TSCA Chemicals-in-Progress Bulletin

Office of Pesticides & Toxic Substances

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This bi-monthly news bulletin is intended to inform all persons concerned with the Toxic Substances Control Act (TSCA) about recent developments and near-term plans. For further information or to request copies of documents mentioned, write the Industry Assistance Office (IAO), (TS-799) OPTS, U.S.E.P.A., Washington, D.C., 20460 or call toll-free 800-424-9065 or, in Washington, D.C., 554-1404.

REGULATORY & REQUIRED ACTIONS

PREMANUFACTURE NOTIFICATION (PMN)... SECTION 5

Under Section 5(a)(1) a person who intends to introduce into commerce a chemical substance not on the TSCA Inventory must notify EPA at least 90 days before beginning manufacture. This rule applies also to importers. The notice must give the chemical identity, production volume, uses, byproducts, occupational exposure and other health and environmental effects information in the submitter's possession. EPA is to use the review period to determine if the substance might present an unreasonable risk that should be remedied through either an order to develop sufficient information or an immediately effective rule. Upon such a determination, EPA issues an order to prohibit manufacture and then applies to the court for an injunction to this effect. This order must be issued 45 days before the notification period ends. The original period may be extended by EPA for up to 90 days for good cause noted in the Federal Register. Absent such an order or immediate rule, the manufacturer may proceed with his plans. EPA publishes in the Federal Register a summary of each PMN shortly after receipt and a status report on all current receipts at the beginning of each month. Copies of the revised proposed forms for manufacturers, importers and exporters are available from IAO for use by submitters during the interim period (See 44 FR 28564, May 15, 1979 and 44 FR 59764, Oct. 16, 1979).

The latest PMN status reports are reproduced below.

SEPTEMBER 1980 PMN STATUS REPORT

PMN No.	Identity/Generic Name	FR Citation	Expiration Date
	Premanufacture Notices Received During the Month		
80-237	Generic name: Aliphatic polyurethane water-borne dispersion	45 FR 63347 9/24/80	12/1/80
80-238	Generic name: Glycerine, 1-alkanoate, 3-substituted alkanoate	45 FR 65662 10/3/80	12/2/80
80-239	2,2,4-trimethyl-1,3-pentanediol, trimethylolpropane, succinic anhydride, adipic acid, isophthalic acid	45 FR 63919 9/26/80	12/2/80

80-240	Generic name: Ethene-alkene-vinyl carbonyl amine polymer	45 FR 65030 10/1/80	12/1/80
80-241	Generic name: Polyurethane polyacrylic polymer	45 FR 63345 9/24/80	12/3/80
80-242	N-(2-Hydroxypropyl)-N-tris(5-hydroxy-2-oxo-pentyl) ammonium acetate	45 FR 64245 9/29/80	12/4/80
80-243	2,2,4-trimethyl-1,3-pentanediol, trimethylolpropane, succinic anhydride, trimellitic anhydride, adipic acid and isophthalic acid	45 FR 65033 10/1/80	12/7/80
80-244	1-Nitronaphthalene-6-sulfonic acid, potassium salt	45 FR 65029 10/1/80	12/7/80
80-245	1-Nitronaphthalene-7-sulfonic acid, potassium salt	45 FR 65029 10/1/80	12/7/80
80-246	Generic name: Disubstituted heptadecane	45 FR 65032 10/1/80	12/7/80
80-247	Generic name: Aliphatic diol	45 FR 65032 10/1/80	12/7/80
80-248	Azelaic acid, 1,4-cyclohexanedimethanol, dimer acid, dimethylol propionic acid, methylene-bis (4-cyclohexyl isocyanate), neopentyl glycol, trimethylol propane polymer	45 FR 65033 10/1/80	12/8/80
80-249	Generic name: Aliphatic polyurethane water-borne dispersion	45 FR 65034 10/1/80	12/9/80
80-250	Propylene glycol, ethylene glycol terephthalic acid polymer, phthalic anhydride and maleic anhydride	45 FR 65664 10/3/80	12/11/80
80-251	Generic name: Carbomonocyclic, carbopolycyclic poyester	In prep.	12/11/80
80-252	Generic name: Acryloxyethylheteromonocycle	45 FR 67449 10/10/80	12/15/80
80-253	Coconut fatty acids, benzoic acid, isophtalic acid, neopentyl glycol, propylene glycol	45 FR 67450 10/10/80	12/15/80
80-254	Generic name: Dimer fatty acid polyamide	45 FR 67450 10/10/80	12/15/80
80-255	1-Octanamine, N, N-dimethyl-, phosphate salt	In prep.	12/16/80
80-256	Generic name: Methylaziridinylcarbonylimino oleyl triimido diisophorone poly(propylene glycol)	In prep.	12/17/80
80-257	Generic name: Unsaturated branched chain hydrocarbon having 10 carbon atoms	In prep.	12/17/80
80-258	Generic name: Unsaturated branched chain ketone having 12 carbon atoms	In prep.	12/17/80
80-260	Generic name: Neutralized polymer of styrene, alkyl acrylates and substituted alkyl methacrylates	In prep.	12/18/80
80-261	Polymer of palm oil, coconut oil, pentaerythritol, benzoic acid, phthalic anhydride and maleic anhydride	In prep.	12/21/80
80-262	Generic name: Fatty acids, esters with polyols	In prep.	12/21/80
80-263	Linseed oil, styrene, glycerine, toluene diisocyanate	In prep.	12/22/80
80-264	Benzenamine, [N-(1-methylhexylidene)-N'-(1-methyl butylidene)-4,4'-methylene bis]	In prep.	12/25/80
80-265	Generic name: Di (substituted alkyl) carbomonocyclicdicarboxylate	In prep.	12/25/80
80-266	Generic name: Polymer of alkanedioic acids, 2-ethyl-2-(hydroxymethyl)-1,3-propanediol, 2,2-dimethyl-1,3-propanediol	In prep.	12/25/80
80-267	Generic name: Substituted phenol, reaction products with sulfur chloride	In prep.	12/28/80
80-268	Generic name: Esterified polyamic acid	In prep.	12/28/80
80-269	Generic name: Dineoalkyl ester of glycerine	In prep.	12/28/80
80-270	Polymer of glycidyl methacrylate, hydroxy propyl methacrylate, 12-hydroxystearic acid, methacrylic acid, methyl methacrylate polymer	In prep.	12/28/80

New Chemical Substances that EPA Has Added to the Inventory During the Month

PMN No.	Submitter	Chemical Identification	FR Citation
80-23	Grow Group Inc.	Polymer of Epichlorohydrinbis A; bisphenol A; -methyl morpholine and acetic acid	45 FR 16006 3/12/80
80-31	Claimed confidential business information CBI	Generic name: chloroorganoaminofluoran dye	45 FR 15644 3/11/80
80-57	Sun Petroleum Products Co.	Generic name: Alkyl biphenyls	45 FR 24696 4/10/80

80-70	CBI	Generic name: Sulfonic acid salt of ureylenebis-(hydro-(xy-[(sulfo-naphtyl)azo])maphthalene	45 FR 27006 4/24/80
80-71	CBI	Generic name: Sulfonic acid of a ureylene bis(hydroxy-[(sulfo-naphthyl)azo])napthalene compound	45 FR 24696 4/10/80
80-75	CBI	Polymer of 12 Hydroxy stearic acid and epoxy resin	45 FR 30127 5/7/80
80-84	CBI	Generic name: Polyester reaction product with isophorone diisocyanate and hydroxypropyl acrylate	45 FR 30132 5/7/80
80-88	Ciba Geigy Corp.	Generic name: Cyanalkyl carbomonocylicsulfonate (Added August 1980)	45 FR 32772 5/19/80

OCTOBER 1980 PMN STATUS REPORT

PMN No.	Identity/Generic Name	FR Citation	Expiration Date
	Premanufacture Notices Received during the Month		
80-272	N-Methyl-N-glucitylstearoylamide	45 FR 73128 11/4/80	1/1/81
80-273	Amines, C 10-16 alkyl dimethyl, phosphate salt	45 FR 73128 11/4/80	1/1/81
80-275	Polymer of tall oil fatty acid, isophthalic acid, trimethylol propane, trimellitic anhydride, methyl methacrylate, ethyl acrylate, methacrylic acid, hydroxy ethyl methacrylate	45 FR 73132 11/4/80	1/4/81
80-276	Generic name: Styrene acrylic polymer	45 FR 71415 10/28/80	1/4/81
80-277	Generic name: Modified terpolymer of mixed alkyl acrylates	45 FR 71415 10/28/80	1/4/81
80-278	Generic name: Modified copolymer of mixed alkyl acrylates	45 FR 71415 10/28/80	1/4/81
80-279	Polymer of 2,2-dimethyl 1,3-propanediol; 2,2,4-trimethyl 1,3-pentanedial; isophthalic acid and fumaric acid	45 FR 73128 11/4/80	1/5/81
80-280	Generic name: Hydrogen zeolites	45 FR 74562 11/10/80	1/7/81
80-281	Polymer of Propylene glycol, neopentyl glycol, isophthalic acid, Empol 1022 dimeric fatty acid, trimellitic anhydride polymer	45 FR 73131 11/4/80	1/8/81
80-282	Aminoalkanol salt, as a 25 percent aqueous solution	45 FR 75752 11/17/80	1/12/81
80-283	Generic name: Styrene methacrylate acrylate polymer	45 FR 74993 11/13/80	1/13/81
80-284	Generic name: Polymer of alkanediols and carbomonocylic anhydrides	45 FR 75752 11/17/80	1/14/81
80-286	N(4-Diazo phenyl) morpholine hexafluorophosphate	45 FR 74993 11/13/80	1/19/81
80-287	Polymer of tall oil fatty acid, isophthalic acid, terephthalic acid, pentaerythritol, benzoic acid and trimethylol propane	In prep.	1/19/81
80-288	Polymer of soybean oil, pentaerythritol, isophthalic acid, benzoic acid, terephthalic acid	In prep.	1/19/81
80-289	Amines, isopropyl, distillation residues	45 FR 75750 11/17/80	1/21/81
80-290	Amines, ethyl, distillation residues	45 FR 75750 11/17/80	1/21/81
80-291	Polymer of epoxy resin, bisphenol A, paraformaldehyde, dibutylamine and diethanolamine	In prep.	1/21/81
80-292	Generic name: Disubstituted carbopolycyclic derivative	In prep.	1/21/81
80-293	Generic name: Dimethyl alkylmethyl silicone glycol copolymer	In prep.	1/25/81
80-294	Generic name: Siloxane, alkoxylated aminoalkyl	In prep.	1/25/81
80-295	Generic name: Disubstitutednitrobenzene	In prep.	1/25/81
80-296	Generic name: Ethyl, substituted, (((sulfopropyl) heteropolycyclic)methyl)alkenyl heteropolycycle	In prep.	1/25/81
80-297	Generic name: Ethyl, substituted, methylheteropolycycle tosylate	In prep.	1/25/81
80-298	Generic name: Substituted, methylheteropolycycle	In prep.	1/25/81
80-299	Generic name: Disubstituted benzene	In prep.	1/25/81
80-300	Generic name: Bis(Nitro, substituted phenyl) substituent	In prep.	1/25/81
80-301	Cyclohexane, 1,1'-methylene bis[4-isocyanato-, reaction products with 1,3-isobenzofurandione, polymer with 1,6-hexanediol, alpha-hydro-omega-hydroxypolyoxy [1,4-butane-diyl] and (2-hydroxyethyla-2-propenoate	In prep.	1/25/81
80-302	Generic name: Modified polyester based on carbomonocyclic anhydride and alkanediols	In prep.	1/26/81
80-303	Generic name: Substituted alkyl peroxycarbonate	In prep.	1/27/81
80-304	Generic name: Alkyl substituted chlorocarbonic acid	In prep.	1/27/81
80-305	Generic name: Polyurethane thermoplastrics	In prep.	1/26/81

80-306	Generic name: Urea/carbamate lacquer	In prep.	1/27/81
80-307	Polymer of tall oil fatty acids, neopentyl glycol, trimethylol ethane, phthalic anhydride	In prep.	1/27/81
80-310	Butanenitrile, 2-methyl, 2,2'-azobis	In prep.	1/28/81
80-311	Butanenitrile, 2-methyl, 2-amino	In prep.	1/28/81
80-312	N-Isocyanatotolyl-abietamide	In prep.	1/28/81

New Chemical Substances that EPA Has Added to the Inventory During the Month

PMN No.	Submitter	Chemical Identification	FR Citation
80-33	Sherwin Williams	Vegetable oil fatty acid ester	45 FR 23509 4/7/80
80-68	Cook Paint	E-Caprolactone, ethylacrylate, hydroxypropyl-methylacrylate, styrene acrylic acid polymer	45 FR 27007 4/22/80
80-127	Claimed confidential business information (CBI)	Generic Name: Polymer product of an acrylate ester and a polyhydroxy compound	45 FR 42012 6/23/80
80-129	General Printing and Ink, Inc.	Generic Name: Poly(amideester) resin X2-669	45 FR 44394 7/1/80
80-130	General Printing and Ink, Inc.	Generic Name: Poly(amideester) resin X2-600	45 FR 44394 7/1/80
80-131	Minnesota Mining and Minerals (3M)	2-[2-[4-(2-hydroxyethoxy) phenyl] ethenyl]-4,6-bis (trichloromethyl)-1,3,5-triazine	45 FR 43461 6/27/80
80-139	CBI.	Generic Name: Polymer of Epon 1044, soya fatty acid, styrene, acrylic acid and di-tertiary butyl peroxide	45 FR 46199 7/9/80
80-157	Du Pont	Generic Name: Halogenated polyimide	45 FR 51264 8/1/80
80-175	McCloskey Varnish Company of the West	Generic Name: Alkyd resin polymer, fatty acid and urethane modified	45 FR 54412 8/15/80

NOVEMBER 1980 PMN STATUS REPORT

PMN No.	Idenity/Generic Name	FR Citation	Expiration Date
	Premanufacturers Notices Received During the Month		
80-313	3-chloro-2-sulfoproplonic acid	In prep.	2/1/80
80-314	2,4-bis[(4-(N-cyano-N-phenyl sulfonylamino) phenyl)] methyl] -N-cyano N-phenyl sulfonyl benzeneamine	In prep.	2/1/81
80-315	4,4'-methylenebis(N-cyanobenzenamine) 2,4-bis[(4-N-cyano-amino) phenyl) methyl]-N-cyanobenzenamino 4,4'-methylenebis[2-[(4-N-cyanoamino)phenyl) methyl]-N-cyanobenzenamine	In prep.	2/1/81
80-316	Generic name: dialkyltin-diricinoleate	45 FR 83030 12/17/80	2/2/81
80-317	Generic name: polymer of modified resin esters and mixed oils	45 FR 83023 12/17/80	2/3/81
80-318	Dimethyl diallyl ammonium chloride-acrylamide-potassium acrylate terpolymer	In prep.	2/5/81
80-319	Generic name: salt form of acrylic acidacrylate copolymer	In prep.	2/5/81
80-320	Vanadic acid, tris (2-methyl propyl)ester	45 FR 83018 12/17/80	2/5/81
80-321	Generic name: polymer of an alkyl acrylate, an alkyl methacrylate, and a saturated cyclic methacnylate	45 FR 82708 12/16/80	2/10/81
80-322	Polymer of epoxidized soybean oil, benzoic acid	45 FR 83021 12/17/80	2/10/81
80-323	Generic name: acrylic resin	In prep.	2/10/81
80-324	Generic name: poly(allyl ether) hydroxy alkyl ester	45 FR 82706 12/16/80	2/11/81
80-325	Generic name: chromophore substituted poly (oxyethylene)	45 FR 82706 12/16/80	2/15/81
80-326	Generic name: chromophore substituted poly (oxyethlene)	45 FR 82706 12/16/80	2/15/81
80-327	Generic name: toluene diisocyanate blocked prepolymer	45 FR 83020 12/17/80	2/15/81
80-328	Generic name: unsaturated melamine formaldehyde methanol resin	45 FR 83022 12/17/80	2/16/81
80-329	Generic name: salt of fatty acid dimer	In prep.	2/16/81

80-330	Generic name: amino alcohol	In prep.	2/18/81
80-331	Generic name: fatty acid modified acrylic	In prep.	2/19/81
80-332	Generic name: dimethylol propionic acid, disoyate ester	In prep.	2/22/81
80-333	Generic name: polymer of substituted alkanediol, alkanedioic acid and alkenedioic acid	In prep.	2/22/81
80-334	Generic name: polymer of substituted alkanediolI, alkanedioic acid and alkenedioic acid	In prep.	2/22/81
80-335	Generic name: polymer of substituted alkanediol, alkanedioic acid and alkenedioic acid	In prep.	2/22/81
80-336	Generic name: 2-antracenesulfonic acid, 1-substituted 9,10-dihydro-9,10-dioxo-4-substituted	In prep.	2/22/81
80-337	Generic name: acrylamid-methacrylic copolymer	In prep.	2/23/81
80-338	Generic name: salt form of acrylic acid-acrylate copolymer	In prep.	2/22/81
80-339	Generic name: salt form of acrylic acid-acrylate copolymer	In prep.	2/22/81
80-340	Generic name: polymer diolI, monocarboxyilc acid diol, diamine and diisocyanate	In prep.	2/24/81

INTERAGENCY TESTING COMMITTE (ITC)... SECTION 4(e)

Under Section 4(e), the ITC was established to recommend to EPA substances which should be tested for specified effects to determine the hazardous potential of the substances to human health or the environment. Committee members are: Council on Environmental Quality (CEQ), Department of Commerce (DOC), Environmental Protection Agency (EPA), National Cancer Institute (NCI), National Institute of Environmental Health Sciences (NIESH), National Institute for Occupational Safety & Health Administration (OSHA). The committee may list up to 50 chemicals or categories and is to consider revising or adding to its list every 6 months. The EPA must respond within one year to each recommendation by initiating rulemaking under Section 4 or stating its reasons for not doing so. Both ITC reports and EPA responses appear in the Federal Register.

On October 24, 1980, the ITC sent to EPA its seventh priority list of chemicals for consideration in promulgating 4(e) test rules. The report, which added two chemicals and two chemical categories and removed one chemical from the list, was published on November 25, 1980 (45 FR 78432). The two added chemicals are benzyl butyl phthalate and butyl glycolyl butyl phthalate, the two new chemical categories are alkyltin compounds and fluoroalkenes. Because EPA had addressed all the ITC's concerns about chloromethane, that chemical was removed from the priority list. With the additions and the deletion the priority list now contains 42 entries.

The TSCA Section 4(e) Priority List

	ENTRY	DATE OF DESIGNATION
1.	Acetonitrile	April 1979
2.	Acrylamide	April 1978(b)(d)
3.	Alkyl epoxides	October 1977(a)
4.	Alkyl phthalates	October 1977(a)
5.	Alkyltin compounds	October 1980
6.	Aniline and bromo, chloro and/or nitro anilines	April 1979
7.	Antimony (metal)	April 1979
8.	Antimony sulfide	April 1979
9.	Anitmony trioxide	April 1979
10.	Aryl phosphates	April 1978(b)
11.	Benzidine-based dyes	November 1979
12.	Benzyl butyl phthalate	October 1980
13.	Butyl glycolyl butyl phthalate	October 1980
14.	Chlorinated benzenes, mono- and di-	October 1977(a), (c)
15.	Chlorinated benzenes, tri-, tetra-, and penta-	October 1978(c)
16.	Chlorianted naphthalenes	April 1978(b)
17.	Chlorinated paraffins	Octcber 1977(a)
18.	Cresols	October1977(a)
19.	Cyclohexanone	April 1979
20.	o-Dianisidine-based dyes	November 1979
21.	Dichloromethane	April 1978(b)
22.	1,2-Dichloropropane	October 1978
23.	Fluoroalkenes	October 1980
24.	Glycidol and its derivatives	October 1978
25.	Halogenated alkyl epoxides	April 1978(b)
26.	Hexachloro-1,3-butadiene	October 1977(a)
27.	Hexachlorocyclopentadiene	April 1977
28.	Hydroquinone	November 1979
29.	Isophorone	April 1979
30.	Mesityl oxide	April 1979
31.	4,4'-Methylenedianiline	April 1979
32.	Methyl ethyl ketone	April 1979
33.	Methyl isobutyl ketone	April 1979
34.	Nitrobenzene	October 1977(a)
35.	Phenylenediamines	April 1980
36.	Polychlorinated terphenyls	April 1978(b)
37.	Pyridine	April 1978(b)
38.	Quinone	November 1979
39.	o-Tolidine-based dyes	November 1979
40.	Toluene	October 1977(a)
41.	1,1,1-Trichloroethane	April 1978(b)
42.	Xylene	October 1977(a)

(a) Responded to by EPA Administrator 43 FR 50134
(b) Responded to by EPA Administrator 44 FR 28095
(c) Responded to by EPA Administrator 45 FR 48524
(d) Responded to by EPA Administrator 45 FR 48510

SIGNIFICANT NEW USE ... SECTION 5(a)(2)

Under 5(a)(2), EPA determines when certain uses of existing chemical substances are for significant new uses (SNUR). A determination is made by a rule promulgated after considering all relevant factors. The factors include the projected volume of manufacturing and processing of the substance, the extent to which the new use changes the type and form of exposure to humans or the environment, the extent to which the use of the substance increases the magnitude and the duration of exposure to humans or the environment and the anticipated manner and methods of manufacturing, processing, distributing in commerce and disposal of the substance. Under Section 5(a)(1)(B), persons must notify EPA at least 90 days before manufacturing, process or import a chemical sustance for a significant new use, as determined by EPA.

On November 26, 1980 (45 FR 78970), EPA proposed that certain uses of N-methanesulfonyl-p-toluene sulfonamide be designated as significant new uses (SNUR) of the chemical substance. A PMN for this

chemical substance was received by EPA on September 5, 1979. On December 4, 1979 the submitter was free to begin production because EPA had determined that it was not necessary to regulate for the use and exposure conditions described in the PMN. However, EPA remained concerned because exposure increases of the substance in the future may present a risk that cannot be evaluated today because there is a lack of toxicity data about this substance.

In the November 26, 1980 notice, EPA proposes to define as a SNUR any qualitative use of this substance other than that described in the September 5, 1979 PMN, or the manufacture or process of more than 1,000 pounds of the substance by any one person for the use described in the PMN.

"The company gave us no information in its 1979 PMN about the effects of this chemical on human health and the environment," said Steven D. Jellinek, EPA's Assistant Administrator for Pesticides and Toxic Substances, when the proposed rule was made public. "As a result, our initial review and lack of immediate concern about its one proposed use were predicated on the fact that human exposure to the chemical would be extremely limited. The low exposure expected was due to the small amount to be produced and the highly restricted way in which it was to be used."

Jellinek said, "The Agency intends to take literally the production and exposure assumptions provided by firms submitting premanufacture notices. If the toxicity of a new substance is either significant or unknown, EPA will require firms to notify the Agency in advance of anticipated use changes or production increases. We will then assess any risks presented by the new activity to determine whether regulatory action is necessary to control or prevent changes in use or production volumes."

This action marks the second time EPA has initiated a significant new use rule and is the first such rule covering a specific chemical. Last August the Agency proposed a "generic" rule applying to a number of chemicals. It extended the safeguards of TSCA to those chemicals normally exempted from the Act--such as pesticides and drugs, which are regulated as such under other legislation--when those substances are processed for new uses that are not exempt from coverage under TSCA. Additional significant new use rules will be issued by EPA on other specific chemical or classes of chemicals, as conditions warrant.

COURT RULES ON PCBs... SECTION 6(e)

Under Section 6(e), EPA is required to control the manufacturing, processing, distributing in commerce, use, disposal and marketing of polychlorinated biphenyls (PCBs). On May 31, 1979, 44 FR (31514) a rule on PCB was promulgated.

On October 30, 1980, the United States Court of Appeals for the District of Columbia Circuit struck down major portions of the rule on PCBs. The Court set aside the rule's definition of intact, non-leaking transformers, capacitors and electromagnets as totally enclosed uses of PCBs. In addition, the Court struck down the portion which limited the rule's application to 50 parts per million or more. The Court issued its opinion in an appellate case brought by the Environmental Defense Fund against EPA.

REVISED INTERIM POLICY STATEMENT... SECTION 5

On November 7, 1980 (45 FR 74378) EPA published a revised interim policy statement for the submission of PMNs. This clarification was issued as a response to comments received on PMNs and to discuss EPA's experience with PMNs received since July 1, 1979. Upon publication this clarification became effective.

On January 10, 1979 (44 FR 2242) EPA proposed rules and PMN forms for new chemicals under Section 5. At the same time an iterim policy for submission of PMNs was established. The interim policy applied to PMNs for substances intended to be manufactured or imported for a commercial purpose during the period between July 1, 1979 (30 days after publication of the TSCA Initial Inventory) and the publication of the PMN rule. On May 15, 1979 (44 FR 28564), EPA issued a statement clarifying aspects of the interim policy, modifying it to a limited degree, and extending the policy to cover all PMNs received prior to July 1, 1979. The May 15, 1979 statement replaced the interim policy published on January 10, 1979.

SUBSTANTIAL RISK ... SECTION 8(e)

Under Section 8(e) persons who obtain information which reasonably supports the conclusion that a substance presents substantial risk of injury to human health or the environment must notify EPA within 15 days. These notices are then reviewed by OPTS preliminarily and an initial evaluation is prepared containing, if appropriate, follow-up questions to the submitter, referrals to other agencies and decisions to list the chemical for a Section 8 reporting rule or to undertake a formal risk assessment. The submissions and the initial evaluations are in the Public Reading Room, 447 East Tower, Waterside Mall, 401 M Street, S.W., Washington, D.C.

Because of the high volume of telephone requests for copies of the Section 8(e) notices, which often are either a one-page letter or an extensive package of data and articles, the Public Document Room will no longer be able to take telephone requests for copying. Persons wishing to request a copy of these notices may write; U.S.E.P.A., Ms. Jerri Green (A-101), Freedom of Information office, Washington, D.C. 20460. Requestors will be charged 20¢ per page for the duplication of documents. However, there will be no charge if the total fee in connection with a request is less than $10.00 (i.e., less than 50 pages). At page 50 of a request for duplication, a charge of 20¢ per page is levied for all subsequent pages and also for the first 49 pages of the request. The reader's attention is called to the fact that many 8(e) notices represent a company's first review of a situation or datum and a judgment in compliance with the statute to submit an notice within 15 days of obtaining the information. The EPA publishes its evaluations of these notices in order to make widely available this Section 8(e) information in an explanatory form that makes it understandable to a broad public.

SECTION 8(e) NOTICES OF SUBSTANTIAL RISK: OCTOBER-NOVEMBER 1980

Log No 8EHQ-			[CAS No.]
1080-0365	9/24/80	1,1,1, Trichloro-ethane	71-55-6
		* Final Report on Acute Aspiration Toxicity	
1080-0366	10/1/80	Dimethyl Hydrogen Phosphite	868-85-9
		* Final Summary Report on Mutagenicity Battery	
1080-0367	10/3/80	Toluene Diamine	25376-45-8
		Dinitrotoluene	25321-14-6
		* NIOSH "Health Hazard Evaluation" on Employee Reproductive Problems	
1080-0368	10/8/80	Organic Compounds	
		* Sampling and Analysis of Chemicals in Plant Site and Surrounding Area Well Water	
1080-0370	10/20/80	1,3-butadiene	106-99-0
		* Preliminary Inhalation Report on Chronic Carcinogenicity Study	
1180-0371	11/11/80	Varisoft 222 (90%)	
		* Final Report on Sensitivity Study	
1180-0372	11/18/80	Dimethlsulfide borane	13292-87-0
		* Acute Dermal and Eye Irritation Study	
1180-0373S	11/19/80	N-ethyl Perfluor-ooctyl-sulfon-amido ethanol	1691-99-2
		N-ethyl Perfluoro-heptyl sulfon-amide ethanol	6855-73-7
		* Preliminary Oral Teratology Study	
1180-0374S	11/19/80	Potassium Salt of Perfluoroalkyl Sulfonates	68391-09-3
		* Preliminary Oral Teratology Study	
1180-0375S	11/21/80	Cadmium Salts of Paratertiary-butyl	
		* Acute Dermal Toxicity Study	
1280-0376	11/26/80	Nitrosamines in alkyl dimethyl amine oxides	16430-20-5
		N-nitrosodimethylamine	62-75-9
		* Preliminary Report on Product Contamination	

S at the end of Log Number means a santized version with Privacy Act items

N.B: All toxicity, carcinogenicity, teratogenicity and mutagenicity studies involve animals. Additional tests (e.g., bacteria cell) are noted or are included in the term "battery."

CITIZENS' PETITIONS... SECTION 21

Under Section 21, any person may petition the Administrator to initiate a proceeding for the issuance, amendment or repeal of a rule under Section 4, 6, or 8, or an order under Section 5(e) or Section 6(b)(2). Within 90 days after the filing of Section 21 petition, EPA must either grant or deny the petition. Under Section 6(a), if EPA finds that there is a reasonable basis to conclude that a chemical substance will present an unreasonable risk of injury to health or the environment it shall apply one or more of several requirements to the extent necessary to protect adequately against this risk.

On May 5, 1980, Mr. Walter Fitzpatrick, of Stony Brook, N.Y., filed a citizen's petition under Section 21, requesting the EPA initiate a proceeding for the issuance of a rule under 6(a) to prohibit the manufacture and distribution of nitrilotriacetic acid (NTA), as a detergent additive. The petition stated that NTA is teratogenic, affects various body functions and does not slow down or stop eutrophecation in coastal and estuarine waters. This petition also asserted that there are safe and economically feasible alternatives to the use of NTA in detergents.

On November 3, 1980 (45 FR 72773) EPA denied the petition based on the findings presented in a document "Final Report, NTA." This risk assessment concluded that the projected levels of general population exposure from the use of NTA in laundry detergents would be generally low and that the associated risks to human health would also be low. However, if at any time substantial new evidence suggesting that NTA presents an unreasonable risk to health or the environment, EPA will reevaluate its position.

At the time of the petition denial, EPA, in a letter to Procter & Gamble, urged manufacturers and processors of NTA to limit occupational exposure and to perform additional monitoring and environmental studies. EPA also recommended that NTA not be used in consumer products to which there is direct dermal or oral exposure, such as in shampoos, foods, and hand washing detergents.

REPORTING RULES

NOTIFICATION OF EXPORT...SECTION 12(b)

Under 12(b), a person in the United States who exports or intends to export to a foreign country a chemical substance or mixture for which certain requirements are in effect must notify EPA of such exportation. Upon receipt of such a notice, EPA must furnish to the government of the country of import, a notice of the TSCA action taken with respect to that substance or mixture. The requirements triggering export notification are: final Section 4 testing rules or Section 5(b)(4) risk listing for test data; proposed and final Section 5 and 6 rules; orders issued under Section 5 and an action pending or relief granted under Section 5 or 7.

On December 16, 1980, (45 FR 82843), EPA published a final rule outlining notification procedures that an exporter must follow in order to comply with Section 12(b). The regulation also outlines what action EPA will take upon receipt of such a notice. The purpose of this rule is to alert a foreign government to hazards that may be associated with certain

chemical substances or mixtures being exported to that country from the customs territory of the United States.

This 12(b) rule requires exporters to submit a notice for the first annual shipment of the substance to any given country. There is no form, but the notice, submitted by mail to EPA, must include the exporter's name and address, the name of the substance or mixture, the date of export or intended export, the country of import and the section of TSCA under which EPA has taken action. Within five working days, EPA will advise the foreign government of the impending exportation and the U.S. regulatory action taken with respect to the substance or mixture. Thus, for a Section 12(b) listed sustance or mixture a company is only obliged to notify once per calendar year per country/chemical transaction. It should be understood that whatever limited scope or limited application of a proposed or final rule, the chemical becomes subject to Section 12(b) notification. Regardless of the scope or purpose of the intended exportation there is an obligation to notify EPA under Section 12(b).

The Section 12(b) rule as of January 15, 1981 applies to the following chemicals by request of the stated TSCA actions:

F = final rule
P = proposed rule

CHEMICALS	TSCA ACTIONS
$PCBs_1$	F
$CFCs_2$	F & P
2,3,7.8 - $TCDD_3$	F
Asbestos	P

1. Polychlorinated Bipheny)ls; 2. Chlorofluorocarbons; 3. 2,3.7,8 Tetrachlorodibenzo-p-dioxin

CHEMICAL IMPORTS AND EXPORTS ... SECTION 13

Under Section 13, the U.S. Treasury Department is required to refuse entry into the United States customs territory to chemical substances, mixtures or articles containing chemical substances or mixtures that do not comply with TSCA rules, or that are offered for entry in violation of any TSCA rule or order under Sections 5, 6, or 7 that are in effect. In addition, Section 13 requires the Treasury Department to consult with EPA and issue rules to administer this program.

On December 1, 1980, there was published jointly in the Federal Register, an EPA Section 13 policy statement (45 FR 79730) and a Treasury Department proposed rule on chemical imports (45 FR 79730). In its notice, the Treasury Department proposes to amend the U. S. Customs laws to regulate, through a certification procedure, any chemical substance, imported in bulk or as a part of a mixture that enters the customs territory of the United States. Chemicals that are a part of articles are exempt at this time but the regulations may be modified later by specific EPA rule to include such chemicals.

Certification will be accomplished by typing a brief statement on standard entry document or invoices to the effect that all chemical substances in a shipment comply with all rules under TSCA and none are offered in violation of TSCA. The importer must sign this statement.

Because TSCA treats import the same as manufacture, any responsibilities placed on domestic manufacturers also extend to importers. Thus, an importer must be aware of whether his chemical import is included in the TSCA inventory or is subject to Premanufacture Notification (PMN) as a "new" chemical. Importers should also check to determine whether their chemical substances fall within significant new use, as defined by a Section 5 rule, and are therefore subject to PMN. In addition, awareness of chemicals subject to specific controls as hazardous substances under Section 6 is required to certify compliance. The requirements for imports will continually change as substances are added to the Inventory and as new rules are developed under other sections of TSCA. Consequently, it is important that importers remain informed of TSCA rules.

Public comment on both proposals are solicited until March 2, 1981. EPA specifically desires comments on ways it can assist the chemical import community in awareness and compliance. There will be an opportunity for persons to make presentations on February 24th and 25, 1981, if signed up through the IAO.

STUDIES & SUPPORT ACTIVITY

GENERAL ACCOUNTING OFFICE REPORT

The United States General Accounting Office (GAO) report to Congress, reviewing EPA's four year administration of TSCA, is available through the Industry Assistance Office.

PCB ALERT for FOOD and FEED FACILITIES

A revised edition of "Polychlorinated Biphenyls: An Alert for Food and Feed Facilities" is available. The booklet urges people in the food and feed industries to be continually aware of the serious potential problems associated with use and disposai of PCB-containing equipment. The booklet provides information to help set up contamination prevention programs and provides information on current PCB reguisitions.

EPA NEW CHEMICAL ACTIVITIES STATUS REPORT

The second edition of EPA's chemical activity status report will be available shortly. Reservations are being accepted for the two-volume set.

The status report, current to July 1980, is a gathering of information of EPA's activities relating to chemical substances but is not limited to chemical

regulatory activities. Included in the report are ongoing and completed technical assistance information, preregulatory assessments, chemical and biological testing and monitoring programs and labeling requirements. This edition is the first to include the chemical activities of EPA's Office of Research and Development.

The data in this report exists in an interactive data base and can be reached for either specific chemicals or specific types of activities. Given a list of chemicals, this report can be used to quickly determine who in EPA regulates, is considering regulating or assessing a chemical and what scientific or technical work has been done on the substance.

REPORTS ON SECTION 5 PROPOSED RULES

EPA has published a draft analysis of the proposed rules implementing Section 5 of TSCA. The more than 70-page report examines the major alternatives that EPA considered in developing Section 5 rules and explains the rationale for the Agency's choice among the alternatives.

In conjunction with the analysis, EPA has also printed a contractor's analysis of the economic impact Section 5 rules will have on the chemical industry. The contractor's analysis consists of a basic report and two appendices.

REPORT ON IMPLEMENTING THE CFC PROPOSED RULE

An EPA contractor study on the economic implications of regulating chlorofluorocarbons (CFCs) emissions is now available. The study focuses attention on the industries that produce and use CFCs and assesses the possible effects of regulation on the industries and their customers. Along with the study, EPA has published three other contractor produced documents containing material related to the study. One report documents a briefing given to EPA executives and others. It sums up the study's results and is recommended to those who seek a concise, nontechnical summary of the basic study. The second document is a more detailed analysis of flexible foam application. The third gives an extensive description of the industries that produce the chemicals used in making CFCs.

SUPPORT DOCUMENTS on ASBESTOS-CONTAINING MATERIALS IN SCHOOLS

EPA has just published a preliminary statement on the health effects and the magnitude of exposure to humans of asbestos-containing friable materials in schools. The more than 100-page support document is a draft and has been released for comment on its technical merit and policy implementation.

Also recently published is an EPA contractor economic impact analysis of the proposed Section 6 identification and notification rule pertaining to asbestos-containing friable materials in schools.

SECOND SECTION 8(e) VOLUME PUBLISHED

EPA has just published a second volume of initial evaluations of substantial risk notices, Section 8(e). The latest volume covers the July 1, 1979 to January 31, 1980 period. The substantial risk volumes are issued to enable the public to have access to the information and to provide examples of submitted information and EPA's evaluation of it. The information should help anyone subject to Section 8(e) to better understand the types of information that should be submitted to EPA.

COMPENDIUM ON EPA-STATE AGREEMENTS

EPA has cooperative agreements on environmental matters with the States and U.S. territories. The agreements are management tools EPA and the more local governments can use to focus attention on environmental activities and problems that need priority attention. The Office of Pesticides and Toxic Substances has just published a book containing synopses of the Agency's FY 1980 environmental agreements. The information in the book "Perspectives on State-EPA Grant Activities" can help state and territory managers to know about each others' activities, encourage program cooperation and lead to an exchange of environmental information.

JELLINEK REVIEWS PMN HISTORY

EPA has learned two important lessons as a result of reviewing about 300 PMNs, Steven D. Jellinek, Assistant Administrator for Pesticides and Toxic Substances, told a Japanese audience recently.

"First, that section 5(e) appears to be a very powerful tool, indeed, and second, that most of the new chemicals we've seen do not appear to require EPA intervention prior to entering commerce," Jellinek said at a Tokyo seminar.

However, new chemicals entering commerce without objection may later require action if the chemical is produced in higher volume or used in ways differently that originally proposed by the initial submitter, Jellinek said. "We will require resubmittal of PMNs for chemicals that don't appear to pose an unreasonable risk as currently projected for use -- such as an enclosed intermediate, but that may pose such risks if used differently -- such as solvents in consumer products."

More than 30 chemicals are now awaiting significant new-use rules under section 5(e)(2), Jellinek said. EPA has proposed one significant new-use rule and a second one is planned.

EPA's PMN experience shows that the U.S. chemical industry generally does not test its new chemicals or evaluate their risks, Jellinek said. Approximately 25 percent of all notices received so far have had no health or safety data, not even on physical or chemical properties. When toxicity data has been included, only limited results such as acute tests and some mutagenicity screens have been given.

"This means that the EPA staff has to develop toxicity profiles on its own by comparing the structure/activity relationship of the new chemical to similar substances and by conducting literature searches on the analogue chemicals," Jellinik said. "This has placed an extraordinary burden of EPA's limited resources. We believe that industry must begin to shoulder the burden."

EPA can use several tools to encourage industry to generate risk information, Jellinek said.

EPA will continue to use section 5(e) when safety information is needed. The Agency will issue testing guidance and designate certain chemicals for a risk list under its 5(b)(4) authority. A company submitting a PMN for a risk list chemical would have to demonstrate that the substance or its use did not present an unreasonable risk.

Jellinek said in the future it is possible that categories of chemicals might be exempt from PMN requirements by an EPA advance determiniation that the chemicals did not present unreasonable risks to health or the environment.

A copy of Mr. Jellinek's October 30, 1980 speech before the Fuji Techno Systems seminar may be obtained by calling the Industry Assistance Office.

"WHERE WE STAND"

EPA has just updated Where We Stand a popular and informal accounting of TSCA activities. The 12-page fact sheet highlights what the TSCA mandate is, and the scope, strategy and priorities of the administration of the law. The latest PMN and testing rule activities are explained along with TSCA action on PCBs, dioxin and asbestos.

TSCA AND THE PRESIDENTS

As of this date, the Toxic Substances Control Act (TSCA) is slightly more than four years old. As a new President enters the White House, this may be a good time to review the role of recent Presidents in TSCA's development.

The genesis of TSCA probably was a Council of Environmental Quality (CEQ) report called "Toxic Substances" offered to President Richard Nixon in 1970. The CEQ itself was new in those days, established by law in 1969 to formulate and recommend to the President policies promoting and improving the Nation's environmental quality.

Using the knowledge gained from "Toxic Substances" and other sources, President Nixon on February 8, 1971 told Congress: "As we have become increasingly dependent on many chemicals and metals we have become acutely aware of the potential toxicity of the materials entering our environment. Each year hundreds of new chemicals are commercially marketed and some of these chemicals may pose serious potential threats. Many existing chemicals and metals, such as PCBs (polychlorinated biphenyls) and mercury, also represent a hazard.
"It is essential," the President continued, "that we take steps to prevent chemical substances from becoming environmental hazards. Unless we develop better methods to assure adequate testing of chemicals, we will be inviting the environmental crises of the future."

Mr. Nixon then became the first President of the United States to propose to Congress a toxic substances control program.

"I propose that the Administrator of EPA be empowered to restrict the use or distribution of any substance which he finds is a hazard to human health or the environment.

"I propose that the Administrator be authorized to stop the sale or use of any substance that violates the provisions of the legislation and to seek immediate injunctive relief when use or distribution of a substance presents and imminent hazard to health or the environment.

"I proposed that the Administrator be authorized to prescribe minimum standard tests to be performed on substances."

Mr. Nixon ended his Congressional message by saying, "the legislation, coupled with the proposal on pesticides and other existing laws, will provide greater protection to humans and wildlife from introduction of toxic substances into the environment. What I propose is not to ban beneficial uses of chemicals, but rather to control the use of those that may be harmful."

Almost immediately, bills on toxic substances were dropped into the hoppers on both sides of the Hill, but legislative action on chemicals in 1971 was limited.

A little over a year later (March 2, 1972) in a special message to Congress on health care, Mr. Nixon reminded Congress that the TSCA action he proposed a year earlier "awaits action by Congress."

The President's 1972 reminder fell on deaf ears. On February 15, 1973 in his State of the Union message on Natural Resources and the Environment, Mr. Nixon told the new 93rd Congress, "I was keenly disappointed when the last Congress failed to take action on many of my legislative requests related to our natural resources and the environment."

That spring and summer both the House and Senate passed TSCA bills. But these bills differed and a TSCA Congressional solution was not to be found until three years later during President Gerald Ford's administration. Although there were strong differences of opinion as to specific features in the proposed law, there was little dispute over the testing provisions (which eventually become section 4 of TSCA). What was to become section 5 - how new chemicals were to be treated - was much discussed. In Congress, there were three basic approaches to reviewing new chemicals. Some forces wanted a premarket clearance system, similiar to the system used to federally register new drugs and pesticides. This approach was favored in the Senate and had the backing of many environmental groups.

A second legislative approach was a premarket notification clearance system, but limited to chemicals that EPA had determined would present an unreasonable risk. Support for this approach was stronger in the House and favored by industry.

The winning legislative idea of a general premarketing notification method originally supported by the Nixon Administration was successfully backed by President Ford. With the Section 5 provision settled, Congress approved the Act and President Ford signed TSCA into law. In signing the legislation, President Ford said on October 12, 1976, "I believe this legislation may be one of the most important pieces of environmental legislation that has been enacted by the Congress.

"This toxic substances control legislation provides broad authority to regulate any of the tens of thousands of chemicals in commerce. Only a few of

these chemicals have been tested for their long-term effects on human health or the environment. Through the testing and reporting requirements of the law, our understanding of these chemicals should be greatly enhanced. If a chemical is found to present a danger to health or the environment, appropriate regulatory action can be taken before it is too late to undo the damage."

President Ford also said "the bill closes a gap in our current array of laws to protect the health of our people and the environment. The Clean Air Act and the Water Pollution Control Act protect the air and water from toxic contaminants. The Food and Drug Act and the Safe Drinking Water Act are used to protect the food we eat and the water we drink against hazardous contaminants. Other provisions of existing laws protect the health and the environment against other polluting contaminants such as pesticides and radiation. However, none of the existing statutes provide comprehensive protection.

"This bill provides broad discretionary authority to protect the health and environment. It is critical, however, that the legislation be administered in a manner so as not to duplicate existing regulatory and enforcement authorities."

President Ford concluded by saying, "the administration, the majority and minority members of the Congress, the chemical industry, labor, consumer, environmental, and other groups all have contributed to the bill as it has finally been enacted. It is a strong bill and will be administered in a way which focuses on the most critical environment problems not covered by existing legislation while not overburdening either the regulatory agency, the regulated industry, or the American people."

The Act became effective on January 1, 1977 just as Jimmy Carter was moving to Washington. In May 1977, President Carter stressed the need for TSCA's preventive approach in his environmental message to Congress. He said, "The presence of toxic chemicals in our environment is one of the grimmest discoveries of the industrial era. Rather than coping with these hazards after they have escaped into our environment, our primary objective must be to prevent them from entering the environment at all."

TSCA enables the Federal Government, for the first time, President Carter said, "to gather the information on chemical substances needed to determine their potential for damaging human health and the environment, and to control them where necessary to protect the public. My FY 1978 budget provides nearly $29 million - a threefold increase over Fiscal 1977 - for the Environmental Protection Agency to implement this important Act."

The law, controlling toxic substances had taken six years to write. It has now been followed by four years of administration.

During the latter period, EPA has promulgated TSCA rules for reporting, storing, retrieving and using chemical information while protecting confidential business information. Under TSCA, chemicals are being assessed and in a few cases controlled by the Act's authority. Legal machinery has been established under TSCA to review new chemicals as to their effect on business and the environment before the substances are manufactured or imported.

To be more specific, under TSCA, an inventory of chemical substances was compiled through a system of reporting that involved some 7,400 chemical manufacturers. This Initial Inventory, published on June 1, 1979 contained over 47,000 chemicals. During a second reporting period, processors and users of chemicals were given an opportunity to report. The Revised Inventory made available on July 30, 1980 brought the total to more than 55,000 chemicals subject to TSCA.

On July 1, 1979, 30 days after publication of the Revised Inventory the premanufacturing notification (PMN) requirements of TSCA became effective. The PMN provision requires any person who intends to manufacture a chemical substance subject to TSCA but not in the Revised Inventory to submit a premanufacturing notice to EPA at least 90 days before manufacture or import. During the PMN review period, EPA must evaluate the health and environmental effects of the chemical throughout the entire life cycle from manufacture to disposal.

TSCA also gives EPA the authority to require testing of chemicals in order to develop data to aid in determining the risks that such substances may present to health and the environment. To aid the Agency in choosing substances the law required the establishing of a group, the Interagency Testing Committee (ITC), to recommend substances to EPA for priority consideration for proposed test rules. The ITC has now recommended 42 chemicals and categories of substances.

TSCA also permits EPA to select, on its own, additional chemicals for testing. EPA has proposed calls for reporting and recordkeeping on chemical production, use, byproduct and exposure on 2,300 chemicals. Here the intention is to let EPA make a sound preliminary assessment of a chemical of high exposure potential or one on which toxicity information has been previously obtained.

Testing under TSCA begins with an hazard assessment of the physical, chemical and biological properties of a substance and its potential for injury to health or the environment. Next, there is an EPA assessment of risk to humans as to what extent people are exposed and under what conditions the exposure occurs.

The TSCA testing standards are to be directed at health effects such as oncogenicity, teratogenicity, mutagenicity and environmental fate, persistence and ecological effects. All EPA test standards must be acceptable to other Federal agencies that require such testing.

These are some of the administrative actions taken in the last four years to fulfill the requirements of TSCA.

Now, the process will continue or change with a new President in the Oval Office. He will be the fourth President to be directly confronted with one of today's serious problems - how to control toxic substances to protect human health and the environment.