impacts.

D. Unfunded Mandates Reform Act

This action contains no Federal mandates for State, local, or tribal governments or the private sector under the provisions of Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1531–1538. This action will not have an annual impact of \$100 million or more on the private sector, nor will it impact State or tribal governments. Based on EPA's experience with past PMNs, State, local,

and tribal governments have not been affected by this reporting requirement, and EPA does not have any reason to believe that any State, local, or tribal government will be affected by this final rule. As such, EPA has determined that this regulatory action does not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of sections 202 or 205 of UMRA.

E. Executive Order 13132

Pursuant to Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999), EPA has determined that this action does not have federalism implications because it will not have substantial direct effects on the States, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in the Order. Thus, Executive Order 13132 does not apply to this final rule.

F. Executive Order 13175

As required by Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000), EPA has determined that this action does not have tribal implications because it will not have any effect on tribal governments, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in the Order. Thus, Executive Order 13175 does not apply to this final rule.

G. Executive Order 13045

EPA interprets Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5-501 of Executive Order 13045 has the potential to influence the regulation. This action is not subject to Executive Order 13045 because it does not establish an environmental standard intended to mitigate health or safety risks.

H. Executive Order 13211

This action is not a "significant energy action" as defined in Executive Order 13211, entitled *Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) because it is not likely to have a significant adverse

effect on the supply, distribution, or use of energy.

I. National Technology Transfer Advancement Act

Since this action does not involve any technical standards, section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note), does not apply to this action.

J. Executive Order 12898

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994). EPA has determined that this final rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it increases the level of environmental protection for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population.

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 723

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: January 15, 2010.

Stephen A. Owens,

Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances.

■ Therefore, 40 CFR chapter I 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. Section 723.250 is amended by adding the definitions below in alphabetical order to paragraph (b) and by adding a new paragraph (d)(6) to read as follows:

§ 723.250 Polymers.

* * * * *

(b) * * *

Fluorotelomers means the products of telomerization, which is the reaction of a telogen (such as pentafluoroethyl iodide) with an ethylenic compound (such as tetrafluoroethylene) to form low molecular weight polymeric compounds, which contain an array of saturated carbon atoms covalently bonded to each other (C-C bonds) and to fluorine atoms (C-F bonds). This array is predominantly a straight chain, and depending on the telogen used produces a compound having an even number of carbon atoms. However, the carbon chain length of the fluorotelomer varies widely. The perfluoroalkyl groups formed by this process are usually, but do not have to be, connected to the polymer through a functionalized ethylene group as indicated by the following structural diagram: (Rf-CH₂CH₂-Anything).

* * * * *

Perfluoroalkyl carboxylate (PFAC) means a group of saturated carbon atoms covalently bonded to each other in a linear, branched, or cyclic array and covalently bonded to a carbonyl moiety and where all carbon-hydrogen (C-H) bonds have been replaced with carbon-fluorine (C-F) bonds. The carbonyl moiety is also covalently bonded to a hetero atom, typically, but not necessarily oxygen (O) or nitrogen (N).

Perfluoroalkyl sulfonate (PFAS) means a group of saturated carbon atoms covalently bonded to each other in a linear, branched, or cyclic array and covalently bonded to a sulfonyl moiety and where all carbon - hydrogen (C-H) bonds have been replaced with carbon - fluorine (C-F) bonds. The sulfonyl moiety is also covalently bonded to a hetero atom, typically, but not necessarily oxygen (O) or nitrogen (N).

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(d) * * *

(6) *Polymers which contain certain perfluoroalkyl moieties consisting of a CF₃- or longer chain length.* Except as provided in paragraph (d)(6)(i), after February 26, 2010, a polymer cannot be manufactured under this section if the polymer contains as an integral part of its composition, except as impurities, one or more of the following perfluoroalkyl moieties consisting of a CF₃- or longer chain length: Perfluoroalkyl sulfonates (PFAS),

perfluoroalkyl carboxylates (PFAC), fluorotelomers, or perfluoroalkyl moieties that are covalently bound to either a carbon or sulfur atom where the carbon or sulfur atom is an integral part of the polymer molecule.

(i) Any polymer that has been manufactured previously in full compliance with the requirements of this section prior to February 26, 2010 may no longer be manufactured under this section after January 27, 2012.

(ii) [Reserved]

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DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

49 CFR Chapter III

Regulatory Guidance Concerning the Applicability of the Federal Motor Carrier Safety Regulations to Texting by Commercial Motor Vehicle Drivers

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of regulatory guidance.

SUMMARY: The FMCSA announces regulatory guidance concerning texting while driving a commercial motor vehicle (CMV). The guidance is applicable to all interstate drivers of CMVs subject to the Federal Motor Carrier Safety Regulations (FMCSRs). **DATES:** *Effective Date:* This regulatory guidance is effective on January 27, 2010.

FOR FURTHER INFORMATION CONTACT: Thomas L. Yager, Chief, Driver and Carrier Operations Division, Office of Bus and Truck Standards and Operations, Federal Motor Carrier Safety Administration, 1200 New Jersey Ave., SE., Washington, DC 20590.

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SUPPLEMENTARY INFORMATION:

Legal Basis

The Motor Carrier Safety Act of 1984 (Pub. L. 98-554, Title II, 98 Stat. 2832, October 30, 1984) (the 1984 Act) provides authority to regulate drivers, motor carriers, and vehicle equipment. It requires the Secretary of Transportation to prescribe regulations which ensure that: (1) CMVs are maintained, equipped, loaded, and operated safely; (2) the responsibilities imposed on operators of CMVs do not impair their ability to operate the

vehicles safely; (3) the physical condition of operators of CMVs is adequate to enable them to operate the vehicles safely; and (4) the operation of CMVs does not have a deleterious effect on the physical condition of the operators. (49 U.S.C. 31136(a)). Section 211 of the 1984 Act also grants the Secretary broad power in carrying out motor carrier safety statutes and regulations to “prescribe recordkeeping and reporting requirements” and to “perform other acts the Secretary considers appropriate.” (49 U.S.C. 31133(a)(8) and (10), respectively).

The Administrator of FMCSA has been delegated authority under 49 CFR 1.73(g) to carry out the functions vested in the Secretary of Transportation by 49 U.S.C. chapter 311, subchapters I and III, relating to commercial motor vehicle programs and safety regulation.

Background

This document provides regulatory guidance concerning the applicability of 49 CFR 390.17, “Additional equipment and accessories,” to CMV operators engaged in “texting” on an electronic device while driving a CMV in interstate commerce.

Currently, 49 CFR 390.17 states, “Nothing in this subchapter shall be construed to prohibit the use of additional equipment and accessories, not inconsistent with or prohibited by this subchapter, *provided such equipment and accessories do not decrease the safety of operation of the commercial motor vehicles on which they are used.*” [Emphasis added]. As used in § 390.17, “this subchapter” means Subchapter B [49 CFR parts 350–399] of Chapter III of Subtitle B of Title 49, Code of Federal Regulations (CFRs).

CMVs are defined in 49 CFR 390.5 as “any self-propelled or towed motor vehicle used on a highway in interstate commerce to transport passengers or property when the vehicle—

(1) Has a gross vehicle weight rating or gross combination weight rating, or gross vehicle weight or gross combination weight, of 4,536 kg (10,001 pounds) or more, whichever is greater; or

(2) Is designed or used to transport more than 8 passengers (including the driver) for compensation; or

(3) Is designed or used to transport more than 15 passengers, including the driver, and is not used to transport passengers for compensation; or

(4) Is used in transporting material found by the Secretary of Transportation to be hazardous under 49 U.S.C. 5103 and transported in a quantity requiring placarding under regulations prescribed