Mixture/substance	Required test	FR citation
(iii) Perfluoroalkyl methacrylate polymer, EPA document control number (DCN) 63040000037A	.....do	Do.
(iv) Substituted methacrylate, propenoic acid, perfluoroalkyl esters, DCN 63040000033B	.....do	Do.
(v) Perfluoroalkyl acrylic polymer, DCN 63040000037C	.....do	Do.
(vi) Poly-.beta.-fluoroalkylethyl acrylate and alkyl acrylate, ACC 174993	.....do	Do.
(vii) Poly(.beta.-fluoroalkylethyl acrylate and alkyl acrylate), ACC 70430	.....do	Do.
(viii) Polysubstituted acrylic copolymer, ACC 157381	.....do	Do.
(ix) Perfluoroalkyl acrylate copolymer latex, ACC No. 70907	.....do	Do.
(2) For Textile containing six of the following chemical substances as specified in the ECA:		
(i) Perfluoroalkylethyl acrylate copolymer, EPA-designated accession number (ACC) 171790	.....do	Do.
(ii) Perfluoroalkyl acrylate copolymer, ACC 158022	.....do	Do.
(iii) Perfluoroalkyl methacrylate polymer, EPA document control number (DCN) 63040000037A	.....do	Do.
(iv) Substituted methacrylate, propenoic acid, perfluoroalkyl esters, DCN 63040000033B	.....do	Do.
(v) Perfluoroalkyl acrylic polymer, DCN 63040000037C	.....do	Do.
(vi) Poly-.beta.-fluoroalkylethyl acrylate and alkyl acrylate, ACC 174993	.....do	Do.
(vii) Poly(.beta.-fluoroalkylethyl acrylate and alkyl acrylate), ACC 70430	.....do	Do.
(viii) Polysubstituted acrylic copolymer, ACC 157381	.....do	Do.
(ix) Perfluoroalkyl acrylate copolymer latex, ACC 70907	.....do	Do.

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BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 799

[OPPT–2003–0071; FRL–7710–5]

Final Enforceable Consent Agreement and Testing Consent Order for Four Formulated Composites of Fluoropolymer Chemicals; Export Notification

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of final consent agreement and order.

SUMMARY: Under section 4 of the Toxic Substances Control Act (TSCA), EPA has issued a testing consent order (Order) that incorporates an enforceable consent agreement (ECA) with AGC Chemicals Americas, Inc.; Daikin America, Inc.; Dyneon, LLC; and E.I. du Pont de Nemours and Company (the Companies). The Companies have agreed to perform incineration testing of four formulated composites of fluoropolymer (FP) chemicals representative of products currently available in the marketplace. This document announces the ECA and the Order that incorporates the ECA for this testing, and summarizes the terms of the ECA. As a result of the ECA and Order that incorporates the ECA, exporters of any of the formulated composites containing FP chemicals, including persons who do not sign the ECA, are subject to export notification requirements under section 12(b) of TSCA. This document adds the four formulated composites of FP chemicals to the table of testing consent orders for substances and mixtures without Chemical Abstract Service (CAS) Registry Numbers. Data developed from the ECA testing will contribute to the Agency's efforts to determine whether municipal and/or medical waste incineration of FPs is a potential source and/or pathway of environmental and human exposure to perfluorooctanoic acid (PFOA). The data will also contribute to the Agency's continuing efforts to achieve healthy communities and ecosystems.

DATES: The effective date of the ECA, the Order that incorporates the ECA, and this action is July 8, 2005.

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number OPPT–2003–0071. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket/*. Although listed in the index, some information is not publicly available, i.e., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will not be placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the OPPT Docket, EPA Docket Center, EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The EPA Docket Center Reading Room telephone number is (202) 566–1744 and the telephone number for the OPPT Docket, which is located in EPA Docket Center, is (202) 566–0280.

FOR FURTHER INFORMATION CONTACT: *For general information contact*: Colby Lintner, Regulatory Coordinator, Environmental Assistance Division (7408M); telephone number: (202) 554–1404; e-mail address: *TSCA-Hotline@epa.gov*.

For information on the ECA, contact: Richard W. Leukroth, Jr., Chemical Control Division (7405M); telephone number: (202) 564–8167; fax number: (202) 564–4765; e-mail address: *leukroth.rich@epa.gov*.

For technical information on testing and availability of ECA test data, contact: John Blouin, Economics, Exposure and Technology Division (7406M); telephone number: (202) 564–8519; fax number: (202) 564–8528; e-mail address: *blouin.john@epa.gov*.

For technical information on export notification, contact: Richard W. Leukroth, Jr., Chemical Control Division (7405M); telephone number: (202) 564–8167; fax number: (202) 564–4765; e-mail address: *leukroth.rich@epa.gov* or Laura L. Bunte, Chemical Control Division (7405M); telephone number: (202) 564–8087; fax number: (202) 564–4765; e-mail address: *bunte.laura@epa.gov*.

To contact any of these individuals by mail, identify the individual by name and Division indicated for that person, and use this address: Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200

Pennsylvania Ave., NW., Washington, DC 20460–0001.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. The requirements in the ECA and the Order that incorporates the ECA only apply to those companies that are specifically named in the ECA. As of July 8, 2005, any person who exports or intends to export any of the four formulated composites of FP chemicals that are the subject of the ECA and the Order that incorporates the ECA are subject to the export notification requirements of TSCA section 12(b) (see 40 CFR part 707, subpart D, and Unit IV.B.). Although other types of entities could also be affected, most chemical manufacturers are usually identified under North American Industrial Classification System (NAICS) code 325. If you have any questions regarding the applicability of this action to a particular entity, contact persons listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET (*http://www.epa.gov/edocket/*), you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 799 is available on E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*. Information on TSCA 12(b) export notification (40 CFR part 707) is available at *http://www.epa.gov/oppt/chemtest/sect12b.htm*.

II. Background

A. What are FP Chemicals?

FP chemicals are polymers mainly consisting of carbon and fluorine atoms, such as polytetrafluoroethylene (PTFE). Many, but not all, commercial fluoropolymers are chemicals made using ammonium perfluorooctanoate (APFO). The fluoropolymer structure is predominantly -(CF2)x- which is a potential source of PFOA. For all fluoropolymer products used in commerce, the -(CF2)- moiety is common to all polymers. The four formulated FP composites that are subject to testing under the ECA are representative of all known commercial FP chemicals and the basic chemistries are represented by the four composite test substances that are subject to testing under this ECA (i.e., dry melt fluoropolymer resin, dry nonmelt PTFE homopolymer resin/gum, dry non-melt fluoroelastomer resin/gum, aqueous fluoropolymer dispersions).

FPs possess a set of special properties that make them highly useful in the products in which they are applied. They are highly resistant to extreme temperatures, chemicals, and weather. FPs have a low friction coefficient, and the lowest dielectric constant of all plastics. They are also flame retardant, and are highly non-stick. FPs are used in a wide variety of industries, and their applications encompass a wide variety of industrial and consumer products. Among the major industrial sectors that use FPs are the automotive, chemical processing, electronics/ semiconductor, aerospace/military, medical/ pharmaceutical, building/construction, and commercial food preparation sectors. Some of the specific applications of FPs in those sectors include wire and cable insulation, O-rings and shaft seals, hoses and tubing, heat resistant/low friction metal coatings, non-stick cookware, thread sealant tape, breathable membranes for apparel, weather-resistant architectural fabric coatings, and personal care products.

B. Why Does EPA Need Environmental Effects Data on FP Chemicals?

EPA has identified potential human health concerns from exposure to PFOA and its salts. The Agency is concerned that residual APFO used to manufacture FPs is a source and/or pathway to environmental and human exposure to PFOA. In addition, there is insufficient data to determine whether FPs could degrade to PFOA by mechanisms that are not fully understood at this time. The high temperatures and retention times used during incineration processes, while destroying most of the polymer molecule, may not completely degrade these polymers. Since the strong C-F bonds are common to all FPs, EPA believes that the 17 individual FPs (see Unit III.B.) with their associated chemistries are representative of the manner in which FPs could degrade, potentially forming PFOA when incinerated under the conditions simulating current municipal and medical waste incinerators as specified by this ECA testing program.

In September 2002, EPA's OPPT initiated a priority review of PFOA because developmental toxicity, carcinogenicity, and blood-monitoring data presented in an interim revised hazard assessment raised the possibility that PFOA might present a significant risk to human health (Ref. 1). On January 4, 2005, OPPT's Risk Assessment Division submitted a draft risk assessment of the potential human health effects associated with exposure to PFOA and its salts to EPA's Science Advisory Board's (SAB) Perfluorooctanoic Acid Risk Assessment Review Panel for peer review (Refs. 2 and 3). These assessments revealed uncertainties associated with the sources and pathways of human exposure. EPA believes that the information to be developed under the ECA testing will better inform the Agency regarding the potential source(s) and/or pathway(s) of environmental and human exposure to PFOA.

III. ECA Development and Conclusion

A. How is EPA Going to Obtain Environmental Testing on FP Chemicals?

In the **Federal Register** of April 16, 2003 (68 FR 18626) (FRL–7303–8), EPA initiated a public process to negotiate ECAs concerning PFOA and fluorpolymers. The two goals of the ECAs resulting from these public discussions are to develop environmental fate and transport data, as well as other data relevant to identifying the pathway(s) that result in human exposure to PFOA by air, water, or soil; and, to characterize how PFOA gets into those pathways, including the products or processes that are responsible for the presence of PFOA in the environment. EPA anticipates that the data to be developed under such ECAs will be supplemental to data being generated by ongoing testing efforts described under industry letters of intent (LOIs) (Refs. 4–7).

In preparation for the initial public meeting on June 6, 2003, EPA developed a preliminary framework document (Ref. 8) outlining Agency data needs that address the outstanding PFOA source and exposure pathway questions identified in the **Federal Register** notice of April 16, 2003. EPA's preliminary framework document was intended to serve as a discussion guide for the June 6, 2003, public meeting and to aid in distinguishing between outstanding EPA data needs and industry LOI commitments. The preliminary framework document was not a predetermined list of information needs defining the outcome of the ECA process.

The ECA described in this document provides for a laboratory-scale incineration testing program for four formulated composites of FP chemicals. Incineration testing of FPs is one of the data needs identified in EPA's preliminary framework document for

PFOA. On June 6, 2003, the PFOA Plenary Group (consisting of EPA and all parties who had identified themselves as being interested in the ECA development proceedings after publication of the April 16, 2003 **Federal Register** notice) acknowledged that such a testing program was an opportunity for ECA development. The PFOA Plenary Group tasked the Fluoropolymer Technical Workgroup (a subgroup of the PFOA Plenary Group) with working out the details that could be incorporated into an ECA between the Companies and EPA.

On July 8, 2003, the Fluoropolymer Technical Workgroup received proposals from the Companies and EPA (Refs. 9 and 10) for incineration testing of FPs. Details of the testing program were then developed by members of the Fluoropolymer Incineration Subgroup (a subgroup of the Fluoropolymer Technical Workgroup) and the subgroup and workgroup reached consensus on the testing to be required under the ECA. On March 31, 2004, the Fluoropolymer Technical Workgroup acknowledged that this testing program had sufficient merit for consideration by the PFOA Plenary Group (Ref. 11). On April 1, 2004, the PFOA Plenary Group discussed the merit of this testing program and recommended that EPA consider entering into an ECA with the Companies (Ref. 12). EPA agreed and initiated steps to enter into this ECA with the Companies. On January 25, 2005, EPA received the ECA signed by the Companies, and on June 28, 2005, EPA signed the ECA and the Order that incorporates the ECA. The effective date of the ECA and the Order that incorporates the ECA is July 8, 2005.

EPA uses ECAs to accomplish testing of chemicals for health and environmental effects where a consensus exists concerning the need for and scope of testing (40 CFR 790.1(c)). The procedures for ECA negotiations and the factors for determining whether a consensus exists are described at 40 CFR 790.22 and 790.24, respectively.

B. What is the Subject of the ECA and Order Incorporating the ECA?

As specified under the ECA, four formulated composites of FP chemicals are the subject of and will be tested under the ECA and the Order that incorporates the ECA. Appendix A and Part XXIV. of the ECA (individual company signature pages) of the ECA provide details on: The rationale for formulating four composites that represent FP chemical products currently available in the marketplace, the identity of the FP chemicals used to formulate each composite, the procedures for formulating each composite, and the procedures by which each company will contribute the FP chemical(s) for which it is obligated under the terms of the ECA. The four formulated composites are identified as: Dry Non-Melt Resin (containing: Ethene, tetrafluoro-, homopolymer, CAS No. 9002–84–0, Polytetrafluoroethylene, Document Control Number (DCN) 63040000018A, and Propane, 1,1,1,2,2,3,3-heptafluoro-3-[(trifluoroethenyl)oxy]-, polymer with tetrafluoroethene, CAS No. 26655–00–5); Dry Melt Fluoropolymer Resin (containing: 1-Propene, 1,1,2,3,3,3-hexafluoro-, polymer with tetrafluoroethene, CAS No. 25067–11–2; Propane, 1,1,1,2,2,3,3-heptafluoro-3-[(trifluoroethenyl)oxy]-, polymer with tetrafluoroethene, CAS No. 26655–00–5; Ethene, tetrafluoro-, polymer with trifluoro(pentafluoroethoxy)ethene, CAS No. 31784–04–0; 1-Propene, 1,1,2,3,3,3-hexafluoro-, polymer with 1,1-difluoroethene and tetrafluoroethene, CAS No. 25190–89–0; ETFE, DCN 63040000026; and, 1-Propene, 1,1,2,3,3,3-hexafluoro-, polymer with ethene and tetrafluoroethene, CAS No. 35560–16–8); Dry Non-Melt Fluoroelastomer Resin/Gum (containing: 1-Propene, 1,1,2,3,3,3-hexafluoro-, polymer with 1,1-difluoroethene, CAS No. 9011–17–0; 1-Propene, 1,1,2,3,3,3-hexafluoro-, polymer with 1,1- difluoroethene and tetrafluoroethene, CAS No. 25190–89–0; 1-Propene, polymer with 1,1-difluoroethene and tetrafluoroethene, CAS No. 54675–89–7; 1-Propene, polymer with tetrafluoroethene, CAS No. 27029–05–6; Ethene, tetrafluoro-, polymer with trifluoro(trifluoromethoxy) ethene, CAS No. 26425–79–6; Ethene, chlorotrifluoro-, polymer with 1,1-difluoroethene, CAS No. 9010–75–7; fluoroelastomer, DCN 63040000018C; fluoroelastomer DCN 63040000018D; and a low temperature fluoroelastomer, ACC 137678; and, Aqueous Fluoropolymer Dispersions (containing: Ethene, tetrafluoro-, homopolymer, CAS No. 9002–84–0; 1-Propene, 1,1,2,3,3,3-hexafluoro-, polymer with tetrafluoroethene), CAS No. 25067–11–2; Propane, 1,1,1,2,2,3,3-heptafluoro-3-[(trifluoroethenyl)oxy]-, polymer with tetrafluoroethene, CAS No. 26655–00–5; 1-Propene, 1,1,2,3,3,3- hexafluoro-, polymer with 1,1-difluoroethene and tetrafluoroethene, CAS No. 25190–89–0; and polytetrafluoroethylene, DCN 63040000018B).

EPA uses a variety of numerical identification systems for tracking chemicals. These include CAS numbers assigned to non-confidential chemicals, premanufacture notice (PMN) numbers assigned by EPA when chemicals enter EPA's new chemical review process, document control numbers (DCN) assigned by the EPA OPPT's Confidential Business Information Center for EPA tracking, and Accession (ACC) numbers provided by EPA when a chemical identity listed on the TSCA Inventory has been claimed as TSCA CBI. In addition, chemicals that qualify for a reporting exemption under the Polymer Exemption Rule (40 CFR 723.250) may have a commercial trade identity or an IES Method I (CAS Inventory Expert Service) name assigned.

C. What Testing Does the ECA for FP Chemicals Require?

The ECA for laboratory-scale incineration testing of four composites of FP chemicals requires environmental testing, as described in Table 1 of this unit, which sets forth the required testing, test standards, and reporting requirements for testing to be conducted under the ECA.

The testing included in the ECA will be conducted in two segments, as follows: Phase I—PFOA Transport Testing (Phase I) and Phase II—Fluorotelomer Incineration Testing (Phase II). Phase I will consist of quantitative transport efficiency testing for PFOA. At the conclusion of Phase I, the Companies will provide EPA with a letter report summarizing the results. In the event that the transport efficiency of PFOA or total fluorine is equal to or greater than 70%, testing will proceed to Phase II. In the event that the transport efficiency of PFOA and total fluorine are both individually less than 70%, the Companies will initiate a technical consultation with EPA to reach agreement on how to proceed. The various outcomes of such a technical consultation are laid out in Part VIII. of the ECA.

Under Phase II, elemental analysis, combustion stoichiometry, thermogravimetric analysis, laboratory-scale combustion testing, and, if required under the ECA (see Table 1, footnote 9 of this unit), release assessment reporting will be performed for the four composites of FP chemicals that are the subject of the ECA.

TABLE 1.—REQUIRED TESTING, TEST STANDARDS, REPORTINGREQUIREMENTS: PHASES OF THE TESTING PROGRAM FOR THE INCINERATION OF FP COMPOSITES

Phase I		
PFOA Transport Testing	Test standard/Reporting requirements	Deadline [1] (Days)
Phase I Study Plan(s)	40 CFR 790.62 (b) as annotated by Part X. of the ECA	60 [3]
Phase I Quality Assurance Project Plan(s)	EPA Requirements for Quality Assurance Project Plans (QA/R5) [10]	90 [3]
Quantitative PFOA transport testing [2]	Appendix C.1. of the ECA	240 [4,5]
Phase II		
Fluoropolomer Incineration Testing	Test standard/Reporting requirements	Deadline [1] (Days)
Phase II Study Plan(s)	40 CFR 790.62 (b) as annotated by Part X. of the ECA	180 [3]
Phase II Quality Assurance Project Plan(s)	EPA Requirements for Quality Assurance Project Plans (QA/R5) [10]	360 [3]
Receipt of composite components by designated facility(ies)	Part XXIV. and Appendix A.3. of the ECA	180 [7]
Elemental Analysis [6]	Appendix C.2.1. of the ECA	450 [8]
Combustion Stoichiometry [6]	Appendix C.2.2. of the ECA	450 [8]
Thermogravimetric Analysis [6]	ASTM E1868-02, as modified in Appendix B.1. of the ECA	450 [8]
Laboratory-scale Combustion Testing [6]	Appendices C.2.4. and C.2.5., as annotated/supplemented by Appendices D.1., D.2., D.3., and D.4. of the ECA	450 [8]
Release Assessment Report	Appendix E.2. of the ECA	450 [9]

[1] Number of days, starting with the day following the event starting the time period in question. Interim progress reports must be submitted by the Companies to EPA every 180 days beginning 180 days from July 8, 2005, until the end of the ECA testing program (see Part XIV. and Appendix E.1. of the ECA).

[2] At the conclusion of Phase I, and prior to initiation of Phase II, the Companies will provide a letter report to EPA summarizing the results of Phase I testing (see Part VII.A. of the ECA). In the event that the transport efficiency of PFOA or of total fluorine (as determined by the formulas in Appendix C.1. of the ECA) is greater than or equal to 70%, then the Companies will proceed to Phase II. In the event that the transport efficiency of PFOA and of total fluorine (as determined by the formulas in Appendix C.1. of the ECA) are both individually less than 70% then the Companies will initiate a Technical Consultation with EPA. The outcomes of the Technical Consultation are described in Part VIII. of the ECA.

[3] Number of days after July 8, 2005, when submission is due.

[4] Number of days after EPA approval of the Study Plan(s) and QAPP(s) for Phase I testing when a letter report describing transport efficiency test result(s) and any contingency testing performed is due to EPA (see Part VII.A. and Appendix C.1.3. of the ECA). If the Study Plan(s) and QAPP(s) are not approved by EPA within 60 days of submission of the Phase I QAPP(s), then this deadline is extended by 180 days to accommodate re-scheduling with the thermal reactor system laboratory.

[5] The final report for Phase I will be submitted to EPA within 60 days of the completion of the Technical Consultation if the consultation does not result in an agreement to conduct further testing. If the Technical Consultation results in an agreement to conduct further testing, the final report for Phase I will be included in the final report for such further testing, unless agreed otherwise in the Technical Consultation (see Part VIII. of the ECA).

[6] The results of this testing will be provided in the final report for Phase II (see Appendix C.2.5. and Appendix E.3. of the ECA).

[7] Number of days from the submission of the Phase I letter report signifying that Phase II can proceed and the approval by EPA of the Phase II QAPP(s) that the Companies must meet their individual obligations to provide the designated facility(ies) with the components for each composite to be tested under the ECA (see Part III.B. of the ECA). If Phase II is required by Technical Consultation agreement (see footnote 2 of this table), the deadline shall be as agreed in the Technical Consultation.

[8] Number of days from the date of the final report from the ECA for the Laboratory-Scale Incineration Testing of Fluorotelomer-Based Polymers (published elsewhere in this FEDERAL REGISTER (EPA Docket ID number OPPT–2004–0001)) and the approval of study plan(s) and QAPP(s) for Phase II testing when this report is due, if all components of each composite are received, or EPA determines that testing shall proceed with a partial composite(s) (see Part III.B. of the ECA). An extension of the deadline for submitting the final report from the ECA for the Laboratory-Scale Incineration Tesing of Fluorotelomer-Based Polymers does not extend this deadline, unless expressly so provided.

[9] In the event that Phase II laboratory-scale incineration testing identifies measurable levels of PFOA resulting from the incineration testing for any or all of the fluoropolymer composites tested under the ECA, as defined in Appendix C.2.5.5. of the ECA, the Companies will prepare a Release Assessment Report to place in perspective the relevance of such measurable levels in the laboratory-scale incineration testing results with respect to full-scale municipal and/or medical waste incinerator operations in the United States. If required, the Release Assessment Report will be submitted in conjunction with the Final Report for Phase II testing (see footnotes 6 and 8 of this table).

[10] Guidance for developing Quality Assurance Project Plans can be found in the EPA document EPA QA/R-5: *EPA Requirements for Quality Assurance Project Plans*, prepared by: Office of Environmental Information, EPA, March 2001. This is also available from the EPA website at *http://epa.gov/quality/qs-docs*.

D. What are the Uses for the Test Data to be Developed Under the ECA?

EPA will use the data obtained from the testing to be conducted under the ECA to assess the potential for waste incineration of FPs to emit PFOA. This analysis will be based on quantitative determination of potential exhaust-gas levels of PFOA that may emanate from laboratory-scale combustion testing under conditions representative of typical municipal and/or medical waste

combustor operations in the United States. The data could provide EPA with an understanding of whether the incineration of FPs is a source and/or pathway for environmental and human exposure to PFOA.

These data could also be used to inform screening level human and environmental exposure assessments. In addition, the data could be used by other Federal Agencies (e.g., the Agency for Toxic Substances and Disease Registry (ATSDR), the National Institute for Occupational Safety and Health (NIOSH), the Occupational Safety and Health Administration (OSHA), the Consumer Product Safety Commission (CPSC), and the Food and Drug Administration (FDA)) in assessing chemical risks and in taking appropriate actions within their programs.

IV. Other Impacts of the ECA

A. What if EPA Should Require Additional Environmental Testing on FP Chemicals?

If EPA decides in the future that it requires additional data on FPs, the Agency would initiate a separate action.

B. How Does the Order Affect TSCA Export Notification?

As of the effective date of the ECA and the Order that incorporates the ECA under TSCA section 4 (i.e., the date of publication of this document in the **Federal Register**) any of the Companies, as well as any other person, who exports or intends to export any of the four formulated composites of FP chemicals that are the subject of this ECA and Order that incorporates the ECA, in any form, are subject to the export notification requirements of TSCA section 12(b). Procedures related to export notification are described in 40 CFR part 707, subpart D. EPA maintains lists of all chemical substances and mixtures with CAS numbers (40 CFR 799.5000) and without CAS numbers (40 CFR 799.5025) that are subject to testing consent orders. This document will add the four formulated composites of FP chemicals that are the subject of this ECA and Order that incorporates the ECA to the list at 40 CFR 799.5025.

Notice and comment rulemaking is not needed to add these chemical substances to the list at 40 CFR 799.5025 because the export notification requirements are imposed by statute. Section 12(b) of TSCA requires any person who exports or intends to export to a foreign country a chemical substance or mixture for which the submission of data is required under TSCA section 4 to submit a notification of the export or intended export to EPA. An ECA is an action under TSCA section 4 requiring the submission of data. 40 CFR 790.1. Accordingly, EPA's ECA regulations require that each ECA contain a statement that manufacturers or processors signing the ECA, as well as any other person, shall comply with export notification requirements in TSCA section 12(b). 40 CFR 790.60(a)(11). The four formulated composites of FP chemicals identified in this document are subject to an Order incorporating an ECA. EPA finds that notice and an opportunity for comment is unnecessary to implement the export notification requirements in TSCA section 12(b) for the reasons stated in this unit.

For chemical substances and mixtures subject to other Orders incorporating ECAs that were issued in the past, EPA initiated separate rulemakings to amend the lists at 40 CFR 799.5000 and 40 CFR 799.5025, thereby affording the public a comment opportunity as well as notifying the public of the existence of an ECA. EPA took this step to ensure that those companies not a party to the ECA or Order noticed their need to comply with TSCA section 12(b). However, EPA now believes that a separate rulemaking or an opportunity to comment on the implementation of the statutory mandate is not necessary.

C. What are the Economic Impacts of the ECA?

Based on the economic analysis conducted for the ECA, the Agency expects the cost of the testing to be performed under this ECA to range from $100,000 to $150,000. This estimate is based on a contact report of an inquiry directed to a university laboratory conducting thermal ''burn'' test research. The estimated total cost for industry to conduct the required testing under the ECA is $150,000, which is the upper end of the estimated cost range. EPA anticipates that the costs for testing under this ECA will have a low potential for adverse economic impact on the regulated community because the costs for testing will be shared across four companies who are signatories to the ECA and the Order that incorporates the ECA.

Export regulations promulgated pursuant to section 12(b) of TSCA—40 CFR part 707, subpart D—require only a one-time notification to each foreign country of export for each chemical for which data are required under section 4 of TSCA. In an analysis of the economic impacts of the July 27, 1993, amendment to the rules implementing section 12(b) of TSCA (58 FR 40238), EPA estimated that the one-time cost of preparing and submitting the TSCA section 12(b) notification for a first- time submitter of any TSCA section12(b) notification was $62.60 (Ref. 13). When inflated from 1992 to 2004 dollars (4thQ) by a factor of 1.538 using the Employment Cost Index for White Collar Occupations (Ref. 14), the current cost is estimated to be $96.12, or a burden of 1.5 hours, for a first-time submitter. An exporter who had previously submitted a 12(b) notification for any chemical/country combination would incur an estimated cost of $31.72 for preparing and submitting a TSCA section 12(b) notification, based on the burden estimate of .5 hours.

V. References

1. U.S. Environmental Protection Agency (EPA). Charles M. Auer. Memorandum to Oscar Hernandez, Mary Ellen Weber, and Ward Penberthy regarding revision of PFOA Hazard Assessment and Next Steps. September 27, 2002. Available from the EPA Administrative Record as AR 226–1127.

2. EPA. Draft Risk Assessment of the Potential Human Health Effects Associated with the Exposure to Perfluorooctanoic Acid and its Salts. January 4, 2005. p. 117. Available from EPA website, *http://www.epa.gov/oppt/pfoa/*.

3. EPA. Science Advisory Board (SAB) Staff Office; Notification of Upcoming Meetings of the Science Advisory Board Perfluorooctanoic Acid Risk Assessment (PFOA) Review Panel. **Federal Register** (70 FR 2157–2158, January 12, 2005) (FRL–7860–5).

4. 3M Company, Dr. Larry Wending. Letter of Intent to Stephen L. Johnson, USEPA, to continue ongoing environmental, health and safety measures by Company relating to Perfluorooctanoic Acid and its Salts (PFOA). March 13, 2003. Available from EPA EDOCKET as OPPT–2003–0012–0007.

5. The Society of the Plastics Industry, Inc., Donald K. Duncan. The Ammonium Perfluorooctanoate (APFO) Users. Letters of Intent to Stephen L. Johnson, EPA, regarding responsive Voluntary Actions by parties to evaluate and control emissions of Ammonium Perfluorooctanoate (APFO). March 14, 2003. Available from EPA EDOCKET as OPPT–2003–0012–0012.

6. Telomer Research Program (TRP) Member Companies. Letter of Intent to Stephen L. Johnson, EPA, regarding addressing concerns raised by EPA about the possible association of Perfluorooctanoic Acid (PFOA) with telomer-based products. March 14, 2003. Available from EPA EDOCKET as OPPT–2003–0012–0013.

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9. Fluoropolymer Manufacturer's Group. Incineration Research Approach. Presentation to the Fluoropolymer Technical Workgroup. July 8, 2003. p. 3. Available from EPA EDOCKET as OPPT–2003–0071–0009.

10. EPA. EPA ECA Proposal for Fluoropolymer Incineration Testing. Presentation to the Fluoropolymer Technical Workgroup. July 8, 2003. p. 2. Available from EPA EDOCKET as OPPT–2003–0071–0009.

11. EPA. PFOA ECA Fluoropolymer Technical Workgroup Meeting Summary. March 31, 2004. p. 11. Available from EPA EDOCKET as OPPT–2003–0071–0103.

12. EPA. Enforceable Consent Agreement Development for Perfluorooctanoic Acid (PFOA) and Fluorinated Telomers. Public Meeting Summary. April 1, 2004. p. 6. Available from EPA EDOCKET as OPPT–2003–0071–0106.

13. EPA. *Economic Analysis in Support of the Final Rule Promulgated under TSCA Section 12(b).* William Silagi. EPA/OPPT/RIB. Washington, DC. June 1992.

14. Bureau of Labor Statistics (BLS). 2003. Employment Cost Index, Total Compensation: White-Collar Occupations (Series ID: ECS11102I), *http://data.bls.gov/cgi-bin/srgate*, extracted February 9, 2005.

15. EPA. Wendy Hoffman. Memorandum to Richard Leukroth regarding calculation of Paperwork Reduction Act burden estimate for the incineration ECAs. October 20, 2004. Available from EPA EDOCKET as OPPT–2003–0071–0007.

16. EPA. Lynne Blake-Hedges. Memorandum to EPAB Staff on Unit Burden Estimates for 12(b) Export Notification for Section 4 Test Rules and Enforceable Consent Agreements (ECAs). July 20, 1999.

17. ASTM. Standard Test Method for Loss-On Drying by Thermogravimetry. *2002 Annual Book of ASTM Standards.* Volume 14.02, Designated E 1868–02. pp. 635–638. August 10, 2002.

VI. Statutory and Executive Order Reviews

A. Executive Order 12866

This action announces an Order that incorporates an ECA between EPA and the Companies. Under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), this action is not a ''regulatory action'' subject to review by the Office of Management and Budget (OMB).

B. Paperwork Reduction Act

According to the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, an agency may not conduct or sponsor, and a person is not required to respond to, an information collection request unless it displays a currently valid control number assigned by OMB. The OMB control numbers for the EPA's regulations in title 40 of the CFR are listed in 40 CFR part 9.

The information collection requirements related to the Order that incorporates the ECA have already been approved by OMB pursuant to the PRA under OMB control number 2070–0033 (EPA ICR No. 1139). The one-time public burden for this collection of information is estimated to be approximately 433 hours per response (i.e., per company), or 1,732 hours total burden for the four companies (Ref. 15). Under the PRA, ''burden'' means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal Agency. For this collection, it includes the time needed to review instructions; complete and review the collection of information; and transmit or otherwise disclose the information.

The information collection requirements related to export notification requirements under section 12(b) of TSCA, including those related to the ECA and the Order that incorporates the ECA, have already been approved by OMB pursuant to PRA under OMB control number 2070–0030 (EPA ICR No. 0795). The public reporting burden for this information collection is estimated to be between .5 hours to 1.5 hours per response. The lower estimate applies to companies that have previously submitted a TSCA section 12(b) notification for any chemical or mixture, and therefore need only update an existing form letter assumed to have been generated electronically. The higher estimate applies to companies that are first-time submitters of a TSCA section 12(b) notification (Ref. 16), and therefore need to write an initial letter.

C. Regulatory Flexibility Act

Since the issuance of the ECA and the Order that incorporates the ECA, as well as the applicability of the export notification requirements of TSCA section 12(b) to chemicals addressed in the ECA and the Order that incorporates the ECA, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

D. Unfunded Mandates Reform Act

This action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4. Therefore, this action is not subject to the requirements of UMRA.

E. Executive Order 13132 and 13175

This action is not expected to impact State or Tribal governments because these governments are not expected to export the chemicals covered by the ECA or the Order that incorporates the ECA. As such, the Agency has determined that this Action will not have a substantial direct effect on 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 Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Nor will this action have Tribal implications because it does not significantly or uniquely affect the communities of Indian Tribal governments, or involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000), do not apply.

F. Executive Order 13045

Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 1985, April 23, 1997), does not apply to this action because this action is not designated as an ''economically significant'' regulatory action as defined by Executive Order 12866 (see Unit VI.A.), nor does this action establish an environmental standard that is intended to have a disproportionate effect on children. To the contrary, this action will provide data and information that EPA and others can use to assess the risks of these chemicals, including potential risks to sensitive subpopulations.

G. Executive Order 13211

This action is not subject to Executive Order 13211, entitled*Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use.

H. National Technology Transfer Advancement Act

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) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

The testing conducted under the ECA involves technical standards. The Agency conducted a search to identify potentially applicable voluntary consensus standards. No such standard was identified for incineration testing of FP chemicals that are the subject of the ECA. However, EPA identified a voluntary consensus standard for thermogravimetric analysis (Ref. 17), which is a required element of the Phase II ECA testing. Appendix B.1. of the ECA describes specific modifications to this voluntary consensus standard that are needed to take into consideration the unique properties of FP chemicals.

Guideline No. (Year)	Guideline name	TSCA Guideline No.	OECD Guideline No.
ASTM E 1868-02 (August 10, 2002)	Standard Test Method for Loss-On-Drying by Thermo-gravimetry	None	None

I. 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).

List of Subjects in Part 799

Environmental protection, Chemicals, Exports, Hazardous substances, Health, Laboratories, Reporting and recordkeeping requirements.

Dated: June 28, 2005.

Margaret Schneider,

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

■ Therefore, 40 CFR Chapter I is amended as follows:

PART 799—[AMENDED]

■ 1. The authority citation for part 799 continues to read as follows:

Authority: 15 U.S.C. 2603, 2611, 2625.

■ 2. Section 799.5025 is amended by adding the following entry to the table in alphabetical order, to read as follows:

§ 799.5025 Testing consent orders for mixtures without Chemical Abstracts Service Registry Numbers.

* * * * *

Mixture/substance	Required test	FR citation
* * * * *	* *	
Fluoropolymer composite substance:		
(1) For Dry Non-Melt Resin containing the following chemical substances as specified in the ECA:		
(i) Ethene, tetrafluoro-, homopolymer, CAS No. 9002–84–0	Environmental effects.	July 8, 2005.
(ii) Polytetrafluoroethylene, Document Control Number (DCN) 63040000018A	.....do	Do.
(iii) Propane, 1,1,1,2,2,3,3-heptafluoro-3-[(trifluoroethenyl)oxy]-, polymer with tetrafluoroethene, CAS No. 26655–00–5	.....do	Do.
(2) For Dry Melt Fluoropolymer Resin containing the following chemical substances as specified in the ECA:		
(i) 1-Propene, 1,1,2,3,3,3-hexafluoro-, polymer with tetrafluoroethene, CAS No. 25067–11–2	.....do	Do.
(ii) Propane, 1,1,1,2,2,3,3-heptafluoro-3-[(trifluoroethenyl)oxy]-, polymer with tetrafluoroethene, CAS No. 26655–00–5	.....do	Do.
(iii) Ethene, tetrafluoro-, polymer with trifluoro(pentafluoroethoxy)ethene, CAS No. 31784–04–0	.....do	Do.
(iv) 1-Propene, 1,1,2,3,3,3-hexafluoro-, polymer with 1,1-difluoroethene and tetrafluoroethene, CAS No. 25190–89–0	.....do	Do.
(v) ETFE, DCN 63040000026	.....do	Do.
(vi) 1-Propene, 1,1,2,3,3,3-hexafluoro-, polymer with ethene and tetrafluoroethene, CAS No. 35560–16–8	.....do	Do.
(3) For Dry Non-Melt Fluoroelastomer Resin/Gum containing the following chemical substances as specified in the ECA:		
(i) 1-Propene, 1,1,2,3,3,3-hexafluoro-, polymer with 1,1- difluoroethene, CAS No. 9011–17–0	.....do	Do.
(ii) 1-Propene, 1,1,2,3,3,3-hexafluoro-, polymer with 1,1- difluoroethene and tetrafluoroethene, CAS No. 25190–89–0	.....do	Do.
(iii) 1-Propene, polymer with 1,1- difluoroethene and tetrafluoroethene, CAS No. 54675–89–7	.....do	Do.
(iv) 1-Propene, polymer with tetrafluoroethene, CAS No. 27029–05–6	.....do	Do.
(v) Ethene, tetrafluoro-, polymer with trifluoro(trifluoromethoxy) ethene, CAS No. 26425–79–6	.....do	Do.

Mixture/substance	Required test	FR citation
(vi) Ethene, chlorotrifluoro-, polymer with 1,1-difluoroethene, CAS No. 9010–75–7	.....do	Do.
(vii) Fluoroelastomer, DCN No. 63040000018C	.....do	Do.
(viii) Fluoroelastomer DCN 63040000018D	.....do	Do.
(ix) A low temperature fluoroelastomer, ACC No. 137678	.....do	Do.
(4) For Aqueous Fluoropolymer Dispersions containing the following chemical substances as specified in the ECA:		
(i) Ethene, tetrafluoro-, homopolymer, CAS No. 9002–84–0	.....do	Do.
(ii) 1-Propene, 1,1,2,3,3,3-hexafluoro-, polymer with tetrafluoroethene, CAS No. 25067–11–2	.....do	Do.
(iii) Propane, 1,1,1,2,2,3,3-heptafluoro-3- [(trifluoroethenyl)oxy]-, polymer with tetrafluoroethene, CAS No. 26655–00–5	.....do	Do.
(iv) 1-Propene, 1,1,2,3,3,3- hexafluoro-, polymer with 1,1-difluoroethene and tetrafluoroethene, CAS No. 25190–89–0	.....do	Do.
(v) Polytetrafluoroethylene, DCN No. 63040000018B	.....do	Do.
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