

ATTACHMENT 3

Premanufacture Notice (PMN) Form and Instructions EPA Form 7710-25

[For electronic copies of the PMN Form and Instructions, see
<http://www.epa.gov/opptintr/newchems/pubs/pmnforms.htm> and follow the appropriate links.]

ATTACHMENT 4

Calculation of Hourly Wage Rates

(Excerpt from Economic Impact Analysis)

APPENDIX A: INFLATORS AND WAGE RATES

This appendix provides a brief discussion of the wage rates, inflators, and methods that were used to derive the final “fully loaded” wages used in the calculation of quantified costs. Base hourly wages for relevant labor categories were loaded with factors for benefits and overhead to derive a loaded hourly rate. If the loaded hourly rate was not already in year 2007 dollars, it was then inflated to year 2007 dollars by multiplying by the appropriate inflation factor. The derivation of fully loaded wages in year 2007 dollars, for each of the labor categories used in the report, is discussed in Section A.1 and is summarized in Table A.1. The derivation of the different inflation factors used to inflate wages to year 2007 dollars is discussed in Section A.2 and is summarized in Table A.2.

A.1. Derivation of Loaded Wage Rates

A.1.1 Technical, Managerial, and Clerical Labor¹

The basic method used to derive loaded wage rates for technical, managerial, and clerical personnel is described more fully in *Wage Rates for Economic Analysis of the Toxics Release Inventory Program* (Rice, 2002).

December 2007 average wages for technical, managerial, and clerical labor were taken from the Employer Costs for Employee Compensation (ECEC) report from the Bureau of Labor Statistics for all goods-producing, private industries (BLS, 2008).²

The additional cost of benefits, such as paid leave and insurance (“fringe benefits”), specific to each labor category, are also taken from the same BLS series. Fringe benefit as a percentage of wage is then calculated separately for each labor category. For example, the

⁹ Many Labor hourly rates in this analysis are lower than hourly rates for the same labor categories in an earlier SNUR economic analysis (EPAB, 1999). EPA does not mean to suggest that actual hourly rates declined. Rather, the apparent decline is due to a changed method of calculating hourly costs for the same labor categories. There were three changes: (1) Previously, the 17% overhead was applied to wages-plus-fringe benefits. Now it is applied only to wages. This change reduces calculated overhead. (2) Before, most wage rates were based on older data and then inflated to current dollars. Here, most wage rates are based on recent data. (3) Finally, fringe benefits were based on an assumed percent of wages. Here, private industry fringe benefits are based on actual fringe benefits taken from recent BLS data.

Employer Costs for Employee Compensation, Private industry workers, Goods-producing industries, white-collar occupations, as published by the U.S. Department of Labor, Bureau of Labor Statistics. The December 2007 values for these series were extracted on February 29, 2008.

average wage rate in December 2007 for technical labor was \$33.25; the average fringe benefit was \$16.54. So fringe benefit as a percentage of wage rate for technical labor was $16.54/33.25$, or approximately 49.7%.

An additional loading factor of 17 percent is applied to wages for overhead.³ This overhead loading factor is added to the benefits loading factor, and the total is then applied to the base wage to derive the fully loaded wage. The fully loaded wage for technical labor, for example, is $\$33.25 \times (1 + 0.497 + 0.17) = \$33.25 \times (1.667) = \$55.44$.

Fully loaded costs for managerial and clerical labor were calculated in a similar manner.

Table A.1 Derivation of Loaded Wage Rates

Labor Category	Data Sources	Uninflated wages and fringes / hour			Fringe benefits as % of wage	Overhead as % of wage*	Fringe + Overhead factor	Loaded Wage Rate before inflation	Inflation factor	Loaded Wage Rate (2003 dollars)
		Date	Wages \$	Fringe benefits \$						
Technical	<i>BLS Employer Costs for Employee Compensation.</i> Private industry, goods-producing industries, Profess. specialty & technical . Dec 03. [BLS, 2008]	Dec 2007	\$33.25	\$16.54	49.7%	17%	1.667	\$55.44	1	\$55.44
Managerial	<i>BLS Employer Costs for Employee Compensation.</i> Private industry, goods-producing industries, Exec, admin, & managerial . Dec 03.	Dec 2007	\$41.40	\$19.74	47.7%	17%	1.647	\$68.18	1	\$68.18

¹⁰ An overhead rate of 17 percent applied to wages is used for consistency with recent EPAB economic analyses for two major rulemakings: *Wage Rates for Economic Analyses of the Toxics Release Inventory Program*, June 10, 2002, and the *Revised Economic Analysis for the Amended Inventory Update Rule: Final Report*, August 2002. In reports for an earlier SNUR (EPAB, 1999), the 17% was applied to wages-plus-fringe benefits. Applying it only to wages reduces calculated overhead.

Labor Category	Data Sources	Uninflated wages and fringes / hour			Fringe benefit s as % of wage	Over- head as % of wage*	Fringe + Overhea d factor	Loaded Wage Rate before inflation	Inflati on factor	Loaded Wage Rate (2003 dollars)
		Date	Wages \$	Fringe benefits \$						
[BLS, 2008]		Dec 2007	\$16.40	\$8.28	50.5%	17%	1.675	\$27.47	1	\$27.47
Clerical	<i>BLS Employer Costs for Employee Compensation.</i> Private industry, goods-producing industries, Admin support, incl. clerical . Dec 03. [BLS, 2008]									

*An overhead rate of 17 percent applied to wages is used for consistency with recent EPAB economic analyses for two major rulemakings: *Wage Rates for Economic Analyses of the Toxics Release Inventory Program*, June 10, 2002, and the *Revised Economic Analysis for the Amended Inventory Update Rule: Final Report*, August 2002.

Note: Calculations are based on unrounded values, so the total may not equal the product of the rounded factors.

A.2. Derivation of Inflation Factors

In general, wages were inflated using the appropriate Employment Cost Index (ECI), seasonally adjusted. Complete information on the derivation of the inflation factors used is given in Table A.2 below.

Table A.2 Derivation of Inflation Factors

Report section	Item	Inflator data source	Starting year	Inflator for starting year (A)	Inflator for 2003 (B)	Inflation factor (B) / (A)
Section 3	Export notification	BLS Employ. Cost Index, Seas. Adj., White Collar Occupations Series ECS11102I, Fourth Q, 1992	1992	63.2	103.6	1.639
Appendix C	Agency Extramural costs	BLS Employ. Cost Index, Seas. Adj., White Collar Occupations Series ECS11102I, Fourth Q, 1993	1993	65.5	103.6	163.1

APPENDIX B: AGENCY COSTS

EPA's costs to review and process industry submissions (SNUNs, requests to modify SNUR, and requests for equivalency determination) are assumed to be the same as EPA costs to review PMNs. EPA's costs associated with SNUR submissions are presented in Table B.1. The EPA staff level (GS-12), staff-year full-time equivalents (FTEs) and extramural costs such as costs for contractor support are derived from the costs estimated for processing PMN submissions (RIB, 1994). The percent of cases are from RIB 1994 and from a 1999 SNUR economic analysis (EPAB, 1999). FTE costs have been calculated using 2007 GS-12 salary data (OPM, 2008) and a loading factor of 1.6 to reflect fringe benefits and overhead (OPPE, 1992).

The original PMN cost estimates were presented as low and high estimates, based on the most junior (Step 1) and the most senior (Step 10) GS-12 pay rates, respectively. For simplicity, this analysis uses the average of the two pay rates.

The GS-12 costs in the table below are calculated by multiplying the number of FTEs (in the first column) by the fully loaded average salary, \$122,854. This shows EPA staff cost for those chemicals requiring this review step. The Extramural Cost column shows costs for contractor support and other outside purchases for those chemicals requiring this review step, inflated from 1993 prices to 2007 using the Employment Cost Index, Total Compensation for White-Collar Occupations (BLS, 2008a). The Weighted Cost column is calculated by multiplying GS-12 staff cost plus extramural costs (Unweighted Cost) by the percentage of cases requiring this review step. This calculation yields total Agency costs for submission review and processing of \$4,203 per case.

Table B.1 Agency Costs for SNUN and Other Submission Review and Processing

Review Step	EPA FTE (1)	EPA staff (GS-12) (a) (2)	Extra-mural Cost		Unweighted Cost (5)=(2)+(4)	Pct. of Cases (6)	Weighted Cost (7)=(5)*(6)
			1993 dollars (3)	2007 dollars (b) (4)			
Prenotice consultation	0.0024	\$294.85	4	\$6.32	\$301.17	41%	\$123.48
Administrative prescreen/notice receipt/user fee	0.0024	\$294.85	92	\$145.54	\$440.39	100%	\$440.39
CRSS (Chemical Review and Search Strategy)	0.0025	\$307.14	268	\$423.98	\$731.12	100%	\$731.127
SAT (Structure Activity Team)	0.0006	\$73.71	14	\$22.15	\$95.86	100%	\$95.86
Engineering/Exposure	0.0015	\$184.28	56	\$88.59	\$272.87	100%	\$272.87
Exposure/Fate	0.0008	\$98.28	0	\$0.00	\$98.28	100%	\$98.28
Focus	0.0009	\$98.28	23	\$36.39	\$134.67	100%	\$134.67
Standard Review Functions	0.0219	\$2,690.50	511	\$808.40	\$3,498.90	29%	\$1,014.6896
Division Directors Meeting	0.0129	\$1,584.82	113	\$179.22	\$1,764.04	15%	\$264.614
Order Development/Negotiation Review	0.0171	\$2,100.80	22	\$34.80	\$2,135.60	3%	\$64.07
Post Order Data Review	0.0886	\$10,884.86	0	\$0.00	\$10,844.86	3%	\$326.55
Order Modification	0.2167	\$26,622.46	0	\$0.00	\$26,622.46	3%	\$798.67
New Chemical SNUR Development	0.0277	\$3,403.06	85	\$134.67	\$3,537.53	7%	\$247.671
Notices of Commencement	0.0012	\$147.42	40	\$63.28	\$210.70	31%	\$65.32
FOIA (Freedom of Information Act) Requests	0.0333	\$4,091.04	287	\$454.03	\$4,545.07	1%	\$45.45
CBI (Confidential Business Information) Substantiation	0.0004	\$49.14	3	\$4.75	\$47.04	100%	\$53.89
TOTAL							\$4,778

Sources: FTEs per review step and 1993 extramural costs are from RIB 1994. Percents of cases are from RIB, 1994 and EPAB, 1999. GS-12 salaries are from OPM, 2008.

(a) The average of GS-12 Step 1 and GS-12 Step 10 salaries for 2007 was $(\$66,767 + \$86,801) / 2 = \$76,784$. This was multiplied by an assumed loading factor of 1.6 to reflect fringe benefits and overhead, resulting in a fully loaded cost per FTE of $1.6 \times \$76,784 = \$122,854$.

(b) Extramural costs consist of contracting support and other purchases directly attributable to the

PMN review process. They were inflated from 1993 prices to 2007 prices using a factor of 1.433 (see Appendix A).

ATTACHMENT 5

Selection Criteria -- TSCA Section 8(a) Rule vs. SNUR

SELECTION CRITERIA: These criteria serve as guidelines and not as rigid standards for the regulatory selection process.

SECTION 8(a) Rules – REQUIREMENTS, TYPES OF DATA, USES:

- Statutory prerequisites: None (i.e., no required risk findings) other than a legitimate Agency need for such data “as the Administrator may reasonably require” and the use of notice and comment rulemaking for the establishment of reporting requirements.
- Scope: EPA can require reporting by manufacturers, importers, and processors of both new (PMN) and existing (initial Inventory) chemical substances.
- Types of data: EPA may use section 8(a) rules to obtain a variety of health and environmental data, including data on chemical identity and structure, uses, volume of production/importation/processing, byproducts, health and environmental effects, exposure, and disposal.
- Data support functions: Section 8(a) rules provide background exposure-related data to support chemical risk assessment; e.g., data support for section 4 testing decisions, voluntary testing decisions, section 6 rulemaking, section 9 referral actions, follow-up SNURs, and chemical advisories.
- Follow-up monitoring function: Section 8(a) rules can be used to monitor certain chemical activities which may cause significant new or ongoing exposures to the subject chemicals (i.e., section 8(a) reporting rules can be triggered by the commencement of certain prescribed chemical activities or by prescribed changes in chemical activities); this type of section 8(a) rule ensures that EPA will receive notification and information concerning the chemical activities described in the rule; however, the Agency can only take follow-up action through lengthy rulemaking (via section 4, 5(a)(2), or 6) or by civil action in cases of extreme and imminent hazard (via section 7).

CRITERIA THAT FAVOR DEVELOPMENT OF A SECTION 8(a) RULE

- A need to gather data for chemical risk assessment, with no perceived need for immediate short-term control action: The basic data support function described above is the primary function of section 8(a) rules.
- Lesser health and environmental concerns: If EPA intends to develop a follow-up/monitoring rule for a particular chemical substance, the Agency would favor a section 8(a) rule when the level of OPPTS concern regarding health and environmental effects of the chemical is not sufficient to require that follow-up action be immediately available (under section 5(e) or 5(f)) once the reporting requirement is triggered and notification is received by EPA (e.g., the substance is an eye or skin irritant; EPA lacks sufficient data on health and environmental effects for purposes of risk assessment; the substance may cause transient neurotoxic effects; the substance has moderate acute toxicity; the substance may persist in the environment; the substance may cause organ damage or reduced sperm counts; chronic exposure to the substance

may result in health effects that generally are reversible).

- Activities are ongoing: If EPA intends to develop a follow-up/monitoring rule for a particular chemical substance, the Agency would favor a section 8(a) rule when the chemical activities in question are ongoing at the time of rulemaking (i.e., currently taking place or recently ceased and likely to resume) or are likely to be ongoing when the rule is proposed. By definition, a SNUR would not be possible under such circumstances.

- A need for long-term monitoring: A section 8(a) rule is favored if OPPTS needs to monitor industry-wide production and exposure trends on a long-term basis, as in the following examples:

- (1) The rule may be triggered by a number of different firms over time, and the activity eventually may be considered ongoing (thereby preventing a SNUR);

- (2) The rule may be triggered a number of times by the same firm, and the activity may be considered ongoing;

- (3) Potential increases in exposure are expected to occur gradually over time and/or at a number of independent sites, making it necessary for the Agency to gather, aggregate, and analyze exposure-related data before making a decision about the potential for unreasonable risk.

SECTION 5(a)(2) SNURS – REQUIREMENTS, TYPES OF DATA, USES:

- Statutory prerequisites: TSCA does not require a risk finding for SNURs. The only statutory requirements are (1) that EPA consider “all relevant factors” (including the four exposure-related factors in section 5(a)(2)) before designating a significant new use, and (2) that the use not be ongoing at the time the SNUR is promulgated (i.e., not currently taking place or recently ceased and likely to resume).

- Scope: SNURs may be applicable to manufacturers, importers, and processors of both new and existing chemical substances.

- Types of data: EPA is authorized to require SNUR notice submitters to report the same types of data as may be required under section 8(a), plus certain types of test data in certain limited cases (note that health and environmental data must already be in the “possession or control” of the person submitting the notice (other health and environmental data which are known to or reasonably ascertainable by the person submitting the notice, which need only be described)); EPA generally requires SNUR respondents to complete the PMN reporting form.

- Follow-up monitoring function: SNURs can serve largely the same monitoring/notification/information function as section 8(a) rules, with three important differences:

- (1) A significant new use must be an activity that is not ongoing at the time the SNUR is promulgated;

(2) A SNUR respondent cannot commence the significant new use while EPA is evaluating the data in the SNUR notice;

(3) TSCA authorizes EPA to take immediate follow-up control action under either section 5(e) (the Agency lacks data but determines that the activity may present an unreasonable risk) or section 5(f) (the activity will present an unreasonable risk and section 6 action is necessary).

CRITERIA THAT FAVOR DEVELOPMENT OF A SECTION 5(a)(2) SNUR:

– Greater health and environmental concerns: If the potential health and environmental hazards posed by a chemical substance are of sufficient concern to OPPTS that the Agency wants to be able to do the following:

(1) Monitor potential exposure/risk which may be caused by non-ongoing activities involving the subject chemical;

(2) Prevent these activities from occurring until OPPTS has completed its assessment of the activities and has determined the potential for release and exposure;

(3) Take immediately effective control action (if necessary) via section 5(e) or 5(f) to prevent the activities from occurring (at least on an interim basis) after the completion of Agency review (e.g., the substance is a possible or probably human carcinogen; the substance may cause human teratogenic or reproductive effects; the substance has high acute toxicity; the substance tends to bioaccumulate in living tissue and is slow to biodegrade; chronic exposure to the substance may result in health effects that generally are irreversible).

– Likely that small businesses engage in the activities: Section 8(a) exempts small manufacturers, importers, and processors (as defined by EPA) from reporting requirements under that section. The Agency therefore may not receive adequate data from a section 8(a) rule in some cases if a substantial number of the firms subject to the rule qualify as “small.” If EPA can determine prior to rulemaking that there is a likelihood that respondents will be small firms, the Agency may wish to ensure that it will have access to information from these key potential respondents by developing a SNUR for data-gathering purposes.

OTHER CRITERIA THAT MAY AFFECT THE REGULATORY SELECTION PROCESS (examined in every case):

- Federal regulatory action and state statutory/regulatory action involving the subject chemical: Relevant to the current need for OPPTS regulatory action, the likelihood of ongoing or future activities, and past experiences involving the subject chemical.

- Know past and present activities and projected future activities involving the subject chemical (including the size of the firms involved, the volume of production/importation/ processing, potential releases and exposures, etc.): If available, this information is a relevant supplement to

all of the section 8(a)/SNUR criteria listed above.

- Concerns and objective of EPA and the technical staff responsible for the subject chemical:
CCD regulatory staff relies heavily on continuing input from management (with regard to long-term regulatory objectives for the subject chemical) and technical staff (with regard to health and environmental concerns and short-term regulatory objectives).

ATTACHMENT 6

Selected SNUR Case History Abstracts

HEXACHLORONORBORNADIENE (CAS # 2432-99-7)

also known as HEX-BCH.

6 TOXICITY

- Extremely persistent compound with a great tendency to bioaccumulate.
 - Slow biodegradation.
- Very toxic to fish.
Possible analogue to known carcinogens.

II. REFERRING OFFICE'S CONCERNS/NEEDS

- Monitor: its manufacture, importation, and processing; intended end uses, and potential worker exposure and environmental releases.
- Once production levels reach a certain point, EPA will reconsider its decision not to test HEX-BCH.

III. USES

A. Past and Ongoing

Commercial batch manufacture and processing.

Intermediate in the production of isodrin which is an intermediate in the production of endrin (both pesticides).

B. Small Business

Capable of production by a small firm.

IV. REGULATORY BACKGROUND

- Listed on the Preliminary Assessment Information Rule. (One-time reporting only).
- Listed on the section 8(d) model health and safety data reporting rule (40 CFR Part 716).
- Local limit on its discharge in a public treatment system. Limit based on plant's treatment capacity and not on human health or environmental risk.

V. RECOMMENDATION/RATIONALE: Section 8(a) rule for ongoing uses and significant new use rule for non-ongoing uses.

Well documented high toxicity concern.

Small businesses potential.

Satisfies referring office's needs.

No federal regulation exists to provide a governmental entity with an opportunity to evaluate potential human and environmental exposures to HEX-BCH from its manufacture, importation, processing, and intended end use; and to protect human beings and the environment from potentially adverse exposures before they occur.

METHYL N-BUTYL KETONE (CAS # 591-78-6)

also known as MBK.

7 TOXICITY

- Causes central and peripheral neuropathy in humans. Nerve damage is irreversible at concentrations as low as 50 ppm.
 - Absorbed readily through the skin.
- Eye and skin irritant.
Limited evidence suggests testicular atrophy.

II. REFERRING OFFICE'S CONCERNS/NEEDS

- Monitor: its resumption of commercial manufacture, importation, and processing; intended end uses, and potential worker and consumer exposure.

III. USES

A. Past

Commercial manufacture, importation and processing.
Solvent in lacquers, sealers, varnish removers, oils, fats, and waxes. (i.e., consumer products).

B. Ongoing

Importation for toxicological research and development.

C. Small Business

Capable of production by a small firm.

IV. REGULATORY BACKGROUND

- Occupational Safety and Health Administration standard (8 hour Time Weighted Average (TWA) 100 ppm).
- American Conference of Governmental Industrial Hygienists TWA 5 ppm. No binding effect.
- National Institute of Occupational Safety and Health TWA 5 ppm. No binding effect.

V. RECOMMENDATION/RATIONALE: Significant new use rule.

Well documented high toxicity concern.
Small businesses potential.
Satisfies referring office's needs.

No federal regulation exists to provide a governmental entity with an opportunity to evaluate potential human and environmental exposures to MBK from its manufacture, importation, processing, and intended end use; and to protect human beings and the environment from potentially adverse exposures before they occur.

URETHANE (CAS # 51-79-6)

Urethane is a name commonly but improperly applied to high molecular weight polyurethanes used as foams, elastomers, and coatings. These products are not made from the urethane, and do not generate urethane upon decomposition.

8 TOXICITY

- Urethane is well established as a carcinogen. Malignant tumors have occurred in many species of animals following the administration of urethane by the oral, inhalation, topical, subcutaneous, and intraperitoneal routes. Urethane is also a transplacental carcinogen that readily traverses the placenta and affects the fetus.
- Toxic fumes when heated; liver toxin; bone marrow depressant.

II. REFERRING OFFICE'S CONCERNS/NEEDS

- Monitor: its resumption of manufacture, importation, and processing; intended end uses, and potential worker and consumer exposure.

III. USES

A. Past

Commercial manufacture, importation and processing.

Intermediate in the production of N-hydroxymethyl derivatives, which are useful as cross-linking agents for imparting wash-and-wear properties to fabrics.

Human medicine: sclerosing agent for varicose veins and hemorrhoids, anti-neoplastic agent, hypnotic, treatment of chronic leukemia, and multiple myeloma.

Pharmaceutical intermediate.

B. Ongoing

Toxicological research.

C. Small Business

Capable of production by a small firm.

IV. REGULATORY BACKGROUND

Banned by the Food and Drug Administration as an active and inactive ingredient in drugs. FDA also prohibited the use of a food preservative that produces urethane when it is used in acidic beverages.

Designated by EPA as a Toxic Hazardous Waste #238.

- Listed as a Hazardous material under the Hazardous Materials Transportation Act.

V. RECOMMENDATION/RATIONALE: Significant new use rule.

Well documented high toxicity concern.

Small businesses potential.

Satisfies referring office's needs.

No federal regulation exists to provide a governmental entity with an opportunity to evaluate potential human and environmental exposures from urethane's manufacture, importation, processing, and intended end use; and to protect human beings and the environment from potentially adverse exposures before they occur.

The consequences of not collecting this information is to allow, without EPA review, human and environmental exposures to toxic chemical substances.

PENTABROMOETHYLBENZENE (CAS # 85-22-3)

also known as PEB.

9 TOXICITY

- Carcinogenicity observed in other structurally related compounds having a polyhalogenated aromatic moiety.
 - Persistent compound with a great tendency to bioaccumulate.
- Slow biodegradation.

II. REFERRING OFFICE'S CONCERNS/NEEDS

- Monitor: its resumption of commercial manufacture, importation, and processing; intended end uses, and potential worker exposure and environmental release.
- If production is to be reinstated, EPA will reconsider its decision not to test HEX-BCH.

III. USES

A. Past and Ongoing

Has been used in the past as an additive-type flame retardant.
No known ongoing uses.

B. Small Business

Capable of production by a small firm.

V. REGULATORY BACKGROUND

The Interagency Testing Committee designed PEB for priority consideration in its 15th report.

Listed on the section 8(d) model health and safety data reporting rule (40 CFR Part 716).

- Listed on the Preliminary Assessment Information Rule. (40 CFR Part 712).
- Proposed, pursuant to section 4(a)(1)(A) findings, that chemical fate and environmental effects testing be performed.
- Proposed Test Rule withdrawn due to termination of all known manufacture and processing operations.

V. RECOMMENDATION/RATIONALE: Significant new use rule.

Structurally analogous to substances of carcinogenic concern.

Small businesses potential.

Satisfies referring office's needs.

No federal regulation exists to provide a governmental entity with an opportunity to evaluate potential human and environmental exposures to PEB from its manufacture, importation, processing, and intended end use; and to protect human beings and the environment from potentially adverse exposures before they occur.